To: Personal Address / Ex. 6
From: Behl, Betsy
Sent: Fri 6/17/2016 10:19:02 PM
Subject: FW: media clips for PFOA PFOS

It's a bit dated, but still neat

From: Behl, Betsy
Sent: Friday, May 20, 2016 9:58 AM
To: Personal Address / Ex. 6
Subject: FW: media clips for PFOA PFOS

Check this out!

From: Loop, Travis
Sent: Friday, May 20, 2016 9:09 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Fuld, John <Fuld.John@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>; Duke, Nia <Duke.Nia@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: media clips for PFOA PFOS

Here is a compilation of media clips on PFOA PFOS. The biggest common error is referring to it as a standard.

Because they asked and had done some digging through data, we provided the list of 63 communities Joel did interviews with USA Today/Gannett and BuzzFeed. I have not seen those stories yet.

EPA sets health advisory level for lifetime exposure to **PFOA**

NEWS10 ABC - 19 hours ago

WASHINGTON (NEWS10) – The U.S. Environmental Protection Agency (**EPA**) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to **PFOA**. The **EPA**said the advisory is to provide Americans, including the most ...

EPA sets new level for chemical **PFOA** in drinking water

Albany Times Union - 12 hours ago

The **EPA's** long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of **PFOA** in public water systems and private wells. The contamination has been linked ...

EPA suggests tighter limits for **PFOA**, PFOS in drinking water

PhillyVoice.com - 3 hours ago

The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney cancers, as well as birth defects and liver damage. "**EPA** will continue sharing the latest science and information so that state and **...**

With New **EPA** Advisory, Dozens of Communities Suddenly Have Dangerous Drinking Water

The Intercept - 17 hours ago

The **EPA** announced new drinking water health advisory levels today for the industrial chemicals**PFOA** and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which **...**

EPA issues health advisory for long-term **PFOA** exposure

The Union Leader - 16 hours ago

“I am pleased that the **EPA** has answered my repeated requests and released the new health advisory standards for **PFOA** and (perfluorooctyl sulfonate) levels,” U.S. Sen. Kelly Ayotte said in a statement on Thursday. “New Hampshire residents deserve to ...

EPA issues **PFOA** health advisory

Nashua Telegraph - 8 hours ago

"The **EPA** has set the health advisory for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion and has recommended that when these two chemicals co-occur in the drinking water source, the sum of the ...

EPA Sets New Guidelines For **PFOA**, PFOS; Superfund Declared For Petersburgh

WAMC - 15 hours ago

In 2009, **EPA** set a short-term exposure guideline of 100 ppt for **PFOA** and PFOS. Perhaps due to a lack of long-term exposure guidlelines, state governments have not had consistent recommended levels. Vermont has acted under a 20 ppt threshold while ...

In Significant Reduction, **EPA** Sets Health Advisory For **PFOA** At 70 Parts Per Trillion

Vermont Public Radio - 18 hours ago

The **EPA** announced last year that it was looking at its health advisory level of 400 parts per trillion for **PFOA**, which was established in 2009. After the chemical was detected in North Bennington, the state of Vermont set a more conservative level **...**

EPA Releases New Health Guidelines for **PFOA**, PFOS Found in Drinking Water

TWC News - 18 hours ago

The **EPA** has released new health guidelines for **PFOA** and PFOS found in drinking water. **PFOA**was the chemical found in the water supply in Hoosick Falls and Petersburgh. The new health advisory levels have been set to 70 parts per trillion. When first ...

EPA Announces Lifetime **PFOA** and PFOS Advisory Level

New Hampshire Public Radio - 13 hours ago

The **EPA** has announced a lifetime health advisory level for two chemicals that have contaminated water in Southern NH and at the former Pease Air Force Base. **PFOA** and PFOS are slippery, stable chemicals used since the 1940s in products like nonstick ...

EPA issues new federal standards for **PFOA** exposure

WCAX - 14 hours ago

There are new federal standards for exposure to **PFOA** and it's three times higher than the level Vermont is using.**PFOA** has been found in drinking water supplies in Bennington and Pownal. Officials believe the chemical came from old Teflon factories.

EPA Releases New 'Lifetime' **PFOA** Exposure Level Data

Patch.com - 14 hours ago

CONCORD, NH - The U.S. Environmental Protection Agency has issued new “lifetime drinking water health advisory levels” for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion (ppt), according to Jim Martin **...**

EPA releases drinking water health advisories for **PFOA** and PFOS

WaterWorld - 18 hours ago

WASHINGTON, May 19, 2016 -- Based on the latest science on two chemical contaminants called**PFOA** and PFOS, **EPA** has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals.

EPA Releases New **PFOA**, PFOS Guidelines

WAMC - 19 hours ago

“I am pleased that the **EPA** has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," New York U.S. Senator Charles Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh ...

EPA declares official standard for **PFOA**, PFOS contamination for lifetime exposure

WRGB - 19 hours ago

'EPA's assessment indicates that drinking water with individual or combined concentrations of**PFOA** and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of **...**

3 Arizona water systems afoul of new **EPA** water guidelines

azcentral.com - 9 hours ago

The agency's latest advisory drops the recommended limit of **PFOA** and PFOS in drinking water from 400 parts per trillion to 70 parts per trillion. The **EPA** cannot enforce that limit, as it is just a recommendation intended to advise water systems on how **...**

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

Wall Street Journal - 17 hours ago

On Thursday, the **EPA** declared that drinking water with **PFOA** concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The **EPA** has been reviewing ...

EPA sets new standards for contaminants

Eagle-Tribune - 1 hour ago

The state has been waiting for some time to hear from the federal **EPA** about its recommendations about acceptable levels of **PFOA** in drinking water, said DES spokesman Jim Martin on Thursday. The new data recommends no more than 70 parts per trillion, ...

New **EPA** Guidelines on PFCs Welcome – but Still Fall Short

Environmental Working Group (blog) - 15 hours ago

Today the Environmental Protection Agency issued a long-awaited drinking water health advisory for the perfluorinated chemicals **PFOA** and PFOS. But **EPA's** advisory falls far short of what's needed to fully protect public health, and it is not a legally ...

Air Force applies new **EPA** guidance

Air Force Link - 15 hours ago

The Air Force has been following a 2009 **EPA** issued short-term provisional health advisory level for **PFOA** at 400 parts per trillion and 200 ppt for PFOS. On May 19, the **EPA** released new lifetime exposure health advisories for PFOS at 70 ppt and for **PFOA ...**

Martinsburg shuts down water plant after **EPA** advisory

Herald-Mail Media - 11 hours ago

The **EPA** issued the stricter guidelines for the chemicals after years of pressure from public-health experts and advocacy groups. The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney ...

EPA releases new safety advisories for chemicals

Burlington County Times - 14 hours ago

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the **EPA** in 2009: 0.4 parts per billion for **PFOA** in drinking water, and 0.2 ppb for PFOS. Thursday's announcement **...**

EPA sets new level for contaminant found in drinking water

WMUR Manchester - 19 hours ago

H. "I will continue to monitor the increasing instances of potentially dangerous **PFOA** and PFOS levels in water resources in several communities across our state and ensure that the **EPA** is working with local officials and communities to take every **...**

'Do not drink' ordered for Vienna water after **EPA** issues C8 guidance

Charleston Gazette-Mail (subscription) - 15 hours ago

“Although it's a long overdue step in the right direction, the guideline is still too high as it allows unacceptable accumulation of **PFOA** to build up in the blood of people drinking it,” said Robert Bilott, a longtime lawyer for residents who had their **...**

EPA Sets New Health Advisory for Toxic Chemicals in Drinking Water

NBC Bay Area - 15 hours ago

The agency set the advisory at 70 parts per trillion of human exposure to two perfluoronated compounds called PFOS and **PFOA**. That means people should not drink water with detections of the chemicals above that level. The new level is nearly six times ...

Amherst water tested for **PFOA**

Cabinet.com - May 19, 2016

After the presence of **PFOA** was detected in private wells in those towns, the DES declared a provisional safe exposure limit of 100 parts per trillion, which is the standard used by Maine. The **EPA** recommends avoiding short-term exposure to more than 400 ...

Federal **EPA** warns of high chemical levels in Martinsburg, Parkersburg and Vienna water sources

West Virginia MetroNews - 14 hours ago

WASHINGTON, D.C. — The federal **EPA** announced Thursday that water sources in Martinsburg, Parkersburg and Vienna contain the chemicals **PFOA** and PFOS at levels higher than previously recommended for public water systems. A ' do not drink' ...

Vermont Department of Health setting **PFOA** advisory level at 20 parts per trillion

NEWS10 ABC - 17 hours ago

Now that **EPA** has set a new advisory level of 70 parts per trillion for **PFOA** and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by**EPA** to assess how this differs from their current **...**

EPA Issues Tighter Limits for Chemical In Water

WILX-TV - 13 hours ago

The cancer-causing chemical **PFOA** has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of**PFOA** in recent years.

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

The Decatur Daily - 17 hours ago

The **EPA** advisory says some studies indicate long-term exposure to higher levels of **PFOA** and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune ...

Do not drink advisory issued for citizens of Vienna

WSAZ-TV - 14 hours ago

WOOD COUNTY, W.Va. (WSAZ) -- The Bureau for Public health has reviewed new information regarding **PFOA** and PFOS that the U.S. **EPA** released Thursday, and have decided to issue a Do Not Drink advisory for citizens of Vienna until additional testing ...

Amherst addresses **PFOA** contamination

WMUR Manchester - May 18, 2016

In Amherst, state environmental officials recently identified the former site of Textiles Coated International on Route 101-A as a likely source of **PFOA** contamination in nearby wells. "Why did this happen, and how is it allowed that we have industry **...**

West Morgan-East Lawrence water customers to receive health warning

The Decatur Daily - 7 hours ago

After the **EPA** on Thursday issued a health advisory, the West Morgan-East Lawrence Water and Sewer Authority said it will notify its 25,000 direct and indirect customers that their drinking water contains excessive amounts of two chemicals.

Newburgh water pollutant now more than twice level of new **EPA** guidelines

Times Herald-Record - 18 hours ago

Sean Maloney had been urging the **EPA** to expedite release of its updated guidelines. "I am pleased that the **EPA**has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," Schumer said in a ...

La Crosse releases drinking water advisory

WXOW.com - 13 hours ago

The contaminants are called Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (**PFOA**). The Environmental Protection Agency or **EPA** now wants municipal water supplies across the county to be tested for unregulated contaminants to be proactive ...

West Virginia communities altering their water sources after new

WHAG - 8 hours ago

... specifically in Martinsburg, Parkersburg and the town of Vienna, are altering their water sources after new **EPA**thresholds were released on Thursday. This comes after officials found raised levels of industrial chemicals of**PFOA** and PFOS in the water.

Doylestown Township shuts down contaminated well

The Intelligencer - 14 hours ago

It (**PFOA**) had not been on any chemical list that governs our permit," the director said. **PFOA** was first found in the Cross Keys well in 2014, the first year the **EPA** tested for the chemical, John said. "Had the **EPA** not looked for it, we wouldn't have **...**

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/**PFOA** from Water and ...

Broadway World - 17 hours ago

The **EPA** issued two public health advisories today for perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. **EPA's** assessment indicates that drinking water with individual or combined concentrations of **PFOA ...**

Newest clips below: PoliticoPro; (Manchester) Union Leader; (all previously clips forwarded below that).

Politico Pro Energy

EPA SETS PFOA LIMIT: EPA today set its long-awaited PFOA limit at 70 parts per trillion. Scott Waldman reports the limit "applies to both long- and short-term exposure and could have a

significant effect on water testing and lawsuits against industry. It is also lower than the current advisory of 100 parts per trillion that the EPA issued in many upstate communities facing exposure to the toxic chemical, which is used in the manufacturing of nonstick products." Communities from New England to West Virginia have been shown to have high levels of the chemical in their drinking water. The New York Times magazine did a deep dive into the chemical back in January.

Union Leader (New Hampshire)

http://www.unionleader.com/environment/epa-issues-health-advisory-for-long-term-pfoa-exposure--20160519

EPA issues health advisory for long-term PFOA exposure

By Kimberly Houghton on 5/19/16 at 4:51pm

Federal officials on Thursday issued a lifetime health advisory for the chemical perfluorooctanoic acid, which is being detected in some water sources in southern New Hampshire.

The U.S. Environmental Protection Agency has now identified 70 parts per trillion of PFOA as a new lifetime drinking water health advisory. Previously, the EPA had a 400 ppt PFOA advisory for short-term exposure.

The new advisory level is less than some levels of PFOA detected in the municipal public water supply wells operated by Merrimack Village District and provided to about 25,000 customers in the area.

At least one Village District well was found to have a PFOA level of 90 ppt, though that well is currently off-line. Ron Miner, superintendent of the district, was not immediately available for comment Thursday. Town Manager Eileen Cabanel directed questions to MVD.

Recently, the New Hampshire Department of Environmental Services began providing bottled water to about 200 properties throughout Litchfield, Merrimack and Amherst that have private

wells detecting PFOA at 100 ppt or more. It will now begin offering bottled water to homeowners with PFOA at 70 ppt in light of the newest recommendations from EPA, according to a release.

The federal advisory level of 70 ppt was derived from a developmental toxicity study in mice, according to the EPA's advisory released on Thursday.

"This lifetime health advisory is based on the latest health effects information for noncancer and cancer effects for PFOA - the lifetime health advisory is therefore protective of the population at large," states the advisory.

Tests on monkeys, rats and mice discovered developmental effects, liver toxicity, kidney toxicity, immune effects and cancers such as liver cancer, testicular cancer and pancreatic cancer as a result of long-term PFOA exposure, according to the advisory.

"Water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas and industrial or municipal waste sites where products are disposed of or applied," it states.

Saint-Gobain Performance Plastics has been identified as the likely source of water contamination in Merrimack and surrounding areas, according to officials with DES. PFOA has also been discovered at the old Merrimack landfill and the former Textiles Coated International plant in Amherst.

To date, 73 private wells within Merrimack, Litchfield and Amherst have detected elevated levels of PFOA above 100 ppt.

"I am pleased that the EPA has answered my repeated requests and released the new health advisory standards for PFOA and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to know whether or not their water resources are safe.

"I will continue to monitor the increasing instances of potentially dangerous PFOA and PFOS levels in water resources in several communities across our state and ensure that the EPA is working with local officials and communities to take every action possible for the safety of all Granite State residents," she said.

4:23 PM

Associated Press

http://hosted.ap.org/dynamic/stories/U/US_DRINKING_WATER_CHEMICALS?SITE=AP&SECTION=

EPA ISSUES TIGHTER LIMITS FOR INDUSTRIAL CHEMICAL IN WATER

By Michael Biesecker on 5/19/16 at 4:12pm

Federal regulators are tightening limits for human exposure to an industrial chemical used for decades in such consumer products as non-stick pans, stain-resistant carpets and microwave popcorn bags.

The cancer-causing chemical PFOA has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of PFOA in recent years.

Also at issue is the related chemical PFOS used in firefighting foam.

The Environmental Protection Agency issued the stricter standards for the chemicals on Thursday, following years of public pressure by advocacy groups. The agency said the new limits we prompted by recent scientific studies linking PFOA and PFOS to testicular and kidney cancers, as well as birth defects and liver damage.

4:12 PM

Wall Street Journal

http://www.wsj.com/articles/epa-issues-new-health-advisories-for-chemical-from-some-plastics-plants-1463687484

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

By Cameron McWhirter on 5/19/16 at 3:51pm

The Environmental Protection Agency announced new health advisories Thursday for perfluorooctanoic acid, a potentially toxic chemical, calling for water utilities across the nation to adhere to stricter guidelines than the agency had previously recommended.

In recent months, state investigators in New York, Vermont and New Hampshire have found high levels of the chemical, known as PFOA, in drinking-water wells and groundwater near former and current chemical plants, alarming residents and raising concern about PFOA contamination in other parts of the country.

The Environmental Working Group, a Washington-based advocacy group that assesses chemicals in consumer products and the environment, sent a letter in late April to EPA Administrator Gina McCarthy urging the agency to set an enforceable drinking-water standard for the chemical and to force former manufacturers to disclose all sites in the U.S. where they used, made or dumped PFOA.

On Thursday, the EPA declared that drinking water with PFOA concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The EPA has been reviewing PFOA guidelines for months, and state environmental agencies have been setting their own guidelines. New York and New Hampshire both set limits of 100 parts per trillion, while Vermont had a stricter standard of 20 parts per trillion.

PFOA can be harmful to animals in high doses, causing tumors in the liver and other parts of the body, according to several scientific studies. A multiyear medical study in the 2000s of 70,000 people near a plant in West Virginia that made PFOA found "some suggestions" of "probable links" between high exposure to the chemical and illnesses, including cancer.

The agency Thursday also set a 70 parts per trillion guideline for perfluorooctane sulfonate, or PFOS, a chemical similar to PFOA that was used to make products stain resistant. PFOS has been found in studies to be harmful to the immune systems of animals.

For both chemicals, the guidelines are lifetime-exposure advisories.

The provisional health advisory for PFOS had been 200 parts per trillion. The EPA stated that if both chemicals were found in drinking water, the 70 parts per trillion limit applies for the two chemicals combined. The advisories are not regulations that can be enforced by the EPA, but health guidelines issued for water utilities, and state environmental and health agencies to consider.

"If these chemicals are found in drinking-water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope and source of contamination," according to an EPA statement. "They should also promptly notify consumers and consult with their state drinking-water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breast-fed or formula-fed infants."

Some state officials were quick to applaud the new guidelines. The New Hampshire Department of Environmental Services spokesman Jim Martin said his department would work to provide bottled water to any communities where drinking-water tests exceeded the 70 parts per trillion limit.

The Environmental Working Group said the new levels aren't strict enough and urged the agency to impose a legally enforceable limit.

Factories for decades used PFOA as a plastic coating and to make consumer products such as Teflon nonstick pans, waterproof jackets and pizza boxes. Former large manufacturers or users of PFOA, including 3M Co. and DuPont Co., agreed in 2006 to phase out PFOA production and use by December 2015. Public concern over PFOA has spread through upstate New York and New England since August 2014, when a resident of Hoosick Falls, N.Y., near the Vermont border, tested his drinking water and found high levels of the acid. The man was concerned because his father, a former employee of the town's plastics plant that used PFOA, died of cancer.

Saint-Gobain Performance Plastics, a subsidiary of Saint-Gobain SA of France, operates plants in Merrimack, N.H., and Hoosick Falls, N.Y., and used to operate a plant in North Bennington, Vt. Since last year, state investigators have found PFOA contamination near all three sites, and they cited the plants as potential sources.

A company spokeswoman said in a statement that, according to the EPA, the new advisory is "not a legally enforceable federal standard and is subject to change as new information becomes available." The company, however, believes the new guidelines will help "state and local governments to make consistent decisions concerning the levels of PFOA in drinking water," she said.

Shawn Dalton, 65, a retired communications manager who lives not far from the Merrimack plant, thought until Thursday that water from his well, which tested 73 parts per trillion for PFOA, was safe. Now he knows it is three parts above the new guideline. He was glad for the new guidelines, however, because it means he now can hold government officials and companies accountable, he said.

"At least now the federal government has put a stake in the ground," he said.

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News 10 (ABC)

http://news10.com/2016/05/19/vermont-department-of-health-setting-pfoa-advisory-level-at-20-parts-per-trillion/

Vermont Department of Health setting PFOA advisory level at 20 parts per trillion

By Ali Stewart on 5/19/16 at 3:24pm

The Vermont Health Department says they evaluated all of the scientific information available at the time when setting Vermont's advisory level of 20 parts per trillion for PFOA in drinking water.

Now that EPA has set a new advisory level of 70 parts per trillion for PFOA and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by EPA to assess how this differs from their current advisory level, and consider if any changes are warranted.

The department says they remain committed to protecting the health of Vermonters from these harmful chemicals.

3:29pm

Decatur Daily

http://www.decaturdaily.com/news/lawrence_county/epa-issues-advisory-on-chemicals-found-in-west-morgan-east/article_2d66630b-b85c-5f14-9c45-e11f422b8457.html

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

By Eric Fleischauer on 5/19/16 at 3:22pm

The Environmental Protection Agency today issued a health advisory for two chemicals that are found in the drinking water of West Morgan-East Lawrence Water Authority.

The lifetime advisory warns of adverse health effects for people exposed to drinking water with more than 70 parts per trillion of two chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to court documents, West Morgan-East Lawrence drinking water exceeds the EPA advisory limit for both chemicals.

The EPA advisory says some studies indicate long-term exposure to higher levels of PFOA and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune effects, thyroid effects and cholesterol changes.

The authority sells water to water departments in Vinemont, Falkville, Trinity, Town Creek and the West Lawrence Water Cooperative. About 25,000 people use water supplied by the authority, it has said in court documents.

West Morgan-East Lawrence in October filed a federal lawsuit alleging 3M Co. and its subsidiary, Dyneon LLC, and Daikin America Inc. released the chemicals into the Tennessee River. The lawsuit alleges the chemical entered the authorities water intake downstream of the companies.

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Virtual-Strategy Magazine (Reprint from Business Wire)

http://www.virtual-strategy.com/2016/05/19/new-water-research-foundation-study-addresses-most-effective-methods-removing-pfospfoa-wa#axzz498AKvTCX

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

(See Business Wire story below)

3:02pm

Times Hearld-Record

http://www.recordonline.com/news/20160519/newburgh-water-pollutant-now-more-than-twice-level-of-new-epa-guidelines

Newburgh water pollutant now more than twice level of new EPA guidelines

By Leonard Sparks on 5/19/16 at 2:49pm

New federal health guidelines issued Thursday for the chemical that has shut down Newburgh's primary water supply are less than half the levels recorded in the city.

The Environmental Protection Agency is now urging action if levels of perfluorooctanoic acid or perfluorooctane sulfonate are above 70 parts per trillion, a significantly stricter standard than previously issued advisory guidelines of 100 parts per trillion for PFOA and 200 parts per trillion for PFOS.

Since its water was first tested in December 2013, Newburgh's Washington Lake has had levels of PFOS ranging from 140 to 170 parts per trillion.

While below the initial EPA guidelines, those levels spurred the closure of the lake on May 2, and Newburgh has been drawing water from its backup supply at Brown's Pond.

U.S. Sen. Charles Schumer and U.S. Rep. Sean Maloney had been urging the EPA to expedite release of its updated guidelines.

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS," Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause."

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The Intercept

https://theintercept.com/2016/05/19/with-new-pfoa-drinking-water-advisory-dozens-of-communities-suddenly-have-dangerous-water/

WITH NEW DRINKING WATER ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS WATER

By Sharon Lerner on 5/19/16 at 2:36pm

The EPA announced new drinking water health advisory levels today for the industrial chemicals PFOA and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which were .4 ppb for PFOA and .2 ppb for PFOS. In areas where both PFOA and PFOS are present, the advisory suggests a maximum combined level of .07 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

The new federal standards may unify what has been an inconsistent official response to the presence of these perfluorinated chemicals, or PFCs, in drinking water. They will also instantaneously create official water contamination crises in dozens of cities and towns across the country.

According to the EPA's most recent data on unregulated drinking water contaminants, released in January, 14 drinking water systems around the country reported levels of PFOA that exceed the new federal threshold, while 40 reported PFOS above the new cutoff. In all, water systems in 18 states, as well as in Guam, are contaminated.

Some of these water systems have already begun to quietly address the problem. In Suffolk County, New York, where public drinking water wells show PFOS levels of .33 and .53 ppb, the contaminated water "has either been blended with other wells to reduce the level of the compound to non-detection or their use has been limited to the greatest extent possible," according to Kevin Durk, director of water quality and laboratory services for the Suffolk County Water Authority. Though he does not know the level of PFOS in the water that comes out of local taps, Durk wrote in an email that "it is a virtual certainty that levels of any detected

chemical would have been reduced."

Similarly, the Security Water and Sanitation District in Colorado Springs has been struggling to clean up its contaminated water since 142 tests detected PFCs. The district has shut down seven out of 26 wells and is blending water to lower levels, according to Roy Heald, the district's general manager.

But other water company operators have yet to lower their PFC levels. Steve Anderson, owner of the Oatman Water Company in Scottsdale, Arizona, where PFOS measured .2 and .23 in the most recent EPA testing, learned that the chemical was in his water only recently, after he received a call from the Arizona Department of Environmental Quality. Anderson, who suspects the PFOS originated from firefighting foam used by the nearby Oatman Fire Department, said he is "trying to come up with a solution."

Until today, there was a wide range of official opinion on the level of contamination that presented a health danger. The military, which is in the throes of a massive cleanup of 664 contaminated fire- and crash-training sites, has been using the EPA's older standards for PFOA and PFOS to guide its efforts and help determine who receives clean drinking water and remediation of contaminated private wells. (The Department of Defense did not responded to inquiries about how the new advisory levels would alter its cleanup plan.)

Others have set more stringent standards. On January 28, the EPA advised residents of Hoosick Falls, New York, not to use water with PFOA levels above .1 ppb. And a panel of scientists who spent years researching some 70,000 people whose water contained PFOA levels of at least .05 ppb, found probable links between that level of exposure and testicular cancer, kidney cancer, thyroid disease, preeclampsia, ulcerative colitis and high cholesterol. In 2010, New Jersey's Drinking Water Quality Institute calculated a safety limit of .04 for PFOA. Vermont currently has the lowest state drinking water limit for PFOA, .02 ppb.

The levels released today are based on numerous studies connecting the chemicals with health effects. For PFOS, the report notes, studies of lab animals exposed to the chemical reported "developmental effects (decreased body weight, survival, and increased serum glucose levels and insulin resistance in adult offspring), reproductive (mating behavior), liver toxicity (liver weight co-occurring with decreased cholesterol, hepatic steatosis), developmental neurotoxicity (altered spatial learning and memory), immune effects, and cancer (thyroid and liver)."

The report also acknowledged research on human populations that has found associations between PFOS and immune suppression, thyroid disease, high cholesterol, and reduced fertility. It also acknowledged a possible connection between PFOS and bladder, colon, and prostate cancer.

For PFOA, the research included studies on monkeys, rats, and mice showing "developmental effects (survival, body weight changes, reduced ossification, delays in eye opening, altered puberty, and retarded mammary gland development), liver toxicity (hypertrophy, necrosis, and effects on the metabolism and deposition of dietary lipids), kidney toxicity (weight), immune effects, and cancer (liver, testicular, and pancreatic)."

The new health advisory for PFOA was also based on human studies, which showed "associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)." The EPA report noted that in humans "the developing fetus and newborn is particularly sensitive to PFOA-induced toxicity."

"Taken together," the report notes, "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." The exact phrasing was used in the PFOS report as well.

While calling the new level "a very long-overdue step in the right direction," Robert Bilott, an attorney overseeing a class-action suit over PFOA contamination near a DuPont plant in West Virginia, cautioned that "the new guideline is still too high, as exposures at even the new guideline level would allow PFOA to continue to build up to ever-increasing, unacceptable levels in human blood."

Bilott also noted that the new levels are informal guidelines, as opposed to enforceable regulatory limits. "If it was enforceable," he said, "the EPA could issue unilateral orders requiring the responsible party to clean it up."

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WaterWorld

http://www.waterworld.com/articles/2016/05/epa-releases-drinking-water-health-advisories-for-pfoa-and-pfos.html

EPA RELEASES DRINKING WATER HEALTH ADVISORIES FOR PFOA AND PFOS

By (No author) on 5/19/16 at 2:42pm

Based on the latest science on two chemical contaminants called PFOA and PFOS, EPA has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals. These advisories will help local water systems and state, tribal and local officials take the appropriate steps to address PFOA and PFOS if needed.

EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations.

For many years, PFOA and PFOS were widely used in carpets, clothing, furniture fabrics, food packaging, and other materials to make them more resistant to water, grease, and stains. PFOA and PFOS were also used for firefighting at airfields and in a number of industrial processes. Between 2000 and 2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer. And EPA asked eight major companies to commit to eliminate their production and use of PFOA by the end of 2015 and they have indicated that they have met their commitments. While there are some limited ongoing uses of these chemicals, in recent years, blood testing data has shown that exposures are declining across the country.

For most people, their source of exposure to PFOA and PFOS has come through food and consumer products. But drinking water can be an additional source of exposure in the small percentage of communities where these chemicals have contaminated water supplies. This is typically a localized issue associated with a specific facility -- for example, in communities where a manufacturing plant or airfield made or used these chemicals.

If these chemicals are found in drinking water systems above these levels, system operators

should quickly conduct additional sampling to assess the level, scope, and source of contamination. They should also promptly notify consumers and consult with their state drinking water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breastfed or formula-fed infants. There are a number of options available to water systems to lower concentrations of these chemicals in the drinking water supply.

EPA will continue sharing the latest science and information so that state and local officials can make informed decisions and take actions to protect public health. This is an important part of our broader effort to support states and public water systems as we work together to strengthen the safety of America's drinking water.

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Business Wire

http://www.businesswire.com/news/home/20160519006484/en/Water-Research-Foundation-Study-Addresses-Effective-Methods

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

By (No author) on 5/19/16 at 2:44pm

The Water Research Foundation (WRF), a leading sponsor of research supporting the water community, has released findings of a study addressing effective methods for removing poly- and perfluoroalkyl substances (PFASs) from water and wastewater. The research report, Treatment Mitigation Strategies for Poly- and Perfluorinated Chemicals (WRF project #4322), contains results of an in-depth treatment study conducted on waters from 13 water and wastewater treatment plants in the United States. Additionally, WRF will be hosting a Webcast on June 2 addressing the project's results and has posted a State of the Science document on PFASs.

The research from project #4322 demonstrated that conventional treatment at wastewater treatment plants and most drinking water treatment plants is ineffective at removing PFASs. Activated carbon and anion exchange can remove many PFASs but are less effective at removing shorter chain PFASs. The most effective treatment technologies are nanofiltration and reverse osmosis, which work even for the smallest PFASs studied.

The EPA issued two public health advisories today for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

"The research results from project #4322 will help the water community understand the best options for removing PFASs from water and wastewater, said Rob Renner, CEO of the Water Research Foundation. "This knowledge is especially important as the EPA continues the process of regulating these chemicals in water."

Poly- and perfluoroalkyl substances (PFASs) are a group of manmade chemicals with past and current uses in industrial processes and consumer products. PFASs are also commonly referred to as perfluorinated chemicals or PFCs. The most notable PFASs are PFOA and PFOS, but there are many others. PFASs are used in firefighting foams, coating for food packaging, ScotchGardTM and TeflonTM, among other products.

Exposure to PFASs can occur through use of products or consumption of food or water containing PFASs. PFASs do not break down easily and therefore persist in the environment. They are also soluble in water and can enter source waters through industrial releases, discharges from wastewater treatment plants, storm water runoff, release of firefighting foams, and land application of contaminated biosolids.

PFASs are a concern because they have been shown to have health effects in animal studies. Data from some human studies suggest that PFASs also affect human health. Additional research is ongoing in order to gain a better understanding of human health effects.

2:45pm

WRGB Albany (CBS)

http://cbs6albany.com/news/hoosick-falls-crisis/epa-declares-official-standard-for-pfoa-pfoh-

contamination

EPA declares official standard for PFOA, PFOS contamination for lifetime exposure

By WRGB Staff on 5/19/16 at 2:19pm

The EPA has released official long- term exposure guidelines for PFOA, PFOS contamination.

Released documents state that concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

Vermont lists safe exposure levels at 20 parts per trillion, including babies and children.

Regional EPA originally set short term exposure as 100 ppt in Hoosick Falls.

'EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations. " , says the EPA in a released document.

2:27 PM

Vermont Public Radio

http://digital.vpr.net/post/significant-reduction-epa-sets-health-advisory-pfoa-70-parts-trillion#stream/0

In Significant Reduction, EPA Sets Health Advisory For PFOA At 70 Parts Per Trillion

By Howard Weiss-Tisman on 5/19/16 at 2:11pm

The Environmental Protection Agency on Thursday issued an updated health advisory for the

suspected carcinogen PFOA.

The EPA says water that contains PFOA in levels at 70 parts per trillion should be considered unsafe to drink.

The EPA previously set its level at 400 ppt. The new, lifetime health advisory replaces that standard.

PFOA, a chemical that was used in a variety of manufacturing applications, has been found in water in North Bennington, Bennington and Pownal.

The contaminant has also been detected in New Hampshire and New York, and in other states around the country.

Vermont set its level at 20 parts per trillion.

(Reprint of Bucks County Courier Times story)

http://www.theintell.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_a404ad5d-a246-5ec2-9d1b-a9af8b6e70d5.html

EPA releases new safety advisories for chemicals

2:20 PM

Time Warner Cable News - Capital Region

http://www.twcnews.com/nys/capital-region/news/2016/05/19/epa-releases-new-pfoa-and-pfos-

health-guidelines.html

EPA Releases New Health Guidelines for PFOA, PFOS Found in Drinking Water

By TWC News Web Staff on 5/19/16 at 1:46pm

The EPA has released new health guidelines for PFOA and PFOS found in drinking water.

PFOA was the chemical found in the water supply in Hoosick Falls and Petersburgh.

The new health advisory levels have been set to 70 parts per trillion.

When first tested at the St. Gobain facility in Hoosick Falls, the EPA measured the levels at 18,000 parts per trillion.

A filtration system has since been installed, eliminating traces of the chemical, making the water safe to use again in Hoosick Falls.

In Petersburgh, multiple homes have tested above the new acceptable levels.

Taconic Plastics is believed to be the source of contamination. Residents in the town have grown impatient with leaders as they await to learn when they can get blood tested.

The town even ran out of bottled water to give to residents over the weekend. That supply has since been replenished.

Also, PFOS levels in Washington Lake and Silver Stream are in the range of 145 to 150 parts per trillion.

Washington Lake used to supply Newburgh's drinking water, until the city found out about the continuing levels of PFOS.

The city switched to Brown's Pond as a drinking source, since almost no levels of PFOS were found in that water.

Newburgh is still working to determine where the PFOS contamination is coming from.

Senator Schumer on New Standards:

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS. Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause. The EPA's new guidance will go a long way in protecting public health and arming local officials with the most up-to-date information to keep our drinking water safe from harmful contaminates."

Bucks County Courier Times (also ran in the Intelligencer)

http://www.buckscountycouriertimes.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_97946008-1de8-11e6-83d3-334d7ea7ce37.html

EPA Releases New Safety Advisories for Chemicals

By Kyle Bagenstose on 5/19/16 at 2:00pm

The Environmental Protection Agency on Thursday released a long-awaited update to its drinking water advisories for unregulated chemicals perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).

According to prior testing data of public and private water supplies in Bucks and Montgomery counties, it appears the updated advisories could mean some drinking water in the area is contaminated with the chemicals at a level above what the EPA deems is safe to consume.

The chemicals already had contaminated about 100 public and private water wells near a trio of current and former military bases in the region: The former Naval Air Station Joint Reserve Base Willow Grove, Horsham Air Guard Station, and former Naval Air Warfare Center in Warminster.

The chemicals are suspected to have originated in firefighting foams used at the bases, and the military already has agreed to spend approximately $19 million to provide replacement water and install filtration systems for public water wells affected by the chemicals, and bottled water and hook-ups to public systems for homes with affected private wells.

But the number of wells now likely will increase.

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the EPA in 2009: .4 parts per billion for PFOA in drinking water, and .2 ppb for PFOS.

Thursday's announcement, however, set an advised limit of .07 ppb for PFOS and PFOA combined, in order to protect against health effects from a lifetime of exposure. In a worst case scenario, that means drinking water with .58 ppb of the chemicals (.39 ppb PFOA and .19 ppb PFOS) previously considered safe, now would be more than eight times the recommended limit.

After the chemicals first were discovered in some local public water supplies by a nationwide EPA testing program in 2013 and 2014, multiple public wells in the area were taken offline.

The Horsham Water and Sewer Authority removed two drinking water wells from its system in

the summer of 2014 after PFOS was found at 1 and .7 ppb. Data from the testing program shows that three more wells also were contaminated with the chemicals at levels above the EPA's new advisory, with a combined .071 ppb, .123 ppb, and .14 ppb.

In a brief email Thursday, authority manager Tina O'Rourke said only two additional wells are above the .07 ppb level as of the most recent testing.

She added that the authority intends to take the wells offline and that existing agreements with the military allow for the authority to take action immediately.

The Warminster Municipal Authority, which previously removed three wells from its supply, also appears to have two more wells contaminated above the new level, with a combined .091 ppb and .09 ppb.

The Warrington Township Water Department previously removed a trio of wells that combined to form a single water source. Based on the EPA's data showing a combined .082 ppb, another well could also be above the new health advisory.

This news organization reached out to all three utilities to obtain the most recent testing information and will update this story as it receives responses.

Although unregulated, a growing body of science has established associations between PFOA and PFOS and a range of health effects, including a variety of cancers.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in a phone interview Thursday that the updated advisories reflect a review of available science and are intended to be protective for lifetime exposure to the chemicals for even vulnerable populations, such as nursing mothers and their children.

"These health advisories are scientific documents … the point is to provide the best available

information to state and local authorities and drinking water system operators," Beauvais said. "They're calculated to reflect a margin or protection to the most sensitive populations."

Beauvais added that the next step for the chemicals is to be considered for a federal drinking water standard that can be enforced, as is the case with more well-known contaminants such as lead or arsenic. However, he was unable to say how long it might take for that decision to be made.

1:59 PM

Albany Times Union

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-water-7716825.php

EPA Sets New Level for Chemical in Drinking Water

By Brendan J. Lyons on 5/19/16 at 1:17pm

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

The EPA's advisory level is well below the levels of PFOA that were detected in public water supplies over the past two years in Hoosick Falls, Petersburgh, North Bennington, Vt., and Merrimack, N.H.

In addition, health and environmental officials said tests have also revealed levels of PFOA in dozens of private wells in Rensselaer County that are much higher than the EPA's guideline.

Officials with the state Health Department and Department of Environmental Conservation could not immediately provide information Thursday about how many water systems in New York may contain PFOA, which has been used since the 1940s to make products such as nonstick coatings, such as Teflon, and heat-resistant wiring and other specialty products.

In 2009, the EPA established a guideline that a level of 400 parts per trillion is a safe level for "short-term" consumption of the water. Earlier this year, the EPA issued a provisional health advisory of 100 ppt. Meanwhile, other states have set far lower acceptable levels of PFOA in public water systems, including New Jersey, which has set a level of 40 ppt.

State Health Commissioner Dr. Howard A. Zucker in January said the state Health Department was reviewing its position on acceptable levels of PFOA in drinking water and would set a new safety limit within weeks. But the state did not issue a new advisory.

Robert A. Bilott, an Ohio attorney who is helping represent an estimated 3,500 people in a class-action lawsuit against DuPont, which manufactured and used perfluorinated chemicals such as PFOA in its products, has been urging the EPA for years to adopt a permanent health advisory for long-term exposure to PFOA in drinking water. Bilott has represented "tens of thousands of individuals in various communities across the country who have been injured because of the contamination of their drinking water with PFOA."

"The lower number and acknowledgement of the need to consider the combined amount of PFCs

in water is a long-overdue step in the right direction, but the guideline is still too high, as it will allow ever-increasing, unacceptable levels of PFOA to continue to build up in the blood of those exposed," Bilott said.

Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

Bilott said the science panel's peer-reviewed report was paid for by DuPont and, as a result of the panel's findings, the company has to concede in the personal-injury lawsuits that PFOA causes cancer.

In Albany, numerous lawsuits were filed this year in U.S. District Court seeking class-action status on behalf of current and former Hoosick Falls residents, including some who allege they suffered serious health effects that could be linked to PFOA exposure.

According to the EPA, PFOA was detected in blood serum in 99 percent of the U.S. population between 1999 and 2012. However, the EPA said the levels of PFOA in human blood have been decreasing since U.S. companies began to phase out production of the chemical more than 10 years ago. Still, water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied, the agency said.

Thousands of people whose blood was tested in that area of the Ohio Valley had elevated levels of PFOA, including at levels as high as 40 parts per billion.

In Hoosick Falls, where hundreds of people signed up for state-sponsored blood tests in February, the results of those tests are expected to be released beginning next week.

In February, the state Department of Environmental Conservation asked two corporations, Saint-

Gobain Performance Plastics and Honeywell International, to enter consent orders that would require them to clean up the remnants of the toxic chemical that polluted water supplies in and around Hoosick Falls.

The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations in Rensselaer County, including the town of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

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WAMC, Northeast Public Radio

http://wamc.org/post/epa-releases-new-pfoa-pfos-guidelines

EPA Releases New PFOA, PFOS Guidelines

By (No author) on 5/19/16 at 1:44pm

The U.S. Environmental Protection Agency has released new health advisories for PFOA and PFOS, the manufacturing chemicals at the center of water contamination crises in several communities in the region including Hoosick Falls, Petersburgh, and North Bennington. The guidelines released today lower the lifetime exposure from drinking water level to 70 parts per trillion. The level of PFOA in affected areas has been much higher than the new benchmark, leading communities to establish alternate water supplies. High exposure can result in cancer, birth defects and other diseases.

WMUR Manchester (ABC)

http://www.wmur.com/health/epa-sets-new-level-for-contaminant-found-in-drinking-water/39629266

EPA sets new level for contaminant found in drinking water

By Kirk Enstrom on 5/19/16 at 1:41pm

The Environmental Protection Agency has set new advisory levels for a contaminant that has been found in drinking water supplies in parts of New Hampshire.

The state Department of Environmental Services said Thursday that the EPA set a lifetime drinking water health advisory level for perfluorooctanoic acid at 70 parts per trillion.

The same level was set for a related chemical, perfluorooctane sulfonate. The EPA said that

when both chemicals are present, the combined concentration shouldn't exceed 70 parts per trillion.

State environmental officials had been advising well water users whose water tested above 100 parts per trillion to drink bottled water instead.

PFOA was found earlier this year in groundwater near the Saint-Gobain Performance Plastics facility in Merrimack after that company conducted tests. The contaminant has since been found in private wells in Litchfield, Manchester, Bedford and other areas.

It was most recently found in Amherst near a former industrial site.

State environmental officials said they are working to review the scientific basis for the new levels. DES said it's also taking steps to provide bottled water to all known private well users who have detected PFOA or PFOS levels greater than 70 parts per trillion.

"The state of New Hampshire will take immediate action to expand distribution of bottled water in affected areas to those whose water supply falls under the new advisory," Gov. Maggie Hassan said.

DES said it plans to move quickly to develop emergency rules for groundwater cleanup and drinking water standards. There will be a public comment process before permanent rules are established.

DES has set up a website to discuss the PFOA investigation.

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NEWS10 ABC

http://news10.com/2016/05/19/epa-issues-health-advisory-level-for-lifetime-exposure-to-pfoa/

EPA Sets Health Advisory Level for Lifetime Exposure to PFOA

By Joe Gullo on 5/19/16 at 1:21pm

The U.S. Environmental Protection Agency (EPA) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to PFOA.

The EPA says the advisory is to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime exposure to PFOA and PFOS from drinking water.

PFOA has been linked to serious health problems such as cancer.

Some local communities, including Petersburgh, Hoosick Falls, Bennington, and Pownal have had wells test positive for the chemical.

PFOA and PFOS have been used to make carpets, clothing, fabrics for furniture, paper packaging for food, and other materials that are resistant to water, grease, or stains. In 2006, the EPA says they asked eight companies using PFOA to phase out use and chemicals used to break down PFOA. Those companies have stated at the end of 2015, they phased out the use of PFOA.

According to the EPA, the establishment of the advisories follows an assessment from the latest peer-reviewed science to provide water system operators, and state, tribal, and local officials who have the primary responsibility of overseeing these systems.

Advisories issued by the EPA are designed to provide information on contaminants that can cause human health effects and are known or anticipated to occur in water.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Baris, Reuben[Baris.Reuben@epa.gov]
From: Behl, Betsy
Sent: Mon 5/23/2016 9:20:44 PM
Subject: Fwd: media clips for PFOA PFOS

Sent from my iPhone

Begin forwarded message:

From: "Behl, Betsy" <Behl.Betsy@epa.gov>
Date: May 20, 2016 at 12:20:39 PM EDT
To: "Echeverria, Marietta" <Echeverria.Marietta@epa.gov>
Subject: FW: media clips for PFOA PFOS

This is why I like this job.

From: Loop, Travis
Sent: Friday, May 20, 2016 9:09 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Fuld, John <Fuld.John@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>; Duke, Nia <Duke.Nia@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: media clips for PFOA PFOS

Here is a compilation of media clips on PFOA PFOS. The biggest common error is referring to it as a standard.

Because they asked and had done some digging through data, we provided the list of 63 communities Joel did interviews with USA Today/Gannett and BuzzFeed. I have not seen those stories yet.

EPA sets health advisory level for lifetime exposure to **PFOA**

NEWS10 ABC - 19 hours ago

WASHINGTON (NEWS10) – The U.S. Environmental Protection Agency (**EPA**) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to **PFOA**. The **EPA**said the advisory is to provide Americans, including the most ...

EPA sets new level for chemical **PFOA** in drinking water

Albany Times Union - 12 hours ago

The **EPA's** long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of **PFOA** in public water systems and private wells. The contamination has been linked ...

EPA suggests tighter limits for **PFOA**, PFOS in drinking water

PhillyVoice.com - 3 hours ago

The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney cancers, as well as birth defects and liver damage. "**EPA** will continue sharing the latest science and information so that state and **...**

With New **EPA** Advisory, Dozens of Communities Suddenly Have Dangerous Drinking Water

The Intercept - 17 hours ago

The **EPA** announced new drinking water health advisory levels today for the industrial chemicals**PFOA** and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which **...**

EPA issues health advisory for long-term **PFOA** exposure

The Union Leader - 16 hours ago

“I am pleased that the **EPA** has answered my repeated requests and released the new health advisory standards for **PFOA** and (perfluorooctyl sulfonate) levels,” U.S. Sen. Kelly Ayotte said in a statement on Thursday. “New Hampshire residents deserve to ...

EPA issues **PFOA** health advisory

Nashua Telegraph - 8 hours ago

"The **EPA** has set the health advisory for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion and has recommended that when these two chemicals co-occur in the drinking water source, the sum of the ...

EPA Sets New Guidelines For **PFOA**, PFOS; Superfund Declared For Petersburgh

WAMC - 15 hours ago

In 2009, **EPA** set a short-term exposure guideline of 100 ppt for **PFOA** and PFOS. Perhaps due to a lack of long-term exposure guidlelines, state governments have not had consistent recommended levels. Vermont has acted under a 20 ppt threshold while ...

In Significant Reduction, **EPA** Sets Health Advisory For **PFOA** At 70 Parts Per Trillion

Vermont Public Radio - 18 hours ago

The **EPA** announced last year that it was looking at its health advisory level of 400 parts per trillion for **PFOA**, which was established in 2009. After the chemical was detected in North Bennington, the state of Vermont set a more conservative level **...**

EPA Releases New Health Guidelines for **PFOA**, PFOS Found in Drinking Water

TWC News - 18 hours ago

The **EPA** has released new health guidelines for **PFOA** and PFOS found in drinking water. **PFOA**was the chemical found in the water supply in Hoosick Falls and Petersburgh. The new health advisory levels have been set to 70 parts per trillion. When first ...

EPA Announces Lifetime **PFOA** and PFOS Advisory Level

New Hampshire Public Radio - 13 hours ago

The **EPA** has announced a lifetime health advisory level for two chemicals that have contaminated water in Southern NH and at the former Pease Air Force Base. **PFOA** and PFOS are slippery,

stable chemicals used since the 1940s in products like nonstick ...

EPA issues new federal standards for **PFOA** exposure

WCAX - 14 hours ago

There are new federal standards for exposure to **PFOA** and it's three times higher than the level Vermont is using.**PFOA** has been found in drinking water supplies in Bennington and Pownal. Officials believe the chemical came from old Teflon factories.

EPA Releases New 'Lifetime' **PFOA** Exposure Level Data

Patch.com - 14 hours ago

CONCORD, NH - The U.S. Environmental Protection Agency has issued new “lifetime drinking water health advisory levels” for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion (ppt), according to Jim Martin **...**

EPA releases drinking water health advisories for **PFOA** and PFOS

WaterWorld - 18 hours ago

WASHINGTON, May 19, 2016 -- Based on the latest science on two chemical contaminants called**PFOA** and PFOS, **EPA** has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals.

EPA Releases New **PFOA**, PFOS Guidelines

WAMC - 19 hours ago

“I am pleased that the **EPA** has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," New York U.S. Senator Charles Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh ...

EPA declares official standard for **PFOA**, PFOS contamination for lifetime exposure

WRGB - 19 hours ago

'**EPA's** assessment indicates that drinking water with individual or combined concentrations of**PFOA** and PFOS below 70 parts per trillion is not expected to result in adverse health effects over

a lifetime of exposure. These levels reflect a margin of **...**

3 Arizona water systems afoul of new **EPA** water guidelines

azcentral.com - 9 hours ago

The agency's latest advisory drops the recommended limit of **PFOA** and PFOS in drinking water from 400 parts per trillion to 70 parts per trillion. The **EPA** cannot enforce that limit, as it is just a recommendation intended to advise water systems on how **...**

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

Wall Street Journal - 17 hours ago

On Thursday, the **EPA** declared that drinking water with **PFOA** concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The **EPA** has been reviewing ...

EPA sets new standards for contaminants

Eagle-Tribune - 1 hour ago

The state has been waiting for some time to hear from the federal **EPA** about its recommendations about acceptable levels of **PFOA** in drinking water, said DES spokesman Jim Martin on Thursday. The new data recommends no more than 70 parts per trillion, ...

New **EPA** Guidelines on PFCs Welcome – but Still Fall Short

Environmental Working Group (blog) - 15 hours ago

Today the Environmental Protection Agency issued a long-awaited drinking water health advisory for the perfluorinated chemicals **PFOA** and PFOS. But **EPA's** advisory falls far short of what's needed to fully protect public health, and it is not a legally ...

Air Force applies new **EPA** guidance

Air Force Link - 15 hours ago

The Air Force has been following a 2009 **EPA** issued short-term provisional health advisory level for **PFOA** at 400 parts per trillion and 200 ppt for PFOS. On May 19, the **EPA** released new lifetime

exposure health advisories for PFOS at 70 ppt and for **PFOA ...**

Martinsburg shuts down water plant after **EPA** advisory

Herald-Mail Media - 11 hours ago

The **EPA** issued the stricter guidelines for the chemicals after years of pressure from public-health experts and advocacy groups. The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney ...

EPA releases new safety advisories for chemicals

Burlington County Times - 14 hours ago

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the **EPA** in 2009: 0.4 parts per billion for **PFOA** in drinking water, and 0.2 ppb for PFOS. Thursday's announcement **...**

EPA sets new level for contaminant found in drinking water

WMUR Manchester - 19 hours ago

H. "I will continue to monitor the increasing instances of potentially dangerous **PFOA** and PFOS levels in water resources in several communities across our state and ensure that the **EPA** is working with local officials and communities to take every **...**

'Do not drink' ordered for Vienna water after **EPA** issues C8 guidance

Charleston Gazette-Mail (subscription) - 15 hours ago

“Although it's a long overdue step in the right direction, the guideline is still too high as it allows unacceptable accumulation of **PFOA** to build up in the blood of people drinking it,” said Robert Bilott, a longtime lawyer for residents who had their **...**

EPA Sets New Health Advisory for Toxic Chemicals in Drinking Water

NBC Bay Area - 15 hours ago

The agency set the advisory at 70 parts per trillion of human exposure to two perfluoronated compounds called PFOS and **PFOA**. That means people should not drink water with detections of

the chemicals above that level. The new level is nearly six times ...

Amherst water tested for **PFOA**

Cabinet.com - May 19, 2016

After the presence of **PFOA** was detected in private wells in those towns, the DES declared a provisional safe exposure limit of 100 parts per trillion, which is the standard used by Maine. The **EPA** recommends avoiding short-term exposure to more than 400 ...

Federal **EPA** warns of high chemical levels in Martinsburg, Parkersburg and Vienna water sources

West Virginia MetroNews - 14 hours ago

WASHINGTON, D.C. — The federal **EPA** announced Thursday that water sources in Martinsburg, Parkersburg and Vienna contain the chemicals **PFOA** and PFOS at levels higher than previously recommended for public water systems. A ' do not drink' ...

Vermont Department of Health setting **PFOA** advisory level at 20 parts per trillion

NEWS10 ABC - 17 hours ago

Now that **EPA** has set a new advisory level of 70 parts per trillion for **PFOA** and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by**EPA** to assess how this differs from their current **...**

EPA Issues Tighter Limits for Chemical In Water

WILX-TV - 13 hours ago

The cancer-causing chemical **PFOA** has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of**PFOA** in recent years.

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

The Decatur Daily - 17 hours ago

The **EPA** advisory says some studies indicate long-term exposure to higher levels of **PFOA** and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune ...

Do not drink advisory issued for citizens of Vienna

WSAZ-TV - 14 hours ago

WOOD COUNTY, W.Va. (WSAZ) -- The Bureau for Public health has reviewed new information regarding **PFOA** and PFOS that the U.S. **EPA** released Thursday, and have decided to issue a Do Not Drink advisory for citizens of Vienna until additional testing ...

Amherst addresses **PFOA** contamination

WMUR Manchester - May 18, 2016

In Amherst, state environmental officials recently identified the former site of Textiles Coated International on Route 101-A as a likely source of **PFOA** contamination in nearby wells. “Why did this happen, and how is it allowed that we have industry **...**

West Morgan-East Lawrence water customers to receive health warning

The Decatur Daily - 7 hours ago

After the **EPA** on Thursday issued a health advisory, the West Morgan-East Lawrence Water and Sewer Authority said it will notify its 25,000 direct and indirect customers that their drinking water contains excessive amounts of two chemicals.

Newburgh water pollutant now more than twice level of new **EPA** guidelines

Times Herald-Record - 18 hours ago

Sean Maloney had been urging the **EPA** to expedite release of its updated guidelines. “I am pleased that the **EPA**has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS,” Schumer said in a ...

La Crosse releases drinking water advisory

WXOW.com - 13 hours ago

The contaminants are called Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (**PFOA**). The Environmental Protection Agency or **EPA** now wants municipal water supplies across the county to be tested for unregulated contaminants to be proactive ...

West Virginia communities altering their water sources after new

WHAG - 8 hours ago

... specifically in Martinsburg, Parkersburg and the town of Vienna, are altering their water sources after new **EPA**thresholds were released on Thursday. This comes after officials found raised levels of industrial chemicals of**PFOA** and PFOS in the water.

Doylestown Township shuts down contaminated well

The Intelligencer - 14 hours ago

It (**PFOA**) had not been on any chemical list that governs our permit," the director said. **PFOA** was first found in the Cross Keys well in 2014, the first year the **EPA** tested for the chemical, John said. "Had the **EPA** not looked for it, we wouldn't have **...**

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/**PFOA** from Water and **...**

Broadway World - 17 hours ago

The **EPA** issued two public health advisories today for perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. **EPA's** assessment indicates that drinking water with individual or combined concentrations of **PFOA ...**

Newest clips below: PoliticoPro; (Manchester) Union Leader; (all previously clips forwarded below that).

Politico Pro Energy

EPA SETS PFOA LIMIT: EPA today set its long-awaited PFOA limit at 70 parts per trillion. Scott Waldman reports the limit "applies to both long- and short-term exposure and could have a significant effect on water testing and lawsuits against industry. It is also lower than the current advisory of 100 parts per trillion that the EPA issued in many upstate communities facing exposure to the toxic chemical, which is used in the manufacturing of nonstick products." Communities from New England to West Virginia have been shown to have high levels of the chemical in their drinking water. The New York Times magazine did a deep dive into the chemical back in January.

Union Leader (New Hampshire)

http://www.unionleader.com/environment/epa-issues-health-advisory-for-long-term-pfoa-exposure--20160519

EPA issues health advisory for long-term PFOA exposure

By Kimberly Houghton on 5/19/16 at 4:51pm

Federal officials on Thursday issued a lifetime health advisory for the chemical perfluorooctanoic acid, which is being detected in some water sources in southern New Hampshire.

The U.S. Environmental Protection Agency has now identified 70 parts per trillion of PFOA as a new lifetime drinking water health advisory. Previously, the EPA had a 400 ppt PFOA advisory for short-term exposure.

The new advisory level is less than some levels of PFOA detected in the municipal public water supply wells operated by Merrimack Village District and provided to about 25,000 customers in the area.

At least one Village District well was found to have a PFOA level of 90 ppt, though that well is currently off-line. Ron Miner, superintendent of the district, was not immediately available for comment Thursday. Town Manager Eileen Cabanel directed questions to MVD.

Recently, the New Hampshire Department of Environmental Services began providing bottled water to about 200 properties throughout Litchfield, Merrimack and Amherst that have private wells detecting PFOA at 100 ppt or more. It will now begin offering bottled water to homeowners with PFOA at 70 ppt in light of the newest recommendations from EPA, according to a release.

The federal advisory level of 70 ppt was derived from a developmental toxicity study in mice, according to the EPA's advisory released on Thursday.

"This lifetime health advisory is based on the latest health effects information for noncancer and cancer effects for PFOA - the lifetime health advisory is therefore protective of the population at large," states the advisory.

Tests on monkeys, rats and mice discovered developmental effects, liver toxicity, kidney toxicity, immune effects and cancers such as liver cancer, testicular cancer and pancreatic cancer as a result of long-term PFOA exposure, according to the advisory.

"Water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas and industrial or municipal waste sites where products are disposed of or applied," it states.

Saint-Gobain Performance Plastics has been identified as the likely source of water contamination in Merrimack and surrounding areas, according to officials with DES. PFOA has also been discovered at the old Merrimack landfill and the former Textiles Coated International plant in Amherst.

To date, 73 private wells within Merrimack, Litchfield and Amherst have detected elevated levels of PFOA above 100 ppt.

"I am pleased that the EPA has answered my repeated requests and released the new health

advisory standards for PFOA and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to know whether or not their water resources are safe.

"I will continue to monitor the increasing instances of potentially dangerous PFOA and PFOS levels in water resources in several communities across our state and ensure that the EPA is working with local officials and communities to take every action possible for the safety of all Granite State residents," she said.

4:23 PM

Associated Press

http://hosted.ap.org/dynamic/stories/U/US_DRINKING_WATER_CHEMICALS?SITE=AP&SECTION

EPA ISSUES TIGHTER LIMITS FOR INDUSTRIAL CHEMICAL IN WATER

By Michael Biesecker on 5/19/16 at 4:12pm

Federal regulators are tightening limits for human exposure to an industrial chemical used for decades in such consumer products as non-stick pans, stain-resistant carpets and microwave popcorn bags.

The cancer-causing chemical PFOA has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of PFOA in recent years.

Also at issue is the related chemical PFOS used in firefighting foam.

The Environmental Protection Agency issued the stricter standards for the chemicals on

Thursday, following years of public pressure by advocacy groups. The agency said the new limits we prompted by recent scientific studies linking PFOA and PFOS to testicular and kidney cancers, as well as birth defects and liver damage.

4:12 PM

Wall Street Journal

http://www.wsj.com/articles/epa-issues-new-health-advisories-for-chemical-from-some-plastics-plants-1463687484

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

By Cameron McWhirter on 5/19/16 at 3:51pm

The Environmental Protection Agency announced new health advisories Thursday for perfluorooctanoic acid, a potentially toxic chemical, calling for water utilities across the nation to adhere to stricter guidelines than the agency had previously recommended.

In recent months, state investigators in New York, Vermont and New Hampshire have found high levels of the chemical, known as PFOA, in drinking-water wells and groundwater near former and current chemical plants, alarming residents and raising concern about PFOA contamination in other parts of the country.

The Environmental Working Group, a Washington-based advocacy group that assesses chemicals in consumer products and the environment, sent a letter in late April to EPA Administrator Gina McCarthy urging the agency to set an enforceable drinking-water standard for the chemical and to force former manufacturers to disclose all sites in the U.S. where they used, made or dumped PFOA.

On Thursday, the EPA declared that drinking water with PFOA concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The EPA has been reviewing PFOA guidelines for months, and state environmental agencies have been setting their own guidelines. New York and New Hampshire both set limits of 100 parts per trillion, while

Vermont had a stricter standard of 20 parts per trillion.

PFOA can be harmful to animals in high doses, causing tumors in the liver and other parts of the body, according to several scientific studies. A multiyear medical study in the 2000s of 70,000 people near a plant in West Virginia that made PFOA found "some suggestions" of "probable links" between high exposure to the chemical and illnesses, including cancer.

The agency Thursday also set a 70 parts per trillion guideline for perfluorooctane sulfonate, or PFOS, a chemical similar to PFOA that was used to make products stain resistant. PFOS has been found in studies to be harmful to the immune systems of animals.

For both chemicals, the guidelines are lifetime-exposure advisories.

The provisional health advisory for PFOS had been 200 parts per trillion. The EPA stated that if both chemicals were found in drinking water, the 70 parts per trillion limit applies for the two chemicals combined. The advisories are not regulations that can be enforced by the EPA, but health guidelines issued for water utilities, and state environmental and health agencies to consider.

"If these chemicals are found in drinking-water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope and source of contamination," according to an EPA statement. "They should also promptly notify consumers and consult with their state drinking-water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breast-fed or formula-fed infants."

Some state officials were quick to applaud the new guidelines. The New Hampshire Department of Environmental Services spokesman Jim Martin said his department would work to provide bottled water to any communities where drinking-water tests exceeded the 70 parts per trillion limit.

The Environmental Working Group said the new levels aren't strict enough and urged the agency to impose a legally enforceable limit.

Factories for decades used PFOA as a plastic coating and to make consumer products such as Teflon nonstick pans, waterproof jackets and pizza boxes. Former large manufacturers or users of PFOA, including 3M Co. and DuPont Co., agreed in 2006 to phase out PFOA production and use by December 2015. Public concern over PFOA has spread through upstate New York and New England since August 2014, when a resident of Hoosick Falls, N.Y., near the Vermont border, tested his drinking water and found high levels of the acid. The man was concerned because his father, a former employee of the town's plastics plant that used PFOA, died of cancer.

Saint-Gobain Performance Plastics, a subsidiary of Saint-Gobain SA of France, operates plants in Merrimack, N.H., and Hoosick Falls, N.Y., and used to operate a plant in North Bennington, Vt. Since last year, state investigators have found PFOA contamination near all three sites, and they cited the plants as potential sources.

A company spokeswoman said in a statement that, according to the EPA, the new advisory is "not a legally enforceable federal standard and is subject to change as new information becomes available." The company, however, believes the new guidelines will help "state and local governments to make consistent decisions concerning the levels of PFOA in drinking water," she said.

Shawn Dalton, 65, a retired communications manager who lives not far from the Merrimack plant, thought until Thursday that water from his well, which tested 73 parts per trillion for PFOA, was safe. Now he knows it is three parts above the new guideline. He was glad for the new guidelines, however, because it means he now can hold government officials and companies accountable, he said.

"At least now the federal government has put a stake in the ground," he said.

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News 10 (ABC)

http://news10.com/2016/05/19/vermont-department-of-health-setting-pfoa-advisory-level-at-20-parts-per-trillion/

Vermont Department of Health setting PFOA advisory level at 20 parts per trillion

By Ali Stewart on 5/19/16 at 3:24pm

The Vermont Health Department says they evaluated all of the scientific information available at the time when setting Vermont's advisory level of 20 parts per trillion for PFOA in drinking water.

Now that EPA has set a new advisory level of 70 parts per trillion for PFOA and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by EPA to assess how this differs from their current advisory level, and consider if any changes are warranted.

The department says they remain committed to protecting the health of Vermonters from these harmful chemicals.

3:29pm

Decatur Daily

http://www.decaturdaily.com/news/lawrence_county/epa-issues-advisory-on-chemicals-found-in-west-morgan-east/article_2d66630b-b85c-5f14-9c45-e11f422b8457.html

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

By Eric Fleischauer on 5/19/16 at 3:22pm

The Environmental Protection Agency today issued a health advisory for two chemicals that are found in the drinking water of West Morgan-East Lawrence Water Authority.

The lifetime advisory warns of adverse health effects for people exposed to drinking water with more than 70 parts per trillion of two chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to court documents, West Morgan-East Lawrence drinking water exceeds the EPA advisory limit for both chemicals.

The EPA advisory says some studies indicate long-term exposure to higher levels of PFOA and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune effects, thyroid effects and cholesterol changes.

The authority sells water to water departments in Vinemont, Falkville, Trinity, Town Creek and the West Lawrence Water Cooperative. About 25,000 people use water supplied by the authority, it has said in court documents.

West Morgan-East Lawrence in October filed a federal lawsuit alleging 3M Co. and its subsidiary, Dyneon LLC, and Daikin America Inc. released the chemicals into the Tennessee River. The lawsuit alleges the chemical entered the authorities water intake downstream of the companies.

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Virtual-Strategy Magazine (Reprint from Business Wire)

http://www.virtual-strategy.com/2016/05/19/new-water-research-foundation-study-addresses-most-effective-methods-removing-pfospfoa-wa#axzz498AKvTCX

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

(See Business Wire story below)

3:02pm

Times Hearld-Record

http://www.recordonline.com/news/20160519/newburgh-water-pollutant-now-more-than-twice-level-of-new-epa-guidelines

Newburgh water pollutant now more than twice level of new EPA guidelines

By Leonard Sparks on 5/19/16 at 2:49pm

New federal health guidelines issued Thursday for the chemical that has shut down Newburgh's primary water supply are less than half the levels recorded in the city.

The Environmental Protection Agency is now urging action if levels of perfluorooctanoic acid or perfluorooctane sulfonate are above 70 parts per trillion, a significantly stricter standard than previously issued advisory guidelines of 100 parts per trillion for PFOA and 200 parts per trillion for PFOS.

Since its water was first tested in December 2013, Newburgh's Washington Lake has had levels of PFOS ranging from 140 to 170 parts per trillion.

While below the initial EPA guidelines, those levels spurred the closure of the lake on May 2, and Newburgh has been drawing water from its backup supply at Brown's Pond.

U.S. Sen. Charles Schumer and U.S. Rep. Sean Maloney had been urging the EPA to expedite release of its updated guidelines.

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS," Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause."

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The Intercept

https://theintercept.com/2016/05/19/with-new-pfoa-drinking-water-advisory-dozens-of-communities-suddenly-have-dangerous-water/

WITH NEW DRINKING WATER ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS WATER

By Sharon Lerner on 5/19/16 at 2:36pm

The EPA announced new drinking water health advisory levels today for the industrial chemicals PFOA and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which were .4 ppb for PFOA and .2 ppb for PFOS. In areas where both PFOA and PFOS are present, the advisory suggests a maximum combined level of .07 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

The new federal standards may unify what has been an inconsistent official response to the presence of these perfluorinated chemicals, or PFCs, in drinking water. They will also instantaneously create official water contamination crises in dozens of cities and towns across the country.

According to the EPA's most recent data on unregulated drinking water contaminants, released in January, 14 drinking water systems around the country reported levels of PFOA that exceed the new federal threshold, while 40 reported PFOS above the new cutoff. In all, water systems in 18 states, as well as in Guam, are contaminated.

Some of these water systems have already begun to quietly address the problem. In Suffolk County, New York, where public drinking water wells show PFOS levels of .33 and .53 ppb, the contaminated water "has either been blended with other wells to reduce the level of the compound to non-detection or their use has been limited to the greatest extent possible," according to Kevin Durk, director of water quality and laboratory services for the Suffolk County Water Authority. Though he does not know the level of PFOS in the water that comes out of local taps, Durk wrote in an email that "it is a virtual certainty that levels of any detected chemical would have been reduced."

Similarly, the Security Water and Sanitation District in Colorado Springs has been struggling to clean up its contaminated water since 142 tests detected PFCs. The district has shut down seven out of 26 wells and is blending water to lower levels, according to Roy Heald, the district's general manager.

But other water company operators have yet to lower their PFC levels. Steve Anderson, owner of the Oatman Water Company in Scottsdale, Arizona, where PFOS measured .2 and .23 in the most recent EPA testing, learned that the chemical was in his water only recently, after he received a call from the Arizona Department of Environmental Quality. Anderson, who suspects the PFOS originated from firefighting foam used by the nearby Oatman Fire Department, said he is "trying to come up with a solution."

Until today, there was a wide range of official opinion on the level of contamination that presented a health danger. The military, which is in the throes of a massive cleanup of 664 contaminated fire- and crash-training sites, has been using the EPA's older standards for PFOA and PFOS to guide its efforts and help determine who receives clean drinking water and remediation of contaminated private wells. (The Department of Defense did not responded to inquiries about how the new advisory levels would alter its cleanup plan.)

Others have set more stringent standards. On January 28, the EPA advised residents of Hoosick Falls, New York, not to use water with PFOA levels above .1 ppb. And a panel of scientists who spent years researching some 70,000 people whose water contained PFOA levels of at least .05 ppb, found probable links between that level of exposure and testicular cancer, kidney cancer, thyroid disease, preeclampsia, ulcerative colitis and high cholesterol. In 2010, New Jersey's Drinking Water Quality Institute calculated a safety limit of .04 for PFOA. Vermont currently has the lowest state drinking water limit for PFOA, .02 ppb.

The levels released today are based on numerous studies connecting the chemicals with health effects. For PFOS, the report notes, studies of lab animals exposed to the chemical reported "developmental effects (decreased body weight, survival, and increased serum glucose levels and insulin resistance in adult offspring), reproductive (mating behavior), liver toxicity (liver weight co-occurring with decreased cholesterol, hepatic steatosis), developmental neurotoxicity (altered spatial learning and memory), immune effects, and cancer (thyroid and liver)."

The report also acknowledged research on human populations that has found associations between PFOS and immune suppression, thyroid disease, high cholesterol, and reduced fertility. It also acknowledged a possible connection between PFOS and bladder, colon, and prostate cancer.

For PFOA, the research included studies on monkeys, rats, and mice showing "developmental effects (survival, body weight changes, reduced ossification, delays in eye opening, altered puberty, and retarded mammary gland development), liver toxicity (hypertrophy, necrosis, and effects on the metabolism and deposition of dietary lipids), kidney toxicity (weight), immune effects, and cancer (liver, testicular, and pancreatic)."

The new health advisory for PFOA was also based on human studies, which showed "associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)." The EPA report noted that in humans "the developing fetus and newborn is particularly sensitive to PFOA-induced toxicity."

"Taken together," the report notes, "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." The exact phrasing was used in the PFOS report as well.

While calling the new level "a very long-overdue step in the right direction," Robert Bilott, an attorney overseeing a class-action suit over PFOA contamination near a DuPont plant in West Virginia, cautioned that "the new guideline is still too high, as exposures at even the new guideline level would allow PFOA to continue to build up to ever-increasing, unacceptable levels in human blood."

Bilott also noted that the new levels are informal guidelines, as opposed to enforceable regulatory limits. "If it was enforceable," he said, "the EPA could issue unilateral orders requiring the responsible party to clean it up."

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WaterWorld

http://www.waterworld.com/articles/2016/05/epa-releases-drinking-water-health-advisories-for-pfoa-and-pfos.html

EPA RELEASES DRINKING WATER HEALTH ADVISORIES FOR PFOA AND PFOS

By (No author) on 5/19/16 at 2:42pm

Based on the latest science on two chemical contaminants called PFOA and PFOS, EPA has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals. These advisories will help local water systems and state, tribal and local officials take the appropriate steps to address PFOA and PFOS if needed.

EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations.

For many years, PFOA and PFOS were widely used in carpets, clothing, furniture fabrics, food packaging, and other materials to make them more resistant to water, grease, and stains. PFOA and PFOS were also used for firefighting at airfields and in a number of industrial processes. Between 2000 and 2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer. And EPA asked eight major companies to commit to eliminate their production and use of PFOA by the end of 2015 and they have indicated that they have met their commitments. While there are some limited ongoing uses of these chemicals, in recent years, blood testing data has shown that exposures are declining across the country.

For most people, their source of exposure to PFOA and PFOS has come through food and consumer products. But drinking water can be an additional source of exposure in the small percentage of communities where these chemicals have contaminated water supplies. This is typically a localized issue associated with a specific facility -- for example, in communities where a manufacturing plant or airfield made or used these chemicals.

If these chemicals are found in drinking water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope, and source of contamination. They should also promptly notify consumers and consult with their state drinking water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breastfed or formula-fed infants. There are a number of options available to water systems to lower concentrations of these chemicals in the drinking water supply.

EPA will continue sharing the latest science and information so that state and local officials can make informed decisions and take actions to protect public health. This is an important part of our broader effort to support states and public water systems as we work together to strengthen the safety of America's drinking water.

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Business Wire

http://www.businesswire.com/news/home/20160519006484/en/Water-Research-Foundation-Study-Addresses-Effective-Methods

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

By (No author) on 5/19/16 at 2:44pm

The Water Research Foundation (WRF), a leading sponsor of research supporting the water community, has released findings of a study addressing effective methods for removing poly- and perfluoroalkyl substances (PFASs) from water and wastewater. The research report, Treatment Mitigation Strategies for Poly- and Perfluorinated Chemicals (WRF project #4322), contains results of an in-depth treatment study conducted on waters from 13

water and wastewater treatment plants in the United States. Additionally, WRF will be hosting a Webcast on June 2 addressing the project's results and has posted a State of the Science document on PFASs.

The research from project #4322 demonstrated that conventional treatment at wastewater treatment plants and most drinking water treatment plants is ineffective at removing PFASs. Activated carbon and anion exchange can remove many PFASs but are less effective at removing shorter chain PFASs. The most effective treatment technologies are nanofiltration and reverse osmosis, which work even for the smallest PFASs studied.

The EPA issued two public health advisories today for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

"The research results from project #4322 will help the water community understand the best options for removing PFASs from water and wastewater, said Rob Renner, CEO of the Water Research Foundation. "This knowledge is especially important as the EPA continues the process of regulating these chemicals in water."

Poly- and perfluoroalkyl substances (PFASs) are a group of manmade chemicals with past and current uses in industrial processes and consumer products. PFASs are also commonly referred to as perfluorinated chemicals or PFCs. The most notable PFASs are PFOA and PFOS, but there are many others. PFASs are used in firefighting foams, coating for food packaging, ScotchGardTM and TeflonTM, among other products.

Exposure to PFASs can occur through use of products or consumption of food or water containing PFASs. PFASs do not break down easily and therefore persist in the environment. They are also soluble in water and can enter source waters through industrial releases, discharges from wastewater treatment plants, storm water runoff, release of firefighting foams, and land application of contaminated biosolids.

PFASs are a concern because they have been shown to have health effects in animal studies.

Data from some human studies suggest that PFASs also affect human health. Additional research is ongoing in order to gain a better understanding of human health effects.

2:45pm

WRGB Albany (CBS)

http://cbs6albany.com/news/hoosick-falls-crisis/epa-declares-official-standard-for-pfoa-pfoh-contamination

EPA declares official standard for PFOA, PFOS contamination for lifetime exposure

By WRGB Staff on 5/19/16 at 2:19pm

The EPA has released official long- term exposure guidelines for PFOA, PFOS contamination.

Released documents state that concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

Vermont lists safe exposure levels at 20 parts per trillion, including babies and children.

Regional EPA originally set short term exposure as 100 ppt in Hoosick Falls.

'EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations. " , says the EPA in a released document.

2:27 PM

Vermont Public Radio

http://digital.vpr.net/post/significant-reduction-epa-sets-health-advisory-pfoa-70-parts-trillion#stream/0

In Significant Reduction, EPA Sets Health Advisory For PFOA At 70 Parts Per Trillion

By Howard Weiss-Tisman on 5/19/16 at 2:11pm

The Environmental Protection Agency on Thursday issued an updated health advisory for the suspected carcinogen PFOA.

The EPA says water that contains PFOA in levels at 70 parts per trillion should be considered unsafe to drink.

The EPA previously set its level at 400 ppt. The new, lifetime health advisory replaces that standard.

PFOA, a chemical that was used in a variety of manufacturing applications, has been found in water in North Bennington, Bennington and Pownal.

The contaminant has also been detected in New Hampshire and New York, and in other states around the country.

Vermont set its level at 20 parts per trillion.

(Reprint of Bucks County Courier Times story)

http://www.theintell.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_a404ad5d-a246-5ec2-9d1b-a9af8b6e70d5.html

EPA releases new safety advisories for chemicals

2:20 PM

Time Warner Cable News - Capital Region

http://www.twcnews.com/nys/capital-region/news/2016/05/19/epa-releases-new-pfoa-and-pfos-health-guidelines.html

EPA Releases New Health Guidelines for PFOA, PFOS Found in Drinking Water

By TWC News Web Staff on 5/19/16 at 1:46pm

The EPA has released new health guidelines for PFOA and PFOS found in drinking water.

PFOA was the chemical found in the water supply in Hoosick Falls and Petersburgh.

The new health advisory levels have been set to 70 parts per trillion.

When first tested at the St. Gobain facility in Hoosick Falls, the EPA measured the levels at 18,000 parts per trillion.

A filtration system has since been installed, eliminating traces of the chemical, making the water safe to use again in Hoosick Falls.

In Petersburgh, multiple homes have tested above the new acceptable levels.

Taconic Plastics is believed to be the source of contamination. Residents in the town have grown impatient with leaders as they await to learn when they can get blood tested.

The town even ran out of bottled water to give to residents over the weekend. That supply has since been replenished.

Also, PFOS levels in Washington Lake and Silver Stream are in the range of 145 to 150 parts per trillion.

Washington Lake used to supply Newburgh's drinking water, until the city found out about the continuing levels of PFOS.

The city switched to Brown's Pond as a drinking source, since almost no levels of PFOS were found in that water.

Newburgh is still working to determine where the PFOS contamination is coming from.

Senator Schumer on New Standards:

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS. Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause. The EPA's new guidance will go a long way in protecting public health and arming local officials with the most up-to-date information to keep our drinking water safe from harmful contaminates."

Bucks County Courier Times (also ran in the Intelligencer)

http://www.buckscountycouriertimes.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_97946008-1de8-11e6-83d3-334d7ea7ce37.html

EPA Releases New Safety Advisories for Chemicals

By Kyle Bagenstose on 5/19/16 at 2:00pm

The Environmental Protection Agency on Thursday released a long-awaited update to its drinking water advisories for unregulated chemicals perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).

According to prior testing data of public and private water supplies in Bucks and Montgomery counties, it appears the updated advisories could mean some drinking water in the area is contaminated with the chemicals at a level above what the EPA deems is safe to consume.

The chemicals already had contaminated about 100 public and private water wells near a trio of current and former military bases in the region: The former Naval Air Station Joint Reserve Base Willow Grove, Horsham Air Guard Station, and former Naval Air Warfare Center in Warminster.

The chemicals are suspected to have originated in firefighting foams used at the bases, and the military already has agreed to spend approximately $19 million to provide replacement water and install filtration systems for public water wells affected by the chemicals, and bottled water and hook-ups to public systems for homes with affected private wells.

But the number of wells now likely will increase.

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the EPA in 2009: .4 parts per billion for PFOA in drinking water, and .2 ppb for PFOS.

Thursday's announcement, however, set an advised limit of .07 ppb for PFOS and PFOA combined, in order to protect against health effects from a lifetime of exposure. In a worst case scenario, that means drinking water with .58 ppb of the chemicals (.39 ppb PFOA and .19 ppb PFOS) previously considered safe, now would be more than eight times the recommended limit.

After the chemicals first were discovered in some local public water supplies by a nationwide EPA testing program in 2013 and 2014, multiple public wells in the area were taken offline.

The Horsham Water and Sewer Authority removed two drinking water wells from its system in the summer of 2014 after PFOS was found at 1 and .7 ppb. Data from the testing program shows that three more wells also were contaminated with the chemicals at levels above the EPA's new advisory, with a combined .071 ppb, .123 ppb, and .14 ppb.

In a brief email Thursday, authority manager Tina O'Rourke said only two additional wells are above the .07 ppb level as of the most recent testing.

She added that the authority intends to take the wells offline and that existing agreements with the military allow for the authority to take action immediately.

The Warminster Municipal Authority, which previously removed three wells from its supply, also appears to have two more wells contaminated above the new level, with a combined .091 ppb and .09 ppb.

The Warrington Township Water Department previously removed a trio of wells that combined to form a single water source. Based on the EPA's data showing a combined .082 ppb, another well could also be above the new health advisory.

This news organization reached out to all three utilities to obtain the most recent testing

information and will update this story as it receives responses.

Although unregulated, a growing body of science has established associations between PFOA and PFOS and a range of health effects, including a variety of cancers.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in a phone interview Thursday that the updated advisories reflect a review of available science and are intended to be protective for lifetime exposure to the chemicals for even vulnerable populations, such as nursing mothers and their children.

"These health advisories are scientific documents … the point is to provide the best available information to state and local authorities and drinking water system operators," Beauvais said. "They're calculated to reflect a margin or protection to the most sensitive populations."

Beauvais added that the next step for the chemicals is to be considered for a federal drinking water standard that can be enforced, as is the case with more well-known contaminants such as lead or arsenic. However, he was unable to say how long it might take for that decision to be made.

1:59 PM

Albany Times Union

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-water-7716825.php

EPA Sets New Level for Chemical in Drinking Water

By Brendan J. Lyons on 5/19/16 at 1:17pm

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water

health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

The EPA's advisory level is well below the levels of PFOA that were detected in public water supplies over the past two years in Hoosick Falls, Petersburgh, North Bennington, Vt., and Merrimack, N.H.

In addition, health and environmental officials said tests have also revealed levels of PFOA in dozens of private wells in Rensselaer County that are much higher than the EPA's guideline.

Officials with the state Health Department and Department of Environmental Conservation could not immediately provide information Thursday about how many water systems in New York may contain PFOA, which has been used since the 1940s to make products such as nonstick coatings, such as Teflon, and heat-resistant wiring and other specialty products.

In 2009, the EPA established a guideline that a level of 400 parts per trillion is a safe level for "short-term" consumption of the water. Earlier this year, the EPA issued a provisional health advisory of 100 ppt. Meanwhile, other states have set far lower acceptable levels of PFOA in public water systems, including New Jersey, which has set a level of 40 ppt.

State Health Commissioner Dr. Howard A. Zucker in January said the state Health Department was reviewing its position on acceptable levels of PFOA in drinking water and would set a new safety limit within weeks. But the state did not issue a new advisory.

Robert A. Bilott, an Ohio attorney who is helping represent an estimated 3,500 people in a class-action lawsuit against DuPont, which manufactured and used perfluorinated chemicals such as PFOA in its products, has been urging the EPA for years to adopt a permanent health advisory for long-term exposure to PFOA in drinking water. Bilott has represented "tens of thousands of individuals in various communities across the country who have been injured because of the contamination of their drinking water with PFOA."

"The lower number and acknowledgement of the need to consider the combined amount of PFCs in water is a long-overdue step in the right direction, but the guideline is still too high, as it will allow ever-increasing, unacceptable levels of PFOA to continue to build up in the blood of those exposed," Bilott said.

Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

Bilott said the science panel's peer-reviewed report was paid for by DuPont and, as a result of the panel's findings, the company has to concede in the personal-injury lawsuits that PFOA causes cancer.

In Albany, numerous lawsuits were filed this year in U.S. District Court seeking class-action status on behalf of current and former Hoosick Falls residents, including some who allege they suffered serious health effects that could be linked to PFOA exposure.

According to the EPA, PFOA was detected in blood serum in 99 percent of the U.S. population between 1999 and 2012. However, the EPA said the levels of PFOA in human blood have been decreasing since U.S. companies began to phase out production of the chemical more than 10 years ago. Still, water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied, the agency said.

Thousands of people whose blood was tested in that area of the Ohio Valley had elevated levels of PFOA, including at levels as high as 40 parts per billion.

In Hoosick Falls, where hundreds of people signed up for state-sponsored blood tests in February, the results of those tests are expected to be released beginning next week.

In February, the state Department of Environmental Conservation asked two corporations, Saint-Gobain Performance Plastics and Honeywell International, to enter consent orders that would require them to clean up the remnants of the toxic chemical that polluted water supplies in and around Hoosick Falls.

The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations in Rensselaer County, including the town of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the

levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

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WAMC, Northeast Public Radio

http://wamc.org/post/epa-releases-new-pfoa-pfos-guidelines

EPA Releases New PFOA, PFOS Guidelines

By (No author) on 5/19/16 at 1:44pm

The U.S. Environmental Protection Agency has released new health advisories for PFOA and PFOS, the manufacturing chemicals at the center of water contamination crises in several communities in the region including Hoosick Falls, Petersburgh, and North Bennington. The guidelines released today lower the lifetime exposure from drinking water level to 70 parts per trillion. The level of PFOA in affected areas has been much higher than the new benchmark, leading communities to establish alternate water supplies. High exposure can result in cancer, birth defects and other diseases.

WMUR Manchester (ABC)

http://www.wmur.com/health/epa-sets-new-level-for-contaminant-found-in-drinking-water/39629266

EPA sets new level for contaminant found in drinking water

By Kirk Enstrom on 5/19/16 at 1:41pm

The Environmental Protection Agency has set new advisory levels for a contaminant that has been found in drinking water supplies in parts of New Hampshire.

The state Department of Environmental Services said Thursday that the EPA set a lifetime drinking water health advisory level for perfluorooctanoic acid at 70 parts per trillion.

The same level was set for a related chemical, perfluorooctane sulfonate. The EPA said that when both chemicals are present, the combined concentration shouldn't exceed 70 parts per trillion.

State environmental officials had been advising well water users whose water tested above 100 parts per trillion to drink bottled water instead.

PFOA was found earlier this year in groundwater near the Saint-Gobain Performance Plastics facility in Merrimack after that company conducted tests. The contaminant has since been found in private wells in Litchfield, Manchester, Bedford and other areas.

It was most recently found in Amherst near a former industrial site.

State environmental officials said they are working to review the scientific basis for the new levels. DES said it's also taking steps to provide bottled water to all known private well users who have detected PFOA or PFOS levels greater than 70 parts per trillion.

"The state of New Hampshire will take immediate action to expand distribution of bottled water in affected areas to those whose water supply falls under the new advisory," Gov. Maggie Hassan said.

DES said it plans to move quickly to develop emergency rules for groundwater cleanup and drinking water standards. There will be a public comment process before permanent rules are established.

DES has set up a website to discuss the PFOA investigation.

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NEWS10 ABC

http://news10.com/2016/05/19/epa-issues-health-advisory-level-for-lifetime-exposure-to-pfoa/

EPA Sets Health Advisory Level for Lifetime Exposure to PFOA

By Joe Gullo on 5/19/16 at 1:21pm

The U.S. Environmental Protection Agency (EPA) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to PFOA.

The EPA says the advisory is to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime exposure to PFOA and PFOS from drinking water.

PFOA has been linked to serious health problems such as cancer.

Some local communities, including Petersburgh, Hoosick Falls, Bennington, and Pownal have had wells test positive for the chemical.

PFOA and PFOS have been used to make carpets, clothing, fabrics for furniture, paper packaging for food, and other materials that are resistant to water, grease, or stains. In 2006, the EPA says they asked eight companies using PFOA to phase out use and chemicals used to break down PFOA. Those companies have stated at the end of 2015, they phased out the use of PFOA.

According to the EPA, the establishment of the advisories follows an assessment from the latest peer-reviewed science to provide water system operators, and state, tribal, and local officials who have the primary responsibility of overseeing these systems.

Advisories issued by the EPA are designed to provide information on contaminants that can cause human health effects and are known or anticipated to occur in water.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Echeverria, Marietta[Echeverria.Marietta@epa.gov]
From: Behl, Betsy
Sent: Fri 5/20/2016 4:20:39 PM
Subject: FW: media clips for PFOA PFOS

This is why I like this job.

From: Loop, Travis
Sent: Friday, May 20, 2016 9:09 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Fuld, John <Fuld.John@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>; Duke, Nia <Duke.Nia@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: media clips for PFOA PFOS

Here is a compilation of media clips on PFOA PFOS. The biggest common error is referring to it as a standard.

Because they asked and had done some digging through data, we provided the list of 63 communities Joel did interviews with USA Today/Gannett and BuzzFeed. I have not seen those stories yet.

EPA sets health advisory level for lifetime exposure to **PFOA**

NEWS10 ABC - 19 hours ago

WASHINGTON (NEWS10) – The U.S. Environmental Protection Agency (**EPA**) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to **PFOA**. The **EPA**said the advisory is to provide Americans, including the most ...

EPA sets new level for chemical **PFOA** in drinking water

Albany Times Union - 12 hours ago

The **EPA's** long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of **PFOA** in public water systems and private wells. The contamination has been linked ...

EPA suggests tighter limits for PFOA, PFOS in drinking water

PhillyVoice.com - 3 hours ago

The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney cancers, as well as birth defects and liver damage. "**EPA** will continue sharing the latest science and information so that state and **...**

With New EPA Advisory, Dozens of Communities Suddenly Have Dangerous Drinking Water

The Intercept - 17 hours ago

The **EPA** announced new drinking water health advisory levels today for the industrial chemicals**PFOA** and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which **...**

EPA issues health advisory for long-term PFOA exposure

The Union Leader - 16 hours ago

“I am pleased that the **EPA** has answered my repeated requests and released the new health advisory standards for **PFOA** and (perfluorooctyl sulfonate) levels,” U.S. Sen. Kelly Ayotte said in a statement on Thursday. “New Hampshire residents deserve to ...

EPA issues PFOA health advisory

Nashua Telegraph - 8 hours ago

"The **EPA** has set the health advisory for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion and has recommended that when these two chemicals co-occur in the drinking water source, the sum of the ...

EPA Sets New Guidelines For PFOA, PFOS; Superfund Declared For Petersburgh

WAMC - 15 hours ago

In 2009, **EPA** set a short-term exposure guideline of 100 ppt for **PFOA** and PFOS. Perhaps due to a lack of long-term exposure guidlelines, state governments have not had consistent recommended levels. Vermont has acted under a 20 ppt threshold while ...

In Significant Reduction, **EPA** Sets Health Advisory For **PFOA** At 70 Parts Per Trillion

Vermont Public Radio - 18 hours ago

The **EPA** announced last year that it was looking at its health advisory level of 400 parts per trillion for **PFOA**, which was established in 2009. After the chemical was detected in North Bennington, the state of Vermont set a more conservative level **...**

EPA Releases New Health Guidelines for **PFOA**, PFOS Found in Drinking Water

TWC News - 18 hours ago

The **EPA** has released new health guidelines for **PFOA** and PFOS found in drinking water. **PFOA**was the chemical found in the water supply in Hoosick Falls and Petersburgh. The new health advisory levels have been set to 70 parts per trillion. When first ...

EPA Announces Lifetime **PFOA** and PFOS Advisory Level

New Hampshire Public Radio - 13 hours ago

The **EPA** has announced a lifetime health advisory level for two chemicals that have contaminated water in Southern NH and at the former Pease Air Force Base. **PFOA** and PFOS are slippery, stable chemicals used since the 1940s in products like nonstick ...

EPA issues new federal standards for **PFOA** exposure

WCAX - 14 hours ago

There are new federal standards for exposure to **PFOA** and it's three times higher than the level Vermont is using.**PFOA** has been found in drinking water supplies in Bennington and Pownal. Officials believe the chemical came from old Teflon factories.

EPA Releases New 'Lifetime' **PFOA** Exposure Level Data

Patch.com - 14 hours ago

CONCORD, NH - The U.S. Environmental Protection Agency has issued new “lifetime drinking water health advisory levels” for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion (ppt), according to Jim Martin **...**

EPA releases drinking water health advisories for **PFOA** and PFOS

WaterWorld - 18 hours ago

WASHINGTON, May 19, 2016 -- Based on the latest science on two chemical contaminants called**PFOA** and PFOS, **EPA** has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals.

EPA Releases New **PFOA**, PFOS Guidelines

WAMC - 19 hours ago

“I am pleased that the **EPA** has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," New York U.S. Senator Charles Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh ...

EPA declares official standard for **PFOA**, PFOS contamination for lifetime exposure

WRGB - 19 hours ago

'**EPA's** assessment indicates that drinking water with individual or combined concentrations of**PFOA** and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of **...**

3 Arizona water systems afoul of new **EPA** water guidelines

azcentral.com - 9 hours ago

The agency's latest advisory drops the recommended limit of **PFOA** and PFOS in drinking water from 400 parts per trillion to 70 parts per trillion. The **EPA** cannot enforce that limit, as it is just a recommendation intended to advise water systems on how **...**

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

Wall Street Journal - 17 hours ago

On Thursday, the **EPA** declared that drinking water with **PFOA** concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The **EPA** has been reviewing ...

EPA sets new standards for contaminants

Eagle-Tribune - 1 hour ago

The state has been waiting for some time to hear from the federal **EPA** about its recommendations about acceptable levels of **PFOA** in drinking water, said DES spokesman Jim Martin on Thursday. The new data recommends no more than 70 parts per trillion, ...

New **EPA** Guidelines on PFCs Welcome – but Still Fall Short

Environmental Working Group (blog) - 15 hours ago

Today the Environmental Protection Agency issued a long-awaited drinking water health advisory for the perfluorinated chemicals **PFOA** and PFOS. But **EPA's** advisory falls far short of what's needed to fully protect public health, and it is not a legally ...

Air Force applies new **EPA** guidance

Air Force Link - 15 hours ago

The Air Force has been following a 2009 **EPA** issued short-term provisional health advisory level for **PFOA** at 400 parts per trillion and 200 ppt for PFOS. On May 19, the **EPA** released new lifetime exposure health advisories for PFOS at 70 ppt and for **PFOA ...**

Martinsburg shuts down water plant after **EPA** advisory

Herald-Mail Media - 11 hours ago

The **EPA** issued the stricter guidelines for the chemicals after years of pressure from public-health experts and advocacy groups. The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney ...

EPA releases new safety advisories for chemicals

Burlington County Times - 14 hours ago

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the **EPA** in 2009: 0.4 parts per billion for **PFOA** in drinking water, and 0.2 ppb for PFOS. Thursday's announcement **...**

EPA sets new level for contaminant found in drinking water

WMUR Manchester - 19 hours ago

H. "I will continue to monitor the increasing instances of potentially dangerous **PFOA** and PFOS levels in water resources in several communities across our state and ensure that the **EPA** is working with local officials and communities to take every **...**

'Do not drink' ordered for Vienna water after **EPA** issues C8 guidance

Charleston Gazette-Mail (subscription) - 15 hours ago

“Although it's a long overdue step in the right direction, the guideline is still too high as it allows unacceptable accumulation of **PFOA** to build up in the blood of people drinking it,” said Robert Bilott, a longtime lawyer for residents who had their **...**

EPA Sets New Health Advisory for Toxic Chemicals in Drinking Water

NBC Bay Area - 15 hours ago

The agency set the advisory at 70 parts per trillion of human exposure to two perfluoronated compounds called PFOS and **PFOA**. That means people should not drink water with detections of the chemicals above that level. The new level is nearly six times ...

Amherst water tested for **PFOA**

Cabinet.com - May 19, 2016

After the presence of **PFOA** was detected in private wells in those towns, the DES declared a provisional safe exposure limit of 100 parts per trillion, which is the standard used by Maine. The **EPA** recommends avoiding short-term exposure to more than 400 ...

Federal **EPA** warns of high chemical levels in Martinsburg, Parkersburg and Vienna water sources

West Virginia MetroNews - 14 hours ago

WASHINGTON, D.C. — The federal **EPA** announced Thursday that water sources in Martinsburg, Parkersburg and Vienna contain the chemicals **PFOA** and PFOS at levels higher than previously recommended for public water systems. A ' do not drink' ...

Vermont Department of Health setting **PFOA** advisory level at 20 parts per trillion

NEWS10 ABC - 17 hours ago

Now that **EPA** has set a new advisory level of 70 parts per trillion for **PFOA** and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by**EPA** to assess how this differs from their current **...**

EPA Issues Tighter Limits for Chemical In Water

WILX-TV - 13 hours ago

The cancer-causing chemical **PFOA** has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of**PFOA** in recent years.

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

The Decatur Daily - 17 hours ago

The **EPA** advisory says some studies indicate long-term exposure to higher levels of **PFOA** and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune ...

Do not drink advisory issued for citizens of Vienna

WSAZ-TV - 14 hours ago

WOOD COUNTY, W.Va. (WSAZ) -- The Bureau for Public health has reviewed new information regarding **PFOA** and PFOS that the U.S. **EPA** released Thursday, and have decided to issue a Do Not Drink advisory for citizens of Vienna until additional testing ...

Amherst addresses **PFOA** contamination

WMUR Manchester - May 18, 2016

In Amherst, state environmental officials recently identified the former site of Textiles Coated International on Route 101-A as a likely source of **PFOA** contamination in nearby wells. "Why did this happen, and how is it allowed that we have industry **...**

West Morgan-East Lawrence water customers to receive health warning

The Decatur Daily - 7 hours ago

After the **EPA** on Thursday issued a health advisory, the West Morgan-East Lawrence Water and Sewer Authority said it will notify its 25,000 direct and indirect customers that their drinking water contains excessive amounts of two chemicals.

Newburgh water pollutant now more than twice level of new **EPA** guidelines

Times Herald-Record - 18 hours ago

Sean Maloney had been urging the **EPA** to expedite release of its updated guidelines. "I am pleased that the **EPA**has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," Schumer said in a ...

La Crosse releases drinking water advisory

WXOW.com - 13 hours ago

The contaminants are called Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (**PFOA**). The Environmental Protection Agency or **EPA** now wants municipal water supplies across the county to be tested for unregulated contaminants to be proactive ...

West Virginia communities altering their water sources after new

WHAG - 8 hours ago

... specifically in Martinsburg, Parkersburg and the town of Vienna, are altering their water sources after new **EPA**thresholds were released on Thursday. This comes after officials found raised levels of industrial chemicals of**PFOA** and PFOS in the water.

Doylestown Township shuts down contaminated well

The Intelligencer - 14 hours ago

It (**PFOA**) had not been on any chemical list that governs our permit," the director said. **PFOA** was first found in the Cross Keys well in 2014, the first year the **EPA** tested for the chemical, John said. "Had the **EPA** not looked for it, we wouldn't have **...**

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/**PFOA** from Water and **...**

Broadway World - 17 hours ago

The **EPA** issued two public health advisories today for perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. **EPA's** assessment indicates that drinking water with individual or combined concentrations of **PFOA ...**

Newest clips below: PoliticoPro; (Manchester) Union Leader; (all previously clips forwarded below that).

Politico Pro Energy

EPA SETS PFOA LIMIT: EPA today set its long-awaited PFOA limit at 70 parts per trillion. Scott Waldman reports the limit "applies to both long- and short-term exposure and could have a significant effect on water testing and lawsuits against industry. It is also lower than the current advisory of 100 parts per trillion that the EPA issued in many upstate communities facing exposure to the toxic chemical, which is used in the manufacturing of nonstick products." Communities from New England to West Virginia have been shown to have high levels of the chemical in their drinking water. The New York Times magazine did a deep dive into the chemical back in January.

Union Leader (New Hampshire)

http://www.unionleader.com/environment/epa-issues-health-advisory-for-long-term-pfoa-exposure--20160519

EPA issues health advisory for long-term PFOA exposure

By Kimberly Houghton on 5/19/16 at 4:51pm

Federal officials on Thursday issued a lifetime health advisory for the chemical perfluorooctanoic acid, which is being detected in some water sources in southern New Hampshire.

The U.S. Environmental Protection Agency has now identified 70 parts per trillion of PFOA as a new lifetime drinking water health advisory. Previously, the EPA had a 400 ppt PFOA advisory for short-term exposure.

The new advisory level is less than some levels of PFOA detected in the municipal public water supply wells operated by Merrimack Village District and provided to about 25,000 customers in the area.

At least one Village District well was found to have a PFOA level of 90 ppt, though that well is currently off-line. Ron Miner, superintendent of the district, was not immediately available for comment Thursday. Town Manager Eileen Cabanel directed questions to MVD.

Recently, the New Hampshire Department of Environmental Services began providing bottled water to about 200 properties throughout Litchfield, Merrimack and Amherst that have private wells detecting PFOA at 100 ppt or more. It will now begin offering bottled water to homeowners with PFOA at 70 ppt in light of the newest recommendations from EPA, according to a release.

The federal advisory level of 70 ppt was derived from a developmental toxicity study in mice, according to the EPA's advisory released on Thursday.

"This lifetime health advisory is based on the latest health effects information for noncancer and cancer effects for PFOA - the lifetime health advisory is therefore protective of the population at large," states the advisory.

Tests on monkeys, rats and mice discovered developmental effects, liver toxicity, kidney toxicity, immune effects and cancers such as liver cancer, testicular cancer and pancreatic cancer as a result of long-term PFOA exposure, according to the advisory.

"Water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas and industrial or municipal waste sites where products are disposed of or applied," it states.

Saint-Gobain Performance Plastics has been identified as the likely source of water contamination in Merrimack and surrounding areas, according to officials with DES. PFOA has also been discovered at the old Merrimack landfill and the former Textiles Coated International plant in Amherst.

To date, 73 private wells within Merrimack, Litchfield and Amherst have detected elevated levels of PFOA above 100 ppt.

"I am pleased that the EPA has answered my repeated requests and released the new health advisory standards for PFOA and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to know whether or not their water resources are safe.

"I will continue to monitor the increasing instances of potentially dangerous PFOA and PFOS levels in water resources in several communities across our state and ensure that the EPA is working with local officials and communities to take every action possible for the safety of all Granite State residents," she said.

4:23 PM

Associated Press

http://hosted.ap.org/dynamic/stories/U/US_DRINKING_WATER_CHEMICALS?SITE=AP&SECTION=

EPA ISSUES TIGHTER LIMITS FOR INDUSTRIAL CHEMICAL IN WATER

By Michael Biesecker on 5/19/16 at 4:12pm

Federal regulators are tightening limits for human exposure to an industrial chemical used for decades in such consumer products as non-stick pans, stain-resistant carpets and microwave popcorn bags.

The cancer-causing chemical PFOA has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of PFOA in recent years.

Also at issue is the related chemical PFOS used in firefighting foam.

The Environmental Protection Agency issued the stricter standards for the chemicals on Thursday, following years of public pressure by advocacy groups. The agency said the new limits we prompted by recent scientific studies linking PFOA and PFOS to testicular and kidney cancers, as well as birth defects and liver damage.

4:12 PM

Wall Street Journal

http://www.wsj.com/articles/epa-issues-new-health-advisories-for-chemical-from-some-plastics-plants-1463687484

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

By Cameron McWhirter on 5/19/16 at 3:51pm

The Environmental Protection Agency announced new health advisories Thursday for perfluorooctanoic acid, a potentially toxic chemical, calling for water utilities across the nation to adhere to stricter guidelines than the agency had previously recommended.

In recent months, state investigators in New York, Vermont and New Hampshire have found high levels of the chemical, known as PFOA, in drinking-water wells and groundwater near former and current chemical plants, alarming residents and raising concern about PFOA contamination in other parts of the country.

The Environmental Working Group, a Washington-based advocacy group that assesses chemicals in consumer products and the environment, sent a letter in late April to EPA Administrator Gina McCarthy urging the agency to set an enforceable drinking-water standard for the chemical and to force former manufacturers to disclose all sites in the U.S. where they used, made or dumped PFOA.

On Thursday, the EPA declared that drinking water with PFOA concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The EPA has been reviewing PFOA guidelines for months, and state environmental agencies have been setting their own guidelines. New York and New Hampshire both set limits of 100 parts per trillion, while Vermont had a stricter standard of 20 parts per trillion.

PFOA can be harmful to animals in high doses, causing tumors in the liver and other parts of the body, according to several scientific studies. A multiyear medical study in the 2000s of 70,000 people near a plant in West Virginia that made PFOA found “some suggestions” of “probable links” between high exposure to the chemical and illnesses, including cancer.

The agency Thursday also set a 70 parts per trillion guideline for perfluorooctane sulfonate, or PFOS, a chemical similar to PFOA that was used to make products stain resistant. PFOS has been found in studies to be harmful to the immune systems of animals.

For both chemicals, the guidelines are lifetime-exposure advisories.

The provisional health advisory for PFOS had been 200 parts per trillion. The EPA stated that if both chemicals were found in drinking water, the 70 parts per trillion limit applies for the two chemicals combined. The advisories are not regulations that can be enforced by the EPA, but health guidelines issued for water utilities, and state environmental and health agencies to consider.

"If these chemicals are found in drinking-water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope and source of contamination," according to an EPA statement. "They should also promptly notify consumers and consult with their state drinking-water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breast-fed or formula-fed infants."

Some state officials were quick to applaud the new guidelines. The New Hampshire Department of Environmental Services spokesman Jim Martin said his department would work to provide bottled water to any communities where drinking-water tests exceeded the 70 parts per trillion limit.

The Environmental Working Group said the new levels aren't strict enough and urged the agency to impose a legally enforceable limit.

Factories for decades used PFOA as a plastic coating and to make consumer products such as Teflon nonstick pans, waterproof jackets and pizza boxes. Former large manufacturers or users of PFOA, including 3M Co. and DuPont Co., agreed in 2006 to phase out PFOA production and use by December 2015. Public concern over PFOA has spread through upstate New York and New England since August 2014, when a resident of Hoosick Falls, N.Y., near the Vermont border, tested his drinking water and found high levels of the acid. The man was concerned because his father, a former employee of the town's plastics plant that used PFOA, died of cancer.

Saint-Gobain Performance Plastics, a subsidiary of Saint-Gobain SA of France, operates plants in Merrimack, N.H., and Hoosick Falls, N.Y., and used to operate a plant in North Bennington, Vt. Since last year, state investigators have found PFOA contamination near all three sites, and they cited the plants as potential sources.

A company spokeswoman said in a statement that, according to the EPA, the new advisory is "not a legally enforceable federal standard and is subject to change as new information becomes available." The company, however, believes the new guidelines will help "state and local governments to make consistent decisions concerning the levels of PFOA in drinking water," she said.

Shawn Dalton, 65, a retired communications manager who lives not far from the Merrimack plant, thought until Thursday that water from his well, which tested 73 parts per trillion for PFOA, was safe. Now he knows it is three parts above the new guideline. He was glad for the new guidelines, however, because it means he now can hold government officials and companies accountable, he said.

"At least now the federal government has put a stake in the ground," he said.

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News 10 (ABC)

http://news10.com/2016/05/19/vermont-department-of-health-setting-pfoa-advisory-level-at-20-parts-per-trillion/

Vermont Department of Health setting PFOA advisory level at 20 parts per trillion

By Ali Stewart on 5/19/16 at 3:24pm

The Vermont Health Department says they evaluated all of the scientific information available at the time when setting Vermont's advisory level of 20 parts per trillion for PFOA in drinking water.

Now that EPA has set a new advisory level of 70 parts per trillion for PFOA and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by EPA to assess how this differs from their current advisory level, and consider if any changes are warranted.

The department says they remain committed to protecting the health of Vermonters from these harmful chemicals.

3:29pm

Decatur Daily

http://www.decaturdaily.com/news/lawrence_county/epa-issues-advisory-on-chemicals-found-in-west-morgan-east/article_2d66630b-b85c-5f14-9c45-e11f422b8457.html

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

By Eric Fleischauer on 5/19/16 at 3:22pm

The Environmental Protection Agency today issued a health advisory for two chemicals that are found in the drinking water of West Morgan-East Lawrence Water Authority.

The lifetime advisory warns of adverse health effects for people exposed to drinking water with more than 70 parts per trillion of two chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to court documents, West Morgan-East Lawrence drinking water exceeds the EPA advisory limit for both chemicals.

The EPA advisory says some studies indicate long-term exposure to higher levels of PFOA and PFOS may result in adverse health effects, including developmental effects to fetuses during

pregnancy or to breast-fed infants, cancer, liver damage, immune effects, thyroid effects and cholesterol changes.

The authority sells water to water departments in Vinemont, Falkville, Trinity, Town Creek and the West Lawrence Water Cooperative. About 25,000 people use water supplied by the authority, it has said in court documents.

West Morgan-East Lawrence in October filed a federal lawsuit alleging 3M Co. and its subsidiary, Dyneon LLC, and Daikin America Inc. released the chemicals into the Tennessee River. The lawsuit alleges the chemical entered the authorities water intake downstream of the companies.

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Virtual-Strategy Magazine (Reprint from Business Wire)

http://www.virtual-strategy.com/2016/05/19/new-water-research-foundation-study-addresses-most-effective-methods-removing-pfospfoa-wa#axzz498AKvTCX

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

(See Business Wire story below)

3:02pm

Times Hearld-Record

http://www.recordonline.com/news/20160519/newburgh-water-pollutant-now-more-than-twice-level-of-new-epa-guidelines

Newburgh water pollutant now more than twice level of new EPA guidelines

By Leonard Sparks on 5/19/16 at 2:49pm

New federal health guidelines issued Thursday for the chemical that has shut down Newburgh's primary water supply are less than half the levels recorded in the city.

The Environmental Protection Agency is now urging action if levels of perfluorooctanoic acid or perfluorooctane sulfonate are above 70 parts per trillion, a significantly stricter standard than previously issued advisory guidelines of 100 parts per trillion for PFOA and 200 parts per trillion for PFOS.

Since its water was first tested in December 2013, Newburgh's Washington Lake has had levels of PFOS ranging from 140 to 170 parts per trillion.

While below the initial EPA guidelines, those levels spurred the closure of the lake on May 2, and Newburgh has been drawing water from its backup supply at Brown's Pond.

U.S. Sen. Charles Schumer and U.S. Rep. Sean Maloney had been urging the EPA to expedite release of its updated guidelines.

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS," Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause."

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The Intercept

https://theintercept.com/2016/05/19/with-new-pfoa-drinking-water-advisory-dozens-of-communities-suddenly-have-dangerous-water/

WITH NEW DRINKING WATER ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS WATER

By Sharon Lerner on 5/19/16 at 2:36pm

The EPA announced new drinking water health advisory levels today for the industrial chemicals PFOA and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which were .4 ppb for PFOA and .2 ppb for PFOS. In areas where both PFOA and PFOS are present, the advisory suggests a maximum combined level of .07 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

The new federal standards may unify what has been an inconsistent official response to the presence of these perfluorinated chemicals, or PFCs, in drinking water. They will also instantaneously create official water contamination crises in dozens of cities and towns across the country.

According to the EPA's most recent data on unregulated drinking water contaminants, released in January, 14 drinking water systems around the country reported levels of PFOA that exceed the new federal threshold, while 40 reported PFOS above the new cutoff. In all, water systems in 18 states, as well as in Guam, are contaminated.

Some of these water systems have already begun to quietly address the problem. In Suffolk County, New York, where public drinking water wells show PFOS levels of .33 and .53 ppb, the contaminated water "has either been blended with other wells to reduce the level of the compound to non-detection or their use has been limited to the greatest extent possible," according to Kevin Durk, director of water quality and laboratory services for the Suffolk County Water Authority. Though he does not know the level of PFOS in the water that comes out of local taps, Durk wrote in an email that "it is a virtual certainty that levels of any detected chemical would have been reduced."

Similarly, the Security Water and Sanitation District in Colorado Springs has been struggling to clean up its contaminated water since 142 tests detected PFCs. The district has shut down seven out of 26 wells and is blending water to lower levels, according to Roy Heald, the district's general manager.

But other water company operators have yet to lower their PFC levels. Steve Anderson, owner of the Oatman Water Company in Scottsdale, Arizona, where PFOS measured .2 and .23 in the most recent EPA testing, learned that the chemical was in his water only recently, after he received a call from the Arizona Department of Environmental Quality. Anderson, who suspects the PFOS originated from firefighting foam used by the nearby Oatman Fire Department, said he is "trying to come up with a solution."

Until today, there was a wide range of official opinion on the level of contamination that presented a health danger. The military, which is in the throes of a massive cleanup of 664 contaminated fire- and crash-training sites, has been using the EPA's older standards for PFOA and PFOS to guide its efforts and help determine who receives clean drinking water and remediation of contaminated private wells. (The Department of Defense did not responded to inquiries about how the new advisory levels would alter its cleanup plan.)

Others have set more stringent standards. On January 28, the EPA advised residents of Hoosick Falls, New York, not to use water with PFOA levels above .1 ppb. And a panel of scientists who spent years researching some 70,000 people whose water contained PFOA levels of at least .05 ppb, found probable links between that level of exposure and testicular cancer, kidney cancer, thyroid disease, preeclampsia, ulcerative colitis and high cholesterol. In 2010, New Jersey's Drinking Water Quality Institute calculated a safety limit of .04 for PFOA. Vermont currently has the lowest state drinking water limit for PFOA, .02 ppb.

The levels released today are based on numerous studies connecting the chemicals with health effects. For PFOS, the report notes, studies of lab animals exposed to the chemical reported "developmental effects (decreased body weight, survival, and increased serum glucose levels and insulin resistance in adult offspring), reproductive (mating behavior), liver toxicity (liver weight co-occurring with decreased cholesterol, hepatic steatosis), developmental neurotoxicity (altered spatial learning and memory), immune effects, and cancer (thyroid and liver)."

The report also acknowledged research on human populations that has found associations between PFOS and immune suppression, thyroid disease, high cholesterol, and reduced fertility. It also acknowledged a possible connection between PFOS and bladder, colon, and prostate cancer.

For PFOA, the research included studies on monkeys, rats, and mice showing "developmental

effects (survival, body weight changes, reduced ossification, delays in eye opening, altered puberty, and retarded mammary gland development), liver toxicity (hypertrophy, necrosis, and effects on the metabolism and deposition of dietary lipids), kidney toxicity (weight), immune effects, and cancer (liver, testicular, and pancreatic)."

The new health advisory for PFOA was also based on human studies, which showed "associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)." The EPA report noted that in humans "the developing fetus and newborn is particularly sensitive to PFOA-induced toxicity."

"Taken together," the report notes, "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." The exact phrasing was used in the PFOS report as well.

While calling the new level "a very long-overdue step in the right direction," Robert Bilott, an attorney overseeing a class-action suit over PFOA contamination near a DuPont plant in West Virginia, cautioned that "the new guideline is still too high, as exposures at even the new guideline level would allow PFOA to continue to build up to ever-increasing, unacceptable levels in human blood."

Bilott also noted that the new levels are informal guidelines, as opposed to enforceable regulatory limits. "If it was enforceable," he said, "the EPA could issue unilateral orders requiring the responsible party to clean it up."

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WaterWorld

http://www.waterworld.com/articles/2016/05/epa-releases-drinking-water-health-advisories-for-pfoa-and-pfos.html

EPA RELEASES DRINKING WATER HEALTH ADVISORIES FOR PFOA AND PFOS

By (No author) on 5/19/16 at 2:42pm

Based on the latest science on two chemical contaminants called PFOA and PFOS, EPA has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals. These advisories will help local water systems and state, tribal and local officials take the appropriate steps to address PFOA and PFOS if needed.

EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations.

For many years, PFOA and PFOS were widely used in carpets, clothing, furniture fabrics, food packaging, and other materials to make them more resistant to water, grease, and stains. PFOA and PFOS were also used for firefighting at airfields and in a number of industrial processes. Between 2000 and 2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer. And EPA asked eight major companies to commit to eliminate their production and use of PFOA by the end of 2015 and they have indicated that they have met their commitments. While there are some limited ongoing uses of these chemicals, in recent years, blood testing data has shown that exposures are declining across the country.

For most people, their source of exposure to PFOA and PFOS has come through food and consumer products. But drinking water can be an additional source of exposure in the small percentage of communities where these chemicals have contaminated water supplies. This is typically a localized issue associated with a specific facility -- for example, in communities where a manufacturing plant or airfield made or used these chemicals.

If these chemicals are found in drinking water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope, and source of contamination. They should also promptly notify consumers and consult with their state drinking water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breastfed or formula-fed infants. There are a number of options available to water systems to lower concentrations of these chemicals in the drinking water supply.

EPA will continue sharing the latest science and information so that state and local officials can

make informed decisions and take actions to protect public health. This is an important part of our broader effort to support states and public water systems as we work together to strengthen the safety of America's drinking water.

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Business Wire

http://www.businesswire.com/news/home/20160519006484/en/Water-Research-Foundation-Study-Addresses-Effective-Methods

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

By (No author) on 5/19/16 at 2:44pm

The Water Research Foundation (WRF), a leading sponsor of research supporting the water community, has released findings of a study addressing effective methods for removing poly- and perfluoroalkyl substances (PFASs) from water and wastewater. The research report, Treatment Mitigation Strategies for Poly- and Perfluorinated Chemicals (WRF project #4322), contains results of an in-depth treatment study conducted on waters from 13 water and wastewater treatment plants in the United States. Additionally, WRF will be hosting a Webcast on June 2 addressing the project's results and has posted a State of the Science document on PFASs.

The research from project #4322 demonstrated that conventional treatment at wastewater treatment plants and most drinking water treatment plants is ineffective at removing PFASs. Activated carbon and anion exchange can remove many PFASs but are less effective at removing shorter chain PFASs. The most effective treatment technologies are nanofiltration and reverse osmosis, which work even for the smallest PFASs studied.

The EPA issued two public health advisories today for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

"The research results from project #4322 will help the water community understand the best options for removing PFASs from water and wastewater, said Rob Renner, CEO of the Water Research Foundation. "This knowledge is especially important as the EPA continues the process of regulating these chemicals in water."

Poly- and perfluoroalkyl substances (PFASs) are a group of manmade chemicals with past and current uses in industrial processes and consumer products. PFASs are also commonly referred to as perfluorinated chemicals or PFCs. The most notable PFASs are PFOA and PFOS, but there are many others. PFASs are used in firefighting foams, coating for food packaging, ScotchGardTM and TeflonTM, among other products.

Exposure to PFASs can occur through use of products or consumption of food or water containing PFASs. PFASs do not break down easily and therefore persist in the environment. They are also soluble in water and can enter source waters through industrial releases, discharges from wastewater treatment plants, storm water runoff, release of firefighting foams, and land application of contaminated biosolids.

PFASs are a concern because they have been shown to have health effects in animal studies. Data from some human studies suggest that PFASs also affect human health. Additional research is ongoing in order to gain a better understanding of human health effects.

2:45pm

WRGB Albany (CBS)

http://cbs6albany.com/news/hoosick-falls-crisis/epa-declares-official-standard-for-pfoa-pfoh-contamination

EPA declares official standard for PFOA, PFOS contamination for lifetime exposure

By WRGB Staff on 5/19/16 at 2:19pm

The EPA has released official long- term exposure guidelines for PFOA, PFOS contamination.

Released documents state that concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

Vermont lists safe exposure levels at 20 parts per trillion, including babies and children.

Regional EPA originally set short term exposure as 100 ppt in Hoosick Falls.

'EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations. " , says the EPA in a released document.

2:27 PM

Vermont Public Radio

http://digital.vpr.net/post/significant-reduction-epa-sets-health-advisory-pfoa-70-parts-trillion#stream/0

In Significant Reduction, EPA Sets Health Advisory For PFOA At 70 Parts Per Trillion

By Howard Weiss-Tisman on 5/19/16 at 2:11pm

The Environmental Protection Agency on Thursday issued an updated health advisory for the suspected carcinogen PFOA.

The EPA says water that contains PFOA in levels at 70 parts per trillion should be considered unsafe to drink.

The EPA previously set its level at 400 ppt. The new, lifetime health advisory replaces that

standard.

PFOA, a chemical that was used in a variety of manufacturing applications, has been found in water in North Bennington, Bennington and Pownal.

The contaminant has also been detected in New Hampshire and New York, and in other states around the country.

Vermont set its level at 20 parts per trillion.

(Reprint of Bucks County Courier Times story)

http://www.theintell.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_a404ad5d-a246-5ec2-9d1b-a9af8b6e70d5.html

EPA releases new safety advisories for chemicals

2:20 PM

Time Warner Cable News - Capital Region

http://www.twcnews.com/nys/capital-region/news/2016/05/19/epa-releases-new-pfoa-and-pfos-health-guidelines.html

EPA Releases New Health Guidelines for PFOA, PFOS Found in Drinking Water

By TWC News Web Staff on 5/19/16 at 1:46pm

The EPA has released new health guidelines for PFOA and PFOS found in drinking water.

PFOA was the chemical found in the water supply in Hoosick Falls and Petersburgh.

The new health advisory levels have been set to 70 parts per trillion.

When first tested at the St. Gobain facility in Hoosick Falls, the EPA measured the levels at 18,000 parts per trillion.

A filtration system has since been installed, eliminating traces of the chemical, making the water safe to use again in Hoosick Falls.

In Petersburgh, multiple homes have tested above the new acceptable levels.

Taconic Plastics is believed to be the source of contamination. Residents in the town have grown impatient with leaders as they await to learn when they can get blood tested.

The town even ran out of bottled water to give to residents over the weekend. That supply has since been replenished.

Also, PFOS levels in Washington Lake and Silver Stream are in the range of 145 to 150 parts per trillion.

Washington Lake used to supply Newburgh's drinking water, until the city found out about the continuing levels of PFOS.

The city switched to Brown's Pond as a drinking source, since almost no levels of PFOS were found in that water.

Newburgh is still working to determine where the PFOS contamination is coming from.

Senator Schumer on New Standards:

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS. Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause. The EPA's new guidance will go a long way in protecting public health and arming local officials with the most up-to-date information to keep our drinking water safe from harmful contaminates."

Bucks County Courier Times (also ran in the Intelligencer)

http://www.buckscountycouriertimes.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_97946008-1de8-11e6-83d3-334d7ea7ce37.html

EPA Releases New Safety Advisories for Chemicals

By Kyle Bagenstose on 5/19/16 at 2:00pm

The Environmental Protection Agency on Thursday released a long-awaited update to its drinking water advisories for unregulated chemicals perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).

According to prior testing data of public and private water supplies in Bucks and Montgomery counties, it appears the updated advisories could mean some drinking water in the area is contaminated with the chemicals at a level above what the EPA deems is safe to consume.

The chemicals already had contaminated about 100 public and private water wells near a trio of

current and former military bases in the region: The former Naval Air Station Joint Reserve Base Willow Grove, Horsham Air Guard Station, and former Naval Air Warfare Center in Warminster.

The chemicals are suspected to have originated in firefighting foams used at the bases, and the military already has agreed to spend approximately $19 million to provide replacement water and install filtration systems for public water wells affected by the chemicals, and bottled water and hook-ups to public systems for homes with affected private wells.

But the number of wells now likely will increase.

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the EPA in 2009: .4 parts per billion for PFOA in drinking water, and .2 ppb for PFOS.

Thursday's announcement, however, set an advised limit of .07 ppb for PFOS and PFOA combined, in order to protect against health effects from a lifetime of exposure. In a worst case scenario, that means drinking water with .58 ppb of the chemicals (.39 ppb PFOA and .19 ppb PFOS) previously considered safe, now would be more than eight times the recommended limit.

After the chemicals first were discovered in some local public water supplies by a nationwide EPA testing program in 2013 and 2014, multiple public wells in the area were taken offline.

The Horsham Water and Sewer Authority removed two drinking water wells from its system in the summer of 2014 after PFOS was found at 1 and .7 ppb. Data from the testing program shows that three more wells also were contaminated with the chemicals at levels above the EPA's new advisory, with a combined .071 ppb, .123 ppb, and .14 ppb.

In a brief email Thursday, authority manager Tina O'Rourke said only two additional wells are above the .07 ppb level as of the most recent testing.

She added that the authority intends to take the wells offline and that existing agreements with the military allow for the authority to take action immediately.

The Warminster Municipal Authority, which previously removed three wells from its supply, also appears to have two more wells contaminated above the new level, with a combined .091 ppb and .09 ppb.

The Warrington Township Water Department previously removed a trio of wells that combined to form a single water source. Based on the EPA's data showing a combined .082 ppb, another well could also be above the new health advisory.

This news organization reached out to all three utilities to obtain the most recent testing information and will update this story as it receives responses.

Although unregulated, a growing body of science has established associations between PFOA and PFOS and a range of health effects, including a variety of cancers.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in a phone interview Thursday that the updated advisories reflect a review of available science and are intended to be protective for lifetime exposure to the chemicals for even vulnerable populations, such as nursing mothers and their children.

"These health advisories are scientific documents … the point is to provide the best available information to state and local authorities and drinking water system operators," Beauvais said. "They're calculated to reflect a margin or protection to the most sensitive populations."

Beauvais added that the next step for the chemicals is to be considered for a federal drinking water standard that can be enforced, as is the case with more well-known contaminants such as lead or arsenic. However, he was unable to say how long it might take for that decision to be made.

1:59 PM

Albany Times Union

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-water-7716825.php

EPA Sets New Level for Chemical in Drinking Water

By Brendan J. Lyons on 5/19/16 at 1:17pm

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

The EPA's advisory level is well below the levels of PFOA that were detected in public water supplies over the past two years in Hoosick Falls, Petersburgh, North Bennington, Vt., and Merrimack, N.H.

In addition, health and environmental officials said tests have also revealed levels of PFOA in dozens of private wells in Rensselaer County that are much higher than the EPA's guideline.

Officials with the state Health Department and Department of Environmental Conservation could not immediately provide information Thursday about how many water systems in New York may contain PFOA, which has been used since the 1940s to make products such as nonstick coatings, such as Teflon, and heat-resistant wiring and other specialty products.

In 2009, the EPA established a guideline that a level of 400 parts per trillion is a safe level for "short-term" consumption of the water. Earlier this year, the EPA issued a provisional health advisory of 100 ppt. Meanwhile, other states have set far lower acceptable levels of PFOA in public water systems, including New Jersey, which has set a level of 40 ppt.

State Health Commissioner Dr. Howard A. Zucker in January said the state Health Department was reviewing its position on acceptable levels of PFOA in drinking water and would set a new safety limit within weeks. But the state did not issue a new advisory.

Robert A. Bilott, an Ohio attorney who is helping represent an estimated 3,500 people in a class-action lawsuit against DuPont, which manufactured and used perfluorinated chemicals such as PFOA in its products, has been urging the EPA for years to adopt a permanent health advisory for long-term exposure to PFOA in drinking water. Bilott has represented "tens of thousands of individuals in various communities across the country who have been injured because of the contamination of their drinking water with PFOA."

"The lower number and acknowledgement of the need to consider the combined amount of PFCs in water is a long-overdue step in the right direction, but the guideline is still too high, as it will allow ever-increasing, unacceptable levels of PFOA to continue to build up in the blood of those exposed," Bilott said.

Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid

disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

Bilott said the science panel's peer-reviewed report was paid for by DuPont and, as a result of the panel's findings, the company has to concede in the personal-injury lawsuits that PFOA causes cancer.

In Albany, numerous lawsuits were filed this year in U.S. District Court seeking class-action status on behalf of current and former Hoosick Falls residents, including some who allege they suffered serious health effects that could be linked to PFOA exposure.

According to the EPA, PFOA was detected in blood serum in 99 percent of the U.S. population between 1999 and 2012. However, the EPA said the levels of PFOA in human blood have been decreasing since U.S. companies began to phase out production of the chemical more than 10 years ago. Still, water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied, the agency said.

Thousands of people whose blood was tested in that area of the Ohio Valley had elevated levels of PFOA, including at levels as high as 40 parts per billion.

In Hoosick Falls, where hundreds of people signed up for state-sponsored blood tests in February, the results of those tests are expected to be released beginning next week.

In February, the state Department of Environmental Conservation asked two corporations, Saint-Gobain Performance Plastics and Honeywell International, to enter consent orders that would require them to clean up the remnants of the toxic chemical that polluted water supplies in and around Hoosick Falls.

The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations in Rensselaer County, including the town

of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

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WAMC, Northeast Public Radio

http://wamc.org/post/epa-releases-new-pfoa-pfos-guidelines

EPA Releases New PFOA, PFOS Guidelines

By (No author) on 5/19/16 at 1:44pm

The U.S. Environmental Protection Agency has released new health advisories for PFOA and PFOS, the manufacturing chemicals at the center of water contamination crises in several communities in the region including Hoosick Falls, Petersburgh, and North Bennington. The guidelines released today lower the lifetime exposure from drinking water level to 70 parts per trillion. The level of PFOA in affected areas has been much higher than the new benchmark, leading communities to establish alternate water supplies. High exposure can result in cancer, birth defects and other diseases.

WMUR Manchester (ABC)

http://www.wmur.com/health/epa-sets-new-level-for-contaminant-found-in-drinking-water/39629266

EPA sets new level for contaminant found in drinking water

By Kirk Enstrom on 5/19/16 at 1:41pm

The Environmental Protection Agency has set new advisory levels for a contaminant that has been found in drinking water supplies in parts of New Hampshire.

The state Department of Environmental Services said Thursday that the EPA set a lifetime drinking water health advisory level for perfluorooctanoic acid at 70 parts per trillion.

The same level was set for a related chemical, perfluorooctane sulfonate. The EPA said that when both chemicals are present, the combined concentration shouldn't exceed 70 parts per trillion.

State environmental officials had been advising well water users whose water tested above 100 parts per trillion to drink bottled water instead.

PFOA was found earlier this year in groundwater near the Saint-Gobain Performance Plastics facility in Merrimack after that company conducted tests. The contaminant has since been found in private wells in Litchfield, Manchester, Bedford and other areas.

It was most recently found in Amherst near a former industrial site.

State environmental officials said they are working to review the scientific basis for the new levels. DES said it's also taking steps to provide bottled water to all known private well users who have detected PFOA or PFOS levels greater than 70 parts per trillion.

"The state of New Hampshire will take immediate action to expand distribution of bottled water in affected areas to those whose water supply falls under the new advisory," Gov. Maggie Hassan said.

DES said it plans to move quickly to develop emergency rules for groundwater cleanup and drinking water standards. There will be a public comment process before permanent rules are established.

DES has set up a website to discuss the PFOA investigation.

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NEWS10 ABC

http://news10.com/2016/05/19/epa-issues-health-advisory-level-for-lifetime-exposure-to-pfoa/

EPA Sets Health Advisory Level for Lifetime Exposure to PFOA

By Joe Gullo on 5/19/16 at 1:21pm

The U.S. Environmental Protection Agency (EPA) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to PFOA.

The EPA says the advisory is to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime exposure to PFOA and PFOS from drinking water.

PFOA has been linked to serious health problems such as cancer.

Some local communities, including Petersburgh, Hoosick Falls, Bennington, and Pownal have had wells test positive for the chemical.

PFOA and PFOS have been used to make carpets, clothing, fabrics for furniture, paper packaging for food, and other materials that are resistant to water, grease, or stains. In 2006, the EPA says they asked eight companies using PFOA to phase out use and chemicals used to break down PFOA. Those companies have stated at the end of 2015, they phased out the use of PFOA.

According to the EPA, the establishment of the advisories follows an assessment from the latest peer-reviewed science to provide water system operators, and state, tribal, and local officials who have the primary responsibility of overseeing these systems.

Advisories issued by the EPA are designed to provide information on contaminants that can cause human health effects and are known or anticipated to occur in water.

Travis Loop

Director of Communications

Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Personal Address / Ex. 6
From: Behl, Betsy
Sent: Fri 5/20/2016 1:58:14 PM
Subject: FW: media clips for PFOA PFOS

Check this out!

From: Loop, Travis
Sent: Friday, May 20, 2016 9:09 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Fuld, John <Fuld.John@epa.gov>; Altieri, Sonia <Altieri.Sonia@epa.gov>; Duke, Nia <Duke.Nia@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: media clips for PFOA PFOS

Here is a compilation of media clips on PFOA PFOS. The biggest common error is referring to it as a standard.

Because they asked and had done some digging through data, we provided the list of 63 communities Joel did interviews with USA Today/Gannett and BuzzFeed. I have not seen those stories yet.

EPA sets health advisory level for lifetime exposure to **PFOA**

NEWS10 ABC - 19 hours ago

WASHINGTON (NEWS10) – The U.S. Environmental Protection Agency (**EPA**) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to **PFOA**. The **EPA**said the advisory is to provide Americans, including the most ...

EPA sets new level for chemical **PFOA** in drinking water

Albany Times Union - 12 hours ago

The **EPA's** long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of **PFOA** in public water systems and private wells. The contamination has been linked ...

EPA suggests tighter limits for PFOA, PFOS in drinking water

PhillyVoice.com - 3 hours ago

The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney cancers, as well as birth defects and liver damage. "**EPA** will continue sharing the latest science and information so that state and **...**

With New EPA Advisory, Dozens of Communities Suddenly Have Dangerous Drinking Water

The Intercept - 17 hours ago

The **EPA** announced new drinking water health advisory levels today for the industrial chemicals**PFOA** and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which **...**

EPA issues health advisory for long-term PFOA exposure

The Union Leader - 16 hours ago

“I am pleased that the **EPA** has answered my repeated requests and released the new health advisory standards for **PFOA** and (perfluorooctyl sulfonate) levels,” U.S. Sen. Kelly Ayotte said in a statement on Thursday. “New Hampshire residents deserve to ...

EPA issues PFOA health advisory

Nashua Telegraph - 8 hours ago

"The **EPA** has set the health advisory for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion and has recommended that when these two chemicals co-occur in the drinking water source, the sum of the ...

EPA Sets New Guidelines For PFOA, PFOS; Superfund Declared For Petersburgh

WAMC - 15 hours ago

In 2009, **EPA** set a short-term exposure guideline of 100 ppt for **PFOA** and PFOS. Perhaps due to a lack of long-term exposure guidlelines, state governments have not had consistent recommended levels. Vermont has acted under a 20 ppt threshold while ...

In Significant Reduction, **EPA** Sets Health Advisory For **PFOA** At 70 Parts Per Trillion

Vermont Public Radio - 18 hours ago

The **EPA** announced last year that it was looking at its health advisory level of 400 parts per trillion for **PFOA**, which was established in 2009. After the chemical was detected in North Bennington, the state of Vermont set a more conservative level **...**

EPA Releases New Health Guidelines for **PFOA**, PFOS Found in Drinking Water

TWC News - 18 hours ago

The **EPA** has released new health guidelines for **PFOA** and PFOS found in drinking water. **PFOA**was the chemical found in the water supply in Hoosick Falls and Petersburgh. The new health advisory levels have been set to 70 parts per trillion. When first ...

EPA Announces Lifetime **PFOA** and PFOS Advisory Level

New Hampshire Public Radio - 13 hours ago

The **EPA** has announced a lifetime health advisory level for two chemicals that have contaminated water in Southern NH and at the former Pease Air Force Base. **PFOA** and PFOS are slippery, stable chemicals used since the 1940s in products like nonstick ...

EPA issues new federal standards for **PFOA** exposure

WCAX - 14 hours ago

There are new federal standards for exposure to **PFOA** and it's three times higher than the level Vermont is using.**PFOA** has been found in drinking water supplies in Bennington and Pownal. Officials believe the chemical came from old Teflon factories.

EPA Releases New 'Lifetime' **PFOA** Exposure Level Data

Patch.com - 14 hours ago

CONCORD, NH - The U.S. Environmental Protection Agency has issued new “lifetime drinking water health advisory levels” for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion (ppt), according to Jim Martin **...**

EPA releases drinking water health advisories for **PFOA** and PFOS

WaterWorld - 18 hours ago

WASHINGTON, May 19, 2016 -- Based on the latest science on two chemical contaminants called**PFOA** and PFOS, **EPA** has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals.

EPA Releases New **PFOA**, PFOS Guidelines

WAMC - 19 hours ago

“I am pleased that the **EPA** has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," New York U.S. Senator Charles Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh ...

EPA declares official standard for **PFOA**, PFOS contamination for lifetime exposure

WRGB - 19 hours ago

'**EPA's** assessment indicates that drinking water with individual or combined concentrations of**PFOA** and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of **...**

3 Arizona water systems afoul of new **EPA** water guidelines

azcentral.com - 9 hours ago

The agency's latest advisory drops the recommended limit of **PFOA** and PFOS in drinking water from 400 parts per trillion to 70 parts per trillion. The **EPA** cannot enforce that limit, as it is just a recommendation intended to advise water systems on how **...**

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

Wall Street Journal - 17 hours ago

On Thursday, the **EPA** declared that drinking water with **PFOA** concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The **EPA** has been reviewing ...

EPA sets new standards for contaminants

Eagle-Tribune - 1 hour ago

The state has been waiting for some time to hear from the federal **EPA** about its recommendations about acceptable levels of **PFOA** in drinking water, said DES spokesman Jim Martin on Thursday. The new data recommends no more than 70 parts per trillion, ...

New **EPA** Guidelines on PFCs Welcome – but Still Fall Short

Environmental Working Group (blog) - 15 hours ago

Today the Environmental Protection Agency issued a long-awaited drinking water health advisory for the perfluorinated chemicals **PFOA** and PFOS. But **EPA's** advisory falls far short of what's needed to fully protect public health, and it is not a legally ...

Air Force applies new **EPA** guidance

Air Force Link - 15 hours ago

The Air Force has been following a 2009 **EPA** issued short-term provisional health advisory level for **PFOA** at 400 parts per trillion and 200 ppt for PFOS. On May 19, the **EPA** released new lifetime exposure health advisories for PFOS at 70 ppt and for **PFOA ...**

Martinsburg shuts down water plant after **EPA** advisory

Herald-Mail Media - 11 hours ago

The **EPA** issued the stricter guidelines for the chemicals after years of pressure from public-health experts and advocacy groups. The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney ...

EPA releases new safety advisories for chemicals

Burlington County Times - 14 hours ago

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the **EPA** in 2009: 0.4 parts per billion for **PFOA** in drinking water, and 0.2 ppb for PFOS. Thursday's announcement **...**

EPA sets new level for contaminant found in drinking water

WMUR Manchester - 19 hours ago

H. "I will continue to monitor the increasing instances of potentially dangerous **PFOA** and PFOS levels in water resources in several communities across our state and ensure that the **EPA** is working with local officials and communities to take every **...**

'Do not drink' ordered for Vienna water after **EPA** issues C8 guidance

Charleston Gazette-Mail (subscription) - 15 hours ago

“Although it's a long overdue step in the right direction, the guideline is still too high as it allows unacceptable accumulation of **PFOA** to build up in the blood of people drinking it,” said Robert Bilott, a longtime lawyer for residents who had their **...**

EPA Sets New Health Advisory for Toxic Chemicals in Drinking Water

NBC Bay Area - 15 hours ago

The agency set the advisory at 70 parts per trillion of human exposure to two perfluoronated compounds called PFOS and **PFOA**. That means people should not drink water with detections of the chemicals above that level. The new level is nearly six times ...

Amherst water tested for **PFOA**

Cabinet.com - May 19, 2016

After the presence of **PFOA** was detected in private wells in those towns, the DES declared a provisional safe exposure limit of 100 parts per trillion, which is the standard used by Maine. The **EPA** recommends avoiding short-term exposure to more than 400 ...

Federal **EPA** warns of high chemical levels in Martinsburg, Parkersburg and Vienna water sources

West Virginia MetroNews - 14 hours ago

WASHINGTON, D.C. — The federal **EPA** announced Thursday that water sources in Martinsburg, Parkersburg and Vienna contain the chemicals **PFOA** and PFOS at levels higher than previously recommended for public water systems. A ' do not drink' ...

Vermont Department of Health setting **PFOA** advisory level at 20 parts per trillion

NEWS10 ABC - 17 hours ago

Now that **EPA** has set a new advisory level of 70 parts per trillion for **PFOA** and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by**EPA** to assess how this differs from their current **...**

EPA Issues Tighter Limits for Chemical In Water

WILX-TV - 13 hours ago

The cancer-causing chemical **PFOA** has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of**PFOA** in recent years.

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

The Decatur Daily - 17 hours ago

The **EPA** advisory says some studies indicate long-term exposure to higher levels of **PFOA** and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune ...

Do not drink advisory issued for citizens of Vienna

WSAZ-TV - 14 hours ago

WOOD COUNTY, W.Va. (WSAZ) -- The Bureau for Public health has reviewed new information regarding **PFOA** and PFOS that the U.S. **EPA** released Thursday, and have decided to issue a Do Not Drink advisory for citizens of Vienna until additional testing ...

Amherst addresses **PFOA** contamination

WMUR Manchester - May 18, 2016

In Amherst, state environmental officials recently identified the former site of Textiles Coated International on Route 101-A as a likely source of **PFOA** contamination in nearby wells. "Why did this happen, and how is it allowed that we have industry **...**

West Morgan-East Lawrence water customers to receive health warning

The Decatur Daily - 7 hours ago

After the **EPA** on Thursday issued a health advisory, the West Morgan-East Lawrence Water and Sewer Authority said it will notify its 25,000 direct and indirect customers that their drinking water contains excessive amounts of two chemicals.

Newburgh water pollutant now more than twice level of new **EPA** guidelines

Times Herald-Record - 18 hours ago

Sean Maloney had been urging the **EPA** to expedite release of its updated guidelines. "I am pleased that the **EPA**has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," Schumer said in a ...

La Crosse releases drinking water advisory

WXOW.com - 13 hours ago

The contaminants are called Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (**PFOA**). The Environmental Protection Agency or **EPA** now wants municipal water supplies across the county to be tested for unregulated contaminants to be proactive ...

West Virginia communities altering their water sources after new

WHAG - 8 hours ago

... specifically in Martinsburg, Parkersburg and the town of Vienna, are altering their water sources after new **EPA**thresholds were released on Thursday. This comes after officials found raised levels of industrial chemicals of**PFOA** and PFOS in the water.

Doylestown Township shuts down contaminated well

The Intelligencer - 14 hours ago

It (**PFOA**) had not been on any chemical list that governs our permit," the director said. **PFOA** was first found in the Cross Keys well in 2014, the first year the **EPA** tested for the chemical, John said. "Had the **EPA** not looked for it, we wouldn't have **...**

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/**PFOA** from Water and **...**

Broadway World - 17 hours ago

The **EPA** issued two public health advisories today for perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. **EPA's** assessment indicates that drinking water with individual or combined concentrations of **PFOA ...**

Newest clips below: PoliticoPro; (Manchester) Union Leader; (all previously clips forwarded below that).

Politico Pro Energy

EPA SETS PFOA LIMIT: EPA today set its long-awaited PFOA limit at 70 parts per trillion. Scott Waldman reports the limit "applies to both long- and short-term exposure and could have a significant effect on water testing and lawsuits against industry. It is also lower than the current advisory of 100 parts per trillion that the EPA issued in many upstate communities facing exposure to the toxic chemical, which is used in the manufacturing of nonstick products." Communities from New England to West Virginia have been shown to have high levels of the chemical in their drinking water. The New York Times magazine did a deep dive into the chemical back in January.

Union Leader (New Hampshire)

http://www.unionleader.com/environment/epa-issues-health-advisory-for-long-term-pfoa-exposure--20160519

EPA issues health advisory for long-term PFOA exposure

By Kimberly Houghton on 5/19/16 at 4:51pm

Federal officials on Thursday issued a lifetime health advisory for the chemical perfluorooctanoic acid, which is being detected in some water sources in southern New Hampshire.

The U.S. Environmental Protection Agency has now identified 70 parts per trillion of PFOA as a new lifetime drinking water health advisory. Previously, the EPA had a 400 ppt PFOA advisory for short-term exposure.

The new advisory level is less than some levels of PFOA detected in the municipal public water supply wells operated by Merrimack Village District and provided to about 25,000 customers in the area.

At least one Village District well was found to have a PFOA level of 90 ppt, though that well is currently off-line. Ron Miner, superintendent of the district, was not immediately available for comment Thursday. Town Manager Eileen Cabanel directed questions to MVD.

Recently, the New Hampshire Department of Environmental Services began providing bottled water to about 200 properties throughout Litchfield, Merrimack and Amherst that have private wells detecting PFOA at 100 ppt or more. It will now begin offering bottled water to homeowners with PFOA at 70 ppt in light of the newest recommendations from EPA, according to a release.

The federal advisory level of 70 ppt was derived from a developmental toxicity study in mice, according to the EPA's advisory released on Thursday.

"This lifetime health advisory is based on the latest health effects information for noncancer and cancer effects for PFOA - the lifetime health advisory is therefore protective of the population at large," states the advisory.

Tests on monkeys, rats and mice discovered developmental effects, liver toxicity, kidney toxicity, immune effects and cancers such as liver cancer, testicular cancer and pancreatic cancer as a result of long-term PFOA exposure, according to the advisory.

"Water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas and industrial or municipal waste sites where products are disposed of or applied," it states.

Saint-Gobain Performance Plastics has been identified as the likely source of water contamination in Merrimack and surrounding areas, according to officials with DES. PFOA has also been discovered at the old Merrimack landfill and the former Textiles Coated International plant in Amherst.

To date, 73 private wells within Merrimack, Litchfield and Amherst have detected elevated levels of PFOA above 100 ppt.

"I am pleased that the EPA has answered my repeated requests and released the new health advisory standards for PFOA and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to know whether or not their water resources are safe.

"I will continue to monitor the increasing instances of potentially dangerous PFOA and PFOS levels in water resources in several communities across our state and ensure that the EPA is working with local officials and communities to take every action possible for the safety of all Granite State residents," she said.

4:23 PM

Associated Press

http://hosted.ap.org/dynamic/stories/U/US_DRINKING_WATER_CHEMICALS?SITE=AP&SECTION=

EPA ISSUES TIGHTER LIMITS FOR INDUSTRIAL CHEMICAL IN WATER

By Michael Biesecker on 5/19/16 at 4:12pm

Federal regulators are tightening limits for human exposure to an industrial chemical used for decades in such consumer products as non-stick pans, stain-resistant carpets and microwave popcorn bags.

The cancer-causing chemical PFOA has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of PFOA in recent years.

Also at issue is the related chemical PFOS used in firefighting foam.

The Environmental Protection Agency issued the stricter standards for the chemicals on Thursday, following years of public pressure by advocacy groups. The agency said the new limits we prompted by recent scientific studies linking PFOA and PFOS to testicular and kidney cancers, as well as birth defects and liver damage.

4:12 PM

Wall Street Journal

http://www.wsj.com/articles/epa-issues-new-health-advisories-for-chemical-from-some-plastics-plants-1463687484

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

By Cameron McWhirter on 5/19/16 at 3:51pm

The Environmental Protection Agency announced new health advisories Thursday for perfluorooctanoic acid, a potentially toxic chemical, calling for water utilities across the nation to adhere to stricter guidelines than the agency had previously recommended.

In recent months, state investigators in New York, Vermont and New Hampshire have found high levels of the chemical, known as PFOA, in drinking-water wells and groundwater near former and current chemical plants, alarming residents and raising concern about PFOA contamination in other parts of the country.

The Environmental Working Group, a Washington-based advocacy group that assesses chemicals in consumer products and the environment, sent a letter in late April to EPA Administrator Gina McCarthy urging the agency to set an enforceable drinking-water standard for the chemical and to force former manufacturers to disclose all sites in the U.S. where they used, made or dumped PFOA.

On Thursday, the EPA declared that drinking water with PFOA concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The EPA has been reviewing PFOA guidelines for months, and state environmental agencies have been setting their own guidelines. New York and New Hampshire both set limits of 100 parts per trillion, while Vermont had a stricter standard of 20 parts per trillion.

PFOA can be harmful to animals in high doses, causing tumors in the liver and other parts of the body, according to several scientific studies. A multiyear medical study in the 2000s of 70,000 people near a plant in West Virginia that made PFOA found “some suggestions” of “probable links” between high exposure to the chemical and illnesses, including cancer.

The agency Thursday also set a 70 parts per trillion guideline for perfluorooctane sulfonate, or PFOS, a chemical similar to PFOA that was used to make products stain resistant. PFOS has been found in studies to be harmful to the immune systems of animals.

For both chemicals, the guidelines are lifetime-exposure advisories.

The provisional health advisory for PFOS had been 200 parts per trillion. The EPA stated that if both chemicals were found in drinking water, the 70 parts per trillion limit applies for the two chemicals combined. The advisories are not regulations that can be enforced by the EPA, but health guidelines issued for water utilities, and state environmental and health agencies to consider.

"If these chemicals are found in drinking-water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope and source of contamination," according to an EPA statement. "They should also promptly notify consumers and consult with their state drinking-water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breast-fed or formula-fed infants."

Some state officials were quick to applaud the new guidelines. The New Hampshire Department of Environmental Services spokesman Jim Martin said his department would work to provide bottled water to any communities where drinking-water tests exceeded the 70 parts per trillion limit.

The Environmental Working Group said the new levels aren't strict enough and urged the agency to impose a legally enforceable limit.

Factories for decades used PFOA as a plastic coating and to make consumer products such as Teflon nonstick pans, waterproof jackets and pizza boxes. Former large manufacturers or users of PFOA, including 3M Co. and DuPont Co., agreed in 2006 to phase out PFOA production and use by December 2015. Public concern over PFOA has spread through upstate New York and New England since August 2014, when a resident of Hoosick Falls, N.Y., near the Vermont border, tested his drinking water and found high levels of the acid. The man was concerned because his father, a former employee of the town's plastics plant that used PFOA, died of cancer.

Saint-Gobain Performance Plastics, a subsidiary of Saint-Gobain SA of France, operates plants in Merrimack, N.H., and Hoosick Falls, N.Y., and used to operate a plant in North Bennington, Vt. Since last year, state investigators have found PFOA contamination near all three sites, and they cited the plants as potential sources.

A company spokeswoman said in a statement that, according to the EPA, the new advisory is "not a legally enforceable federal standard and is subject to change as new information becomes available." The company, however, believes the new guidelines will help "state and local governments to make consistent decisions concerning the levels of PFOA in drinking water," she said.

Shawn Dalton, 65, a retired communications manager who lives not far from the Merrimack plant, thought until Thursday that water from his well, which tested 73 parts per trillion for PFOA, was safe. Now he knows it is three parts above the new guideline. He was glad for the new guidelines, however, because it means he now can hold government officials and companies accountable, he said.

"At least now the federal government has put a stake in the ground," he said.

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News 10 (ABC)

http://news10.com/2016/05/19/vermont-department-of-health-setting-pfoa-advisory-level-at-20-parts-per-trillion/

Vermont Department of Health setting PFOA advisory level at 20 parts per trillion

By Ali Stewart on 5/19/16 at 3:24pm

The Vermont Health Department says they evaluated all of the scientific information available at the time when setting Vermont's advisory level of 20 parts per trillion for PFOA in drinking water.

Now that EPA has set a new advisory level of 70 parts per trillion for PFOA and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by EPA to assess how this differs from their current advisory level, and consider if any changes are warranted.

The department says they remain committed to protecting the health of Vermonters from these harmful chemicals.

3:29pm

Decatur Daily

http://www.decaturdaily.com/news/lawrence_county/epa-issues-advisory-on-chemicals-found-in-west-morgan-east/article_2d66630b-b85c-5f14-9c45-e11f422b8457.html

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

By Eric Fleischauer on 5/19/16 at 3:22pm

The Environmental Protection Agency today issued a health advisory for two chemicals that are found in the drinking water of West Morgan-East Lawrence Water Authority.

The lifetime advisory warns of adverse health effects for people exposed to drinking water with more than 70 parts per trillion of two chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to court documents, West Morgan-East Lawrence drinking water exceeds the EPA advisory limit for both chemicals.

The EPA advisory says some studies indicate long-term exposure to higher levels of PFOA and PFOS may result in adverse health effects, including developmental effects to fetuses during

pregnancy or to breast-fed infants, cancer, liver damage, immune effects, thyroid effects and cholesterol changes.

The authority sells water to water departments in Vinemont, Falkville, Trinity, Town Creek and the West Lawrence Water Cooperative. About 25,000 people use water supplied by the authority, it has said in court documents.

West Morgan-East Lawrence in October filed a federal lawsuit alleging 3M Co. and its subsidiary, Dyneon LLC, and Daikin America Inc. released the chemicals into the Tennessee River. The lawsuit alleges the chemical entered the authorities water intake downstream of the companies.

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Virtual-Strategy Magazine (Reprint from Business Wire)

http://www.virtual-strategy.com/2016/05/19/new-water-research-foundation-study-addresses-most-effective-methods-removing-pfospfoa-wa#axzz498AKvTCX

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

(See Business Wire story below)

3:02pm

Times Hearld-Record

http://www.recordonline.com/news/20160519/newburgh-water-pollutant-now-more-than-twice-level-of-new-epa-guidelines

Newburgh water pollutant now more than twice level of new EPA guidelines

By Leonard Sparks on 5/19/16 at 2:49pm

New federal health guidelines issued Thursday for the chemical that has shut down Newburgh's primary water supply are less than half the levels recorded in the city.

The Environmental Protection Agency is now urging action if levels of perfluorooctanoic acid or perfluorooctane sulfonate are above 70 parts per trillion, a significantly stricter standard than previously issued advisory guidelines of 100 parts per trillion for PFOA and 200 parts per trillion for PFOS.

Since its water was first tested in December 2013, Newburgh's Washington Lake has had levels of PFOS ranging from 140 to 170 parts per trillion.

While below the initial EPA guidelines, those levels spurred the closure of the lake on May 2, and Newburgh has been drawing water from its backup supply at Brown's Pond.

U.S. Sen. Charles Schumer and U.S. Rep. Sean Maloney had been urging the EPA to expedite release of its updated guidelines.

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS," Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause."

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The Intercept

https://theintercept.com/2016/05/19/with-new-pfoa-drinking-water-advisory-dozens-of-communities-suddenly-have-dangerous-water/

WITH NEW DRINKING WATER ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS WATER

By Sharon Lerner on 5/19/16 at 2:36pm

The EPA announced new drinking water health advisory levels today for the industrial chemicals PFOA and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which were .4 ppb for PFOA and .2 ppb for PFOS. In areas where both PFOA and PFOS are present, the advisory suggests a maximum combined level of .07 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

The new federal standards may unify what has been an inconsistent official response to the presence of these perfluorinated chemicals, or PFCs, in drinking water. They will also instantaneously create official water contamination crises in dozens of cities and towns across the country.

According to the EPA's most recent data on unregulated drinking water contaminants, released in January, 14 drinking water systems around the country reported levels of PFOA that exceed the new federal threshold, while 40 reported PFOS above the new cutoff. In all, water systems in 18 states, as well as in Guam, are contaminated.

Some of these water systems have already begun to quietly address the problem. In Suffolk County, New York, where public drinking water wells show PFOS levels of .33 and .53 ppb, the contaminated water "has either been blended with other wells to reduce the level of the compound to non-detection or their use has been limited to the greatest extent possible," according to Kevin Durk, director of water quality and laboratory services for the Suffolk County Water Authority. Though he does not know the level of PFOS in the water that comes out of local taps, Durk wrote in an email that "it is a virtual certainty that levels of any detected chemical would have been reduced."

Similarly, the Security Water and Sanitation District in Colorado Springs has been struggling to clean up its contaminated water since 142 tests detected PFCs. The district has shut down seven out of 26 wells and is blending water to lower levels, according to Roy Heald, the district's general manager.

But other water company operators have yet to lower their PFC levels. Steve Anderson, owner of the Oatman Water Company in Scottsdale, Arizona, where PFOS measured .2 and .23 in the most recent EPA testing, learned that the chemical was in his water only recently, after he received a call from the Arizona Department of Environmental Quality. Anderson, who suspects the PFOS originated from firefighting foam used by the nearby Oatman Fire Department, said he is "trying to come up with a solution."

Until today, there was a wide range of official opinion on the level of contamination that presented a health danger. The military, which is in the throes of a massive cleanup of 664 contaminated fire- and crash-training sites, has been using the EPA's older standards for PFOA and PFOS to guide its efforts and help determine who receives clean drinking water and remediation of contaminated private wells. (The Department of Defense did not responded to inquiries about how the new advisory levels would alter its cleanup plan.)

Others have set more stringent standards. On January 28, the EPA advised residents of Hoosick Falls, New York, not to use water with PFOA levels above .1 ppb. And a panel of scientists who spent years researching some 70,000 people whose water contained PFOA levels of at least .05 ppb, found probable links between that level of exposure and testicular cancer, kidney cancer, thyroid disease, preeclampsia, ulcerative colitis and high cholesterol. In 2010, New Jersey's Drinking Water Quality Institute calculated a safety limit of .04 for PFOA. Vermont currently has the lowest state drinking water limit for PFOA, .02 ppb.

The levels released today are based on numerous studies connecting the chemicals with health effects. For PFOS, the report notes, studies of lab animals exposed to the chemical reported "developmental effects (decreased body weight, survival, and increased serum glucose levels and insulin resistance in adult offspring), reproductive (mating behavior), liver toxicity (liver weight co-occurring with decreased cholesterol, hepatic steatosis), developmental neurotoxicity (altered spatial learning and memory), immune effects, and cancer (thyroid and liver)."

The report also acknowledged research on human populations that has found associations between PFOS and immune suppression, thyroid disease, high cholesterol, and reduced fertility. It also acknowledged a possible connection between PFOS and bladder, colon, and prostate cancer.

For PFOA, the research included studies on monkeys, rats, and mice showing "developmental

effects (survival, body weight changes, reduced ossification, delays in eye opening, altered puberty, and retarded mammary gland development), liver toxicity (hypertrophy, necrosis, and effects on the metabolism and deposition of dietary lipids), kidney toxicity (weight), immune effects, and cancer (liver, testicular, and pancreatic)."

The new health advisory for PFOA was also based on human studies, which showed "associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)." The EPA report noted that in humans "the developing fetus and newborn is particularly sensitive to PFOA-induced toxicity."

"Taken together," the report notes, "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." The exact phrasing was used in the PFOS report as well.

While calling the new level "a very long-overdue step in the right direction," Robert Bilott, an attorney overseeing a class-action suit over PFOA contamination near a DuPont plant in West Virginia, cautioned that "the new guideline is still too high, as exposures at even the new guideline level would allow PFOA to continue to build up to ever-increasing, unacceptable levels in human blood."

Bilott also noted that the new levels are informal guidelines, as opposed to enforceable regulatory limits. "If it was enforceable," he said, "the EPA could issue unilateral orders requiring the responsible party to clean it up."

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WaterWorld

http://www.waterworld.com/articles/2016/05/epa-releases-drinking-water-health-advisories-for-pfoa-and-pfos.html

EPA RELEASES DRINKING WATER HEALTH ADVISORIES FOR PFOA AND PFOS

By (No author) on 5/19/16 at 2:42pm

Based on the latest science on two chemical contaminants called PFOA and PFOS, EPA has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals. These advisories will help local water systems and state, tribal and local officials take the appropriate steps to address PFOA and PFOS if needed.

EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations.

For many years, PFOA and PFOS were widely used in carpets, clothing, furniture fabrics, food packaging, and other materials to make them more resistant to water, grease, and stains. PFOA and PFOS were also used for firefighting at airfields and in a number of industrial processes. Between 2000 and 2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer. And EPA asked eight major companies to commit to eliminate their production and use of PFOA by the end of 2015 and they have indicated that they have met their commitments. While there are some limited ongoing uses of these chemicals, in recent years, blood testing data has shown that exposures are declining across the country.

For most people, their source of exposure to PFOA and PFOS has come through food and consumer products. But drinking water can be an additional source of exposure in the small percentage of communities where these chemicals have contaminated water supplies. This is typically a localized issue associated with a specific facility -- for example, in communities where a manufacturing plant or airfield made or used these chemicals.

If these chemicals are found in drinking water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope, and source of contamination. They should also promptly notify consumers and consult with their state drinking water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breastfed or formula-fed infants. There are a number of options available to water systems to lower concentrations of these chemicals in the drinking water supply.

EPA will continue sharing the latest science and information so that state and local officials can

make informed decisions and take actions to protect public health. This is an important part of our broader effort to support states and public water systems as we work together to strengthen the safety of America's drinking water.

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Business Wire

http://www.businesswire.com/news/home/20160519006484/en/Water-Research-Foundation-Study-Addresses-Effective-Methods

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

By (No author) on 5/19/16 at 2:44pm

The Water Research Foundation (WRF), a leading sponsor of research supporting the water community, has released findings of a study addressing effective methods for removing poly- and perfluoroalkyl substances (PFASs) from water and wastewater. The research report, Treatment Mitigation Strategies for Poly- and Perfluorinated Chemicals (WRF project #4322), contains results of an in-depth treatment study conducted on waters from 13 water and wastewater treatment plants in the United States. Additionally, WRF will be hosting a Webcast on June 2 addressing the project's results and has posted a State of the Science document on PFASs.

The research from project #4322 demonstrated that conventional treatment at wastewater treatment plants and most drinking water treatment plants is ineffective at removing PFASs. Activated carbon and anion exchange can remove many PFASs but are less effective at removing shorter chain PFASs. The most effective treatment technologies are nanofiltration and reverse osmosis, which work even for the smallest PFASs studied.

The EPA issued two public health advisories today for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

"The research results from project #4322 will help the water community understand the best options for removing PFASs from water and wastewater, said Rob Renner, CEO of the Water Research Foundation. "This knowledge is especially important as the EPA continues the process of regulating these chemicals in water."

Poly- and perfluoroalkyl substances (PFASs) are a group of manmade chemicals with past and current uses in industrial processes and consumer products. PFASs are also commonly referred to as perfluorinated chemicals or PFCs. The most notable PFASs are PFOA and PFOS, but there are many others. PFASs are used in firefighting foams, coating for food packaging, ScotchGardTM and TeflonTM, among other products.

Exposure to PFASs can occur through use of products or consumption of food or water containing PFASs. PFASs do not break down easily and therefore persist in the environment. They are also soluble in water and can enter source waters through industrial releases, discharges from wastewater treatment plants, storm water runoff, release of firefighting foams, and land application of contaminated biosolids.

PFASs are a concern because they have been shown to have health effects in animal studies. Data from some human studies suggest that PFASs also affect human health. Additional research is ongoing in order to gain a better understanding of human health effects.

2:45pm

WRGB Albany (CBS)

http://cbs6albany.com/news/hoosick-falls-crisis/epa-declares-official-standard-for-pfoa-pfoh-contamination

EPA declares official standard for PFOA, PFOS contamination for lifetime exposure

By WRGB Staff on 5/19/16 at 2:19pm

The EPA has released official long- term exposure guidelines for PFOA, PFOS contamination.

Released documents state that concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

Vermont lists safe exposure levels at 20 parts per trillion, including babies and children.

Regional EPA originally set short term exposure as 100 ppt in Hoosick Falls.

'EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations. " , says the EPA in a released document.

2:27 PM

Vermont Public Radio

http://digital.vpr.net/post/significant-reduction-epa-sets-health-advisory-pfoa-70-parts-trillion#stream/0

In Significant Reduction, EPA Sets Health Advisory For PFOA At 70 Parts Per Trillion

By Howard Weiss-Tisman on 5/19/16 at 2:11pm

The Environmental Protection Agency on Thursday issued an updated health advisory for the suspected carcinogen PFOA.

The EPA says water that contains PFOA in levels at 70 parts per trillion should be considered unsafe to drink.

The EPA previously set its level at 400 ppt. The new, lifetime health advisory replaces that

standard.

PFOA, a chemical that was used in a variety of manufacturing applications, has been found in water in North Bennington, Bennington and Pownal.

The contaminant has also been detected in New Hampshire and New York, and in other states around the country.

Vermont set its level at 20 parts per trillion.

(Reprint of Bucks County Courier Times story)

http://www.theintell.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_a404ad5d-a246-5ec2-9d1b-a9af8b6e70d5.html

EPA releases new safety advisories for chemicals

2:20 PM

Time Warner Cable News - Capital Region

http://www.twcnews.com/nys/capital-region/news/2016/05/19/epa-releases-new-pfoa-and-pfos-health-guidelines.html

EPA Releases New Health Guidelines for PFOA, PFOS Found in Drinking Water

By TWC News Web Staff on 5/19/16 at 1:46pm

The EPA has released new health guidelines for PFOA and PFOS found in drinking water.

PFOA was the chemical found in the water supply in Hoosick Falls and Petersburgh.

The new health advisory levels have been set to 70 parts per trillion.

When first tested at the St. Gobain facility in Hoosick Falls, the EPA measured the levels at 18,000 parts per trillion.

A filtration system has since been installed, eliminating traces of the chemical, making the water safe to use again in Hoosick Falls.

In Petersburgh, multiple homes have tested above the new acceptable levels.

Taconic Plastics is believed to be the source of contamination. Residents in the town have grown impatient with leaders as they await to learn when they can get blood tested.

The town even ran out of bottled water to give to residents over the weekend. That supply has since been replenished.

Also, PFOS levels in Washington Lake and Silver Stream are in the range of 145 to 150 parts per trillion.

Washington Lake used to supply Newburgh's drinking water, until the city found out about the continuing levels of PFOS.

The city switched to Brown's Pond as a drinking source, since almost no levels of PFOS were found in that water.

Newburgh is still working to determine where the PFOS contamination is coming from.

Senator Schumer on New Standards:

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS. Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause. The EPA's new guidance will go a long way in protecting public health and arming local officials with the most up-to-date information to keep our drinking water safe from harmful contaminates."

Bucks County Courier Times (also ran in the Intelligencer)

http://www.buckscountycouriertimes.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_97946008-1de8-11e6-83d3-334d7ea7ce37.html

EPA Releases New Safety Advisories for Chemicals

By Kyle Bagenstose on 5/19/16 at 2:00pm

The Environmental Protection Agency on Thursday released a long-awaited update to its drinking water advisories for unregulated chemicals perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).

According to prior testing data of public and private water supplies in Bucks and Montgomery counties, it appears the updated advisories could mean some drinking water in the area is contaminated with the chemicals at a level above what the EPA deems is safe to consume.

The chemicals already had contaminated about 100 public and private water wells near a trio of

current and former military bases in the region: The former Naval Air Station Joint Reserve Base Willow Grove, Horsham Air Guard Station, and former Naval Air Warfare Center in Warminster.

The chemicals are suspected to have originated in firefighting foams used at the bases, and the military already has agreed to spend approximately $19 million to provide replacement water and install filtration systems for public water wells affected by the chemicals, and bottled water and hook-ups to public systems for homes with affected private wells.

But the number of wells now likely will increase.

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the EPA in 2009: .4 parts per billion for PFOA in drinking water, and .2 ppb for PFOS.

Thursday's announcement, however, set an advised limit of .07 ppb for PFOS and PFOA combined, in order to protect against health effects from a lifetime of exposure. In a worst case scenario, that means drinking water with .58 ppb of the chemicals (.39 ppb PFOA and .19 ppb PFOS) previously considered safe, now would be more than eight times the recommended limit.

After the chemicals first were discovered in some local public water supplies by a nationwide EPA testing program in 2013 and 2014, multiple public wells in the area were taken offline.

The Horsham Water and Sewer Authority removed two drinking water wells from its system in the summer of 2014 after PFOS was found at 1 and .7 ppb. Data from the testing program shows that three more wells also were contaminated with the chemicals at levels above the EPA's new advisory, with a combined .071 ppb, .123 ppb, and .14 ppb.

In a brief email Thursday, authority manager Tina O'Rourke said only two additional wells are above the .07 ppb level as of the most recent testing.

She added that the authority intends to take the wells offline and that existing agreements with the military allow for the authority to take action immediately.

The Warminster Municipal Authority, which previously removed three wells from its supply, also appears to have two more wells contaminated above the new level, with a combined .091 ppb and .09 ppb.

The Warrington Township Water Department previously removed a trio of wells that combined to form a single water source. Based on the EPA's data showing a combined .082 ppb, another well could also be above the new health advisory.

This news organization reached out to all three utilities to obtain the most recent testing information and will update this story as it receives responses.

Although unregulated, a growing body of science has established associations between PFOA and PFOS and a range of health effects, including a variety of cancers.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in a phone interview Thursday that the updated advisories reflect a review of available science and are intended to be protective for lifetime exposure to the chemicals for even vulnerable populations, such as nursing mothers and their children.

"These health advisories are scientific documents … the point is to provide the best available information to state and local authorities and drinking water system operators," Beauvais said. "They're calculated to reflect a margin or protection to the most sensitive populations."

Beauvais added that the next step for the chemicals is to be considered for a federal drinking water standard that can be enforced, as is the case with more well-known contaminants such as lead or arsenic. However, he was unable to say how long it might take for that decision to be made.

1:59 PM

Albany Times Union

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-water-7716825.php

EPA Sets New Level for Chemical in Drinking Water

By Brendan J. Lyons on 5/19/16 at 1:17pm

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

The EPA's advisory level is well below the levels of PFOA that were detected in public water supplies over the past two years in Hoosick Falls, Petersburgh, North Bennington, Vt., and Merrimack, N.H.

In addition, health and environmental officials said tests have also revealed levels of PFOA in dozens of private wells in Rensselaer County that are much higher than the EPA's guideline.

Officials with the state Health Department and Department of Environmental Conservation could not immediately provide information Thursday about how many water systems in New York may contain PFOA, which has been used since the 1940s to make products such as nonstick coatings, such as Teflon, and heat-resistant wiring and other specialty products.

In 2009, the EPA established a guideline that a level of 400 parts per trillion is a safe level for "short-term" consumption of the water. Earlier this year, the EPA issued a provisional health advisory of 100 ppt. Meanwhile, other states have set far lower acceptable levels of PFOA in public water systems, including New Jersey, which has set a level of 40 ppt.

State Health Commissioner Dr. Howard A. Zucker in January said the state Health Department was reviewing its position on acceptable levels of PFOA in drinking water and would set a new safety limit within weeks. But the state did not issue a new advisory.

Robert A. Bilott, an Ohio attorney who is helping represent an estimated 3,500 people in a class-action lawsuit against DuPont, which manufactured and used perfluorinated chemicals such as PFOA in its products, has been urging the EPA for years to adopt a permanent health advisory for long-term exposure to PFOA in drinking water. Bilott has represented "tens of thousands of individuals in various communities across the country who have been injured because of the contamination of their drinking water with PFOA."

"The lower number and acknowledgement of the need to consider the combined amount of PFCs in water is a long-overdue step in the right direction, but the guideline is still too high, as it will allow ever-increasing, unacceptable levels of PFOA to continue to build up in the blood of those exposed," Bilott said.

Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid

disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

Bilott said the science panel's peer-reviewed report was paid for by DuPont and, as a result of the panel's findings, the company has to concede in the personal-injury lawsuits that PFOA causes cancer.

In Albany, numerous lawsuits were filed this year in U.S. District Court seeking class-action status on behalf of current and former Hoosick Falls residents, including some who allege they suffered serious health effects that could be linked to PFOA exposure.

According to the EPA, PFOA was detected in blood serum in 99 percent of the U.S. population between 1999 and 2012. However, the EPA said the levels of PFOA in human blood have been decreasing since U.S. companies began to phase out production of the chemical more than 10 years ago. Still, water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied, the agency said.

Thousands of people whose blood was tested in that area of the Ohio Valley had elevated levels of PFOA, including at levels as high as 40 parts per billion.

In Hoosick Falls, where hundreds of people signed up for state-sponsored blood tests in February, the results of those tests are expected to be released beginning next week.

In February, the state Department of Environmental Conservation asked two corporations, Saint-Gobain Performance Plastics and Honeywell International, to enter consent orders that would require them to clean up the remnants of the toxic chemical that polluted water supplies in and around Hoosick Falls.

The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations in Rensselaer County, including the town

of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

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WAMC, Northeast Public Radio

http://wamc.org/post/epa-releases-new-pfoa-pfos-guidelines

EPA Releases New PFOA, PFOS Guidelines

By (No author) on 5/19/16 at 1:44pm

The U.S. Environmental Protection Agency has released new health advisories for PFOA and PFOS, the manufacturing chemicals at the center of water contamination crises in several communities in the region including Hoosick Falls, Petersburgh, and North Bennington. The guidelines released today lower the lifetime exposure from drinking water level to 70 parts per trillion. The level of PFOA in affected areas has been much higher than the new benchmark, leading communities to establish alternate water supplies. High exposure can result in cancer, birth defects and other diseases.

WMUR Manchester (ABC)

http://www.wmur.com/health/epa-sets-new-level-for-contaminant-found-in-drinking-water/39629266

EPA sets new level for contaminant found in drinking water

By Kirk Enstrom on 5/19/16 at 1:41pm

The Environmental Protection Agency has set new advisory levels for a contaminant that has been found in drinking water supplies in parts of New Hampshire.

The state Department of Environmental Services said Thursday that the EPA set a lifetime drinking water health advisory level for perfluorooctanoic acid at 70 parts per trillion.

The same level was set for a related chemical, perfluorooctane sulfonate. The EPA said that when both chemicals are present, the combined concentration shouldn't exceed 70 parts per trillion.

State environmental officials had been advising well water users whose water tested above 100 parts per trillion to drink bottled water instead.

PFOA was found earlier this year in groundwater near the Saint-Gobain Performance Plastics facility in Merrimack after that company conducted tests. The contaminant has since been found in private wells in Litchfield, Manchester, Bedford and other areas.

It was most recently found in Amherst near a former industrial site.

State environmental officials said they are working to review the scientific basis for the new levels. DES said it's also taking steps to provide bottled water to all known private well users who have detected PFOA or PFOS levels greater than 70 parts per trillion.

"The state of New Hampshire will take immediate action to expand distribution of bottled water in affected areas to those whose water supply falls under the new advisory," Gov. Maggie Hassan said.

DES said it plans to move quickly to develop emergency rules for groundwater cleanup and drinking water standards. There will be a public comment process before permanent rules are established.

DES has set up a website to discuss the PFOA investigation.

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NEWS10 ABC

http://news10.com/2016/05/19/epa-issues-health-advisory-level-for-lifetime-exposure-to-pfoa/

EPA Sets Health Advisory Level for Lifetime Exposure to PFOA

By Joe Gullo on 5/19/16 at 1:21pm

The U.S. Environmental Protection Agency (EPA) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to PFOA.

The EPA says the advisory is to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime exposure to PFOA and PFOS from drinking water.

PFOA has been linked to serious health problems such as cancer.

Some local communities, including Petersburgh, Hoosick Falls, Bennington, and Pownal have had wells test positive for the chemical.

PFOA and PFOS have been used to make carpets, clothing, fabrics for furniture, paper packaging for food, and other materials that are resistant to water, grease, or stains. In 2006, the EPA says they asked eight companies using PFOA to phase out use and chemicals used to break down PFOA. Those companies have stated at the end of 2015, they phased out the use of PFOA.

According to the EPA, the establishment of the advisories follows an assessment from the latest peer-reviewed science to provide water system operators, and state, tribal, and local officials who have the primary responsibility of overseeing these systems.

Advisories issued by the EPA are designed to provide information on contaminants that can cause human health effects and are known or anticipated to occur in water.

Travis Loop

Director of Communications

Office of Water

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202-870-6922

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To: Hisel-Mccoy, Sara[Hisel-McCoy.Sara@epa.gov]
From: Behl, Betsy
Sent: Fri 5/20/2016 1:55:36 PM
Subject: RE: OST in the News!

Thanks Sara!

From: Hisel-Mccoy, Sara
Sent: Friday, May 20, 2016 9:43 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Fleisig, Erica <Fleisig.Erica@epa.gov>
Subject: FW: OST in the News!

Huge congratulations, guys!!!!!

Sara

From: Conerly, Octavia
Sent: Friday, May 20, 2016 7:05 AM
To: OST-EVERYONE <OSTEVERYONE@epa.gov>
Subject: OST in the News!

Good morning OST,

The health advisories for PFOA and PFOS were published yesterday! Your colleagues in HECD have worked very hard to complete these documents.

EPA Issues Drinking Water Health Advisories for PFOS, PFOA

BNA Snapshot

PFOS, PFOA Health Advisories

Key Development: The EPA issued lifetime drinking water health advisories for perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), setting each unenforceable benchmark at 0.07 microgram per liter.

Potential Impact: The health advisories are intended to offer a guideline and benchmark for determining whether the concentrations of chemicals in tap water from utilities are safe for public consumption.

What's Next: The EPA didn't rule out later issuing an enforceable rule on these chemicals.

By Rachel Leven

May 19 — The Environmental Protection Agency released voluntary benchmarks May 19 to guide local water systems, states and others in determining what concentration levels of certain highly fluorinated chemicals in drinking water are safe for public health.

The EPA set the same benchmark—0.07 microgram per liter or 70 parts per trillion—in its two lifetime drinking water health advisories on perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA). Individual or combined exposure to the chemicals, which were previously widely used in products like carpets to make them more water- or stain-resistant, could result in negative health effects including cancer, the agency said.

Reactions were mixed as to whether the health advisory levels that are lower than 2009 provisional levels for the chemicals are protective enough. But the advisories won't be the end of the issue: The EPA left the option open to develop enforceable rules on the chemicals.

“This is going to be the next lead … because its in many people's drinking water and people are just finding out about it,” Arlene Blum, executive director for the Green Science Policy Institute, told Bloomberg BNA. “Right now, it's an emergency. We need to find out where the highly fluorinated chemicals are in drinking water and help people prevent harm.”

“But in the big picture: we need to question the use of these chemicals in products,” Blum, who is also a visiting scholar at the University of California, Berkeley, said of the chemicals that don't easily break down in the human body or the environment. “Things that never break down, you're making a big decision.”

Persistent Chemicals

PFOS is no longer manufactured domestically—it was voluntarily phased out between 2000 and 2002 domestically by 3M, it's primary manufacturer.

DuPont, the primary manufacturer of PFOA, has stopped making that chemical. PFOA and PFOA-related chemicals are still used for limited purposes, according to the EPA.

Exposure generally is declining nationwide, the EPA said. However, exposure through consumer products, food and drinking water continues.

Exposure through drinking water is generally limited to communities where supplies have been contaminated around a specific PFOS or PFOA-manufacturing or using facility, such as an airfield where the chemicals were used in firefighting efforts, the EPA said.

In January 2009, the EPA issued provisional health advisories for each chemical for exposure that could result in negative health effects in weeks or months. The provisional advisory for PFOA of 0.4 microgram per liter (400 parts per trillion) and for PFOS of 0.2 microgram per liter (200 parts per trillion) were intended to offer guidance to public water systems as the agency developed a lifetime health advisory.

But years have passed since then and states and even the EPA have issued different recommendations about what is safe, including the EPA's special advisory to Hoosick Falls, N.Y., in late February, when the agency said not to drink water with PFOA concentrations of 0.1 microgram per liter (100 parts per trillion). Governors, members of Congress, environmental advocates and others have urged the EPA to clarify what levels are safe in drinking water.

Protectiveness Examined

Depending who is asked, the numbers reached by the EPA for the lifetime health advisories are very protective—or up to 70 times too high.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in an agency blog post that the unenforceable benchmark of limiting exposure to under 0.07 microgram per liter (70 parts per trillion) won't cause negative health effects. It actually “reflect[s] a margin of protection, including for the most sensitive populations,” he said.

Janet Smith, a spokeswoman for the DuPont-created Chemours Co., told Bloomberg BNA in an e-mail, “We believe the Agency set the health advisory at 70 parts per trillion with the goal of being extremely protective.” Smith said her company is reviewing the data posted on the EPA website, and has been preparing water treatment and monitoring measures to meet the new advisory.

But Bill Walker, investigations editor for the Environmental Working Group, disagreed. While he acknowledged the advisory was a step forward for public health protection, he told Bloomberg BNA the benchmark for these chemicals isn't low enough and pointed to research that found a 1-part-per-trillion level for these types of chemicals is more appropriate.

States will now take these advisories and “move to the front lines” to respond to public queries, according to Alexandra Dapolito Dunn, executive director for the Environmental Council of the States.

States will work with federal agencies and national associations to provide “clear and effective information to all Americans in the coming weeks and months,” Dunn said.

What's Next

“We anticipate public concern to be real and immediate,” Dunn said in a statement.

Both PFOA and PFOS are required contaminants to monitor under the EPA's third unregulated contaminant monitoring rule, and the agency will consider this information alongside others to determine whether to begin developing a national primary drinking water regulation, it said.

But Walker expressed frustration at the pace of EPA action.

“They really demonstrate the problems with toxics regulation under [the Toxic Substances Control Act],” Walker said. “They've known about this [issue] for quite some time, and yet they're just acting now. We can hardly think of a better poster child for the failures of TSCA than what's happening around these chemicals.”

The Association of Metropolitan Water Agencies declined to comment, saying it needed more time to review the advisories. The American Water Works Association and 3M, the former main manufacturer of PFOS, didn't respond to requests for comment.

To contact the reporter on this story: Rachel Leven in Washington at rleven@bna.com

To contact the editor responsible for this story: Larry Pearl at lpearl@bna.com

For More Information

The drinking water health advisories for PFOA and PFOS and related information are available at http://src.bna.com/fbb.

Octavia Conerly

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Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

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PHONE: (202) 566-1094

FAX: (202) 566-0441

To: Fleisig, Erica[Fleisig.Erica@epa.gov]
From: Behl, Betsy
Sent: Fri 5/20/2016 1:55:20 PM
Subject: RE: OST in the News!

Thanks Erica! That was a lot of work!

From: Fleisig, Erica
Sent: Friday, May 20, 2016 9:46 AM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Cc: Behl, Betsy <Behl.Betsy@epa.gov>
Subject: Fw: OST in the News!

I think Sara meant this for the other "Fl" surname in OST :) Nice work!!

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“This is going to be the next lead … because its in many people's drinking water and people are just finding out about it,” Arlene Blum, executive director for the Green Science Policy Institute, told Bloomberg BNA. “Right now, it's an emergency. We need to find out where the highly

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To: Harper, Ashley[harper.ashley@epa.gov]
From: Behl, Betsy
Sent: Thur 5/19/2016 6:15:21 PM
Subject: RE: Albany Times Union: EPA sets new level for chemical in local water systems

This was one of the interviews this am

From: Harper, Ashley
Sent: Thursday, May 19, 2016 1:15 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: FW: Albany Times Union: EPA sets new level for chemical in local water systems

Nothing earth shattering in here but thought you would like to know there is already an article!

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

From: Dennis, Allison
Sent: Thursday, May 19, 2016 1:10 PM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>; Perry, Dale <Perry.Dale@epa.gov>
Subject: FW: Albany Times Union: EPA sets new level for chemical in local water systems

From: Lee, Monica
Sent: Thursday, May 19, 2016 1:02 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Purchia, Liz <Purchia.Liz@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Mears, Mary <Mears.Mary@epa.gov>; Fuld, John <Fuld.John@epa.gov>
Subject: Albany Times Union: EPA sets new level for chemical in local water systems

This is one of the local reporters Joel spoke with this morning. Pretty straight forward rundown.

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-water-7716825.php

EPA sets new level for chemical in local water systems

Level for lifetime exposure of PFOA lower than levels found in public water supplies

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

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Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

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The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations in Rensselaer County, including the town of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

By Brendan J. Lyons

Monica Lee

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lee.monica@epa.gov

To: Lalley, Cara[Lalley.Cara@epa.gov]
From: Behl, Betsy
Sent: Fri 4/29/2016 4:46:03 PM
Subject: FW: PFCs
PFOA PFOS Key Messages 4-28-16.docx
PFCs HAs Roll Out 4.29.16docx.docx
Monitoring Wrap PFOA-PFOS.DOCX
PFOA-PFOS FACT SHEET 4-29-16.docx

FYI

-----Original Message-----
From: Dennis, Allison
Sent: Friday, April 29, 2016 12:45 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>
Subject: RE: PFCs

+ Ashley and Ann

All- I've done my best making sure the comms plan and it's Q&As following the Fact Sheet's messaging. You will see the revised docs in the "Current Version" folder on SP and attached. Happy to make additional tweaks.

I also tweaked the Monitoring Wrap by carrying over the 70 ppt unit. (also attached)

You will see two other docs in that Current Version Folder:

Key Messages: this is a document Joel, Liz, and Travis worked on last night. Let me know if you have any edits.

List of systems with elevated PFOS/PFOS Levels Fact Sheet- this is meant to be posted online and used by media and the general public as a quick way to scan the total list (63?) of public water systems with elevated levels. It follows the monitoring wrap language almost to a T. It would be great to get OD review of this fact sheet sometime next week.

Best, Allison

-----Original Message-----
From: Behl, Betsy
Sent: Friday, April 29, 2016 12:24 PM
To: Dennis, Allison <Dennis.Allison@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: PFCs

I will send the Q&A on breastfeeding as soon as I review it. The Q&A you provided is accurate. Was there a specific attribute you think needs updating?

-----Original Message-----
From: Dennis, Allison
Sent: Friday, April 29, 2016 12:06 PM

To: Behl, Betsy <Behl.Betsy@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Subject: RE: PFCs

- Joel Ann and Karen

Great! Betsy, can you send it to me via email and I'll add it in?

Also, is this Q&A still good ort does it need to be updated? (see below)

Deliberative Process / Ex. 5

-----Original Message-----
From: Behl, Betsy
Sent: Friday, April 29, 2016 11:24 AM
To: Loop, Travis <Loop.Travis@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Cc: Beauvais, Joel <Beauvais.Joel@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Subject: RE: PFCs

As a result of the call today we are developing and QA regarding breastfeeding for consideration. ATSDR indicated they expect to get asked this question.

-----Original Message-----
From: Loop, Travis
Sent: Friday, April 29, 2016 11:07 AM
To: Grevatt, Peter <Grevatt.Peter@epa.gov>
Cc: Beauvais, Joel <Beauvais.Joel@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Gude, Karen <Gude.Karen@epa.gov>; Campbell, Ann <Campbell.Ann@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>
Subject: Re: PFCs

Adding Allison. If there are no further edits today to fact sheet we can begin aligning language in QA with it.

Travis Loop
Communications Director for Water
U.S. Environmental Protection Agency
Phone: 202.870.6922
Follow us on Twitter @EPAwater

> On Apr 29, 2016, at 11:04 AM, Grevatt, Peter <Grevatt.Peter@epa.gov> wrote:

Deliberative Process / Ex. 5

>
> -----Original Message-----
> From: Beauvais, Joel
> Sent: Friday, April 29, 2016 9:01 AM
> To: Grevatt, Peter <Grevatt.Peter@epa.gov>; Southerland, Elizabeth
> <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>;
> Burneson, Eric <Burneson.Eric@epa.gov>; Loop, Travis
> <Loop.Travis@epa.gov>
> Cc: Gude, Karen <Gude.Karen@epa.gov>; Campbell, Ann
> <Campbell.Ann@epa.gov>
> Subject: PFCs
>
> Can I get an updated set of all the docs (including Fact Sheet after you review my edits, key messages, internal Q and A, and UCMR spreadsheet and "wrap") at some point by midday-ish so I can use for my 4:30? Also I will need a readout of convo with ATSDR and any updates on OECA discussions. Thank you.
>
> Joel

To: Harper, Ashley[harper.ashley@epa.gov]
From: Behl, Betsy
Sent: Fri 3/11/2016 4:40:55 PM
Subject: ppt
PFOA-PFOS-OW HAs ADMIN BRIEF 031016.ppt

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

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phone: 202.566.0788

room 5233H

United States Environmental Protection Agency

Emerging Contaminants – Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

March 2014

EMERGING CONTAMINANTS FACT SHEET – PFOS and PFOA

At a Glance

- Fully fluorinated compounds that are human-made substances and are not naturally found in the environment.
- Used as a surface-active agent and in a variety of products, such as firefighting foams, coating additives and cleaning products.
- Do not hydrolyze, photolyze or biodegrade under typical environmental conditions and are extremely persistent in the environment.
- Studies have shown they have the potential to bioaccumulate and biomagnify in wildlife.
- Readily absorbed after oral exposure and accumulate primarily in the serum, kidney and liver.
- Toxicological studies on animals indicate potential developmental, reproductive and systemic effects.
- Health-based advisories or screening levels for PFOS and PFOA have been developed by the EPA and state agencies.
- Standard detection methods include high-performance liquid chromatography and tandem mass spectrometry.
- Common ex situ water treatment technologies include activated carbon filters and reverse osmosis units.

Introduction

An "emerging contaminant" is a chemical or material that is characterized by a perceived, potential, or real threat to human health or the environment or by a lack of published health standards. A contaminant may also be "emerging" because a new source or a new pathway to humans has been discovered or a new detection method or treatment technology has been developed (DoD 2011). This fact sheet, developed by the U.S. Environmental Protection Agency (EPA) Federal Facilities Restoration and Reuse Office (FFRRO), provides a summary of the emerging contaminants perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), including physical and chemical properties; environmental and health impacts; existing federal and state guidelines; detection and treatment methods; and additional sources of information. This fact sheet is intended for use by site managers who may address PFOS and PFOA at cleanup sites or in drinking water supplies and for those in a position to consider whether these chemicals should be added to the analytical suite for site investigations.

PFOS and PFOA are extremely persistent in the environment and resistant to typical environmental degradation processes. As a result, they are widely distributed across the higher trophic levels and are found in soil, air and groundwater at sites across the United States. The toxicity, mobility and bioaccumulation potential of PFOS and PFOA pose potential adverse effects for the environment and human health.

What are PFOS and PFOA?

- PFOS and PFOA are fully fluorinated, organic compounds and are the two perfluorinated chemicals (PFCs) that have been produced in the largest amounts within the United States (ATSDR 2009; EFSA 2008).
- PFOS is a perfluoralkyl sulfonate that is commonly used as a simple salt (such as potassium, sodium or ammonium) or is incorporated into larger polymers (EFSA 2008; EPA 2009c).
- PFOA is a perfluoralkyl carboxylate that is produced synthetically as a salt. Ammonium salt is the most widely produced form (EFSA 2008; EPA 2009c).

Disclaimer: The U.S. EPA prepared this fact sheet from publicly available sources; additional information can be obtained from the source documents. This fact sheet is not intended to be used as a primary source of information and is not intended, nor can it be relied on, to create any rights enforceable by any party in litigation with the United States. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

What are PFOS and PFOA? (continued)

- PFOS synonyms include 1-octanesulfonic acid, heptadecafluoro-, 1-perfluorooctanesulfonic acid, heptadecafluoro-1-octanesulfonic acid, perfluoro-n-octanesulfonic acid, perfluoroctanesulfonic acid and perfluoroctylsulfonic acid (ATSDR 2009; UNEP 2005).
- PFOA synonyms include pentadecafluoro1-octanoic acid, pentadecafluoro-n-octanoic acid, pentadecaflurooctanoic acid, perfluorocaprylic acid, perfluoroctanoic acid, perfluoroheptanecarboxylic acid and octanoic acid (ATSDR 2009).
- They are stable chemicals that include long carbon chains. Because of their unique lipid- and water-repellent characteristics, PFOS and PFOA are used as surface-active agents in various high-temperature applications and as a coating on surfaces that contact with strong acids or bases (Schultz and others 2003; UNEP 2005).
- PFCs are used in a wide variety of industrial and commercial products such as textiles and leather products, metal plating, the photographic industry, photolithography, semi-conductors, paper and packaging, coating additives, cleaning products and pesticides (ATSDR 2009; EPA 2009c; OECD 2002).
- Through 2001, PFCs were used to manufacture Aqueous Film Forming Foam (AFFF). PFOS-based AFFF is used to extinguish flammable liquid fires (for example, hydrocarbon fueled), such as fires involving gas tankers and oil refineries (EPA 2013a; DoD SERDP 2012).
- They are human-made compounds and do not occur naturally in the environment (ATSDR 2009; EPA 2009c).
- PFOS and PFOA can also be formed by environmental microbial degradation or by metabolism in larger organisms from a large group of related substances or precursor compounds (ATSDR 2009; UNEP 2006).
- The 3M Company, the primary manufacturer of PFOS, completed a voluntary phase-out of PFOS production in 2002 (ATSDR 2009; 3M 2008).

Exhibit 1: Physical and Chemical Properties of PFOS and PFOA
(ATSDR 2009; Brooke and others 2004; EFSA 2008; Environment Canada 2012; EPA 2002b; OECD 2002; UNEP 2006)

Property	PFOS (Potassium Salt)	PFOA (Free Acid)
Chemical Abstracts Service (CAS) Number	2795-39-3	335-67-1
Physical Description (physical state at room temperature and atmospheric pressure)	White powder	White powder/ waxy white solid
Molecular weight (g/mol)	538	414
Water solubility at 25°C (mg/L)	550 to 570 (purified), 370 (fresh water), 25 (filtered sea water)	9.5×10^3(purified)
Melting Point (°C)	> 400	45 to 54
Boiling point (°C)	Not measurable	188 to 192
Vapor pressure at 20 °C (mm Hg)	2.48×10^{-6}	0.017[1]
Octanol-water partition coefficient (log K_{ow})	Not measurable	Not measurable
Organic-carbon partition coefficient (log K_{oc})	2.57 (Value estimated based on anion and not the salt)	2.06
Henry's law constant (atm-m^3/mol)	3.05×10^{-9}	Not measurable
Half-Life	Atmospheric: 114 days Water: > 41 years (at 25° C)	Atmospheric: 90 days[2] Water: > 92 years (at 25° C)

Abbreviations: g/mol – grams per mole; mg/L – milligrams per liter; °C – degree Celsius; mm Hg – millimeters of mercury; atm-m^3/mol – atmosphere-cubic meters per mole.
[1] Extrapolation from measurement.
[2] The atmospheric half-life value identified for PFOA is estimated based on available data determined from short study periods.

What are PFOS and PFOA? (continued)

- PFOS chemicals are no longer manufactured in the United States; however, EPA significant new use rules (SNURs) allow for the continuation of a few, limited, highly technical applications of PFOS-related substances where no known alternatives are available. In addition, existing stocks of PFC-based chemicals that were manufactured or imported into the United States before the effective date of the SNURs (for example, PFOS-based AFFF produced before the rules took effect in 2002) can still be used (EPA 2009c, 2013a).
- PFOA as its ammonium salt is manufactured primarily for use as an aqueous dispersion agent and in the manufacture of fluoropolymers (which are used in a wide variety of mechanical and industrial components) such as electrical wire casings, fire- and chemical-resistant tubing and plumbing seal tape. They are also produced unintentionally by the degradation of some fluorotelomers (ATSDR 2009; EPA 2009c).
- As part of the EPA's PFOA stewardship program, eight companies committed to achieve the following by 2010: (1) reduce global facility emissions of PFOA to all media; (2) reduce precursor chemicals that break down to PFOA and related higher homologue chemicals; and (3) PFOA product content (95 percent). The companies also agreed to work toward eliminating these chemicals from emissions and products by 2015 (EPA 2013a).

What are the environmental impacts of PFOS and PFOA?

- During past manufacturing processes, large amounts of PFOS and PFOA were released to the air, water and soil in and around fluorochemical facilities (ATSDR 2009).
- PFOS and PFOA have been detected in a number of U.S. cities in surface water and sediments downstream of former fluorochemical production facilities and in wastewater treatment plant effluent, sewage sludge and landfill leachate (EPA 2002b; OECD 2002).
- The environmental release of PFOS-based AFFF may also occur from tank and supply line leaks, use of aircraft hangar fire suppression systems and firefighting training (DoD SERDP 2012).
- Both PFOS and PFOA are the stable end products resulting from the degradation of precursor substances through a variety of abiotic and biotic transformation pathways (Conder and others 2010).
- Because of their chemical structure, PFCs, including PFOS and PFOA, are chemically and biologically stable in the environment and resist typical environmental degradation processes, including atmospheric photooxidation, direct photolysis and hydrolysis. As a result, these chemicals are extremely persistent in the environment (OECD 2002; Schultz and others 2003).
- PFOS and PFOA have very low volatility because of their ionic nature. Therefore, they will be persistent in water and soil (3M 2000; ATSDR 2009).
- When released directly to the atmosphere, PFCs are expected to adsorb to particles and settle to the ground through wet or dry deposition (Barton and others 2007; Hurley and others 2004).
- In their anionic forms, PFOA and PFOS are water-soluble and can migrate readily from soil to groundwater, where they can be transported long distances (Davis and others 2007; Post and others 2012).
- Monitoring data from the Arctic region and at sites remote from known point sources have shown levels of PFOS and PFOA in environmental media and biota, indicating that long-range transport has occurred. For example, PFOA and PFOS have been detected in concentrations from the low- to mid- picograms per liter (pg/L) range in remote regions of the Arctic caps. In addition, PFOS concentrations detected in the liver of the Canadian Arctic polar bear range from 1,700 to more than 4,000 nanograms per gram (ng/g) (Lau and others 2007; Martin and others 2004; Young and others 2007).
- Causes of long-range PFC transport include (1) atmospheric transport of precursor compounds (such as perfluoroalkyl sulfonamides), followed by degradation to form PFCs and (2) direct, long-range transport of PFCs via ocean currents or in the form of marine aerosols (Armitage and others 2006; Post and others 2012).

What are the environmental impacts of PFOS and PFOA? (continued)

- The wide distribution of PFCs increases the potential for bioaccumulation and bioconcentration as they are transferred from low to higher trophic level organisms. Because of their persistence and long-term accumulation, higher trophic level wildlife such as fish, piscivorous birds and other biota can continue to be exposed to PFOS and PFOA (EPA 2006a; UNEP 2006).
- The bioaccumulation potential of PFCs increases with increasing carbon chain length (ATSDR 2009; Furdui and others 2007).
- PFOS is the only PFC that has been shown to accumulate to levels of concern in fish tissue. The estimated bioconcentration factor in fish ranges from 1,000 to 4,000 (EFSA 2008; MDH 2011; OECD 2002).
- As of 2013, the Superfund Information Systems Database indicates PFCs have been reported in the 5-year reviews of 14 hazardous waste sites on the EPA National Priorities List (EPA 2013b).
- Data gathered in 2008 from the DoD Knowledge Based Corporate Reporting System show that 594 DoD facilities have been categorized as Fire/Crash/Training Sites and, therefore, have the potential for PFC contamination based on historical use of AFFF (DoD 2008; DoD SERDP 2012).

What are the routes of exposure and the health effects of PFOS and PFOA?

- Studies have found PFOS and PFOA in the blood samples of the general human population and wildlife nationwide, indicating that exposure to the chemicals is widespread (ATSDR 2009; EPA 2006a).
- Reported data indicate that serum concentrations of PFOS and PFOA are higher in workers and individuals living near fluorochemical production facilities than for the general population (Calafat and others 2007; EPA 2009c).
- Potential pathways, which may lead to widespread exposure, include ingestion of food and water, use of commercial products or inhalation from long-range air transport of PFC-containing particulate matter (ATSDR 2009; EPA 2009c).
- Based on the limited information available, fish and fishery products seem to be one of the primary sources of human exposure to PFOS (EFSA 2008).
- While a federal screening level or toxicity value for the consumption of fish has not yet been established, the Dutch National Institute for Public Health and the Environment has calculated a maximum permissible concentration for PFOS of 0.65 nanograms per liter (ng/L) for fresh water (based on consumption of fish by humans as the most critical route) (Moermond and others 2010).
- Studies also indicate that continued exposure to low levels of PFOA in drinking water may result in adverse health effects (Post and others 2012).
- Toxicology studies show that PFOS and PFOA are readily absorbed after oral exposure and accumulate primarily in the serum, kidney and liver. No further metabolism is expected (EPA 2006a, 2009c).
- PFOS and PFOA have half-lives in humans ranging from 2 to 9 years, depending on the study. This half-life results in continued exposure that could increase body burdens to levels that would result in adverse outcomes (ATSDR 2009; EPA 2009c; Kärrman and others 2006; Olsen and others 2007).
- Acute- and intermediate-duration oral studies on rodents have raised concerns about potential developmental, reproductive and other systemic effects of PFOS and PFOA (Austin and others 2003; EPA 2006a).
- The ingestion of PFOA-contaminated water was found to cause adverse effects on mammary gland development in mice (Post and others 2012).
- One study indicated that exposure to PFOS can affect the neuroendocrine system in rats; however, the mechanism by which PFOS affects brain neurotransmitters is still unclear (Austin and others 2003).
- Both PFOS and PFOA have a high affinity for binding to B-lipoproteins and liver fatty acid-binding protein. Several studies on animals have shown that these compounds can interfere with fatty acid metabolism and may deregulate metabolism of lipids and lipoproteins (EFSA 2008; EPA 2009c).

What are the routes of exposure and the health effects of PFOS and PFOA? (continued)

- In May 2006, the EPA Science Advisory Board suggested that PFOA cancer data are consistent with the EPA guidelines for the Carcinogen Risk Assessment descriptor "likely to be carcinogenic to humans." EPA is still evaluating this information and additional research pertaining to the carcinogenicity of PFOA (EPA 2006b, 2013a).
- The American Conference of Governmental Industrial Hygienists (ACGIH) has classified PFOA as a Group A3 carcinogen — confirmed animal carcinogen with unknown relevance to humans (ACGIH 2002).
- The chronic exposure to PFOS and PFOA can lead to the development of tumors in the liver of rats; however, more research is needed to determine if there are similar cancer risks for humans (ATSDR 2009; OECD 2002).
- In a retrospective cohort mortality study of more than 6,000 PFOA-exposed employees at one plant, results identified elevated standardized mortality ratios for kidney cancer and a statistically significant increase in diabetes mortality for male workers. The study noted that additional investigations are needed to confirm these findings (DuPont 2006; Lau and others 2007).
- Studies have shown that PFCs may induce modest effects on reactive oxygen species and deoxyribonucleic acid (DNA) damage in the cells of the human liver (Eriksen and others 2010; Reistad and others 2013).
- Analysis of U.S. National Health and Nutrition Examination Survey representative study samples indicate that higher concentrations of serum PFOA and PFOS are associated with thyroid disease in the U.S. general adult population. Further analysis is needed to identify the mechanisms underlying this association (Melzer and others 2010).
- Epidemiologic studies have shown an association between PFOS exposure and bladder cancer; however, further research and analysis are needed to understand this association (Alexander and others 2004; Lau and others 2007).

Are there any federal and state guidelines and health standards for PFOS and PFOA?

- In January 2009, the EPA's Office of Water established a provisional health advisory (PHA) of 0.2 micrograms per liter (µg/L) for PFOS and 0.4 µg/L for PFOA to assess the potential risk from short-term exposure of these chemicals through drinking water. PHAs reflect reasonable, health-based hazard concentrations above which action should be taken to reduce exposure to unregulated contaminants in drinking water (EPA 2009d, 2013a).
- EPA Region 4 calculated a residential soil screening level of 6 milligrams per kilogram (mg/kg) for PFOS and 16 mg/kg for PFOA (EPA Region 4 2009).
- Various states have established drinking water and groundwater guidelines, including the following:
  - Minnesota has established a chronic health risk limit of 0.3 µg/L for PFOS and PFOA in drinking water (MDH 2011).
  - New Jersey has established a preliminary health-based guidance value of 0.04 µg/L for PFOA in drinking water (NJDEP 2013).
  - North Carolina has established an interim maximum allowable concentration (IMAC) of 2 µg/L for PFOA in groundwater (NCDENR 2006).
  - In 2010, the North Carolina Secretary's Science Advisory Board (NCSAB) on Toxic Air Pollutants recommended that the IMAC be reduced to 1 µg/L based on a review of the toxicological literature and discussions with scientists conducting research on the health effects associated with exposure to PFOA. As of February 2014, the NCSAB's recommendation was still pending review by the North Carolina Division of Water Quality (NCSAB 2010).
- Under the Toxic Substances Control Act (TSCA), the EPA finalized two SNURs in 2002 for 88 PFOS-related substances, which require companies to notify the EPA 90 days before starting to manufacture or importing these substances for a significant new use; this pre-notification allows time to evaluate the new use (EPA 2002a, 2013a).
- In 2007, the SNURs were amended to include 183 additional PFOS-related substances (EPA 2006a, 2013a).

Are there any federal and state guidelines and health standards for PFOS and PFOA? (continued)

- On September 30, 2013, the EPA issued a final SNUR requiring companies to report 90 days in advance of all new uses of long-chain perfluoroalkyl carboxylic (LCPFAC) chemicals (defined as having perfluorinated carbon chain lengths equal to or greater than seven carbons and less than or equal to 20 carbons) for use as part of carpets or to treat carpets, including the import of new carpet containing LCPFACs. In addition, the EPA is amending the existing SNUR to add PFOS-related substances that have completed the TSCA new chemical review process but have not yet commenced production or importation, and to designate processing as a significant new use (EPA 2012, 2013a).
- The SNURs allow for continued use for a few highly technical applications of PFOS-related substances where no alternatives are available; these specialized uses are characterized by very low volume, low exposure and low releases (EPA 2009c, 2013a).
- The Agency for Toxic Substances and Disease Registry has not established a minimal risk level (MRL) for PFOS or PFOA; when the draft toxicological profile was published, human studies were insufficient to determine with a sufficient degree of certainty that the effects are either exposure-related or adverse (ATSDR 2009).
- The EPA has not derived a chronic oral reference dose (RfD) or chronic inhalation reference concentration (RfC) for PFOS or PFOA and has not classified PFOS or PFOA carcinogenicity.
- The EPA removed PFOS and PFOA from the Integrated Risk Information System (IRIS) agenda in a Federal Register notice released on October 18, 2010. At this time, EPA is not conducting an IRIS assessment for these chemicals (EPA 2010).
- PFOS and PFOA were included on the third drinking water contaminant candidate list, which is a list of unregulated contaminants that are known to, or anticipated to, occur in public water systems and may require regulation under the Safe Drinking Water Act (EPA 2009a).

What detection and site characterization methods are available for PFOS and PFOA?

- PFOS and PFOA are commonly deposited in the environment as discrete particles with strongly heterogeneous spatial distributions. Unless precautions are taken, this distribution causes highly variable soil data that can lead to confusing or contradictory conclusions about the location and degree of contamination. Proper sample collection (using an incremental field sampling approach), sample processing (which includes grinding) and incremental subsampling are required to obtain reliable soil data (EPA 2003, 2013c).
- PFOS and PFOA in anionic form can be extracted from environmental media by conventional methods using either acidification or ion pairing to obtain a neutral form of the analyte. Sample preparation methods used for PFCs have included solvent extraction, ion-pair extraction, solid-phase extraction and column-switching extraction (Flaherty and others 2005).
- Precursors and intermediate degradation products can be extracted using solvents (Dasu and others 2012; Ellington and others 2009).
- Air samples may be collected using high-volume air samplers that employ sampling modules containing glass-fiber filters and glass columns with a polyurethane foam (Jahnke and others 2007a).
- Detection methods for PFCs are primarily based on high-performance liquid chromatography (HPLC) coupled with tandem mass spectrometry (MS/MS). HPLC-MS/MS has allowed for more sensitive determinations of individual PFOS and PFOA in air, water and soil (EFSA 2008; Jahnke and others 2007b; Washington and others 2008).
- Both liquid chromatography (LC)-MS/MS and gas chromatography-mass spectrometry (GC-MS) can be used to identify the precursors of PFOS and PFOA (EFSA 2008).
- EPA Method 537, Version 1.1, is an LC-MS/MS method used to analyze selected perfluorinated alkyl acids in drinking water. While most sampling protocols for organic compounds require sample collection in glass, this method requires plastic sample bottles because PFCs are known to adhere to glass (EPA 2009b).
- The development of LC - electrospray ionization (ESI) MS and LC-MS/MS has improved the analysis of PFOS and PFOA (EFSA 2008).
- Reported sensitivities for the available detection methods include low picograms per cubic meter (pg/m^3) levels in air, high picograms per liter (pg/L) to low ng/L levels in water and high picogram per gram to low ng/g levels in soil (ATSDR 2009).

What technologies are being used to treat PFOS and PFOA?

- Because of their unique physicochemical properties (strong fluorine-carbon bond and low vapor pressure), PFOS and PFOA resist most conventional in situ treatment technologies, such as direct oxidation (Hartten 2009; Vectis and others 2009).
- Factors to consider when selecting a treatment method in all media include: (1) initial concentration of PFCs; (2) the background organic and metal concentration; (3) available degradation time; and (4) other site-specific conditions (Vectis and others 2009).
- Ex situ treatments including activated carbon filters, nanofiltration and reverse osmosis units have been shown to remove PFCs from water; however, incineration of the concentrated waste would be needed for the complete destruction of PFCs (Hartten 2009; MDH 2008; Vectis and others 2009).
- Research into a cost-effective treatment approach for PFOS and PFOA is ongoing (DoD SERDP 2012).
- Alternative technologies studied for PFOS and PFOA degradation in water, soil and solid waste include photochemical oxidation and thermally induced reduction, which have achieved some bench-scale success (Hartten 2009; Vectis and others 2009).
- Laboratory-scale studies have also evaluated sonochemical degradation (that is, ultrasonic irradiation) to treat PFOS and PFOA in groundwater and have reported a sonochemical degradation half-life less than 30 minutes for both PFOS and PFOA (Cheng and others 2008, 2010).
- Results from a laboratory-scale study suggested the promising potential of using a double-layer permeable reactive barrier (DL-PRB) system for the in situ containment of PFC-contaminated soil and groundwater. The DL-PRB system is composed of an oxidant-releasing material layer followed by a layer of quartz sands immobilized with humification enzymes. The system drives enzyme-catalyzed oxidative humification reactions to degrade PFCs in the PRB (DoD SERDP 2013).
- In situ chemical oxidation is being explored as a possible means to treat PFCs in water. Laboratory-scale study results indicate that heat-activated persulfate and permanganate can effectively degrade PFOS and PFOA in water (Liu and others 2012a, b).

Where can I find more information about PFOS and PFOA?

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Where can I find more information about PFOS and PFOA? (continued)

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Where can I find more information about PFOS and PFOA? (continued)

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Where can I find more information about PFOS and PFOA? (continued)

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Contact Information

If you have any questions or comments on this fact sheet, please contact: Mary Cooke, FFRRO, by phone at (703) 603-8712 or by email at cooke.maryt@epa.gov.

To: Harper, Ashley[harper.ashley@epa.gov]
From: Behl, Betsy
Sent: Sat 2/13/2016 7:31:22 PM
Subject: Fwd: Regional PFC issues chart
Regional PFC Issues.docx
ATT00001.htm

This looks like what joel is looking for as s tracker. I will try to get Eric to pick it up. Not the gis project I envisioned!

Sent from my iPhone

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: February 13, 2016 at 1:42:46 PM EST
To: "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Behl, Betsy" <Behl.Betsy@epa.gov>
Subject: Regional PFC issues chart

Here is my compilation of info that I have so far - not vetted and subject to change, but will help us discuss

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Behl, Betsy
Sent: Thur 2/4/2016 5:45:20 PM
Subject: FW: Please Help Schedule an Administrator Briefing on HAs for PFOA and PFOS
Appendix D OW DW HEALTH ADVISORIES PFOA PFOS 02 04 16 v2.docx
APPENDIX F Briefing Memo PFOA PFOS 2 4 16 v2.docx

Please make sure Betsy reads them before we go forward. thx

From: Harper, Ashley
Sent: Thursday, February 04, 2016 12:25 PM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Subject: Please Help Schedule an Administrator Briefing on HAs for PFOA and PFOS

Octavia,

Please see the attached Appendix D and Appendix F for scheduling a briefing with the Administrator.

Jamie Strong is the POC

Thank you for your help,

Ashley

Ashley S. Harper | **Communications Specialist**

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Cantilli, Robert[Cantilli.Robert@epa.gov]
From: Behl, Betsy
Sent: Mon 2/1/2016 8:09:24 PM
Subject: Re: Question on Hoosick Falls, NY Health Advisory for PFOA

I can give France a call

Sent from my iPhone

On Feb 1, 2016, at 3:07 PM, Cantilli, Robert <Cantilli.Robert@epa.gov> wrote:

Thanks, will do. FYI, I haven't responded to France Lemieux. Bob.

From: Behl, Betsy
Sent: Monday, February 01, 2016 3:04 PM
To: Cantilli, Robert <Cantilli.Robert@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: RE: Question on Hoosick Falls, NY Health Advisory for PFOA

We have been responding to questions all week. Feel free to send to me and I will get them to the right source.

From: Cantilli, Robert
Sent: Monday, February 01, 2016 2:49 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: FW: Question on Hoosick Falls, NY Health Advisory for PFOA

Betsy and Jamie: Is there someone in OW fielding all questions on PFOA? I assume you are getting lots of calls after last week? Please let me know who we should refer all calls and emails to. Thanks, Bob.

From: France Lemieux [mailto:France.Lemieux@hc-sc.gc.ca]
Sent: Monday, February 01, 2016 2:33 PM
To: Shao, Nicole <Shao.Nicole@epa.gov>
Cc: Cantilli, Robert <Cantilli.Robert@epa.gov>
Subject: Question on Hoosick Falls, NY Health Advisory for PFOA

Hi Nicole,

It was good to talk to you on this issue. Thank you for the suggestion that I talk to Robert about the context behind the revised lifetime health advisory level for PFOA of 100 part per trillion (http://www.cnn.com/2016/01/30/us/new-york-hoosick-falls-water/).

We're currently in the approvals process to publishing our Guidelines for PFOS/PFOA for public comment as well as dealing with a potential contamination issue. As such, we would like to be able to respond to questions about the EPA HA values. However, I noted in a CNN article published on Saturday, states that "The lifetime health advisory level for PFOA was 400 parts per trillion but has now been updated to 100 part per trillion while the EPA continues to assess its guidance on the chemical."

I tried to find a reference to this new HA on the EPA website but haven't been able to track it down. So, we're wondering if this is based on the Draft HED published in 2014 or if this is the value EPA is about to publish subsequent to the peer review of the HED? Or, is this a site-specific value for Hoosick Falls.

I'll follow up with Robert by telephone to see if he can provide some clarification.

Thanks again for your help.

Regards,

France

France Lemieux, M. Eng.
Head, Materials and Treatment Section
Water Quality Program Division
Water and Air Quality Bureau
Health Canada
email: France.Lemieux@hc-sc.gc.ca
Tel.: 613-941-3166

To: Personal Address / Ex. 6
From: Behl, Betsy
Sent: Fri 1/29/2016 11:29:45 PM
Subject: FW: AA briefing - PFOA/PFOS
PFOA-PFOS-OW HAs 1.27.16.ppt

From: Flaherty, Colleen
Sent: Friday, January 29, 2016 5:16 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: AA briefing - PFOA/PFOS

Here's the latest in case something happens to me this weekend!

To: Personal Email / Ex. 6
From: Behl, Betsy
Sent: Mon 1/25/2016 2:43:29 PM
Subject: Fwd: AA PFOA PFOS briefing
PFOA-PFOS-OW HAs 01_23_2016.ppt
ATT00001.htm

Sent from my iPhone

Begin forwarded message:

From: "Strong, Jamie" <Strong.Jamie@epa.gov>
Date: January 23, 2016 at 2:48:26 PM EST
To: "Behl, Betsy" <Behl.Betsy@epa.gov>
Cc: "Flaherty, Colleen" <Flaherty.Colleen@epa.gov>
Subject: AA PFOA PFOS briefing

Betsy,

Here are the slides for the PFOA an PFOS HAs for Joel. There are a few place holders for USGS, OGWDW, and Fed Facilities. I also have Joyce checking a few numbers (the HA comparison table). I wanted to get this to you to get feedback on content. Is everything there we need? Things we can lose?

Colleen (thank you!!) sent me the response to comments, cleaned up. I have to go through that. I also got the PFOA HA from Joyce late last night. I will work on those next. Hopefully, I can turn both around before Monday. It all depends on naps.

I am also trying to get that SHPD PBDE report off my desk.

Thanks,

Jamie

From: Beauvais, Joel
Required Attendees: Grevatt, Peter; Clark, Becki; Burneson, Eric; Southerland, Elizabeth; Behl, Betsy; Strong, Jamie; Wadlington, Christina; Greene, Ashley; Lalley, Cara; Conerly, Octavia; Huff, Lisa
Optional Attendees: Davis, CatherineM; Harper, Ashley
Location: 3233 WJCE
Importance: Normal
Subject: Pre-brief for Administrator Briefing on PFC HAs
Start Date/Time: Wed 3/9/2016 9:00:00 PM
End Date/Time: Wed 3/9/2016 9:45:00 PM
OW Meeting Request Form_PFC HA.DOCX
PWS PFOS PFOA above ref conc_with avg_021616_v2.xlsx
PFOA-PFOS HA Fact Sheet draft 030816.docx
PFOA-PFOS-OW HAs ADMIN BRIEF 030916.ppt

From: Bragan, Mary Jo
Required Attendees: Bahrman, Sarah; Capacasa, Jon; Flournoy, Karen; Garcia, Bert; Giattina, James; Hamilton, Karen; Honker, William; Hyde, Tinka; Matthews, Joan; Montgomery, Michael; Moraff, Kenneth; Opalski, Dan; Pomponio, John; Torres, Tomas; Cote, Mel; Downing, Jane; Fernandez, Cristina; Garcia, David; Ghosh, Mita; Gratz, Jeff; Gullatt, Kristin; Hamjian, Lynne; Henry, Timothy; Hunter, Johanna; Lueckenhoff, Dominique; Mitchell, Gail; Psyk, Christine; Ringel, Donna; Robichaud, Jeffery; Taylor, Jori; Zapata, Cesar; Allenbach, Becky; Campbell-Dunbar, Shawneille; Heard, Anne; Jones-Johnson, Shea; Grevatt, Peter; Southerland, Elizabeth; Penman, Crystal; Greene, Ashley; Conerly, Octavia; Marcus, Pam; Mary Jo Bragan (Bragan.Maryjo@epa.gov); Shapiro, Mike; Gilinsky, Ellen; Dunn, Michael; Impellitteri, Christopher; Williams, Joe; Coleman, Sam
Optional Attendees: Pabst, Douglas; Anderson, Arlene; Beauvais, Joel; Behl, Betsy; Flaherty, Colleen; Strong, Jamie; Johnson, KarenD; rogers, rick; Crumlish, Karen; Rodrigues, Cecil; Jennings, Marie; Holsman, Marianne; Gray, Fredianne; Skadowski, Suzanne; DRA; Jenkins, Brandi; HicksWhite, Javoyne; Brown, Jamesr; Ngo, Kim; Watson, Jane; Saunders, Jerry; Li, Corine; Strauss, Alexis; Burneson, Eric; Bergman, Ronald (Bergman.Ronald@epa.gov); Corr, Elizabeth; Lopez-Carbo, Maria; Thompkins, Anita; Rupp, Mark; Pirzadeh, Michelle; Kahn, Lisa; Shoven, Heather; Szaro, Deb; Melvin, Karen; Kraft, Nicole; Brincks, Mike; Thomas, Deb; Ludzia, Peter; Laura Mohollen; Albert, Ryan; vanDrunick, Suzanne (vanDrunick.Suzanne@epa.gov); Michelle Latham; Rea, Anne (Rea.Anne@epa.gov); Pachnowski, Maya (Pachnowski.Maya@epa.gov); Greene, Rick (Greene.Rick@epa.gov); Murphy, Stacy; Mccabe, Catherine; Enforcement Division Directors; Shinkman, Susan; Kelley, Rosemarie; Pollins, Mark; Armstead, John A.; Nann, Barbara; Rodriguez, Roberto; TROMBADORE, CLAIRE; Kao, Jessica; Denton, Loren; King, Carol; Theis, Joseph; Gray, Stuart; McGuire, Karen; Durack, Patrick; McKenna, Douglas; Gilrein, Stephen; Blevins, John; Bohan, Suzanne; Chow, James; Hayes, Sharon; Bush, William; Klevs, Mardi; Geliga, Jaime; Guerriero, Margaret; Gettle, Jeaneanne; Esher, Diana; LaPosta, Dore; Wadlington, Christina; Kempic, Jeffrey; Huff, Lisa; Carroll, Gregory; Tiffany Cooper; Bissonette, Eric; Kier, Lori; Field, Stephen; Jamieson, Cheryl; Seager, Cheryl; McDonald, Scott
Location: 1 **Conference Code/ Ex. 6**
Importance: Normal
Subject: AD HOC HOT ISSUES CALL...Drinking Water Health Advisories for PFCs and Pb/Cu Rule
Start Date/Time: Wed 2/3/2016 6:00:00 PM
End Date/Time: Wed 2/3/2016 8:00:00 PM
2016 Feb 3 Drinking Water Hot Issues Call.docx
attachment for WDD hot issues meeting on PFCs.docx
STATEMENT PFOA Status 1.29.16.docx

Attached is the PFOA statement.

I have attached the longer agenda for today's call at 1:00 along with the Draft Summary of guideline values (2/3/2016) for PFOA and PFOS. The short agenda is below.

Hot Topics Call: Drinking Water – Health Advisories for PFCs/POFAs and Pb/Cu Rule
Wednesday, February 3, 2016 from 1:00 – 3:00 pm Eastern
Call in number: 866-299-3188 Code: 404-562-9275

1:00 – 1:15 HQ/Regional Roll Call Region 4
1:15 – 2:00 Flint, Michigan and Lead/

To: Harper, Ashley[harper.ashley@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Mon 6/27/2016 4:46:46 PM
Subject: today's presentation
PFOA-PFOS-OW HAs 062716.ppt

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0788

room 5233H

To: Strong, Jamie[Strong.Jamie@epa.gov]
Cc: Behl, Betsy[Behl.Betsy@epa.gov]; Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Ramasamy, Santhini
Sent: Mon 6/13/2016 12:25:42 PM
Subject: FW: WDD Notes Follow-up
WDD Notes SR.docx

Good Morning Jamie,

FYI- I have some raw notes from the WDD meeting. Adrienne, Julie and I are going to meet this morning and will exchange our notes and will clean this up.

Thank you all for the opportunity. It was a great experience listening in and learnt a lot on the implementation aspects.

Santhini

From: Ramasamy, Santhini
Sent: Monday, June 13, 2016 8:20 AM
To: Harris, Adrienne <Harris.Adrienne@epa.gov>; Javier, Julie <Javier.Julie@epa.gov>
Subject: RE: WDD Notes Follow-up

Good Morning Adrienne and Julie,

Please see my raw notes attached.

See you shortly.

Thanks.

Santhini

-----Original Appointment-----
From: Harris, Adrienne
Sent: Wednesday, June 08, 2016 12:45 PM
To: Harris, Adrienne; Javier, Julie; Ramasamy, Santhini; DCRoomEast2406/DC-ICC-OW-OGWDW; DCRoomEast2133/DC-ICC-OW-OGWDW; DCRoomEast2227/DC-ICC-OW-OGWDW; DCRoomEast2339/DC-ICC-OW-OGWDW; DCRoomEast2418/DC-ICC-OW-OGWDW
Subject: WDD Notes Follow-up
When: Monday, June 13, 2016 9:00 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomEast2406/DC-ICC-OW-OGWDW

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]; Flaherty, Colleen[Flaherty.Colleen@epa.gov]
From: Behl, Betsy
Sent: Mon 6/6/2016 7:07:52 PM
Subject: Re: Hoosick falls Pfoa blood serum results

Got it from Judith Enk.

Sent from my iPhone

On Jun 6, 2016, at 2:37 PM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:

Sent from my iPhone

Begin forwarded message:

From: "Spalding, Curt" <Spalding.Curt@epa.gov>
Date: June 6, 2016 at 1:27:02 PM EDT
To: "Enck, Judith" <Enck.Judith@epa.gov>
Cc: "Beauvais, Joel" <Beauvais.Joel@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Rupp, Mark" <Rupp.Mark@epa.gov>, "Etzel, Ruth" <Etzel.Ruth@epa.gov>, "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Thompkins, Anita" <Thompkins.Anita@epa.gov>, "Burke, Thomas" <Burke.Thomas@epa.gov>, "Garvin, Shawn" <garvin.shawn@epa.gov>, "Shapiro, Mike" <Shapiro.Mike@epa.gov>
Subject: Re: Hoosick falls Pfoa blood serum results

Thanks Judith.

Sent from my iPad

On Jun 6, 2016, at 8:38 AM, Enck, Judith <Enck.Judith@epa.gov> wrote:

In short : the average American has 2.08 ppb in pfoa in blood. The residents of hoosick falls have 23.5 ppb. Older residents have higher numbers Judith

Subject: News Clips (PFCs)

<image001.gif>

Times Union: High PFOA levels seen in blood of Hoosick-area residents

2,000 residents above average

By Brendan J. Lyons

June 4, 2016

Albany

The typical level of a toxic chemical found in the blood samples of more than 2,000 Rensselaer County residents is about 11 times higher than the national average, but well below levels detected in other areas of the nation where the contaminant has also polluted public water supplies, state officials said Friday.

The announcement came as the state Health Department began sending out the results of blood samples that were taken from residents beginning in February in eastern Rensselaer County, including Hoosick Falls and Petersburgh. Traces of the chemical, perfluorooctanoic acid or PFOA, were detected in water supplies in those communities at levels far above those recommended by the U.S. Environmental Protection Agency.

Most of the tests were performed on residents in and around the village of Hoosick Falls, where PFOA was discovered in the public water system in August 2014 by a village resident, Michael Hickey, who started researching the issue after he observed what he thought was a high rate of cancer and other serious diseases in that area.

State officials said the letters disclosing the level of PFOA in each resident's blood serum were accompanied by information packets describing what PFOA is and what similar blood testing has revealed in other parts of the nation where the substance has been a problem.

As the test results were being distributed, the state Department of Environmental Conservation announced it had reached consent orders with two corporations, Saint-Gobain Performance Plastics and Honeywell International, that will require them to initiate and pay for cleanup of several manufacturing sites in and around Hoosick Falls that were identified as potential sources of the contamination.

Under the agreements, which were signed Thursday but not announced until Friday afternoon, the corporations did not admit any wrongdoing but agreed to pay for costs the state incurs to investigate the contamination, conduct health monitoring and provide clean water in that area.

"These orders send a strong message to industries operating in New York that they have an ethical and legal obligation to protect public health, safety and the environment," said DEC Acting Commissioner Basil Seggos. "We will continue to ensure all communities across the state have access to clean, drinkable water."

Dr. Nathan Graber, director of the Health Department's Center for Environmental Health, said the agency will continue to take blood samples from residents, and health officials will be available at a village armory for residents seeking additional information on PFOA. Some of the results were also being mailed to residents' physicians if those residents requested it, he said.

Graber and other state officials declined to provide the range of PFOA levels in the blood samples, including the highest level of PFOA detected in any sample. They said they wanted that information to be delivered to residents before it was reported in the news.

"The very important message is that these results can really only tell you about your exposure," Graber said, "and that's very important for them to understand what the risks are for health effects in the future. People are going to be very concerned and they need reliable sources of information. We encourage people to speak with their physicians."

The data being distributed by the state is based on a "geometric mean," so the very highest and lowest samples were thrown out so that they would not skew the results and give a more accurate view of the average level of PFOA found in a person's blood in that area, state officials said.

The geometric mean level is 23.5 parts per billion, which is well above the average level of PFOA — 2.08 parts per billion — found in the blood of most people, officials said.

"We also analyzed these data by gender and age," Graber said. "The age results do show increasing PFOA levels in blood with age, which is probably reflective of longer exposure."

Graber said that without additional elevated exposure to PFOA, such as having it in drinking water, the level of the man-made chemical in a person's system usually decreases to about half in four years, and may drop to levels more in line with the national average in about nine years.

David Engel, an attorney for Healthy Hoosick Water, a grassroots group that formed more than a year ago to urge Hoosick Falls village leaders to take more aggressive action in dealing with the contamination, including warning the public to stop drinking contaminated water, said the organization is "particularly interested in what the range of the numbers are."

"Some people stopped drinking water there a couple year ago, when they became aware of the concerns, and their results are certainly going to be

influenced by what behavioral changes they made," Engel said. "The people who have been exposed through the workplace undoubtedly are going to show higher values and we'll have to wait and see what those numbers are.

"It's still unclear why it's taken four months to get these numbers," he said.

The Health Department, meanwhile, has retained Mount Sinai Hospital in New York City to consult and monitor a medical analysis the state will conduct to determine whether Rensselaer County residents exposed to the chemical have experienced elevated levels of serious diseases or other adverse health effects.

"We've begun that review and we're going to be working with Mount Sinai to review our work and provide input on how we can improve it," Graber said.

Three years ago, a science panel released the results of a multi-year study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from a manufacturing plant in Parkersburg, W. Va. The study found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension. In some of those communities, blood samples of residents and factory workers showed elevated levels of PFOA at hundreds of parts per billion, and in some cases more than 1,000 parts per billion.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. The McCaffrey Street plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA has been used since the 1940s to make products such as nonstick coatings and heat-resistant wiring.

Opinion

Hoosick Falls: The hearings Cuomo can't have

New York Post - 9 hours ago

It’s now clear why Assembly Speaker Carl Heastie doesn’t want to hold hearings on the Hoosick Falls water crisis: They’d spotlight the Cuomo administration’s reckless failure to warn residents about the tainted water for nearly a year and a half.

“We don’t want to alarm people” about the water issues, a top state health official, Nathan Graber, told his federal Environmental Protection Agency counterparts last year, according to a Politico report Thursday.

Albany also pooh-poohed EPA guidelines as overly cautious: “There’s a margin of safety that’s built into the [EPA’s] health advisories,” a Health Department aide told Politico.

By November, the feds were growing frantic. “We need the state health department to focus on the water supply issues fast,” one wrote.

Yet it was only after the Hoosick Falls mess got big press attention in February that Gov. Cuomo finally acted, promising a new water supply and water filters.

Legislative hearings might uncover new facts about how and why Team Cuomo ignored the crisis — but lawmakers evidently fear that would outrage Cuomo.

In February, Heastie & Co. vowed to hold hearings by April on the state’s water quality, due to “issues at places like Hoosick Falls and Flint, Mich.” Then the speaker reneged, saying hearings aren’t “necessary.” He’s now saying maybe, someday — while the state Senate hasn’t even threatened a probe.

As evidence of Team Cuomo’s recklessness grows, so does the importance of hearings — and, alas, the pressure to block them.

Two people in Hoosick Falls had blood tests showing very high levels of PFOA

By Lauren Linder

June 5, 2016, 10:28 pm

HOOSICK FALLS, NY (NEWS10) – Many people living in Hoosick Falls are still relying on bottled water. At the same time, they’re finally starting to get some answers about PFOA’s impact on their health.

“It was kind of a surprise, they actually held up,” said Harold Stevens, who received blood test results.

After four months of waiting for answers, Harold and Marion Stevens now know how much PFOA they have in their bloodstreams.

“I said wow, we’re, we’re up there,” said Harold.

Their numbers are pretty high. Test results show Harold has 159 micrograms per liter or parts per billion while Marion has 104.

According to the DOH, the average level of those sampled in Hoosick Falls is 23.5 parts per billion, five times higher than the national average.

"We've got to learn what the effects now are going to be, because I don't know what these numbers represent, "said Marion.

The Stevens' said they're now going to go to the doctors to find out what this means for their health in the long run. But until that time, they don't know how to feel about their results.

"We don't know to feel worried or not worried because until we talk and learn more about those results, that's when we're going to be able to know exactly what to feel, "said Marion.

On the other hand, they still have strong feelings of disappointment about the local and state governments.

"We feel that we've been deceived, especially when we have seen what Vermont has done in such a short time, and then we have kind of been put on a back burner," said Harold and Marion.

But even after all this time waiting for answers, they're hopeful for the future.

"I'm hoping for a tomorrow. I'm still hoping that there is a new water source that comes into Hoosick Falls. I'm hoping that our governor steps up to the plate to his promises," said Marion.

Now the Stevens' are just two people who have received their results so far. Many others including, their children and grandchildren, still haven't yet.

If you have any concerns about your test results, the Department of Health will be at the Armory to answer your questions on Tuesday at 2 p.m.

Hoosick Falls woman receives PFOA blood test results; son still waiting on his results

By Lauren Linder

June 5, 2016

HOOSICK FALLS, NY (NEWS10) – People in Hoosick Falls are finally learning how much PFOA is in their bloodstream.

Since the PFOA crisis began, many people living in Hoosick Falls have turned to bottled water. As they continue to do so, they're now getting some answers on their test results.

"I've been robbed," said Heather Clifford, who just received her blood test results.

Four months after getting her blood tested for PFOA, Heather Clifford finally received her results.

“Mine came back at 47.6,” said Clifford.

Clifford said her PFOA levels are 24 times higher than the average female in the U.S. She said it’s a scary fact and doesn’t know what it will mean in the long-run.

All the while, her son is still waiting for his results.

“After expecting these results within a few weeks, waiting all of this time to only have a few of them mailed, it’s very frustrating,” said Will Clifford.

Will Clifford said it’s upsetting that they’re not getting many answers.

“We need this information. We need to know what’s happening in our own bodies, in our own homes, and we’re not getting that,” said Will Clifford.

In the meantime, the Cliffords’ have lost their trust in the town’s water system.

“Little did we know we were actually hurting ourselves more and paying per gallon for metered water,” said Heather Clifford.

Heather ended up installing her own filtration system in her home in addition to the town’s filtration system.

But after what’s happened, she’s still having trust issues.

“It feels like a stolen identity you know. If I woke up one morning and found out about this, there’s nothing I can do about it. There’s no way to quickly fix it and it just wreaks havoc, “said Heather Clifford.

Now she’s just trying to ingest her results and waiting for her son’s.

“I don’t think we have the ability to be that naive anymore, and it’s not just Hoosick Falls, I think it’s everywhere, “said Heather Clifford.

The Department of Health will be at the Armory in Hoosick Falls on Tuesday at 2 p.m. to answer any questions people have on their results.

PFOA Blood Test Results Has Hoosick Falls Residents Afraid and Confused

TWC News

By Michael Howard

Sunday, June 5, 2016

HOOSICK FALLS, N.Y. -- People in Hoosick Falls are finally starting to learn the health impacts of drinking water contaminated with PFOA. Their blood tests were mailed out this week, and many are still trying to make sense of what it all means.

"I try to think in hindsight what could I have done differently," Hoosick Falls resident Heather Clifford said.

Speaking through tears Clifford is now faced with the reality so many of her Hoosick falls neighbors share, they have the harmful chemical PFOA in their blood.

The single mother of two boys was one of more than 2,000 that will receive a letter from the New York State Department of Health, listing lab results from a February blood test. Clifford's letter lists her PFOA level as 47.6 parts ber billion.

"It wasn't very encouraging, so I'm just trying to take it minute by minute right now," she said.

The letter compares the average amount of PFOA in Clifford's blood to samples taken from residents in other communities where the chemical has leached into water sources.

Clifford's resutls are slightly higher than the third highest national Average in Ohio. The average of 23.5 parts per billion for Hoosick Falls residents is 11 times higher than the general population. A hard reality for her to face.

"I don't know what it means completely, I don't know who to believe," Clifford said.

Out of the thousands of blood samples taken by state health officials, they would not say if the results indicate the potential for a future illness or if a person's current health issue is related to PFOA. Adding to Clifford's stress and questioning why it took so long to find out.

"Conspiracy theories like they're intentionally holding the results, I don't believe that," Clifford said. "I know there's a lot of information to pull together, but it does still make you wonder why four months?"

First PFOA blood test results arrive in Hoosick Falls

By WRGB Staff Sunday, June 5th 2016

HOOSICK FALLS -- Harold and Marion Stevens have lived in Hoosick Falls for 35 years. They were among the group of residents who had their blood drawn back in February on the first day the New York State Department of Health began taking blood from residents to test it for the presence of PFOA. The Department of Health mailed the results on Friday and the couple received their letter on Saturday. "To tell you the truth we really didn't expect it to come; they've been stalling for so long and the fact that it was in the mailbox yesterday was a surprise," Mr. Stevens said.

Harold's number was 159 micrograms per liter; Marion's 104 micrograms per liter. According to the Health Department the 50th percentile number derived from the samples taken from more than 2,000 Hoosick Falls residents is 28.3 micrograms per liter. According to the Centers for Disease Control the 50th percentile number for the United States population is 2.08 micrograms per liter. So the Stevens' numbers are higher than the average. "It's high, we are in the 95th percentile," Mrs. Stevens said.

The couple now have a lot of questions for their doctor. "How is this impacting me, how is this hurting my health or could it hurt my health," Mr. Stevens said.

According to the Department of Health, older people tend to have higher levels because of a longer period of exposure. There is no treatment to reduce levels, but they will generally decrease by half over a period of 2-4 years.

WNYT

For one Hoosick Falls couple, blood tests create more questions than answers

WNYT Staff

Updated: 06/05/2016 6:24 PM

HOOSICK FALLS – When Harold and Marion Stevens received their blood test results that showed the amount of exposure they've had to the toxic chemical PFOA, their attention was caught right away.

"Wow, this is something else," thought Harold Stevens.

Something else because the Stevens' say the numbers seemed a bit high. Marion tested at 104 parts per billion. Her husband was higher at 159 parts per billion.

"I know it's high," said Harold Stevens. "But what does that high number mean?"

To put those figures in perspective, state officials say the average in Hoosick Falls is 23.5 parts per billion. That's still more than 10 times the sample from the average American.

The Stevens' lived in their home on Wilder Avenue for more than 35 years. They've been drinking the municipal water where the PFOA contamination was discovered.

No one knows exactly how long the man-made chemical that's been linked to cancer and other illnesses has been in the water supply.

The Stevens' are planning a visit with their physician to try to make sense of the numbers and how they could impact their health.

"We both are concerned, said Marion Stevens. "We're going to both be retiring. What's going to be our future medical costs if something develops out of this? We don't know."

Blood testing began back in February. The Stevens' were part of the first groups to be tested and one of the first couples to receive their results.

NY Health Department releases some Hoosick Falls blood test results

By Lindsay Nielsen and Rachel Yonkunas

June 4, 2016, 4:48 pm

ALBANY, N.Y. (NEWS10) – The New York Department of Health (DOH) released some of the Hoosick Falls blood test results with NEWS10 ABC Friday afternoon.

NEWS10 reporters Lindsay Nielsen and Rachel Yonkunas were on a conference call with Jim Malatras the NYS Director of State Operations, Dr. Nathan Graber the Director of Environmental Health at the DOH, and the Director of Public Affairs at the DOH Friday afternoon. It was during this call the state officials shared some blood test results.

When asked why NEWS10 was not allowed to use direct audio or quotes, we were not given any specific reason other than that is how the officials wanted to handle the release of the information. For months, the DOH has refused to talk to NEWS10 on camera about any issues regarding PFOA in Hoosick Falls, and they did the same on Friday.

To date, the DOH has analyzed more than 2,000 blood samples from people living in Hoosick Falls. During the phone call, the DOH said the results are what they expected considering the degree of exposure in the community.

Officials did not release any personal information, but they did explain that older individuals will likely see higher levels, especially those who have worked closely with PFOA.

The DOH tells NEWS10ABC the general population has an average of 2.08 ppb of PFOA in their blood, a number from the Centers for Disease Control and Prevention. The DOH says the 95th percentile have PFOA levels of 5.68 ppb in their blood.

According to the blood results, the average level of those sampled in Hoosick Falls is 23.5 ppb. It's more than five times higher than the national average, but it is still significantly lower than what PFOA experts consider a "health risk."

The health department did not say during the phone call what the highest or lowest levels were. They only stated the average.

Michael Hickey first alerted the village of Hoosick Falls to the PFOA contamination in 2014. He's hopeful the results can help with early diagnosis of the illnesses linked to PFOA.

"In my dad's case, maybe if we knew his number back then, maybe we could have caught his kidney cancer earlier on in the process," he said. "It's something that you hope that this gains."

State officials said some studies do not show health risks associated with higher levels of PFOA in a person's blood. But when Rachel challenged that claim, she was met with silence.

"CDC and ACS and WHO all actually recognize that the studies were done by the C8 Science Panel," she said during the phone call. "Very little research done prior to that. If you know of studies that dispute their research, I would like to hear which studies those are."

No one gave an answer.

People living in Hoosick Falls told NEWS10 they are tired of the state's lack of transparency.

"We're not stupid people," Catherine Dawson said. "We need the information. We need to be able to advocate for our own health care and know what's coming down the pike for us."

When people get their results in the mail, it will include a letter with information that compares their level to those who have been exposed through drinking water and PFOA working environments in other states.

The department said they continue to collect blood samples at the Hoosick Falls Armory. They have also reached out to healthcare providers that will be looking at their patients' results.

Anyone with questions is advised to speak to their healthcare provider.

Jim Plastiras, Dir. of Public Affairs for NYS DOH, released the following statement late Friday evening:

“The NYS Department of Health has completed the analysis of more than 2,000 blood samples of residents in Hoosick Falls. Residents have been mailed a comprehensive packet of information to help them understand their results and have been provided with multiple options for reaching physicians and staff should they have additional questions.”

Some Hoosick Falls residents yet to receive PFOA blood test results

WNYT Staff

Created: 06/04/2016 6:13 PM

HOOSICK FALLS -- Representatives from the state health department were ready to go Saturday morning, all set to answer questions from residents who might have gotten their blood test results in the mail.

But no residents showed up.

“There are a couple of thousand results that have to be mailed out,” said Hoosick Falls Mayor David Borge. “That'll take a little bit of time. I have not received my results.”

Borge says the results are being mailed out in terms of when the sample was taken.

“If you were one of the first people to be sampled, you'd be one of the first people to get the results,” he said.

Testing began about four months ago after the toxic chemical PFOA was discovered in the village water supply and in private wells in the surrounding area. PFOA has been linked to many illnesses, including cancer.

“The results would really just be a predictor of how long you've been exposed to PFOA,” Borge said.

A state health official said the average person in Hoosick Falls tested 23.5 parts per billion PFOA in their blood. They said that's more than 10 times what the average American has in their blood.

Residents are expected to get a comprehensive packet of information to

help them understand their results. Department of Health staff members will be available in the village to provide additional information.

Meanwhile, Borge says he's glad things are progressing and that a second blood test in the future will reflect that even more.

“Now that we have clean water going through the municipal system, that major exposure is no longer there,” he said.

Assemblyman McLaughlin asking Bharara for DOH, Cuomo investigation into Hoosick Falls

By WRGB Staff Friday, June 3rd 2016

TROY - Assemblyman Steve McLaughlin has written to US Attorneys calling for an investigation on Governor Cuomo's administration handled the Hoosick Falls water crisis.

The republican lawmaker, citing a Politico article, saying that Cuomo's administration and the NYS DOH 'botched' the handling of the water crisis and did not follow EPA guidelines.

U.S. Attorney Preet Bharara and U.S. Attorney Richard Hartunian were addressed in the letter.

"The residents I represent believe that the Cuomo Administration and DOH perpetuated and facilitated the consumption of contaminated village water and demonstrated a pathetic level of accountability and transparency in handling the matter," McLaughlin wrote. "I am asking you to open an in-depth investigation into the state's handling of the Hoosick Falls water crisis because our residents deserve answers and government officials should be held accountable.", said McLaughlin in his letter.

Times Union

State says Hoosick companies will pay for water, filtration

By Rick Karlin, Capitol bureau

June 3, 2016 at 5:05 PM

The Cuomo Administration is out with news of an agreement that holds two companies in Hoosick Falls responsible for the PFOA contamination in the community’s water supply. The news comes as blood test results are being sent back to residents from the state Department of Health. The state has

been calling for a consent order with two manufacturers with plants in the area, Saint Gobain and Honeywell, for several months.

Here are the details and agreements:

New York State Department of Environmental Conservation (DEC) Acting Commissioner Basil Seggos today announced that the state has executed two Consent Orders (http://www.dec.ny.gov/docs/regions_pdf/stgobainco632016.pdf, and http://www.dec.ny.gov/docs/regions_pdf/oakmaterialsco62016.pdf) that will hold Saint Gobain and Honeywell responsible for the PFOA contamination in the Hoosick Falls area. Under the Consent Orders the State will require the companies to:

· Investigate the source and determine the full scope and extent of contamination at four Honeywell and two St. Gobain plants;

· Investigate feasibility of an alternate water supply which may include a new well field, a surface water supply source, or an interconnection with an existing municipal water supply system, among others;

· Fund the installation and maintenance of temporary and full capacity filtration systems for the Village municipal water supply;

· Reimburse State for costs incurred for response and investigation into the contamination, and well sampling; and

· Continue to pay for bottled water for Village and Town residents until successful installation of the full capacity filtration system.

In addition the State will rehabilitate Well 3 on the municipal water system to improve effectiveness of the Village's carbon treatment system. The State is also transferring payment to the Village for rebates to residents for past water bills for water that was determined to be unsafe for use.

"The State is taking aggressive action to hold all parties accountable for the costs associated with the full remediation of the contamination in the Hoosick Falls area," DEC Acting Commissioner Seggos said. "These orders send a strong message to industries operating in New York that they have an ethical and legal obligation to protect public health, safety and the environment. We will continue to ensure all communities across the state have access to clean, drinkable water."

Funding for Village Water Filtration System

The McCaffrey Street Consent Order memorializes Saint Gobain's commitment to pay for the maintenance of the existing temporary drinking water filtration system on the Village's municipal water supply which is currently filtering PFOA out of the drinking water. Saint Gobain will be required to pay for all costs associated with the design, installation and

operation of a full capacity water treatment system, and all additional incidental operation and maintenance costs of the municipal water system caused by the installation of the full capacity system. Honeywell and Saint Gobain will continue to provide bottled water to residents of the Village until the full capacity system is in place and to Town of Hoosick residents until their point of entry treatment (POET) systems installed for private drinking water wells are cleared for all uses.

The State will also rehabilitate Well 3 of the municipal supply system as an interim remedial measure to attempt to improve the effectiveness of the Village's carbon treatment system and will seek to recover any cost associated with the rehabilitation of Well 3 from the responsible parties. The Consent Order also requires Honeywell and Saint Gobain to negotiate with the Village with respect to the Village's past costs. As part of this component, Honeywell and Saint Gobain have indicated to the State that they will make a comprehensive offer to reimburse the Village for costs associated with the Village's response, and that their offer will provide reimbursement for rebates provided to Village Municipal Water Supply users.

Alternate Water Supply

As part of the State Superfund program's required Remedial Investigation and Feasibility Study, Honeywell and Saint Gobain will conduct an evaluation of the feasibility of an alternate water supply for the Village of Hoosick Falls, including, but not limited to a new well field, a surface water supply source, an interconnection with an existing municipal water supply system, continuing the treatment provided, or any combination of those alternatives.

Following the Remedial Investigation and Feasibility Study, the State will issue a Record of Decision that will establish a comprehensive remedy to clean-up the Hoosick Falls area and to continue to provide long term safe drinking water to the residents of the Village and Town. The public will have an opportunity to comment on the selected remedy before it is finalized.

Water Bill Rebates to Residents

To address concerns from Village of Hoosick Falls residents regarding their water bills, the State is transferring funds to the Village to provide rebates for past water bills for water that was determined to be unsafe for use and for water that was used for flushing the Village's water system during the installation of the temporary treatment system that was recently completed. The State will seek to recover this cost from the responsible parties.

Reimburse State for Past Costs

Honeywell and Saint Gobain also agreed to pay for the State's costs of the ongoing response and investigation into the contamination, including the sampling of private water wells in the Town and Village, sampling of the

Hoosic River and the bus garage on River Road, sampling of soils, the State's preliminary efforts to evaluate alternative water supplies, and the costs associated with developing, overseeing, administering and enforcing the Orders. Additionally, under a separate Order, Honeywell will commence work to determine possible contamination at several potential disposal sites, and will be responsible for paying all the State's costs in overseeing implementation of that Order.

State Actions to Date

To date, the State has undertaken the following actions to help residents in the Village of Hoosick Falls and Town of Hoosick to secure clean water:

· Tested more than 1,000 private wells throughout the Hoosick Falls area and testing is ongoing;

· Installed 765 POET Systems on private water systems and cleared 652 systems for all uses;

· Initiated a confidential PFOA biomonitoring project for more than 2,000 residents of the Hoosick Falls area to measure PFOA levels in blood to provide information to residents on exposure;

· Conducted regular informational sessions at the Armory in the Village of Hoosick Falls every Tuesday, Thursday and Saturday beginning in March to meet with residents and allow them to sign up for well testing and for the biomonitoring project. The State also established a hotline to keep the public informed: 1-800-801-8092;

· Issued emergency regulations to first classify PFOA and then add PFOS and several associated chemicals as hazardous substances to provide the State with the legal authority to pursue State Superfund designation and cleanup of the site using State Superfund resources;

· Urged EPA to take vigorous action on the federal level to regulate PFOA and to initiate an evaluation of the addition of the Hoosick Falls Saint Gobain – McCaffrey Street site to the Superfund National Priorities List;

· Achieved significant progress in its efforts to identify alternate drinking water sources, including groundwater, surface water and connection to existing water supplies and has identified the first phase of potential groundwater locations; and

· Commenced sampling of certain gardens, residential soil and select surface waters as part of the State's Superfund investigation.

WAMC

DEC Announces Consent Order To Hold Companies Responsible For Hoosick Falls PFOA Contamination

By Lucas Willard

Jun 4, 2016

The New York State Department of Environmental Conservation has secured an agreement that holds companies Saint-Gobain and Honeywell responsible for the PFOA contamination in Hoosick Falls and surrounding area.

Under consent orders the state will require the companies to investigate the source and extent of the chemical contamination and the feasibility of an alternative water supply.

The state is ordering the companies to fund the installation of water filtration systems, continue to pay for bottled water for village and town residents, and reimburse costs incurred by the state in its response, including water sampling.

In a prepared statement, Hoosick Falls mayor David Borge said the village is "actively pursuing the agreement in order to ensure local taxpayers do not bear the costs of a situation they did not create."

DEC holds St. Gobain, Honeywell responsible for Hoosick Falls PFOA contamination

By Joe Gullo

June 3, 2016, 9:13 pm

HOOSICK FALLS, N.Y. (NEWS10) – The New York State Department of Environmental Conservation secures agreement that holds Saint Gobain and Honeywell responsible for PFOA contamination in Hoosick Falls.

According to the DEC, the announcement means the companies will have to pay for the village water system and will have to reimburse the state for costs incurred.

"The State is taking aggressive action to hold all parties accountable for the costs associated with the full remediation of the contamination in the Hoosick Falls area," DEC Acting Commissioner Basil Seggos said. "These orders send a strong message to industries operating in New York that they have an ethical and legal obligation to protect public health, safety and the environment. We will continue to ensure all communities across the state have access to clean, drinkable water."

Under the agreement the State will require companies to:

- Investigate the source and determine the full scope and extent of contamination at four Honeywell and two St. Gobain plants;

- Investigate feasibility of an alternate water supply which may include a new well field, a surface water supply source, or an interconnection with an existing municipal water supply system, among others;

- Fund the installation and maintenance of temporary and full capacity filtration systems for the Village municipal water supply;

- Reimburse State for costs incurred for response and investigation into the contamination, and well sampling; and

- Continue to pay for bottled water for Village and Town residents until successful installation of the full capacity filtration system.

Times Union

PFOA test results: 'At first it took my breath away'

Residents start to get PFOA test results by mail on Saturday

By Kenneth C. Crowe II

Updated 8:43 pm, Saturday, June 4, 2016

HOOSICK FALLS — PFOA blood test results began trickling in to residents by mail Saturday — and the above-average numbers started raising concerns.

Village resident Heather Clifford's results came in at 47.6 parts per billion, more than twice the village geometric mean average (a measure that removes the low and the high) of 23.5 ppb released by the state Friday.

"At first, it took my breath away," Clifford said, describing her reaction to the state Department of Health's letter and pamphlet. Clifford immediately began researching cancer risks.

"I'm hopeful because my exposure has been only for eight years," Clifford said.

PFOA, the shorthand for perfluorooctanoic acid, is considered to be carcinogenic. It's a chemical compound used to manufacture non-stick surfaces such as Teflon and in other processes.

Click here for the history of the Hoosick Falls water crisis

The average reading in Hoosick Falls at 23.5 parts per billion is more than 11 times higher than the average level of 2.08 found in most people.

PFOA contamination has been found in the public and private water systems in Hoosick Falls and the towns of Hoosick and Petersburgh.

Water contamination has been traced to the Taconic plant in Petersburgh and the Saint-Gobain facilities in Hoosick Falls. Both locations have been declared state Superfund sites. Wells are being tested and filters installed.

"Clean water should be a given," Clifford said about the village's water system.

Resident Harold Stevens has a PFOA count of 159 after living in the village for 36 years.

"I've got a lot of PFOA in my blood," Stevens said. "There's nothing I can do."

Stevens said he will have to rely on his doctors.

The notifications that arrived Saturday were only a handful of the more than 2,000 residents in Rensselaer County who have been tested for PFOA contamination. Clifford said her results arrived, but her teenage son's did not. They were tested on Feb. 13.

Hoosick Falls Mayor David Borge said most results are expected to arrive Monday and Tuesday. He said he has not received his results.

Average Hoosick Falls resident has ten times more PFOA in blood than average American

Asa Stackel

WRGB

Created: 06/03/2016 6:54 PM

The results are in the mail for the more than 2000 people who had their blood tested for PFOA in Hoosick Falls. On Friday, a state health official gave us a small overview of those results.

The average test came back at 23.5 parts per billion PFOA. That official says that's more than ten times the average American's level of 2.08 ppb. The 95th percentile of Americans hit the 5.68 ppb level.

The official said older people seem to have higher levels of PFOA because of longer exposure. He says every two to four years your PFOA level should be cut in half if you stop consuming contaminated water.

So what does that mean? The state health official says there's just not enough research to say.

The state department of health will be in Hoosick Falls Saturday to answer questions or concerns residents may have about those blood test results. They'll have representatives at the armory from 10 a.m. to 2 p.m. The school district says any student, parent or guardian who has questions will find support from its nurses and school physician. The department has briefed local doctors to deal with worried patients.

We contacted the health department and the governor's office for comment. The two high ranking officials told us we could only identify them as a state official and a health official. But after our 5 o'clock piece aired, they called us back and told us we could identify them.

We were talking to Jim Malatras, the governor's state director of operations, and Dr. Nathan Graber from the health Department.

We asked those two officials their thoughts on hundreds of pages of documents we obtained from the EPA. Emails that showed the EPA seemingly frustrated with the health department's handling of the PFOA crisis.

In November, Region Two EPA director Judith Enck wrote in an email to staff.

"Bottom line: the town of Hoosick Falls has known about this contamination in their water supply for over a year. We need the state health department to focus on the water supply issues fast."

She went on to say:

"State health department seems to be relying on negotiations between the mayor and the company. There is a clear need for regulatory oversight by either the state or EPA or both."

That same day, Nidal Azzam from the EPA wrote, "Apparently DOH does not want to take the lead, although I have tried to push them into that path about three weeks ago."

Malatras admitted the health department has known about PFOA since 2014. He says they were in the lead and anything less is a false characterization.

The DEC, announced an agreement today, that holds Saint Gobain and

Honeywell responsible for the PFOA contamination. Among the agreement, the companies will investigate the contamination, pay for the village water system and reimburse the state for the costs. The DEC says village residents will receive rebates for the water bills from the state.

After Politico first reported on those emails, Assemblyman Steve McLaughlin asked US Attorneys, Preet Bharara and Richard Hartunian to look into the water crisis. He sent a letter, Friday, calling for an investigation into how the Cuomo administration and the health department, "botched" the handling of the Hoosick Falls water crisis.

We have reached out to ask if the two attorneys have received McLaughlin's letter and if they've decided what their response. We've received no response yet.

DOH releases PFOA information

By WRGB Staff Friday, June 3rd 2016

CBS6 received information from the NYS DOH, as residents of Hoosick Falls wait to receive blood test results detailing their p-f-o-a exposure.

The DOH tells us samples taken in Hoosick Falls show an average contamination level of 23.5 micrograms per liter.

According to the CDC the general population in a community not dealing with the crisis shows a median contamination level of just 2.08 micrograms per liter.

This new information comes amid more breaking news from the state...

State DEC officials tell us they have reached an agreement to formally hold Saint Gobain and Honeywell, two manufacturing plants, responsible for the PFOA contamination in Hoosick Falls.

The agreement will require the companies to investigate the contamination and look into supplying the town with an alternative water source.

The state gave us some information on what those residents can expect -- and what the results mean...

These tests are meant to give an indication of PFOA exposure over time. According to Laurel Schaider, a Massachusetts research scientist we spoke with, nearly all Americans have traces of the chemical in their bodies.

Even when there is no drinking water contamination, we can be exposed through food, food packaging, and household products.

A PFOA study conducted in DuPont, Ohio found there are six health issues with a probable link to the chemical - testicular and kidney cancer, thyroid disease, ulcerative colitis, pregnancy induced hypertension, and high cholesterol.

According to a test of two thousand Americans done by the centers for disease control and prevention, 2.08 micrograms per liter is considered the median blood concentration of PFOA.

But Schaider says it's important to keep in mind that these kinds of benchmarks don't necessarily provide an indication of health effects.

Schaider says PFOA has a half-life in the human body of three years, which means it would take three years to rid yourself of just half of the amount in your body.

She also says there is no real way to help the body eliminate PFOA more quickly than it would naturally on its own.

We have reached out members of the C8 panel about these numbers to find out more about what they mean in terms of health risks.

Study finds Hoosick Falls area residents have elevated PFOA levels in blood

Testing results from Hoosick Falls area residents

By Edward Damon

berkshireeagle.com

Posted: 06/03/2016 10:20:57 PM EDT

HOOSICK FALLS, NY >> Results from a study that found area residents have elevated PFOA levels have been mailed to its participants.

The study found residents in the Hoosick Falls area had an average of 23.5 micrograms per liter of PFOA in their blood, according to the New York Department of Health (DOH). That's up to 10 times higher than the average American — most people have between 2 and 5 micrograms per liter of PFOA in their blood, according to the Center for Disease Control (CDC).

The first results from the biomonitoring study, which aimed to measure residents' exposure to the potentially harmful chemical, were mailed on Thursday to Friday.

A fact sheet included with the results states "the result only provides exposure information" and "comparison to people living elsewhere."

"Because scientists and public health experts are still learning about PFOA and human health, the blood testing result does not indicate if a person's current illness is due to PFOA, or if a person will experience illness in the future due to PFOA," the DOH fact sheet states.

Residents will be encouraged to speak with their physician about potential health effects, according to Nathan Graber, director of the Center for Environmental Health at DOH.

Graber told the Banner that, in general, the results showing higher PFOA levels among participants correlate with higher ages, reflective of higher exposure in the past.

Graber said DOH staff are reviewing data from surveys completed by residents. Additional blood draw clinics are slated for June 18 and 28.

Graber said representatives from his agency will continue holding informational sessions at the Hoosick Armory, 80 Church St. They will be there Saturday from 10 a.m. to 2 p.m.

Information on the study is available here: https://www.health.ny.gov/environmental/investigations/hoosick.

It's been four months since DOH launched the biomonitoring study for PFOA, or perfluorooctanoic acid, in blood. Some residents from nearby Petersburgh, where PFOA also turned up in wells and a municipal water supply, also participated, according to Graber.

The man-made chemical was used to make Teflon for decades. Saint-Gobain and Honeywell International are responsible for the contamination, according to the state Department of Environmental Conservation, because both companies are successors of past manufacturing facilities.

PFOA has been under increased scrutiny and the federal EPA only recently issued a health advisory level. Its use was widespread across the country. Manufacturers 3M and Dupont are facing class action suits alleging they knew about the harmful health affects decades ago.

Graber said results will come in a mailed packet with a letter from DOH, information about the program and other resources. One sheet will include a table showing residents their result and for comparison, the average levels for the general public and residents of other communities across the country.

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<DEC Order stgobainco632016.pdf>

<hoosick-falls-mayor-david-borge-on-nys-consent-orders-sent-to-saint-gobain-and-honeywell.pdf>

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]; Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
Cc: Lape, Jeff[lape.jeff@epa.gov]
From: Conerly, Octavia
Sent: Thur 5/12/2016 11:22:05 AM
Subject: Inside EPA articles - Daily News: Northeast States To Meet With EPA Over PFCs, Eyeing Lessons Learned & EPA Region 1 Grappling With Authority, Technology To Address PFCs

FYI...

Daily News

Northeast States To Meet With EPA Over PFCs, Eyeing Lessons Learned

May 11, 2016

State regulators from the Northeast plan to privately meet with EPA later this month as part of an academic forum in order to exchange information and lessons learned on perfluorinated chemicals (PFC), a class of chemicals that is drawing growing regulatory and public attention.

The May 23 meeting to be held in Worcester, MA, will include EPA and representatives from Northeastern states' waste site cleanup, drinking water and health departments in order to discuss the toxicology, fate and transport, sampling and remediation of poly- and perfluoroalkyl (PFAS) substances, which also are often referred to as PFCs.

They also plan to discuss state and EPA guidelines and standards, recent state experiences and lessons learned in New York, New Hampshire and Vermont, and research questions and next steps, according to a notice of the meeting.

The meeting is being sponsored by the Northeast Waste Management Officials' Association (NEWMOA) and Brown University's Superfund Research Program.

The class of chemicals known as PFCs -- known for their non-stick, persistent qualities -- "is presenting a significant challenge to several NEWMOA states and is likely to [affect] all the northeast states due to its widespread use," the notice says. PFCs have been used widely in carpet and fabric protection and food packaging, as well as in aqueous film-forming foams used in firefighting. Studies conducted by an independent panel created as part of a lawsuit settlement around a DuPont plant in Parkersburg, WV, found probable links between perfluorooctanoic acid (PFOA), a PFC, and six adverse health impacts including kidney and testicular cancer.

The meeting comes as some states are wrestling with what safety levels for PFOA in drinking water to apply in communities amid conflicting advisory levels among states and EPA, and as states, environmentalists and others press EPA to set a uniform health advisory for PFOA for long-term exposures to the chemical in drinking water.

One state, which in the face of discovering PFOA in drinking water quickly set an aggressive, interim groundwater quality enforcement standard of 20 parts per trillion (ppt), now is confronted with a lawsuit filed by a chemical manufacturer challenging the standard.

The April 13 suit, filed in Vermont Superior Court, contends that Vermont violated state requirements as it failed to involve the public in the rulemaking and derived the standard from a draft health effects document EPA developed that has yet to be finalized. The Vermont standard applies the most sensitive receptor -- a young child -- to EPA's draft oral reference dose for the chemical.

The lawsuit, filed by Saint-Gobain Performance Plastics (SGPP) Corporation, says the state has applied the groundwater standard to the company demanding that it undertake certain investigatory and remedial actions at a former industrial facility in North Bennington, VT. But SGPP argues that the interim standard was adopted in violation of Vermont law, "without regard to the public participation and other requirements set forth in [Vermont statute on groundwater protection], and is based solely on a draft document that is still under review," referring to EPA's 2014 draft health effects document for PFOA.

EPA Advisory

EPA is developing a first-time, long-term exposure health advisory based on the draft oral reference dose from the 2014 draft health effects document, expecting to issue it this spring. The agency is under increasing pressure to release it following EPA Region 2's advice earlier this year to residents of Hoosick Falls, NY, where PFOA was identified in drinking water supplies.

EPA Region 2 in January advised Hoosick Falls residents to refrain from consuming private well water that exceeds 100 ppt PFOA, a much lower level than the agency's existing short-term exposure health advisory level of 400 ppt -- a disparity EPA has been widely criticized for.

New York, Vermont and New Hampshire's governors in March called on EPA to give states uniform guidance for assessing safe levels of PFOA. New York Gov. Andrew Cuomo (D) also added the site in Hoosick Falls to the state's Superfund list and issued an emergency regulation to classify PFOA as a hazardous substance.

One attorney with expertise on PFCs believes Vermont and New York's prompt actions on the chemical are the "new bellwether" for state action on PFOA, a change from previous state reaction, the source says. The source notes that in response to PFOA contamination that previously arose in southeast Ohio, the state of Ohio lacked a response.

The attorney says the scientific evidence is available for states to act on PFOA, and they should not use the excuse that they are waiting for EPA to act before addressing the chemical.

Another state that has started to take action is Michigan, which in April released draft enforceable drinking water standards for PFOA and perfluorooctane sulfonate (PFOS), calling for a standard of 89 ppt for PFOA and 120 ppt for PFOS in drinking water, according to a state source.

An environmentalist following the issue doubts there will be a rush by states to adopt the new long-term exposure health advisory level EPA issues, if for instance it follows along the lines of the level derived from the draft health effects documents -- which would equate to 100 ppt. State scientists closely tracking the issue may not believe such a level is much of an advance, the source says. Some environmentalists believe the long-term exposure level should be more stringent than 100 ppt. This source believes a 100 ppt standard would also provide "cover for industry" to say anything below that level is safe.

But another state source believes states will take a "hard look" at what EPA releases as its long-term exposure health advisory for PFOA "and take it from there." The source believes states are looking for the chemical at manufacturing locations and sites where fire-fighting training repeatedly occurred. -- *Suzanne Yohannan* (syohannan@iwpnews.com)

Daily News

EPA Region 1 Grappling With Authority, Technology To Address PFCs

May 11, 2016

EPA Region 1 Administrator Curt Spalding says the region is grappling with how to address the class of emerging contaminants known as perfluorinated

chemicals (PFCs) -- especially at non-Superfund sites where there is not clear authority on action levels -- while facing limited laboratory analytical capacity and tightening budgets.

Spalding, speaking during a May 9 webinar hosted by Northeastern University's Superfund Research Program, noted in contrast that the agency has many tools it can use when determining if PFCs are a contaminant at Superfund National Priorities List sites.

"It's important to note that the federal response is very different when we are dealing with a known site within our Superfund program. Then we have lots of tools," Spalding said.

According to slides Spalding presented, the region's Superfund program is "evaluating possible presence of PFCs at several National Priorities List sites." One state source says this effort seems to be reflective of a growing awareness among regions' program offices of PFCs.

Region 1, which covers several Northeast states, is also helping Vermont sample for PFCs at non-Superfund sites though the detection of any PFCs raises more challenges, he said. "[T]hen comes the question, well, what if we find it? Is it a high enough level for us to act? And that's a big question as we go forward," he said.

The region has been at the forefront of dealing with PFCs as a contaminant in drinking water supplies, including issuing last year a first-time Safe Drinking Water Act administrative order for the Air Force to clean up PFC contamination at the former Pease Air Force Base in New Hampshire. The contaminants are commonly found in firefighting foams that were used by the Air Force to extinguish fires at its facilities and airports.

Vermont recently established a strict interim groundwater quality standard of 20 parts per trillion (ppt) for the PFC perfluorooctanoic acid (PFOA) after discovering the chemical in drinking water. A chemical manufacturer is challenging the standard in state court.

But the region has struggled to be able to test for the chemicals due to a lack of laboratory analytical capability, Spalding said. "Limited laboratory capacity has been a big problem for us when it comes to perfluorinated compounds," he said, noting that one of the region's labs could not perform the analysis work when PFCs first emerged in Vermont and New Hampshire. The agency "spent a scrambled period getting our methods together to actually do the work," he said.

Additionally, continual budget cuts have made it harder to address emerging contaminants, Spalding said. “In our Superfund program the resources are getting more and more strained as we go forward,” he said, noting that EPA’s flat annual budget of $8 billion really reflects a 5 percent decline every year. “So we’re looking at a declining resource base against new problems. Very challenging,” he said.

Growing Problem

Spalding noted that the more regulators look for PFOA, the more they will find it, due to its widespread use in a variety of applications, including Teflon.

EPA and state regulators are under escalating pressure to apply stricter drinking water treatment levels to water supplies contaminated with PFOA, a toxic and persistent non-stick chemical, amid conflicting health advisory levels EPA and states are currently using, and as more communities have become aware of the chemical’s presence in their drinking water.

State regulators from the Northeast plan to privately meet with EPA later this month as part of an academic forum in order to exchange information and lessons learned on PFCs.

EPA officials have said the agency will issue a health advisory for long-term exposures to PFOA in drinking water this spring, coming under increasing pressure to release it after EPA Region 2 bypassed the agency’s provisional short-term exposure advisory level of 400 ppt and advised private drinking water well users in a New York community with PFOA-contaminated water not to consume water above 100 ppt.

Provisional short-term advisories, which EPA has for PFOA and another PFC, perfluorooctane sulfonate, have helped guide action, Spalding said, but noted that it “got a bit complicated” when Region 2 advised 100 ppt for PFOA. While the agency has an “official advisory” for short-term exposures of 400 ppt, “we’ve moved to [a] potentially practical outcome of 100 ppt,” he said.

“We’re now working on potentially clarifying that in the next couple weeks,” when the agency releases a long-term health advisory for PFOA, he said. -- *Suzanne Yohannan* (syohannan@iwpnews.com)

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To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Thur 3/24/2016 7:44:58 PM
Subject: LOOK
PFOA-PFOS HAs_rollout 3-24 v1.docx

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | harper.ashley@epa.gov

To: Loop, Travis[Loop.Travis@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Mon 3/21/2016 4:21:24 PM
Subject: administrator briefing for PFC due today
PFOA-PFOS-OW HAs ADMIN BRIEF 03 18 16 AA draft.ppt

Travis, we need to send the administrator's briefing forward today. Any changes to the last slide on the roadmap?

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0788

room 5233H

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Southerland, Elizabeth
Sent: Sat 3/19/2016 2:02:55 PM
Subject: Fwd: FYI on PFOA testing in New Hampshire

Sent from my iPhone

Begin forwarded message:

From: "Loop, Travis" <Loop.Travis@epa.gov>
Date: March 19, 2016 at 8:29:46 AM EDT
To: "Beauvais, Joel" <Beauvais.Joel@epa.gov>, "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Subject: FYI on PFOA testing in New Hampshire

FYI on PFOA in New Hampshire

FOR IMMEDIATE RELEASE

DATE: March 18, 2016

CONTACT: Jim Martin, 603 271-3710

des.nh.gov

twitter.com/NHDES

NHDES Receives Initial Drinking Water Well Tests for Perfluorooctanoic Acid (PFOA) in Southern New Hampshire

Concord NH - The New Hampshire Department of Environmental Services (NHDES) has received the drinking water well test results from an initial round of testing for Perfluorooctanoic Acid (PFOA) in Merrimack and Litchfield, New Hampshire. The test results show levels of PFOA from 17 to 820 parts per trillion. Test results from the Merrimack Village Water District ranged from 17 to 90 parts per trillion.

The United States Environmental Protection Agency (EPA) has not set an enforceable drinking water standard for PFOA under the federal Safe Drinking Water Act. EPA's Office of Water has, however, established a Provisional Health Advisory (PHA) of 0.4 micrograms per liter (µg/L) or 400 parts per trillion for PFOA. That level is set based upon short-term contact and the EPA is currently developing guidance for long-term exposure levels, which EPA is expected to release in the near future. Since EPA has not yet established a Health Advisory for lifetime exposure to PFOA, NHDES, out of an abundance of caution, has decided to provide bottle drinking water to locations using a private well for drinking water for human consumption that contains over 100 parts per trillion of PFOA. NHDES will reassess this situation once EPA provides more definitive guidance.

The Merrimack Village Water District public water supply wells all tested below both the PHA of 400 parts per trillion and the level at which NHDES determined it would be appropriate to initially provide bottled water. Based on this first round of testing, NHDES has initiated additional testing of drinking water wells in both Merrimack and Litchfield.

PFOA, a perfluorochemcial (PFC), is part of a family of manmade chemicals that were used for decades as ingredients to make products that resist heat, oil, stains, grease, and water, such as non-stick cookware, weather resistant outdoor clothing and gear, and stain resistant carpeting. Many chemicals in this group, including PFOA, are commonly present in the environment and do not break down easily.

Studies have shown that nearly all people have some level of PFCs in their blood. Potential health effects from exposure to low levels of PFCs are not well understood. To date studies have not provided consistent answers as to whether PFCs can affect growth and development, hormone levels including thyroid hormone, liver enzyme levels, cholesterol levels, immune function or occurrence of certain types of cancer.

NHDES and the Division of Public Health Services, in coordination with the Towns of Merrimack and Litchfield, invite the public to Public Information Meetings to be held in the Towns of Merrimack and Litchfield to discuss the results of recent drinking water tests related to an investigation of the presence of PFOA in drinking water. Below is the meeting information:

Merrimack: **(NOTE: UPDATED LOCATION)**

Wednesday, March 23, 2016, 7:00 p.m.

James Mastricola Upper Elementary School all-purpose room

26 Baboosic Lake Road, Merrimack, NH 03054

Litchfield:

Thursday, March 24, 2016, 7:00 p.m.

Litchfield Middle School cafeteria

19 McElwain Drive, Litchfield, NH 03052

For background, the investigation into the potential presence of perfluorochemicals (PFCs) in drinking water in Merrimack, began several week ago when Saint-Gobain Performance Plastics notified NHDES that perfluorooctanoic acid (PFOA) was detected at low levels [0.03 micrograms per liter (µg/L)] in samples taken from four water faucets within their Merrimack facility, which is served by the Merrimack Village District Water System. PFOA has been detected in the Hoosick Falls, NY, water supply and in some private wells in North Bennington, VT, near other Saint-Gobain facilities. Because materials containing PFOA have been used at the plant in Merrimack and out of an abundance of caution, Saint-Gobain voluntarily tested the water at its Merrimack facility and intends to test the groundwater at its facility.

For more information, please visit the NHDES website at www.des.nh.gov or call Jim Martin, NHDES at (603)-271-3710.

# # #

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Flaherty, Colleen
Sent: Mon 3/14/2016 8:32:37 PM
Subject: Slides
PFOA-PFOS-OW HAs ADMIN BRIEF 031416 cf.ppt

Here's the latest draft of the slides. The RSC slide needs some work.

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Southerland, Elizabeth
Sent: Fri 3/11/2016 3:59:33 PM
Subject: Fwd: Region 2 News Clips (PFOA)

Sent from my iPhone

Begin forwarded message:

From: "Enck, Judith" <Enck.Judith@epa.gov>
Date: March 11, 2016 at 9:56:33 AM EST
To: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Subject: Region 2 News Clips (PFOA)

Hi Betsy Thank you for facilitating the meeting with nj dep yesterday. It was a good exchange of information. Below is today's package of news clips. The pfoa issue has been in the news every day for the past few months. Judith

Local governors write letter to EPA demanding a regulatory PFOA level

By Lindsay Nielsen

March 10, 2016, 6:06 pm

HOOSICK FALLS, NY (NEWS10) – There is an advisory level for PFOA. It's 400 PPT for the federal level except in an EPA region to where it was lowered to 100 PPT. There is still no regulatory level and officials want that to change.

"I think it's probably going to be probably more like six months," said Carolyn Weatherwax of Hoosick Falls.

Carolyn Weatherwax said she wasn't surprised to learn Thursday that it will be at the least two more weeks before testing is completed to determine if the temporary filtration system in Hoosick Falls is working to reduce the level of PFOA contamination in water.

She said she does not have trust in local or state officials after emails showed officials knew of contamination before people were told by the EPA not to drink the water.

"Why weren't you disclosing it? That's your public duty, "said Weatherwax.

The Rensselaer County Health Department said there's a reason. They said a lack of regulatory standard from state or the federal government made it extremely difficult to determine how to achieve safe water and how to advise people to reduce potential health effects.

In an email in October of 2014 that discussed Hoosick Falls PFOA results, an employee of the Rensselaer County Health Department said to an employee of the State Health Department quote "From talking with the mayor this may become a very public issue once they release these and since they are above the only guidance we have (even though it is not regulated) it may get messy".

"Oh it's going to get messy. It's going to get messy," said Weatherwax.

Thursday in a letter to the EPA from Governor Cuomo, Vermont Governor Shumlin, and New Hampshire Governor Hassan it reads quote:

"We urge the EPA, under your leadership, to expeditiously review the best available science on this contaminant, and provide uniform guidance to states that our health and environmental officials can use in assessing the safety of our drinking water".

"If you don't have the information you can't make an informed decision and that's not anybody else's right to take that away from you," said Weatherwax.

This is the letter from Governors Cuomo, Shumlin, and Hassan r to EPA Administrator Gina McCarthy:

"It is clear that PFOA contamination is not a state problem or a regional problem.It's a national problem that requires federal guidelines and a consistent, science-based approach".

Here is the EPA's response to the letter:

"The EPA has received and will review and respond to the letter appropriately".

3 Governors Ask EPA for Review After Chemical Found in Water

By THE ASSOCIATED PRESS

MARCH 10, 2016

CONCORD, N.H. — The governors of New Hampshire, New York and Vermont are urging the U.S. Environmental Protection Agency to review and issue new safe drinking water guidelines regarding an emerging contaminant that's shown up in water systems and in private wells.

They wrote to EPA Administrator Gina McCarthy on Thursday asking for a review of the best available science regarding PFOA. It's part of a family of chemicals used to make nonstick cookware and stain-resistant carpeting.

Last month, Honeywell International and Saint-Gobain Performance Plastics were sued in New York. Regulators identified them as potentially responsible for chemical contamination in Hoosick Falls' water.

Saint-Gobain last owned the now-closed ChemFab plant in southwestern Vermont. It's been providing bottled water to residents since PFOA was found in North Bennington. It also found PFOA in samples in Merrimack, New Hampshire.

Times Union

Governors ask EPA for 'uniform guidance' on PFOA

Cuomo joins leaders of New Hampshire, Vermont

By Casey Seiler

Published 10:38 pm, Thursday, March 10, 2016

Albany

Gov. Andrew Cuomo on Thursday joined his fellow state executives Peter Shumlin of Vermont and Maggie Hassan of New Hampshire in formally asking the Environmental Protection Agency to "conduct a review of the best available science regarding perfluorooctanoic acid (PFOA), in order to assess and ensure the safety of drinking water exposed to the contaminant."

"It is clear that PFOA contamination is not a state problem or a regional problem — it's a national problem that requires federal guidelines and a consistent, science-based approach," said the letter, addressed to EPA Administrator Gina McCarthy.

PFOA, used in the production of non-stick cookware, is the contaminant that has been at the center of the water crises in the Rensselaer County communities of Hoosick Falls and Petersburgh as well as North Bennington, Vt., and Merrimack, N.H. Exposure to PFOA has been linked to a number of human maladies, including several forms of cancer.

In Hoosick Falls, the EPA's regional office in January set 100 parts per trillion as the safe level for the sort of long-term exposure found in residential use. Nationally, EPA has set 400 ppt as the safe level for short-term exposure.

The governors complained the less stringent limit remains in effect for the rest of the nation. "We urge the EPA ... to expeditiously review the best available science on this contaminant, and provide uniform guidance to states that our health and environmental officials can use in assessing the safety of our drinking water," they wrote.

Facing criticism of the state's response to the situation in Hoosick Falls, Cuomo and other elected officials have pointed to the fact that PFOA remains unregulated on the federal level, though it is characterized by EPA as an "emerging contaminant." In January, Cuomo's administration declared PFOA to be a regulated substance, a move that allowed the state to designate contaminated areas as Superfund sites.

The governors' letter also asked for full federal funding of the federal Drinking Water State Revolving Fund and the Clean Water Revolving Fund, two pools of money designed to facilitate water infrastructure projects through low- or no-interest loans.

Last year, the EPA rebuffed the Cuomo administration's attempt to allocate more than $500 million from the Clean Water State Revolving Fund to finance elements of the construction of the Tappan Zee Bridge replacement, though a little more than $30 million from the fund was disbursed for a reduced set of bridge-related projects.

An EPA spokesman said the agency "has received and will review and respond to the letter appropriately."

Times Union

Cuomo, two other regional govs call on EPA to set PFOA safe levels

By Casey Seiler, Capitol bureau chief

March 10, 2016

Gov. Andrew Cuomo joined his fellow state executives Peter Shumlin of Vermont and Maggie Hassan of New Hampshire in formally asking the Environmental Protection Agency to “conduct a review of the best available science regarding perfluorooctanoic acid (PFOA), in order to assess and ensure the safety of drinking water exposed to the contaminant.”

PFOA, used in the production of non-stick cookware, is the contaminant that has been at the center of the water crises in the Rensselaer County communities of Hoosick Falls and Petersburgh as well North Bennington, Vt., and Merrimack, N.H.

The same letter asks for full federal funding of the Drinking Water State Revolving Fund and the Clean Water Revolving Fund. (Regular readers may recall that the EPA rebuffed the Cuomo administration’s attempts to allocate more than $500 million in low- and no-cost loans from the state’s tributary of that fund to finance the construction of the Tappan Zee Bridge replacement.)

The EPA in January set 100 parts per trillion as the safe level for the sort of long-term exposure found in residential use (drinking, bathing, cooking). It had previously set 400 ppt as the safe level for short-term exposure, while advising residents in the affected communities to use bottled water.

The EPA’s regional press office didn’t immediately respond to a request for comment.

The requests came in a letter to EPA Administrator Gina McCarthy:

Dear Administrator McCarthy,

We write as Governors whose states are all in the midst of addressing local drinking water contamination involving the federally unregulated chemical perfluorooctanoic acid (PFOA). We are deeply concerned for the health and well-being of our communities grappling with this contaminant. In New York and New Hampshire, tests have indicated the presence of this chemical in public drinking water systems, and in New York and Vermont the chemical has been detected in several private wells. It is clear that PFOA contamination is not a state problem or a regional problem – it's a national problem that requires federal guidelines and a consistent, science-based approach.

The EPA's PFOA health advisory was recently lowered in one village in New York by the EPA's Regional Office, though the higher advisory remains in the rest of the country. We urge the EPA, under your leadership, to expeditiously review the best available science on this contaminant, and provide uniform guidance to states that our health and environmental officials can use in assessing the safety of our drinking water. In addition, we seek your help and support for additional drinking water testing and analysis in communities exposed to PFOA.

We also are all strong supporters of full federal funding for water infrastructure. The Drinking Water State Revolving Fund is a critical tool for states to invest in modern and safe drinking water upgrades. Unfortunately, over the last six years funding for this program, and its companion Clean Water Revolving Fund, have been flat or declining. This comes even as the American Society of Civil Engineers points out massive gaps between our water infrastructure needs and our investment. We should invest more in both the Drinking Water State Revolving Fund and the Clean Water Revolving Fund, and we look forward to working with you to make that happen.

We respectfully request your personal attention to the challenges created by PFOA contamination in our states. Consistency, accuracy, and uniformity are paramount. We look forward to your response and assistance as we work to identify the polluters responsible for this contamination, and hold them accountable for their actions. It is unacceptable to us that any community should have to be concerned about the safety of their drinking water. Families in our states are worried about potentially tragic short and long-term health impacts, not to mention the potential loss in property values for homes in affected areas. It has been our priority to ensure that residents are being provided clean and safe water immediately, and that our infrastructure be modernized to eliminate these concerns in the future.

Thank you,

New Jersey News/AP

Military to check for water contamination at 664 sites

By JENNIFER McDERMOTT

Mar. 10, 2016 6:12 pm

PROVIDENCE, R.I. (AP)

The military plans to examine hundreds of sites nationwide to determine whether chemicals from foam used to fight fires have contaminated groundwater and spread to drinking water, the Defense Department said.

The checks are planned for 664 sites where the military has conducted fire or crash training, military officials told The Associated Press this week.

Since December, tests have been carried out at 28 naval sites in mostly coastal areas. Drinking water at a landing field in Virginia and the groundwater at another site in New Jersey have been found to contain levels above the guidance given by the federal Environmental Protection Agency, the Navy said. Results of the other tests have either come up under federally acceptable levels or are pending.

The Navy is giving bottled water to its personnel at the Naval Auxiliary Landing Field Fentress in Chesapeake, Virginia, and is testing wells in a nearby rural area after the discovery of perfluorinated chemicals in drinking water, which the federal Agency for Toxic Substances and Disease Registry says may be associated with prostate, kidney and testicular cancer, along with other health issues.

The Navy found perfluorinated chemicals in the groundwater monitoring wells at Naval Weapons Station Earle in Colts Neck, New Jersey, but not in the drinking water supply. Test results from off-base drinking water wells are expected this month.

And several congressmen are raising concerns about the safety of drinking water near two former Navy bases in suburban Philadelphia. The lawmakers say firefighting foams might be the source of chemicals found in nearly 100 public and private wells near the Naval Air Station Joint Reserve Base Willow Grove and the Naval Air Warfare Center in Warminster.

The foam is used where potentially catastrophic fuel fires can occur, such as in a plane crash, because it can rapidly extinguish them. It contains perfluorooctane sulfonate and perfluorooctanoic acid, or PFOS and PFOA, both considered emerging contaminants by the U.S. Environmental Protection Agency.

The Defense Department said that until foam without perfluorinated chemicals can be certified for military use, it is removing stocks of it in some places and also trying to prevent any uncontrolled releases during training exercises.

The military is beginning to assess the risk to groundwater at the training sites not only to determine the extent of contamination, but also to identify any action the Defense Department needs to take, said Lt. Col. Eric D. Badger, a department spokesman.

California has the most sites, with 85, followed by Texas, with 57, Florida, with 38, and

Alaska and South Carolina, each with 26, according to a list provided to the AP. Each state has at least one site.

Knowledge about the chemicals' effects has been evolving, and the EPA does not regulate them. The agency in 2009 issued guidance on the level at which they are considered harmful to health, but it was only an advisory — not a standard that could be legally enforced.

The EPA said then that it was assessing the potential risk from short-term exposure through drinking water. It later began studying the health effects from a lifetime of exposure. Those studies remain in progress.

The Navy started handing out bottled water in January to about 50 people at the contaminated Virginia site, and it worked with the city to set up a water station for concerned property owners after it found perfluorinated chemicals in on-base drinking water wells above the concentrations in the EPA advisory.

The Navy is testing private wells of nearby property owners; those results are due next week.

Chris Evans, of the Virginia Department of Environmental Quality, credited the Navy with being proactive but said he's concerned anytime there's a potential threat to human health and the environment.

Some states have established their own drinking water and groundwater guidelines for the maximum allowable concentrations of the chemicals; Virginia uses the EPA's.

"We'll follow EPA's lead as this develops," Evans said.

There's a lot of evolving science around perfluorinated chemicals, said Lawrence Hajna, a spokesman for the New Jersey Department of Environmental Protection.

"The more that we hear, the more that we realize that this is a very important health concern," he said.

The former Naval Air Station Joint Reserve Base Willow Grove and present day Horsham Air Guard Station is shown Thursday, March 10, 2016, in Horsham, Pa. The military is checking whether chemicals from firefighting foam might have contaminated groundwater at hundreds of sites nationwide and potentially tainted drinking water, the Defense Department said. (AP Photo/Matt Rourke)

The Associated Press

In this Feb. 2, 2016 photo, area residents gather around an aerial photograph of Fentress Naval Auxiliary Landing Field during a meeting at a school, in Chesapeake, Va. The military is beginning to check whether chemicals from its firefighting foam may have contaminated groundwater at hundreds of sites nationwide, according to the Defense Department. The Navy started handing out bottled water in January to people who work at Fentress. (Steve Earley/The Virginian-Pilot via AP) MAGS OUT; MANDATORY CREDIT

The Associated Press

The front of the former Naval Air Station Joint Reserve Base Willow Grove and present day Horsham Air Guard Station is photographed, Thursday, March 10, 2016, in Horsham, Pa. The military is checking whether chemicals from firefighting foam might have contaminated groundwater at hundreds of sites nationwide and potentially tainted drinking water, the Defense Department said. (AP Photo/Matt Rourke)

The Associated Press

WNYT

Filters causing frustrations for people in Town of Hoosick

Anna Meiler

Created: 03/10/2016 11:59 PM

HOOSICK FALLS – The Department of Environmental Conservation installed a filtration system at Amy Breese's house to reduce the level of PFOA in her water. Dealing with a toxic chemical in her private well has been troubling enough, but she says the problems keep on coming- like black specks in her water.

“You notice it when you flush the toilet or if you unscrew the faucet you can see a bit of the carbon particles,” said Breese.

DEC workers came to her house to check out the problem on Wednesday, but told her there's nothing wrong with how her filtration system is set up. They left without making any changes.

“If it's running through the system and it's going to clog the washing machine or the dishwasher that's potentially another expense,” she said.

Breese is also worried because the DEC accidentally installed valves at several homes with warning labels attached that say they're illegal to use in the United States for drinking water and contain a chemical known to cause cancer. Amy's valves didn't have a label, but she says DEC workers don't know if they're safe.

“They couldn't give me a definitive answer on whether my valves are okay or not,” she said. “He said we’re replacing all the valves. When they come on Saturday they’re replacing all the valves just in case.”

But a spokesperson for the DEC tells NewsChannel 13 that's not true and says they're only replacing the faulty valves.

“We are getting mixed messages,” she said.

Breese says the bottom line is people with private wells don't want filters at all. They want a completely new source of water- just like the governor has promised people in the village of Hoosick Falls.

“I think it's imperative for everyone to have clean, healthy water,” said Breese.

Breese also says she finds it discouraging that Governor Cuomo hasn't visited the town or village yet.

Governor Cuomo's office tells NewsChannel 13 he will be going soon.

Water contamination stresses taking toll on residents; church program steps up to help

By WRGB Staff Thursday, March 10th 2016

HOOSICK FALLS - A local church group is stepping forward to help those dealing with the water crisis in Hoosick Falls.

It has been months now since the people who live in the Rensselaer County village were told not to drink the water. A chemical called PFOA, which is linked to cancer and other health issues, was found in dangerous levels in the village water supply.

Since that time, living in Hoosick Falls with no drinkable running water has become hectic, especially for the Allen family.

"We don't bathe as often. Not even close to what we use to do," Heather Allen said.

Allen heats up bottled water to wash little faces and for brushing teeth she created a contraption using a cooler with a spigot and a bowl to make sure her four young kids remember not to use the tap. Usually it is she and her husband who forget.

"You'll hear us brushing our teeth and, 'Ah! Did you do it again?' 'I did it again.'"

Allen laughs now but she admits the contamination has taken away precious time and added stress to every single day.

"At first it was devastating but I try to remember there are people all over the world that have water that makes them sick and they don't have a choice," Allen said.

The constant mental and emotional strains in Hoosick Falls are something church goers are silently praying about but Bob Woodward and Sandy Dooley, who both are ministry leaders of a faith-based support group, wanted to make sure people could be heard by their neighbors, if they want to.

"That's why we wanted to let people know, not everybody knows, we're here," Dooley

said.

Every Thursday at 6:30 p.m. the faith-based 12-step program Celebrate Recovery meets at the Hoosick Falls Community Alliance Church and its members listen.

"Alcohol, co-dependency, low self esteem, addictions," Woodward said.

The two ministry leaders say the stresses from the water crisis is the newest issue they are here to help with. They say Celebrate Recovery is there to support anyone who wants to come and talk or just observe.

"We will get through this. We're a strong community. We're strong people so we can get through this, it's just going to be one step at a time," Dooley said.

The weekly meetings are held in the church sanctuary and are completely anonymous, so people can come confidentially and speak freely about anything.

Vermont NPR

State Will Look For PFOA Contamination Beyond North Bennington

By HOWARD WEISS-TISMAN • 15 HOURS AGO

Brian Phillips does a water test in North Bennington. The state says it will test water around the state near suspected sites that used PFOA in manufacturing.

Howard Weiss-Tisman / VPR

The state is conducting water tests on private wells in North Bennington following the discovery of the suspected carcinogen PFOA in five private wells. Now Vermont officials are setting their sights beyond North Bennington to see if the contaminant shows up in other water sources.

The chemical was used for decades before it was phased out, and it was potentially used all over the state.

Audio for this story will be posted by approximately 11 a.m. on Friday, March 11.

Alyssa Schuren, commissioner of the Department of Environmental Conservation, says her department has been receiving calls from people who say there are other sites around the state that should be tested.

"We are right now making a plan for testing outside of North Bennington," she says.

The Warren Wire Company in Pownal manufactured teflon coated wire, and the factory is just one of the sites Vermont health and environmental officials are eyeing as they begin to investigate PFOA contamination around the state.

Schuren and her team have been pretty busy in North Bennington, tracking down every private well within a mile and a half of the former Chemfab factory, which is the suspected source of the dangerous chemical.

"You make these great things ... your stain-resistant carpets, your fancy waterproof gear ... But all of those things have to be made. This chemical is used in thousands of things." - Janet Foley, Bennington College professor

But there's a new challenge emerging, as state officials try to discover other sources of potential PFOA contamination.

"We are taking a few people and looking into other industries that may have created similar type products," Schuren says. "We're going to track down every lead ... We're going to work proactively to pull together a list of other industries where we might find these chemicals. And then we're going to do some sampling in those areas as well."

PFOA was extremely useful; it allowed companies to apply a variety of different chemicals to surfaces. It was used in firefighting foam, and to put teflon on cooking utensils, waterproof materials on Gore-Tex and flame retardants on to carpet and clothing.

DEC Commissioner Alyssa Schuren speaks at a meeting in North Bennington. Schuren says the department is already looking at other potential sources of PFOA across the state.

Credit Howard Weiss-Tisman / VPR

At Chemfab in North Bennington, it was used to apply protective coatings onto fabric.

Janet Foley is a chemistry professor at Bennington College, and she says PFOA was widely used because after the application process was complete, the PFOA simply went up smokestacks or was washed down sinks.

And she says the wide ranging applications of PFOA mean it will likely turn up across Vermont and the rest of the country.

"You make these great things. You know, you make your stain-resistant carpets, your fancy waterproof gear, and everyone loves that," Foley says. "But all of those things have to be made. This chemical is used in thousands of things."

When scientists discovered that PFOA might be a carcinogen, the EPA tested public water supplies around the country.

"We need to know how to focus our resources on where we suspect problems might be. We need to figure out where PFOA was, and begin to ask lots of questions around those sites." - David Bond, Center for the Advancement of Public Action

Between 2013 and 2015, public water supplies were tested in Bennington, Barre City, Brattleboro, Burlington, Jay Peak Basin Complex, Lyndonville, Rutland City,

Shaftsbury, South Burlington and Winhall Stratton Fire District 1. PFOA wasn't detected in any of the systems.

David Bond, the associate director of the Center for the Advancement of Public Action at Bennington College, says the situation in North Bennington highlights just how challenging it will be to conduct statewide water safety tests.

"It's an impossible task," says Bond. "We need smarter maps. We need to know how to focus our resources on where we suspect problems might be, and a better sort of regime of tests and questions for those sites in a focused way. We haven't done that up to this point. This is one of those things we're beginning to learn, is that, figure out where PFOA was, and begin to ask lots of questions around those sites."

Small manufacturers come and go, and they can leave behind a toxic legacy.

The chemical remains hidden in the soil and water. And as soon as the situation stabilizes in North Bennington, the state says it's going to start looking for it.

# # #

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Fri 3/4/2016 6:12:17 PM
Subject: Take a look at these Qs and As
QA PFOA PFOS Master List 3 4 16 .docx

Hey Jamie, can you please take a look at these. We have added some more since last you looked

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | harper.ashley@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]; Harper, Ashley[harper.ashley@epa.gov]
From: Lalley, Cara
Sent: Wed 2/24/2016 7:24:58 PM
Subject: FW: FOR SPEEDY REVIEW: PFOA QA
PFOA only- INTERNAL Q&A_OST.docx

Betsy,

OPA is leading development of a PFOA-only set of Q&A for the Administrator. Multiple AAships have weighed in. I have reviewed and inserted Track Changes edits to the "general statement on PFOA" at the beginning of the attachment to correct changes made by non-OW folks who didn't understand what we did in 2014.

Please review my Track Changes and feel free to make other corrections in the document if needed—but this is quick turnaround. Not sure of exact deadline, but sometime today.

Thanks

From: Schollhamer, Mary
Sent: Wednesday, February 24, 2016 1:36 PM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: FOR SPEEDY REVIEW: PFOA QA

Here's the consolidated PFOA doc. Issues with the attached are best known sooner rather than later. Thanks!

Mary G Schollhamer

Acting Deputy Director of Communications

Office of Water

U.S. Environmental Protection Agency

Office: 202-564-5759

Mobile: 202-853-5317

schollhamer.mary@epa.gov

Begin forwarded message:

From: "Perry, Dale" <Perry.Dale@epa.gov>
Date: February 24, 2016 at 1:22:56 PM EST
To: "Loop, Travis" <Loop.Travis@epa.gov>, "Flattery, Priscilla" <Flattery.Priscilla@epa.gov>
Cc: "Purchia, Liz" <Purchia.Liz@epa.gov>, "Harrison, Melissa" <Harrison.Melissa@epa.gov>, "Schollhamer, Mary" <Schollhamer.Mary@epa.gov>, "Strauss, Linda" <Strauss.Linda@epa.gov>, "Mears, Mary" <Mears.Mary@epa.gov>, "Hull, George" <Hull.George@epa.gov>
Subject: Re: Use This Version: Revised PFOA QA

Thanks all. Please use this version that now include OCSPP's newest addition.

Dale H. Perry, Ph.D.

Science Advisor, Office of Public Affairs

1200 Pennsylvania Ave. NW, Mail Code 1703A

Washington, DC 20460

Desk: 202.564.7338

Cell: 202.380.6517

From: Loop, Travis
Sent: Wednesday, February 24, 2016 1:21 PM
To: Flattery, Priscilla
Cc: Purchia, Liz; Perry, Dale; Harrison, Melissa; Schollhamer, Mary; Strauss, Linda; Mears, Mary; Hull, George
Subject: Re: Use This Version: Revised PFOA QA

We will run this back through our folks

Travis Loop

Communications Director for Water

U.S. Environmental Protection Agency

Phone: 202.870.6922

Follow us on Twitter @EPAwater

On Feb 24, 2016, at 1:17 PM, Flattery, Priscilla <Flattery.Priscilla@epa.gov> wrote:

Deliberative Process / Ex. 5

Priscilla Flattery

Chief of Staff, OPPT

202-564-2718

From: Purchia, Liz
Sent: Wednesday, February 24, 2016 1:05 PM
To: Perry, Dale <Perry.Dale@epa.gov>; Harrison, Melissa <Harrison.Melissa@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>; Schollhamer, Mary <Schollhamer.Mary@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Mears, Mary <Mears.Mary@epa.gov>; Hull, George <Hull.George@epa.gov>
Subject: RE: Use This Version: Revised PFOA QA

Thanks Dale.

We need OW and OCSPP input in here next. There are some outstanding comments and questions.

From: Perry, Dale
Sent: Wednesday, February 24, 2016 12:12 PM

To: Purchia, Liz <Purchia.Liz@epa.gov>; Harrison, Melissa <Harrison.Melissa@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>; Schollhamer, Mary <Schollhamer.Mary@epa.gov>; Strauss, Linda <Strauss.Linda@epa.gov>; Flattery, Priscilla <Flattery.Priscilla@epa.gov>; Mears, Mary <Mears.Mary@epa.gov>; Hull, George <Hull.George@epa.gov>
Subject: Use This Version: Revised PFOA QA

Hi Liz,

I am attaching the most recent version of the tough PFOA QA that includes R2 and OW comments. I didn't do redline because it was nearly impossible to follow but there are still some actions that OW and OCSPP need to take on this version (which are included as comments).

I am sending to you and the whole group to ensure that everyone has one version that they are working from in an attempt at some version control.

OW/R2/OCSPP - if you have additional edits please only make them on this version.

Thanks,

Dale

Dale H. Perry, Ph.D.

Science Advisor, Office of Public Affairs

1200 Pennsylvania Ave. NW, Mail Code 1703A

Washington, DC 20460

Desk: 202.564.7338

Cell: 202.380.6517

<INTERNAL ONLY QA on All PFOA (00000002).pf.docx>

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Tue 2/23/2016 5:07:30 PM
Subject: Please Review these QA's for PFOA PFOS
QA PFOA PFOS Sent to Jamie for revision 2.23.16 .docx

Q's 13-16 are being looked at by outside office's. Please let me know in the comments section what other offices you think need to look at individual sections.

(If you could send me back who else should look at individual Questions and responses BEFORE you review that would be super helpful for the comms meeting with Travis Thursday—and it gives you some time for your responses.)

Thanks!

Don't stress too much!

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Southerland, Elizabeth
Sent: Tue 2/23/2016 12:27:32 PM
Subject: Fwd: For your review: Inside EPA Media Inquiry on PFOA in NYS

Sent from my iPhone

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: February 22, 2016 at 6:49:05 PM EST
To: "Schollhamer, Mary" <Schollhamer.Mary@epa.gov>, "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Burke, Thomas" <Burke.Thomas@epa.gov>, "Purchia, Liz" <Purchia.Liz@epa.gov>
Cc: "Loop, Travis" <Loop.Travis@epa.gov>
Subject: RE: For your review: Inside EPA Media Inquiry on PFOA in NYS

Deliberative Process / Ex. 5

Joel

From: Schollhamer, Mary
Sent: Monday, February 22, 2016 4:15 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: For your review: Inside EPA Media Inquiry on PFOA in NYS

Hi Joel,

Below, for your review, you will find an inquiry from Inside EPA and draft responses. The responses have been cleared with OECA and Region 3.

Please let me know if there's anything I can do to facilitate your review.

Thank you

Question: Are all of EPA's regional offices investigating or giving notice to communities where drinking water is being reported to have PFOA levels at 0.1 parts per billion or higher, given EPA's Jan. 28 decision at Hoosick Falls to apply 0.1 ppb, rather than 0.4 ppb as a health advisory?

Deliberative Process / Ex. 5

Question: Will EPA be recommending bottled water or alternate water sources in those identified places as well (where 0.1 ppb PFOA or higher has been discovered)?

Deliberative Process / Ex. 5

Question: Is EPA replying to a Feb.16 letter from attorney Rob Bilott (who previously led a lawsuit over PFOA contamination at a DuPont, WV facility) asking about this?

Deliberative Process / Ex. 5

Mary Schollhamer

Acting Deputy Director of Communications

Office of Water

U.S. Environmental Protection Agency

Office: 202-564-5759

Mobile: 202-853-5317

schollhamer.mary@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Southerland, Elizabeth
Sent: Tue 2/16/2016 3:03:44 PM
Subject: Fw: inside EPA article on PFCs

From: Beauvais, Joel
Sent: Tuesday, February 16, 2016 10:00 AM
To: Grevatt, Peter; Southerland, Elizabeth; Fritz, Matthew; Purchia, Liz; Distefano, Nichole
Subject: FW: inside EPA article on PFCs

FYI

From: Stanislaus, Mathy
Sent: Tuesday, February 16, 2016 9:56 AM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Jones, Jim <Jones.Jim@epa.gov>
Subject: Fwd: inside EPA article on PFCs

Not sure whether you saw this.

Mathy Stanislaus

USEPA Assistant Administrator

Office of Land and Emergency Management

Follow us on Twitter @EPALand

Begin forwarded message:

From: "Woolford, James" <Woolford.James@epa.gov>
Date: February 16, 2016 at 9:40:41 AM EST
To: "Stanislaus, Mathy" <Stanislaus.Mathy@epa.gov>, "Breen, Barry" <Breen.Barry@epa.gov>, "Bertrand, Charlotte" <Bertrand.Charlotte@epa.gov>, "Natarajan, Nitin" <Natarajan.Nitin@epa.gov>, "Fitz-James, Schatzi" <Fitz-James.Schatzi@epa.gov>, "Hostage, Barbara" <Hostage.Barbara@epa.gov>
Cc: "Richardson, RobinH" <Richardson.RobinH@epa.gov>, "Deitz, Randy" <Deitz.Randy@epa.gov>, "Wells, Suzanne" <Wells.Suzanne@epa.gov>, "Ammon, Doug" <Ammon.Doug@epa.gov>, "Brooks, Becky" <Brooks.Becky@epa.gov>, "Akinnusotu, Bunmi" <Akinnusotu.Bunmi@epa.gov>, "Hilosky, Nick" <Hilosky.Nick@epa.gov>, "Gervais, Gregory" <Gervais.Gregory@epa.gov>, "Cooke, Maryt" <Cooke.Maryt@epa.gov>
Subject: inside EPA article on PFCs

Daily News

EPA Region 2 Plans To Expand PFOA Focus, Apply Stricter Safety Level

February 12, 2016

Propelled by contamination from a persistent perfluorinated chemical (PFC) found in drinking water in a New York community, EPA Region 2 officials are at the beginning stages of an effort to identify other locations with similar drinking water contamination, and will likely apply a non-enforceable health safety level more stringent than the agency's existing short-term exposure advisory level of 400 parts per trillion (ppt), according to a regional official.

In an "exercise of caution," EPA Region 2 will use a limit of 100 ppt of perfluorooctanoic acid (PFOA) in drinking water as a "watch guide," in the Village of Hoosick Falls and Town of Hoosick, NY, "and presumably elsewhere," EPA Region 2 Emergency & Remedial Response Division Director Walter Mugdan told *Inside EPA* on the sidelines of a Feb. 4 American Law Institute Continuing Legal Education course titled Environmental Law 2016, in Washington, D.C.

EPA for now is applying the 100 ppt level as a "more prudent and cautious number than the 400 parts per trillion," he said, referring to health safety levels. He noted that EPA's 400 ppt health advisory is designed for short-term exposures such as that occurring over weeks or months, whereas the 100 ppt level is likely more appropriate to apply to long-term exposures.

Region 2 last month instructed residents of the Hoosick Falls community not to consume drinking water with PFOA levels above 100 ppt, saying in a Jan. 28 statement that it is not waiting for finalization of its health advisory for chronic exposure of PFOA in drinking water before applying the 100 ppt value.

The agency in a PFOA toxicity report that underwent external peer review in 2014 identified a toxicity value for the chemical that would result in a lifetime

health advisory of 100 ppt, an EPA spokeswoman said in late January. She stressed that EPA has not yet finalized the figure as its lifetime health advisory for the chemical but decided to "share the best available science to protect public health" in this case and is using the figure "out of an abundance of caution."

The agency is also under pressure from high-level New York state officials to set an enforceable drinking water standard for the chemical -- something EPA is currently not developing.

PFCs are a class of extremely persistent, toxic chemicals that have been widely used for various commercial and industrial applications due to their non-stick, water resistant qualities. The chemicals are emerging contaminants but currently not federally regulated, although EPA is in the midst of finalizing risk estimates for chronic drinking water exposures to PFOA and a related PFC -- values that will eventually allow regulators to craft long-term health advisory levels and cleanup requirements at sites with the contaminants.

Other Locations

Mugdan said that in addition to addressing concerns over PFOA contamination at Hoosick Falls, Region 2 is also beginning to explore whether other locations in the region may have PFOA drinking water contamination. He said the regional office is working with the states of New York and New Jersey to find out whether they have information about other locations, based on the agency's Unregulated Contaminant Monitoring Rule (UCMR) results, where PFOA has been found in drinking water. The region will also be working with those states to ask about locations of factories that used or made PFOA "where we should be having a look at the water."

He noted that regulators "are at the very beginning of that process."

While Mugdan could not speak for other EPA regional offices, he says he has "no doubt" all of the regions "are paying heightened concern to any kind of situation where municipal drinking water supplies or other drinking water supplies could be contaminated." Where the agency has some information about that, it needs to ensure that it quickly takes action in the best interests of public health, he said.

Under the third UCMR, EPA required public water systems to report from 2013 to 2015 on PFOA occurrences, among 29 other emerging contaminants, in drinking water above the minimum reporting level (MRL) of 0.02 micrograms/Liter, which in this case is equivalent to 0.02 parts per billion (ppb). A summary of data published last October by EPA on the UCMR found just 103 of a total of 4,764 public water systems tested with PFOA greater than the MRL and none of the systems were found to have levels above the reference concentration of 0.4 ppb, or 400 ppt.

Mugdan noted that smaller public water systems are not required to test for PFOA and other emerging contaminants under the UCMR, but said the agency nonetheless may investigate a location if a company in the area had used PFOA, for example by EPA itself conducting testing, or requesting the company or municipality to test for it.

Region 2's interest in focusing on PFOA in drinking water, even before any decision has been made on whether the agency will pursue an enforceable drinking water standard, known as a maximum contaminant level (MCL), comes as environmentalists are pressuring New Jersey regulators to act quickly to set drinking water standards in the state for PFCs, including PFOA. The environmentalists are also criticizing EPA's level for reporting PFOA under the UCMR in drinking water systems.

In a Jan. 20 letter to New Jersey Department of Environmental Protection (DEP) Commissioner Bob Martin, Delaware Riverkeeper Network calls for the state to take immediate action on PFCs by setting drinking water standards aimed at removing PFCs from drinking water, investigating contamination sources and engaging responsible parties in cleanup. The group contends state regulators appear to be dragging their feet on adopting safe drinking water and groundwater standards for PFOA and a related chemical.

New Studies

The group notes that, according to UCMR data, PFOA is more frequently found in New Jersey public water systems than nationally, but argues that EPA's "unreasonably high reporting level" means "this could just be the tip of the iceberg."

"Recent studies that set a safe level much lower (.001 ppb) than DEP's guidance level and EPA's reporting level elevates this issue even further," the group says, pointing to an August 2015 study by authors from the Harvard School of Public Health and University of Massachusetts at Lowell. "Not only does this recent Harvard report propose a much lower level as safe, it also highlights the inadequacy of EPA's reporting level of .02 ppb, which is far too high to accurately reflect the occurrence of PFCs in drinking water sources."

The Harvard report, which looked at health risks of PFCs, says, "Existing drinking water limits are based on less complete evidence tha[n] was available before 2008 and may be more than 100-fold too high."

A source with Delaware Riverkeeper Network says she believes that the study's 0.001 ppb level "is an important conclusion that should be part of the equation in setting a safe drinking water standard."

EPA is also under pressure from New York state officials to more widely and thoroughly address PFOA contamination, with New York Department of Environmental Conservation Acting Commissioner Basil Seggos and Department of Health Commissioner Howard Zucker appealing to EPA Administrator Gina McCarthy to aggressively address PFOA by lowering the 400 ppt provisional health advisory for the chemical in order to account for "the most current scientific evidence," and to expeditiously adopt an MCL for the chemical, among other actions.

Mugdan said the agency is expected to respond soon to the request.

Sen. Kirsten Gillibrand (D-NY) has also joined the calls for EPA to expedite its response to PFOA contamination, writing in a Feb. 1 letter to EPA Region 2 that she is "extremely concerned" about the water in Hoosick Falls.

"The residents of Hoosick Falls deserve to know that every available resource at both the state and federal levels is being used to fully investigate the source of the PFOA contamination, and that aggressive steps are being taken by the EPA to identify the responsible parties and ensure that full remediation will occur," the letter says. -- *Suzanne Yohannan* (syohannan@iwpnews.com)

Related News | Toxics | Waste | Water |

188830

Jim Woolford, Director

Office of Superfund Remediation and Technology Innovation

Office of Land and Emergency Management

US Environmental Protection Agency

1200 Penn. Ave., NW

Washington, DC 20460

(Mail Code 5201-P)

Phone: (703) 603 8960– Main Office Line

Physically located at:

Room 5622

One Potomac Yard (South)
2777 S. Crystal Dr.
Arlington, VA 22202

To: Strong, Jamie[Strong.Jamie@epa.gov]
Cc: Christ, Lisa[Christ.Lisa@epa.gov]; Wadlington, Christina[Wadlington.Christina@epa.gov]
From: Huff, Lisa
Sent: Fri 2/12/2016 10:58:39 PM
Subject: RE: Q&A for PFOS and PFOA for review
New additional QandA from Cara JBS021016 LH 2 12.docx
QandA PFOA PFOS 011916 LH 2 12 16.docx

Jamie,

I reviewed the Qs and As and made some comments in track changes. There are still some unanswered questions that it is noted should be directed to other offices e.g. OLEM.

Christina is working on risk communication materials for PFOA and PFOS too so I'm cc'g her to share info and make sure there isn't anything contradictory in these Qs and As from what she is developing (particularly Q10-13).

Lisa Foersom Huff

Associate Branch Chief

Targeting and Analysis Branch

Standards and Risk Management Division

Office of Groundwater and Drinking Water

U.S. EPA

EPA East Bldg. Rm. 2331 C

202-566-0787

From: Strong, Jamie
Sent: Wednesday, February 10, 2016 11:22 AM
To: Huff, Lisa <Huff.Lisa@epa.gov>
Subject: Q&A for PFOS and PFOA

Lisa,

Have you all had a chance to look at the Q&As Ashley Harper, HECD comms, sent to you? Our comms package is due to go up the chain next week I believe.

Thanks,

Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Southerland, Elizabeth
Sent: Wed 2/10/2016 10:53:54 PM
Subject: Fwd: Revised draft NY PFOA response letter
16-000-3344 NYDEC DOH PFOA clean 2 5 16_Clean JB.docx
ATT00001.htm
16-000-3344 NYDEC DOH PFOA_2 5 16_Tracked.docx
ATT00002.htm

Fyi

Sent from my iPhone

Begin forwarded message:

From: "Grevatt, Peter" <Grevatt.Peter@epa.gov>
Date: February 10, 2016 at 11:27:46 AM EST
To: "Woolford, James" <Woolford.James@epa.gov>, "Richardson, RobinH" <Richardson.RobinH@epa.gov>, "Cleland-Hamnett, Wendy" <Cleland-Hamnett.Wendy@epa.gov>, "Matthews, Joan" <Matthews.Joan@epa.gov>
Cc: "Powell-Dickson, Antoinette" <Powell-Dickson.Antoinette@epa.gov>, "Mccabe, Catherine" <McCabe.Catherine@epa.gov>, "Jones, Jim" <Jones.Jim@epa.gov>, "Beauvais, Joel" <Beauvais.Joel@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>
Subject: Revised draft NY PFOA response letter

Please see attached track-changes and clean versions of the PFOA letter which has been revised to address comments from Joel Beauvais. With the exception of a question for R2 and OLEM in a comment box on page 2, Joel's comments are restricted to the first 3 paragraphs of the letter. I will very much appreciate your quick review of the revised document and in the case of R2 and OLEM, any recommended changes you have to the document in response to Joel's question on page 2. As soon as we have this back from you we will move to the AO for Stan's signature. Thanks, P. Grevatt

To: Flaherty, Colleen[Flaherty.Colleen@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Wed 2/10/2016 5:26:42 PM
Subject: draft slides for PFC roadmap brief for the administrator
slides for PFC roadmap 2-15-16.ppt

Let me know what you think about these for the administrator briefing

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Tue 2/9/2016 1:16:21 AM
Subject: need help with hot issues agenda
Talking points for Betsy Southerland for WDD hot issues meeting on PFCs.docx
WDD Agenda Draft Jan 2 2016 short agenda pfc.docx
WDD Agenda Draft Jan 2 2016 short agenda for lead as example.docx

Can you have John take a crack at an agenda. Mary Jo wanted it this Wednesday. I told her that would be hard. Attached is what we did for pfoa and a second example from ogwdw for lead. If we could shoot for Thursday/Friday that would be good.

We can use the briefing we have been developing, maybe updated a bit. Let's try to get the package to Betsy to look at on Wednesday or Thursday.

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Flaherty, Colleen
Sent: Mon 2/8/2016 10:39:38 PM
Subject: slides
PFOA-PFOS-OW HAs 02 08 16.ppt

Caught a few typos. Latest draft attached. Note that the most sensitive group is lactating females, not pregnant females.

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]; Harper, Ashley[harper.ashley@epa.gov]
From: Conerly, Octavia
Sent: Thur 2/4/2016 5:58:19 PM
Subject: RE: Please Help Schedule an Administrator Briefing on HAs for PFOA and PFOS
APPENDIX F Briefing Memo PFOA PFOS 2 4 16.docx
Appendix D OW DW HEALTH ADVISORIES PFOA PFOS 02 04 16.docx

I also changed the date at the top of Appendix F to today's date. It had January 27th on it. See attached.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Behl, Betsy
Sent: Thursday, February 04, 2016 12:45 PM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>
Subject: FW: Please Help Schedule an Administrator Briefing on HAs for PFOA and PFOS

Please make sure Betsy reads them before we go forward. thx

From: Harper, Ashley
Sent: Thursday, February 04, 2016 12:25 PM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>

Cc: Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Subject: Please Help Schedule an Administrator Briefing on HAs for PFOA and PFOS

Octavia,

Please see the attached Appendix D and Appendix F for scheduling a briefing with the Administrator.

Jamie Strong is the POC

Thank you for your help,

Ashley

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]
Cc: Flaherty, Colleen[Flaherty.Colleen@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Thur 2/4/2016 4:45:00 PM
Subject: Please Approve memos for Administrator briefing on PFOA PFOS
APPENDIX F Briefing Memo PFOA PFOS 2 4 16.docx
OW DW HEALTH ADVISORIES PFOA PFOS- Request for Administrator Briefing 02 04 16.docx

Betsy,

Please approve the attached memos for the, so that I can submit the request to Octavia today.

Thank you,

Ashley

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Wed 2/3/2016 4:01:10 PM
Subject: RE: briefing with admin on PFOA PFOS
APPENDIX F Briefing Memo PFOA PFOS 1272016.docx

No, because you haven't had the chance to review the memo. I have re-attached the memo for you.

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

From: Strong, Jamie
Sent: Wednesday, February 03, 2016 9:18 AM
To: Harper, Ashley <harper.ashley@epa.gov>
Subject: briefing with admin on PFOA PFOS

Ashley,
Did we submit this yet?

Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Flaherty, Colleen
Sent: Tue 2/2/2016 8:57:02 PM
Subject: slides
PFOA-PFOS-OW HAs 02 01 2016JMD.ppt

To: Lalley, Cara[Lalley.Cara@epa.gov]; Loop, Travis[Loop.Travis@epa.gov]; Harper, Ashley[harper.ashley@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Mon 2/1/2016 10:12:39 PM
Subject: FW: STATEMENT PFOA Status 1 29 16.docx
STATEMENT PFOA Status 1 29 16.docx

Any chance we can get in on the distribution list for communications related to PFCs? I got this from Region 2.

From: Matthews, Joan
Sent: Monday, February 01, 2016 4:53 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Subject: STATEMENT PFOA Status 1 29 16.docx

Betsy,

Mary Jo Bragan just sent this.

Joan

To: Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Flaherty, Colleen
Sent: Fri 1/29/2016 10:15:39 PM
Subject: AA briefing - PFOA/PFOS
PFOA-PFOS-OW HAs 1.27.16.ppt

Here's the latest in case something happens to me this weekend!

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Fri 1/29/2016 9:57:23 PM
Subject: FW: PFOA HESD for final internal agency review
PFOA Post External Review 010816_lgtg.docx

Good news!

From: Gaines, Linda
Sent: Friday, January 29, 2016 4:48 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Scozzafava, MichaelE <Scozzafava.MichaelE@epa.gov>
Subject: FW: PFOA HESD for final internal agency review
Importance: High

Betsy,

Thank you for me allowing to review this. As with PFOS, this was a really good, comprehensive document. I have a few edits and comments. All of them are editorial. Please let me know if you have any questions.

Linda

Linda G.T. Gaines, Ph.D., P.E.
Environmental Health Scientist
U.S. Environmental Protection Agency
OLEM/OSRTI/ARD/Science Policy Branch
Gaines.Linda@epa.gov
Phone: (703) 603-7189

From: Scozzafava, MichaelE
Sent: Friday, January 08, 2016 11:56 AM
To: Gaines, Linda <Gaines.Linda@epa.gov>; Burgess, Michele <Burgess.Michele@epa.gov>; Kirk, Andrea <Kirk.Andrea@epa.gov>
Subject: FW: PFOA HESD for final internal agency review
Importance: High

Hi Guys,

We need to review this. I'll send PFOS shortly. These are the tox assessments, not the Health Advisory docs

It looks like Betsy meant to send to me (she left me a VM) in December, but sent it to "mfocazio" instead. LOL.

Let's touch base on Monday to discuss who can review.

Mike

From: Behl, Betsy
Sent: Friday, January 08, 2016 11:52 AM
To: Scozzafava, MichaelE <Scozzafava.MichaelE@epa.gov>
Subject: PFOA HESD for final internal agency review
Importance: High

Mike, as per my voicemail, this is the PFOA HESD for review by 1/29.

From: Behl, Betsy
Sent: Friday, January 08, 2016 10:46 AM
To: Cantilli, Robert <cantilli.robert@epa.gov>; Fegley, Robert <Fegley.Robert@epa.gov>; Foos, Brenda <Foos.Brenda@epa.gov>; Cooke, Maryt <Cooke.Maryt@epa.gov>; 'Focazio, Michael' <mfocazio@usgs.gov>; Henry, Tala <Henry.Tala@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: PFOA HESD for final internal agency review
Importance: High

Many thanks to you all for your review of our PFOS document. We are expecting comments by Monday January 11, so that we can keep to our schedule to publish final HAs. As you can imagine, the recent report of PFCs in drinking water in Hoosick Falls, NY and articles in the press have heightened interest in EPA finalizing these HAs as well as our timetable.

Attached above is the final draft PFOA Health Effects Support Document (HESD) for your review. This is the second and last HESD for PFCs which we requesting you to review. Like the PFOS document, this document has been spell checked but has not been through a final technical edit. We plan to address your comments and have then have a final technical edit done prior to the issuance of the Health Advisories (HAs). We are also attaching the external peer review comments, for your information.

This HESD provides the key science support for the point of departure for PFOA that will be used in the HA calculation. OW would like to release the HAs in March, which is coming up fast. This is our plan for internal review of all the PFC documents:

- PFOS HESD: begins internal review 12/17/2015. **Comments due 1/11/2016**

- PFOA HESD: begins internal review 1/8/2016. Comments due 1/29/2016 (3 weeks) (current document)

- PFOA and PFOS HAs: begin internal review late January/early February. Comments due 2 weeks later.

Many thanks in advance for your comments, Betsy

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0788

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Fri 1/29/2016 8:17:03 PM
Subject: FW: New Clips (Hoosick Falls)

fyi

From: Beauvais, Joel
Sent: Friday, January 29, 2016 3:08 PM
To: Loop, Travis <Loop.Travis@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Subject: FW: New Clips (Hoosick Falls)

From: Enck, Judith
Sent: Friday, January 29, 2016 3:04 PM
To: Beauvais, Joel <Beauvais.Joel@epa.gov>; Burke, Thomas <Burke.Thomas@epa.gov>; Grantham, Nancy <Grantham.Nancy@epa.gov>; Purchia, Liz <Purchia.Liz@epa.gov>
Subject: New Clips (Hoosick Falls)

Subject: New Clips (Hoosick Falls)

New York Times Online: **EPA: New York Village Should Test Water for Teflon Chemical**

By THE ASSOCIATED PRESS

JAN. 28, 2016, 5:01 P.M. E.S.T.

HOOSICK FALLS, N.Y. — The U.S. Environmental Protection Agency is telling people in an upstate New York village to have their well water tested for a chemical used in making Teflon.

The agency on Thursday advised residents of Hoosick to have their wells tested for PFOA, which has been linked to cancer and other illnesses. It has been detected in municipal wells in Hoosick Falls, a village within the Rensselaer (rehn-suh-LEER') County town.

The agency says water with a level of PFOA higher than 100 parts per trillion shouldn't be used for drinking or cooking. That's a quarter of the EPA's current advised limit of 400 ppt.

An EPA administrator says the lower number reflects a new limit being developed by the agency.

Officials are investigating the extent of PFOA pollution in Hoosick Falls.

Hoosick Falls residents praise EPA intervention in water crisis

WRGB TV CBS NEWS 6

By Hubert Wiggins

January 28th 2016

HOOSICK FALLS -- Yvette McIntosh-Sauer purchased her dream home in Hoosick Falls last year. But now with the city's drinking water supply contaminated by a chemical linked to cancer that dream is now a nightmare. "We just bought property five months ago and there was no disclosure; if we had known we would have looked elsewhere because our health is important, and we feel trapped right now," Ms. McIntosh-Sauer said.

Late last year tests of samples taken from the town's water supply showed levels of the chemical Perfluooctanoic, also known as PFOA. On Wednesday the State Health Commissioner and the Acting Commissioner of the Department of Environmental Conservation announced a series of actions designed to remediate the water crisis. One step is the implementation of water filtration systems in schools and community gathering places. McIntosh-Sauer is hoping the town's water will be made safe because using bottled water for an indefinite period of time is not practical. "There is a temporary fix that should be coming in a few weeks they say, but we'll see," Ms. McIntosh-Sauer said. McIntosh-Sauer adds she is glad that the EPA is now involved. "If it weren't for the EPA we would be still be using the water," Ms. McIntosh-Sauer said.

Musician George Villarini has lived in Hoosick Falls for more than three decades. He now wonders if the health problems that have plagued him for years are related to the water. "I've had a liver transplant, I've had heart problems, I've had a valve replacement, and tumors," Mr. Villarini said.

Beginning in mid-February state health officials will begin blood testing for residents who would like to be tested. A hotline has been set up where people can call to get information related to the Hoosick Falls water crisis. The number is 1-800-801-8092.

WAMC

EPA Issues Statement On Private Wells In Town Of Hoosick

By LUCAS WILLARD • 16 HOURS AGO

The U.S. Environmental Protection Agency has issued a statement regarding those with private wells in the Town of Hoosick and Village of Hoosick Falls.

The statement released Thursday afternoon reads:

"The EPA is developing a lifetime health advisory level for PFOA. While this work continues, the EPA recommends that people in the Town of Hoosick and the Village of Hoosick Falls who have private wells at which PFOA has been found to be present at a level greater than 100 parts per trillion not use that water for drinking or cooking, and instead take advantage of the free bottled water that is being made available at the Tops Market in Hoosick Falls. In addition, the EPA recommends that people in the Town of Hoosick and the Village of Hoosick Falls who have private wells that have not yet been tested for the presence of PFOA ask the New York State Department of Health to test their well and, in the meantime, take advantage of the bottled water available at the Tops Market in Hoosick Falls."

Previously, those on the Village of Hoosick Falls water system have been asked to avoid cooking or drinking water from the public supply.

Also, environmental activist Erin Brockovich will meet with those affected by the contamination at a community meeting scheduled between noon and 2 p.m. in the Greenwall Auditorium at Bennington College in Bennington Vermont.

On Wednesday, the Saint-Gobain Performance Plastics site in Hoosick Falls was declared a New York State superfund.

TIMES UNION BLOG

EPA sets safe limit for PFOA in Hoosick Falls water supply

By Casey Seiler, Capitol bureau chief

January 28, 2016

(Note: This post has been updated to reflect the state Health Department's adoption of EPA's guidance.) The federal Environmental Protection Agency is advising that people in the Town of Hoosick and the Village of Hoosick Falls who have private wells where the substance PFOA has been found should not drink or cook with that water if the PFOA level is above 100 parts per trillion.

In a statement Thursday afternoon, EPA said residents whose water shows levels higher than 100 ppt should take advantage of the free bottled water that is being made available at Tops Market in Hoosick Falls.

A few hours later, a state Department of Health spokesman said the agency would use the EPA's guidance as it conducts its "risk analysis to determine an appropriate health guidance value."

In a Wednesday-afternoon news conference, DOH Commissioner Howard Zucker repeatedly said his agency would start with a 400 ppt safety measure, the EPA's maximum allowable level for short-term exposure, as it began its health assessment of the contamination in the Rensselaer County community.

"We're going to work from there and identify what point how far down we're going to go," Zucker said, adding that the work should be done within the next month.

The state agency changed its stance on the safety of residential Hoosick Falls water use in recent weeks, after EPA determined that residents with affected water supplies should curtail their usage.

On Wednesday, Gov. Andrew Cuomo's administration took action to designate the Saint-Gobain Performance Plastics plant, which has been identified as the most likely point of origin for the PFOA in the local water supply, as a Superfund site.

PFOA has been linked to several ailments in humans, including certain forms of cancer.

The EPA advised that residents in the town and village whose water has not yet been tested should contact the state Department of Health to have their wells tested. Until that testing takes place, the free bottled water should be used for drinking and cooking.

Looking down on Carey Ave. the Saint-Gobain Performance Plastics plant is seen in the background in Hoosick Falls. (Paul Buckowski / Times Union)

TIMES UNION

Feds: Don't drink water

EPA urges Hoosick Falls-area residents to get wells tested for toxic chemical

By Casey Seiler

Updated 7:41 am, Friday, January 29, 2016

The federal Environmental Protection Agency is advising Rensselaer County residents whose private water wells show a toxic substance in excess of 100 parts per trillion that they should not drink their water or cook with it.

In a statement Thursday afternoon issued in response to a Times Union query, the EPA said people in the Town of Hoosick and the Village of Hoosick Falls whose water shows levels of perfluorooctanoic acid higher than 100 ppt should take advantage of free bottled water that has been made available at Tops Market in Hoosick Falls.

A few hours later, a state Department of Health spokesman said the agency would use the EPA's guidance as it conducts its "risk analysis to determine an appropriate health guidance value."

PFOA is a man-made chemical used to make nonstick and other household and commercial products that are heat-resistant and repel grease and water.

Under an agreement reached with the EPA a decade ago, major PFOA makers have phased out its use. Exposure to PFOA has been linked to a range of adverse health effects, including cancer and thyroid disease.

Although the source of the contamination has not been identified, officials have focused on the Saint-Gobain Performance Plastics plant, which is located near several wells that supply Hoosick Falls' water treatment plant. The company is the community's largest employer.

On Wednesday, Gov. Andrew Cuomo's administration took action to designate the Saint-Gobain plant as a Superfund site, a status that allows the state to fast-track environmental remediation and legal actions.

POST STAR

Granville testing its water for PFOA

Saint-Gobain Performance Plastics

Steve Jacobs photos—sjacobs@poststar.com

A senior manager for the Saint-Gobain Performance Plastics plant in Granville, seen Thursday in the village, says the Granville facility has never used PFOA — perfluorooctanoic acid — in its manufacturing process. The village is having its water tested nonetheless, in hopes of assuring residents there is nothing to worry about after water in Hoosick Falls was found to be contaminated by PFOA used by the Saint-Gobain factory there.

2 hours ago • KATHLEEN MOORE kmoore@poststar.com

GRANVILLE There is good news for those who live near the Saint-Gobain Performance Plastics factory in the village.

Unlike Saint-Gobain's factory in Hoosick Falls, the Granville plant does not use the hazardous chemical — perfluorooctanoic acid — that contaminated the drinking water in Hoosick Falls.

At the Granville plant, about 130 people make specialty sealants, primarily for the automotive and construction markets.

"We have never used PFOA in the manufacturing processes in Granville," said Dina Silver Pokedoff, a senior manager for the company.

But the Granville plant was owned by two other companies before Saint Gobain, and there is no telling whether PFOA was used then.

"It's been here since 1962. It's changed owners three times," said village Public Works Superintendent Dan Williams. "You never really know. The new owner buys the old owner's problems."

Granville officials are getting the water tested, just to make sure.

"My mayor's told me, just get this test done so we can calm fears," Williams said.

It will take 20 days for a lab to test the water, plus time to ship samples out. He expects to get results in about 30 days.

The test will cost $550 to $600, and the sample must be sent out of state. His local water lab could find only two labs capable of testing for the uncommon chemical, Williams said.

The price is quite high for a water test, but he is willing to pay it. He is just hoping to get the right answer back.

"You hope it's a one-time thing," Williams said.

He thinks Granville's water supply is somewhat protected from groundwater contamination, in which a chemical leak or improper disposal leeches into the ground and eventually makes its way to the wellfield.

Granville's wells are relative shallow and mostly recharged by a river, not groundwater, Williams said.

But the wellfields are only about a quarter-mile away from the Saint Gobain plant.

In Hoosick Falls, the wellfields are also close to the Saint-Gobain plant, and PFOA was detected in the water in 2014. As of Wednesday, the plant had been classified as a Superfund site. Gov. Andrew Cuomo has classified PFOA as a hazardous substance, which gives the state the power to begin cleanup operations.

Residents of Hoosick Falls were told to stop drinking the town water. Saint-Gobain is providing bottled water and paying for water filters.

Manufacturers agreed to stop using PFOA by the end of 2015 because of its health risks. It was used to make non-stick cookware, stain-resistant carpeting, microwave popcorn bags and other items.

Politico

EPA recommends more-stringent rules in Hoosick Falls

By Scott Waldman

Jan. 28, 2016

ALBANY — The federal Environmental Protection Agency on Thursday recommended a more-stringent water quality standard in Hoosick Falls.

The EPA is now developing a lifetime health advisory for the toxic chemical perfluorooctanoic acid, or PFOA, which has been found in the village water supply. The EPA considers 400 parts per trillion a safe level, but is now recommending that residents whose water contains levels greater than 100 parts per trillion to "not use that water for drinking or cooking," according to an agency statement. EPA officials advised those residents to get free bottled water offered at a Tops market in Hoosick Falls.

The new federal figure is about a quarter of the baseline that state Department of Health Commissioner Howard Zucker said the state would use on Wednesday evening. Previously, state officials relied on the far higher rate of 50,000 parts per trillion even as other states recognized the danger of PFOA and used the federal benchmark.

After a hastily assembled meeting at Gov. Andrew Cuomo's office on Wednesday, state officials declared the source of possible pollution as a Superfund site in need of remediation.

For more than a year, state officials told village residents that the water was safe to use. However, after EPA officials publicly warned local residents to stop using their water late last year, state officials changed their recommendation.

For decades, the Saint-Gobain factory in Hoosick Falls produced Teflon-coated materials that the EPA says may have polluted the village water supply with PFOA, which is used in non-stick cookware, stain-resistant carpets and packaging. The EPA is investigating whether that chemical may have seeped into village wells when workers cleaned smokestack filters and other equipment at the factory, which Saint-Gobain has owned since 1999. Other factories in town may have also used the chemical, so its exact source has not yet been pinpointed.

U.S. Sen. Charles Schumer urged Saint-Gobain to cooperate with state and federal officials to clean the water until the cause has been discovered and mitigated. Schumer sent a letter to the company's president and CEO Tom Kinisky urging him not to follow the same strategy of alleged polluters in the past who elected "to stall for time, to litigate, to stonewall, to stall and to frustrate."

"These developments, and others, have cast a pall of uncertainty and fear over the Hoosick Falls community, with wide ranging impacts from health and emotional well-being to the local economy," he wrote in the letter. "The only way that this uncertainty and fear can be addressed is by speedily defining all potential sources of the contamination, the nature of the contamination, the threat the contamination poses to human health and how far it has spread."

Health Commissioner Howard Zucker held a press conference Wednesday evening. (Scott Waldman)

Editorial: Action in Hoosick Falls

TIMES UNION

January 28, 2016

THE ISSUE:

After moving too slowly, authorities are taking action in the Hoosick Falls water crisis.

THE STAKES:

They now must fulfill promises to fix the problem and address public health needs.

Maybe you could call it the Flint effect. Almost overnight, potentially dangerous levels of a cancer-causing chemical in a Rensselaer County village's water supply have started to receive the high-level attention they deserve.

On Wednesday, leaders of the village of Hoosick Falls, the town of Hoosick and the local school district were summoned to the state Capitol for a meeting with Gov. Andrew Cuomo and top state health and environmental officials.

Immediately afterward, the state announced the site of a Saint-Gobain Performance Plastics plant, believed to be the source of the pollution, will be declared a state Superfund site. The move clears the way for increased state resources to begin remediation and to explore what impact this has had on public health. The state also issued an emergency regulation formally classifying the chemical involved — perfluorooctanoic acid, PFOA — as a hazardous substance.

That's good news for the 3,500 Hoosick Falls residents, many of whom have been in a near panic in recent weeks after disclosures of the water problem and its possible connection to cancer and other illnesses. Just as troubling was that village officials first learned of the elevated levels of PFOA in 2014 but failed to communicate the potential health risks to citizens or address the problem. Now, authorities are, as they say, all over it — trying to make up for the reasonable perception that officials weren't moving urgently enough.

The latest response could be partly attributable to a very different situation that is making nationwide headlines. To save money, the financially stressed city of Flint, Mich., switched to an unsafe water source contaminated with lead and other pollutants. Evidence has surfaced that Michigan officials had been aware for some time of the threat to public health, and children in particular, yet failed to address it and publicly disagreed when health experts raised concerns. Now Michigan Gov. Rick Snyder is paying politically, with calls for his resignation, as his state rushes to implement costly remedies.

In New York, by contrast, it seems a necessary sense of urgency is taking hold. Health Commissioner Howard A. Zucker says the state will take blood samples from residents to assess the health risk, re-test private wells in the village and install filters at schools and other gathering places. U.S. Sen. Charles Schumer on Thursday pressed Saint-Cobain to be proactive. A well-known personal injury law firm has descended on the community, seemingly ready to litigate.

What happens next will be the real test. The public deserves a full picture of the problem, not potentially deceptive assurances like Commissioner Zucker's observation that "there hasn't been any health effects that we've noticed," or Mr. Cuomo's suggestion that people's concerns

have "nothing to do with reality." The reality is that they don't yet know what the reality is. The public looks to them to do all it takes to find out.

Photo illustration by Jeff Boyer / Times Union

EPA advises Hoosick residents to test private wells

ASSOCIATED PRESS

Updated 14 hrs ago

HOOSICK FALLS, N.Y. (AP) — The U.S. Environmental Protection Agency is telling people in an upstate New York town to have their well water tested for a chemical used in making Teflon and similar materials.

The agency on Thursday advised residents of Hoosick to have their wells tested for PFOA, which has been linked to cancer and other illnesses. It has been detected in municipal wells in Hoosick Falls, a village within the Rensselaer County town. The agency said water with a level of PFOA higher than 100 parts per trillion shouldn't be used for drinking or cooking. That's a quarter of the EPA's current advised limit of 400 ppt.

EPA Region 2 Administrator Judith Enck says the lower number reflects a new limit being developed by the agency. State and federal officials are investigating the extent of PFOA pollution in Hoosick Falls.

WAMC

Schumer Wants Transparency With Company Saint-Gobain

By LUCAS WILLARD • 18 HOURS AGO

New York U.S. Senator Charles Schumer is asking the Saint-Gobain company to cooperate with state and federal authorities as work begins to remove a chemical contaminant from the Hoosick Falls public water supply.

On Thursday, Senator Schumer wrote to Saint-Gobain Performance Plastics President and CEO Tom Kinisky to work “promptly, proactively and transparently” in addressing the perfluorooctanoic acid, or PFOA, contamination in the Rensselaer county community’s water system.

Saint-Gobain owns buildings in the community that are at the center of the water contamination question. The company is paying for temporary and permanent filtration systems for the village water supply and is providing village residents with bottled water.

On Wednesday, the New York State Department of Environmental Conservation declared the Saint-Gobain site in Hoosick Falls a Superfund.

ALBANY BUSINESS REVIEW

MORNING EDITION

Hoosick Falls water filtration still weeks away

Jan 29, 2016, 6:57am EST Updated Jan 29, 2016, 7:14am EST

Michael DeMasi ReporterAlbany Business Review

Two large tanks were delivered this week to the water treatment plant in Hoosick Falls,… more

DONNA ABBOTT-VLAHOS

A temporary water filtration system being installed in Hoosick Falls, New York is expected to be up and running in two to three weeks, but residents will have to wait longer before their tap water is considered safe to drink.

Two large tanks were delivered this week to the village's water treatment plant, part of a carbon filtration treatment that's expected to reduce the amount of perfluorooctanoic acid (PFOA) in the municipal water supply to safe drinking levels.

The village is leasing the system from Calgon Carbon of Pittsburgh at a cost of $300,000.

Saint-Gobain Performance Plastic Co., whose manufacturing plant in the Rensselaer County village is the suspected source of the contaminant in the water wells, is paying for the leasing, installation and maintenance of the system.

A Saint-Gobain spokeswoman, Dina Pokedoff, said the system is expected to go online in two to three weeks.

The New York State Health Department, which approved the temporary filter until a permanent one can be designed and installed, said the village has indicated the system will be connected in that time frame.

"At that point, treated water will be in the system," said Erin Silk, a spokeswoman for the health department. "This will be followed by a period of flushing all of the water lines to remove any residual PFOA in the system, and testing to make sure that the water is of acceptable quality. In the meantime, bottled water will be provided to residents until the system is up and running and the water is determined to be of acceptable quality."

The free bottled water is being distributed to residents and businesses at the Tops Market on Route 22 in Hoosick Falls. Saint-Gobain is paying for the water.

Saint-Gobain, headquartered in France with North American operations, makes a wide variety of building and construction materials and is one of the world's 100 largest corporations. U.S. and

Canadian sales totaled $6.2 billion in 2014.

A total of 186 people work at Saint-Gobain's two facilities in Hoosick Falls, including the MaCaffrey Street plant which is near the village's water wells. The McCaffrey Street plant makes high-performance tapes and films for the automotive, life sciences, electronics, architectural and aerospace industries.

The company doesn't manufacture the toxic substance found in the municipal water, but small amounts of PFOA were present in some of the raw materials that were supplied to the company, Pokeduff said. The company has been phasing out the use of PFOA in materials at Hoosick Falls and eliminated them entirely in December 2014 after tests found elevated levels in the municipal water supply.

As work on the temporary filter continues, Gov. Andrew Cuomo has declared the Saint-Gobain plant a Superfund site, enabling it investigate and clean-up the contamination and recover the costs from the responsible parties.

Separately, the U.S. Environmental Protection Agency, which has advised people to not drink or cook with the water, issued a new, more stringent guideline Thursday regarding the presence of perfluorooctanoic acid (PFOA) in water.

The EPA now recommends people in the town or village of Hoosick Falls who have private wells where PFOA is greater than 100 parts per trillion to not use it for drinking or cooking. The agency is also recommending those with private wells who haven't yet tested their water for the presence of the substance to contact the state Health Department to request a test.

PFOA is found in non-stick cookware, stain-resistant carpets and fabric, and other products.

Studies have associated exposure to PFOA with an increased risk for several health effects in the liver, immune system, thyroid gland, cholesterol levels, blood pressure during pregnancy, and kidney and testicular cancer

The EPA says it is "developing a liftetime health advisory level for PFOA."

Hoosick Falls Residents Relieved Action Taken to Investigate Chemicals in Water

TIME WARNER CABLE NEWS

By Katie Eastman

Hoosick Falls is a village that's seen better days, but Wednesday's Superfund site announcement is bringing hope to a place that's worried it's been drinking poisoned water for a while.

"We are a poor town," said the owner of Thorpe's Pharmacy, Jim Monahan.

The population has been declining since factories left and jobs slowly disappeared.

"And now there's nothing in the village," said a Penny, a woman who's lived there her whole life.

It's still a place where about 3,500 people live and work.

"You know everybody, you know," said Nancy Martelle.

Many of them get their paychecks from the largest employer in town, Saint Gobain Performance Plastics. The France-based company makes Teflon-coated materials. The only factory left in this town is also the reason the people in Hoosick Falls can't drink their water.

"I've been drinking the water my whole life, so who knows what's in my system?" said Michael Kaufmann.

The EPA says high levels of the cancer causing chemical Perfluorooctanoic, or PFOA, is in the public drinking water and some private wells. They believe it came from Saint Gobain's waste and the factories here before it.

Even after locals took it upon themselves to test the water in 2014 when they started seeing rare forms of cancer, it took a while before anyone in charge acknowledged there was a problem. Just last month, village officials and the state told residents to continue drinking the water.

"The village says it's OK, the state says it's OK, what do you think?" Monahan said of questions he started getting at his pharmacy. "And like I said, I wouldn't want to see a young child have baby formula mixed with it."

For the past few months, headlines have shown the frustration of a village that felt like no one was hearing it.

"The initial state response, I thought, was silly," said Monahan.

On December 2, a spokesman with the NYSDOH told Time Warner Cable News that "we don't expect any health effects in the community, but we don't like the PFOA being there." The state's tune changed on Wednesday with the announcement of the Superfund site, and Monahan says it's about time.

"We're looking for some good news now, and I think yesterday was a start," he said.

A temporary water filtration system for the municipal water will start working in three weeks. Saint Gobain has promised to pay for a permanent fix.

ALBANY BUSINESS REVIEW

Hoosick Falls water contamination crisis will be helped by Superfund designation, school superintendent says (Video)

Jan 28, 2016

Ken Facin started his day Wednesday morning frustrated and upset by the New York State Health Department's response to the chemical contamination found in the drinking water in the village of Hoosick Falls.

"Our local leaders have put forth their best efforts but this is really much bigger than a community issue," said Facin, superintendent of the Hoosick Falls Central School District in eastern Rensselaer County, near the Vermont border. "I do believe the Department of Health has been negligent in how they've handled this, and the lack of seriousness for this community."

Facin made his remarks during an interview with Albany Business Review. Hours later, he was unexpectedly called to a private meeting with Gov. Andrew Cuomo at the Capitol, where he and other officials learned the governor was taking the extraordinary step of declaring the Saint-Gobain Performance Plastics plant in Hoosick Falls a state Superfund site.

“We are taking immediate and aggressive actions to protect the health of Hoosick Falls residents,” Cuomo said afterward.

Besides the Superfund declaration, the Department of Environmental Conservation is classifying perfluorooctanoic acid (PFOA), the contaminant found in the village’s water supply, as a hazardous substance.

The actions allow the state to tap into its Superfund to investigate and clean up the contamination more quickly than waiting for a federal Superfund designation, Cuomo's office said. The state can also try to recover the cost from the responsible parties.

The Saint-Gobain plant is the suspected source of PFOA, which was detected in the village's water wells at levels exceeding those deemed safe by the U.S. Environmental Protection Agency.

Although the use of the chemical is being phased out, it is still used to make household and commercial products that resist heat, and repel oil, stains, grease, and water, such as nonstick cookware, stain-resistant carpets and fabric, and paper and cardboard food packaging, according to Cuomo's office.

Studies of people have associated exposure to PFOA with an increased risk for several health effects in the liver, immune system, thyroid gland, cholesterol levels, blood pressure during pregnancy, and kidney and testicular cancer.

The EPA recommends village residents don't drink the water or use it for cooking. Showering and bathing are acceptable, though children and people with skin conditions should avoid prolonged contact.

The discovery of the toxic chemical has disrupted lives and fanned fears in the small village, anxieties compounded by the conflicting and incomplete information about the water supply that had been released by village government, the state and EPA.

People are worried there's a correlation between the contaminant and family members and friends who have died from, or been diagnosed with, aggressive forms of cancer.

Homeowners and businesses have to make regular trips to the Top's Market store on Route 22

to pick up free bottled water as the crisis unfolds. A temporary carbon filtration system is now being installed at the municipal water treatment plant.

One longtime real estate agent says the phone has stopped ringing over the past several weeks for properties in the village, and two local banks have temporarily stopped writing new mortgages for homes.

Cuomo announced other steps that will be taken, including a health risk analysis by the state Health Department; blood testing for residents who request it; re-testing 24 private wells near the Saint-Gobain plant; installing water filtration systems at the school district, public health facilities and other community gathering places; and a hotline for residents to stay informed, 800-801-8092

Facin, the school superintendent, said the meeting with Cuomo was "productive and meaningful" and that the Superfund designation is a critical step.

The school's main campus on Route 22 isn't connected to the village's water system, and testing there has found no contamination. But, the chemical has been found in the water drawn from a well serving the school district's bus garage a mile away.

Facin and others want a permanent solution that would replace the village's water supply with another source, such as the Tomhannock Reservoir that serves the city of Troy.

Ken Facin, superintendent of Hoosick Falls Central School District, holds up test results/DONNA ABBOTT-VLAHOS

State declaring Hoosick Falls plastics plant a state Superfund site

By Kimberly Howard Thursday, January 28th 2016

WRGB TV CBS NEWS 6

HOOSICK FALLS-- The chemical perfluorooctanoic acid or PFOA, which is linked to cancer and other health conditions and has also been found in the municipal water supply in Hoosick Falls, may be more dangerous than previously thought.

The Environmental Protection Agency is urging people who have private wells where the levels of PFOA have been found to be greater than 100 parts per trillion to not use that water for drinking or cooking.

That level is four times lower than what the EPA previously said was safe to drink. 400 parts per trillion had been the standard since 2009.

Gary and Daraine Niegoda have lived in Hoosick Falls for decades but as the full extent of what has become a water crisis has been realized life has become complicated.

"I mean you gotta brush your teeth with, you know, bottled water. I mean it's like you're camping," Daraine Niegoda said.

The couple is happy that the Saint Gobain Performance Plastics plant was deemed a state superfund site on Wednesday and so will eventually be cleaned up with state resources and money but they still have concerns.

"I've had a few problems. I don't really want to discuss them but I've had a few problems. [Daraine's] got a few problems right now that I'm kind of worried about," Gary Niegoda said.

Meanwhile, even though the well water at the Hoosick Falls Central School District has tested negative for PFOAs Superintendent Ken Facine says he is not taking any chances.

"We're going to put a carbon filtration system on our well, continue to test each month for PFOAs," Facine said.

The state, Facine says, will pay for that now that the superfund designation has been made in Hoosick Falls.

Meanwhile, Dr. Marcus Martinez, who believes his own cancer diagnosis is linked to the water in Hoosick Falls, hopes state funds can also be used for something more long term.

"We've seen a lot. We've definitely seen a lot of cancer here. There's no doubt about it," Martinez said. "If [the superfund designation] allows a health study to move along faster to start studying this area to see, you know, what's been happening here for years and what's going to happen moving forward because people certainly have been exposed."

The village is still on track to have a temporary water filtration system up and running by the end of February and a permanent water filtration system in place by October.

NEWS 10 ABC

Hoosick Falls concerned about long-term effects of contaminated water

By Anya Tucker Published: January 27, 2016, 6:52 pm Updated: January 27, 2016, 9:41 pm

HOOSICK FALLS, N.Y. (NEWS10) – Folks in the village of Hoosick Falls remain concerned about what impact the contaminated water has had on their bodies over the years.

Two, large carbon filters were brought to the water department on Tuesday. The temporary filtration system was paid for by Saint-Gobain Performance Plastics. The company is being called the source of the PFOA contamination.

The filter is expected to filter 500,000 gallons of water per day. But the fears of contamination are still felt throughout the village, and it can still be seen on the ground.

Multiple rolls of Teflon tape rolls can be found not far from the Saint-Gobain plant. People in the village call it an old, illegal dump. There's no way of knowing if the chemical is still contained in them, but only a few yards away, more rolls were found near a stream.

But did they come from Saint-Gobain? And if they did, when and how did they get there?

The how and why and when isn't as important as the here and now for resident Doris Brooks. She grew up a few doors down from the plant. She said she was diagnosed with cancer three years ago.

"It's like a leukemia thing," she said. "It's in my lymph nodes. I'd like to know what caused it. Wouldn't you?"

Dr. Marcus Martinez also grew up in Hoosick Falls. He has a family practice in the village. He said he's been battling bronchial and liver cancer. He was never a smoker.

He suspects the water contamination may have led to his cancer diagnosis. He wants to see the state test the people in Hoosick Falls to see if cancer there has a higher rate than across the state.

As for the supposed dump site, Saint-Gobain sent the following statement:

"We do not know about the practices of our predecessors; however, we can say this is not a practice that has been engaged in under our ownership."

Dina Pokedoff/Saint-Gobain Spokesperson

Saint-Gobain purchased the plant in 1996.

NEWS 10 ABC

Despite filtration system, Hoosick Falls hesitant to use water

By Lindsay Nielsen Published: January 28, 2016, 5:24 pm Updated: January 28, 2016, 11:08 pm

HOOSICK FALLS, N.Y. (NEWS10) – Some progress has been made in the installation of a water filtration system in Hoosick Falls, but a lot of work is still left to be done.

People living in the village of Hoosick Falls have been living off bottled water for months, and they aren't happy with how the situation has been handled.

A temporary water filtration system was placed into cement and pipes were attached on Thursday, but it will be a while longer before people in the village can drink the water again. But even then, some said they won't drink it because they've been lied to too many times about the issue.

Gary and Daraine Niegoda said they feel like they've been camping for weeks. They haven't been able to use the village water since it was found to be contaminated with a chemical called PFOA.

Gary said he bought a carbon filter at the advice of his daughter when he noticed the water contained strange particles a few years ago.

In 2014, Michael Hickey tested the water on his own and found dangerous levels of PFOA. Hickey said he told the mayor about his findings, but people weren't told to stop drinking the water until the Environmental Protection Agency sent a letter to the mayor in December 2015.

"That's the attitude we've kind of gotten here," the Niegodas said. "'How bad can it be? It's no different than drinking out of a plastic bottle,' they said."

The Niegodas, however, did not want to say who made that assertion.

The NYS Department of Environmental Conservation declared Saint-Gobain Performance Plastics as a superfund site, which is defined as a polluted location that needs a long-term response. Saint-Gobain has paid for the temporary filtration system.

"I don't understand that," Gary said. "If I was not guilty, I wouldn't be paying for somebody's problems."

The system was partially installed on Thursday.

"I still don't know if I'm going to be drinking water because who's to say after they clean up under the mill – is that going to take care of it?" the Niegodas questioned. "And how much will be removed by the filtration system?"

Mayor David Borge was not at the village hall on Thursday. NEWS10 ABC found him at his home, but he said he would speak on Friday.

Borge said the system will be running in about a month. The New York State Department of Health said they expect the system to be connected in two to three weeks, which is when water will be in the system. It will then be followed by a period of flushing of all the water lines to remove any residual PFOA in the system and testing to ensure the water is acceptable quality.

"Too late; doesn't make much difference," Gary said. "Well, she's got a growth – a cyst on her kidney – that was bigger than a pear and that was, what, two years ago longer than that. I've had three GI bleeds, and I don't know what they're caused by."

To learn more, visit the village website, HERE.

The New York State Department of Health said residents can call the DOH at (518) 402-7950 to ask to be included in the testing. They can also log onto the DOH website, HERE, to sign up. Blood testing and sampling will begin in February.

In addition, anyone concerned about the ongoing water issue can go to a public town hall in Bennington, Vt. Famous environmental activist Erin Brockovich will be at Bennington College from noon to 2 p.m. on Saturday, January 30 in the Greenfield Auditorium. She will share her experiences dealing with water contamination.

News 13 NBC

Hoosick Falls schools take extra steps to ensure clean water

WNYT Staff

Updated: 01/28/2016 6:18 PM

HOOSICK FALLS - It's not just the municipal water supply in Hoosick Falls that's tested positive for PFOA. Many private wells also came back with the cancer causing chemical.

From private homes to schools, everyone wants to make sure the right steps are being taken to make sure their water is safe.

Hoosick Falls K through 12 is one building, serviced by an underground well 145 feet below.

“We have tested our water. We are testing our water every month,” noted Hoosick Falls Superintendent Kenneth Facin.

The water is clean from PFOA, according to Facin. However, he says he's not taking anything for granted -- he'll be installing a carbon filtration system to make sure the kids, staff and parents continue to drink clean water.

“There's been no PFOA detected in our water. But as a preventative measure, we want to have that system on,” acknowledged Facin.

PFOA, a man made chemical that's been linked to cancer, was found in the Hoosick Falls municipal water supply. Private wells, not too far from the school have also tested positive for PFOA.

“Our bus facility, which is 1.2 miles up the road, did test positive for PFOA. 2535

Saint Gobain, a plastics company in town is being looked at as the possible source. The state designated it as a superfund site on Wednesday. Facin says that declaration opens up state funds to pay for the school's filtration system.

“The governor said he would pay for the system at the school and the system on private wells, which is really a powerful release of resources,” Facin pointed out.

By the way the EPA says if you have a private well and it's been tested positive for PFOA at 100 parts per trillion or more, don't drink the water, and take advantage of free water at Tops Supermarket paid for by Saint Gobain. The agency says if your private well has not been tested, contact the state Department of Health. In the meantime, they suggest you get the

Free bottled water as well.

Erin Brockovich to convene town hall meeting on water pollution, tour Hoosick Falls

By Edward Damon

Berkshire eagle

01/28/2016

BENNINGTON — Erin Brockovich, the famous environmental and consumer activist, will speak at Bennington College on Saturday about water contamination in nearby Hoosick Falls, N.Y.

The town hall meeting, announced Thursday by the New York City law firm Brockovich consults with, will be at the college's Greenwall Auditorium between noon and 2 p.m. The meeting is free and open to the public, but seating is on a first come, first serve basis and subject to capacity. For directions to the auditorium, visit: www.benningtondance.org/greenwall.html.

In addition to speaking about her experiences with water contamination, Brockovich will also tour the village where potentially dangerous levels of perfluorooctanoic acid, often called PFOA or C8, was found in the water supply serving some 4,900 people.

"Open meetings are a great way for us to meet community members," Robin Greenwall, at attorney with Weitz & Luxenberg who heads the firm's Environmental, Toxic Tort & Consumer Protection litigation unit, told the Banner on Thursday.

Brochovich, who was portrayed by Julia Roberts in a 2000 biographical film carrying her name, maintains a website and, according to Greenwall, receives messages from concerned people living around the country. Brochovich has been contacted by concerned Hoosick Falls residents, Greenwall said, and they both decided it would be a good idea to organize a meeting in the area.

Since earlier this month, Brochovich and her legal team with Weitz & Luxenberg have been studying causes and effects of PFOA, a synthetic substance formerly used in manufacturing products like no-stick cookware, dental floss and electrical insulation.

The investigation was conducted "to allow the firm to seek justice for affected residents from those responsible for the contamination," according to Greenwall.

PFOA was first found in the water supply in 2014 after a concerned resident paid to have water samples tested. Testing found PFOA levels above the EPA's recommended limit for human consumption. High levels were found at the Saint-Gobain Performance Plastic property at 14 McCaffrey St.

The EPA issued a statement in December 2015 warning residents not to drink or cook with the water and limit exposure as much as possible.

In a wide sweeping action plan announced by Gov. Andrew M. Cuomo this week, the McCaffrey Street facility was added to the list of state Superfund sites, a move that unlocks money for a cleanup. The state has also requested the area be listed as a federal Superfund Site. The EPA says a full investigation is necessary to determine how far the contamination has spread in the groundwater and what company caused the contamination.

Saint-Gobain, the French multinational corporation that has owned the McCaffrey Street site since the mid 1990s, says PFOA has not been manufactured there. But the company has been paying for bottled water for residents and will pay for carbon filters for the village.

SENATOR SCHUMER NEWS RELEASE

FOR IMMEDIATE RELEASE: CONTACT: Jason Kaplan

January 28, 2016 202-224-7433

SCHUMER URGES SAINT-GOBAIN TO BE TRANSPARENT AND TO PROACTIVELY COOPERATE WITH EPA/DEC – AND NOT TO STONEWALL, STALL AND LITIGATE WHEN IT COMES TO DEFINING EXTENT OF PFOA CONTAMINATION AND EXECUTING CLEAN-UP

SENATOR URGES COMPANY TO IMMEDIATELY AGREE TO A COMPREHENSIVE & AGGRESSIVE WATER TESTING PLAN FOR PUBLIC AND PRIVATE DRINKING WATER SOURCES, SAYING COMPANY'S NUMBER ONE PRIORITY MUST BE TO FULLY COOPERATE WITH FEDS, STATE, & LOCAL OFFICIALS TO DETERMINE THE EXTENT OF PFOA CONTAMINATION AND CLEAN IT UP

Recent Discovery Of Perfluorooctanoic Acid (PFOA) In Hoosick Falls, NY Could Pose Environmental & Health Risks To The Hoosick Falls Community

Schumer: A Pall of Uncertainly and Fear is Hanging Over Hoosick Falls and Only a Cooperative and Transparent Saint-Gobain Can Clear That Up; There Can Be No Foot-Dragging or Stonewalling When it Comes to Detailing the PFOA Contamination and Cleaning it Up

In a letter to Saint-Gobain Performance Plastics President and CEO Tom Kinisky, U.S. Senator Charles E. Schumer today urged Saint-Gobain Performance Plastics to work "promptly, proactively and transparently" with both federal and state environmental officials – and not to "litigate, stonewall, stall and frustrate" – to define and clean-up the Perfluorooctanoic acid (PFOA) contamination in Hoosick Falls, NY.

PFOA is a man-made chemical used to make non-stick and other household and commercial products that are heat-resistant and repel grease and water. However, PFOA exposure has been linked to increased health risks, including birth defects and cancers that impact organs like the kidneys and thyroid. Schumer said that because PFOA was used to manufacture products for an extended period of time, both before and after Saint-Gobain's ownership of the Hoosick Falls facility at McCaffrey Street, it is critical that the company cooperates with all federal, state and local stakeholders – including the U.S. Environmental Protect Agency (EPA) and the New York State Department of Environmental Conservation (DEC) – to define the precise source and nature of the contamination and the risk it may pose to the environment and human health in the region.

Following a rundown of the recent discovery of elevated levels of the highly toxic chemical PFOA in various drinking water sources and EPA'a order not to consume or cook with this water, Schumer wrote in his letter:

"These developments, and others, have cast a pall of uncertainty and fear over the Hoosick Falls community, with wide ranging impacts from health and emotional well-being to the local economy. The only way that this uncertainty and fear can be addressed is by speedily defining all potential sources of the contamination, the nature of the contamination, the threat the contamination poses to human health and how far it has spread. Then, it must be cleaned up . . . And on all these matters the speedy cooperation of Saint-Gobain is essential.

I write, therefore, to urge Saint-Gobain Performance Plastics to work promptly, proactively and transparently with the U.S. Environmental Protect Agency (EPA) and the New York State Department of Environmental Conservation (DEC) to define and clean-up the perfluorooctanoic acid (PFOA) contamination in Hoosick Falls. It is absolutely crucial that Saint-Gobain maximally cooperate with all federal, state, and local stakeholders to address this situation and the risk it poses to our environment and human health in the region.

While it is possible within the enforcement process to stall for time, to litigate, to stonewall, to stall and to frustrate – as other polluting companies have chosen that route – the urgency of this situation cries out against Saint-Gobain using that option. From experience in other similarly-impacted communities in New York, I know that working cooperatively and transparently to confront this challenge is in the best interests of both the people of Hoosick Falls and Saint-Gobain," said Schumer.

Saint-Gobain has had a presence in the Hoosick Falls area since 1999, when they first purchased the plant on McCaffrey Street. However, the recent discovery of PFOA water contamination in the area has many residents concerned for their health and safety, as this dangerous chemical has been linked to numerous health risks and was used to manufacture

products for an extended period of time at the McCaffrey Street plant. Schumer explained that, according to the EPA, PFOA levels of more than 400 parts per trillion (PPT), are considered unsafe for consumption. Schumer said this is concerning because, in June 2015, the four samples of drinking water collected from the public water supply in Hoosick Falls contained more than 600ppt. In addition, groundwater testing samples at the Saint-Gobain facility were found to have levels as high as 18,000ppt.

These initial water testing results have many local residents and officials in the Hoosick Falls area worried, as the Saint-Gobain plant is located only a short distance away from the community's water treatment facility. According to a recent report from The New York Times, companies that were previously found to be using PFOA noted that the harmful chemical should be incinerated or sent to chemical-waste facilities, rather than flushed into surface water or sewers because of the potential environmental and health risks. Schumer said the particularly high level of 18,000ppt PFOA contamination found in local groundwater testing results means a wide variety of environmental and health risks could impact the Hoosick Falls community.

Schumer said this contamination needs to be remediated as soon as possible, which is why he is urging Saint-Gobain to work with the federal EPA, NYS DEC and local stakeholders to determine the full size and scope of this contamination, in order to better assess the threats to the community and begin the clean-up process as soon as possible. Schumer is therefore pushing the company to agree to an aggressive and comprehensive testing regime to define the extent of the pollution – and not to drag out the process via litigation, stalling and lack of transparency. Schumer said it is essential that Saint-Gobain pledge to support the clean-up efforts so that the community may recover quickly and with minimal threat to the environment and residents.

"Saint-Gobain should be an open book when it comes to delineating the sources of contamination and an open check book when it comes to pollution clean-up," said Senator Schumer, "should that process clearly show them the responsible party."

Schumer said that while Saint-Gobain has taken steps to assist the community, more must be done. And fast. Schumer said the company's purchasing of drinking water for residents and its paying for the planned installation of both a temporary filter and a permanent carbon-filter system at the village treatment plant that would remove PFOA from the water is a great start that must be turned into long-term solutions. Schumer said the scope of the contamination must be determined and the pollution removed in order for the physical and economic health of the Town of Hoosick Falls to be truly addressed.

A copy of Schumer's letter to the company appears below:

As you are aware, an urgent public health crisis has developed in Hoosick Falls, NY involving the unfortunate discovery of elevated levels of the highly toxic chemical perfluorooctanoic acid (PFOA) in area drinking water sources. This situation has appropriately attracted the attention of the federal Environmental Protection Agency (EPA), which on November 25, 2015 officially recommended "that people not drink the water from the Hoosick Falls public water supply or use it for cooking." More recently the New York State Department of Environmental Conservation asked the EPA to list certain areas in and around Saint-Gobain facilities, which used PFOA in its manufacturing process for many years, on the federal Superfund list. And, just yesterday, the state Department of Environmental Conservation took further action adding the area to the state's Superfund list.

These developments, and others, have cast a pall of uncertainty and fear over the Hoosick Falls community, with wide ranging impacts from health and emotional well-being to the local economy. The only way that this uncertainty and fear can be addressed is by speedily defining all potential sources of the contamination, the nature of the contamination, the threat the contamination poses to human health and how far it has spread. Then, it must be cleaned up – and paid for by those responsible for causing the pollution. And on all these matters the immediate cooperation of Saint-Gobain is essential.

I write, therefore, to urge Saint-Gobain Performance Plastics to work promptly, proactively and transparently with the U.S. Environmental Protect Agency (EPA) and the New York State Department of Environmental Conservation (DEC) to define and clean-up the perfluorooctanoic acid (PFOA) contamination in Hoosick Falls. It is absolutely crucial that Saint-Gobain maximally cooperate with all federal, state, and local stakeholders to address this situation and the risk it poses to our environment and human health in the region.

While it is possible within the enforcement process to stall for time, to litigate, to stonewall and frustrate – and, unfortunately, other polluting companies have chosen that route – the urgency of this situation cries out against Saint-Gobain using that option. From experience in other similarly-impacted communities in New York, I know that working cooperatively and transparently to confront this challenge is in the best interests of both the people of Hoosick Falls and Saint-Gobain.

As you know, Saint-Gobain has had a presence in the Hoosick Falls, New York area since 1999, when they purchased the plant on McCaffrey Street. The McCaffrey Street plant, which is located only a short distance away from the community's water treatment facility, used PFOA to manufacture products for an extended period of time, both before and after Saint-Gobain's ownership. According to the EPA, PFOA levels of more than 400 parts per trillion (PPT), are considered unsafe for consumption. On June 4, 2015, four samples of drinking water were collected from the public water supply in Hoosick Falls. These sample contained more than

600ppt, while additional groundwater testing at the Saint-Gobain facility were found to have levels as high as 18,000 ppt. This high level of PFOA contamination presents a wide variety of environmental and health risks to the Hoosick Falls community, which needs to be remediated as soon as possible.

Now that enforcement actions have commenced, it is imperative that Saint-Gobain work with the Hoosick Falls community, the EPA, and the DEC to develop a plan to ensure that the PFOA contamination can be remedied as soon as possible. I appreciate the steps that Saint-Gobain has taken to assist the community, for example, by purchasing drinking water for residents and by paying for the planned installation of both a temporary filter and a permanent carbon-filter system at the village treatment plant that would remove PFOA from the water. That is an important start, but it is by no means sufficient. Specifically, Hoosick Falls must have an aggressive and comprehensive testing regime that covers public and private drinking water sources -- to define the scope and content of the pollution. All sources must be identified and those sources require regular monitoring. Further, if a pollution plume exists, it must be precisely defined and then remediated.

As mentioned above, Saint-Gobain is in a unique position to move this community from uncertainty to certainty. This is best accomplished via a cooperative and speedy effort to define the facts – and by pledging to support the clean-up efforts so that the community may recover as soon as possible. Saint-Gobain has been a valuable employer in upstate New York, and your assistance in delivering clean water to the people of Hoosick Falls is appreciated, but the scope of the contamination must be determined and the pollution removed to restore the physical and economic health of Hoosick Falls. Thank you for your attention to this important request. I look forward to working with your company to address these concerns.

Sincerely,

Charles E. Schumer

United States Senator

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TIMES UNION

Erin Brockovich to meet with Hoosick Falls residents

By Rick Karlin, Capitol Bureau on January 28, 2016 at 1:40 PM

The state on Wednesday unveiled a plan to deal with water pollution in Hoosick Falls including naming it a state Superfund site.

Now, the nationally known tort firm, Weitz & Luxenberg, which has been looking for potential litigants, is bringing environmental activist Erin Brockovich to town.

Brockovich, who helped propel a case against Pacific Gas & Electric in the 1990s and was depicted by Julia Roberts in a movie about her life, has worked with Weitz & Luxenberg before, including a 2009 visit to Ravena when residents were worried about mercury emissions from a concrete plant there.

Here are the details on her visit which will also include a public meeting in Bennington, Vt., which is a larger town a few miles away:

Environmental activist Erin Brockovich, together with a team of Weitz & Luxenberg attorneys, look forward to meeting with victims of the Hoosick Falls, New York PFOA groundwater contamination on Saturday, January 30, said the nationally known personal injury and mass tort law firm.

This community meeting will be held between noon and 2 p.m. in the Greenwall Auditorium at Bennington College, Bennington, Vermont, 15 minutes away from Hoosick Falls. Here are directions to the Auditorium: http://www.benningtondance.org/greenwall.html.

Ms. Brockovich also plans to visit the stricken upstate New York town for a tour, followed by a discussion at the Auditorium with residents about the local water contamination. She will be accompanied by Weitz & Luxenberg's Robin L. Greenwald, who heads the firm's Environmental, Toxic Tort & Consumer Protection litigation unit, and other attorneys from the firm.

Ms. Brockovich, a long time environmental advocate, will share her experiences dealing with water contamination. Weitz & Luxenberg will discuss the legal options and remedies available to Hoosick Falls clients and other residents who seek assistance, the firm announced.

PFOA Contamination Making Residents Sick

Ms. Brockovich and Weitz & Luxenberg have been investigating suspected causes and

consequences of the PFOA water contamination problem affecting Hoosick Falls since early January, said Ms. Greenwald. “This investigation was conducted to allow us to seek justice for the affected residents from those responsible for the contamination,” she stated.

PFOA is a synthetic substance used in the manufacture of no-stick cookware, dental floss, electrical insulation and other familiar products.

The municipal water supply in Hoosick Falls has been found to contain potentially dangerous levels of PFOA. Some residents of the town have reported falling ill after using this water for drinking and cooking.

Chronic PFOA exposure has been linked to testicular cancer, kidney cancer, thyroid disease, high cholesterol, ulcerative colitis and pregnancy-induced hypertension. Studies suggest other possible health consequences including a possible connection to pancreatic cancer.

EPA Also Looking Into PFOA Problem

Ms. Brockovich’s visit comes after a January 14 public meeting that the U.S. Environmental Protection Agency (EPA) conducted. Officials with the New York State Department of Health and Department of Environmental Conservation also attended that meeting, stated Weitz & Luxenberg.

According to the Albany, New York, Times Union newspaper, angry and frustrated residents filled the auditorium looking for answers and solutions.

EPA Regional Administrator Judith Enck led the meeting and apologized to residents for the misery they are enduring.

“I’m very, very sorry that you have been going through this,” the Times Union quoted Ms. Enck as saying. “I’m sorry that we don’t know how long you have been drinking contaminated water…. Action should be taken to protect your health.”

State officials at the meeting announced that they had requested that the EPA place the suspected major source of Hoosick Falls PFOA contamination on the EPA’s Superfund cleanup site list. EPA officials announced that the earliest that Hoosick Falls could be considered for Superfund status would be in the fall of 2016, said the firm.

For more information, visit the Weitz & Luxenberg Hoosick Falls webpage at http://hoosickfallslawsuit.com

# # #

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Wed 1/27/2016 11:18:07 PM
Subject: Appendix F memo for PFOA PFOS
APPENDIX F Briefing Memo PFOA PFOS 1272016.docx

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | harper.ashley@epa.gov

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Wed 1/20/2016 1:27:11 PM
Subject: FW: Housatonic Falls New York
PFOA PFOS EPR REPORT AUG 2014.pdf

Thanks. I think you read this correctly. Good news

From: Strong, Jamie
Sent: Wednesday, January 20, 2016 7:30 AM
To: Cooperstein, Sharon <Cooperstein.Sharon@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Housatonic Falls New York

Sharon,
Attached is the peer review report.

Thanks,

Jamie

From: Cooperstein, Sharon
Sent: Tuesday, January 19, 2016 12:57 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Housatonic Falls New York

Hi Jaime,

I'm wondering if there's a report summarizing peer review comments on the draft Health Effects Documents for PFAS/PFOA I might be able to take a look at.

Thanks,

Sharon

From: Cooperstein, Sharon
Sent: Tuesday, January 19, 2016 9:28 AM
To: Strong, Jamie <Strong.Jamie@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Housatonic Falls New York

Thank you!

From: Strong, Jamie
Sent: Tuesday, January 19, 2016 7:29 AM
To: Cooperstein, Sharon <Cooperstein.Sharon@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Housatonic Falls New York

Here is the EPA site:

http://www.epa.gov/aboutepa/hoosick-falls-water-contamination

From: Cooperstein, Sharon
Sent: Thursday, January 14, 2016 3:15 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: Housatonic Falls New York

Hi Betsy,

You mentioned and I've heard others allude to a recent instance of PFC contamination in New York, but I haven't caught wind of it other than by word of mouth (and a quick google search isn't bringing much up- probably because I have the name of the city wrong). Do you have any more information?

Thank you!

Sharon

Sharon Cooperstein

Environmental Protection Agency

Office of Policy

WJC North 3521D |Mail Code 1803A

202-564-7051

Peer Review Summary Report

External Peer Review of EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

November 17, 2014

Peer Reviewers:

James V. Bruckner, Ph.D.
Deborah A. Cory-Slechta, Ph.D.
Jamie C. DeWitt, Ph.D.
Jeffrey W. Fisher, Ph.D.
William L. Hayton, Ph.D.
Matthew P. Longnecker, Sc.D, M.D
Angela L. Slitt, Ph.D.

Contract No. EP-C-13-010
Task Order 2013-06

Prepared for:
U.S. Environmental Protection Agency
Office of Science and Technology/Office of Water
Health & Ecological Criteria Division
1200 Pennsylvania Avenue, NW (MC4304T)
Washington, DC 20460

Prepared by:
Versar, Inc.
6850 Versar Center
Springfield, VA 22151

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EXECUTIVE SUMMARY

Versar, Inc. (Versar), a contractor for the Environmental Protection Agency (EPA), coordinated an external peer review of EPA's draft health effects documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS), and organized a two-day public peer review meeting in Arlington, Virginia on August 21 and 22, 2014. The peer review of EPA's draft health effects documents was initiated with a pre-meeting written peer review managed by Versar and conducted by seven independent expert peer reviewers. The role of the peer reviewers was to evaluate the scientific and technical merit of the draft documents and provide their responses to 12 charge questions. Peer reviewers were charged only with evaluating the quality of the science included in EPA's draft health effects documents and were not charged with making any regulatory recommendations or reaching consensus in either their deliberations or written comments. The two-day peer review meeting, which directly followed the written peer review period, was held to discuss the scientific basis supporting EPA's draft health effects documents and to provide members of the public with an opportunity to observe the peer reviewer deliberations.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. In addition, EPA provided background information on the draft documents and approach used in the development of the documents. Following opening remarks by Versar and EPA, the peer reviewers began their discussions on the PFOA draft document, moderated by the Chair, Dr. Deborah Cory-Slechta. The discussions centered on individual responses to EPA's 12 charge questions. Additionally, some comments submitted to the public docket prior to the meeting were also discussed. The second day of the meeting began with brief remarks from Versar followed by discussions focusing on the PFOS draft document.

The reviewers began the discussion on the first day with the recognition of the significant amount of data that is available for both PFOA and PFOS and thus to be considered by the EPA for incorporation into the document and for the ultimate derivation of reference dose (RfD) values. In general, the reviewers commended EPA in doing a very good job of pulling together this significant and extensive body of information and of condensing it into its most critical pieces for the derivation of RfD values. This was especially the case given that there is significant human and animal data available for both chemicals, as well as inconsistencies in the data.

The reviewers did offer numerous suggestions for improving the documents, many of which are applicable to both PFOA and PFOS. In general, the suggestions relate to the statement of the problem and defining the database that was utilized, clarity and ease of presentation, and transparency of the reports, as well as to issues of modeling, use of human data, and liver weight increases as the most sensitive endpoint. These comments are summarized below, but please note that this does not reflect a consensus or group perspective.

- All reviewers agreed that it would be extremely useful to include an opening section of the document describing in some detail the literature that was reviewed. More specifically, this would include a description of the dates that were included in the

literature review, whether requirements for peer-reviewed materials were imposed, and what criteria were used in eliminating studies from consideration. This would assist in identifying studies that should potentially have been included. Many additional studies of importance were suggested for review at the meeting by the peer reviewers.

- The reviewers also agreed that there are some significant studies that have been published recently on PFOA and PFOS that may be relevant, and these should be included in the documents during the current revisions.
- Reviewers also felt that the Tables in the documents could be made much more useful to readers with the addition of columns that included more study details. This would minimize the amount of back-and-forth to the text that was required to assess conclusions.
- Additionally, there was a strong agreement that the Hazard Identification section of the documents should include a more systematic review of study strengths and limitations. These were noticeably absent in the human studies, where all studies were considered equivalent but also applicable to animal studies.
- Reviewers also felt that each Chapter should include introductory paragraphs, as well as concluding paragraphs, that would provide better integration of the material across the Chapters, as well as summarize the conclusions arrived at from the text in the Chapter. This would also facilitate the ability of readers to follow the presentations provided in Chapter 5 of the derivation of RfDs.
- As pointed out at the peer review meeting, the authors would be well advised to base these documents on the new documents being produced by EPA's National Center for Environmental Assessment (NCEA) for the Integrated Risk Information System (IRIS) program. While the reviewers recognize that the PFOA and PFOA health effect documents will not be used specifically for the same purpose, they will still likely be held to the same standards of presentation, clarity and transparency and thus, the new NCEA formats provide good models to follow.
- With respect to content of the documents, there was initial confusion around some of the modeling outcomes and assumptions based on values that were provided in the documents. However, following explanation from EPA personnel in response to clarifying questions from the reviewers at the peer review meeting, it became clear that there were errors in these values and once these were corrected, concerns about the specific values used in some modeling were allayed.
- Even with the corrections to the modeling, there were residual concerns among reviewers based on toxicokinetic properties of these chemicals, with respect to applying the same candidate RfD values to both short and long-term exposures, which in animal studies ranged from 11 to 182 days with reviewers expressing a need for this to be re-considered.
- There were mixed comments by reviewers with respect to the decision not to use human data in the derivation of RfD values. All reviewers generally agreed that the rationales provided for the exclusion of the human data were not actually appropriate, as it is certainly not the case that such use would be precluded by the fact that there were

multiple and not sole exposures to either PFOA or PFOS. There was discussion as to the possibility of whether human data could be utilized in these assessments, and that ranged from an opinion that these data would not be useful to the view that it might be possible to use these data, despite the absence of information on route of exposure. Collectively, the range of opinions suggests that the issue should be revisited, and that appropriate rationales should be provided for the decision that is reached in the revised version.

- For both PFOA and PFOS, the RfDs were ultimately based on increases in liver weights in animal studies. There was significant discussion among reviewers as to the appropriateness of this endpoint for the derivation of the RfDs. That range of opinion spanned from an interpretation that these did constitute adverse effects in that they are a direct effect of a chemical exposure, whereas other reviewers saw these as adaptive effects. Collectively, the range of opinions suggests that the issue should be revisited, and that appropriate rationales should be provided for the decision that is reached in the revised version.

Following the meeting, peer reviewers were given additional time to complete their individual written reviews, which were submitted to Versar upon completion. These final written comments are contained in Sections III, IV, V of this report and fall into three categories: general impressions, responses to charge questions, and specific observations. Written peer review comments, as well as comments submitted to the docket by members of the public, will be considered by EPA as it revises the draft documents.

I. INTRODUCTION

I.1 Background on Draft Health Effects Documents

On February 28, 2014, the EPA's Office of Water (OW) announced in the Federal Register the release of the draft health effects documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS) for purposes of public comment (scientific views) and peer review (http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf). The draft documents and charge questions were prepared by the Health and Ecological Criteria Division (HECD), within EPA's OW, in order to support future regulatory evaluations and decisions. EPA will consider the public comments and peer reviewer comments when revising the documents. Once the PFOA and PFOS health effects documents are finalized, they will be utilized to develop lifetime health advisory values for each chemical. PFOA and PFOS are listed on the third Contaminant Candidate List (CCL3)[1] and both chemicals are currently being monitored under the third Unregulated Contaminant Monitoring Rule (UCMR3)[2].

I.2 Peer Review Process

Consistent with guidelines for the peer review of highly influential scientific assessments, Versar, an EPA contractor, was tasked with assembling six to seven scientific experts to evaluate the draft PFOA and PFOS documents. The purpose of the peer review was to provide a documented, independent, and critical review of the draft health effects documents, and identify any necessary improvements to the documents prior to being published. In assembling these peer reviewers and coordinating the peer review, Versar was charged with evaluating the qualifications of peer review candidates, conducting a thorough conflict of interest (COI) screening process, independently selecting the peer reviewers, distributing review materials, maintaining contact with the peer reviewers, organizing and hosting the public peer review meeting, and developing a final peer review report.

The peer review selection process was initiated with a three-week public nomination period that was held from February 28, 2014 to March 21, 2014, as documented in the Federal Register on February 28, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf). During this period, members of the public were able to nominate scientific experts with knowledge and experience in one or more of the following areas: (1) epidemiology, (2) toxicology (liver effects, immunotoxicity, neurotoxicity, developmental and reproductive toxicology, etc.), (3) membrane transport, (4) human health risk assessment, (5) pharmacokinetic models, and (6) mode-of-action for cancer and noncancer effects. Concurrently, Versar conducted an independent search for qualified scientific experts to augment the list of publically-nominated candidates. In total, Versar evaluated 29 interested and available candidates who were either nominated by the public (n=18) or identified by Versar (n=11).

[1] CCL3 is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulation under the Safe Drinking Water Act (SDWA). Additional information about the CCL3 can be found at the following website: http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl3.cfm.

[2] EPA uses the Unregulated Contaminant Monitoring (UCM) program to collect data for unregulated contaminants suspected to be present in drinking water. Results from UCMR3 can be examined as they become available at the following website: http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/ucmr3/.

Versar considered and screened all 29 candidates against the selection criteria described in the Federal Register dated February 28, 2014, which included: (1) having demonstrated expertise in the areas described above, based on information in their submitted resume, biographical sketch and/or current publications, (2) being free of any COI and the appearance of the lack of impartiality, and (3) being available to participate in-person in a two-day peer review meeting in the Washington DC area in the July or August 2014 timeframe. Following the screening process, Versar narrowed the list of potential reviewers to 15 candidates and provided to EPA the names of the candidates selected by Versar to be on the interim list. Additionally, information on the 15 candidates, including their professional affiliations, expertise, education, and professional experience were provided for the interim list and published in the Federal Register on April 30, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-04-30/pdf/2014-09888.pdf). The Federal Register also requested the public to submit relevant information or documentation on the interim list of candidates that Versar should consider during the evaluation process of selecting the final six to seven reviewers.

Following the close of the public comment period on the interim list of potential reviewers, Versar re-evaluated each interim candidate's credentials to select the experts who, collectively, provided expertise spanning the multiple subject matter areas covered in the draft documents and provided a balance of perspectives. In addition, Versar evaluated the availability of each candidate to ensure all final peer reviewers were available on the same days for the meeting in the selected timeframe. Once the evaluation process was completed, Versar narrowed the interim list of 15 candidates and selected the seven final peer reviewers. In addition, Versar selected Dr. Deborah Cory-Slechta as Chair of the peer review meeting due to her expertise in toxicology as well as her strong record of chairing and participating in peer review panels, scientific meetings, and workshops. A list of the final seven peer reviewers who participated in this review is provided below. In addition, each reviewer's biographical sketch is included in Appendix A.

Following the selection process, Versar distributed EPA's draft PFOA and PFOS documents and 12 charge questions (see Section II) to the peer reviewers. The peer reviewers were asked to evaluate the scientific and technical merit of the draft documents and provide their responses to the 12 charge questions. This included evaluating the appropriateness of the quality, accuracy, and relevance of the data in the documents. Peer reviewers were not charged with making any regulatory recommendations or reaching consensus in either their written comments or public deliberations. In addition to being provided the draft documents and charge questions, comments submitted to EPA's public docket (Docket ID number EPA–HQ–OW–2014–0138) during each document's 60-day public comment period were provided to the peer reviewers ahead of the meeting for their consideration. Also, a brief summary of the public comments was developed by Versar and provided to the reviewers. However, peer reviewers were not asked to evaluate or respond to comments submitted to the docket.

Versar managed the pre-meeting peer review period, which provided the peer reviewers approximately two months to evaluate the draft health effects document and complete their written reviews. Following receipt of the peer reviewers' draft comments, Versar compiled the comments into a pre-meeting peer review report and distributed them to the peer reviewers and

EPA to prepare for the public peer review meeting. These preliminary responses to the charge questions formed the basis of reviewer discussions on Days 1 and 2 of the public meeting.

Peer Reviewers:

James V. Bruckner, Ph.D.
University of Georgia

Deborah A. Cory-Slechta, Ph.D.
University of Rochester School of Medicine and Dentistry

Jamie C. DeWitt, Ph.D.
East Carolina University

Jeffrey W. Fisher, Ph.D.
U.S. Food & Drug Administration

William L. Hayton, Ph.D.
The Ohio State University

Matthew P. Longnecker, Sc.D, M.D
National Institute of Environmental Health Sciences

Angela L. Slitt, Ph.D.
University of Rhode Island

I.3 Peer Review Meeting

On August 21 and 22, 2014, Versar convened a public peer review meeting in Arlington, Virginia. This meeting was held to discuss the scientific basis supporting EPA's draft health effects documents and to provide members of the public with an opportunity to observe the peer reviewer deliberations. The meeting followed both the documents' public comment period, during which members of the public were able to submit written comments, and the pre-meeting written peer review period, during which the seven selected peer reviewers evaluated EPA's draft health effects documents and provided preliminary comments in response to the charge questions.

Versar managed the pre-meeting registration period, which allowed members of the public to register to attend the meeting in person or remotely via teleconference and/or webinar. Members of the public were able to register online, via Versar's registration website (http://peerreview.versar.com/epa/pfoa/) as well as by telephone, email, or U.S. mail. In advance of the meeting, Versar provided all registered attendees with pre-meeting handouts, which included the agenda and logistics information.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. In addition, EPA provided background

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information on the draft documents and approach used in the development of the documents. Following opening remarks by Versar and EPA, the peer reviewers began their discussions on the PFOA draft document, which centered on individual responses to EPA's 12 charge questions. The remainder of the day was dedicated to discussions on the PFOA document, which were moderated by the Chair, Dr. Deborah Cory-Slechta. The second day of the meeting began with brief remarks from Versar followed by discussions focusing on the PFOS draft document. Approximately 23 public observers attended the peer review meeting in person and 21 observers attended the meeting via teleconference and/or webinar. Please see Appendix B for the meeting agenda and Appendix C for a list of public attendees.

Following the public peer review meeting, peer reviewers were given additional time to complete their individual written reviews. These final written comments are contained in Sections III, IV, and V of this report. Written peer review comments, as well as comments submitted to the EPA docket by members of the public, will be considered by EPA as it revises the draft health effects documents.

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II. CHARGE TO REVIEWERS

PFOA and PFOS are environmentally persistent organic fluorocarbons (PFC) that have been identified in ambient waters, ground water, drinking water, and biosolids. They are metabolically inert but have the ability to bind to and interact with a variety of biomolecules leading to responses in living organisms. Both compounds have a substantial database of epidemiological, pharmacokinetic, toxicological and mechanistic studies. The two documents submitted for peer review include health assessment chapters that will be used 1) to provide information to drinking water treatment plant operators regarding the significance of monitoring results with respect to potential health outcomes and 2) to determine whether the perfluorinated compounds currently being monitored at Public Drinking Water Systems require regulation. The health information at that time will be accompanied with chapters on environmental fate, occurrence at public drinking water systems and occurrence in other media. The quantitative aspects of the Health Assessment documents will also be used to develop lifetime Health Advisories for both compounds.

Charge Questions

1. Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

2. Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

3. The OW concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment of the OW characterization of the data.

4. Please comment on the transparency and characterization of the epidemiological data.

5. The OW has concluded that the cancer classifications for PFOA and PFOS are most consistent with respective classifications of suggestive evidence for carcinogenicity as described the EPA Guidelines for Carcinogen Risk Assessment (pp. 2-56, 2-57). Please comment on the strengths and weaknesses of this classification.

6. Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

7. Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

8. The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

9. A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

10. The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days, and occur at comparable human equivalent dose (HED) levels. The current, draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

11. In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.

12. Please describe any suggestions you have for improving the clarity, organization, and/or transparency of the draft documents.

III. GENERAL IMPRESSIONS

James V. Bruckner

PFOA-specific comments

This is one of the most comprehensive Health Effects Documents I have reviewed. The clarity and accuracy of accounts of pertinent research reports/publications are excellent. It is obvious considerable time and efforts were devoted to its composition. If anything, the amount of detail is so great that it is difficult to distill the mass of information on each topic and capture its "essence". This is likely the result of directions the authors were given for writing the document. Some topics in the Hazard Identification section do have summarizing sentences, in which the key/critical studies and their finding(s) are integrated and conclusions reached. It would be very helpful to devote much more attention to this for more topics, perhaps as an addition to Section 4.4 Hazard Characterization.

I do have a real problem with the scientific basis and soundness of certain conclusions in the document. The primary effect of PFOA in different species is increased absolute and/or relative liver weight. These are quite modest, reversible, non-specific effects that usually are not considered toxicologically significant. Livers of mice and rats dosed with PFOA typically exhibited hypertrophy characterized by increased peroxisomes, numerous mitochondria, reduced rough endoplasmic reticulum (RER), proliferation of smooth endoplasmic reticulum (SER), and increased autophagosomes or lipid-like droplets. Such morphological changes, particularly those in RER and SER, are manifestations of microsomal enzyme induction. This is considered adaptive, rather than adverse. Hall et al. (2012) points out that activation of a battery of genes involved in xenobiotic metabolism and transport serve to maintain homeostasis by enhancing the systemic elimination of the foreign chemical. Although PFOA is very poorly metabolized, it does persistently induce microsomal enzymes and the accompanying hepatocellular morphological changes. Upregulation of genes responsible for biliary excretion may be beneficial, since excretion of bilirubin, bile acids and conjugates of toxic chemicals/metabolites would be enhanced.

There are substantial qualitative and quantitative differences in responses of rodents and humans to PPARα activation. Therefore, many of the PFOA-induced alterations in lipid metabolism/homeostasis and associated biological processes in mice will be absent or an order of magnitude less pronounced at comparable doses in humans. Many of PFOA's effects on the liver of rodents are dependent on PPARα activation, though some effects appear to be PPARα-independent. Studies in PPARα-knockout mice show activation of other nuclear receptors by PFOA, including PXR, CAR, LXRA and FXR. Bjork et al. (2011) observed markedly lower transcriptional responses of PPARα, PXR, CAR and FXR to PFOA in cultured human than in cultured rat hepatocytes. These more subtle effects lead the investigators to conclude the changes in human cells reflected an adaptive metabolic remodeling rather than overt metabolic dysregulation, or disorder occurring in rat cells. The PFOA document's authors should go into detail discussing and summarizing the relative toxicological significance of non-PPARα effects in rodents versus humans.

It is important to recognize that clearly adverse effects of PFOA are seen. Lovelass et al. (2008), Cui et al. (2009) and others have seen focal necrosis and degenerative changes in the liver of mice and rats given relatively high doses of PFOA, as well as modest elevations in serum (hepatic) enzyme activities. Wolf et al. (2008a) observed a variety of degenerative structural changes in the liver of PPARα-null mice dosed with PFOA. Sakr et al. (2007a,b) and Olsen and Zobel (2007) reported associations between serum PFOA levels and slightly elevated serum enzyme activities in some occupationally-exposed populations. The increases in enzymes may have been attributable to factors other than PFOA. In light of the foregoing, it would be preferable to utilize hepatic morphological changes in rodents and/or elevated serum enzymes as the critical effect(s), rather than increased liver weight. These are clearly adverse effects seen in both rodents and humans.

An international panel of experts (Hall et al., 2012) opined that an increase in liver weight of ≤ 150%, at doses of chemical that do not produce structural or biochemical evidence of hepatocellular damage, would not be considered adverse. Absolute and relative liver weights were not increased as much as 50% by most PFOA doses in the majority rodent and monkey studies. Perkins et al. (2004), for example, reported dose-dependent increases in liver/body weight in rats fed 1, 10, 30 and 100 ppm PFOA for 13 weeks of 0, 10, 30, and 41%, respectively. Butenhoff et al. (2002) measured increases of 17, 21 and 37.5% and relative liver weight in monkeys given 3, 10 or 30/20 mg PFOA/kg/day for 26 weeks, respectively. Liver hypertrophy of this magnitude does not warrant such a low RfD. By adhering to EPA policies of calculating a $BMDL_{10}$ and using multiple UFs, regardless of the (lack of) severity of the critical effect and relatively low level of concern about other potential health effects, the end result is a vanishingly low RfD (i.e. 0.00002 mg/kg/day). A great deal of time and effort were spent on the PFOA hazard assessment, toxicokinetic modeling and extrapolations, dose metric and POD considerations, etc. Despite all of these scientifically-credible exercises and deliberations, the end result (RfD) seems to this reviewer to have been preordained-- to be extremely low.

Logic expressed on page 5-6, in support of use of liver weight gain as a critical effect and biomarker of loss of hepatocellular homeostasis seems flawed. As pointed out in the second paragraph, liver weight changes were not observed in PFOA-treated mice with a humanized PPARα receptor. It is noted that changes in gene products that modulate lipid metabolism do occur in these mice. EPA argues that this supports adoption of increased liver weight as a biomarker/critical effect. It has not been established that these changes in gene expression are adverse, or whether they are sufficient in magnitude to significantly alter lipid metabolism. It would be expected that repeated dosing with enough of a molecule (i.e., PFOA) that resembles a fatty acid would affect expression of such genes. Reversible changes in total cholesterol, bile acids, bilirubin, etc. have been observed. It has not been established, however, whether mild fluctuations in these indices are detrimental. No increases in mortality from cerebrevascular disease or ischemic heart disease have been found in PFOA-exposed humans. How then does the concurrence of alteration of expression of such genes and of liver weight gain support the latter as toxicologically-significant effect that should be prevented by setting the RfD low enough?

PFOS-specific comments

This Health Effects Document, like that for PFOA, is quite comprehensive. Its descriptions of the many studies of PFOS are clear, quite complete, and apparently quite accurate. As with the

PFOA document, so much detail is given about many studies in the Hazard Identification section, that is difficult to compare study designs/dosage regimens/species/indices/findings/etc. and to draw conclusions. The summary tables for single and multiple studies, however, are quite helpful in this regard. It would also be very useful to have more summary statements or paragraphs at the end of each topic. These should address the scientific importance of findings, their relevance to humans; and their impact on the weight of evidence on an issue.

The hazard characterization section (4.4) is, for the most part, inclusive and balanced in its presentation and integration of findings of the more important studies in each subject area. This is true for both non-cancer and cancer effects in humans and animals. It concerns me, however, that the document's authors do not focus in the remainder of the document on science (i.e., the candidate critical effects and their relevance to human health), but merely choose the most sensitive end-points and stress how similar the RfDs are after dosimetry modeling estimates and adjustments. I am not sure how this similarity of derived points of departure and other values, calculated from dissimilar endpoints, supports or validates the final RfD.

I recommend that an additional section be written, in which the primary adverse effects of PFOS are discussed-- in terms of their relative toxicological significance, their apparent mechanism(s), their relevance to humans, their likelihood in realistic exposure scenarios, and implications of altered experimental indices to actual organ dysfunction.

I am quite concerned about the increased rat pup mortality in several studies at relatively low maternal doses, but not about reversible liver weight changes or centrilobular hypertrophy. Is the decreased pup survival in several studies at relatively low maternal doses of PFOS relevant to humans?-- Is the dose-response curve steep, as suggested by Luebker et al. (2005a), such that there would be less concern about sub-threshold doses? -- What is the most likely mode of action (pulmonary surfactant or maturation, dietary, hormonal)? -- Is decreased survival PPARα-related? -- Is the mechanism in rats relevant to other species? -- Does pup mortality occur in other species at comparable doses? -- Might there be a dose-dependent alteration of maternal-fetal partitioning of PFOS?

Deborah A. Cory-Slechta

Both documents, although the PFOA document to some degree more than PFOS, overall are more of a tabulation of studies than a critical review of studies from which a rationale is presented for a choice of studies to model and from which to derive associated RfDs. The Executive summaries are too abbreviated and do not include sufficient rationale, description and detail to provide the reader with an understanding of how decisions described in Chapter 5 were made. Since in some cases, this will be the only sections read, they could provide a more informative summary.

It would be very helpful to provide a section up front that describes all of the parameters of the literature search, including the years that are included in the document review, as well as descriptions of criteria for studies that were included vs. those that were excluded. In addition, it should be indicated whether there was a criterion that studies be peer-reviewed. This is particularly important given the voluminous size of the data base that has accumulated for these

two chemicals. Given that revisions will be done and that such documents do not get updated with any frequency, it would be good to attempt to include as much of the new pertinent literature as possible.

The section on Toxicokinetics in the documents present studies in detail, but no real conclusions; this is true of most of the sections in these documents. Chapters 3 and 4 in particular read like tabulations of studies rather than critical reviews and because of that, the documents seem disjointed and Section 5, i.e., derivation of values, tend to be difficult to read through and require constant searching back to the original chapters in which they are described. It is critical to identify the strengths and weaknesses of the various studies, and which were given weight to use in the final determinations. It would be helpful if Sections 3, 4 and 5 included an introductory paragraph describing the goal of the chapter, and that each ends with an overall summary with conclusions. The tables in these chapters also would benefit from the inclusion of additional information that ultimately permits comparisons within the Table and does not require continually returning to the text to recall the species, sample sizes, etc.

In the sections on Hazard Identification, it is useful that studies are summarized by target organ, but there are almost no conclusions and no discussions of strengths or weaknesses of studies and therefore their use or not in future decisions. In fact, one is left with the impression that all studies are equal, especially in the section describing human studies. Within Chapter 4, the sub-sections entitled "evaluative and integrative" are actually neither. Data are presented simply as positive or negative with no real discussion of the strengths and limitations and what was concluded overall. For this reason, Chapter 5 is also lacking. It provides very little in the way of rationale and conclusions. Thus, the transparency of the process is really insufficient.

Jamie C. DeWitt

The information presented throughout the documents appears to be accurate (with one minor exception noted in Table 1 of these comments) and is presented clearly. For PFOA, a reference dose (RfD) of 0.00002 mg/kg/day was determined and evidence of carcinogenicity is considered suggestive with a human equivalent dose (HED) of 0.58 mg/kg/day. The RfD was based on changes in liver weight reported as a common denominator in four rodent (three rat and one mouse) studies and carcinogenicity was based on a limited number of epidemiology studies linking kidney and testicular tumors with exposure and evidence of tumor induction in the liver, testes, and pancreas (the "tumor triad") in rats. For PFOS, a RfD of 0.00003 mg/kg/day was determined and evidence of carcinogenicity is considered suggestive but with insufficient evidence to determine human carcinogenic potential. The RfD was based on developmental neurotoxicity and changes in liver weight.

While the carcinogenicity assessment seems appropriate for the two compounds given the limitations of the data sets, changes in liver weight as a basis of both of the RfDs is questionable in terms of its significance to exposed humans. Exposure to these agents increases liver weight and hepatocellular hypertrophy in rodents (and the definition of these endpoints as "adverse" or "toxic" also is contentious); this has been demonstrated across various rodent strains and under myriad exposure paradigms. However, there is no consensus in the scientific community regarding the mechanism by which exposure to these compounds increases liver weight and

induces hepatocellular hypertrophy in rodents and whether any of the putative mechanisms are sufficient to induce hepatotoxicity in exposed humans. Proposed mechanisms include peroxisome proliferator activated receptor alpha (PPARα) activation, activation of other nuclear receptors, peroxisome proliferation (which may or may not be dependent on PPARα activation), and oxidative stress. Humans can certainly respond to PPARα agonists (i.e., fibrate drugs are used as hypolipidemic agents) and a handful of epidemiological studies of highly exposed human populations have reported associations between PFOA/PFOS and alterations in liver enzymes, but the clinical relevance of the changes to the liver enzymes reported for these studies is uncertain. These liver-related changes in humans generally occur at higher doses than required to induce changes in the livers of rodents, which occurs at relatively lower doses than other observed effects. Therefore, a critical endpoint that occurs at very low doses in rodents, has no agreed upon mechanism that may or may not be relevant in humans at relatively high doses, may not be the best choice for the basis of a RfD. Liver weight change has been reported to occur in several species, including non-human primates, and at low doses, it may be an adaptive response and not a toxicological response. While this response may be protective of human health because it is common following low dose exposure to PFOA or PFOS, other endpoints may be more relevant to humans, especially endocrine system effects, including changes to thyroid hormones and mammary gland development, and immune system effects. Endocrine and immune system effects have been reported in exposed humans, suggesting that such endpoints may operate via a mechanism that is more relevant to humans than mechanisms related to changes in liver weights.

In addition, the one developmental neurotoxicity study used, in part, for the PFOS RfD is only weakly supported by additional studies in rodents or other species and is based on behavioral responses that could be influenced by factors other than direct effects on the nervous system. Additional confirmatory studies are necessary for this observation to be considered a critical effect of PFOS exposure.

Finally, while well-written overall, the documents lacked an overall critical analysis or depth required of a risk assessment. Why specific studies were included or not should be better explicated in the text.

Jeffrey W. Fisher

The document was well written in terms of balance and presenting information. Summary statements are needed for chapters; a synthesis/analyses of the data are needed in some cases. A more critical evaluation of the human and non-human responses to PFOA/PFOS is required to justify not using human or non-human primate data. A rationale for the modeling approaches is needed given the more recent PBPK models that are available.

William L. Hayton

The literature that pertains to the health effects of PFOA and PFOS is large and presents a major challenge to accurately summarize and analyze it and develop an RfD for PFOA and PFOS. Reported health effects in animals and humans, sometimes contradictory, include exposure-associated changes in serum cholesterol, lipids, uric acid, and thyroid hormones, obesity-related

metabolism, immune system function, and effects on reproduction, development of the mammary gland, the nervous system, and behavior. Target organ effects (e.g., liver, kidney) have been reported, as well as associations of PFOA and PFOS exposure with testicular, prostate and kidney cancer. Studies in several laboratory animal species have added the complications of interspecies comparisons and extrapolation of findings to humans. In humans, there have been a Phase I clinical trial of PFOA, and epidemiological studies of populations exposed to PFOA and PFOS occupationally and in communities with and without water supplies contaminated with PFOA and PFOS. The draft documents have accurately presented in summary form the results of many animal and human studies and used pharmacokinetic methods to link PFOA and PFOS exposure rates to internal dose metrics such as serum concentration. While the overall effort is commendable, there are two issues that the draft documents raise: 1) the literature cited does not include many apparently relevant published works. The cut-off date for cited literature was early 2013 (this should be indicated in the documents), but commenter's noted a number of pertinent publications in 2011 and 2012 that were not cited, and there have appeared several highly pertinent papers since the cut-off date, and 2) while the descriptions of individual studies are generally clear and accurate, there is a lack of independent, critical analysis of the studies and a lack of synthesis of results from multiple studies common to a particular health effect.

Matthew P. Longnecker

The PFOA and PFOS documents achieve the goal of identifying RfDs that are well founded. My main criticism is that the rationale for not using the human data to provide a POD needs to be strengthened.

For example, in the PFOA document, on page 5-19, first paragraph below the table, it says "human data … lack the exposure information for dose-response modeling." This statement is logically inconsistent with techniques that were used to estimate HED on the basis of serum concentration, as given on page 5-17, near the bottom. Or, in some cases, such as in the C8 study, the exposure estimates that were calculated based on water district were sufficiently good that a dose-response analysis would be possible. In other words, because many human studies have serum concentration of PFOA or reasonable estimated exposure values, the corresponding HED could be estimated, and hence the dose-response could be modeled. Granted, some assumptions would be needed, but the methods could be serviceable (see response to item 3 below). (Some of the above also applies to pages 5-1 and 5-2). More compelling arguments for not basing the POD on human data are, e.g., that: 1) the low probability that humans are 1,000 times more sensitive to PFOA than other species (the number is based on the last column in table 5-9 compared with PFOA values in the C8 study and background exposed populations), especially given the relatively tight agreement between LOAEL (average serum concentration basis) among other species, 2) the possibility that the observed associations in humans were due to unmeasured confounding factors or reverse causality, and 3) other weaknesses in the epidemiologic data such as inconsistent results across studies (selected outcomes), unreplicated findings, or associations with clinical chemistry results for which corresponding adverse clinical correlates (i.e., morbidity) are not clearly established.

Angela L Slitt

The documents provide a very thorough evaluation of PFOA and PFOS studies. It is logically organized, presenting findings in a way that the reader can understand the findings related to human, monkey, and rodents. The organization of the document allows the reader to easily find information about each species within the subchapters and summarizes key points in table form. PFOA is a well-studied compound, with a substantial amount of toxicokinetic and endpoint studies in rodents. Mechanistic data describing the role of membrane transporters to understand gender differences in PFOA elimination in rats is fairly well written. Little data exist regarding contribution of membrane transporters to PFOS disposition and elimination. The documents thoroughly describe species differences in PPAR-alpha signaling that might contribute to observed endpoints in rats, but not humans or monkeys. Overall, both documents are very thorough and provide a reliable basis for PFOS and PFOA evaluation.

For PFOA toxicokinetics, mechanisms of PFOA transport are important for understanding species differences in response to PFOA exposure, with focus placed on kidney. Figure 3-2 in the PFOA document does not adequately present the localization of renal transporters with relationship to their contribution to the urine compartment or renal reabsorption. A very nice diagram showing the subcellular localization of renal transporters presented by Klaassen and Aleksunes (Pharmacol Rev. 2010 Mar;62(1):1-96) clearly depicts the contribution of various transporters to filtrate or blood. This is an easier diagram to put PFOA elimination into context than the one presented. Contribution of membrane transporters to species differences in PFOA excretion Section 3 (specifically 3.4.1) would be put in better context if a table could be generated to compare Km and Vmax values for PFOA for various transporters, with specific focus on species information for OATPs and OATs. Data regarding information on contribution for OATps in liver accumulation of PFOS and PFOA is lacking, with specific regard to species differences. As PFOS is a likely candidate for hepatic uptake transport, understanding a mechanism to explain species differences in hepatic effects possibly due to difference in hepatic exposure is critical. Understanding impact species specific regulation of OATp expression in liver (e.g. whether species difference in PPAR-alpha signaling contributes) is also important in putting rodent distribution data into context.

Increased liver weight is considered to be a critical effect, but how increased liver weight relates to the observed human and monkey health effects needs to be further explained. First, use of liver weight alone might not be substantiate of an effect for point of departure compared to other liver effects observed at higher concentrations, such as increased serum ALT or AST.
The studies that have evaluated these endpoints are well conducted. In layman terms, if someone is walking around with an increased liver weight, is he or she at risk for disease? Will his/her life span be shortened? To increase transparency of the document, a more comprehensive explanation is needed to justify why increased liver weight should be considered as a critical endpoint for human health.

However, it should be noted for future consideration that there are a few publications in mice that do also ascribe liver weight changes in increased lipid accumulation along with increased expression of genes that contribute to fatty liver disease. This is considered to be a gap in knowledge for the field. Will relatively low dose PFOS exposures associated with hepatic

steatosis have other endocrine related effects known to be associated with NAFLD (insulin resistance, impaired glucose tolerance)? Emerging studies are evaluating whether PFOS induces hepatic steaosis and whether it is a PPAR-α mediated effect. For example a study performed by Wan et al. (2012) administered 0, 1, 5 or 10 mg/kg/day PFOS to adult male CD-1 mice for 3, 7, 14 or 21 days. Histological analysis of liver sections, and biochemical/molecular analysis of biomarkers for hepatic lipid metabolism were assessed. Overall, the study reported that PFOS-administration induced hepatic steatosis in a time- and dose-dependent manner. The study also shows a high correlation between liver weight and lipid content. Increased expression of a lipogenic target (CD36/FAT) was observed at 5 and 10 mg/kg PFOS. A second study by Bijland et al. (2011) illustrated that PFOS administration increased liver weight (+ 107%, $p < 0.0001$), which was accompanied by an increased hepatic TG content (+ 192%, $p < 0.0001$, respectively) in E3L.CETP mice on a C57Bl/6 background. At the age of 8–10 weeks, mice were fed a semisynthetic Western-type diet, containing 0.25% (wt/wt) cholesterol, 1% (wt/wt) corn oil, and 14% (wt/wt) bovine fat for 4 weeks in three independent experiments. Upon randomization according to body weight, plasma TC, and TG levels, mice were fed a Western-type diet without or with PFOS (0.003%, ~3 mg/kg/day) for 4–6 weeks. In summary, there is evidence that administration of relatively low PFOS doses to mice can result in hepatic lipid accumulation in the absence of overt "wasting."

Data is lacking as to whether higher species, such as monkeys or humans will also develop PFOS-induced steatosis, which is confounding. Studies have profiled gene expression in wild-type and PPARα-null mice administered PFOS, finding that there is pathology and gene expression consistent with lipid-promoting effects in liver that are independent of PPARα, as they are observed in PPARα-null mice (Rosen et al., 2010). Limitations to the studies are that they did not specifically quantify hepatic lipid content, but inferred that the PFOS-induced vacuolization in liver pathology observed was potentially related to triglycerides. Studies by Bjork et al. (2011) comparing rat and human primary hepatocytes treated with PFOS (25 μM) demonstrated that human hepatocytes were slightly less responsive to the induction of lipid oxidation and synthesis genes, as well as induction of carbohydrate metabolism. It should be noted that the hepatocytes from the study are from a single human donor, the hepatocyte lipid content was not determine, and hepatocyte culture conditions were standard and not optimized to induce steatosis. In summary, the current literature is lacking robust information regarding whether PFOS, which highly concentrates in liver, has a steatotic-inducing effect in human or monkey liver. The evidence in PPARα-null mice indicates that it might have some PPARα independent effects related to hepatic fat accumulation. Because evidence for hepatic lipid content in PPARα-null mice after PFOA or PFOS has been described only by pathology, more robust studies are needed to conclude whether the effects can occur independent of PPARα and the observed increased liver weight is due not only to hypertrophy due to nuclear receptor activation, but lipid accumulation. However, this reviewer is noting this as a concern for the future and area where a gap in knowledge exists.

Moreover, because the reviewer is noting a concern for hepatic fat accumulation that exists in the absence of PPARα, it should be appreciated that traditional markers, such as AST and ALT have poor prognosis for NAFLD or toxicant associated steatohepatitis. Most patients with NAFLD are asymptomatic and the disease is often diagnosed following findings of elevated aminotransferases, especially when combined with other features of metabolic syndrome. These

abnormal liver function tests usually require the physician to distinguish between NAFLD and alcoholic fatty liver disease (AFLD). Some have suggested that a serum AST/ALT ratio >1 are indicative of AFLD. Other possible signs of AFLD include elevated HDL-cholesterol with hypertriglyceridemia. While most diagnoses of NAFLD may result from altered liver function tests, normal serum aminotransferase tests can be seen in patients with both steatosis and NASH (Ipekci, et al., 2003; Mofrad, et al., 2003). Indeed, it is reported that two-thirds of NASH patients may have normal aminotransferase levels at any given time (Oh, et al., 2008; Delgado, 2008; Wieckowska and Feldstein, 2008). Kunde et al. investigated the accuracy of NASH diagnosis by serum ALT in women undergoing gastric bypass surgery (Kunde, et al., 2005). They compared two different reference laboratory cutoffs for "normal" ALT levels, the previous guideline of 30U/L, and new lower level of 19U/L that was suggested to aid in the diagnosis of NAFLD. Importantly, the authors reported that the diagnostic utility of serum ALT remained poor even at the new lower cutoff. Sensitivity and specificity of serum ALT levels were found to be 42% and 80% (ALT > 30U/L) versus 74% and 42% (ALT > 19U/L). These and other studies (Lizardi-Cervera, et al., 2006; Amarapurkar and Patel, 2004; Amarapurka, et al., 2006; Chen, et al., 2006; Fracanzani, et al., 2008; Sorrentino, et al., 2004; Mofrad, et al., 2003; Uslusoy, et al., 2009) illustrate the need for a more effective diagnostic measure for NAFLD, especially the NASH stage. In sum, use of ALT and AST elevation to base the point of departure must be taken into context because they are poor prognostic markers for increased liver accumulation, NAFLD, or even NASH. Use of ALT and AST might not be an appropriate biomarker for measurement of PFOA or PFOS-induced adverse effects on liver and should be considered as a gap in our knowledge for future work.

In the review panel discussion, there was discussion regarding a publication by Hall et al. (2012), which summarized the outcome of a workshop regarding liver hypertrophy and hepatocarcinogenesis. Overall, the workshop concluded that "hepatomegaly as a consequence of hepatocellular hypertrophy without histologic or clinical pathology alterations indicative of liver toxicity was considered an adaptive and a non-adverse reaction". This conclusion is taken in the context of hepatic hypertrophy caused by nuclear receptor activation. This differs from others that have concluded in mouse NTP studies where correlations between liver weight increases and histological parameters and carcinogenesis were assessed, the authors concluded that ''the best single predictor of liver cancer in mice was hepatocellular hypertrophy'' (Allen et al. 2004). Based on the conclusions presented in Hall et al. (2012), increased liver weight might not be considered an appropriate POD because of lack of overt toxicity and hepatomegaly being considered an adverse effect. It should be noted that this reviewer still has concerns regarding this conclusion for PFOS and PFOA because the pathology described in PPARα-null mice reflect increased hepatic lipids and not hepatomegaly due to nuclear receptor activation that is described in this opinion publication. If one considers the pathology examples of hypertrophy presented in Hall et al. (2012), it is quite different from the pathology described for PFOS and PFOA. For clarity, the document should try to delineate the cellular components that are contributing to increased liver weight caused by PFOA and PFOS administration, if such a publication exists (e.g. how much of the liver is associated with protein/peroxisome proliferation increase versus lipid increase). Because the literature is not clear regarding what exactly in the liver is causing increased liver weight, studies documenting hepatic lipid accumulation should not be currently considered for POD. Given the recent opinion cited by Hall et al. (2012), it is

recommended that studies documenting liver damage, such as ALT and AST elevation be currently used as the POD.

The documents often have redundancy in information, especially in regard to hormone effects (there are very similar write ups in sections about effects on thyroid hormone) and metabolic/cardiovascular disease risk factors (e.g. lipid endpoints).

IV. RESPONSE TO CHARGE QUESTIONS

Charge Questions

Question 1. Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

James V. Bruckner

PFOA-specific comments
The document's authors have done a good job describing and integrating the findings of the numerous studies in which liver weight gain was observed. Although there is a consensus about the effect and the dosage required to elicit it in different species, this reviewer does not believe it should be utilized, as described above. There are several clearly adverse effects such as elevated serum (hepatic) enzyme activities, focal hepatocellular necrosis, bile duct degeneration and fibrosis, etc. These effects are generally seen in response to relatively high PFOA doses, so the PODs will be higher than with liver weight increase. Alternatively, a human endpoint such as elevated serum cholesterol could be considered. See responses to Charge Question 3.

PFOS-specific comments
There have been a substantial number of well-conducted toxicological studies of PFOS. My major concern, as expressed above, is its potential to cause adverse effects in children. Other than that, PFOS doesn't appear to produce effects other than those anticipated from a repetitive, cumulative dose of an 8-carbon fatty acid.

Deborah A. Cory-Slechta

In general, it appears that, at least with respect to the animal studies, the choices are appropriate both in the case of PFOA and PFOS. The derivation of the RfDs/RfCs are based on studies of sufficient strength, duration and represent the most sensitive endpoints.

Having said that, in both documents, the reader is forced to that conclusion with no real assistance from the text itself. There is virtually no discussion of the strengths and weaknesses of the studies overall. Human study outcomes for the most part are simply enumerated, although an occasional statement will be made about a limitation (usually) of one of those studies. There is no discussion in the human studies of the power to detect effects, the sample sizes, etc. Much weight seems to be given to occupational studies in some cases, being used to essentially dismiss effects in a community cohort as the same effect was not seen in occupationally exposed workers, when in fact finding effects in a population with seemingly longer, albeit lower exposure levels actually makes the outcome more robust. Also, population studies with smaller sample sizes that nevertheless find significant effects are in fact more compelling and suggest robust effects which can be detected even with a small sample size. This deficiency is manifest in statements such as those in the PFOS document (p. 5-1) that 'in most cases the findings are suggestive and not conclusive of an effect'.

There is a bit more discussion of the animal studies in both documents, at least with respect to methods, but as with the human studies, there is little text addressing which studies represent stronger studies or what the weaknesses are. From these increase liver weight has been chosen as the endpoint from which to derive RfDs. This reviewer does not have an issue with that choice, as while it has been described as adaptive by some, it represents a response to an involuntary exposure with a direction of effect that is potentially associated with adverse consequences. The fact that it is reversible when exposure ends seems irrelevant as reversal of exposure is not happening in the human environment.

Jamie C. DeWitt

Strengths: The studies selected as key for quantification were generally well-conducted studies, employing a range of doses and sample sizes large enough for detecting statistical differences. Additionally, the doses associated with LOAELs for the identified critical endpoints were not associated with signs of overt or systemic toxicity in the animal models and nearly all of the studies measured serum and/or tissue concentrations of the parent compounds.

Weaknesses: No obvious experimental design weaknesses were noted in any of the studies selected as key for quantification.

Characterization: The studies selected as key for quantification for PFOA are all rodent studies while at least one study selected for PFOS quantification includes a non-human primate study. It is therefore surprising that the PFOA database does not include, as a study key for quantification, the Butenhoff et al. 2002 study of non-human primates. Additionally variability in putative mechanisms among species was not adequately addressed in the characterization of the selective studies, although all of the selective studies were descriptive and not mechanistic.

Jeffrey W. Fisher

PFOA and PFOS: Data bases are massive and both need to be updated. Several human studies and a few non-human primate toxicity studies are available. The authors need to explain why these studies are not adequate for causality (dose-response).

William L. Hayton

An advantage to assessment of health effects for both PFOA and PFOS is the large amount of published work that informs the topic. While the draft health-effects documents have summarized the results of many pertinent studies, the literature reviewed was not comprehensive, which projects an appearance of weakness. The documents do not state whether the intention was to include all relevant health-effects literature, or to be selective and summarize those studies judged to be most relevant. Such a statement at the beginning of the documents would be helpful; a cut-off date for the literature review would also frame expectations of readers. If the intention was to be selective, a description of selection criteria would help allay concerns of readers about papers that were not included. If the intention was to comprehensively review all the PFOA and PFOS health-effects literature, then it appears that

more work should be done to include omitted works. Public comments list a number of works to consider for inclusion.

A general, albeit minor weakness of the literature is that PFOA and PFOS serum concentrations in control animals were not measured for many studies – they were likely non-zero and, since there is no information on how high they were, it is possible that baseline health-effects metrics were affected and that dose-response relationships were affected, especially in the low dose range. It is perhaps worthwhile to mention this shortcoming somewhere in the health effects documents.

Matthew P. Longnecker

EPA may want to consider the article by AP Hall et al. 2012, about liver hypertrophy. The defense of increased liver weight as the POD (or a POD) could be strengthened by evaluating the evidence in the context of Hall's Figure 9, where evidence regarding hepatoxicity and toxic mechanisms are also considered. In this case, the possibility of an unknown mechanism exists that could be relevant to humans, and long-term exposure could have effects that have not yet been detected. See Hall page 986, where it defines adverse as: "…affects [response] to an additional environmental challenge". Thus, an adverse effect, via an unknown mechanism, by this definition is possible and has not been studied in animals or humans.

While AP Hall's article is not all that supportive of using increased liver weight as a point of departure (unless certain criteria are met), they are focused on animal studies, especially those done in rodents. If increased relative liver weight were to occur in a human population, I suspect that it would be considered an adverse outcome, whether or not there was evidence of hepatotoxicity or a specific mechanism. Note also that for PFOA, in monkeys, there was an increase in relative liver weight with chronic exposure (PFOA document, page 4-66), so increase in liver weight in the animal experiments may be relevant to humans.

An additional comment of relevance here pertains to whether the human data support hepatoxicity. While there are studies that report elevated liver function tests in subjects with higher serum concentrations of perfluorakyl substances, these elevations do not clearly support the presence of toxicity. Again, AP Hall's discussion of what constitutes evidence of hepatoxicity is relevant here, and takes into account the number of LFTs elevated, the specific LFTs involved, and the magnitude of their elevation.

Finally, as discussed at the meeting, for the PFOA document on page 5-23 ("RfD Selection"), and the PFOS document on page 5-26 ("RfD selection"), I suggest minor editorial changes to deemphasize the "consistency of response" point and instead focus a little more on how the RfD is robust to choice of POD endpoints. If the selection of RfD does not hinge on increased liver weight as a POD, it will be more defendable.

Transparency might be increased by saying why (more clearly, or more clearly by implicit reasoning) the Macon et al. 2011 study, in which the LOAEL was 0.01 mg PFOA/kg from GD10 to GD17, based on delayed mammary gland development, was not considered as a POD, and why the Hines et al. 2009 study, in which the LOAEL was 0.01 mg PFOA/kg from GD1 to

GD17, based on various outcomes, was not considered as a POD. The PFOS studies with low LOAELs were considered in the dose-response assessment (no suggestions for improvement there).

Angela L Slitt

My response is basically the same as my General Impressions above.

The documents provide a very thorough evaluation of PFOA and PFOS studies. It is logically organized, presenting findings in a way that the reader can understand the findings related to human, monkey, and rodents. The organization of the document makes allows the reader to easily find information about each species within the subchapters and summarizes key points in table form. PFOA is a well-studied compound, with a substantial amount of toxicokinetic and endpoint studies in rodents. Mechanistic data describing the role of membrane transporters to understand gender differences in PFOA elimination in rats is fairly well written. Little data exist regarding contribution of membrane transporters to PFOS disposition and elimination. The documents thoroughly describe species differences in PPAR-alpha signaling that might contribute to observed endpoints in rats, but not humans or monkeys. Overall, both documents are very thorough are provide a reliable basis for PFOS and PFOA evaluation.

For PFOA toxicokinetics, mechanisms of PFOA transport are important for understanding species differences in response to PFOA exposure, with focus placed on kidney. Figure 3-2 in the PFOA document does not adequately present the localization of renal transporters with relationship to their contribution to the urine compartment or renal reabsorption. A very nice diagram showing the subcellular localization of renal transporters presented by Klaassen and Aleksunes (Pharmacol Rev. 2010 Mar;62(1):1-96) clearly depicts the contribution of various transporters to filtrate or blood. This is an easier diagram to put PFOA elimination into context than the one presented. Contribution of membrane transporters to species differences in PFOA excretion Section 3 (specifically 3.4.1) would be put in better context if a table could be generated to compare Km and Vmax values for PFOA for various transporters, with specific focus on species information for OATps and OATs. Data regarding information on contribution for OATps in liver accumulation of PFOS and PFOA is lacking, with specific regard to species differences. As PFOS is a likely candidate for hepatic uptake transport, understanding a mechanism to explain species differences in hepatic effects possibly due to difference in hepatic exposure is critical. Understanding impact species specific regulation of OATp expression in liver (e.g. whether species difference in PPAR-alpha signaling contributes) is also important in putting rodent distribution data into context.

Increased liver weight is considered to be a critical effect, but how increased liver weight relates to the observed human and monkey health effects needs to be further explained. In layman terms, if someone is walking around with an increased liver weight, is he or she at risk for disease? Will his/her life span be shortened? To increase transparency of the document, a more comprehensive explanation is needed to justify why increased liver weight should be considered as a critical endpoint for human health.

Use of humanized PPARα mice are a sexy tool to delineate species differences in effects associated with peroxisome proliferation. For transparency, the document should acknowledge the limitations of that model. Specifically, lack of response may not necessarily correlate to a lack of response for human PPARα because of species differences in binding to cogate DNA elements (e.g. a human receptor may have lower binding capacity to mouse DNA due to structural differences and species differences in co-activator/co-repressor interactions). Wording in the documents using these mice should acknowledge this limitation.

The documents often have redundancy in information, especially in regard to hormone effects (there are very similar write ups in sections about effects on thyroid hormone) and metabolic/cardiovascular disease risk factors (e.g. lipid endpoints).

Question 2. Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

James V. Bruckner

PFOA-specific comments
Fabrega, F. et al. (2014). PBPK modeling for PFOS and PFOA: Validation with human experimental data. Toxicol. Lett. On line. (Hard copy available)

Stahl, T., Mattern D and Brunn, H. (2011). Toxicology of perfluorinated compounds. Environ. Sci. Europe 23: 38-60.

Hall, A. P., et al. 2012. Liver hypertrophy: A review of adaptive (adverse and non-adverse) changes- Conclusions from the 3rd International ESTP Expert Workshop. Toxicol. Pathol. 40: 971-994.

Bjork, J. A., Butenhoff, J. L., and Wallace, K. B. 2011. Multiplicity of nuclear receptor activation by PFOA and PFOS in primary human and rat hepatocytes. Toxicology 228: 8-17.

PFOS-specific comments
No additional references were located.

Deborah A. Cory-Slechta

For both PFOA and PFOS, the document should include a description of the process through which studies were identified and how they were processed for inclusion or not. It is not clear what the exact dates of the studies examined included, i.e., what the cut-off date was for these studies. This makes it difficult to evaluate whether there are missing studies. That said, this reviewer is not aware of any specific omissions in the peer-reviewed literature other than those that were discussed at the face-to-face meeting.

Jamie C. DeWitt

Granum, B., Haug, L.S., Namork, E., et al. 2013. Pre-natal exposure to perfluoroalkyl substances may be associated with altered vaccine antibody levels and immune-related health outcomes in early childhood. J Immunotoxicol. 10:373–379; Looker, C., Luster, M.I., Calafat, A.M., et al. 2014. Influenza vaccine response in adults exposed to perfluorooctanoate and perfluorooctanesulfonate. Toxicol. Sci. 138:76–88.

Any time the Grandjean et al. (2012) findings related to PFAS and vaccine responses are discussed, these references could/should be discussed as well as they report related findings in human populations. Although they also are confounded by multiple PFAS (as was the Grandjean et al. study), they lend additional support to immunotoxicity as an endpoint worthy of consideration. However, it is noted that these references were published after the cutoff date for consideration for inclusion in the document.

Lopez-Espinosa, M.J., et al. 2012. Thyroid function and perfluoroalkyl acids in children living near a chemical plant. Environ.Health Perspect. 120:1036–1041. This study is missing from the discussion of thyroid hormone disruption. It reports a positive correlation between hypothyroidism and PFOA in children from the C8 population aged 1-17.

Corsini E., et al. 2011. In vitro evaluation of the immunotoxic potential of perfluorinated compounds (PFCs). Toxicol. Appl. Pharmacol. 250:108-116. Corsini E. et al. 2012. In vitro characterization of the immunotoxic potential of several perfluorinated compounds (PFCs). Toxicol. Appl. Pharmacol. 258:248-255.These studies are in vitro/ex vivo studies of human-derived cells that provide evidence that in vitro measures of immunocompetence in mice may be relevant to the human experience.

Jeffrey W. Fisher

For completeness sake, at least, please update lab animal studies conducted since 2012.

William L. Hayton

A review of PFOA health-effects literature (GB Post et al. (2012) Environ. Res. 116: 93-117) provides an excellent, in-depth discussion of many issues covered in the PFOA health effects document. Consider citing this review in the document.

The literature on PFOA and PFOS toxicokinetics (Section 3) has been comprehensively covered in the health effects documents, with the notable omission of Wambaugh et al., Dosimetric Anchoring of *In Vivo* and *In Vitro* Studies for Perfluorooctanoate and Perfluorooctanesulfonate. Toxicol. Sci. 136:308-327, 2013. This paper informed a significant part of the health effects documents.

Commenter's have suggested a number of references to consider with regard to Section 4 Hazard Identification. Many recent publications report on toxicity associated with PFOA/PFOS exposure. For the Dose-Response Assessment (Section 5) it is desirable to focus on those toxicities that have occurred at the lowest PFOA/PFOS exposures. For PFOA, the literature that is used in Section 5 to determine an RfD was published prior to 2009 (Tables 5-8 – 5-11). The benchmark response chosen based on the Section 4 literature was a 10% increase in liver weight, which was the biological response that occurred at the lowest PFOA exposure; it was acknowledged that this response "… is a biomarker for systemic exposure in rodents, rather than a biomarker of adversity …" (p. 5-6). More recent studies of hazard have identified potential adverse effects that result from, or are associated with, PFOA exposures that are lower than the LOAEL for a 10% increase in liver weight. For example, adverse effects on fetal, neonatal and early childhood stages of development may occur at lower exposures than does liver weight gain, which suffers in addition from not being a biomarker of adversity, and which therefore raises a question about the validity of any RfD based upon it. Macon et al. 2011 reported an LOAEL for delayed mammary gland development of 0.01 mg/kg administered to pregnant CD-1 mice during GD10 – GD17. As this relatively brief exposure was well below that required for steady state, it is possible that had the dams been at steady state at the time of conception (about 9 weeks of exposure) a much lower LOAEL may have been observed; i.e., a much lower dose

rate at steady state would have produced the same exposure to the fetal pups as did the 0.01 mg/kg administered to the dams during GD10 – GD17. The steady state situation is more relevant to adverse effects in humans than is a brief exposure.

Matthew P. Longnecker

I suggest you include the following citation and include a discussion of the evidence presented: Paula I. Johnson, Patrice Sutton, Dylan S. Atchley, Erica Koustas, Juleen Lam, Saunak Sen, Karen A. Robinson, Daniel A. Axelrad, and Tracey J. Woodruff. The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth. Environ Health Perspect; DOI:10.1289/ehp.1307893 (in press and available through the journal's website).

Based on the meta-analysis in this paper, the evidence that PFOA is associated with lower birthweight is consistent. Thus, the rationale for not basing the POD on the human data needs to be strengthened, as noted above. The Johnson et al. report could be discussed in the section on anthropometric endpoints that begins on p 4-22.

The relationship between birthweight and PFOA or PFOS may be confounded because glomerular filtration (and hence excretion of the compounds) is proportional to birthweight, as discussed in:

Morken NH, Travlos GS, Wilson RE, Eggesbø M, Longnecker MP. Maternal glomerular filtration rate in pregnancy and fetal size. PLoS One. 2014 Jul 8;9(7):e101897

In the PFOA document, on page 4-18, you might want to also cite:

Taylor KW, Hoffman K, Thayer KA, Daniels JL. Polyfluoroalkyl chemicals and menopause among women 20-65 years of age (NHANES). Environ Health Perspect. 2014 Feb;122(2): 145-50.

The Taylor et al., like the Knox et al. report (already cited in the PFOA document) is from a large-cross sectional study. Both studies, in their discussion sections, note that the association of PFOA or PFOS concentration in serum with age at menopause could be expected because postmenopausal women have lost a route of excretion for the compound and will have higher serum concentrations on that basis. It would be worth noting this possible explanation in the PFOA document on page 4-18, and in the PFOS document on page 4-8.

Additional data are available on the potential carcinogenicity of PFOA:

- Steenland K, Woskie S. Cohort mortality study of workers exposed to perfluorooctanoic acid. Am J Epidemiol. 2012;176(10):909-17.
- Barry V, Winquist A, Steenland K. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. Environ Health Perspect. 2013;121(11-12):1313-8
- Hall AP et al. Toxicol Pathol 2012:40:971-94. (About liver hypertrophy.)

The Steenland and Barry reports could be discussed in Section 4.1.2, on pages 4-28 and 4-29, respectively.

Angela L. Slitt

1) Evidence is presented for PFOA and PFOS as substrates for the related OATp1d1 in zebra fish. Establishing whether PFOS is an OATp transporter substrate is needed to better understand PFOS accumulation in liver. This study suggests that it might be. The following finding should be included in the PFOS document in Section 3.2.3 and the PFOA document in Section 3.0:
    a. Popovic M, Zaja R, Fent K, Smital T. Toxicol Appl Pharmacol. 2014 Interaction of environmental contaminants with zebrafish organic anion transporting polypeptide, OATp1d1 (Slco1d1).

2) This publication presents the finding that PFOS inhibits Pgp, Mrp1, and Mrp4 activity. The following finding should be included in the PFOS document in Section 3.2.3 and the PFOA document in Section 3.0:
    a. Dankers AC1, Roelofs MJ, Piersma AH, Sweep FC, Russel FG, van den Berg M, van Duursen MB, Masereeuw R. Toxicol Sci. 2013 Dec;136(2):382-91. Endocrine disruptors differentially target ATP-binding cassette transporters in the blood-testis barrier and affect Leydig cell testosterone secretion in vitro.

3) PFOS induced ABC transporters in grey mullets.
    a. de Cerio OD1, Bilbao E, Cajaraville MP, Cancio I. Gene. 2012 Apr 25;498(1):50-8. Regulation of xenobiotic transporter genes in liver and brain of juvenile thicklip grey mullets (Chelon labrosus) after exposure to Prestige-like fuel oil and to perfluorooctane sulfonate.

4) These are new publications regarding epidemiology findings for PFOS and PFOA exposure and serum lipids:
    a. Fitz-Simon N, Fletcher T, Luster MI, Steenland K, Calafat AM, Kato K, Armstrong B. Epidemiology. 2013 Jul;24(4):569-76. doi: 10.1097/EDE.0b013e31829443ee. Erratum in: Epidemiology. 2013 Nov;24(6):941.
    b. Starling AP, Engel SM, Whitworth KW, Richardson DB, Stuebe AM, Daniels JL, Haug LS, Eggesbø M, Becher G, Sabaredzovic A, Thomsen C, Wilson RE, Travlos GS, Hoppin JA, Baird DD, Longnecker MP. Perfluoroalkyl substances and lipid concentrations in plasma during pregnancy among women in the Norwegian Mother and Child Cohort Study. Environ Int. 2014 Jan;62:104-12.
    c. Fu Y, Wang T, Fu Q, Wang P, Lu Y. Associations between serum concentrations of perfluoroalkyl acids and serum lipid levels in a Chinese population. Ecotoxicol Environ Saf. 2014 Aug;106:246-52.
5) These are publications regarding PFOS exposure and hepatic steatosis:
    a. Lv Z, Li G, Li Y, Ying C, Chen J, Chen T, Wei J, Lin Y, Jiang Y, Wang Y, Shu B, Xu B, Xu S. Glucose and lipid homeostasis in adult rat is impaired by early-life exposure to perfluorooctane sulfonate. Environ Toxicol. 2013 Sep;28(9):532-42. doi: 10.1002/tox.20747. Epub 2011 Aug 24. PMID: 23983163 Select item 22484034

b. Wan HT, Zhao YG, Wei X, Hui KY, Giesy JP, Wong CK. PFOS-induced hepatic steatosis, the mechanistic actions on β-oxidation and lipid transport. Biochim Biophys Acta. 2012 Jul;1820(7):1092-101. doi: 10.1016/j.bbagen.2012.03.010. Epub 2012 Mar 28. PMID: 22484034 [PubMed - indexed for MEDLINE] Free Article
c. Bijland S, Rensen PC, Pieterman EJ, Maas AC, van der Hoorn JW, van Erk MJ, Havekes LM, Willems van Dijk K, Chang SC, Ehresman DJ, Butenhoff JL, Princen HM. Perfluoroalkyl sulfonates cause alkyl chain length-dependent hepatic steatosis and hypolipidemia mainly by impairing lipoprotein production in APOE*3-Leiden CETP mice. Toxicol Sci. 2011 Sep;123(1):290-303. doi: 10.1093/toxsci/kfr142. Epub 2011 Jun 24.

Question 3. The OW concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment of the OW characterization of the data.

James V. Bruckner

PFOA-specific comments
The document's authors have done a good job summarizing and accurately characterizing the epidemiology literature for various endpoints in Section 4.4 - Hazard Characterization. It is true there are a number of confounding factors that make estimation of PFOA exposures difficult. The EPA might consider, however, utilization of reverse dosimetry modeling. There is a reasonable body of data on serum PFOA levels, which could be used to estimate a range of PFOA exposures that would result in such internal doses.

PFOS-specific comments
I agree that human epidemiology data do not provide an adequate basis for calculation of a RfD or RfC. A reverse dosimetry modeling approach, however, could be used to estimate a range of PFOS exposures that could have resulted in measured body burdens. The human data might then be utilized in the risk assessment.

Deborah A. Cory-Slechta

It is not clear that such an assertion should be used in the construction of this document. It is not clear why the route of exposure should be raised to a concern in the calculations, in fact in the human environment, there are exposures from multiple routes, no doubt and thus this is consistent with human environmental exposures. Further, if there is data on serum levels, it should reflect that cumulative exposure across exposure routes. Indeed, at the end, the goal is to arrive at an RfD based on serum levels. There is, moreover, no guarantee that there is no contamination in studies in animals from food, glassware etc.

Furthermore, in many epidemiological studies in which mixed exposures are the norm, controlling for other exposures is utilized to address this concern and to therefore make conclusions about individual exposures. In point of fact, in every single human study, there will invariably be other exposures and not a single exposure, and thus this strategy essentially says that no human studies can ever be used for any risk assessments. The stated rationales for not using human data based on these statements is not adequate. This is why it is important as well to evaluate the strengths and weaknesses of each of the studies in terms of whether appropriate controlling for other known exposures was carried out and sample sizes sufficient etc. to arrive at some conclusions with respect to their ultimate usability in constructing RfDs.

Jamie C. DeWitt, Ph.D..

While the OW characterization of the epidemiological data for PFOA/PFOS is, technically, true, it also is somewhat misguided. Almost any epidemiological database will contain uncertainty regarding the routes, levels, and timing of exposures and will have confounding influences of other compounds. Very few epidemiological studies are free from these uncertainties, but when similar observations and conclusions are reached from multiple studies with these types of uncertainties, the database becomes useful for determining a candidate RfD or other value relevant to human health. What is particularly valuable about the PFOA/PFOS database is that it is relatively extensive in that it includes data not only from occupationally-exposed humans, but from people highly exposed to environmental concentrations of PFOA/PFOS and from people in the general population who have detectable concentrations of these compounds. Additionally, for establishing an RfD, do all of these uncertainties need to be absent? In other words, do animal studies used to derive RfDs lack these uncertainties?

What is missing from the OW characterization of the epidemiological data is a thorough evaluation concerning hepatotoxicity and developmental toxicity reported in human populations and how these endpoints are relevant to or related to animal studies.

Jeffrey W. Fisher

The use of non-human and human data is very important for interpreting exposure extrapolations from rats. I am not an epidemiologist so I cannot comment with authority on the epidemiology data for dose-response. Justify why human data are not suitable for use in the analysis of the health hazards of PFOA and PFOS.

William L. Hayton

There are a number of epidemiological studies that have been based on large numbers of subjects chronically exposed (over decades in some studies) to the subject compounds over a broad range of intakes. Steady state serum concentrations have also been available for quantification of the systemic exposure. While the route, levels and timing of the exposures may have been uncertain, the long half-lives of PFOA and PFOS in humans and the long periods of exposure to them indicate that 1) subject serum concentrations were generally at steady state, and 2) daily fluctuations in the amount and timing of the exposure would not produce much day-to-day fluctuation in the serum concentration of PFOA/PFOS. These consequences of the long exposure period and long half-life indicate that variability in the route and level of exposure would not have led to a measured serum concentration that was unrepresentative of the subjects' long-term average serum concentration. The serum concentration then should be relatively stable over time and it should reflect an integrated measure of the individual's exposure to PFOA and PFOS.

The serum concentration is a quantitative measure of systemic exposure to the subject chemicals, and is arguably a better metric of exposure than are intake rate. The over-all rate of intake (R) that produces a particular steady state serum concentration (Css) can readily be

calculated from the clearance (CL) of the chemicals, which is about 0.08 mL/d/kg body weight: R = Css x CL. The calculated rate of intake would represent all intake routes.

Confounding influences of other PFCs and indeed other chemicals and life-style factors such as smoking, diet, alcohol use, etc. would have to be considered, as is generally the case with epidemiological studies. Methodology exists for dealing with such influences.

Thus it appears that the epidemiological results should be used in the RfD determination. Their strength is that uncertainties associated with extrapolation from laboratory animal studies are avoided. Health effects that are positively associated with serum PFOA/PFOS concentration and that are observed in large populations of subjects should seriously be considered as potentially arising from PFOA/PFOS exposure. If mode of action studies in lab animals or in vitro studies support a cause-effect relationship, then the threshold serum concentration could inform the calculation of the RfD.

Matthew P. Longnecker

As noted in the General Impressions section above, the human studies with data on plasma or serum concentrations of PFOA and PFOS, especially for several categories of such levels, could be used to estimate dose-response information. However, there are other reasons why the human data may not be useful for setting the RfD (see above). Either PK or PBPK models might be useful for estimating the dose that human are exposed to; an advantage of a PBPK model is that it could incorporate information about routes and timing of exposure. Estimates of the contribution of various routes are available (e.g., Haug et al. 2011; Lorber & Egeghy 2011), and exposure trends could be assumed and evaluated in sensitivity analyses. Some occupational studies had data that allowed an estimate of serum levels, or measured them directly. Several reports show estimated exposure based on serum concentrations of PFOA or PFOS (Locissano et al. 2013; Lorber & Egeghy 2011; Thompson et al. 2010). With respect to confounding, the assessment of how likely this is could be informed by: 1) the correlation of serum concentration of PFOA, PFOS, and other compounds of this type in a particular study population (or in a series of studies), and 2) whether the other compound(s) has been associated with the particular outcome being considered. If the correlation is low or the other compound has not been associated with the outcome, concern about confounding may not be strongly justified. Without additional consideration of data that address these points, it may be premature to assume confounding would be a problem.

Angela L. Slitt

Strengths of the studies: Several studies, which all demonstrate a positive association between serum PFOA and/or PFOS and cholesterol or LDL levels are based on drinking water as a route of exposure. These studies are in agreement with Nelson et al., 2010, which was analyzing data from the 2003-4 NHANES study. Steenland et al., 2009 (*Environ Health Perspect*. Jul 2009; 117(7): 1083–1088) as part of the C8 Health Project collected data on 69,030 subjects with findings that serum PFOA was higher for males, those consuming local vegetables, and those using well water rather than public water, and *lower for those using bottled water.* The estimated response rate for participants >20 years of age was 81% and mean serum PFOA

concentration was 83 ng/l. Subjects were eligible to participate in the C8 Health Project if they had consumed drinking water for at least one year before 3 December 2004 supplied by Little Hocking Water Association (Ohio), City of Belpre (Ohio), Tuppers Plains Chester Water District (Ohio), Village of Pomeroy (Ohio), Lubeck Public Service District (West Virginia), Mason County Public Service District (West Virginia), or private water sources within these areas that were contaminated with PFOA. Subjects were also eligible if they could document that they had either worked in a contaminated water district or went to school there for at least one year. From this population, which the route of exposure is considered to be primarily via drinking water, serum lipids were analyzed with regard to PFOA levels and a positive correlation was observed for all serum lipids except HDL. Frisbee further characterized this cohort, analyzing 12, 476 children and adolescents included in the C8 Health Project, finding an increase in total cholesterol.

A recent epidemiology study (Fitz-Simon et al., 2013), not included in the current documents, described positive associations between PFOA and PFOS in serum LDL cholesterol. This study examined a study population that consisted of 560 adults living in parts of Ohio and West Virginia where public drinking water had been contaminated with PFOA. They had participated in a cross-sectional study in 2005-2006, and were followed up in 2010, by which time exposure to PFOA had been substantially reduced. Overall, the findings demonstrate a positive association between serum PFOA and PFOS levels and serum and LDL cholesterol.

Weaknesses: The studies did not appear to analyze PFOS or PFOA levels in drinking water from the participants analyzed and did not analyze data based on the length of exposure.

Question 4. Please comment on the transparency and characterization of the epidemiological data.

James V. Bruckner

PFOA-specific comments
See comments above.

PFOS-specific comments
The document's authors have done a good job describing and summarizing the designs and findings of the epidemiology studies.

Deborah A. Cory-Slechta

The PFOA document in particular and to some extent the PFOS document present all of the epidemiological studies but do not actually evaluate them; there is not a consistent indication of individual strengths and limitations of the studies, failures or not to adequately control potential confounding variables. Furthermore, there is no 'power analysis' type of evaluation, i.e., some of these studies included very small sample sizes and thus their power to actually detect effects may be limited, and yet they all appear to be weighted basically the same, i.e., studies with very small sample sizes with obviously extremely limited power to detect any effects appear to be considered the same as those with extremely large sample sizes. Studies with small sample sizes that nevertheless do find an effect of PFOA or PFOS actually suggest a robust type of effect.

The discarding of positive associations in human epidemiological studies because they do not produce frank clinical disease seems inappropriate and inconsistent with other EPA documents. For example, p. 4-3 in the PFOS document states that only a small number of ALT values were outside the normal range making the results difficult to interpret in terms of health. Physiological changes that are moving in the wrong direction, even if sub-clinical at the time, are still adverse effects. Are actual clinical diagnoses required for an adverse effect? This is especially the case given that the ranges of normal across populations are extremely broad.

The latter also raises the question of the cumulative toxicity of PFOA and PFOS and whether any consideration is being given to this.

Another such example is in the PFOS document, where it actually refers to a statistically significant, but not toxicologically significant effect (p.4-38); what does that mean? Also, p. 5-4 appears to dismiss any changes in thyroid function since no evidence of clinical hypothyroidism actually occurred. This whole approach with the human studies seems quite inconsistent with the reliance on increased liver weight in the absence of clinical pathology as the endpoint in the human studies.

Jamie C. DeWitt

It is not obviously or abundantly clear how the OW characterized the epidemiological data for either PFOA or PFOS. The studies were well-described, but the contribution of particular studies

to the overall assessment was not. The results of studies described in the hazard characterization section (4.4) need to be better characterized. For example, in the PFOA risk assessment:

- An increase in serum lipids associated with PFOA/PFOS exposure in humans is discussed as a risk factor for cardiovascular disease in humans; however, no evidence of increased cardiovascular disease has been observed in human populations. Additionally, serum lipids typically are decreased in animal models after PFOA/PFOS exposure, which is thought to be associated with/typical of exposure to agents that activate PPARα. If humans are known to respond to PPARα activators (i.e., fibrate drugs), why would the results between humans and animal models be discordant? This should be discussed.
- Several epidemiological studies reporting changes in liver enzymes clearly state that the clinical relevance of the changes in enzymes is unknown. Therefore, stating that the human studies "suggest effects on the liver as indicated by increases in liver enzymes" amounts to a mischaracterization of the data.
- No direct evidence of hepatotoxicity has been reported in epidemiological studies. This should be discussed.
- More in-depth characterizations are needed for the additional sections of the hazard characterization, with the exception of the thyroid section, which was well-described.

For example, in the PFOS risk assessment: Similarly to the PFOA risk assessment, the hazard characterization section needs to better discussion differences and similarities between effects reported in humans and effects reported in animal models.

Jeffrey W. Fisher

I am not an epidemiologist, but it appears to be adequate. Better characterization of the pros and cons of the human analyses and interpretation of the outcomes would be helpful.

William L. Hayton

The characterization of the individual epidemiological studies presented seems to be adequate. Public comments have identified the need to distinguish positive and negative associations with statistical significance, which seems to be a fair criticism. As noted in the response to Question 2, there are relevant studies that have not been described in the health-effects documents that ought to be considered and this includes some epidemiological studies. Most of the cited epidemiological studies have focused on healthy adults – workers exposed occupationally, residents of communities with or without contaminated water. These populations might be expected to be less sensitive to adverse effects than would early life stages and particular disease populations. Studies of potentially more sensitive populations would be desirable. The Frisbee et al. (2010) study of children 1-11.9 years and adolescents 12-17.9 years showed significant positive associations with serum lipid levels. Studies such as this one would be informative.

Matthew P. Longnecker

Please see the long paragraph above, under General Impressions, and some of the comments in response to item #2 above. Another point that the authors may want to consider is that studies that examine external exposure in relation to health outcomes may have special advantages in the case of PFOA and PFOS. While in general it is considered best to have a measure of exposure that is based on a biomarker of internal exposure, this may be problematic for several outcomes for PFOA and PFOS, because of the possibility of confounding or reverse causality that would not be an issue if an external estimate of exposure were used. For example, in Steenland K, Zhao L, Winquist A. A cohort study of workers exposed to PFOA. Occup Environ Med. 2014 Jun;71 Suppl 1:A55, when an external estimate of exposure was used for the Washington Works employees, no association with elevated cholesterol was found. The Viera et al. (2013) results are based on external estimates of exposure, whereas the similar study by Barry et al. (2013) are based on serum levels or estimates based on serum levels. The fact that association with kidney cancer is present in the Viera study decreases concern that the association was due to reverse causality. Steenland et al. 2012 used an external estimate of exposure to study cancer mortality and also found an association with kidney cancer. Lundin et al. (external estimate of exposure) had no cases of kidney cancer, though their study was also small.

Angela L. Slitt

The epidemiology data is well described and a thorough read. The data would be put in better context for the reader if there are average serum concentrations or ranges for the studies summarized in tables in addition to other key pieces of information.

A recent publication should be included in the document for consideration. Simon N, Fletcher T, Luster MI, Steenland K, Calafat AM, Kato K, Armstrong B. Epidemiology. 2013 Jul;24(4):569-76. doi: 10.1097/EDE.0b013e31829443ee.

Question 5. The OW has concluded that the cancer classifications for PFOA and PFOS are most consistent with respective classifications of suggestive evidence for carcinogenicity as described the EPA Guidelines for Carcinogen Risk Assessment (pp. 2-56, 2-57). Please comment on the strengths and weaknesses of this classification.

James V. Bruckner

PFOA-specific comments
I agree with EPA's choice of "Suggestive Evidence for Carcinogenicity." Epidemiological findings in occupationally-exposed and general populations to date are equivocal. Increases in Leydig cell tumors and liver adenomas have been reported in high-dose male rats. Increased incidences of pancreatic cell hyperplasia/adenomas and ovarian stromal hyperplasia/adenoma have been observed in female rats. More studies are necessary to confirm/expand these findings, and to assess carcinogenic potential in other species. Most mutagenicity and genotoxicity assays have been negative. Thus, there is some, but not undue cause for concern about the human carcinogenic potential of PFOA.

PFOS-specific comments
The document's authors have adequately and convincingly presented evidence for classifying PFOS as "suggestive of carcinogenicity."

Deborah A. Cory-Slechta

The classification of both PFOA and PFOS evidence for carcinogenicity as suggestive seems consistent with the clear limitations in the available data bases. In addition, the animal studies are limited to one species and mutagenicity does not occur in response to PFOA.

Jamie C. DeWitt

This classification is appropriate for both PFOA and PFOS given the epidemiological evidence, which is somewhat limited for PFOA and quite limited for PFOS. For PFOA, there is an association between kidney and testicular cancer, but there are limited data in animal models for these cancers and there is uncertainty that the mechanism of PFOA-induced carcinogenicity in animal models is applicable to humans. Studies of PFOS have the same limitations, but epidemiological studies have failed to find an association between PFOS exposure and cancer.

Jeffrey W. Fisher

I did not review the cancer studies for PFOA and PFOS.

William L. Hayton

The classification of "suggestive" is not unreasonable. The epidemiological studies, while showing apparent associations between PFOA exposure and cancer incidence in testicle and kidney as well as other tissues, do not provide a cause-effect relationship. However, they certainly do raise a concern about the carcinogenicity of the subject substances. Studies in animals have demonstrated conclusively that PFOA causes liver cancer in rats but the MOA that involves PPAR activation is absent in humans and it has been concluded that PFOA and PFOS cannot be carcinogenic in humans via this mechanism.

An EPA SAB panel (2006) consideration of this question resulted in a majority of the panel members favoring a classification of "likely to be carcinogenic" for PFOA. Board members acknowledged the PPAR MOA argument against causation of cancer in humans, but also found evidence that liver cancer in rats administered PFOA may also have had a MOA independent of PPAR activation. Recent epidemiological studies have added to the weight of evidence for an association between PFOA/PFOS exposure and cancer. Therefore a classification of "likely" is also not unreasonable to this reviewer. Lacking expertise in the nuances of applying the EPA's classification scheme, it is difficult for this reviewer to argue in favor of either "suggestive" or "likely".

Matthew P. Longnecker

The classification as "suggestive evidence for carcinogenicity" for both PFOA and PFOS is consistent with the guidelines put forth in the EPA Guidelines for Carcinogen Risk Assessment (2005). There are few pertinent data, including some suggestive but weak human evidence. There is clearly not enough evidence to classify these agents as likely human carcinogens.

Angela L. Slitt

Overall, the assessments for each PFOS and PFOA appear to be consistent with the EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a).

Strengths: Both classifications use evidence from human studies as guidance.

PFOS: The limited data that exist regarding PFOS and cancer were presented, the classification for PFOS under the EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a) is currently consistent with the suggestive evidence of carcinogenic potential descriptor. This assessment is reasonable, given that it is based on two studies that show a slight increase in adenomas that occurred in males and females.

PFOA: There is conflicting evidence regarding PFOA exposure and cancer risk. However, several human studies have found associations between PFOA exposure and elevation of cancer of the bladder and kidney. This is also supported by a chronic bioassay in rats, which demonstrated that PFOA was tumorigenic.

Question 6. Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

James V. Bruckner

PFOA-specific comments
The adjustments made to accommodate the influence of albumin binding and saturable renal tubular resorption of PFOA seem reasonable. I would defer, however, to someone with more experience in providing for these processes in PBPK models.

PFOS-specific comments
The PBPK model adjustments to estimate human equivalent doses appear to be appropriate. I defer to someone more qualified on the subject.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

Jamie C. DeWitt

Several PK models have been reported in the literature for these compounds and are relatively well described in the documents. The documents assert that the existing PK models do not consider the impact of renal tubule transporters and albumin binding; while, many of the existing models appropriately predict serum concentrations in humans and other species, but they are mostly based on empirical models. Please explain the weaknesses of such empirical models.

Additionally, numerous studies for both compounds report serum and tissue concentrations in humans and other species, which can be compared to existing models. Both documents present a revised model that amounts to a reanalysis of data from studies that report serum concentrations. A more thorough discussion of the improvements made by the reanalysis is needed to better understand if the improved model adequately estimates or predicts the clearance rate and other parameters for which confidence is low. Alternatively, the publication (Wambaugh et al., 2013) that thoroughly describes the reanalysis could be referenced.

Jeffrey W. Fisher

Serum protein binding: Both PFOA and PFOS are highly bound in serum proteins across species, thus model adjustments seem trivial for interspecies extrapolation. Steady-state conditions can be assumed to estimate the free fraction (e.g., 2% based on paper by Han et al., 2003 for humans). I did not find a discussion about the half-life of serum proteins, which may have some influence on the 'apparent' serum half-life of PFOA and PFOS. The estimated fraction of free PFOA or PFOS is important for describing urinary and fecal elimination in rats (and other species) and the plasma concentrations of total PFOA and PFOS. Thus, the model predicts total PFOA and PFOS in serum or plasma, but the free fraction estimates drive the gradual clearance of total BPA from plasma or serum by describing clearance of free.

Renal reabsorption: The renal reabsorption hypothesis involving species specific and sometimes gender specific transporters to describe the pharmacokinetic data represents sound judgment. This departure from normal allometric scaling is suggestive of active transport processes. Few PBPK models explicitly describe transporters with drugs or chemicals, although the field is moving in this direction. Thus, the approach used for PFOA and PFOS is adequate, that is, a hypothesis was evaluated by employing empirical PK-based kinetic analyses. Because the mechanistic details are missing for each species/gender, scaling of this biological phenomenon is not possible at this time. This is not a weakness, but represents the state of the science.

William L. Hayton

A very important strength of the documents is the attempt to deal with the interspecies differences in pharmacokinetics so that adverse effects across species are compared on the basis of internal, systemic exposure to PFOA and PFOS, instead of basing comparisons on the administered mg/kg dosages. PFOA and PFOS have complicated pharmacokinetics that have proven difficult to model. While a relatively simple one-compartment model appears adequate to analyze single, low doses, this model fails when it is extended to higher doses and repeated doses. Nonlinearities appear associated with saturable plasma protein binding and with saturation of transporters thought to be involved in the reabsorption of the compounds from renal filtrate.

A weakness of the pharmacokinetic model adjustments is the lack of robustness of the models. Despite the extensive efforts of talented pharmacokineticists, development of a model that scales across species and handles a range of dosages and a variety of administration routes has proven elusive. The two compartment model of Andersen et al. (2006) has formed the basis of the model used in the draft documents. The model incorporates saturable resorption of PFOA and PFOS from renal tubular filtrate. While protein binding is known to be saturable (fraction free increases with concentration), the model uses a species-specific but constant free fraction. Model parameter values for mouse, rat and monkey were used to predict reasonably well measured serum concentrations after a fixed daily dosing regimen, Tables 5-6 – 5-8 for PFOA and 5-8 and 5-10 for PFOS. This agreement between predicted and measured serum concentrations gives confidence that the model-calculated AUC values and final serum concentrations associated with adverse health effects (or in the case of liver weight, biological marker of exposure) are realistic and a basis for estimation of RfD. While the model used

appears adequate for the purpose, the model parameters that were used have some markedly non-physiological values. (Information subsequently provided at the reviewers meeting explained some of the departure from expected physiological values, as discussed in a following section.)

Matthew P. Longnecker

For PFOA and PFOA, the MCMC model results (predicted final serum value) were compared to the measured final serum values, and the agreement was fairly good. For PFOS, the MCMC model results were compared to those from Loccisano et al. (2012b) and were found to be similar, which is also reassuring. Because the PBPK models of PFOA and PFOS are empirical, and have been shown to give results that agree reasonably well with observed data, the adjustments to accommodate the impact of albumin binding and renal tubule transporters are not critical. More data on albumin binding and renal tubule transporters might allow improved understanding of the pharmacokinetics of these compounds, but may not necessarily cause substantial improvements in the empirical predictions from current models.

Angela L. Slitt

The current weakness of the models is that data on species differences in PFOA and PFOA for various key transporters is limited and the document is also using mRNA data for various transport proteins to explain gender differences in urinary elimination. First, with regard to PFOS accumulation in the liver compartment, it is necessary to compare affinity of human versus rat for OATp mediated transport. This alone is tricky because of species differences in OATps. If PFOS-induced liver effects are related to PFOS accumulation in liver, it is would be helpful to understand whether a lower affinity of human OATp1b1 and 1b3 compared to rat OATp1a1 predicts lower hepatic PFOS accumulation. More is known about PFOA, but a similar argument can be made for PFOA. In addition, more comprehensive, controlled assessment of renal transporter affinity for PFOA and PFOS is needed to better model the species difference in urinary elimination.

The document often speculates about PFOA or PFOS regulation of transporter expression, but some papers cited (Cheng and Klaasen) do not have enough data at the protein level to support whether these differences in transporter expression are the drivers of toxicokinetic differences between males and females.

Question 7. Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

James V. Bruckner

PFOA-specific comments
Despite the complexities and unknowns involved in plasma protein binding and renal tubular functions (i.e., glomerular filtration, basolateral tubular excretion and resorption, and apical tubular excretion and resorption), it is necessary to: (a) simply model only for saturable tubular resorption; and (b) use a range, or distribution of parameter values consistent with existing kinetic data. Unfortunately, optimization sometimes results in selection of physiological parameters that are not biologically-realistic, or plausible.

PFOS-specific comments
The parameters used in the modeling are biologically plausible.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

One unclear component of Table 5-7 in the PFOA document is the column labeled Species/Strain Used for prediction, which in every case is the same as the column labeled Species/Strain and is not otherwise adequately explained.

Jamie C. DeWitt

It is not clear that the parameters in Table 5-5 in the PFOA document and Table 5-7 in the PFOS document are from the Andersen et al. 2006 PK model or if they are parameters used in the reanalysis of the data. This needs to be better explained in both documents. Additionally, all of the units in the tables need to be explained and re-checked for accuracy.

Jeffrey W. Fisher

The authors should entertain the calculation of data derived AUC (e.g. Table 5-6) to compare to the model derived AUC, just as was done with measurement of total PFOA in serum. This works for the animal studies. The choice of using the empirical model over the more recent physiological models may be a weakness and our understanding of transporters advance.
The evolution of chemical-specific PBPK models for use in risk assessment and regulatory applications has repeated itself several times. This is, the first empirical non-physiological model(s) or PBPK models contain hypotheses generating ideas and later models test some of

these hypotheses, especially if additional experimental data become available. In the case of PFOA and PFOS, the EPA selected not to use the most recent PBPK models for PFOA and PFOS, but instead use a computational empirical based model (Andersen et al. 2006) that was the first attempt to quantitatively interpret the kinetics of PFOA and PFOS across species of laboratory animals. The authors did publish their model (Wambaugh et al., 2013). The authors chose not to use a human model because a lack of information for Bayesian analyses. The justification for their extrapolation methods should be stated and the published reference for the model should be cited.

Model parameter distributions (Bayesian analyses) appear to be biologically implausible in some cases, covering many orders of magnitude. The authors should discuss this issue and check the units of model parameters in Tables.

Both model parameters tables need to include a description of what the parameter represents and cite a figure. The figures showing the Andersen et al. 2006 model do not show all the model parameters and have different nomenclature.

The Andersen et al. 2006 paper is a critical paper offering a quantitative explanation for the PFOA and PFOS kinetic data sets.

William L. Hayton

In the "Pharmacokinetic Model Approach" sections of the documents, it is not made sufficiently clear that the parameter values in Table 5-5 (PFOA) and Table 5-7 (PFOS) were from re-fitting the published data, rather than using parameter values from the original literature reports.

PFOA Table 5-5, p. 5-12

Body Weight and Cardiac Output values are reasonable and typical.

k_a values for mouse and monkey seem extremely large; absorption half-lives would be on the order of 10 seconds, which is physiologically unrealistic. All of an oral dose would be absorbed within a minute, mimicking a rapid i.v. bolus dose. Serum concentration-time profiles may not be sensitive to these values, however so they are not disconcerting for the intended use of the models. The rat values appear reasonable.

V_{cc} values appear reasonable. The total steady-state volume of distribution value [$V_{ss} = V_{cc} \times (1 + R_{v2:v1})$] compares favorably with one-compartment V_d values for CD1 mouse, but V_{ss} values for the other columns (species) appear too large, due to the large $R_{v2:v1}$ values.

k_{12} values vary a lot across the columns, suggesting that k_{12} may be highly correlated with another parameter (e.g., $R_{v2:v1}$).

$R_{v2:v1}$ values also vary a lot across the columns.

T_{maxc} values are consistent across the columns; expressed in Gm/hr, they seem very large. For example, 2032 Gm/hr (4.91 moles x 414 Gm/mole) for the CD1 mouse. Even on a kg body weight basis could mouse renal tubules resorb 2 kg PFOA per hour? This maximum rate of resorption must far exceed the rate of filtration of PFOA at the glomerulus. (Clarification at the reviewers meeting explained this apparent departure from physiological reality. The units had been mis-specified in Tables 5-5 and 5-7. They were in fact micromole per hour

and micromolar for T_{maxc} and k_T instead of molar based. Thus T_{maxc} mouse value was 2 mg/hr, which is physiologically plausible.)

k_T values are the concentration in glomerular filtrate that half saturates the resorption transporters. Expressed in mg/mL, they seem large, much larger than the urine concentration that would be expected; e.g., for CD1 mouse, k_T is 15 mg/mL where free serum concentrations (Free x C_{serum}) would be about 0.3 µg/mL with 10 mg/kg in the mouse. So the transporter would not become saturated except at extreme doses. The value used by Andersen et al. (2006) for monkey was 0.00001 mg/mL. Unit specified in Tables 5-5 and 5-7 should be µM, not M.

Free fraction values measured in vitro are 0.01 or less at low PFOA serum concentrations (Table 3-1). The Free values for rat seem much higher than the measured values.

Q_{filc} is defined as a fraction of blood flow (renal or cardiac output?) to the filtrate (bottom of p. 5-11) but has units of flow in Table 5-5.

V_{filc} values are much smaller than the 0.01 L value used by Andersen et al. (2006), although Andersen et al. state that the model output is insensitive to this parameter and that their value was assumed.

PFOS Table 5-7, p. 5-15

Body Weight and Cardiac Output values are reasonable and typical.

k_a values for female mouse and monkey seem extremely large – see comment above for PFOA.

V_{cc} values appear reasonable. See comment above for PFOA.

k_{12} values vary a lot across the columns, suggesting that k_{12} may be highly correlated with another parameter.

$R_{v2:v1}$ values appear reasonable and consistent with other reports of V_{ss} values for PFOS.

T_{maxc} values are highly variable across the columns and seem much higher than physiological reality would allow. See comment above for PFOA.

k_T values are physiologically unrealistic and highly variable across columns. See comment above for PFOA.

Free fraction values have been measured in vitro and are 0.01 or less at low PFOS serum concentrations (Table 3-1, p. 3-3). The Free values in Table 5-7 are consistent with the measured values.

Q_{filc} is defined as a fraction of blood flow (renal or cardiac output?) to the filtrate (bottom of p. 5-14) but has units of flow in Table 5-7.

V_{filc} values are much smaller than the 0.01 L value used by Andersen et al. (2006), although Andersen et al. state that the model output is insensitive to this parameter and that their value was assumed.

While the parameter values for the pharmacokinetic models predict reasonable serum concentrations that generally agree with measured values (Tables 5-6 – 5-8 for PFOA and Tables 5-8 and 5-10 for PFOS), their high interspecies variability suggest that the models may be unreliable for prediction of internal exposures after other intake regimens and during a depuration phase.

Matthew P. Longnecker

Please see the answer to the previous question.

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Angela L. Slitt

The parameters included appear to be appropriate, but this lies outside of my area of expertise.

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Question 8. The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

James V. Bruckner

PFOA-specific comments
The adult male rat data of Kemper (2003), from which the rat half-life and clearance (CL) were obtained, appear to be solid. It is reasonable to select the human half-life of 2.3 years reported by Bartell et al. (2010), as their study population included equal numbers of males and females. Division of the rat CL by the human CL to yield a value of 219 is fine. I did not examine the publication of Bartell et al. (2010) to evaluate their data or methodology used to derive a human half-life of 2.3 years. Therefore, I am uncertain about its accuracy.

PFOS-specific comments
I would again defer to someone with more expertise.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

Jamie C. DeWitt

While the overview of the individual studies that calculated Vd and half-life for each compound was detailed and complete, the rationale and analysis concerning *why* particular values were selected were insufficient. Additionally, as addressed in Charge Question 6, the rate of clearance/elimination likely contributes to the differences in half-life that are not associated with differences in the Vd. Therefore, a 3-fold uncertainty factor for species differences in pharmacodynamics (UF_A) was utilized for both compounds. What was the justification for using a UF_A of 3? The section on UF application needs a more thorough discussion regarding the choice of this value given differences in clearance. If the section on model adjustment (a suggestion in Charge Question 6) is better described, this comment may no longer be applicable.

Jeffrey W. Fisher

The use of this non-compartmental method should be justified. Why not use a PBPK model? Assuming steady state in the humans does allow for calculation a human equivalent serum concentration associated with a laboratory animal concentration. In what region of the exposure-dose range would nonlinearity occur in humans? Some type of discussion is needed

about the assumptions of this methodology and why it was used. I would like to see statements about if the NOAEL, LOAEL, and a BMDL doses are in the linear range for kinetics.

The authors should use the Bayesian analysis for animal studies to inform the UF. Use percentiles to explore Vd and half-life to support UF values. I did not see any attempt to use distribution information generated from the model beyond the central tendency or mean values. Please state why this is the case. It seems that the distribution information generated from the Bayesian analysis could be used to support UF development.

William L. Hayton

PFOA-specific comments

For male rat, the Kemper (2003) study appears to be the best source of pharmacokinetic parameter values, which were obtained by a model-independent analysis of serum concentration-time data from rats that were dosed by oral gavage at dosages of 0.1, 1.0, 5.0 and 25 mg/kg. In addition, there was a 1.0 mg/kg dosage administered intravenously, and a 0.1 mg/kg oral gavage dose with an extended sampling time. Each treatment used four animals. The CL and $t_{1/2}$ values appeared to be independent of dosage and route of administration. It would therefore be reasonable to average all 6 mean values for each parameter to give an over-all mean of 24 determinations. The average (n=24) values for male rat were CL = 0.0209 L/kg/d and $t_{1/2}$ = 7.83 d. These values can be used to calculate a V_d value ($t_{1/2}$ x CL / ln 2), which is 0.236 L/kg.

It is not apparent on p. 5-20 why a V_d value of 0.17 was used with half-life to calculate CL_{rat} when Kemper (2003) reported CL values and not $t_{1/2}$ values. (At the peer review meeting, it was clarified that the data of Kemper (2003) were re-analyzed and as a result the parameter values in the health effects documents differ somewhat from those published with the data in the original reports.)

The CL_{human} value was taken to be 0.00014 L/kg/d. There are no direct measurements of this parameter. Thompson et al. (2010) assumed that the intake rate of PFOA for subjects using PFOA-contaminated water was 91% of the PFOA in 1.4 L/d of water. This intake rate was used along with a PFOA half-life of 2.3 years to calculate a V_d value of 0.17 L/kg. This is the same value that was used in the health effects document for the rat (p. 5-20). The V_d values available in mouse, rat and monkey are about 0.2 L/kg, so the $V_{d,human}$ set at 0.17 L/kg is not unreasonable but it lacks the certainty of the rat V_d value.

The health effects document used a $t_{1/2}$ for PFOA in human of 839.5 d (2.3 years), which seems to be toward the low end of the range of values that have been reported. Along with Vd = 0.17 L/kg one arrives at CLhuman = ln 2 x 0.17 / 839.5 = 0.00014 L/kg/d.

The ratio CL_{rat} / CL_{human} calculated using the mean CL_{rat} from Kemper (2003) would be 0.0209 / 0.00014 = 149, which is about twice the value calculated on p. 5-21. This difference arises from the calculation of CL_{rat} using the $V_{d,human}$ and a half life of 11.5 d instead of using the CL_{rat} directly from Kemper (2003). The mean half life from Kemper (2003) was 7.8 d.

The CL_{mouse} / CL_{human} ratio is accurate, using Lou et al. (2009) data. A calculation for monkey is not shown.

PFOS-specific comments
Chang et al. (2012) appears to be the best source of pharmacokinetic parameter values for mouse, rat and monkey. Butenhoff and Chang (2007) is given as the reference for a 48-day half-life in rat; this is a final report, internal to 3M. The Chang paper gives half-life values for male and female Sprague-Dawley rat at 2 mg/kg and 15 mg/kg. The average V_d for the four groups of three/group was 0.71 L/kg. This is higher than the 0.23 L/kg value used in the draft document (p. 5-23). The 0.71 L/kg value is also higher than values for mouse, monkey and human, which are closer to the 0.23 L/kg value used in the draft document. The draft document ought to acknowledge this difference; it may be that the value in the 3M report is lower than the published value; Chang was a co-author for both sources. The Chang et al. (2012) paper gives CL_{rat} values that are 0.0051 L/h/kg for female (similar for 2 and 15 mg/kg doses) and for males, 0.022 and 0.011 L/h/kg for the 2 and 15 mg/kg doses. A single average value for CL_{rat} would be 0.011 L/h/kg, about 3 times the value used for the UF_A calculation in the draft document. The male value is about 2-3 times the female value and it may be appropriate to calculate a different UF_A value for each sex. Using the single CL_{rat} averaged across two doses and both sexes (0.011 L/H/kg) would give a CL_{rat} / CL_{human} ratio of 0.011 / 0.000081 = 135 and a UF_A = 407, substantially higher than the value of 123 in Table 5-15.

The UF_A values calculated for mouse and monkey appear to be in line with the literature values for PFOS CL values in these species.

Matthew P. Longnecker

The PBPK model of Loccisano et al. 2013 (for humans) can be used to calculate a volume of distribution for PFOA of 177 ml/kg, which is very close to the value of 170 ml/kg based on Thompson et al.'s 2010 one-compartment model . For PFOS, the corresponding value from the PBPK is 280 ml/kg, compared with the value of 230 ml/kg used in the Health Effects Document. This 22% difference could have an impact on some calculations. (Note: the PBPK model-based volumes of distribution were calculated by Marc-Andre Verner of the University of Montreal. He had calculated these values in the course of a separate project.)

For humans, the half-life data all depend on the assumption that ongoing exposure is negligible compared to baseline exposure, a reasonable assumption in most of the populations used to estimate half-life. While the Seals et al. (2011) gave estimates that were slightly different for PFOA in some cases, the methods employed in this study were not as strong as for Bartell et al. (2010) or the Burris et al. studies (2000; 2002). The agreement within species for the half-life estimates for PFOS are reassuring. The animal data on the half-life of PFOA are relatively sparse (2 rat studies that agreed reasonably well, 1 mouse study, 1 monkey study). For PFOA, the UF_As and RfD that were calculated based on the half-lives (expressed as clearance) would not have been substantially altered by alternate choices for specific values. The same is true for PFOS.

Angela L. Slitt

Strengths of the available data is that for the several species thorough evaluated, the half-life values are very consistent. For example, the several human studies cited report a range in calculated PFOS half-life in humans to be 4.1-8.67 years, two studies putting monkeys at 110-132 days, and rat generally has a narrow range with 3 out of 4 values provided ranging from 39.8-48.2 days for PFOS. An inconsistency is the Chang et al., 2012 describing a half-life of females of 66.7 days when in general female rodents may have faster elimination of PFOS.

Question 9. A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

James V. Bruckner

PFOA-specific comments
The procedure used to calculate PODs adheres to standard EPA guidelines and policy. The presentation of their derivation is clear, concise and transparent. It is certainly interesting that the range of PODs and resulting candidate RfDs is so narrow. Nevertheless, as discussed previously, I do not agree with their selection.

PFOS-specific comments
See my comments under General Impressions.

Deborah A. Cory-Slechta

While it is the case for both PFOA and PFOS that values from different points of departure are fairly narrow, the transparency of the analyses in neither case is clear. There is no rationale described even as to why these analyses were done on all of the studies, what was the primary study and how others related to that etc., i.e., this presentation does not follow the typical presentation format of IRIS documents in either its presentation of rationales and strategies, nor in the conclusions that it reaches. In both cases, it is only the single sentence indicating that modeling from one particular study will be protective of effects at other studies using higher exposures. This section in both documents needs introductory paragraphs that describe the specific strategy, choices of studies and the rationales for those choices.

As noted in response to Charge Question 3, the rationale for discarding the human epidemiological studies is not sufficient and requires rationale other than that stated and therefore, the question of using the human data remains open. As noted in response to Charge Question 1, in this reviewer's opinion, the increased liver weight can be justified as a departure point for assessment of RfDs, but as discussed at the face-to-face meeting, additional text supporting this choice is needed.

Jamie C. DeWitt

This particular section contained inadequate detail on why particular studies *were* or *were not* chosen. For example, immunotoxicity as an endpoint was not chosen for PFOS, based on "*in vitro* measures of immunocompetence on mice may not be relevant to the human experience and limited human data from epidemiology studies are inconclusive regarding the immunotoxicity of PFOS in humans"; however, the breadth of data from in vitro/ex vivo immunotoxicity studies for PFOS were not thoroughly discussed (please see Charge Question #2 for two additional in vitro studies).

For both compounds, an increase in absolute liver weight was selected as an endpoint as it was a common *effect* [sic] in both short and long term studies. However, the toxicological relevance of an increase in absolute liver weight was not discussed other than to indicate that it was a sign of altered homeostasis. Further, the co-occurrence of increases in absolute liver weight with other toxicologically-relevant endpoints (i.e., immunotoxicity and/or reproductive/developmental toxicity) is not a toxicologically valid justification for the use of liver weight as an endpoint for an RfD. Therefore, the analysis was not sufficiently transparent to deduce its relative strengths and weaknesses. Certainly, choosing an endpoint that occurs across species and occurs at relatively low doses will likely be protective of exposed humans; however, will it be a defensible endpoint? As currently written, the choice of this endpoint for an RfD is not adequately defended.

Jeffrey W. Fisher

I did not review the toxicity data.

William L. Hayton

For PFOA, a 10% increase in liver weight was selected as the metric for effect, which was "… not made based on toxicity but on the desire to find a common denominator against which to evaluate dose-response across studies and justified by the fact that other adverse effects accompanied the LOAEL for increased liver weight in some cases." The lowest serum concentration associated with an increase in liver weight was calculated for female mouse to be 20.33 mg/L (p. 5-16, PFOA document). These data are referenced to DeWitt (2008); this paper has only summary information on liver weights, all of which exceeded 20% weight gain, going as high as 70%; and it is not apparent in PFOA document how these liver weight gains were used to estimate an LOAEL for 10% liver weight gain.

Many of the animal studies of hazard assessment were conducted under conditions where the duration of the exposure was relatively short compared with the half-life, and steady state had not been achieved. It is not apparent how the NOAEL and LOAEL values from such studies were adjusted to account for the non-steady state situation. For example, the 20.33 mg/L PFOA concentration associated with a 10% increase in liver weight (Table 5-9) emanated from a 15 day drinking water exposure to 0.94 mg/kg/day that resulted in an average serum exposure of 20.33 mg/L (0 – 29.7 mg/L over 15 d, Tables 5-7, 5-9). For a fixed daily dose, the time to 90% steady state for mouse would be about 63 days (3.3 x half life, which was 19 days), and after 15 days the serum concentration would only be about 15% of its steady-state value. This seems to suggest that the RfD would have been over-estimated by a factor of 7, since the 0.94 mg/kg/day at steady state would have produced a serum concentration of about 150 mg/L, not 20.33 mg/L. This analysis is based upon the behavior expected from one-compartment model pharmacokinetics. As discussed on p.5-9 of the PFOA document, the steady-state serum concentration of PFOA is achieved in a much shorter time than one-compartment model kinetics would predict. Whether the target-site steady-state concentration of PFOA also occurs in a much shorter time than one-compartment model kinetics would predict (3.3 x half life) is apparently unknown.

Matthew P. Longnecker

This part of the document seemed especially strong and transparent. The agreement between methods was reassuring. The weaknesses and assumptions were well discussed. Please see the minor editorial comment on this issue given for Charge Question 1, above.

Angela L. Slitt

The RfD Point of Departure was based on animal studies that include monkey and rat.

Question 10. The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days, and occur at comparable human equivalent dose (HED) levels. The current, draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

James V. Bruckner

PFOA-specific comments
I do not believe it is appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures. Steady-state is apparently achieved in monkeys within 4 - 6 weeks (Butenhoff et al., 2002). Steady-state likely takes considerably longer in humans. Thus, RfDs for shorter periods of exposure should be based upon results of studies of similar duration.

PFOS-specific comments
I do not believe the candidate RfDs, as calculated, are applicable to different durations of exposure.

Deborah A. Cory-Slechta

While initially believing that it was appropriate conclusion for PFOA and PFOS, based on the correspondences in RfDs across short and longer term exposure, discussion at the face-to-face meeting made clear that this approach is not reasonable and requires additional consideration.

Jamie C. DeWitt

This approach may be appropriate given the relative similarity of serum concentrations attained regardless of study duration, i.e., steady state in serum is attained after a relatively short period of exposure. This appears to be consistent across studies with various species of animal models. However, the document authors might need to reconsider given what we may or may not know about liver hypertrophy. In the Hall et al. (2012) paper on liver hypertrophy (discussed during the public meeting), increase in liver weight is an adaptive response that may not be adverse UNLESS weight increases >150% over a three month or longer period may. Following this large and prolonged increase in weight, the end result may be a hepatocarcinogenic response. However, none of the studies contained in the documents indicate that longer term exposures increase liver weight to this degree.

Jeffrey W. Fisher

The departure from K=CXT (Haber's law) should be based on the toxicity endpoints of concern and what is known about dose-exposure kinetics/responses for these chemicals and other chemicals that target the same endpoint, not that the HED values are comparable. The NAS

AEGL committee only considered primary irritation for inhaled chemicals as an endpoint that was independent of duration of exposure. There is an SOP if needed for reference.
The time to steady state should be included in a table for the lab animals. Toxicity studies conducted for less than 30 days (perhaps?) are not at steady state for the pharmacokinetics of PFOA. Thus the measured serum levels would be different than at steady state. The shorter the duration of the toxicity test, the more impact this could have on extrapolation to chronic exposures in humans. My personal preference would be to use PBPK models for all species and consider only long term exposures for extrapolation to humans.

William L. Hayton

This depends in part on how quickly the PFOA/PFOS concentrations at sites of toxicity come to steady state. Since the Vd for these chemicals is small (~ 0.3 L/kg) it seems likely that the concentrations in tissues rise in pseudo equilibrium with the rise in serum concentration. That said, the half lives are relatively long due to the very small clearance ($t_{1/2} = \ln 2 \times V_d / CL$). If one-compartment kinetics apply, then a guideline for time to 90% steady state is 3.3 $t_{1/2}$. For studies that expose animals for a period of time shorter than 3.3 $t_{1/2}$, the serum concentration would not be at steady state and the internal systemic exposure (serum concentration) would be less than what it would be if the exposure were longer than 3.3 $t_{1/2}$. This effect would seem to lead to overestimation of the intake rate that was associated with a particular internal exposure and associated biological endpoint. For example, the $t_{1/2}$ of PFOS in mouse is about 36 days and 3.3 $t_{1/2}$ is 120 days. Consider a 28-day exposure using a fixed daily dose that produced an LOAEL of "X" mg/kg/day. On Day 28, the body level would only be 42% of the steady state level, and the average body level over the 28-day period would be about 21% (approximating the increase as linear and not exponential). The true LOAEL would be 0.21 "X" mg/kg/day; i.e., intake of 0.21 "X" mg/kg/day would produce a body level at steady state that was the same as the average body level produced by X mg/kg/day administered over 28 days. The time to 90% steady state for a fixed intake rate is quite long; from the literature in the health effects documents, the times in the following table were calculated. From this line of reasoning, exposure times less than two half-lives begin to significantly overestimate intake rates associated with particular endpoints. This analysis is based upon the behavior expected from one-compartment model pharmacokinetics. As discussed on p.5-9 of the PFOA document, the steady-state serum concentration of PFOA is achieved in a much shorter time than one-compartment model kinetics would predict. Whether the target-site steady-state concentration of PFOA also occurs in a much shorter time than one-compartment model kinetics would predict (3.3 x half life) is apparently unknown.

	CL		Vd		$t_{1/2}$		Time to 90% steady state	
	[mL/d/kg]		[mL/kg]		[d]		[d]	
Species	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS
Mouse	6.6	5	180	265	19	36	63	120
Rat - Male	23	16	273	947	8.4	40	28	92
Rat - Female	776	5.2	150	476	0.13	66	0.43	218
Monkey	6.3	1.4	190	238	27	121	89	400
Human	0.085	0.08	170	230	1378	2000	12.5 yr	18 yr

In addition, this line of reasoning may be incorrect if the assumption of one-compartment kinetics is incorrect. For multi-compartment models the serum concentration and target organ/tissue could come to their pseudo steady state levels relatively quickly while slowly equilibrating (deep) sites slowly approached steady state. Simulation with PBPK models for PFOS and PFOA may help answer this question.

Associated with the uncertainty introduced by exposures that were shorter than the time to achieve steady-state concentration at the target site is the exposure time required for the adverse effect to be expressed. While some adverse effects may occur immediately and directly in proportion to the concentration of PFOA or PFOS at the target site, other adverse effects may be slow to become manifest. These "indirect adverse response" behaviors are well known in the drug action arena; e.g., certain antidepressant drugs require several weeks exposure to the target site before the effect of the drug appears. This lag time is not associated with pharmacokinetics (time to steady state) but with indirect-response pharmacodynamics. It could be argued that uncertainty factors are needed for both pharmacokinetics (pre-steady state condition) and pharmacodynamics (or toxicodynamics) to account for possible indirect response behavior.

Matthew P. Longnecker

EPA might want to consider using an uncertainty factor for duration, for two reasons. First, the monkey data for PFOS used for the point of departure were from a study where the duration of exposure was relatively short-term relative to the half-life, and it appeared that duration of dose affected liver and other adverse outcomes detected at higher doses, and no monkey data were used in the POD for PFOA. Second, questions raised by Drs. Hayton and Fisher at the peer-review meeting made me less comfortable with the calculations that used average serum concentration derived from the AUC and duration of dosing to compare with humans, who are more likely to be near steady-state.

Angela L. Slitt

Yes, but this lies outside of my area of expertise.

Question 11. In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.

James V. Bruckner

PFOA-specific comments
No comment.

PFOS-specific comments
No comment.

Deborah A. Cory-Slechta

In initial response to charge questions, I found it difficult to understand specifically what this charge question was asking for a response to: Does this refer to the data in Table 5-10 for PFOA? Wouldn't you include animal to human UF values at the least. Since the data for the studies listed in the Table is not clear as to their duration (columns are needed for this information, or add to the Study box), it is not clear whether a UF for study duration is warranted. It is not clear how sex differences are being accommodated in any of these.

At the face-to-face meeting, however, with some additional input from EPA, it was clear to all that there was no need to do such derivations from animal to human, which could instead be derived directly from the human data and thus presumably this is no longer an issue.

Jamie C. DeWitt

Would this approach take into account differences between animal studies that have a defined exposure duration and data from NHANES, where exposure duration is assumed to be continuous (although it may not be), if exposure duration does not appear significantly impact serum concentrations? Additionally, how would the half-life estimations from the Seals et al. (2011) study, which contained two half-life estimations based on concentration and time, impact this approach?

Jeffrey W. Fisher

Again, is the system linear in the exposure/dose ranges of interest? I would try to determine an UF by exploring a range of predicted human serum levels. Attempt to use 5,50, and 95% for animal serum concentrations with a 5,50, and 95% CL values in the animals and for the human perhaps use two CL values representing a high and low. The idea is to use as much information

as you can to determine the possible range of values. This will help guide the selection of uncertainty values.

William L. Hayton

This calculation is equivalent to dividing the animal dosage by the CLhuman, assuming that the animal serum concentration is at steady state ($C_{ss,animal}$) maintained by a constant dose rate (DR).

$$C_{ss,animal} / CL_{human} \div CL_{animal} = CL_{animal} * C_{ss,animal} / CL_{human} = DR / CL_{human}$$

This calculation would give the steady-state serum concentration in human that would be produced by the animal dose rate. (I will have to study this to understand the question; the calculation does not make sense to me.)

At the peer review meeting, the aim of this calculation was clarified. Authors desired a way to calculate a steady-state serum concentration ($C_{ss,human}$) that would result from the human equivalent dose rate (HED) administered until steady state. The appropriate calculation would be:

$$C_{ss,human} = HED / CL_{human}$$

Matthew P. Longnecker

The proposed division by animal clearance ratios does not make sense to me. The average serum values from animal studies is already taking pharmacokinetic variability in blood levels during the observation period into account, and human blood levels will be relatively constant. Thus, it would make sense to directly compare the POD estimated average serum concentrations from animal models to the blood levels in NHANES. With respect to uncertainty factors that would be need consideration for this approach, it seems that UF_H, UF_L (For LOAEL and HED_{LOAEL}), UF_D, and the component of UF_A that takes pharmacodynamics into account would all still be applicable.

Angela L. Slitt

This is outside of my area of expertise.

Question 12. Please describe any suggestions you have for improving the clarity, organization, and/or transparency of the draft documents.

James V. Bruckner

PFOA and PFOS-specific questions
See specific observations.

Deborah A. Cory-Slechta

While the EPA authors are aware of updates in the IRIS process, it might be very helpful to look at some of the new documents coming through that process for guidance as to the levels of critique and evaluation that are now included in these documents. They also include an introductory chapter focused specifically on the literature searches and literature that is included vs. excluded.

The Executive summary does not provide sufficient rationale and descriptions to lead a reader through the steps to what is concluded and reads more like an abstract than an Executive Summary. Since this may be the only section read by many reviewers, it is important that it provide a succinct journey through the process. Here again, the new IRIS documents (e.g., trimethylbenzene) could provide a useful template.

Chapters 3, 4 and 5 could each benefit from an opening paragraph describing what the section's goals are, and integration and conclusion sections at the end that establish the basis for the presentation in Chapter 5. Currently the Hazard Identification studies generally treat all studies as of equal strength/power, which is certainly not the case. These chapters should present that kind of critical and transparent assessment as it ultimately serves as the basis for decisions that are made.

The inclusion of sections on in Vitro data did not ultimately seem particularly relevant in the outcome for these compounds and could be significantly shortened to add more to Chapter 4 on study strengths and weaknesses. However, where pertinent, it would probably be more useful to break that section up and insert test where it follows an in vivo discussion.

Tables could be considerably improved and made far more useful to the reader for comparative assessments. As of now, they require going back and forth to the text to capture additional details of the studies, e.g., sample sizes, species etc. and could benefit the reader significantly with those additions. For the human assessments, it is equally important to include these details in the chapter as well as a column of study strengths and limitations.

While charge questions ask whether the appropriate studies were chosen as key studies, this reviewer does not remember that that term was even used in the documents, certainly no explicit mention was made as to which studies were considered key studies. This would seem to be a section that should be included in Chapter 4 more explicitly. Chapter 5 of both documents, more so PFOA, are confusing as almost all studies are subjected to modeling, for reasons that are

never presented in sufficient detail and simply followed by statements that a selected study (not really well presented in Chapter 4 as a selected study) will protect against other adverse effects.

Jamie C. DeWitt

The documents lack a critical analysis of differences between findings of epidemiological studies and findings of animal models. As stated in the comments to Charge Question #3, what is particularly valuable about the PFOA/PFOS database is that it is relatively extensive in that it includes data not only from occupationally-exposed humans, but from people highly exposed to environmental concentrations of PFOA/PFOS, and from people in the general population who have detectable concentrations of these compounds.

Critical to this analysis is a discussion of concordance and lack of concordance between human data and animal model data. For example, immunotoxicological findings appear to be consistent between humans and rodent models whereas serum lipids are not. How do these differences impact the overall confidence in the database and derivation of the RfD?

All of the sections related to the PK models developed by ORD need additional information for clarity and transparency. As written, it is not clear that the PK values presented throughout the document actually represent a reanalysis of existing data from studies that reported serum concentrations. The Wambaugh et al. (2013) study could be referenced to shorten this exercise as this publication provides details on the reanalysis of existing data.

Justifications for choosing or not choosing particular values or endpoints need to be more thoroughly detailed throughout both documents, especially for endpoints that appear to occur in both experimental animal models and exposed humans (i.e., thyroid hormone disruption and immunotoxicity).

Jeffrey W. Fisher

These documents represent an enormous undertaking to describe studies with PFOA and PFOS. Keep the same writing style for reporting studies. This was very good. A synthesis of the most important studies is needed and some statements about why other studies are not used by EPA. It is easy to get lost in the document because of its size, but if there was an analysis or synthesis section for the key toxicity studies and another for PK modeling rationale, it would help readers.

William L. Hayton

It would be helpful to use one set of units for test article amount and concentration. The draft documents use ng/mL, µg/mL, µg/L, ppb, ppm, and µM for PFOA/PFOS concentration in water, diet, and serum. It would be more straightforward to use one concentration term, preferably ng/mL, and perhaps µg/mL in addition as necessary. But making comparisons among ng/mL, ppm, and µM is a distraction.

In Section 3 of both documents, it would be helpful to include a summary table of primary pharmacokinetic parameter values for the species included in this section. Tables 3-17 – 3-20 in

the PFOS draft document are a good start. In the PFOA document, Table 3-23 lacks CL values, and Tables 3-24 and 3-25 lack V_d values. For the pharmacokinetic model analyses presented, primary parameters values could be limited to CL, Vd_{ss}, and half life (see table in response to question 10). The CL and V_{dss} values should be normalized to body weight. Where there are multiple models for a species, there should be separate entries for each study. Where there are multiple dosages for a species, there should be separate entries for each dosage. For the PBPK models, V_{dss} values are not available and therefore should not be included. Such a table would be helpful to show consistency or lack thereof among studies and would facilitate selection of the best available values for CL and V_{dss} for use in a human PK model that would predict steady-state serum concentration from intake (dosing) rate and, conversely, predict intake rate from steady-state serum concentration. These predictions are probably the primary reason to include a pharmacokinetics section in the documents.

The pharmacokinetic sections of both documents lack example graphs of serum concentration-time data on semilog coordinates for PFOA and PFOS. Inclusion of a few representative graphs would help the reader evaluate the consistency of the data used to generate the pharmacokinetic parameter values, and where model-based equations have been fitted to the data, the scatter of the measured concentrations around the model-predicted line would be informative as to the goodness of fit and the validity of the model and its parameters.

Matthew P. Longnecker

I can see advantages to treating this more like a systematic review of the literature, where the specific search algorithm for included articles is laid out, as are the range of dates of publication to be considered, and any other selection criteria applied for articles considered. In these documents, while the review of earlier literature appears to be comprehensive, after some point there must have been some decision making about which of the more recent articles to include.

The EPA has many guidelines about how data like these are to be evaluated, yet in the document few, if any, references to these guidelines were cited. Because so many guidelines exist, it could help readers if the authors cited specific places in critical documents that provide guidance for specific decisions.

Angela L. Slitt

The document reads very well. Although not included in the RfD determination, including a table of the observed human effects along with serum concentrations in Section 5.0 would put Tables 5-2 and 5-3 into context. Some sort of layman explanation to help understand why only non-human exposures are being included would be helpful to the general public.

V. SPECIFIC OBSERVATIONS

James V. Bruckner

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
3-11	5, lines 7-11	It is stated that the PFOA concentration in bile increased by a factor of 12.5 with the increase in PFOA dose from 12.5 to 25 umol/kg in wild-type mice and 19.5 in PPARα-null mice. These factors should be 2.8 for wild-type and 6.1 for PPARα-null mice. The document's authors may want to rethink their interpretation of the data. The results for the wild-type mice do suggest saturation of transport from liver to bile ducts, but the PPARα-null results do not, indicating a role for PPARα in this process. In contrast to the foregoing, the findings of Lou et al. (2009) (p. 3-11, pgr. 2) indicate their highest dose of PFOA is cleared from the blood of mice more rapidly than lower doses, suggesting saturation of hepatic and/or renal reuptake transporters. What is the relative importance of biliary and renal elimination of PFOA?
3-12	3, lines 2-4	It should also be stated that upregulation of MRP3&4 and the OATs may be <u>beneficial</u>, due to increased biliary excretion of bile acids, bilirubin, conjugated metabolites of toxic chemicals, etc.
3-14	1 & 2	It might be stated that the findings of Hinderliter (2004) support those of Han (2003), in regards to development of female rats.
3-14& 3-15		It is problematic to try to compare values in Table 3-14 with values referred to at the end of the second paragraph on p. 3-17. Whole pup and pup serum PFOA levels decrease between PND 1&18 for each dosage in the table. It would be preferable to include another table showing the PFOA levels with body weight taken into account. Table 3 – 14 and other tables should include the species in the title. It would also be helpful to include some details of the experimental protocol in the footnotes.
3-20		It would be useful at the end of this section (Distribution During Pregnancy and Lactation) to summarize the primary findings, or conclusions that can be drawn from the data that were presented.
3-23	4, line 2	It should be emphasized that urinary excretion of PFOA was substantially higher in female than male rats.
3-28	2, line 4	Replace "receptors" with "transporters".
3-28	6	Did 10 uM PFOA inhbit PAH and estrone uptake to a greater extent than 100 uM PFOA?
3-29	3 & 4	It is not clear what Yang et al. (2009) concluded about the role of OATp1a1 in the uptake of PFOA from glomerular filtrate.
3-32	3 & 4	These two summary paragraphs are very helpful.
3-37	1, line 1	Should "adsorption" be "absorption"?

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
4-7 & 4-9	Tables 4-1 & 4-2	Tables 4-1 and 4-2 are quite helpful in integrating the results of studies of occupationally-exposed populations.
4-13		A concluding sentence should be added to summarize the findings of a lack of association of PFOA with diabetes, metabolic syndrome, etc.
4-32		The NOAEL and/or LOAEL for this study should be stated at the end of the paragraph.
4-34	2	Is the LOAEL for liver effects 1 ppm in the study of Loveless et al. (2008)?
4-38	1	Include the meaning of the abbreviation "mPPARα".
4-39		Inclusion of the table for Minata et al. (2010) would be useful to help readers better comprehend the study findings.
4-40		A table of short-term LOAELs and NOAELs should be added here or in Section 5.
4-47	2	It is hard to believe, judging from the slight difference in mean values and their standard deviations, that absolute and relative liver weights are significantly higher than controls in the 1 mg/kg/day group.
4-67	2, line 5	Insert "absolute" before "liver weight".
4-69	1, lines 1 & 2	It might be worthwhile to point out that the actual study by Butenhoff et al. was conducted prior to 2004.
4-73		A summary sentence (or two) should be added at the end of the Mutagenicity and Genotoxicity section.
4-83		A summary paragraph should be included at the end of the Immunotoxicity section.
4-101	1, line 14	Insert the word "some" before "occupational studies". In order to present a more balanced perspective of findings in occupational studies, the following sentences could be added at the end of the paragraph: "Olson and Zobel (2007) examined groups of male workers at 3 fluorochemical production facilities. Serum PFOA concentrations were not associated with total cholesterol, LDL or HDL in workers at these facilities."
4-102	4	It should be stated that the increases in serum enzyme activity in workers were quite modest/small. The following sentence should be added at the end of the paragraph: "Emmett et al. (2006), however, found no association between serum PFOA and liver or renal enzymes".
4-103	2, line 2	Change "apoptotic or necrotic damage of" to "apoptosis or necrosis of". Apoptosis and necrosis are types of cell death, not damage/injury.
4-103	3, line 1	It is true that PFOA may interfere with the biliary excretion of other compounds that are transported by the same transporters. Upregulation of the genes for these transporters, however, may be beneficial in that the excretion of bile acids, bilirubin and conjugates

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
		of toxic chemicals/metabolites may be hastened.
4-103	4, line 2	I would avoid the word "critical" until the section on Dose-Response Assessment.
4-103	4	Increases in absolute and relative liver weights were dose-dependent (Cui et al., 2009; Elcombe et al., 2010; Wolf et al., 2008a)
4-103	5	It is important to distinguish between effects of PFOA on rough and smooth endoplasmic reticulum (RER and SER). RER content was diminished, but there was a proliferation of SER.
4-104	2, line 5	This last line should be amended to read "that PFOA has some effects of unknown toxicological significance that appear to be independent of PPARα activation.
4-104	4, line 3-5	The meaning of the sentence is not clear. Has something been omitted?
4-105	3, line 3	Add "of offspring" between "abilities" and "at 6 and 18". Include Fei and Olsen's (2011) finding of no association between prenatal PFOA exposure and behavioral or coordination problems in children at age 7.
4-109	3	The species (i.e., mice) studied by White et al. (2009) and by Wolf et al. (2007) should be stated.
4-111	4, line 2	Replace "examine" with "determine whether there was".
4-112	2, lines 1 & 2	The first sentence is misleading and should be rewritten. Butenhoff et al. (2012) did not see a significant increase in liver adenomas or carcinomas. Biegel et al. (2001) reported an increased incidence of hepatic adenoma but not carcinoma.
4-112	2, line 13	What is hepatic cystoid degeneration?
4-114	2, line 3	Insert "decreased" before "apoptosis".
4-115	5, line 2	What is meant by "PRAR exposures"?
4-116		There is no mention of PFOA-induced changes in expression of genes (e.g., cell cycle control, peroxisomes biogenesis, inflammation, etc.) that are PRARα-dependent. There is no mention of the role of PRARα or peroxisomes in oxidative injury and carcinogenesis.
4-120	1, lines 11 & 12	Insert "these" between "that" and "hormones".
4-121	3	It would be helpful to give the PFOA dosages of White et al. (2007) and one or two other studies, so the reader will have some idea of the magnitude of PFOA exposure required to alter mammary gland development.
5-1		RfD: Omit the word "wealth" from the bullet pertaining to epidemiology studies. There have been relatively few epidemiology studies of PFOA-exposed populations.

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
5-2	1, lines 2-6	Another obvious point should be made here, mainly that occupational exposures result in much higher plasma PFOA levels and body burdens than do environmental exposures. Thus, it would be anticipated that adverse effects would be more apparent in PFOA facility workers.
5-2	1, line 5	Include the words "in some instances" between the words "shown" and "between". Otherwise, it appears from this paragraph the serum PFOA concentrations are consistently/usually associated with the various maladies.
5-2	3, line 8	Insert "failure to attain" between the words "with" and "developmental".
5-7	2, line 4	Insert the word "rodent" between "between" and "species"
5-19	1, line 1	Insert "from some studies" between "data" and "have".

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
3-2	5, lines 2 & 3	It is stated here that "the ratio of PFOS identified in serum and liver tissue are similar". Do the authors mean that PFOS concentrations in the serum and liver are similar?
3-2	6	How does PFOS distribute between plasma lipoproteins and proteins/albumin?
3-5	1, lines 9& 10	How much lower were milk PFOS levels than serum levels?
3-7	1, line 2	Oral and gavage are redundant.
3-16	Figure 3-1	This figure nicely illustrates relative PFOS levels in dams and fetuses/pups over time.
3-19	1,line 3	Insert "groups" between "day" and "on".
3-21	1, line 10	Substitute "longer" for "slower".
3-23	2	It is not clear who conducted the human PBPK modeling nor which model they used.
4-21	2, lines 1-3	What did the 2nd monkey die from?
4-26	3, line 3	The word "concentrations" should be replaced by "doses".
4-39	1	Does an increase in motor activity on PND 17, but no such effect on PND 13, 21 or 61, constitute a toxicologically-significant effect?
4-56	2, lines 1 & 2	It is stated that "taken together, these studies suggest a PPARα-independent mechanism…" Of the studies reviewed to this point in the document, only that of Abbott et al. (2009) supports this premise. Qazi et al. (2009), Rosen et al. (2010) and other groups of investigators have reported other PPARα-independent effects of PFOS.
4-60	2, lines 15-17	Is oxidative damage likely to be operative to a significant extent at lower PFOS doses?

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
4-61	2, line 4	What is meant by "The concentration…"?
4-61	4, line 2	Change "dose of exposure is" to "levels of exposure are".
4-62	1, lines 2 & 3	What did Olsen et al. (2003) find correlation between?
4-62	3, lines 4 & 5	Identify the species (i.e., rat) studied by Chang et al. (2009) and Stein et al. (2012).
4-62	5	The liver of rats and monkeys was examined for histopathological changes, but the histological changes should not be considered lesions nor pathological.
4-68	4, lines 5 & 6	The elevated incidence of hepatocellular adenomas/ carcinomas was almost entirely due to adenomas. Only 1 of 60 high-dose female rats exhibited carcinoma.
4-69	5, lines 3 & 4	It is stated here that there was no increase in hepatocellular proliferation detected in the subchronic study of Seacat et al. (2003). It is stated previously on page 4-69 that "the data for PFOS are adequate to support some but not all key events…" I assume that cell proliferation is thought to be a missing event. Seacat et al. (2003) reported that the average hepatocyte proliferation index was not increased, but that some animals exhibited mild increases. It is clear in the current document that PFOS is not as potent a PPARα inducer as PFOA.
5-4	2 & 5, line 7	Again the terms "histopathological" and "lesions" are misnomers.
5-4	3, line 9	What is meant by a "biologically significant decrease in survival" at 0.8 mg/kg?

Deborah A. Cory-Slechta

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
Chapter 5		The text of Chapter 5 in the PFOA document (and other places) continues to state that a 10% increase in liver weight would not be an adverse effect, but merely a denominator for loss of homeostasis. On what basis was this conclusion derived? What is the support for this statement? It appears that benchmark dosing was applied to studies that had liver weight as the common denominator, but does this accommodate the lowest NOAELS and LOAELS observed for any endpoint in the long duration studies? Use of just studies with the common denominator because they provide replication ignores the fact that some other effect may occur at lower levels but simply hasn't been evaluated in as many studies as focused on PPARa-based targets. If this isn't the case, then the text should clearly address this.
5-7	2	States that the $BMDL_{10}$ values all fall below the experimental LOAELs. So, what does that mean, is there some conclusion that is supposed to be reached from this? IF so, please state it.
5-13	1	States "Generally these values were similar." What does similar mean? What is acceptable in this context?
5-16	3	States that the half-life value Bartell et al. (2010) was sued for half-life because it seemed more relevant to scenarios where exposure result from ingestion of contaminated drinking water by members of the general population. This rationale does not appear to consider the potential different strengths and weaknesses of the other potential studies. Is it necessarily the case that general population is more important than occupational studies? The rationale needs to be described in greater detail. Virtually no rationale is provided for the choice of the Thompson et al. (2010) study for a volume of distribution value.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
1-1	4	There are similar concerns for the PFOS document. Loose terminology should be eliminated, e.g., what is a 'finding of note' as used in the executive summary for PFOS.
Executive summary		The PFOS executive summary is of limited utility; for many readers this may be as much of the document as they read; as currently written it is not clear or transparent nor does it sufficiently explain how it arrived at an RfD.
3-3	Table 3-1	Couldn't a sentence essentially substitute for Table 3-1; it really isn't useful.
3-25	1	Loose terminology should be eliminated, e.g., what is "generally good"
3-26	Figure 3-7	Figure 3-7 has no explanation of what is the black vs. gray line.
All tables		There is a need to improve all of the tables; they should always include study name/year, sample size and exposure duration information on them; this would make all of the comparisons easier to evaluate and not require the reader to continue to go back and forth to the text.
4-4	Table 4-1	For example, table 4-1 has only study name and year, but what really matters is also exposure duration and sample sizes, because the comparisons of outcomes in the Table depend upon the power of the study to detect effects at the very least.
4-9	Table 4-2	The same comment applies to Table 4-2 and any others with this intended purpose.
4-11	Table 4-3	Table 4-3 needs sample sizes, exposure duration etc.
4-24	Table 4-7	Tables that summarize a significant amount of data from a single study (e.g., 4-7) should include the study authors and year in the Table title so it doesn't have to be searched for.
		In several instances in the PFOS document, adverse effects early that appear to be reversed at a later age are discounted with the suggestion that they therefore do not matter; given our increasing understanding of the importance of early changes in terms of epigenetic changes, this is no longer appropriate and in fact, misleading.
5-16	Table 5-8	What do the parentheses signify?
5-17	Table 5-9	What do the parentheses signify?

Jamie C. DeWitt

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
4-102	2 & 3	DeWitt et al. 2009 also included data on triglyceride levels in C57BL/6 mice exposed to PFOA for 15 days; triglyceride levels were dose-responsively decreased.

Jeffrey W. Fisher

No specific observations.

William L. Hayton

Specific Observations for *Health Effects Document for Perfluorooctanoic acid*		
Page	**Paragraph**	**Comment or Question**
1-2	Last, line 5	Delete "in"; should read "… in rats was analyzed …"
3-2	1, lines 6-8	Assumption that fecal excretion represented unabsorbed PFOA is problematic; suggest rephrasing this sentence.
3-3	Table 3-1	Protein binding is important for PK modeling, where the fraction unbound (fup) is the important parameter, not the fraction bound. Suggest listing fup values rather than percent bound.
3-6	Last, line 3	"concentration" should be "dose rate"
3-8	2, line 4	In addition to liver, kidney, and blood, other tissues are prominent. E.G., Table 42 of Kemper shows that in male at 1 mg/kg, t=Tmax, GI tract, GI contents, muscle, bone and skin contained a greater percentage of dose than did the kidney.
3-8	2, line 8	"Blood to kidney" should be "kidney to blood"
3-8	2, line 10-11	In Kemper, Tables 44-45, blood to kidney ratios are not 10 or higher in males.
3-8	2	This paragraph reports both percent of dose found in tissues, and concentrations found in tissues. But Tables 3-4 and 3-5 present only the former. When presenting tissue concentrations, please make it clear that those data are not shown.
3-18	Last, line 3	"were" is repeated.
3-19	1, line 1	Technically incorrect to say that the level peaked at PND7; that was the earliest sample time. The peak may have occurred before PND7.
3-19	Table 3-15	The last dose was on GD17; strange that at 1 and 3 mg/kg the serum concentration increases from PND7 to PND14.
3-22	4	Last sentence is garbled.
3-22	4, 5	Agree that biliary elimination is possible, but it could be that chloestyramine binds PFOA and PFOS in the GI tract lumen after they passively diffuse from the blood to the gut. There seems to be no direct evidence of biliary elimination, e.g., bile collected from treated animals.
3-23	Last, line 4	Should be Table 3-18.
3-34	Last, line 9	Should be "nonlinear least squares"
3-35	Table 3-23	Column 2, "Adsorption" should be "Absorption"
3-38 3-38	2 Figure 3-7	The arrow from Gut to Liver appears to point in the wrong direction; it should represent biliary excretion of PFOA from Liver to Gut.
3-43	Last line	"… indicating the absence of active excretion in human kidneys." This does not follow from the observation of renal clearance being about 0.001% of GFR. A plasma free fraction of 0.001 would

Specific Observations for *Health Effects Document for Perfluorooctanoic acid*		
Page	**Paragraph**	**Comment or Question**
		account for the CLr being 0.1% of GFR, and passive tubular reabsorption would make it 0.001% of GFR since urine flow is about 1% of GFR. Other scenarios are possible that do not invoke the absence or presence of active excretion.
3-44	Table 3-24	Should report all data values with three significant figures. For example, Lambda z values have only one sig. fig., while $T_{1/2}$ values have 5-6.
3-46	2	This reviewer does not follow the derivation and use of a value for volume of distribution with regard to intake rate and serum concentration of PFOA. If the subjects were at steady state, the body burden would have to be known. At steady state, the serum concentration would be independent of the volume of distribution, so any V value ought to match the intake rate to the steady state serum concentration.
4-9	1	Log transformed concentration was 1.51 and 1.48 ng/mL – are these the logarithms? IE, are the actual concentrations 10^1.51 = 32 and 10^1.48 = 30 ng/mL?
4-20	2, line 8	Anderson here is spelled Andersen in the reference list.
4-30	1, line 9	prostrate should be prostate.
4-31	4, line 10	decreased should be decrease.
4-112	1	It would be helpful to restate the serum concentrations for the Eriksen and Vieira studies, or refer reader to p. 4-29 where they are provided.
4-112	1, line 9	Delete "for".
4-112	2, line 12	Delete "were".
4-118	4	Delete "of actions" after MOAs
4-120	3	The broad range of half lives could also be due to person-to-person variability in the free fraction of PFOA in serum (fup). This is the case for highly bound drugs; e.g., warfarin.
5-1	3	Pharmacokinetic is misspelled.
5-1	5	Disagree – exposure assessment based on the human data is feasible. In fact, the serum concentrations are a better measure of exposure than are intake measures as they reflect all intake pathways and eliminate bioavailability and pharmacokinetic influences on internal exposure.
5-12	Last	Table numbers should be 5-6, 5-7, and 5-8.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
3-5	3	The low CSF : serum concentration ratio could also be due to an export transporter that pumps PFOS out of the CSF and/or to extensive serum protein binding, where only the free serum concentration of PFOS is in equilibrium with the free PFOS concentration in the CSF.
3-22	2	The free fraction used for the model is much larger than that determined experimentally, Table 3-1; this should be pointed out in the text.
3-22 3-23	2 Figure 3-5	The arrow from Gut to Liver appears to point in the wrong direction; it should represent biliary excretion of PFOS from Liver to Gut.
3-24	4	Anderson should be Andersen.
4-26	4	"concentrations" should be "dosages".
5.2	3	Should note for many of these studies, that steady state may not have been achieved due to the long half-life of PFOS. Half-life values from Section 3 are: mouse, 37 days; rat male, 40 days and female 64 days; monkey, 120 days. Using a one-compartment PK model, the time to 90% steady state is 3.3 half lives.
5-5	3	The NOAEL for liver effects in rats of 0.072 mg/kg/day is not consistent with p. 5.4, para. 2, which states that lesions of the liver <u>were</u> observed in male rats after 104 weeks at this dosage.
5-7	2	For female rat, the PFOS half life is about 60 d and the period of gestation is about 20 d or one-third of a half life. If PFOS is administered to the dam only during gestation at a fixed daily dose, the serum concentration of PFOS would rise from 0 to 21% of the steady-state serum concentration that the fixed dose rate would produce at steady state. The exposure of the fetus during gestation would average only about 10% of the exposure that would have occurred if the dam had received PFOS for 4 half-lives (240 days) prior to mating. BMDs based on such a fixed dose could be elevated by as much as a factor of 10 compared with the steady state situation. Steady state would be the relevant situation for humans. For the Luebker study (Table 5-3) the serum concentration during gestation would have increased from about 38% to 50% of the eventual steady state concentration.

Matthew P. Longnecker

Specific Observations for *Health Effects Document for Perfluorooctanoic*		
Page	**Paragraph**	**Comment or Question**
3-28	1st complete	Should the end of the sentence be "increase the transporters" rather than "increase the receptors"?
3-30	2nd complete	L 3, would insert "transfected" between "OAT3" and "cells"
3-39	1st complete	Next to last sentence: I doubt that Olsen assumed the major source of exposure was drinking water in the occupational study
3-41	4th complete	In the first formula listed, the plus sign should be an equal sign
4-9	1st complete	L 3 from bottom: the values of 1.51 and 1.48 given are probably better described as geometric means.
4-16	2nd complete	L 3 from bottom: would insert "draw" after "blood"
4-21	2nd complete	L 5: the value of 6.78 ug/L is a water level, not a serum level; this issue recurs on P 4-23, paragraph at bottom
4-30	1st complete	L 8: should read "exposure categories" rather than "cancer categories"?
4-37	Table	Would note dose of PFOA somewhere in table or footnote
4-55	Last para	L 3: should the ">" be a "<"?
4-79	Last para	Last sentence: should "50 and 25" be "50 and 250"?
4-80	1st complete	The last sentence does not accurately describe the table. E.G., the CD4+CD8+ cells decreased at the 47.21 mg/kg/d dose
4-82	Next to last para	Last sentence: the 37.5 mg/kg/dose is not mentioned earlier, so this is a little confusing.
4-85	Last para	L 2: should "0.5" be "0.05"?; Same issue for L 5.
4-89	4th para	How long were the animals dosed?
4-110	3rd complete para	L 5: should "serum" be "blood"?
4-113	3rd complete para	L 1: insert "in" before "liver cells"
5-4	Last para	Were the criteria for inclusion in Table 5.2 the same as for Table 5.1?
5-12	Para below table	8-6, 8-7, and 8-8 should be 5-6, 5-7, and 5-8
5-16	Last line	I do not see in the Thompson et al. (2010) study any mention of using exposure data from NHANES to calibrate the volume of distribution. Other sources of data were used, where the water had been contaminated.
5-17	1st formula	"/day" should be deleted from "0.17 $L/kg_{bw}/day$"
5-20	Table 5-12	The first three values in the UF_{total} column need to be corrected; they should be 21900, 219000, and 21900
5-21	Paragraph above table	Last sentence: UF_L should be UF_H
5-21	Last sentence	UD_S should be UF_S

Specific Observations for *Health Effects Document for Perfluorooctanoic*		
Page	**Paragraph**	**Comment or Question**
5-27	Calculations	The text says the body weight conversions should be based on the ¾ power. If so, the HED formulas are incorrect, and the HED should be 1.99 x 0.0254 = 0.0506, the dosimetric adjustment factor should be 0.0254, and the CSF should be 1.57. All the figures here should be checked as should the paragraph on P 5-28. The HED is 2,530-fold greater than the RfD, not 29,000.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
1-1	2nd	1st sentence: would revise for clarity. Do you mean uncertainties exist about whether PFOS-induced peroxisome proliferation is involved in causing PFOS-induced hepatic lesions?
1-1	3rd	1st sentence: would revise for clarity; the occupational studies were done at PFOS production plants, but to my knowledge there are no residential populations that have been studied for health effects who lived near PFOS production plants. (Mid-Ohio valley factory was a source of PFOA.) In the 2nd sentence, I do not believe that exposure was mainly through contaminated drinking water in any of these studies.
4-66	2nd	The earlier summary of the Bloom et al. study (P 4-10) said the results were not statistically significant, whereas here the interpretation appears to be that the study found an association. The interpretation does not seem consistent across the two sections.
5-17	Below table	L 3: the word "terminal" should be deleted from this sentence
5-20	1st formula	The "/day" should come out of "0.23 L/kg bw/day"
5-26	L 2 from bottom	This should be 35 ug/L not 35 mg/L

Angela L. Slitt

No specific observations.

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APPENDIX A: PEER REVIEWER BIOSKETCHES

ED_000915_Redeliver_PSTs-DD_00076684-00075

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 21 and 22, 2014

LIST OF PEER REVIEWERS

James Bruckner, Ph.D.
University of Georgia

Deborah Cory-Slechta, Ph.D. (chair)
University of Rochester School of Medicine and Dentistry

Jamie DeWitt, Ph.D.
East Carolina University

Jeffrey Fisher, Ph.D.
U.S. Food & Drug Administration

William Hayton, Ph.D.
The Ohio State University (Emeritus)

Matthew Longnecker, Sc.D., M.D
National Institute of Environmental Health Sciences

Angela Slitt, Ph.D.
University of Rhode Island

BIOGRAPHICAL SKETCHES OF PEER REVIEWERS

James Bruckner, Ph.D.
University of Georgia

Dr. Bruckner is Professor of Pharmacology and Toxicology at the University of Georgia College of Pharmacy. He is also Professor in the Department of Physiology and Pharmacology at the University of Georgia College of Veterinary Medicine. He received his Ph.D. in Toxicology from the University of Michigan in 1974. He has previously held faculty positions at the University of Kansas and the University of Texas Medical School at Houston. He is actively engaged in graduate education and in federally-funded research projects. Dr. Bruckner's research focus is on the toxicology and toxicokinetics of solvents, drug-solvent interactions at occupational exposure levels, and toxicokinetic bases for susceptibility of children to insecticides and other chemicals. Dr. Bruckner has published more than 200 journal articles, book chapters, and abstracts. He has also served on a variety of expert panels and committees for the EPA, National Institutes of Health, National Aeronautics and Space Administration, Agency for Toxic Substances and Disease Registry, Food and Drug Administration, and the National Academy of Sciences.

Deborah Cory-Slechta, Ph.D. (chair)
University of Rochester School of Medicine and Dentistry

Dr. Cory-Slechta is a Professor in the Department of Environmental Medicine and the Department of Pediatrics at the University of Rochester School of Medicine and Dentistry, where she also serves as co-director of the Behavioral Sciences Facility Core and director of the Animal Behavior Core. Dr. Cory-Slechta received her Ph.D. from the University of Minnesota in 1977 and worked as a junior staff fellow of the National Center for Toxicological Research beginning in 1979. She was appointed to the faculty of the University of Rochester Medical School in 1982 and was appointed Chair of the Department of Environmental Medicine and Director of the NIEHS Environmental Health Sciences Center at the University of Rochester in 1998. From 2000 to 2002, she was the Dean for Research and Director of the AAB Institute for Biomedical Sciences. Following her appointment as Dean, she served from 2003 to 2007 as the Chair of the Department of Environmental and Occupational Medicine at Robert Wood Johnson Medical School and as Director of the Environmental and Occupational Health Sciences Institute, a joint Institute of the Robert Wood Johnson Medical School and Rutgers. Dr. Cory-Slechta's research has focused largely on environmental neurotoxicants as risk factors for behavioral disorders and neurodegenerative disease. These research efforts have resulted in over 170 papers and book chapters to date. Dr. Cory-Slechta has served on numerous national research review and advisory panels, including committees of the National Institutes of Health, the National Institute of Environmental Health Sciences, the Food and Drug Administration, the National Center for Toxicological Research, the Environmental Protection Agency, the National Academy of Sciences, the Institute of Medicine, and the Agency for Toxic Substances and Disease Registry, Centers for Disease Control. In addition, Dr. Cory-Slechta has served on the editorial boards of several journals including *Environmental Health Perspectives*, *Neurotoxicology*, *Toxicology*, *Toxicological Sciences*, *Fundamental and Applied Toxicology*, *Neurotoxicology* and *Teratology*, and *American Journal of Mental Retardation*. She has held the elected positions of President of the Neurotoxicology Specialty Section of the Society of Toxicology, President of the Behavioral Toxicology Society, and been named a Fellow of the American Psychological Association. She also previously served on the EPA Science Advisory Board Perfluorooctanoic Acid Risk Assessment Review Panel.

Jamie DeWitt, Ph.D.
East Carolina University

Dr. DeWitt is an Assistant Professor in the Department of Pharmacology and Toxicology at the Brody School of Medicine at East Carolina University (ECU). She is affiliated with The Harriet and John Wooten Laboratory for Alzheimer's and Neurodegenerative Diseases Research and holds an adjunct appointment in the ECU Department of Public Health. Dr. DeWitt received her Ph.D. in Environmental Science and Neural Science from the School of Public and Environmental Affairs and Program in Neural Science at Indiana University in 2004. She also completed postdoctoral training in Developmental Cardiotoxicity at Indiana University-Bloomington and in Immunotoxicology at EPA through a cooperative training agreement with the University of North Carolina at Chapel Hill. Dr. DeWitt's main research focus is on how toxicants found in the environment can lead to neurodevelopmental and neurodegenerative disorders via disruption of the developing immune system. Much of her past research has

involved the immunotoxicity of perfluorooctanoic acid (PFOA) and related polyfluroalkyl substances (PFASs). Dr. DeWitt has published seven peer reviewed research articles, three review papers and two book chapters that address the biological effects of PFOA, as well as one paper on the effects of PFOS on immune function. Her publications describe effects as well as underlying mechanisms following adult and developmental exposure. Her research experience and publication record (more than 25 peer reviewed manuscripts, 6 review articles, 9 book chapters) extend beyond the effects of PFAAs and working with rodent models. She is currently editing a book on the general toxicity of PFASs and is a current member of the mechanistic working group for Monograph 110 of the International Agency for Research on Cancer, which will include an assessment of PFOA. She is on the editorial boards of the *Journal of Immunotoxicology* and the *Journal of Environmental Toxicology and Health* and has reviewed grants for the Department of Defense and the National Institute of Occupational Safety and Health. She has also been manuscript reviewer for more than 20 journals. Dr. DeWitt is the current president of the North Carolina chapter of the Society of Toxicology and the Junior Councilor for the Immunotoxicology Specialty Section of the Society of Toxicology. She also was awarded the Outstanding Young Investigator Award from the Immunotoxicology Specialty Section in 2013.

Jeffrey Fisher, Ph.D.
U.S. Food & Drug Administration

Dr. Fisher is a Research Toxicologist at the U.S. Food and Drug Administration (FDA), National Center for Toxicological Research. He was formerly a Professor in the Department of Environmental Health Science, College of Public Health at the University of Georgia (UGA). He joined UGA in 2000 and served as Department Head of the Department of Environmental Health Sciences from 2000 to 2006 and Director of the Interdisciplinary Toxicology Program from 2006-2010. Prior to joining UGA, he spent most of his career at Wright Patterson Air Force Base (AFB), where he was Principal Investigator and Senior Scientist in the Toxics Hazards Division and Technical Advisor for the Operational Toxicology Branch. Dr. Fisher's research interests are in the development and application of biologically based mathematical models to ascertain health risks from environmental, food-borne and occupational chemical exposures. Dr. Fisher's modeling experience includes working with chlorinated and non-chlorinated solvents, fuels, pesticides, perchlorate and bisphenol A. He has developed physiologically-based pharmacokinetic (PBPK) models for use in cancer risk assessment, estimating lactational transfer of solvents, understanding in utero and neonatal dosimetry, quantifying metabolism of solvent mixtures and developing biologically motivated models for the hypothalamic-pituitary-thyroid axis in rodents and humans. Dr. Fisher has published over 140 papers on pharmacokinetics and PBPK modeling in laboratory animals and humans. He has served on several national panels and advisory boards for the DoD, ATSDR, USEPA and non-profit organizations. He was a U.S. delegate for the North Atlantic Treaty Organization. Dr. Fisher served on the International Life Sciences Institute Steering Committee, which evaluated chloroform and dichloroacetic acid using EPA-proposed Carcinogen Risk Guidelines. He is Past President of the Biological Modeling Specialty Section of the Society of Toxicology, reviewer for several toxicology journals, and was Co-Principal Investigator on a National Institutes of Health (NIH)-supported workshop on Mathematical Modeling at the University of Georgia in the fall of 2003. Dr. Fisher was also a member of the National Academy of Sciences subcommittee on Acute Exposure

Guideline Levels (AEGLs) from 2004-2010 and Science Advisory Board (SAB) for the US EPA (2007-2010). He is an ad hoc EPA SAB member for dioxin and perchlorate. Dr. Fisher is a Fellow of the Academy of Toxicological Sciences, an associate editor for Toxicological Sciences, and on the editorial board of *Journal of Environmental Science and Health Part C Environmental Carcinogenesis & Ecotoxicology Reviews*.

William Hayton, Ph.D.
The Ohio State University (Emeritus)

Dr. Hayton is a Professor Emeritus in the College of Pharmacy at The Ohio State University. Dr. Hayton received a Ph.D. in Pharmaceutics from the State University of New York at Buffalo in 1967. He was a member of the Washington State University College of Pharmacy faculty for 19 years, rising to Chair of the Pharmacology/Toxicology Graduate Program in 1982 and Acting Dean at the College of Pharmacy in 1987. In 1990, he transferred to the Ohio State University as Chair of the Division of Pharmaceutics, where he later served as Associate Dean for the Graduate Programs and Research until his retirement in 2010. Dr. Hayton's expertise is pharmacokinetics, particularly construction and validation of mathematical models that describe or explain the kinetics of complex biological systems. One recent research interest is characterization of the Fc receptor-mediated transport and catabolism of albumin and IgG in wild type and FcR knockout mice. A second recent project is the quantitative modeling of the female hypothalamus-pituitary-gonad (HPG) axis in the female rainbow trout (Oncorhynchus mykiss). The model is based on and integrates the biology of gonadotropin, estrogen, androgen and maturational hormone signaling systems, and it includes key intermediate steps in the signaling pathways; viz., gonadotropin and sex steroid synthesis, hormone receptors and their corresponding mRNA levels. Dr. Hayton's expertise extends to interspecies scaling of pharmacokinetic model parameter values and xenobiotic metabolism. Dr. Hayton is author or co-author of over 100 peer-reviewed scientific publications and has held peer-reviewed grant support from the National Institutes of Health, EPA, Air Force Office of Scientific Research, Food and Drug Administration, and U.S. Fish and Wildlife Service. He previously served on the EPA Science Advisory Board Perfluorooctanoic Acid Risk Assessment Review Panel.

Matthew Longnecker, Sc.D., M.D
National Institute of Environmental Health Sciences

Dr. Longnecker, M.D., Sc.D., is the head of the Biomarker-based Epidemiology Group at the National Institute of Environmental Health Sciences (NIEHS). Dr. Longnecker received an M.D. from Dartmouth Medical School and completed a residency in internal medicine at Temple University Hospital in Philadelphia. After receiving a Sc.D. in Epidemiology from Harvard School of Public Health in 1989, he served as an Assistant Professor in the Department of Epidemiology at the University of California, Los Angeles, School Of Public Health. Since 1996, Dr. Longnecker has served as Adjunct Professor/ Associate Professor in the Department of Epidemiology, School of Public Health, University of North Carolina at Chapel Hill. He came to the NIEHS Epidemiology Branch in 1995, as a tenure-track investigator. Dr. Longnecker's research program is focused on the health effects of persistent organic pollutants (e.g., the DDT metabolite p,p'-DDE, and polychlorinated biphenyls). He is particularly interested in the effects of intrauterine exposure to persistent organic pollutants in relation to intrauterine growth,

preterm birth, birth defects, neurologic findings at birth, growth, neurodevelopment, intelligence, and hearing. Recently, Dr. Longnecker has completed and has ongoing a series of studies on perfluorinated alkyl substances in relation to reproductive and pediatric outcomes. In addition, he has begun studying the effects of early, low-level exposure to the nonpersistent pollutants, bisphenol A and organophosphate pesticides. Dr. Longnecker's research efforts have resulted in over 180 papers and book chapters to date. He has served as a leader for numerous national and international committees, such as for the Society for Epidemiologic Research and the International Society for Environmental Epidemiology, and has been on numerous national and international scientific advisory boards, including the EPA Science Advisory Board for the Perfluorooctanoic Acid Risk Assessment Review.

Angela Slitt, Ph.D.
University of Rhode Island

Dr. Slitt is an Associate Professor in the Department of Biomedical and Pharmaceutical Sciences at the University of Rhode Island. Dr. Slitt received her Ph.D. in Pharmacology and Toxicology from the University of Connecticut in 2000, and then served until 2004 as a postdoctoral fellow at the University of Kansas Medical Center. Dr. Slitt has been a faculty member at the University of Rhode Island since 2006. Dr. Slitt's graduate and postdoctoral training was heavily focused on liver biology and health, with a focus in the area of toxicology, and included research in nuclear receptors, biotransformation, and transporter expression. Her current research interests focus on how 1) expression of drug transporters affects chemical disposition and toxicity, 2) nutrition and intake of dietary antioxidants affects the expression of drug transporters, 3) liver disease (i.e., diabetes, cholestasis, and ethanol cirrhosis) affects transporter expression and chemical disposition, and 4) transporter expression affects cholesterol transport and susceptibility to gallstone formation. She has also recently investigated the effect of PFOS on caloric restriction in mice. Dr. Slitt is presently on the Editorial Board of *BMC Pharmacology and Toxicology, Journal of Biochemical and Molecular Toxicology*, and *Toxicology Methods and Mechanism*, and is an ad-hoc reviewer for numerous other journals. She is author or co-author of over 50 peer-reviewed scientific publications, and was recently awarded the University of Rhode Island Early Career Faculty Research Excellence Award.

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APPENDIX B: MEETING AGENDA

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AGENDA

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 21, 2014

Day 1 – PFOA Health Effects Document

8:30 AM	**Meeting Sign-In Begins**
9:00 AM	**Welcome, Goals of Meeting, and Introductions** David Bottimore, Versar, Inc.
9:15 AM	**Welcome by EPA and Overview of PFOA/PFOS Health Effects Documents** Elizabeth Doyle, Chief, EPA/OST/OW/HECD
9:30 AM	**Chair's Introduction and Review of Charge** Deborah Cory-Slechta, *Chair*
10:00 AM	**Discussion Session – "Round Table" General Overview Comments**
10:45 AM	*Break**
11:00 AM	**PFOA Discussion Session – Responses to Charge Questions:** Question 1: Strengths, Weaknesses, and Characterization of the Studies Selected Question 2: Additional References for Consideration Question 3: Conclusions on Human Epidemiology Data Question 4: Transparency and Characterization of Epidemiologic Data
12:15 PM	*Lunch**
1:15 PM	**PFOA Discussion Session – Response to Charge Questions:** Question 5: Cancer Classification Question 6: Pharmacokinetic Model Adjustments Question 7: Selected Parameters for Pharmacokinetic Model Question 8: Volume of Distribution (Vd) and Half-life Values
2:45 PM	*Break**
3:00 PM	**PFOA Discussion Session – Response to Charge Questions:** Question 9: Points of Departure and RfDs Question 10: RfDs and Applicability to Short-and Long-term Exposures Question 11: Uncertainty Factors Question 12: Other Suggestions for Improving the Document
5:00 PM	**Adjourn**

**Time for breaks and lunch are approximate and at the Chair's discretion.*

AGENDA

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 22, 2014

Day 2 – PFOS Health Effects Document

9:00 AM	**Recap of Day 1 and Agenda for Day 2** David Bottimore, Versar, Inc.
9:15 AM	**Chair's Review of Charge for Day 2** Deborah Cory-Slechta, *Chair*
9:30 AM	**Discussion Session – "Round Table" General Overview Comments**
10:00 AM	*Break**
10:15 AM	**PFOS Discussion Session – Responses to Charge Questions:** Question 1: Strengths, Weaknesses, and Characterization of the Studies Selected Question 2: Additional References for Consideration Question 3: Conclusions on Human Epidemiology Data Question 4: Transparency and Characterization of Epidemiologic Data
11:30 PM	*Lunch Break**
12:30 PM	**PFOS Discussion Session – Response to Charge Questions:** Question 5: Cancer Classification Question 6: Pharmacokinetic Model Adjustments Question 7: Selected Parameters for Pharmacokinetic Model Question 8: Volume of Distribution (Vd) and Half-life Values
2:15 PM	*Break**
2:30 PM	**PFOS Discussion Session – Response to Charge Questions:** Question 9: Points of Departure and RfDs Question 10: RfDs and Applicability to Short-and Long-term Exposures Question 11: Uncertainty Factors Question 12: Other Suggestions for Improving the Document
5:00 PM	**Adjourn**

**Time for breaks and lunch are approximate and at the Chair's discretion.*

EPA-HQ-2016-005679 06/14/2017

APPENDIX C: MEETING ATTENDEE LIST

ED_000915_Redeliver_PSTs-DD_00076684-00084

LIST OF OBSERVERS ATTENDING MEETING IN PERSON
August 21 and 22, 2014

External Peer Review Meeting on
EPA's Draft Health Effects Documents for
Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Name	Affiliation
Janet Anderson, Ph.D.	U.S. Air Force
Robert Bilott	Taft Stettinius & Hollister LLP
Norman Birchfield	U.S. EPA
John Butenhoff, Ph.D.	3M Company
Sue Chang, Ph.D.	3M Company
C-H Selene Chou, Ph.D.	Agency for Toxic Substances and Registry
Steven Chranowski	Chemistry Council of New Jersey
Joyce Donohue	U.S. EPA
Elizabeth Doyle	U.S. EPA
Colleen Flaherty	U.S. EPA
Maria Hegstad	Inside EPA
Gerald Kennedy	DuPont
La Rae Landers	Dept of the Navy BRAC PMO
Willington Lin	Public
Angela Lynch, Ph.D.	American Chemistry Council
Geary Olsen, Ph.D.	3M Company
Gloria Post, Ph.D.	New Jersey Department of Environmental Protection
Resha Putzrath, Ph.D.	Navy and Marine Corps Public Health Center
Jennifer Seed	U.S. EPA
Shalene Thomas	AMEC Environment & Infrastructure
Steve Via	American Water Works Association
Anthony Walters	United Science, LLC
Carol Wood	Oak Ridge National Laboratory

LIST OF OBSERVERS ATTENDING VIA PHONE
August 21 and 22, 2014

External Peer Review Meeting on
EPA's Draft Health Effects Documents for
Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Name	Affiliation
Matthew Bailor	Gilmore & Associates, Inc.
Victoria Binetti	U.S. EPA
Stuart Cagen, Ph.D.	Shell Health
Andrea Candara	New York State Department of Health
Tom Cleveland	Decatur Utilities
Jason Conder	ENVIRON International Corporation
Michelle Deveau	Health Canada
Stiven Foster	U.S. EPA
Helen Goeden	Minnesota Department of Health
Christopher Lau, Ph.D.	U.S. EPA
Anita Meyer, DABT	U.S. Army Corps of Engineers
Jonathan Naile, Ph.D.	Shell Health
Jessica Nelson	Minnesota Department of Health
Bridget O'Brien	U.S. EPA
Ramasamy Santhini	U.S. EPA
Robert Rickard	U.S. EPA
John Wambaugh	U.S. EPA
Carol Rowan West, Ph.D.	Massachusetts Department of Environmental Protection
Linda Wilson	New York State Office of the Attorney General
Virginia Yingling	Minnesota Department of Health
Tsedash Zewdie	Massachusetts Department of Environmental Protection

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Fri 1/8/2016 4:54:36 PM
Subject: FW: PFOA HESD for final internal agency review
PFOA Post External Review 010816.docx
PFOA PFOS EPR REPORT AUG 2014.pdf

fyi

From: Behl, Betsy
Sent: Friday, January 08, 2016 11:52 AM
To: Scozzafava, MichaelE <Scozzafava.MichaelE@epa.gov>
Subject: PFOA HESD for final internal agency review
Importance: High

Mike, as per my voicemail, this is the PFOA HESD for review by 1/29.

From: Behl, Betsy
Sent: Friday, January 08, 2016 10:46 AM
To: Cantilli, Robert <cantilli.robert@epa.gov>; Fegley, Robert <Fegley.Robert@epa.gov>; Foos, Brenda <Foos.Brenda@epa.gov>; Cooke, Maryt <Cooke.Maryt@epa.gov>; 'Focazio, Michael' <mfocazio@usgs.gov>; Henry, Tala <Henry.Tala@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: PFOA HESD for final internal agency review
Importance: High

Many thanks to you all for your review of our PFOS document. We are expecting comments by Monday January 11, so that we can keep to our schedule to publish final HAs. As you can imagine, the recent report of PFCs in drinking water in Hoosick Falls, NY and articles in the press have heightened interest in EPA finalizing these HAs as well as our timetable.

Attached above is the final draft PFOA Health Effects Support Document (HESD) for your review. This is the second and last HESD for PFCs which we requesting you to review. Like the PFOS document, this document has been spell checked but has not been through a final

technical edit. We plan to address your comments and have then have a final technical edit done prior to the issuance of the Health Advisories (HAs). We are also attaching the external peer review comments, for your information.

This HESD provides the key science support for the point of departure for PFOA that will be used in the HA calculation. OW would like to release the HAs in March, which is coming up fast. This is our plan for internal review of all the PFC documents:

•□□□□□□□□ PFOS HESD: begins internal review 12/17/2015. **Comments due 1/11/2016**

•□□□□□□□□ PFOA HESD: begins internal review 1/8/2016. Comments due 1/29/2016 (3 weeks) (current document)

•□□□□□□□□ PFOA and PFOS HAs: begin internal review late January/early February. Comments due 2 weeks later.

Many thanks in advance for your comments, Betsy

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0788

Peer Review Summary Report

External Peer Review of EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

November 17, 2014

Peer Reviewers:

James V. Bruckner, Ph.D.
Deborah A. Cory-Slechta, Ph.D.
Jamie C. DeWitt, Ph.D.
Jeffrey W. Fisher, Ph.D.
William L. Hayton, Ph.D.
Matthew P. Longnecker, Sc.D, M.D
Angela L. Slitt, Ph.D.

Contract No. EP-C-13-010
Task Order 2013-06

Prepared for:
U.S. Environmental Protection Agency
Office of Science and Technology/Office of Water
Health & Ecological Criteria Division
1200 Pennsylvania Avenue, NW (MC4304T)
Washington, DC 20460

Prepared by:
Versar, Inc.
6850 Versar Center
Springfield, VA 22151

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EXECUTIVE SUMMARY

Versar, Inc. (Versar), a contractor for the Environmental Protection Agency (EPA), coordinated an external peer review of EPA's draft health effects documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS), and organized a two-day public peer review meeting in Arlington, Virginia on August 21 and 22, 2014. The peer review of EPA's draft health effects documents was initiated with a pre-meeting written peer review managed by Versar and conducted by seven independent expert peer reviewers. The role of the peer reviewers was to evaluate the scientific and technical merit of the draft documents and provide their responses to 12 charge questions. Peer reviewers were charged only with evaluating the quality of the science included in EPA's draft health effects documents and were not charged with making any regulatory recommendations or reaching consensus in either their deliberations or written comments. The two-day peer review meeting, which directly followed the written peer review period, was held to discuss the scientific basis supporting EPA's draft health effects documents and to provide members of the public with an opportunity to observe the peer reviewer deliberations.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. In addition, EPA provided background information on the draft documents and approach used in the development of the documents. Following opening remarks by Versar and EPA, the peer reviewers began their discussions on the PFOA draft document, moderated by the Chair, Dr. Deborah Cory-Slechta. The discussions centered on individual responses to EPA's 12 charge questions. Additionally, some comments submitted to the public docket prior to the meeting were also discussed. The second day of the meeting began with brief remarks from Versar followed by discussions focusing on the PFOS draft document.

The reviewers began the discussion on the first day with the recognition of the significant amount of data that is available for both PFOA and PFOS and thus to be considered by the EPA for incorporation into the document and for the ultimate derivation of reference dose (RfD) values. In general, the reviewers commended EPA in doing a very good job of pulling together this significant and extensive body of information and of condensing it into its most critical pieces for the derivation of RfD values. This was especially the case given that there is significant human and animal data available for both chemicals, as well as inconsistencies in the data.

The reviewers did offer numerous suggestions for improving the documents, many of which are applicable to both PFOA and PFOS. In general, the suggestions relate to the statement of the problem and defining the database that was utilized, clarity and ease of presentation, and transparency of the reports, as well as to issues of modeling, use of human data, and liver weight increases as the most sensitive endpoint. These comments are summarized below, but please note that this does not reflect a consensus or group perspective.

- All reviewers agreed that it would be extremely useful to include an opening section of the document describing in some detail the literature that was reviewed. More specifically, this would include a description of the dates that were included in the

literature review, whether requirements for peer-reviewed materials were imposed, and what criteria were used in eliminating studies from consideration. This would assist in identifying studies that should potentially have been included. Many additional studies of importance were suggested for review at the meeting by the peer reviewers.

- The reviewers also agreed that there are some significant studies that have been published recently on PFOA and PFOS that may be relevant, and these should be included in the documents during the current revisions.
- Reviewers also felt that the Tables in the documents could be made much more useful to readers with the addition of columns that included more study details. This would minimize the amount of back-and-forth to the text that was required to assess conclusions.
- Additionally, there was a strong agreement that the Hazard Identification section of the documents should include a more systematic review of study strengths and limitations. These were noticeably absent in the human studies, where all studies were considered equivalent but also applicable to animal studies.
- Reviewers also felt that each Chapter should include introductory paragraphs, as well as concluding paragraphs, that would provide better integration of the material across the Chapters, as well as summarize the conclusions arrived at from the text in the Chapter. This would also facilitate the ability of readers to follow the presentations provided in Chapter 5 of the derivation of RfDs.
- As pointed out at the peer review meeting, the authors would be well advised to base these documents on the new documents being produced by EPA's National Center for Environmental Assessment (NCEA) for the Integrated Risk Information System (IRIS) program. While the reviewers recognize that the PFOA and PFOA health effect documents will not be used specifically for the same purpose, they will still likely be held to the same standards of presentation, clarity and transparency and thus, the new NCEA formats provide good models to follow.
- With respect to content of the documents, there was initial confusion around some of the modeling outcomes and assumptions based on values that were provided in the documents. However, following explanation from EPA personnel in response to clarifying questions from the reviewers at the peer review meeting, it became clear that there were errors in these values and once these were corrected, concerns about the specific values used in some modeling were allayed.
- Even with the corrections to the modeling, there were residual concerns among reviewers based on toxicokinetic properties of these chemicals, with respect to applying the same candidate RfD values to both short and long-term exposures, which in animal studies ranged from 11 to 182 days with reviewers expressing a need for this to be re-considered.
- There were mixed comments by reviewers with respect to the decision not to use human data in the derivation of RfD values. All reviewers generally agreed that the rationales provided for the exclusion of the human data were not actually appropriate, as it is certainly not the case that such use would be precluded by the fact that there were

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multiple and not sole exposures to either PFOA or PFOS. There was discussion as to the possibility of whether human data could be utilized in these assessments, and that ranged from an opinion that these data would not be useful to the view that it might be possible to use these data, despite the absence of information on route of exposure. Collectively, the range of opinions suggests that the issue should be revisited, and that appropriate rationales should be provided for the decision that is reached in the revised version.

- For both PFOA and PFOS, the RfDs were ultimately based on increases in liver weights in animal studies. There was significant discussion among reviewers as to the appropriateness of this endpoint for the derivation of the RfDs. That range of opinion spanned from an interpretation that these did constitute adverse effects in that they are a direct effect of a chemical exposure, whereas other reviewers saw these as adaptive effects. Collectively, the range of opinions suggests that the issue should be revisited, and that appropriate rationales should be provided for the decision that is reached in the revised version.

Following the meeting, peer reviewers were given additional time to complete their individual written reviews, which were submitted to Versar upon completion. These final written comments are contained in Sections III, IV, V of this report and fall into three categories: general impressions, responses to charge questions, and specific observations. Written peer review comments, as well as comments submitted to the docket by members of the public, will be considered by EPA as it revises the draft documents.

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I. INTRODUCTION

I.1 Background on Draft Health Effects Documents

On February 28, 2014, the EPA's Office of Water (OW) announced in the Federal Register the release of the draft health effects documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS) for purposes of public comment (scientific views) and peer review (http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf). The draft documents and charge questions were prepared by the Health and Ecological Criteria Division (HECD), within EPA's OW, in order to support future regulatory evaluations and decisions. EPA will consider the public comments and peer reviewer comments when revising the documents. Once the PFOA and PFOS health effects documents are finalized, they will be utilized to develop lifetime health advisory values for each chemical. PFOA and PFOS are listed on the third Contaminant Candidate List (CCL3)[1] and both chemicals are currently being monitored under the third Unregulated Contaminant Monitoring Rule (UCMR3)[2].

I.2 Peer Review Process

Consistent with guidelines for the peer review of highly influential scientific assessments, Versar, an EPA contractor, was tasked with assembling six to seven scientific experts to evaluate the draft PFOA and PFOS documents. The purpose of the peer review was to provide a documented, independent, and critical review of the draft health effects documents, and identify any necessary improvements to the documents prior to being published. In assembling these peer reviewers and coordinating the peer review, Versar was charged with evaluating the qualifications of peer review candidates, conducting a thorough conflict of interest (COI) screening process, independently selecting the peer reviewers, distributing review materials, maintaining contact with the peer reviewers, organizing and hosting the public peer review meeting, and developing a final peer review report.

The peer review selection process was initiated with a three-week public nomination period that was held from February 28, 2014 to March 21, 2014, as documented in the Federal Register on February 28, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf). During this period, members of the public were able to nominate scientific experts with knowledge and experience in one or more of the following areas: (1) epidemiology, (2) toxicology (liver effects, immunotoxicity, neurotoxicity, developmental and reproductive toxicology, etc.), (3) membrane transport, (4) human health risk assessment, (5) pharmacokinetic models, and (6) mode-of-action for cancer and noncancer effects. Concurrently, Versar conducted an independent search for qualified scientific experts to augment the list of publically-nominated candidates. In total, Versar evaluated 29 interested and available candidates who were either nominated by the public (n=18) or identified by Versar (n=11).

[1] CCL3 is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulation under the Safe Drinking Water Act (SDWA). Additional information about the CCL3 can be found at the following website: http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl3.cfm.

[2] EPA uses the Unregulated Contaminant Monitoring (UCM) program to collect data for unregulated contaminants suspected to be present in drinking water. Results from UCMR3 can be examined as they become available at the following website: http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/ucmr3/.

Versar considered and screened all 29 candidates against the selection criteria described in the Federal Register dated February 28, 2014, which included: (1) having demonstrated expertise in the areas described above, based on information in their submitted resume, biographical sketch and/or current publications, (2) being free of any COI and the appearance of the lack of impartiality, and (3) being available to participate in-person in a two-day peer review meeting in the Washington DC area in the July or August 2014 timeframe. Following the screening process, Versar narrowed the list of potential reviewers to 15 candidates and provided to EPA the names of the candidates selected by Versar to be on the interim list. Additionally, information on the 15 candidates, including their professional affiliations, expertise, education, and professional experience were provided for the interim list and published in the Federal Register on April 30, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-04-30/pdf/2014-09888.pdf). The Federal Register also requested the public to submit relevant information or documentation on the interim list of candidates that Versar should consider during the evaluation process of selecting the final six to seven reviewers.

Following the close of the public comment period on the interim list of potential reviewers, Versar re-evaluated each interim candidate's credentials to select the experts who, collectively, provided expertise spanning the multiple subject matter areas covered in the draft documents and provided a balance of perspectives. In addition, Versar evaluated the availability of each candidate to ensure all final peer reviewers were available on the same days for the meeting in the selected timeframe. Once the evaluation process was completed, Versar narrowed the interim list of 15 candidates and selected the seven final peer reviewers. In addition, Versar selected Dr. Deborah Cory-Slechta as Chair of the peer review meeting due to her expertise in toxicology as well as her strong record of chairing and participating in peer review panels, scientific meetings, and workshops. A list of the final seven peer reviewers who participated in this review is provided below. In addition, each reviewer's biographical sketch is included in Appendix A.

Following the selection process, Versar distributed EPA's draft PFOA and PFOS documents and 12 charge questions (see Section II) to the peer reviewers. The peer reviewers were asked to evaluate the scientific and technical merit of the draft documents and provide their responses to the 12 charge questions. This included evaluating the appropriateness of the quality, accuracy, and relevance of the data in the documents. Peer reviewers were not charged with making any regulatory recommendations or reaching consensus in either their written comments or public deliberations. In addition to being provided the draft documents and charge questions, comments submitted to EPA's public docket (Docket ID number EPA–HQ–OW–2014–0138) during each document's 60-day public comment period were provided to the peer reviewers ahead of the meeting for their consideration. Also, a brief summary of the public comments was developed by Versar and provided to the reviewers. However, peer reviewers were not asked to evaluate or respond to comments submitted to the docket.

Versar managed the pre-meeting peer review period, which provided the peer reviewers approximately two months to evaluate the draft health effects document and complete their written reviews. Following receipt of the peer reviewers' draft comments, Versar compiled the comments into a pre-meeting peer review report and distributed them to the peer reviewers and

EPA to prepare for the public peer review meeting. These preliminary responses to the charge questions formed the basis of reviewer discussions on Days 1 and 2 of the public meeting.

Peer Reviewers:

James V. Bruckner, Ph.D.
University of Georgia

Deborah A. Cory-Slechta, Ph.D.
University of Rochester School of Medicine and Dentistry

Jamie C. DeWitt, Ph.D.
East Carolina University

Jeffrey W. Fisher, Ph.D.
U.S. Food & Drug Administration

William L. Hayton, Ph.D.
The Ohio State University

Matthew P. Longnecker, Sc.D, M.D
National Institute of Environmental Health Sciences

Angela L. Slitt, Ph.D.
University of Rhode Island

I.3 Peer Review Meeting

On August 21 and 22, 2014, Versar convened a public peer review meeting in Arlington, Virginia. This meeting was held to discuss the scientific basis supporting EPA's draft health effects documents and to provide members of the public with an opportunity to observe the peer reviewer deliberations. The meeting followed both the documents' public comment period, during which members of the public were able to submit written comments, and the pre-meeting written peer review period, during which the seven selected peer reviewers evaluated EPA's draft health effects documents and provided preliminary comments in response to the charge questions.

Versar managed the pre-meeting registration period, which allowed members of the public to register to attend the meeting in person or remotely via teleconference and/or webinar. Members of the public were able to register online, via Versar's registration website (http://peerreview.versar.com/epa/pfoa/) as well as by telephone, email, or U.S. mail. In advance of the meeting, Versar provided all registered attendees with pre-meeting handouts, which included the agenda and logistics information.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. In addition, EPA provided background

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information on the draft documents and approach used in the development of the documents. Following opening remarks by Versar and EPA, the peer reviewers began their discussions on the PFOA draft document, which centered on individual responses to EPA's 12 charge questions. The remainder of the day was dedicated to discussions on the PFOA document, which were moderated by the Chair, Dr. Deborah Cory-Slechta. The second day of the meeting began with brief remarks from Versar followed by discussions focusing on the PFOS draft document. Approximately 23 public observers attended the peer review meeting in person and 21 observers attended the meeting via teleconference and/or webinar. Please see Appendix B for the meeting agenda and Appendix C for a list of public attendees.

Following the public peer review meeting, peer reviewers were given additional time to complete their individual written reviews. These final written comments are contained in Sections III, IV, and V of this report. Written peer review comments, as well as comments submitted to the EPA docket by members of the public, will be considered by EPA as it revises the draft health effects documents.

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II. CHARGE TO REVIEWERS

PFOA and PFOS are environmentally persistent organic fluorocarbons (PFC) that have been identified in ambient waters, ground water, drinking water, and biosolids. They are metabolically inert but have the ability to bind to and interact with a variety of biomolecules leading to responses in living organisms. Both compounds have a substantial database of epidemiological, pharmacokinetic, toxicological and mechanistic studies. The two documents submitted for peer review include health assessment chapters that will be used 1) to provide information to drinking water treatment plant operators regarding the significance of monitoring results with respect to potential health outcomes and 2) to determine whether the perfluorinated compounds currently being monitored at Public Drinking Water Systems require regulation. The health information at that time will be accompanied with chapters on environmental fate, occurrence at public drinking water systems and occurrence in other media. The quantitative aspects of the Health Assessment documents will also be used to develop lifetime Health Advisories for both compounds.

Charge Questions

1. Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

2. Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

3. The OW concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment of the OW characterization of the data.

4. Please comment on the transparency and characterization of the epidemiological data.

5. The OW has concluded that the cancer classifications for PFOA and PFOS are most consistent with respective classifications of suggestive evidence for carcinogenicity as described the EPA Guidelines for Carcinogen Risk Assessment (pp. 2-56, 2-57). Please comment on the strengths and weaknesses of this classification.

6. Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

7. Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

8. The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

9. A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

10. The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days, and occur at comparable human equivalent dose (HED) levels. The current, draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

11. In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.

12. Please describe any suggestions you have for improving the clarity, organization, and/or transparency of the draft documents.

III. GENERAL IMPRESSIONS

James V. Bruckner

PFOA-specific comments

This is one of the most comprehensive Health Effects Documents I have reviewed. The clarity and accuracy of accounts of pertinent research reports/publications are excellent. It is obvious considerable time and efforts were devoted to its composition. If anything, the amount of detail is so great that it is difficult to distill the mass of information on each topic and capture its "essence". This is likely the result of directions the authors were given for writing the document. Some topics in the Hazard Identification section do have summarizing sentences, in which the key/critical studies and their finding(s) are integrated and conclusions reached. It would be very helpful to devote much more attention to this for more topics, perhaps as an addition to Section 4.4 Hazard Characterization.

I do have a real problem with the scientific basis and soundness of certain conclusions in the document. The primary effect of PFOA in different species is increased absolute and/or relative liver weight. These are quite modest, reversible, non-specific effects that usually are not considered toxicologically significant. Livers of mice and rats dosed with PFOA typically exhibited hypertrophy characterized by increased peroxisomes, numerous mitochondria, reduced rough endoplasmic reticulum (RER), proliferation of smooth endoplasmic reticulum (SER), and increased autophagosomes or lipid-like droplets. Such morphological changes, particularly those in RER and SER, are manifestations of microsomal enzyme induction. This is considered adaptive, rather than adverse. Hall et al. (2012) points out that activation of a battery of genes involved in xenobiotic metabolism and transport serve to maintain homeostasis by enhancing the systemic elimination of the foreign chemical. Although PFOA is very poorly metabolized, it does persistently induce microsomal enzymes and the accompanying hepatocellular morphological changes. Upregulation of genes responsible for biliary excretion may be beneficial, since excretion of bilirubin, bile acids and conjugates of toxic chemicals/metabolites would be enhanced.

There are substantial qualitative and quantitative differences in responses of rodents and humans to PPARα activation. Therefore, many of the PFOA-induced alterations in lipid metabolism/homeostasis and associated biological processes in mice will be absent or an order of magnitude less pronounced at comparable doses in humans. Many of PFOA's effects on the liver of rodents are dependent on PPARα activation, though some effects appear to be PPARα-independent. Studies in PPARα-knockout mice show activation of other nuclear receptors by PFOA, including PXR, CAR, LXRA and FXR. Bjork et al. (2011) observed markedly lower transcriptional responses of PPARα, PXR, CAR and FXR to PFOA in cultured human than in cultured rat hepatocytes. These more subtle effects lead the investigators to conclude the changes in human cells reflected an adaptive metabolic remodeling rather than overt metabolic dysregulation, or disorder occurring in rat cells. The PFOA document's authors should go into detail discussing and summarizing the relative toxicological significance of non-PPARα effects in rodents versus humans.

It is important to recognize that clearly adverse effects of PFOA are seen. Lovelass et al. (2008), Cui et al. (2009) and others have seen focal necrosis and degenerative changes in the liver of mice and rats given relatively high doses of PFOA, as well as modest elevations in serum (hepatic) enzyme activities. Wolf et al. (2008a) observed a variety of degenerative structural changes in the liver of PPARα-null mice dosed with PFOA. Sakr et al. (2007a,b) and Olsen and Zobel (2007) reported associations between serum PFOA levels and slightly elevated serum enzyme activities in some occupationally-exposed populations. The increases in enzymes may have been attributable to factors other than PFOA. In light of the foregoing, it would be preferable to utilize hepatic morphological changes in rodents and/or elevated serum enzymes as the critical effect(s), rather than increased liver weight. These are clearly adverse effects seen in both rodents and humans.

An international panel of experts (Hall et al., 2012) opined that an increase in liver weight of ≤ 150%, at doses of chemical that do not produce structural or biochemical evidence of hepatocellular damage, would not be considered adverse. Absolute and relative liver weights were not increased as much as 50% by most PFOA doses in the majority rodent and monkey studies. Perkins et al. (2004), for example, reported dose-dependent increases in liver/body weight in rats fed 1, 10, 30 and 100 ppm PFOA for 13 weeks of 0, 10, 30, and 41%, respectively. Butenhoff et al. (2002) measured increases of 17, 21 and 37.5% and relative liver weight in monkeys given 3, 10 or 30/20 mg PFOA/kg/day for 26 weeks, respectively. Liver hypertrophy of this magnitude does not warrant such a low RfD. By adhering to EPA policies of calculating a $BMDL_{10}$ and using multiple UFs, regardless of the (lack of) severity of the critical effect and relatively low level of concern about other potential health effects, the end result is a vanishingly low RfD (i.e. 0.00002 mg/kg/day). A great deal of time and effort were spent on the PFOA hazard assessment, toxicokinetic modeling and extrapolations, dose metric and POD considerations, etc. Despite all of these scientifically-credible exercises and deliberations, the end result (RfD) seems to this reviewer to have been preordained-- to be extremely low.

Logic expressed on page 5-6, in support of use of liver weight gain as a critical effect and biomarker of loss of hepatocellular homeostasis seems flawed. As pointed out in the second paragraph, liver weight changes were not observed in PFOA-treated mice with a humanized PPARα receptor. It is noted that changes in gene products that modulate lipid metabolism do occur in these mice. EPA argues that this supports adoption of increased liver weight as a biomarker/critical effect. It has not been established that these changes in gene expression are adverse, or whether they are sufficient in magnitude to significantly alter lipid metabolism. It would be expected that repeated dosing with enough of a molecule (i.e., PFOA) that resembles a fatty acid would affect expression of such genes. Reversible changes in total cholesterol, bile acids, bilirubin, etc. have been observed. It has not been established, however, whether mild fluctuations in these indices are detrimental. No increases in mortality from cerebrevascular disease or ischemic heart disease have been found in PFOA-exposed humans. How then does the concurrence of alteration of expression of such genes and of liver weight gain support the latter as toxicologically-significant effect that should be prevented by setting the RfD low enough?

PFOS-specific comments

This Health Effects Document, like that for PFOA, is quite comprehensive. Its descriptions of the many studies of PFOS are clear, quite complete, and apparently quite accurate. As with the

PFOA document, so much detail is given about many studies in the Hazard Identification section, that is difficult to compare study designs/dosage regimens/species/indices/findings/etc. and to draw conclusions. The summary tables for single and multiple studies, however, are quite helpful in this regard. It would also be very useful to have more summary statements or paragraphs at the end of each topic. These should address the scientific importance of findings, their relevance to humans; and their impact on the weight of evidence on an issue.

The hazard characterization section (4.4) is, for the most part, inclusive and balanced in its presentation and integration of findings of the more important studies in each subject area. This is true for both non-cancer and cancer effects in humans and animals. It concerns me, however, that the document's authors do not focus in the remainder of the document on science (i.e., the candidate critical effects and their relevance to human health), but merely choose the most sensitive end-points and stress how similar the RfDs are after dosimetry modeling estimates and adjustments. I am not sure how this similarity of derived points of departure and other values, calculated from dissimilar endpoints, supports or validates the final RfD.

I recommend that an additional section be written, in which the primary adverse effects of PFOS are discussed-- in terms of their relative toxicological significance, their apparent mechanism(s), their relevance to humans, their likelihood in realistic exposure scenarios, and implications of altered experimental indices to actual organ dysfunction.

I am quite concerned about the increased rat pup mortality in several studies at relatively low maternal doses, but not about reversible liver weight changes or centrilobular hypertrophy. Is the decreased pup survival in several studies at relatively low maternal doses of PFOS relevant to humans?-- Is the dose-response curve steep, as suggested by Luebker et al. (2005a), such that there would be less concern about sub-threshold doses? -- What is the most likely mode of action (pulmonary surfactant or maturation, dietary, hormonal)? -- Is decreased survival PPARα-related? -- Is the mechanism in rats relevant to other species? -- Does pup mortality occur in other species at comparable doses? -- Might there be a dose-dependent alteration of maternal-fetal partitioning of PFOS?

Deborah A. Cory-Slechta

Both documents, although the PFOA document to some degree more than PFOS, overall are more of a tabulation of studies than a critical review of studies from which a rationale is presented for a choice of studies to model and from which to derive associated RfDs. The Executive summaries are too abbreviated and do not include sufficient rationale, description and detail to provide the reader with an understanding of how decisions described in Chapter 5 were made. Since in some cases, this will be the only sections read, they could provide a more informative summary.

It would be very helpful to provide a section up front that describes all of the parameters of the literature search, including the years that are included in the document review, as well as descriptions of criteria for studies that were included vs. those that were excluded. In addition, it should be indicated whether there was a criterion that studies be peer-reviewed. This is particularly important given the voluminous size of the data base that has accumulated for these

two chemicals. Given that revisions will be done and that such documents do not get updated with any frequency, it would be good to attempt to include as much of the new pertinent literature as possible.

The section on Toxicokinetics in the documents present studies in detail, but no real conclusions; this is true of most of the sections in these documents. Chapters 3 and 4 in particular read like tabulations of studies rather than critical reviews and because of that, the documents seem disjointed and Section 5, i.e., derivation of values, tend to be difficult to read through and require constant searching back to the original chapters in which they are described. It is critical to identify the strengths and weaknesses of the various studies, and which were given weight to use in the final determinations. It would be helpful if Sections 3, 4 and 5 included an introductory paragraph describing the goal of the chapter, and that each ends with an overall summary with conclusions. The tables in these chapters also would benefit from the inclusion of additional information that ultimately permits comparisons within the Table and does not require continually returning to the text to recall the species, sample sizes, etc.

In the sections on Hazard Identification, it is useful that studies are summarized by target organ, but there are almost no conclusions and no discussions of strengths or weaknesses of studies and therefore their use or not in future decisions. In fact, one is left with the impression that all studies are equal, especially in the section describing human studies. Within Chapter 4, the sub-sections entitled "evaluative and integrative" are actually neither. Data are presented simply as positive or negative with no real discussion of the strengths and limitations and what was concluded overall. For this reason, Chapter 5 is also lacking. It provides very little in the way of rationale and conclusions. Thus, the transparency of the process is really insufficient.

Jamie C. DeWitt

The information presented throughout the documents appears to be accurate (with one minor exception noted in Table 1 of these comments) and is presented clearly. For PFOA, a reference dose (RfD) of 0.00002 mg/kg/day was determined and evidence of carcinogenicity is considered suggestive with a human equivalent dose (HED) of 0.58 mg/kg/day. The RfD was based on changes in liver weight reported as a common denominator in four rodent (three rat and one mouse) studies and carcinogenicity was based on a limited number of epidemiology studies linking kidney and testicular tumors with exposure and evidence of tumor induction in the liver, testes, and pancreas (the "tumor triad") in rats. For PFOS, a RfD of 0.00003 mg/kg/day was determined and evidence of carcinogenicity is considered suggestive but with insufficient evidence to determine human carcinogenic potential. The RfD was based on developmental neurotoxicity and changes in liver weight.

While the carcinogenicity assessment seems appropriate for the two compounds given the limitations of the data sets, changes in liver weight as a basis of both of the RfDs is questionable in terms of its significance to exposed humans. Exposure to these agents increases liver weight and hepatocellular hypertrophy in rodents (and the definition of these endpoints as "adverse" or "toxic" also is contentious); this has been demonstrated across various rodent strains and under myriad exposure paradigms. However, there is no consensus in the scientific community regarding the mechanism by which exposure to these compounds increases liver weight and

induces hepatocellular hypertrophy in rodents and whether any of the putative mechanisms are sufficient to induce hepatotoxicity in exposed humans. Proposed mechanisms include peroxisome proliferator activated receptor alpha (PPARα) activation, activation of other nuclear receptors, peroxisome proliferation (which may or may not be dependent on PPARα activation), and oxidative stress. Humans can certainly respond to PPARα agonists (i.e., fibrate drugs are used as hypolipidemic agents) and a handful of epidemiological studies of highly exposed human populations have reported associations between PFOA/PFOS and alterations in liver enzymes, but the clinical relevance of the changes to the liver enzymes reported for these studies is uncertain. These liver-related changes in humans generally occur at higher doses than required to induce changes in the livers of rodents, which occurs at relatively lower doses than other observed effects. Therefore, a critical endpoint that occurs at very low doses in rodents, has no agreed upon mechanism that may or may not be relevant in humans at relatively high doses, may not be the best choice for the basis of a RfD. Liver weight change has been reported to occur in several species, including non-human primates, and at low doses, it may be an adaptive response and not a toxicological response. While this response may be protective of human health because it is common following low dose exposure to PFOA or PFOS, other endpoints may be more relevant to humans, especially endocrine system effects, including changes to thyroid hormones and mammary gland development, and immune system effects. Endocrine and immune system effects have been reported in exposed humans, suggesting that such endpoints may operate via a mechanism that is more relevant to humans than mechanisms related to changes in liver weights.

In addition, the one developmental neurotoxicity study used, in part, for the PFOS RfD is only weakly supported by additional studies in rodents or other species and is based on behavioral responses that could be influenced by factors other than direct effects on the nervous system. Additional confirmatory studies are necessary for this observation to be considered a critical effect of PFOS exposure.

Finally, while well-written overall, the documents lacked an overall critical analysis or depth required of a risk assessment. Why specific studies were included or not should be better explicated in the text.

Jeffrey W. Fisher

The document was well written in terms of balance and presenting information. Summary statements are needed for chapters; a synthesis/analyses of the data are needed in some cases. A more critical evaluation of the human and non-human responses to PFOA/PFOS is required to justify not using human or non-human primate data. A rationale for the modeling approaches is needed given the more recent PBPK models that are available.

William L. Hayton

The literature that pertains to the health effects of PFOA and PFOS is large and presents a major challenge to accurately summarize and analyze it and develop an RfD for PFOA and PFOS. Reported health effects in animals and humans, sometimes contradictory, include exposure-associated changes in serum cholesterol, lipids, uric acid, and thyroid hormones, obesity-related

metabolism, immune system function, and effects on reproduction, development of the mammary gland, the nervous system, and behavior. Target organ effects (e.g., liver, kidney) have been reported, as well as associations of PFOA and PFOS exposure with testicular, prostate and kidney cancer. Studies in several laboratory animal species have added the complications of interspecies comparisons and extrapolation of findings to humans. In humans, there have been a Phase I clinical trial of PFOA, and epidemiological studies of populations exposed to PFOA and PFOS occupationally and in communities with and without water supplies contaminated with PFOA and PFOS. The draft documents have accurately presented in summary form the results of many animal and human studies and used pharmacokinetic methods to link PFOA and PFOS exposure rates to internal dose metrics such as serum concentration. While the overall effort is commendable, there are two issues that the draft documents raise: 1) the literature cited does not include many apparently relevant published works. The cut-off date for cited literature was early 2013 (this should be indicated in the documents), but commenter's noted a number of pertinent publications in 2011 and 2012 that were not cited, and there have appeared several highly pertinent papers since the cut-off date, and 2) while the descriptions of individual studies are generally clear and accurate, there is a lack of independent, critical analysis of the studies and a lack of synthesis of results from multiple studies common to a particular health effect.

Matthew P. Longnecker

The PFOA and PFOS documents achieve the goal of identifying RfDs that are well founded. My main criticism is that the rationale for not using the human data to provide a POD needs to be strengthened.

For example, in the PFOA document, on page 5-19, first paragraph below the table, it says "human data … lack the exposure information for dose-response modeling." This statement is logically inconsistent with techniques that were used to estimate HED on the basis of serum concentration, as given on page 5-17, near the bottom. Or, in some cases, such as in the C8 study, the exposure estimates that were calculated based on water district were sufficiently good that a dose-response analysis would be possible. In other words, because many human studies have serum concentration of PFOA or reasonable estimated exposure values, the corresponding HED could be estimated, and hence the dose-response could be modeled. Granted, some assumptions would be needed, but the methods could be serviceable (see response to item 3 below). (Some of the above also applies to pages 5-1 and 5-2). More compelling arguments for not basing the POD on human data are, e.g., that: 1) the low probability that humans are 1,000 times more sensitive to PFOA than other species (the number is based on the last column in table 5-9 compared with PFOA values in the C8 study and background exposed populations), especially given the relatively tight agreement between LOAEL (average serum concentration basis) among other species, 2) the possibility that the observed associations in humans were due to unmeasured confounding factors or reverse causality, and 3) other weaknesses in the epidemiologic data such as inconsistent results across studies (selected outcomes), unreplicated findings, or associations with clinical chemistry results for which corresponding adverse clinical correlates (i.e., morbidity) are not clearly established.

Angela L Slitt

The documents provide a very thorough evaluation of PFOA and PFOS studies. It is logically organized, presenting findings in a way that the reader can understand the findings related to human, monkey, and rodents. The organization of the document allows the reader to easily find information about each species within the subchapters and summarizes key points in table form. PFOA is a well-studied compound, with a substantial amount of toxicokinetic and endpoint studies in rodents. Mechanistic data describing the role of membrane transporters to understand gender differences in PFOA elimination in rats is fairly well written. Little data exist regarding contribution of membrane transporters to PFOS disposition and elimination. The documents thoroughly describe species differences in PPAR-alpha signaling that might contribute to observed endpoints in rats, but not humans or monkeys. Overall, both documents are very thorough and provide a reliable basis for PFOS and PFOA evaluation.

For PFOA toxicokinetics, mechanisms of PFOA transport are important for understanding species differences in response to PFOA exposure, with focus placed on kidney. Figure 3-2 in the PFOA document does not adequately present the localization of renal transporters with relationship to their contribution to the urine compartment or renal reabsorption. A very nice diagram showing the subcellular localization of renal transporters presented by Klaassen and Aleksunes (Pharmacol Rev. 2010 Mar;62(1):1-96) clearly depicts the contribution of various transporters to filtrate or blood. This is an easier diagram to put PFOA elimination into context than the one presented. Contribution of membrane transporters to species differences in PFOA excretion Section 3 (specifically 3.4.1) would be put in better context if a table could be generated to compare Km and Vmax values for PFOA for various transporters, with specific focus on species information for OATPs and OATs. Data regarding information on contribution for OATps in liver accumulation of PFOS and PFOA is lacking, with specific regard to species differences. As PFOS is a likely candidate for hepatic uptake transport, understanding a mechanism to explain species differences in hepatic effects possibly due to difference in hepatic exposure is critical. Understanding impact species specific regulation of OATp expression in liver (e.g. whether species difference in PPAR-alpha signaling contributes) is also important in putting rodent distribution data into context.

Increased liver weight is considered to be a critical effect, but how increased liver weight relates to the observed human and monkey health effects needs to be further explained. First, use of liver weight alone might not be substantiate of an effect for point of departure compared to other liver effects observed at higher concentrations, such as increased serum ALT or AST.
The studies that have evaluated these endpoints are well conducted. In layman terms, if someone is walking around with an increased liver weight, is he or she at risk for disease? Will his/her life span be shortened? To increase transparency of the document, a more comprehensive explanation is needed to justify why increased liver weight should be considered as a critical endpoint for human health.

However, it should be noted for future consideration that there are a few publications in mice that do also ascribe liver weight changes in increased lipid accumulation along with increased expression of genes that contribute to fatty liver disease. This is considered to be a gap in knowledge for the field. Will relatively low dose PFOS exposures associated with hepatic

steatosis have other endocrine related effects known to be associated with NAFLD (insulin resistance, impaired glucose tolerance)? Emerging studies are evaluating whether PFOS induces hepatic steaosis and whether it is a PPAR-α mediated effect. For example a study performed by Wan et al. (2012) administered 0, 1, 5 or 10 mg/kg/day PFOS to adult male CD-1 mice for 3, 7, 14 or 21 days. Histological analysis of liver sections, and biochemical/molecular analysis of biomarkers for hepatic lipid metabolism were assessed. Overall, the study reported that PFOS-administration induced hepatic steatosis in a time- and dose-dependent manner. The study also shows a high correlation between liver weight and lipid content. Increased expression of a lipogenic target (CD36/FAT) was observed at 5 and 10 mg/kg PFOS. A second study by Bijland et al. (2011) illustrated that PFOS administration increased liver weight (+ 107%, $p < 0.0001$), which was accompanied by an increased hepatic TG content (+ 192%, $p < 0.0001$, respectively) in E3L.CETP mice on a C57Bl/6 background. At the age of 8–10 weeks, mice were fed a semisynthetic Western-type diet, containing 0.25% (wt/wt) cholesterol, 1% (wt/wt) corn oil, and 14% (wt/wt) bovine fat for 4 weeks in three independent experiments. Upon randomization according to body weight, plasma TC, and TG levels, mice were fed a Western-type diet without or with PFOS (0.003%, ~3 mg/kg/day) for 4–6 weeks. In summary, there is evidence that administration of relatively low PFOS doses to mice can result in hepatic lipid accumulation in the absence of overt "wasting."

Data is lacking as to whether higher species, such as monkeys or humans will also develop PFOS-induced steatosis, which is confounding. Studies have profiled gene expression in wild-type and PPARα-null mice administered PFOS, finding that there is pathology and gene expression consistent with lipid-promoting effects in liver that are independent of PPARα, as they are observed in PPARα-null mice (Rosen et al., 2010). Limitations to the studies are that they did not specifically quantify hepatic lipid content, but inferred that the PFOS-induced vacuolization in liver pathology observed was potentially related to triglycerides. Studies by Bjork et al. (2011) comparing rat and human primary hepatocytes treated with PFOS (25 μM) demonstrated that human hepatocytes were slightly less responsive to the induction of lipid oxidation and synthesis genes, as well as induction of carbohydrate metabolism. It should be noted that the hepatocytes from the study are from a single human donor, the hepatocyte lipid content was not determine, and hepatocyte culture conditions were standard and not optimized to induce steatosis. In summary, the current literature is lacking robust information regarding whether PFOS, which highly concentrates in liver, has a steatotic-inducing effect in human or monkey liver. The evidence in PPARα-null mice indicates that it might have some PPARα independent effects related to hepatic fat accumulation. Because evidence for hepatic lipid content in PPARα-null mice after PFOA or PFOS has been described only by pathology, more robust studies are needed to conclude whether the effects can occur independent of PPARα and the observed increased liver weight is due not only to hypertrophy due to nuclear receptor activation, but lipid accumulation. However, this reviewer is noting this as a concern for the future and area where a gap in knowledge exists.

Moreover, because the reviewer is noting a concern for hepatic fat accumulation that exists in the absence of PPARα, it should be appreciated that traditional markers, such as AST and ALT have poor prognosis for NAFLD or toxicant associated steatohepatitis. Most patients with NAFLD are asymptomatic and the disease is often diagnosed following findings of elevated aminotransferases, especially when combined with other features of metabolic syndrome. These

abnormal liver function tests usually require the physician to distinguish between NAFLD and alcoholic fatty liver disease (AFLD). Some have suggested that a serum AST/ALT ratio >1 are indicative of AFLD. Other possible signs of AFLD include elevated HDL-cholesterol with hypertriglyceridemia. While most diagnoses of NAFLD may result from altered liver function tests, normal serum aminotransferase tests can be seen in patients with both steatosis and NASH (Ipekci, et al., 2003; Mofrad, et al., 2003). Indeed, it is reported that two-thirds of NASH patients may have normal aminotransferase levels at any given time (Oh, et al., 2008; Delgado, 2008; Wieckowska and Feldstein, 2008). Kunde et al. investigated the accuracy of NASH diagnosis by serum ALT in women undergoing gastric bypass surgery (Kunde, et al., 2005). They compared two different reference laboratory cutoffs for "normal" ALT levels, the previous guideline of 30U/L, and new lower level of 19U/L that was suggested to aid in the diagnosis of NAFLD. Importantly, the authors reported that the diagnostic utility of serum ALT remained poor even at the new lower cutoff. Sensitivity and specificity of serum ALT levels were found to be 42% and 80% (ALT > 30U/L) versus 74% and 42% (ALT > 19U/L). These and other studies (Lizardi-Cervera, et al., 2006; Amarapurkar and Patel, 2004; Amarapurka, et al., 2006; Chen, et al., 2006; Fracanzani, et al., 2008; Sorrentino, et al., 2004; Mofrad, et al., 2003; Uslusoy, et al., 2009) illustrate the need for a more effective diagnostic measure for NAFLD, especially the NASH stage. In sum, use of ALT and AST elevation to base the point of departure must be taken into context because they are poor prognostic markers for increased liver accumulation, NAFLD, or even NASH. Use of ALT and AST might not be an appropriate biomarker for measurement of PFOA or PFOS-induced adverse effects on liver and should be considered as a gap in our knowledge for future work.

In the review panel discussion, there was discussion regarding a publication by Hall et al. (2012), which summarized the outcome of a workshop regarding liver hypertrophy and hepatocarcinogenesis. Overall, the workshop concluded that "hepatomegaly as a consequence of hepatocellular hypertrophy without histologic or clinical pathology alterations indicative of liver toxicity was considered an adaptive and a non-adverse reaction". This conclusion is taken in the context of hepatic hypertrophy caused by nuclear receptor activation. This differs from others that have concluded in mouse NTP studies where correlations between liver weight increases and histological parameters and carcinogenesis were assessed, the authors concluded that ''the best single predictor of liver cancer in mice was hepatocellular hypertrophy'' (Allen et al. 2004). Based on the conclusions presented in Hall et al. (2012), increased liver weight might not be considered an appropriate POD because of lack of overt toxicity and hepatomegaly being considered an adverse effect. It should be noted that this reviewer still has concerns regarding this conclusion for PFOS and PFOA because the pathology described in PPARα-null mice reflect increased hepatic lipids and not hepatomegaly due to nuclear receptor activation that is described in this opinion publication. If one considers the pathology examples of hypertrophy presented in Hall et al. (2012), it is quite different from the pathology described for PFOS and PFOA. For clarity, the document should try to delineate the cellular components that are contributing to increased liver weight caused by PFOA and PFOS administration, if such a publication exists (e.g. how much of the liver is associated with protein/peroxisome proliferation increase versus lipid increase). Because the literature is not clear regarding what exactly in the liver is causing increased liver weight, studies documenting hepatic lipid accumulation should not be currently considered for POD. Given the recent opinion cited by Hall et al. (2012), it is

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recommended that studies documenting liver damage, such as ALT and AST elevation be currently used as the POD.

The documents often have redundancy in information, especially in regard to hormone effects (there are very similar write ups in sections about effects on thyroid hormone) and metabolic/cardiovascular disease risk factors (e.g. lipid endpoints).

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IV. RESPONSE TO CHARGE QUESTIONS

Charge Questions

Question 1. Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

James V. Bruckner

PFOA-specific comments
The document's authors have done a good job describing and integrating the findings of the numerous studies in which liver weight gain was observed. Although there is a consensus about the effect and the dosage required to elicit it in different species, this reviewer does not believe it should be utilized, as described above. There are several clearly adverse effects such as elevated serum (hepatic) enzyme activities, focal hepatocellular necrosis, bile duct degeneration and fibrosis, etc. These effects are generally seen in response to relatively high PFOA doses, so the PODs will be higher than with liver weight increase. Alternatively, a human endpoint such as elevated serum cholesterol could be considered. See responses to Charge Question 3.

PFOS-specific comments
There have been a substantial number of well-conducted toxicological studies of PFOS. My major concern, as expressed above, is its potential to cause adverse effects in children. Other than that, PFOS doesn't appear to produce effects other than those anticipated from a repetitive, cumulative dose of an 8-carbon fatty acid.

Deborah A. Cory-Slechta

In general, it appears that, at least with respect to the animal studies, the choices are appropriate both in the case of PFOA and PFOS. The derivation of the RfDs/RfCs are based on studies of sufficient strength, duration and represent the most sensitive endpoints.

Having said that, in both documents, the reader is forced to that conclusion with no real assistance from the text itself. There is virtually no discussion of the strengths and weaknesses of the studies overall. Human study outcomes for the most part are simply enumerated, although an occasional statement will be made about a limitation (usually) of one of those studies. There is no discussion in the human studies of the power to detect effects, the sample sizes, etc. Much weight seems to be given to occupational studies in some cases, being used to essentially dismiss effects in a community cohort as the same effect was not seen in occupationally exposed workers, when in fact finding effects in a population with seemingly longer, albeit lower exposure levels actually makes the outcome more robust. Also, population studies with smaller sample sizes that nevertheless find significant effects are in fact more compelling and suggest robust effects which can be detected even with a small sample size. This deficiency is manifest in statements such as those in the PFOS document (p. 5-1) that 'in most cases the findings are suggestive and not conclusive of an effect'.

There is a bit more discussion of the animal studies in both documents, at least with respect to methods, but as with the human studies, there is little text addressing which studies represent stronger studies or what the weaknesses are. From these increase liver weight has been chosen as the endpoint from which to derive RfDs. This reviewer does not have an issue with that choice, as while it has been described as adaptive by some, it represents a response to an involuntary exposure with a direction of effect that is potentially associated with adverse consequences. The fact that it is reversible when exposure ends seems irrelevant as reversal of exposure is not happening in the human environment.

Jamie C. DeWitt

Strengths: The studies selected as key for quantification were generally well-conducted studies, employing a range of doses and sample sizes large enough for detecting statistical differences. Additionally, the doses associated with LOAELs for the identified critical endpoints were not associated with signs of overt or systemic toxicity in the animal models and nearly all of the studies measured serum and/or tissue concentrations of the parent compounds.

Weaknesses: No obvious experimental design weaknesses were noted in any of the studies selected as key for quantification.

Characterization: The studies selected as key for quantification for PFOA are all rodent studies while at least one study selected for PFOS quantification includes a non-human primate study. It is therefore surprising that the PFOA database does not include, as a study key for quantification, the Butenhoff et al. 2002 study of non-human primates. Additionally variability in putative mechanisms among species was not adequately addressed in the characterization of the selective studies, although all of the selective studies were descriptive and not mechanistic.

Jeffrey W. Fisher

PFOA and PFOS: Data bases are massive and both need to be updated. Several human studies and a few non-human primate toxicity studies are available. The authors need to explain why these studies are not adequate for causality (dose-response).

William L. Hayton

An advantage to assessment of health effects for both PFOA and PFOS is the large amount of published work that informs the topic. While the draft health-effects documents have summarized the results of many pertinent studies, the literature reviewed was not comprehensive, which projects an appearance of weakness. The documents do not state whether the intention was to include all relevant health-effects literature, or to be selective and summarize those studies judged to be most relevant. Such a statement at the beginning of the documents would be helpful; a cut-off date for the literature review would also frame expectations of readers. If the intention was to be selective, a description of selection criteria would help allay concerns of readers about papers that were not included. If the intention was to comprehensively review all the PFOA and PFOS health-effects literature, then it appears that

more work should be done to include omitted works. Public comments list a number of works to consider for inclusion.

A general, albeit minor weakness of the literature is that PFOA and PFOS serum concentrations in control animals were not measured for many studies – they were likely non-zero and, since there is no information on how high they were, it is possible that baseline health-effects metrics were affected and that dose-response relationships were affected, especially in the low dose range. It is perhaps worthwhile to mention this shortcoming somewhere in the health effects documents.

Matthew P. Longnecker

EPA may want to consider the article by AP Hall et al. 2012, about liver hypertrophy. The defense of increased liver weight as the POD (or a POD) could be strengthened by evaluating the evidence in the context of Hall's Figure 9, where evidence regarding hepatoxicity and toxic mechanisms are also considered. In this case, the possibility of an unknown mechanism exists that could be relevant to humans, and long-term exposure could have effects that have not yet been detected. See Hall page 986, where it defines adverse as: "…affects [response] to an additional environmental challenge". Thus, an adverse effect, via an unknown mechanism, by this definition is possible and has not been studied in animals or humans.

While AP Hall's article is not all that supportive of using increased liver weight as a point of departure (unless certain criteria are met), they are focused on animal studies, especially those done in rodents. If increased relative liver weight were to occur in a human population, I suspect that it would be considered an adverse outcome, whether or not there was evidence of hepatotoxicity or a specific mechanism. Note also that for PFOA, in monkeys, there was an increase in relative liver weight with chronic exposure (PFOA document, page 4-66), so increase in liver weight in the animal experiments may be relevant to humans.

An additional comment of relevance here pertains to whether the human data support hepatoxicity. While there are studies that report elevated liver function tests in subjects with higher serum concentrations of perfluorakyl substances, these elevations do not clearly support the presence of toxicity. Again, AP Hall's discussion of what constitutes evidence of hepatoxicity is relevant here, and takes into account the number of LFTs elevated, the specific LFTs involved, and the magnitude of their elevation.

Finally, as discussed at the meeting, for the PFOA document on page 5-23 ("RfD Selection"), and the PFOS document on page 5-26 ("RfD selection"), I suggest minor editorial changes to deemphasize the "consistency of response" point and instead focus a little more on how the RfD is robust to choice of POD endpoints. If the selection of RfD does not hinge on increased liver weight as a POD, it will be more defendable.

Transparency might be increased by saying why (more clearly, or more clearly by implicit reasoning) the Macon et al. 2011 study, in which the LOAEL was 0.01 mg PFOA/kg from GD10 to GD17, based on delayed mammary gland development, was not considered as a POD, and why the Hines et al. 2009 study, in which the LOAEL was 0.01 mg PFOA/kg from GD1 to

GD17, based on various outcomes, was not considered as a POD. The PFOS studies with low LOAELs were considered in the dose-response assessment (no suggestions for improvement there).

Angela L Slitt

My response is basically the same as my General Impressions above.

The documents provide a very thorough evaluation of PFOA and PFOS studies. It is logically organized, presenting findings in a way that the reader can understand the findings related to human, monkey, and rodents. The organization of the document makes allows the reader to easily find information about each species within the subchapters and summarizes key points in table form. PFOA is a well-studied compound, with a substantial amount of toxicokinetic and endpoint studies in rodents. Mechanistic data describing the role of membrane transporters to understand gender differences in PFOA elimination in rats is fairly well written. Little data exist regarding contribution of membrane transporters to PFOS disposition and elimination. The documents thoroughly describe species differences in PPAR-alpha signaling that might contribute to observed endpoints in rats, but not humans or monkeys. Overall, both documents are very thorough are provide a reliable basis for PFOS and PFOA evaluation.

For PFOA toxicokinetics, mechanisms of PFOA transport are important for understanding species differences in response to PFOA exposure, with focus placed on kidney. Figure 3-2 in the PFOA document does not adequately present the localization of renal transporters with relationship to their contribution to the urine compartment or renal reabsorption. A very nice diagram showing the subcellular localization of renal transporters presented by Klaassen and Aleksunes (Pharmacol Rev. 2010 Mar;62(1):1-96) clearly depicts the contribution of various transporters to filtrate or blood. This is an easier diagram to put PFOA elimination into context than the one presented. Contribution of membrane transporters to species differences in PFOA excretion Section 3 (specifically 3.4.1) would be put in better context if a table could be generated to compare Km and Vmax values for PFOA for various transporters, with specific focus on species information for OATps and OATs. Data regarding information on contribution for OATps in liver accumulation of PFOS and PFOA is lacking, with specific regard to species differences. As PFOS is a likely candidate for hepatic uptake transport, understanding a mechanism to explain species differences in hepatic effects possibly due to difference in hepatic exposure is critical. Understanding impact species specific regulation of OATp expression in liver (e.g. whether species difference in PPAR-alpha signaling contributes) is also important in putting rodent distribution data into context.

Increased liver weight is considered to be a critical effect, but how increased liver weight relates to the observed human and monkey health effects needs to be further explained. In layman terms, if someone is walking around with an increased liver weight, is he or she at risk for disease? Will his/her life span be shortened? To increase transparency of the document, a more comprehensive explanation is needed to justify why increased liver weight should be considered as a critical endpoint for human health.

Use of humanized PPARα mice are a sexy tool to delineate species differences in effects associated with peroxisome proliferation. For transparency, the document should acknowledge the limitations of that model. Specifically, lack of response may not necessarily correlate to a lack of response for human PPARα because of species differences in binding to cogate DNA elements (e.g. a human receptor may have lower binding capacity to mouse DNA due to structural differences and species differences in co-activator/co-repressor interactions). Wording in the documents using these mice should acknowledge this limitation.

The documents often have redundancy in information, especially in regard to hormone effects (there are very similar write ups in sections about effects on thyroid hormone) and metabolic/cardiovascular disease risk factors (e.g. lipid endpoints).

Question 2. Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

James V. Bruckner

PFOA-specific comments
Fabrega, F. et al. (2014). PBPK modeling for PFOS and PFOA: Validation with human experimental data. Toxicol. Lett. On line. (Hard copy available)

Stahl, T., Mattern D and Brunn, H. (2011). Toxicology of perfluorinated compounds. Environ. Sci. Europe 23: 38-60.

Hall, A. P., et al. 2012. Liver hypertrophy: A review of adaptive (adverse and non-adverse) changes- Conclusions from the 3rd International ESTP Expert Workshop. Toxicol. Pathol. 40: 971-994.

Bjork, J. A., Butenhoff, J. L., and Wallace, K. B. 2011. Multiplicity of nuclear receptor activation by PFOA and PFOS in primary human and rat hepatocytes. Toxicology 228: 8-17.

PFOS-specific comments
No additional references were located.

Deborah A. Cory-Slechta

For both PFOA and PFOS, the document should include a description of the process through which studies were identified and how they were processed for inclusion or not. It is not clear what the exact dates of the studies examined included, i.e., what the cut-off date was for these studies. This makes it difficult to evaluate whether there are missing studies. That said, this reviewer is not aware of any specific omissions in the peer-reviewed literature other than those that were discussed at the face-to-face meeting.

Jamie C. DeWitt

Granum, B., Haug, L.S., Namork, E., et al. 2013. Pre-natal exposure to perfluoroalkyl substances may be associated with altered vaccine antibody levels and immune-related health outcomes in early childhood. J Immunotoxicol. 10:373–379; Looker, C., Luster, M.I., Calafat, A.M., et al. 2014. Influenza vaccine response in adults exposed to perfluorooctanoate and perfluorooctanesulfonate. Toxicol. Sci. 138:76–88.

Any time the Grandjean et al. (2012) findings related to PFAS and vaccine responses are discussed, these references could/should be discussed as well as they report related findings in human populations. Although they also are confounded by multiple PFAS (as was the Grandjean et al. study), they lend additional support to immunotoxicity as an endpoint worthy of consideration. However, it is noted that these references were published after the cutoff date for consideration for inclusion in the document.

Lopez-Espinosa, M.J., et al. 2012. Thyroid function and perfluoroalkyl acids in children living near a chemical plant. Environ.Health Perspect. 120:1036–1041. This study is missing from the discussion of thyroid hormone disruption. It reports a positive correlation between hypothyroidism and PFOA in children from the C8 population aged 1-17.

Corsini E., et al. 2011. In vitro evaluation of the immunotoxic potential of perfluorinated compounds (PFCs). Toxicol. Appl. Pharmacol. 250:108-116. Corsini E. et al. 2012. In vitro characterization of the immunotoxic potential of several perfluorinated compounds (PFCs). Toxicol. Appl. Pharmacol. 258:248-255.These studies are in vitro/ex vivo studies of human-derived cells that provide evidence that in vitro measures of immunocompetence in mice may be relevant to the human experience.

Jeffrey W. Fisher

For completeness sake, at least, please update lab animal studies conducted since 2012.

William L. Hayton

A review of PFOA health-effects literature (GB Post et al. (2012) Environ. Res. 116: 93-117) provides an excellent, in-depth discussion of many issues covered in the PFOA health effects document. Consider citing this review in the document.

The literature on PFOA and PFOS toxicokinetics (Section 3) has been comprehensively covered in the health effects documents, with the notable omission of Wambaugh et al., Dosimetric Anchoring of *In Vivo* and *In Vitro* Studies for Perfluorooctanoate and Perfluorooctanesulfonate. Toxicol. Sci. 136:308-327, 2013. This paper informed a significant part of the health effects documents.

Commenter's have suggested a number of references to consider with regard to Section 4 Hazard Identification. Many recent publications report on toxicity associated with PFOA/PFOS exposure. For the Dose-Response Assessment (Section 5) it is desirable to focus on those toxicities that have occurred at the lowest PFOA/PFOS exposures. For PFOA, the literature that is used in Section 5 to determine an RfD was published prior to 2009 (Tables 5-8 – 5-11). The benchmark response chosen based on the Section 4 literature was a 10% increase in liver weight, which was the biological response that occurred at the lowest PFOA exposure; it was acknowledged that this response "… is a biomarker for systemic exposure in rodents, rather than a biomarker of adversity …" (p. 5-6). More recent studies of hazard have identified potential adverse effects that result from, or are associated with, PFOA exposures that are lower than the LOAEL for a 10% increase in liver weight. For example, adverse effects on fetal, neonatal and early childhood stages of development may occur at lower exposures than does liver weight gain, which suffers in addition from not being a biomarker of adversity, and which therefore raises a question about the validity of any RfD based upon it. Macon et al. 2011 reported an LOAEL for delayed mammary gland development of 0.01 mg/kg administered to pregnant CD-1 mice during GD10 – GD17. As this relatively brief exposure was well below that required for steady state, it is possible that had the dams been at steady state at the time of conception (about 9 weeks of exposure) a much lower LOAEL may have been observed; i.e., a much lower dose

rate at steady state would have produced the same exposure to the fetal pups as did the 0.01 mg/kg administered to the dams during GD10 – GD17. The steady state situation is more relevant to adverse effects in humans than is a brief exposure.

Matthew P. Longnecker

I suggest you include the following citation and include a discussion of the evidence presented: Paula I. Johnson, Patrice Sutton, Dylan S. Atchley, Erica Koustas, Juleen Lam, Saunak Sen, Karen A. Robinson, Daniel A. Axelrad, and Tracey J. Woodruff. The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth. Environ Health Perspect; DOI:10.1289/ehp.1307893 (in press and available through the journal's website).

Based on the meta-analysis in this paper, the evidence that PFOA is associated with lower birthweight is consistent. Thus, the rationale for not basing the POD on the human data needs to be strengthened, as noted above. The Johnson et al. report could be discussed in the section on anthropometric endpoints that begins on p 4-22.

The relationship between birthweight and PFOA or PFOS may be confounded because glomerular filtration (and hence excretion of the compounds) is proportional to birthweight, as discussed in:

Morken NH, Travlos GS, Wilson RE, Eggesbø M, Longnecker MP. Maternal glomerular filtration rate in pregnancy and fetal size. PLoS One. 2014 Jul 8;9(7):e101897

In the PFOA document, on page 4-18, you might want to also cite:

Taylor KW, Hoffman K, Thayer KA, Daniels JL. Polyfluoroalkyl chemicals and menopause among women 20-65 years of age (NHANES). Environ Health Perspect. 2014 Feb;122(2): 145-50.

The Taylor et al., like the Knox et al. report (already cited in the PFOA document) is from a large-cross sectional study. Both studies, in their discussion sections, note that the association of PFOA or PFOS concentration in serum with age at menopause could be expected because postmenopausal women have lost a route of excretion for the compound and will have higher serum concentrations on that basis. It would be worth noting this possible explanation in the PFOA document on page 4-18, and in the PFOS document on page 4-8.

Additional data are available on the potential carcinogenicity of PFOA:

- Steenland K, Woskie S. Cohort mortality study of workers exposed to perfluorooctanoic acid. Am J Epidemiol. 2012;176(10):909-17.
- Barry V, Winquist A, Steenland K. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. Environ Health Perspect. 2013;121(11-12):1313-8
- Hall AP et al. Toxicol Pathol 2012:40:971-94. (About liver hypertrophy.)

The Steenland and Barry reports could be discussed in Section 4.1.2, on pages 4-28 and 4-29, respectively.

Angela L. Slitt

1) Evidence is presented for PFOA and PFOS as substrates for the related OATp1d1 in zebra fish. Establishing whether PFOS is an OATp transporter substrate is needed to better understand PFOS accumulation in liver. This study suggests that it might be. The following finding should be included in the PFOS document in Section 3.2.3 and the PFOA document in Section 3.0:
    a. Popovic M, Zaja R, Fent K, Smital T. Toxicol Appl Pharmacol. 2014 Interaction of environmental contaminants with zebrafish organic anion transporting polypeptide, OATp1d1 (Slco1d1).

2) This publication presents the finding that PFOS inhibits Pgp, Mrp1, and Mrp4 activity. The following finding should be included in the PFOS document in Section 3.2.3 and the PFOA document in Section 3.0:
    a. Dankers AC1, Roelofs MJ, Piersma AH, Sweep FC, Russel FG, van den Berg M, van Duursen MB, Masereeuw R. Toxicol Sci. 2013 Dec;136(2):382-91. Endocrine disruptors differentially target ATP-binding cassette transporters in the blood-testis barrier and affect Leydig cell testosterone secretion in vitro.

3) PFOS induced ABC transporters in grey mullets.
    a. de Cerio OD1, Bilbao E, Cajaraville MP, Cancio I. Gene. 2012 Apr 25;498(1):50-8. Regulation of xenobiotic transporter genes in liver and brain of juvenile thicklip grey mullets (Chelon labrosus) after exposure to Prestige-like fuel oil and to perfluorooctane sulfonate.

4) These are new publications regarding epidemiology findings for PFOS and PFOA exposure and serum lipids:
    a. Fitz-Simon N, Fletcher T, Luster MI, Steenland K, Calafat AM, Kato K, Armstrong B. Epidemiology. 2013 Jul;24(4):569-76. doi: 10.1097/EDE.0b013e31829443ee. Erratum in: Epidemiology. 2013 Nov;24(6):941.
    b. Starling AP, Engel SM, Whitworth KW, Richardson DB, Stuebe AM, Daniels JL, Haug LS, Eggesbø M, Becher G, Sabaredzovic A, Thomsen C, Wilson RE, Travlos GS, Hoppin JA, Baird DD, Longnecker MP. Perfluoroalkyl substances and lipid concentrations in plasma during pregnancy among women in the Norwegian Mother and Child Cohort Study. Environ Int. 2014 Jan;62:104-12.
    c. Fu Y, Wang T, Fu Q, Wang P, Lu Y. Associations between serum concentrations of perfluoroalkyl acids and serum lipid levels in a Chinese population. Ecotoxicol Environ Saf. 2014 Aug;106:246-52.
5) These are publications regarding PFOS exposure and hepatic steatosis:
    a. Lv Z, Li G, Li Y, Ying C, Chen J, Chen T, Wei J, Lin Y, Jiang Y, Wang Y, Shu B, Xu B, Xu S. Glucose and lipid homeostasis in adult rat is impaired by early-life exposure to perfluorooctane sulfonate. Environ Toxicol. 2013 Sep;28(9):532-42. doi: 10.1002/tox.20747. Epub 2011 Aug 24. PMID: 23983163 Select item 22484034

b. Wan HT, Zhao YG, Wei X, Hui KY, Giesy JP, Wong CK. PFOS-induced hepatic steatosis, the mechanistic actions on β-oxidation and lipid transport. Biochim Biophys Acta. 2012 Jul;1820(7):1092-101. doi: 10.1016/j.bbagen.2012.03.010. Epub 2012 Mar 28. PMID: 22484034 [PubMed - indexed for MEDLINE] Free Article
c. Bijland S, Rensen PC, Pieterman EJ, Maas AC, van der Hoorn JW, van Erk MJ, Havekes LM, Willems van Dijk K, Chang SC, Ehresman DJ, Butenhoff JL, Princen HM. Perfluoroalkyl sulfonates cause alkyl chain length-dependent hepatic steatosis and hypolipidemia mainly by impairing lipoprotein production in APOE*3-Leiden CETP mice. Toxicol Sci. 2011 Sep;123(1):290-303. doi: 10.1093/toxsci/kfr142. Epub 2011 Jun 24.

Question 3. The OW concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment of the OW characterization of the data.

James V. Bruckner

PFOA-specific comments
The document's authors have done a good job summarizing and accurately characterizing the epidemiology literature for various endpoints in Section 4.4 - Hazard Characterization. It is true there are a number of confounding factors that make estimation of PFOA exposures difficult. The EPA might consider, however, utilization of reverse dosimetry modeling. There is a reasonable body of data on serum PFOA levels, which could be used to estimate a range of PFOA exposures that would result in such internal doses.

PFOS-specific comments
I agree that human epidemiology data do not provide an adequate basis for calculation of a RfD or RfC. A reverse dosimetry modeling approach, however, could be used to estimate a range of PFOS exposures that could have resulted in measured body burdens. The human data might then be utilized in the risk assessment.

Deborah A. Cory-Slechta

It is not clear that such an assertion should be used in the construction of this document. It is not clear why the route of exposure should be raised to a concern in the calculations, in fact in the human environment, there are exposures from multiple routes, no doubt and thus this is consistent with human environmental exposures. Further, if there is data on serum levels, it should reflect that cumulative exposure across exposure routes. Indeed, at the end, the goal is to arrive at an RfD based on serum levels. There is, moreover, no guarantee that there is no contamination in studies in animals from food, glassware etc.

Furthermore, in many epidemiological studies in which mixed exposures are the norm, controlling for other exposures is utilized to address this concern and to therefore make conclusions about individual exposures. In point of fact, in every single human study, there will invariably be other exposures and not a single exposure, and thus this strategy essentially says that no human studies can ever be used for any risk assessments. The stated rationales for not using human data based on these statements is not adequate. This is why it is important as well to evaluate the strengths and weaknesses of each of the studies in terms of whether appropriate controlling for other known exposures was carried out and sample sizes sufficient etc. to arrive at some conclusions with respect to their ultimate usability in constructing RfDs.

Jamie C. DeWitt, Ph.D..

While the OW characterization of the epidemiological data for PFOA/PFOS is, technically, true, it also is somewhat misguided. Almost any epidemiological database will contain uncertainty regarding the routes, levels, and timing of exposures and will have confounding influences of other compounds. Very few epidemiological studies are free from these uncertainties, but when similar observations and conclusions are reached from multiple studies with these types of uncertainties, the database becomes useful for determining a candidate RfD or other value relevant to human health. What is particularly valuable about the PFOA/PFOS database is that it is relatively extensive in that it includes data not only from occupationally-exposed humans, but from people highly exposed to environmental concentrations of PFOA/PFOS and from people in the general population who have detectable concentrations of these compounds. Additionally, for establishing an RfD, do all of these uncertainties need to be absent? In other words, do animal studies used to derive RfDs lack these uncertainties?

What is missing from the OW characterization of the epidemiological data is a thorough evaluation concerning hepatotoxicity and developmental toxicity reported in human populations and how these endpoints are relevant to or related to animal studies.

Jeffrey W. Fisher

The use of non-human and human data is very important for interpreting exposure extrapolations from rats. I am not an epidemiologist so I cannot comment with authority on the epidemiology data for dose-response. Justify why human data are not suitable for use in the analysis of the health hazards of PFOA and PFOS.

William L. Hayton

There are a number of epidemiological studies that have been based on large numbers of subjects chronically exposed (over decades in some studies) to the subject compounds over a broad range of intakes. Steady state serum concentrations have also been available for quantification of the systemic exposure. While the route, levels and timing of the exposures may have been uncertain, the long half-lives of PFOA and PFOS in humans and the long periods of exposure to them indicate that 1) subject serum concentrations were generally at steady state, and 2) daily fluctuations in the amount and timing of the exposure would not produce much day-to-day fluctuation in the serum concentration of PFOA/PFOS. These consequences of the long exposure period and long half-life indicate that variability in the route and level of exposure would not have led to a measured serum concentration that was unrepresentative of the subjects' long-term average serum concentration. The serum concentration then should be relatively stable over time and it should reflect an integrated measure of the individual's exposure to PFOA and PFOS.

The serum concentration is a quantitative measure of systemic exposure to the subject chemicals, and is arguably a better metric of exposure than are intake rate. The over-all rate of intake (R) that produces a particular steady state serum concentration (Css) can readily be

calculated from the clearance (CL) of the chemicals, which is about 0.08 mL/d/kg body weight: R = Css x CL. The calculated rate of intake would represent all intake routes.

Confounding influences of other PFCs and indeed other chemicals and life-style factors such as smoking, diet, alcohol use, etc. would have to be considered, as is generally the case with epidemiological studies. Methodology exists for dealing with such influences.

Thus it appears that the epidemiological results should be used in the RfD determination. Their strength is that uncertainties associated with extrapolation from laboratory animal studies are avoided. Health effects that are positively associated with serum PFOA/PFOS concentration and that are observed in large populations of subjects should seriously be considered as potentially arising from PFOA/PFOS exposure. If mode of action studies in lab animals or in vitro studies support a cause-effect relationship, then the threshold serum concentration could inform the calculation of the RfD.

Matthew P. Longnecker

As noted in the General Impressions section above, the human studies with data on plasma or serum concentrations of PFOA and PFOS, especially for several categories of such levels, could be used to estimate dose-response information. However, there are other reasons why the human data may not be useful for setting the RfD (see above). Either PK or PBPK models might be useful for estimating the dose that human are exposed to; an advantage of a PBPK model is that it could incorporate information about routes and timing of exposure. Estimates of the contribution of various routes are available (e.g., Haug et al. 2011; Lorber & Egeghy 2011), and exposure trends could be assumed and evaluated in sensitivity analyses. Some occupational studies had data that allowed an estimate of serum levels, or measured them directly. Several reports show estimated exposure based on serum concentrations of PFOA or PFOS (Locissano et al. 2013; Lorber & Egeghy 2011; Thompson et al. 2010). With respect to confounding, the assessment of how likely this is could be informed by: 1) the correlation of serum concentration of PFOA, PFOS, and other compounds of this type in a particular study population (or in a series of studies), and 2) whether the other compound(s) has been associated with the particular outcome being considered. If the correlation is low or the other compound has not been associated with the outcome, concern about confounding may not be strongly justified. Without additional consideration of data that address these points, it may be premature to assume confounding would be a problem.

Angela L. Slitt

Strengths of the studies: Several studies, which all demonstrate a positive association between serum PFOA and/or PFOS and cholesterol or LDL levels are based on drinking water as a route of exposure. These studies are in agreement with Nelson et al., 2010, which was analyzing data from the 2003-4 NHANES study. Steenland et al., 2009 (*Environ Health Perspect.* Jul 2009; 117(7): 1083–1088) as part of the C8 Health Project collected data on 69,030 subjects with findings that serum PFOA was higher for males, those consuming local vegetables, and those using well water rather than public water, and *lower for those using bottled water.* The estimated response rate for participants >20 years of age was 81% and mean serum PFOA

concentration was 83 ng/l. Subjects were eligible to participate in the C8 Health Project if they had consumed drinking water for at least one year before 3 December 2004 supplied by Little Hocking Water Association (Ohio), City of Belpre (Ohio), Tuppers Plains Chester Water District (Ohio), Village of Pomeroy (Ohio), Lubeck Public Service District (West Virginia), Mason County Public Service District (West Virginia), or private water sources within these areas that were contaminated with PFOA. Subjects were also eligible if they could document that they had either worked in a contaminated water district or went to school there for at least one year. From this population, which the route of exposure is considered to be primarily via drinking water, serum lipids were analyzed with regard to PFOA levels and a positive correlation was observed for all serum lipids except HDL. Frisbee further characterized this cohort, analyzing 12, 476 children and adolescents included in the C8 Health Project, finding an increase in total cholesterol.

A recent epidemiology study (Fitz-Simon et al., 2013), not included in the current documents, described positive associations between PFOA and PFOS in serum LDL cholesterol. This study examined a study population that consisted of 560 adults living in parts of Ohio and West Virginia where public drinking water had been contaminated with PFOA. They had participated in a cross-sectional study in 2005-2006, and were followed up in 2010, by which time exposure to PFOA had been substantially reduced. Overall, the findings demonstrate a positive association between serum PFOA and PFOS levels and serum and LDL cholesterol.

Weaknesses: The studies did not appear to analyze PFOS or PFOA levels in drinking water from the participants analyzed and did not analyze data based on the length of exposure.

Question 4. Please comment on the transparency and characterization of the epidemiological data.

James V. Bruckner

PFOA-specific comments
See comments above.

PFOS-specific comments
The document's authors have done a good job describing and summarizing the designs and findings of the epidemiology studies.

Deborah A. Cory-Slechta

The PFOA document in particular and to some extent the PFOS document present all of the epidemiological studies but do not actually evaluate them; there is not a consistent indication of individual strengths and limitations of the studies, failures or not to adequately control potential confounding variables. Furthermore, there is no 'power analysis' type of evaluation, i.e., some of these studies included very small sample sizes and thus their power to actually detect effects may be limited, and yet they all appear to be weighted basically the same, i.e., studies with very small sample sizes with obviously extremely limited power to detect any effects appear to be considered the same as those with extremely large sample sizes. Studies with small sample sizes that nevertheless do find an effect of PFOA or PFOS actually suggest a robust type of effect.

The discarding of positive associations in human epidemiological studies because they do not produce frank clinical disease seems inappropriate and inconsistent with other EPA documents. For example, p. 4-3 in the PFOS document states that only a small number of ALT values were outside the normal range making the results difficult to interpret in terms of health. Physiological changes that are moving in the wrong direction, even if sub-clinical at the time, are still adverse effects. Are actual clinical diagnoses required for an adverse effect? This is especially the case given that the ranges of normal across populations are extremely broad.

The latter also raises the question of the cumulative toxicity of PFOA and PFOS and whether any consideration is being given to this.

Another such example is in the PFOS document, where it actually refers to a statistically significant, but not toxicologically significant effect (p.4-38); what does that mean? Also, p. 5-4 appears to dismiss any changes in thyroid function since no evidence of clinical hypothyroidism actually occurred. This whole approach with the human studies seems quite inconsistent with the reliance on increased liver weight in the absence of clinical pathology as the endpoint in the human studies.

Jamie C. DeWitt

It is not obviously or abundantly clear how the OW characterized the epidemiological data for either PFOA or PFOS. The studies were well-described, but the contribution of particular studies

to the overall assessment was not. The results of studies described in the hazard characterization section (4.4) need to be better characterized. For example, in the PFOA risk assessment:

- An increase in serum lipids associated with PFOA/PFOS exposure in humans is discussed as a risk factor for cardiovascular disease in humans; however, no evidence of increased cardiovascular disease has been observed in human populations. Additionally, serum lipids typically are decreased in animal models after PFOA/PFOS exposure, which is thought to be associated with/typical of exposure to agents that activate PPARα. If humans are known to respond to PPARα activators (i.e., fibrate drugs), why would the results between humans and animal models be discordant? This should be discussed.
- Several epidemiological studies reporting changes in liver enzymes clearly state that the clinical relevance of the changes in enzymes is unknown. Therefore, stating that the human studies "suggest effects on the liver as indicated by increases in liver enzymes" amounts to a mischaracterization of the data.
- No direct evidence of hepatotoxicity has been reported in epidemiological studies. This should be discussed.
- More in-depth characterizations are needed for the additional sections of the hazard characterization, with the exception of the thyroid section, which was well-described.

For example, in the PFOS risk assessment: Similarly to the PFOA risk assessment, the hazard characterization section needs to better discussion differences and similarities between effects reported in humans and effects reported in animal models.

Jeffrey W. Fisher

I am not an epidemiologist, but it appears to be adequate. Better characterization of the pros and cons of the human analyses and interpretation of the outcomes would be helpful.

William L. Hayton

The characterization of the individual epidemiological studies presented seems to be adequate. Public comments have identified the need to distinguish positive and negative associations with statistical significance, which seems to be a fair criticism. As noted in the response to Question 2, there are relevant studies that have not been described in the health-effects documents that ought to be considered and this includes some epidemiological studies. Most of the cited epidemiological studies have focused on healthy adults – workers exposed occupationally, residents of communities with or without contaminated water. These populations might be expected to be less sensitive to adverse effects than would early life stages and particular disease populations. Studies of potentially more sensitive populations would be desirable. The Frisbee et al. (2010) study of children 1-11.9 years and adolescents 12-17.9 years showed significant positive associations with serum lipid levels. Studies such as this one would be informative.

Matthew P. Longnecker

Please see the long paragraph above, under General Impressions, and some of the comments in response to item #2 above. Another point that the authors may want to consider is that studies that examine external exposure in relation to health outcomes may have special advantages in the case of PFOA and PFOS. While in general it is considered best to have a measure of exposure that is based on a biomarker of internal exposure, this may be problematic for several outcomes for PFOA and PFOS, because of the possibility of confounding or reverse causality that would not be an issue if an external estimate of exposure were used. For example, in Steenland K, Zhao L, Winquist A. A cohort study of workers exposed to PFOA. Occup Environ Med. 2014 Jun;71 Suppl 1:A55, when an external estimate of exposure was used for the Washington Works employees, no association with elevated cholesterol was found. The Viera et al. (2013) results are based on external estimates of exposure, whereas the similar study by Barry et al. (2013) are based on serum levels or estimates based on serum levels. The fact that association with kidney cancer is present in the Viera study decreases concern that the association was due to reverse causality. Steenland et al. 2012 used an external estimate of exposure to study cancer mortality and also found an association with kidney cancer. Lundin et al. (external estimate of exposure) had no cases of kidney cancer, though their study was also small.

Angela L. Slitt

The epidemiology data is well described and a thorough read. The data would be put in better context for the reader if there are average serum concentrations or ranges for the studies summarized in tables in addition to other key pieces of information.

A recent publication should be included in the document for consideration. Simon N, Fletcher T, Luster MI, Steenland K, Calafat AM, Kato K, Armstrong B. Epidemiology. 2013 Jul;24(4):569-76. doi: 10.1097/EDE.0b013e31829443ee.

Question 5. The OW has concluded that the cancer classifications for PFOA and PFOS are most consistent with respective classifications of suggestive evidence for carcinogenicity as described the EPA Guidelines for Carcinogen Risk Assessment (pp. 2-56, 2-57). Please comment on the strengths and weaknesses of this classification.

James V. Bruckner

PFOA-specific comments
I agree with EPA's choice of "Suggestive Evidence for Carcinogenicity." Epidemiological findings in occupationally-exposed and general populations to date are equivocal. Increases in Leydig cell tumors and liver adenomas have been reported in high-dose male rats. Increased incidences of pancreatic cell hyperplasia/adenomas and ovarian stromal hyperplasia/adenoma have been observed in female rats. More studies are necessary to confirm/expand these findings, and to assess carcinogenic potential in other species. Most mutagenicity and genotoxicity assays have been negative. Thus, there is some, but not undue cause for concern about the human carcinogenic potential of PFOA.

PFOS-specific comments
The document's authors have adequately and convincingly presented evidence for classifying PFOS as "suggestive of carcinogenicity."

Deborah A. Cory-Slechta

The classification of both PFOA and PFOS evidence for carcinogenicity as suggestive seems consistent with the clear limitations in the available data bases. In addition, the animal studies are limited to one species and mutagenicity does not occur in response to PFOA.

Jamie C. DeWitt

This classification is appropriate for both PFOA and PFOS given the epidemiological evidence, which is somewhat limited for PFOA and quite limited for PFOS. For PFOA, there is an association between kidney and testicular cancer, but there are limited data in animal models for these cancers and there is uncertainty that the mechanism of PFOA-induced carcinogenicity in animal models is applicable to humans. Studies of PFOS have the same limitations, but epidemiological studies have failed to find an association between PFOS exposure and cancer.

Jeffrey W. Fisher

I did not review the cancer studies for PFOA and PFOS.

William L. Hayton

The classification of "suggestive" is not unreasonable. The epidemiological studies, while showing apparent associations between PFOA exposure and cancer incidence in testicle and kidney as well as other tissues, do not provide a cause-effect relationship. However, they certainly do raise a concern about the carcinogenicity of the subject substances. Studies in animals have demonstrated conclusively that PFOA causes liver cancer in rats but the MOA that involves PPAR activation is absent in humans and it has been concluded that PFOA and PFOS cannot be carcinogenic in humans via this mechanism.

An EPA SAB panel (2006) consideration of this question resulted in a majority of the panel members favoring a classification of "likely to be carcinogenic" for PFOA. Board members acknowledged the PPAR MOA argument against causation of cancer in humans, but also found evidence that liver cancer in rats administered PFOA may also have had a MOA independent of PPAR activation. Recent epidemiological studies have added to the weight of evidence for an association between PFOA/PFOS exposure and cancer. Therefore a classification of "likely" is also not unreasonable to this reviewer. Lacking expertise in the nuances of applying the EPA's classification scheme, it is difficult for this reviewer to argue in favor of either "suggestive" or "likely".

Matthew P. Longnecker

The classification as "suggestive evidence for carcinogenicity" for both PFOA and PFOS is consistent with the guidelines put forth in the EPA Guidelines for Carcinogen Risk Assessment (2005). There are few pertinent data, including some suggestive but weak human evidence. There is clearly not enough evidence to classify these agents as likely human carcinogens.

Angela L. Slitt

Overall, the assessments for each PFOS and PFOA appear to be consistent with the EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a).

Strengths: Both classifications use evidence from human studies as guidance.

PFOS: The limited data that exist regarding PFOS and cancer were presented, the classification for PFOS under the EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a) is currently consistent with the suggestive evidence of carcinogenic potential descriptor. This assessment is reasonable, given that it is based on two studies that show a slight increase in adenomas that occurred in males and females.

PFOA: There is conflicting evidence regarding PFOA exposure and cancer risk. However, several human studies have found associations between PFOA exposure and elevation of cancer of the bladder and kidney. This is also supported by a chronic bioassay in rats, which demonstrated that PFOA was tumorigenic.

Question 6. Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

James V. Bruckner

PFOA-specific comments
The adjustments made to accommodate the influence of albumin binding and saturable renal tubular resorption of PFOA seem reasonable. I would defer, however, to someone with more experience in providing for these processes in PBPK models.

PFOS-specific comments
The PBPK model adjustments to estimate human equivalent doses appear to be appropriate. I defer to someone more qualified on the subject.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

Jamie C. DeWitt

Several PK models have been reported in the literature for these compounds and are relatively well described in the documents. The documents assert that the existing PK models do not consider the impact of renal tubule transporters and albumin binding; while, many of the existing models appropriately predict serum concentrations in humans and other species, but they are mostly based on empirical models. Please explain the weaknesses of such empirical models.

Additionally, numerous studies for both compounds report serum and tissue concentrations in humans and other species, which can be compared to existing models. Both documents present a revised model that amounts to a reanalysis of data from studies that report serum concentrations. A more thorough discussion of the improvements made by the reanalysis is needed to better understand if the improved model adequately estimates or predicts the clearance rate and other parameters for which confidence is low. Alternatively, the publication (Wambaugh et al., 2013) that thoroughly describes the reanalysis could be referenced.

Jeffrey W. Fisher

Serum protein binding: Both PFOA and PFOS are highly bound in serum proteins across species, thus model adjustments seem trivial for interspecies extrapolation. Steady-state conditions can be assumed to estimate the free fraction (e.g., 2% based on paper by Han et al., 2003 for humans). I did not find a discussion about the half-life of serum proteins, which may have some influence on the 'apparent' serum half-life of PFOA and PFOS. The estimated fraction of free PFOA or PFOS is important for describing urinary and fecal elimination in rats (and other species) and the plasma concentrations of total PFOA and PFOS. Thus, the model predicts total PFOA and PFOS in serum or plasma, but the free fraction estimates drive the gradual clearance of total BPA from plasma or serum by describing clearance of free.

Renal reabsorption: The renal reabsorption hypothesis involving species specific and sometimes gender specific transporters to describe the pharmacokinetic data represents sound judgment. This departure from normal allometric scaling is suggestive of active transport processes. Few PBPK models explicitly describe transporters with drugs or chemicals, although the field is moving in this direction. Thus, the approach used for PFOA and PFOS is adequate, that is, a hypothesis was evaluated by employing empirical PK-based kinetic analyses. Because the mechanistic details are missing for each species/gender, scaling of this biological phenomenon is not possible at this time. This is not a weakness, but represents the state of the science.

William L. Hayton

A very important strength of the documents is the attempt to deal with the interspecies differences in pharmacokinetics so that adverse effects across species are compared on the basis of internal, systemic exposure to PFOA and PFOS, instead of basing comparisons on the administered mg/kg dosages. PFOA and PFOS have complicated pharmacokinetics that have proven difficult to model. While a relatively simple one-compartment model appears adequate to analyze single, low doses, this model fails when it is extended to higher doses and repeated doses. Nonlinearities appear associated with saturable plasma protein binding and with saturation of transporters thought to be involved in the reabsorption of the compounds from renal filtrate.

A weakness of the pharmacokinetic model adjustments is the lack of robustness of the models. Despite the extensive efforts of talented pharmacokineticists, development of a model that scales across species and handles a range of dosages and a variety of administration routes has proven elusive. The two compartment model of Andersen et al. (2006) has formed the basis of the model used in the draft documents. The model incorporates saturable resorption of PFOA and PFOS from renal tubular filtrate. While protein binding is known to be saturable (fraction free increases with concentration), the model uses a species-specific but constant free fraction. Model parameter values for mouse, rat and monkey were used to predict reasonably well measured serum concentrations after a fixed daily dosing regimen, Tables 5-6 – 5-8 for PFOA and 5-8 and 5-10 for PFOS. This agreement between predicted and measured serum concentrations gives confidence that the model-calculated AUC values and final serum concentrations associated with adverse health effects (or in the case of liver weight, biological marker of exposure) are realistic and a basis for estimation of RfD. While the model used

appears adequate for the purpose, the model parameters that were used have some markedly non-physiological values. (Information subsequently provided at the reviewers meeting explained some of the departure from expected physiological values, as discussed in a following section.)

Matthew P. Longnecker

For PFOA and PFOA, the MCMC model results (predicted final serum value) were compared to the measured final serum values, and the agreement was fairly good. For PFOS, the MCMC model results were compared to those from Loccisano et al. (2012b) and were found to be similar, which is also reassuring. Because the PBPK models of PFOA and PFOS are empirical, and have been shown to give results that agree reasonably well with observed data, the adjustments to accommodate the impact of albumin binding and renal tubule transporters are not critical. More data on albumin binding and renal tubule transporters might allow improved understanding of the pharmacokinetics of these compounds, but may not necessarily cause substantial improvements in the empirical predictions from current models.

Angela L. Slitt

The current weakness of the models is that data on species differences in PFOA and PFOA for various key transporters is limited and the document is also using mRNA data for various transport proteins to explain gender differences in urinary elimination. First, with regard to PFOS accumulation in the liver compartment, it is necessary to compare affinity of human versus rat for OATp mediated transport. This alone is tricky because of species differences in OATps. If PFOS-induced liver effects are related to PFOS accumulation in liver, it is would be helpful to understand whether a lower affinity of human OATp1b1 and 1b3 compared to rat OATp1a1 predicts lower hepatic PFOS accumulation. More is known about PFOA, but a similar argument can be made for PFOA. In addition, more comprehensive, controlled assessment of renal transporter affinity for PFOA and PFOS is needed to better model the species difference in urinary elimination.

The document often speculates about PFOA or PFOS regulation of transporter expression, but some papers cited (Cheng and Klaasen) do not have enough data at the protein level to support whether these differences in transporter expression are the drivers of toxicokinetic differences between males and females.

Question 7. Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

James V. Bruckner

PFOA-specific comments
Despite the complexities and unknowns involved in plasma protein binding and renal tubular functions (i.e., glomerular filtration, basolateral tubular excretion and resorption, and apical tubular excretion and resorption), it is necessary to: (a) simply model only for saturable tubular resorption; and (b) use a range, or distribution of parameter values consistent with existing kinetic data. Unfortunately, optimization sometimes results in selection of physiological parameters that are not biologically-realistic, or plausible.

PFOS-specific comments
The parameters used in the modeling are biologically plausible.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

One unclear component of Table 5-7 in the PFOA document is the column labeled Species/Strain Used for prediction, which in every case is the same as the column labeled Species/Strain and is not otherwise adequately explained.

Jamie C. DeWitt

It is not clear that the parameters in Table 5-5 in the PFOA document and Table 5-7 in the PFOS document are from the Andersen et al. 2006 PK model or if they are parameters used in the reanalysis of the data. This needs to be better explained in both documents. Additionally, all of the units in the tables need to be explained and re-checked for accuracy.

Jeffrey W. Fisher

The authors should entertain the calculation of data derived AUC (e.g. Table 5-6) to compare to the model derived AUC, just as was done with measurement of total PFOA in serum. This works for the animal studies. The choice of using the empirical model over the more recent physiological models may be a weakness and our understanding of transporters advance.
The evolution of chemical-specific PBPK models for use in risk assessment and regulatory applications has repeated itself several times. This is, the first empirical non-physiological model(s) or PBPK models contain hypotheses generating ideas and later models test some of

these hypotheses, especially if additional experimental data become available. In the case of PFOA and PFOS, the EPA selected not to use the most recent PBPK models for PFOA and PFOS, but instead use a computational empirical based model (Andersen et al. 2006) that was the first attempt to quantitatively interpret the kinetics of PFOA and PFOS across species of laboratory animals. The authors did publish their model (Wambaugh et al., 2013). The authors chose not to use a human model because a lack of information for Bayesian analyses. The justification for their extrapolation methods should be stated and the published reference for the model should be cited.

Model parameter distributions (Bayesian analyses) appear to be biologically implausible in some cases, covering many orders of magnitude. The authors should discuss this issue and check the units of model parameters in Tables.

Both model parameters tables need to include a description of what the parameter represents and cite a figure. The figures showing the Andersen et al. 2006 model do not show all the model parameters and have different nomenclature.

The Andersen et al. 2006 paper is a critical paper offering a quantitative explanation for the PFOA and PFOS kinetic data sets.

William L. Hayton

In the "Pharmacokinetic Model Approach" sections of the documents, it is not made sufficiently clear that the parameter values in Table 5-5 (PFOA) and Table 5-7 (PFOS) were from re-fitting the published data, rather than using parameter values from the original literature reports.

PFOA Table 5-5, p. 5-12

Body Weight and Cardiac Output values are reasonable and typical.

k_a values for mouse and monkey seem extremely large; absorption half-lives would be on the order of 10 seconds, which is physiologically unrealistic. All of an oral dose would be absorbed within a minute, mimicking a rapid i.v. bolus dose. Serum concentration-time profiles may not be sensitive to these values, however so they are not disconcerting for the intended use of the models. The rat values appear reasonable.

V_{cc} values appear reasonable. The total steady-state volume of distribution value [$V_{ss} = V_{cc} \times (1 + R_{v2:v1})$] compares favorably with one-compartment V_d values for CD1 mouse, but V_{ss} values for the other columns (species) appear too large, due to the large $R_{v2:v1}$ values.

k_{12} values vary a lot across the columns, suggesting that k_{12} may be highly correlated with another parameter (e.g., $R_{v2:v1}$).

$R_{v2:v1}$ values also vary a lot across the columns.

T_{maxc} values are consistent across the columns; expressed in Gm/hr, they seem very large. For example, 2032 Gm/hr (4.91 moles x 414 Gm/mole) for the CD1 mouse. Even on a kg body weight basis could mouse renal tubules resorb 2 kg PFOA per hour? This maximum rate of resorption must far exceed the rate of filtration of PFOA at the glomerulus. (Clarification at the reviewers meeting explained this apparent departure from physiological reality. The units had been mis-specified in Tables 5-5 and 5-7. They were in fact micromole per hour

and micromolar for T_{maxc} and k_T instead of molar based. Thus T_{maxc} mouse value was 2 mg/hr, which is physiologically plausible.)

k_T values are the concentration in glomerular filtrate that half saturates the resorption transporters. Expressed in mg/mL, they seem large, much larger than the urine concentration that would be expected; e.g., for CD1 mouse, k_T is 15 mg/mL where free serum concentrations (Free x C_{serum}) would be about 0.3 µg/mL with 10 mg/kg in the mouse. So the transporter would not become saturated except at extreme doses. The value used by Andersen et al. (2006) for monkey was 0.00001 mg/mL. Unit specified in Tables 5-5 and 5-7 should be µM, not M.

Free fraction values measured in vitro are 0.01 or less at low PFOA serum concentrations (Table 3-1). The Free values for rat seem much higher than the measured values.

Q_{filc} is defined as a fraction of blood flow (renal or cardiac output?) to the filtrate (bottom of p. 5-11) but has units of flow in Table 5-5.

V_{filc} values are much smaller than the 0.01 L value used by Andersen et al. (2006), although Andersen et al. state that the model output is insensitive to this parameter and that their value was assumed.

PFOS Table 5-7, p. 5-15

Body Weight and Cardiac Output values are reasonable and typical.

k_a values for female mouse and monkey seem extremely large – see comment above for PFOA.

V_{cc} values appear reasonable. See comment above for PFOA.

k_{12} values vary a lot across the columns, suggesting that k_{12} may be highly correlated with another parameter.

$R_{v2:v1}$ values appear reasonable and consistent with other reports of V_{ss} values for PFOS.

T_{maxc} values are highly variable across the columns and seem much higher than physiological reality would allow. See comment above for PFOA.

k_T values are physiologically unrealistic and highly variable across columns. See comment above for PFOA.

Free fraction values have been measured in vitro and are 0.01 or less at low PFOS serum concentrations (Table 3-1, p. 3-3). The Free values in Table 5-7 are consistent with the measured values.

Q_{filc} is defined as a fraction of blood flow (renal or cardiac output?) to the filtrate (bottom of p. 5-14) but has units of flow in Table 5-7.

V_{filc} values are much smaller than the 0.01 L value used by Andersen et al. (2006), although Andersen et al. state that the model output is insensitive to this parameter and that their value was assumed.

While the parameter values for the pharmacokinetic models predict reasonable serum concentrations that generally agree with measured values (Tables 5-6 – 5-8 for PFOA and Tables 5-8 and 5-10 for PFOS), their high interspecies variability suggest that the models may be unreliable for prediction of internal exposures after other intake regimens and during a depuration phase.

Matthew P. Longnecker

Please see the answer to the previous question.

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Angela L. Slitt

The parameters included appear to be appropriate, but this lies outside of my area of expertise.

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Question 8. The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

James V. Bruckner

PFOA-specific comments
The adult male rat data of Kemper (2003), from which the rat half-life and clearance (CL) were obtained, appear to be solid. It is reasonable to select the human half-life of 2.3 years reported by Bartell et al. (2010), as their study population included equal numbers of males and females. Division of the rat CL by the human CL to yield a value of 219 is fine. I did not examine the publication of Bartell et al. (2010) to evaluate their data or methodology used to derive a human half-life of 2.3 years. Therefore, I am uncertain about its accuracy.

PFOS-specific comments
I would again defer to someone with more expertise.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

Jamie C. DeWitt

While the overview of the individual studies that calculated Vd and half-life for each compound was detailed and complete, the rationale and analysis concerning *why* particular values were selected were insufficient. Additionally, as addressed in Charge Question 6, the rate of clearance/elimination likely contributes to the differences in half-life that are not associated with differences in the Vd. Therefore, a 3-fold uncertainty factor for species differences in pharmacodynamics (UF_A) was utilized for both compounds. What was the justification for using a UF_A of 3? The section on UF application needs a more thorough discussion regarding the choice of this value given differences in clearance. If the section on model adjustment (a suggestion in Charge Question 6) is better described, this comment may no longer be applicable.

Jeffrey W. Fisher

The use of this non-compartmental method should be justified. Why not use a PBPK model? Assuming steady state in the humans does allow for calculation a human equivalent serum concentration associated with a laboratory animal concentration. In what region of the exposure-dose range would nonlinearity occur in humans? Some type of discussion is needed

about the assumptions of this methodology and why it was used. I would like to see statements about if the NOAEL, LOAEL, and a BMDL doses are in the linear range for kinetics.

The authors should use the Bayesian analysis for animal studies to inform the UF. Use percentiles to explore Vd and half-life to support UF values. I did not see any attempt to use distribution information generated from the model beyond the central tendency or mean values. Please state why this is the case. It seems that the distribution information generated from the Bayesian analysis could be used to support UF development.

William L. Hayton

PFOA-specific comments

For male rat, the Kemper (2003) study appears to be the best source of pharmacokinetic parameter values, which were obtained by a model-independent analysis of serum concentration-time data from rats that were dosed by oral gavage at dosages of 0.1, 1.0, 5.0 and 25 mg/kg. In addition, there was a 1.0 mg/kg dosage administered intravenously, and a 0.1 mg/kg oral gavage dose with an extended sampling time. Each treatment used four animals. The CL and $t_{1/2}$ values appeared to be independent of dosage and route of administration. It would therefore be reasonable to average all 6 mean values for each parameter to give an over-all mean of 24 determinations. The average (n=24) values for male rat were CL = 0.0209 L/kg/d and $t_{1/2}$ = 7.83 d. These values can be used to calculate a V_d value ($t_{1/2}$ x CL / ln 2), which is 0.236 L/kg.

It is not apparent on p. 5-20 why a V_d value of 0.17 was used with half-life to calculate CL_{rat} when Kemper (2003) reported CL values and not $t_{1/2}$ values. (At the peer review meeting, it was clarified that the data of Kemper (2003) were re-analyzed and as a result the parameter values in the health effects documents differ somewhat from those published with the data in the original reports.)

The CL_{human} value was taken to be 0.00014 L/kg/d. There are no direct measurements of this parameter. Thompson et al. (2010) assumed that the intake rate of PFOA for subjects using PFOA-contaminated water was 91% of the PFOA in 1.4 L/d of water. This intake rate was used along with a PFOA half-life of 2.3 years to calculate a V_d value of 0.17 L/kg. This is the same value that was used in the health effects document for the rat (p. 5-20). The V_d values available in mouse, rat and monkey are about 0.2 L/kg, so the $V_{d,human}$ set at 0.17 L/kg is not unreasonable but it lacks the certainty of the rat V_d value.

The health effects document used a $t_{1/2}$ for PFOA in human of 839.5 d (2.3 years), which seems to be toward the low end of the range of values that have been reported. Along with Vd = 0.17 L/kg one arrives at CLhuman = ln 2 x 0.17 / 839.5 = 0.00014 L/kg/d.

The ratio CL_{rat} / CL_{human} calculated using the mean CL_{rat} from Kemper (2003) would be 0.0209 / 0.00014 = 149, which is about twice the value calculated on p. 5-21. This difference arises from the calculation of CL_{rat} using the $V_{d,human}$ and a half life of 11.5 d instead of using the CL_{rat} directly from Kemper (2003). The mean half life from Kemper (2003) was 7.8 d.

The CL_{mouse} / CL_{human} ratio is accurate, using Lou et al. (2009) data. A calculation for monkey is not shown.

PFOS-specific comments
Chang et al. (2012) appears to be the best source of pharmacokinetic parameter values for mouse, rat and monkey. Butenhoff and Chang (2007) is given as the reference for a 48-day half-life in rat; this is a final report, internal to 3M. The Chang paper gives half-life values for male and female Sprague-Dawley rat at 2 mg/kg and 15 mg/kg. The average V_d for the four groups of three/group was 0.71 L/kg. This is higher than the 0.23 L/kg value used in the draft document (p. 5-23). The 0.71 L/kg value is also higher than values for mouse, monkey and human, which are closer to the 0.23 L/kg value used in the draft document. The draft document ought to acknowledge this difference; it may be that the value in the 3M report is lower than the published value; Chang was a co-author for both sources. The Chang et al. (2012) paper gives CL_{rat} values that are 0.0051 L/h/kg for female (similar for 2 and 15 mg/kg doses) and for males, 0.022 and 0.011 L/h/kg for the 2 and 15 mg/kg doses. A single average value for CL_{rat} would be 0.011 L/h/kg, about 3 times the value used for the UF_A calculation in the draft document. The male value is about 2-3 times the female value and it may be appropriate to calculate a different UF_A value for each sex. Using the single CL_{rat} averaged across two doses and both sexes (0.011 L/H/kg) would give a CL_{rat} / CL_{human} ratio of 0.011 / 0.000081 = 135 and a UF_A = 407, substantially higher than the value of 123 in Table 5-15.

The UF_A values calculated for mouse and monkey appear to be in line with the literature values for PFOS CL values in these species.

Matthew P. Longnecker

The PBPK model of Loccisano et al. 2013 (for humans) can be used to calculate a volume of distribution for PFOA of 177 ml/kg, which is very close to the value of 170 ml/kg based on Thompson et al.'s 2010 one-compartment model . For PFOS, the corresponding value from the PBPK is 280 ml/kg, compared with the value of 230 ml/kg used in the Health Effects Document. This 22% difference could have an impact on some calculations. (Note: the PBPK model-based volumes of distribution were calculated by Marc-Andre Verner of the University of Montreal. He had calculated these values in the course of a separate project.)

For humans, the half-life data all depend on the assumption that ongoing exposure is negligible compared to baseline exposure, a reasonable assumption in most of the populations used to estimate half-life. While the Seals et al. (2011) gave estimates that were slightly different for PFOA in some cases, the methods employed in this study were not as strong as for Bartell et al. (2010) or the Burris et al. studies (2000; 2002). The agreement within species for the half-life estimates for PFOS are reassuring. The animal data on the half-life of PFOA are relatively sparse (2 rat studies that agreed reasonably well, 1 mouse study, 1 monkey study). For PFOA, the UF_As and RfD that were calculated based on the half-lives (expressed as clearance) would not have been substantially altered by alternate choices for specific values. The same is true for PFOS.

Angela L. Slitt

Strengths of the available data is that for the several species thorough evaluated, the half-life values are very consistent. For example, the several human studies cited report a range in calculated PFOS half-life in humans to be 4.1-8.67 years, two studies putting monkeys at 110-132 days, and rat generally has a narrow range with 3 out of 4 values provided ranging from 39.8-48.2 days for PFOS. An inconsistency is the Chang et al., 2012 describing a half-life of females of 66.7 days when in general female rodents may have faster elimination of PFOS.

Question 9. A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

James V. Bruckner

PFOA-specific comments
The procedure used to calculate PODs adheres to standard EPA guidelines and policy. The presentation of their derivation is clear, concise and transparent. It is certainly interesting that the range of PODs and resulting candidate RfDs is so narrow. Nevertheless, as discussed previously, I do not agree with their selection.

PFOS-specific comments
See my comments under General Impressions.

Deborah A. Cory-Slechta

While it is the case for both PFOA and PFOS that values from different points of departure are fairly narrow, the transparency of the analyses in neither case is clear. There is no rationale described even as to why these analyses were done on all of the studies, what was the primary study and how others related to that etc., i.e., this presentation does not follow the typical presentation format of IRIS documents in either its presentation of rationales and strategies, nor in the conclusions that it reaches. In both cases, it is only the single sentence indicating that modeling from one particular study will be protective of effects at other studies using higher exposures. This section in both documents needs introductory paragraphs that describe the specific strategy, choices of studies and the rationales for those choices.

As noted in response to Charge Question 3, the rationale for discarding the human epidemiological studies is not sufficient and requires rationale other than that stated and therefore, the question of using the human data remains open. As noted in response to Charge Question 1, in this reviewer's opinion, the increased liver weight can be justified as a departure point for assessment of RfDs, but as discussed at the face-to-face meeting, additional text supporting this choice is needed.

Jamie C. DeWitt

This particular section contained inadequate detail on why particular studies *were* or *were not* chosen. For example, immunotoxicity as an endpoint was not chosen for PFOS, based on "*in vitro* measures of immunocompetence on mice may not be relevant to the human experience and limited human data from epidemiology studies are inconclusive regarding the immunotoxicity of PFOS in humans"; however, the breadth of data from in vitro/ex vivo immunotoxicity studies for PFOS were not thoroughly discussed (please see Charge Question #2 for two additional in vitro studies).

For both compounds, an increase in absolute liver weight was selected as an endpoint as it was a common *effect* [sic] in both short and long term studies. However, the toxicological relevance of an increase in absolute liver weight was not discussed other than to indicate that it was a sign of altered homeostasis. Further, the co-occurrence of increases in absolute liver weight with other toxicologically-relevant endpoints (i.e., immunotoxicity and/or reproductive/developmental toxicity) is not a toxicologically valid justification for the use of liver weight as an endpoint for an RfD. Therefore, the analysis was not sufficiently transparent to deduce its relative strengths and weaknesses. Certainly, choosing an endpoint that occurs across species and occurs at relatively low doses will likely be protective of exposed humans; however, will it be a defensible endpoint? As currently written, the choice of this endpoint for an RfD is not adequately defended.

Jeffrey W. Fisher

I did not review the toxicity data.

William L. Hayton

For PFOA, a 10% increase in liver weight was selected as the metric for effect, which was "… not made based on toxicity but on the desire to find a common denominator against which to evaluate dose-response across studies and justified by the fact that other adverse effects accompanied the LOAEL for increased liver weight in some cases." The lowest serum concentration associated with an increase in liver weight was calculated for female mouse to be 20.33 mg/L (p. 5-16, PFOA document). These data are referenced to DeWitt (2008); this paper has only summary information on liver weights, all of which exceeded 20% weight gain, going as high as 70%; and it is not apparent in PFOA document how these liver weight gains were used to estimate an LOAEL for 10% liver weight gain.

Many of the animal studies of hazard assessment were conducted under conditions where the duration of the exposure was relatively short compared with the half-life, and steady state had not been achieved. It is not apparent how the NOAEL and LOAEL values from such studies were adjusted to account for the non-steady state situation. For example, the 20.33 mg/L PFOA concentration associated with a 10% increase in liver weight (Table 5-9) emanated from a 15 day drinking water exposure to 0.94 mg/kg/day that resulted in an average serum exposure of 20.33 mg/L (0 – 29.7 mg/L over 15 d, Tables 5-7, 5-9). For a fixed daily dose, the time to 90% steady state for mouse would be about 63 days (3.3 x half life, which was 19 days), and after 15 days the serum concentration would only be about 15% of its steady-state value. This seems to suggest that the RfD would have been over-estimated by a factor of 7, since the 0.94 mg/kg/day at steady state would have produced a serum concentration of about 150 mg/L, not 20.33 mg/L. This analysis is based upon the behavior expected from one-compartment model pharmacokinetics. As discussed on p.5-9 of the PFOA document, the steady-state serum concentration of PFOA is achieved in a much shorter time than one-compartment model kinetics would predict. Whether the target-site steady-state concentration of PFOA also occurs in a much shorter time than one-compartment model kinetics would predict (3.3 x half life) is apparently unknown.

Matthew P. Longnecker

This part of the document seemed especially strong and transparent. The agreement between methods was reassuring. The weaknesses and assumptions were well discussed. Please see the minor editorial comment on this issue given for Charge Question 1, above.

Angela L. Slitt

The RfD Point of Departure was based on animal studies that include monkey and rat.

Question 10. The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days, and occur at comparable human equivalent dose (HED) levels. The current, draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

James V. Bruckner

PFOA-specific comments
I do not believe it is appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures. Steady-state is apparently achieved in monkeys within 4 - 6 weeks (Butenhoff et al., 2002). Steady-state likely takes considerably longer in humans. Thus, RfDs for shorter periods of exposure should be based upon results of studies of similar duration.

PFOS-specific comments
I do not believe the candidate RfDs, as calculated, are applicable to different durations of exposure.

Deborah A. Cory-Slechta

While initially believing that it was appropriate conclusion for PFOA and PFOS, based on the correspondences in RfDs across short and longer term exposure, discussion at the face-to-face meeting made clear that this approach is not reasonable and requires additional consideration.

Jamie C. DeWitt

This approach may be appropriate given the relative similarity of serum concentrations attained regardless of study duration, i.e., steady state in serum is attained after a relatively short period of exposure. This appears to be consistent across studies with various species of animal models. However, the document authors might need to reconsider given what we may or may not know about liver hypertrophy. In the Hall et al. (2012) paper on liver hypertrophy (discussed during the public meeting), increase in liver weight is an adaptive response that may not be adverse UNLESS weight increases >150% over a three month or longer period may. Following this large and prolonged increase in weight, the end result may be a hepatocarcinogenic response. However, none of the studies contained in the documents indicate that longer term exposures increase liver weight to this degree.

Jeffrey W. Fisher

The departure from K=CXT (Haber's law) should be based on the toxicity endpoints of concern and what is known about dose-exposure kinetics/responses for these chemicals and other chemicals that target the same endpoint, not that the HED values are comparable. The NAS

AEGL committee only considered primary irritation for inhaled chemicals as an endpoint that was independent of duration of exposure. There is an SOP if needed for reference.
The time to steady state should be included in a table for the lab animals. Toxicity studies conducted for less than 30 days (perhaps?) are not at steady state for the pharmacokinetics of PFOA. Thus the measured serum levels would be different than at steady state. The shorter the duration of the toxicity test, the more impact this could have on extrapolation to chronic exposures in humans. My personal preference would be to use PBPK models for all species and consider only long term exposures for extrapolation to humans.

William L. Hayton

This depends in part on how quickly the PFOA/PFOS concentrations at sites of toxicity come to steady state. Since the Vd for these chemicals is small (~ 0.3 L/kg) it seems likely that the concentrations in tissues rise in pseudo equilibrium with the rise in serum concentration. That said, the half lives are relatively long due to the very small clearance ($t_{1/2} = \ln 2 \times V_d / CL$). If one-compartment kinetics apply, then a guideline for time to 90% steady state is 3.3 $t_{1/2}$. For studies that expose animals for a period of time shorter than 3.3 $t_{1/2}$, the serum concentration would not be at steady state and the internal systemic exposure (serum concentration) would be less than what it would be if the exposure were longer than 3.3 $t_{1/2}$. This effect would seem to lead to overestimation of the intake rate that was associated with a particular internal exposure and associated biological endpoint. For example, the $t_{1/2}$ of PFOS in mouse is about 36 days and 3.3 $t_{1/2}$ is 120 days. Consider a 28-day exposure using a fixed daily dose that produced an LOAEL of "X" mg/kg/day. On Day 28, the body level would only be 42% of the steady state level, and the average body level over the 28-day period would be about 21% (approximating the increase as linear and not exponential). The true LOAEL would be 0.21 "X" mg/kg/day; i.e., intake of 0.21 "X" mg/kg/day would produce a body level at steady state that was the same as the average body level produced by X mg/kg/day administered over 28 days. The time to 90% steady state for a fixed intake rate is quite long; from the literature in the health effects documents, the times in the following table were calculated. From this line of reasoning, exposure times less than two half-lives begin to significantly overestimate intake rates associated with particular endpoints. This analysis is based upon the behavior expected from one-compartment model pharmacokinetics. As discussed on p.5-9 of the PFOA document, the steady-state serum concentration of PFOA is achieved in a much shorter time than one-compartment model kinetics would predict. Whether the target-site steady-state concentration of PFOA also occurs in a much shorter time than one-compartment model kinetics would predict (3.3 x half life) is apparently unknown.

	CL		Vd		$t_{1/2}$		Time to 90% steady state	
	[mL/d/kg]		[mL/kg]		[d]		[d]	
Species	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS
Mouse	6.6	5	180	265	19	36	63	120
Rat - Male	23	16	273	947	8.4	40	28	92
Rat - Female	776	5.2	150	476	0.13	66	0.43	218
Monkey	6.3	1.4	190	238	27	121	89	400
Human	0.085	0.08	170	230	1378	2000	12.5 yr	18 yr

In addition, this line of reasoning may be incorrect if the assumption of one-compartment kinetics is incorrect. For multi-compartment models the serum concentration and target organ/tissue could come to their pseudo steady state levels relatively quickly while slowly equilibrating (deep) sites slowly approached steady state. Simulation with PBPK models for PFOS and PFOA may help answer this question.

Associated with the uncertainty introduced by exposures that were shorter than the time to achieve steady-state concentration at the target site is the exposure time required for the adverse effect to be expressed. While some adverse effects may occur immediately and directly in proportion to the concentration of PFOA or PFOS at the target site, other adverse effects may be slow to become manifest. These "indirect adverse response" behaviors are well known in the drug action arena; e.g., certain antidepressant drugs require several weeks exposure to the target site before the effect of the drug appears. This lag time is not associated with pharmacokinetics (time to steady state) but with indirect-response pharmacodynamics. It could be argued that uncertainty factors are needed for both pharmacokinetics (pre-steady state condition) and pharmacodynamics (or toxicodynamics) to account for possible indirect response behavior.

Matthew P. Longnecker

EPA might want to consider using an uncertainty factor for duration, for two reasons. First, the monkey data for PFOS used for the point of departure were from a study where the duration of exposure was relatively short-term relative to the half-life, and it appeared that duration of dose affected liver and other adverse outcomes detected at higher doses, and no monkey data were used in the POD for PFOA. Second, questions raised by Drs. Hayton and Fisher at the peer-review meeting made me less comfortable with the calculations that used average serum concentration derived from the AUC and duration of dosing to compare with humans, who are more likely to be near steady-state.

Angela L. Slitt

Yes, but this lies outside of my area of expertise.

Question 11. In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.

James V. Bruckner

PFOA-specific comments
No comment.

PFOS-specific comments
No comment.

Deborah A. Cory-Slechta

In initial response to charge questions, I found it difficult to understand specifically what this charge question was asking for a response to: Does this refer to the data in Table 5-10 for PFOA? Wouldn't you include animal to human UF values at the least. Since the data for the studies listed in the Table is not clear as to their duration (columns are needed for this information, or add to the Study box), it is not clear whether a UF for study duration is warranted. It is not clear how sex differences are being accommodated in any of these.

At the face-to-face meeting, however, with some additional input from EPA, it was clear to all that there was no need to do such derivations from animal to human, which could instead be derived directly from the human data and thus presumably this is no longer an issue.

Jamie C. DeWitt

Would this approach take into account differences between animal studies that have a defined exposure duration and data from NHANES, where exposure duration is assumed to be continuous (although it may not be), if exposure duration does not appear significantly impact serum concentrations? Additionally, how would the half-life estimations from the Seals et al. (2011) study, which contained two half-life estimations based on concentration and time, impact this approach?

Jeffrey W. Fisher

Again, is the system linear in the exposure/dose ranges of interest? I would try to determine an UF by exploring a range of predicted human serum levels. Attempt to use 5,50, and 95% for animal serum concentrations with a 5,50, and 95% CL values in the animals and for the human perhaps use two CL values representing a high and low. The idea is to use as much information

as you can to determine the possible range of values. This will help guide the selection of uncertainty values.

William L. Hayton

This calculation is equivalent to dividing the animal dosage by the CLhuman, assuming that the animal serum concentration is at steady state ($C_{ss,animal}$) maintained by a constant dose rate (DR).

$C_{ss,animal} / CL_{human} \div CL_{animal} = CL_{animal} * C_{ss,animal} / CL_{human} = DR / CL_{human}$

This calculation would give the steady-state serum concentration in human that would be produced by the animal dose rate. (I will have to study this to understand the question; the calculation does not make sense to me.)

At the peer review meeting, the aim of this calculation was clarified. Authors desired a way to calculate a steady-state serum concentration ($C_{ss,human}$) that would result from the human equivalent dose rate (HED) administered until steady state. The appropriate calculation would be:

$$C_{ss,human} = HED / CL_{human}$$

Matthew P. Longnecker

The proposed division by animal clearance ratios does not make sense to me. The average serum values from animal studies is already taking pharmacokinetic variability in blood levels during the observation period into account, and human blood levels will be relatively constant. Thus, it would make sense to directly compare the POD estimated average serum concentrations from animal models to the blood levels in NHANES. With respect to uncertainty factors that would be need consideration for this approach, it seems that UF_H, UF_L (For LOAEL and HED_{LOAEL}), UF_D, and the component of UF_A that takes pharmacodynamics into account would all still be applicable.

Angela L. Slitt

This is outside of my area of expertise.

Question 12. Please describe any suggestions you have for improving the clarity, organization, and/or transparency of the draft documents.

James V. Bruckner

PFOA and PFOS-specific questions
See specific observations.

Deborah A. Cory-Slechta

While the EPA authors are aware of updates in the IRIS process, it might be very helpful to look at some of the new documents coming through that process for guidance as to the levels of critique and evaluation that are now included in these documents. They also include an introductory chapter focused specifically on the literature searches and literature that is included vs. excluded.

The Executive summary does not provide sufficient rationale and descriptions to lead a reader through the steps to what is concluded and reads more like an abstract than an Executive Summary. Since this may be the only section read by many reviewers, it is important that it provide a succinct journey through the process. Here again, the new IRIS documents (e.g., trimethylbenzene) could provide a useful template.

Chapters 3, 4 and 5 could each benefit from an opening paragraph describing what the section's goals are, and integration and conclusion sections at the end that establish the basis for the presentation in Chapter 5. Currently the Hazard Identification studies generally treat all studies as of equal strength/power, which is certainly not the case. These chapters should present that kind of critical and transparent assessment as it ultimately serves as the basis for decisions that are made.

The inclusion of sections on in Vitro data did not ultimately seem particularly relevant in the outcome for these compounds and could be significantly shortened to add more to Chapter 4 on study strengths and weaknesses. However, where pertinent, it would probably be more useful to break that section up and insert test where it follows an in vivo discussion.

Tables could be considerably improved and made far more useful to the reader for comparative assessments. As of now, they require going back and forth to the text to capture additional details of the studies, e.g., sample sizes, species etc. and could benefit the reader significantly with those additions. For the human assessments, it is equally important to include these details in the chapter as well as a column of study strengths and limitations.

While charge questions ask whether the appropriate studies were chosen as key studies, this reviewer does not remember that that term was even used in the documents, certainly no explicit mention was made as to which studies were considered key studies. This would seem to be a section that should be included in Chapter 4 more explicitly. Chapter 5 of both documents, more so PFOA, are confusing as almost all studies are subjected to modeling, for reasons that are

never presented in sufficient detail and simply followed by statements that a selected study (not really well presented in Chapter 4 as a selected study) will protect against other adverse effects.

Jamie C. DeWitt

The documents lack a critical analysis of differences between findings of epidemiological studies and findings of animal models. As stated in the comments to Charge Question #3, what is particularly valuable about the PFOA/PFOS database is that it is relatively extensive in that it includes data not only from occupationally-exposed humans, but from people highly exposed to environmental concentrations of PFOA/PFOS, and from people in the general population who have detectable concentrations of these compounds.

Critical to this analysis is a discussion of concordance and lack of concordance between human data and animal model data. For example, immunotoxicological findings appear to be consistent between humans and rodent models whereas serum lipids are not. How do these differences impact the overall confidence in the database and derivation of the RfD?

All of the sections related to the PK models developed by ORD need additional information for clarity and transparency. As written, it is not clear that the PK values presented throughout the document actually represent a reanalysis of existing data from studies that reported serum concentrations. The Wambaugh et al. (2013) study could be referenced to shorten this exercise as this publication provides details on the reanalysis of existing data.

Justifications for choosing or not choosing particular values or endpoints need to be more thoroughly detailed throughout both documents, especially for endpoints that appear to occur in both experimental animal models and exposed humans (i.e., thyroid hormone disruption and immunotoxicity).

Jeffrey W. Fisher

These documents represent an enormous undertaking to describe studies with PFOA and PFOS. Keep the same writing style for reporting studies. This was very good. A synthesis of the most important studies is needed and some statements about why other studies are not used by EPA. It is easy to get lost in the document because of its size, but if there was an analysis or synthesis section for the key toxicity studies and another for PK modeling rationale, it would help readers.

William L. Hayton

It would be helpful to use one set of units for test article amount and concentration. The draft documents use ng/mL, µg/mL, µg/L, ppb, ppm, and µM for PFOA/PFOS concentration in water, diet, and serum. It would be more straightforward to use one concentration term, preferably ng/mL, and perhaps µg/mL in addition as necessary. But making comparisons among ng/mL, ppm, and µM is a distraction.

In Section 3 of both documents, it would be helpful to include a summary table of primary pharmacokinetic parameter values for the species included in this section. Tables 3-17 – 3-20 in

the PFOS draft document are a good start. In the PFOA document, Table 3-23 lacks CL values, and Tables 3-24 and 3-25 lack V_d values. For the pharmacokinetic model analyses presented, primary parameters values could be limited to CL, Vd_{ss}, and half life (see table in response to question 10). The CL and V_{dss} values should be normalized to body weight. Where there are multiple models for a species, there should be separate entries for each study. Where there are multiple dosages for a species, there should be separate entries for each dosage. For the PBPK models, V_{dss} values are not available and therefore should not be included. Such a table would be helpful to show consistency or lack thereof among studies and would facilitate selection of the best available values for CL and V_{dss} for use in a human PK model that would predict steady-state serum concentration from intake (dosing) rate and, conversely, predict intake rate from steady-state serum concentration. These predictions are probably the primary reason to include a pharmacokinetics section in the documents.

The pharmacokinetic sections of both documents lack example graphs of serum concentration-time data on semilog coordinates for PFOA and PFOS. Inclusion of a few representative graphs would help the reader evaluate the consistency of the data used to generate the pharmacokinetic parameter values, and where model-based equations have been fitted to the data, the scatter of the measured concentrations around the model-predicted line would be informative as to the goodness of fit and the validity of the model and its parameters.

Matthew P. Longnecker

I can see advantages to treating this more like a systematic review of the literature, where the specific search algorithm for included articles is laid out, as are the range of dates of publication to be considered, and any other selection criteria applied for articles considered. In these documents, while the review of earlier literature appears to be comprehensive, after some point there must have been some decision making about which of the more recent articles to include.

The EPA has many guidelines about how data like these are to be evaluated, yet in the document few, if any, references to these guidelines were cited. Because so many guidelines exist, it could help readers if the authors cited specific places in critical documents that provide guidance for specific decisions.

Angela L. Slitt

The document reads very well. Although not included in the RfD determination, including a table of the observed human effects along with serum concentrations in Section 5.0 would put Tables 5-2 and 5-3 into context. Some sort of layman explanation to help understand why only non-human exposures are being included would be helpful to the general public.

V. SPECIFIC OBSERVATIONS

James V. Bruckner

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
3-11	5, lines 7-11	It is stated that the PFOA concentration in bile increased by a factor of 12.5 with the increase in PFOA dose from 12.5 to 25 umol/kg in wild-type mice and 19.5 in PPARα-null mice. These factors should be 2.8 for wild-type and 6.1 for PPARα-null mice. The document's authors may want to rethink their interpretation of the data. The results for the wild-type mice do suggest saturation of transport from liver to bile ducts, but the PPARα-null results do not, indicating a role for PPARα in this process. In contrast to the foregoing, the findings of Lou et al. (2009) (p. 3-11, pgr. 2) indicate their highest dose of PFOA is cleared from the blood of mice more rapidly than lower doses, suggesting saturation of hepatic and/or renal reuptake transporters. What is the relative importance of biliary and renal elimination of PFOA?
3-12	3, lines 2-4	It should also be stated that upregulation of MRP3&4 and the OATs may be <u>beneficial</u>, due to increased biliary excretion of bile acids, bilirubin, conjugated metabolites of toxic chemicals, etc.
3-14	1 & 2	It might be stated that the findings of Hinderliter (2004) support those of Han (2003), in regards to development of female rats.
3-14& 3-15		It is problematic to try to compare values in Table 3-14 with values referred to at the end of the second paragraph on p. 3-17. Whole pup and pup serum PFOA levels decrease between PND 1&18 for each dosage in the table. It would be preferable to include another table showing the PFOA levels with body weight taken into account. Table 3 – 14 and other tables should include the species in the title. It would also be helpful to include some details of the experimental protocol in the footnotes.
3-20		It would be useful at the end of this section (Distribution During Pregnancy and Lactation) to summarize the primary findings, or conclusions that can be drawn from the data that were presented.
3-23	4, line 2	It should be emphasized that urinary excretion of PFOA was substantially higher in female than male rats.
3-28	2, line 4	Replace "receptors" with "transporters".
3-28	6	Did 10 uM PFOA inhbit PAH and estrone uptake to a greater extent than 100 uM PFOA?
3-29	3 & 4	It is not clear what Yang et al. (2009) concluded about the role of OATp1a1 in the uptake of PFOA from glomerular filtrate.
3-32	3 & 4	These two summary paragraphs are very helpful.
3-37	1, line 1	Should "adsorption" be "absorption"?

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
4-7 & 4-9	Tables 4-1 & 4-2	Tables 4-1 and 4-2 are quite helpful in integrating the results of studies of occupationally-exposed populations.
4-13		A concluding sentence should be added to summarize the findings of a lack of association of PFOA with diabetes, metabolic syndrome, etc.
4-32		The NOAEL and/or LOAEL for this study should be stated at the end of the paragraph.
4-34	2	Is the LOAEL for liver effects 1 ppm in the study of Loveless et al. (2008)?
4-38	1	Include the meaning of the abbreviation "mPPARα".
4-39		Inclusion of the table for Minata et al. (2010) would be useful to help readers better comprehend the study findings.
4-40		A table of short-term LOAELs and NOAELs should be added here or in Section 5.
4-47	2	It is hard to believe, judging from the slight difference in mean values and their standard deviations, that absolute and relative liver weights are significantly higher than controls in the 1 mg/kg/day group.
4-67	2, line 5	Insert "absolute" before "liver weight".
4-69	1, lines 1 & 2	It might be worthwhile to point out that the actual study by Butenhoff et al. was conducted prior to 2004.
4-73		A summary sentence (or two) should be added at the end of the Mutagenicity and Genotoxicity section.
4-83		A summary paragraph should be included at the end of the Immunotoxicity section.
4-101	1, line 14	Insert the word "some" before "occupational studies". In order to present a more balanced perspective of findings in occupational studies, the following sentences could be added at the end of the paragraph: "Olson and Zobel (2007) examined groups of male workers at 3 fluorochemical production facilities. Serum PFOA concentrations were not associated with total cholesterol, LDL or HDL in workers at these facilities."
4-102	4	It should be stated that the increases in serum enzyme activity in workers were quite modest/small. The following sentence should be added at the end of the paragraph: "Emmett et al. (2006), however, found no association between serum PFOA and liver or renal enzymes".
4-103	2, line 2	Change "apoptotic or necrotic damage of" to "apoptosis or necrosis of". Apoptosis and necrosis are types of cell death, not damage/injury.
4-103	3, line 1	It is true that PFOA may interfere with the biliary excretion of other compounds that are transported by the same transporters. Upregulation of the genes for these transporters, however, may be beneficial in that the excretion of bile acids, bilirubin and conjugates

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
		of toxic chemicals/metabolites may be hastened.
4-103	4, line 2	I would avoid the word "critical" until the section on Dose-Response Assessment.
4-103	4	Increases in absolute and relative liver weights were dose-dependent (Cui et al., 2009; Elcombe et al., 2010; Wolf et al., 2008a)
4-103	5	It is important to distinguish between effects of PFOA on rough and smooth endoplasmic reticulum (RER and SER). RER content was diminished, but there was a proliferation of SER.
4-104	2, line 5	This last line should be amended to read "that PFOA has some effects of unknown toxicological significance that appear to be independent of PPARα activation.
4-104	4, line 3-5	The meaning of the sentence is not clear. Has something been omitted?
4-105	3, line 3	Add "of offspring" between "abilities" and "at 6 and 18". Include Fei and Olsen's (2011) finding of no association between prenatal PFOA exposure and behavioral or coordination problems in children at age 7.
4-109	3	The species (i.e., mice) studied by White et al. (2009) and by Wolf et al. (2007) should be stated.
4-111	4, line 2	Replace "examine" with "determine whether there was".
4-112	2, lines 1 & 2	The first sentence is misleading and should be rewritten. Butenhoff et al. (2012) did not see a significant increase in liver adenomas or carcinomas. Biegel et al. (2001) reported an increased incidence of hepatic adenoma but not carcinoma.
4-112	2, line 13	What is hepatic cystoid degeneration?
4-114	2, line 3	Insert "decreased" before "apoptosis".
4-115	5, line 2	What is meant by "PRAR exposures"?
4-116		There is no mention of PFOA-induced changes in expression of genes (e.g., cell cycle control, peroxisomes biogenesis, inflammation, etc.) that are PRARα-dependent. There is no mention of the role of PRARα or peroxisomes in oxidative injury and carcinogenesis.
4-120	1, lines 11 & 12	Insert "these" between "that" and "hormones".
4-121	3	It would be helpful to give the PFOA dosages of White et al. (2007) and one or two other studies, so the reader will have some idea of the magnitude of PFOA exposure required to alter mammary gland development.
5-1		RfD: Omit the word "wealth" from the bullet pertaining to epidemiology studies. There have been relatively few epidemiology studies of PFOA-exposed populations.

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
5-2	1, lines 2-6	Another obvious point should be made here, mainly that occupational exposures result in much higher plasma PFOA levels and body burdens than do environmental exposures. Thus, it would be anticipated that adverse effects would be more apparent in PFOA facility workers.
5-2	1, line 5	Include the words "in some instances" between the words "shown" and "between". Otherwise, it appears from this paragraph the serum PFOA concentrations are consistently/usually associated with the various maladies.
5-2	3, line 8	Insert "failure to attain" between the words "with" and "developmental".
5-7	2, line 4	Insert the word "rodent" between "between" and "species"
5-19	1, line 1	Insert "from some studies" between "data" and "have".

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
3-2	5, lines 2 & 3	It is stated here that "the ratio of PFOS identified in serum and liver tissue are similar". Do the authors mean that PFOS concentrations in the serum and liver are similar?
3-2	6	How does PFOS distribute between plasma lipoproteins and proteins/albumin?
3-5	1, lines 9& 10	How much lower were milk PFOS levels than serum levels?
3-7	1, line 2	Oral and gavage are redundant.
3-16	Figure 3-1	This figure nicely illustrates relative PFOS levels in dams and fetuses/pups over time.
3-19	1,line 3	Insert "groups" between "day" and "on".
3-21	1, line 10	Substitute "longer" for "slower".
3-23	2	It is not clear who conducted the human PBPK modeling nor which model they used.
4-21	2, lines 1-3	What did the 2nd monkey die from?
4-26	3, line 3	The word "concentrations" should be replaced by "doses".
4-39	1	Does an increase in motor activity on PND 17, but no such effect on PND 13, 21 or 61, constitute a toxicologically-significant effect?
4-56	2, lines 1 & 2	It is stated that "taken together, these studies suggest a PPARα-independent mechanism…" Of the studies reviewed to this point in the document, only that of Abbott et al. (2009) supports this premise. Qazi et al. (2009), Rosen et al. (2010) and other groups of investigators have reported other PPARα-independent effects of PFOS.
4-60	2, lines 15-17	Is oxidative damage likely to be operative to a significant extent at lower PFOS doses?

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
4-61	2, line 4	What is meant by "The concentration…"?
4-61	4, line 2	Change "dose of exposure is" to "levels of exposure are".
4-62	1, lines 2 & 3	What did Olsen et al. (2003) find correlation between?
4-62	3, lines 4 & 5	Identify the species (i.e., rat) studied by Chang et al. (2009) and Stein et al. (2012).
4-62	5	The liver of rats and monkeys was examined for histopathological changes, but the histological changes should not be considered lesions nor pathological.
4-68	4, lines 5 & 6	The elevated incidence of hepatocellular adenomas/ carcinomas was almost entirely due to adenomas. Only 1 of 60 high-dose female rats exhibited carcinoma.
4-69	5, lines 3 & 4	It is stated here that there was no increase in hepatocellular proliferation detected in the subchronic study of Seacat et al. (2003). It is stated previously on page 4-69 that "the data for PFOS are adequate to support some but not all key events…" I assume that cell proliferation is thought to be a missing event. Seacat et al. (2003) reported that the average hepatocyte proliferation index was not increased, but that some animals exhibited mild increases. It is clear in the current document that PFOS is not as potent a PPARα inducer as PFOA.
5-4	2 & 5, line 7	Again the terms "histopathological" and "lesions" are misnomers.
5-4	3, line 9	What is meant by a "biologically significant decrease in survival" at 0.8 mg/kg?

Deborah A. Cory-Slechta

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
Chapter 5		The text of Chapter 5 in the PFOA document (and other places) continues to state that a 10% increase in liver weight would not be an adverse effect, but merely a denominator for loss of homeostasis. On what basis was this conclusion derived? What is the support for this statement? It appears that benchmark dosing was applied to studies that had liver weight as the common denominator, but does this accommodate the lowest NOAELS and LOAELS observed for any endpoint in the long duration studies? Use of just studies with the common denominator because they provide replication ignores the fact that some other effect may occur at lower levels but simply hasn't been evaluated in as many studies as focused on PPARa-based targets. If this isn't the case, then the text should clearly address this.
5-7	2	States that the $BMDL_{10}$ values all fall below the experimental LOAELs. So, what does that mean, is there some conclusion that is supposed to be reached from this? IF so, please state it.
5-13	1	States "Generally these values were similar." What does similar mean? What is acceptable in this context?
5-16	3	States that the half-life value Bartell et al. (2010) was sued for half-life because it seemed more relevant to scenarios where exposure result from ingestion of contaminated drinking water by members of the general population. This rationale does not appear to consider the potential different strengths and weaknesses of the other potential studies. Is it necessarily the case that general population is more important than occupational studies? The rationale needs to be described in greater detail. Virtually no rationale is provided for the choice of the Thompson et al. (2010) study for a volume of distribution value.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
1-1	4	There are similar concerns for the PFOS document. Loose terminology should be eliminated, e.g., what is a 'finding of note' as used in the executive summary for PFOS.
Executive summary		The PFOS executive summary is of limited utility; for many readers this may be as much of the document as they read; as currently written it is not clear or transparent nor does it sufficiently explain how it arrived at an RfD.
3-3	Table 3-1	Couldn't a sentence essentially substitute for Table 3-1; it really isn't useful.
3-25	1	Loose terminology should be eliminated, e.g., what is "generally good"
3-26	Figure 3-7	Figure 3-7 has no explanation of what is the black vs. gray line.
All tables		There is a need to improve all of the tables; they should always include study name/year, sample size and exposure duration information on them; this would make all of the comparisons easier to evaluate and not require the reader to continue to go back and forth to the text.
4-4	Table 4-1	For example, table 4-1 has only study name and year, but what really matters is also exposure duration and sample sizes, because the comparisons of outcomes in the Table depend upon the power of the study to detect effects at the very least.
4-9	Table 4-2	The same comment applies to Table 4-2 and any others with this intended purpose.
4-11	Table 4-3	Table 4-3 needs sample sizes, exposure duration etc.
4-24	Table 4-7	Tables that summarize a significant amount of data from a single study (e.g., 4-7) should include the study authors and year in the Table title so it doesn't have to be searched for.
		In several instances in the PFOS document, adverse effects early that appear to be reversed at a later age are discounted with the suggestion that they therefore do not matter; given our increasing understanding of the importance of early changes in terms of epigenetic changes, this is no longer appropriate and in fact, misleading.
5-16	Table 5-8	What do the parentheses signify?
5-17	Table 5-9	What do the parentheses signify?

Jamie C. DeWitt

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
4-102	2 & 3	DeWitt et al. 2009 also included data on triglyceride levels in C57BL/6 mice exposed to PFOA for 15 days; triglyceride levels were dose-responsively decreased.

Jeffrey W. Fisher

No specific observations.

William L. Hayton

Specific Observations for *Health Effects Document for Perfluorooctanoic acid*		
Page	**Paragraph**	**Comment or Question**
1-2	Last, line 5	Delete "in"; should read "… in rats was analyzed …"
3-2	1, lines 6-8	Assumption that fecal excretion represented unabsorbed PFOA is problematic; suggest rephrasing this sentence.
3-3	Table 3-1	Protein binding is important for PK modeling, where the fraction unbound (fup) is the important parameter, not the fraction bound. Suggest listing fup values rather than percent bound.
3-6	Last, line 3	"concentration" should be "dose rate"
3-8	2, line 4	In addition to liver, kidney, and blood, other tissues are prominent. E.G., Table 42 of Kemper shows that in male at 1 mg/kg, t=Tmax, GI tract, GI contents, muscle, bone and skin contained a greater percentage of dose than did the kidney.
3-8	2, line 8	"Blood to kidney" should be "kidney to blood"
3-8	2, line 10-11	In Kemper, Tables 44-45, blood to kidney ratios are not 10 or higher in males.
3-8	2	This paragraph reports both percent of dose found in tissues, and concentrations found in tissues. But Tables 3-4 and 3-5 present only the former. When presenting tissue concentrations, please make it clear that those data are not shown.
3-18	Last, line 3	"were" is repeated.
3-19	1, line 1	Technically incorrect to say that the level peaked at PND7; that was the earliest sample time. The peak may have occurred before PND7.
3-19	Table 3-15	The last dose was on GD17; strange that at 1 and 3 mg/kg the serum concentration increases from PND7 to PND14.
3-22	4	Last sentence is garbled.
3-22	4, 5	Agree that biliary elimination is possible, but it could be that chloestyramine binds PFOA and PFOS in the GI tract lumen after they passively diffuse from the blood to the gut. There seems to be no direct evidence of biliary elimination, e.g., bile collected from treated animals.
3-23	Last, line 4	Should be Table 3-18.
3-34	Last, line 9	Should be "nonlinear least squares"
3-35	Table 3-23	Column 2, "Adsorption" should be "Absorption"
3-38 3-38	2 Figure 3-7	The arrow from Gut to Liver appears to point in the wrong direction; it should represent biliary excretion of PFOA from Liver to Gut.
3-43	Last line	"… indicating the absence of active excretion in human kidneys." This does not follow from the observation of renal clearance being about 0.001% of GFR. A plasma free fraction of 0.001 would

Specific Observations for *Health Effects Document for Perfluorooctanoic acid*		
Page	**Paragraph**	**Comment or Question**
		account for the CLr being 0.1% of GFR, and passive tubular reabsorption would make it 0.001% of GFR since urine flow is about 1% of GFR. Other scenarios are possible that do not invoke the absence or presence of active excretion.
3-44	Table 3-24	Should report all data values with three significant figures. For example, Lambda z values have only one sig. fig., while $T_{1/2}$ values have 5-6.
3-46	2	This reviewer does not follow the derivation and use of a value for volume of distribution with regard to intake rate and serum concentration of PFOA. If the subjects were at steady state, the body burden would have to be known. At steady state, the serum concentration would be independent of the volume of distribution, so any V value ought to match the intake rate to the steady state serum concentration.
4-9	1	Log transformed concentration was 1.51 and 1.48 ng/mL – are these the logarithms? IE, are the actual concentrations 10^1.51 = 32 and 10^1.48 = 30 ng/mL?
4-20	2, line 8	Anderson here is spelled Andersen in the reference list.
4-30	1, line 9	prostrate should be prostate.
4-31	4, line 10	decreased should be decrease.
4-112	1	It would be helpful to restate the serum concentrations for the Eriksen and Vieira studies, or refer reader to p. 4-29 where they are provided.
4-112	1, line 9	Delete "for".
4-112	2, line 12	Delete "were".
4-118	4	Delete "of actions" after MOAs
4-120	3	The broad range of half lives could also be due to person-to-person variability in the free fraction of PFOA in serum (fup). This is the case for highly bound drugs; e.g., warfarin.
5-1	3	Pharmacokinetic is misspelled.
5-1	5	Disagree – exposure assessment based on the human data is feasible. In fact, the serum concentrations are a better measure of exposure than are intake measures as they reflect all intake pathways and eliminate bioavailability and pharmacokinetic influences on internal exposure.
5-12	Last	Table numbers should be 5-6, 5-7, and 5-8.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
3-5	3	The low CSF : serum concentration ratio could also be due to an export transporter that pumps PFOS out of the CSF and/or to extensive serum protein binding, where only the free serum concentration of PFOS is in equilibrium with the free PFOS concentration in the CSF.
3-22	2	The free fraction used for the model is much larger than that determined experimentally, Table 3-1; this should be pointed out in the text.
3-22 3-23	2 Figure 3-5	The arrow from Gut to Liver appears to point in the wrong direction; it should represent biliary excretion of PFOS from Liver to Gut.
3-24	4	Anderson should be Andersen.
4-26	4	"concentrations" should be "dosages".
5.2	3	Should note for many of these studies, that steady state may not have been achieved due to the long half-life of PFOS. Half-life values from Section 3 are: mouse, 37 days; rat male, 40 days and female 64 days; monkey, 120 days. Using a one-compartment PK model, the time to 90% steady state is 3.3 half lives.
5-5	3	The NOAEL for liver effects in rats of 0.072 mg/kg/day is not consistent with p. 5.4, para. 2, which states that lesions of the liver <u>were</u> observed in male rats after 104 weeks at this dosage.
5-7	2	For female rat, the PFOS half life is about 60 d and the period of gestation is about 20 d or one-third of a half life. If PFOS is administered to the dam only during gestation at a fixed daily dose, the serum concentration of PFOS would rise from 0 to 21% of the steady-state serum concentration that the fixed dose rate would produce at steady state. The exposure of the fetus during gestation would average only about 10% of the exposure that would have occurred if the dam had received PFOS for 4 half-lives (240 days) prior to mating. BMDs based on such a fixed dose could be elevated by as much as a factor of 10 compared with the steady state situation. Steady state would be the relevant situation for humans. For the Luebker study (Table 5-3) the serum concentration during gestation would have increased from about 38% to 50% of the eventual steady state concentration.

Matthew P. Longnecker

Specific Observations for *Health Effects Document for Perfluorooctanoic*		
Page	**Paragraph**	**Comment or Question**
3-28	1st complete	Should the end of the sentence be "increase the transporters" rather than "increase the receptors"?
3-30	2nd complete	L 3, would insert "transfected" between "OAT3" and "cells"
3-39	1st complete	Next to last sentence: I doubt that Olsen assumed the major source of exposure was drinking water in the occupational study
3-41	4th complete	In the first formula listed, the plus sign should be an equal sign
4-9	1st complete	L 3 from bottom: the values of 1.51 and 1.48 given are probably better described as geometric means.
4-16	2nd complete	L 3 from bottom: would insert "draw" after "blood"
4-21	2nd complete	L 5: the value of 6.78 ug/L is a water level, not a serum level; this issue recurs on P 4-23, paragraph at bottom
4-30	1st complete	L 8: should read "exposure categories" rather than "cancer categories"?
4-37	Table	Would note dose of PFOA somewhere in table or footnote
4-55	Last para	L 3: should the ">" be a "<"?
4-79	Last para	Last sentence: should "50 and 25" be "50 and 250"?
4-80	1st complete	The last sentence does not accurately describe the table. E.G., the CD4+CD8+ cells decreased at the 47.21 mg/kg/d dose
4-82	Next to last para	Last sentence: the 37.5 mg/kg/dose is not mentioned earlier, so this is a little confusing.
4-85	Last para	L 2: should "0.5" be "0.05"?; Same issue for L 5.
4-89	4th para	How long were the animals dosed?
4-110	3rd complete para	L 5: should "serum" be "blood"?
4-113	3rd complete para	L 1: insert "in" before "liver cells"
5-4	Last para	Were the criteria for inclusion in Table 5.2 the same as for Table 5.1?
5-12	Para below table	8-6, 8-7, and 8-8 should be 5-6, 5-7, and 5-8
5-16	Last line	I do not see in the Thompson et al. (2010) study any mention of using exposure data from NHANES to calibrate the volume of distribution. Other sources of data were used, where the water had been contaminated.
5-17	1st formula	"/day" should be deleted from "0.17 $L/kg_{bw}/day$"
5-20	Table 5-12	The first three values in the UF_{total} column need to be corrected; they should be 21900, 219000, and 21900
5-21	Paragraph above table	Last sentence: UF_L should be UF_H
5-21	Last sentence	UD_S should be UF_S

Specific Observations for *Health Effects Document for Perfluorooctanoic*		
Page	**Paragraph**	**Comment or Question**
5-27	Calculations	The text says the body weight conversions should be based on the ¾ power. If so, the HED formulas are incorrect, and the HED should be 1.99 x 0.0254 = 0.0506, the dosimetric adjustment factor should be 0.0254, and the CSF should be 1.57. All the figures here should be checked as should the paragraph on P 5-28. The HED is 2,530-fold greater than the RfD, not 29,000.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
1-1	2nd	1st sentence: would revise for clarity. Do you mean uncertainties exist about whether PFOS-induced peroxisome proliferation is involved in causing PFOS-induced hepatic lesions?
1-1	3rd	1st sentence: would revise for clarity; the occupational studies were done at PFOS production plants, but to my knowledge there are no residential populations that have been studied for health effects who lived near PFOS production plants. (Mid-Ohio valley factory was a source of PFOA.) In the 2nd sentence, I do not believe that exposure was mainly through contaminated drinking water in any of these studies.
4-66	2nd	The earlier summary of the Bloom et al. study (P 4-10) said the results were not statistically significant, whereas here the interpretation appears to be that the study found an association. The interpretation does not seem consistent across the two sections.
5-17	Below table	L 3: the word "terminal" should be deleted from this sentence
5-20	1st formula	The "/day" should come out of "0.23 L/kg bw/day"
5-26	L 2 from bottom	This should be 35 ug/L not 35 mg/L

Angela L. Slitt

No specific observations.

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APPENDIX A: PEER REVIEWER BIOSKETCHES

ED_000915_Redeliver_PSTs-DD_00077515-00075

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 21 and 22, 2014

LIST OF PEER REVIEWERS

James Bruckner, Ph.D.
University of Georgia

Deborah Cory-Slechta, Ph.D. (chair)
University of Rochester School of Medicine and Dentistry

Jamie DeWitt, Ph.D.
East Carolina University

Jeffrey Fisher, Ph.D.
U.S. Food & Drug Administration

William Hayton, Ph.D.
The Ohio State University (Emeritus)

Matthew Longnecker, Sc.D., M.D
National Institute of Environmental Health Sciences

Angela Slitt, Ph.D.
University of Rhode Island

BIOGRAPHICAL SKETCHES OF PEER REVIEWERS

James Bruckner, Ph.D.
University of Georgia

Dr. Bruckner is Professor of Pharmacology and Toxicology at the University of Georgia College of Pharmacy. He is also Professor in the Department of Physiology and Pharmacology at the University of Georgia College of Veterinary Medicine. He received his Ph.D. in Toxicology from the University of Michigan in 1974. He has previously held faculty positions at the University of Kansas and the University of Texas Medical School at Houston. He is actively engaged in graduate education and in federally-funded research projects. Dr. Bruckner's research focus is on the toxicology and toxicokinetics of solvents, drug-solvent interactions at occupational exposure levels, and toxicokinetic bases for susceptibility of children to insecticides and other chemicals. Dr. Bruckner has published more than 200 journal articles, book chapters, and abstracts. He has also served on a variety of expert panels and committees for the EPA, National Institutes of Health, National Aeronautics and Space Administration, Agency for Toxic Substances and Disease Registry, Food and Drug Administration, and the National Academy of Sciences.

Deborah Cory-Slechta, Ph.D. (chair)
University of Rochester School of Medicine and Dentistry

Dr. Cory-Slechta is a Professor in the Department of Environmental Medicine and the Department of Pediatrics at the University of Rochester School of Medicine and Dentistry, where she also serves as co-director of the Behavioral Sciences Facility Core and director of the Animal Behavior Core. Dr. Cory-Slechta received her Ph.D. from the University of Minnesota in 1977 and worked as a junior staff fellow of the National Center for Toxicological Research beginning in 1979. She was appointed to the faculty of the University of Rochester Medical School in 1982 and was appointed Chair of the Department of Environmental Medicine and Director of the NIEHS Environmental Health Sciences Center at the University of Rochester in 1998. From 2000 to 2002, she was the Dean for Research and Director of the AAB Institute for Biomedical Sciences. Following her appointment as Dean, she served from 2003 to 2007 as the Chair of the Department of Environmental and Occupational Medicine at Robert Wood Johnson Medical School and as Director of the Environmental and Occupational Health Sciences Institute, a joint Institute of the Robert Wood Johnson Medical School and Rutgers. Dr. Cory-Slechta's research has focused largely on environmental neurotoxicants as risk factors for behavioral disorders and neurodegenerative disease. These research efforts have resulted in over 170 papers and book chapters to date. Dr. Cory-Slechta has served on numerous national research review and advisory panels, including committees of the National Institutes of Health, the National Institute of Environmental Health Sciences, the Food and Drug Administration, the National Center for Toxicological Research, the Environmental Protection Agency, the National Academy of Sciences, the Institute of Medicine, and the Agency for Toxic Substances and Disease Registry, Centers for Disease Control. In addition, Dr. Cory-Slechta has served on the editorial boards of several journals including *Environmental Health Perspectives*, *Neurotoxicology*, *Toxicology*, *Toxicological Sciences*, *Fundamental and Applied Toxicology*, *Neurotoxicology* and *Teratology*, and *American Journal of Mental Retardation*. She has held the elected positions of President of the Neurotoxicology Specialty Section of the Society of Toxicology, President of the Behavioral Toxicology Society, and been named a Fellow of the American Psychological Association. She also previously served on the EPA Science Advisory Board Perfluorooctanoic Acid Risk Assessment Review Panel.

Jamie DeWitt, Ph.D.
East Carolina University

Dr. DeWitt is an Assistant Professor in the Department of Pharmacology and Toxicology at the Brody School of Medicine at East Carolina University (ECU). She is affiliated with The Harriet and John Wooten Laboratory for Alzheimer's and Neurodegenerative Diseases Research and holds an adjunct appointment in the ECU Department of Public Health. Dr. DeWitt received her Ph.D. in Environmental Science and Neural Science from the School of Public and Environmental Affairs and Program in Neural Science at Indiana University in 2004. She also completed postdoctoral training in Developmental Cardiotoxicity at Indiana University-Bloomington and in Immunotoxicology at EPA through a cooperative training agreement with the University of North Carolina at Chapel Hill. Dr. DeWitt's main research focus is on how toxicants found in the environment can lead to neurodevelopmental and neurodegenerative disorders via disruption of the developing immune system. Much of her past research has

involved the immunotoxicity of perfluorooctanoic acid (PFOA) and related polyfluroalkyl substances (PFASs). Dr. DeWitt has published seven peer reviewed research articles, three review papers and two book chapters that address the biological effects of PFOA, as well as one paper on the effects of PFOS on immune function. Her publications describe effects as well as underlying mechanisms following adult and developmental exposure. Her research experience and publication record (more than 25 peer reviewed manuscripts, 6 review articles, 9 book chapters) extend beyond the effects of PFAAs and working with rodent models. She is currently editing a book on the general toxicity of PFASs and is a current member of the mechanistic working group for Monograph 110 of the International Agency for Research on Cancer, which will include an assessment of PFOA. She is on the editorial boards of the *Journal of Immunotoxicology* and the *Journal of Environmental Toxicology and Health* and has reviewed grants for the Department of Defense and the National Institute of Occupational Safety and Health. She has also been manuscript reviewer for more than 20 journals. Dr. DeWitt is the current president of the North Carolina chapter of the Society of Toxicology and the Junior Councilor for the Immunotoxicology Specialty Section of the Society of Toxicology. She also was awarded the Outstanding Young Investigator Award from the Immunotoxicology Specialty Section in 2013.

Jeffrey Fisher, Ph.D.
U.S. Food & Drug Administration

Dr. Fisher is a Research Toxicologist at the U.S. Food and Drug Administration (FDA), National Center for Toxicological Research. He was formerly a Professor in the Department of Environmental Health Science, College of Public Health at the University of Georgia (UGA). He joined UGA in 2000 and served as Department Head of the Department of Environmental Health Sciences from 2000 to 2006 and Director of the Interdisciplinary Toxicology Program from 2006-2010. Prior to joining UGA, he spent most of his career at Wright Patterson Air Force Base (AFB), where he was Principal Investigator and Senior Scientist in the Toxics Hazards Division and Technical Advisor for the Operational Toxicology Branch. Dr. Fisher's research interests are in the development and application of biologically based mathematical models to ascertain health risks from environmental, food-borne and occupational chemical exposures. Dr. Fisher's modeling experience includes working with chlorinated and non-chlorinated solvents, fuels, pesticides, perchlorate and bisphenol A. He has developed physiologically-based pharmacokinetic (PBPK) models for use in cancer risk assessment, estimating lactational transfer of solvents, understanding in utero and neonatal dosimetry, quantifying metabolism of solvent mixtures and developing biologically motivated models for the hypothalamic-pituitary-thyroid axis in rodents and humans. Dr. Fisher has published over 140 papers on pharmacokinetics and PBPK modeling in laboratory animals and humans. He has served on several national panels and advisory boards for the DoD, ATSDR, USEPA and non-profit organizations. He was a U.S. delegate for the North Atlantic Treaty Organization. Dr. Fisher served on the International Life Sciences Institute Steering Committee, which evaluated chloroform and dichloroacetic acid using EPA-proposed Carcinogen Risk Guidelines. He is Past President of the Biological Modeling Specialty Section of the Society of Toxicology, reviewer for several toxicology journals, and was Co-Principal Investigator on a National Institutes of Health (NIH)-supported workshop on Mathematical Modeling at the University of Georgia in the fall of 2003. Dr. Fisher was also a member of the National Academy of Sciences subcommittee on Acute Exposure

Guideline Levels (AEGLs) from 2004-2010 and Science Advisory Board (SAB) for the US EPA (2007-2010). He is an ad hoc EPA SAB member for dioxin and perchlorate. Dr. Fisher is a Fellow of the Academy of Toxicological Sciences, an associate editor for Toxicological Sciences, and on the editorial board of *Journal of Environmental Science and Health Part C Environmental Carcinogenesis & Ecotoxicology Reviews*.

William Hayton, Ph.D.
The Ohio State University (Emeritus)

Dr. Hayton is a Professor Emeritus in the College of Pharmacy at The Ohio State University. Dr. Hayton received a Ph.D. in Pharmaceutics from the State University of New York at Buffalo in 1967. He was a member of the Washington State University College of Pharmacy faculty for 19 years, rising to Chair of the Pharmacology/Toxicology Graduate Program in 1982 and Acting Dean at the College of Pharmacy in 1987. In 1990, he transferred to the Ohio State University as Chair of the Division of Pharmaceutics, where he later served as Associate Dean for the Graduate Programs and Research until his retirement in 2010. Dr. Hayton's expertise is pharmacokinetics, particularly construction and validation of mathematical models that describe or explain the kinetics of complex biological systems. One recent research interest is characterization of the Fc receptor-mediated transport and catabolism of albumin and IgG in wild type and FcR knockout mice. A second recent project is the quantitative modeling of the female hypothalamus-pituitary-gonad (HPG) axis in the female rainbow trout (Oncorhynchus mykiss). The model is based on and integrates the biology of gonadotropin, estrogen, androgen and maturational hormone signaling systems, and it includes key intermediate steps in the signaling pathways; viz., gonadotropin and sex steroid synthesis, hormone receptors and their corresponding mRNA levels. Dr. Hayton's expertise extends to interspecies scaling of pharmacokinetic model parameter values and xenobiotic metabolism. Dr. Hayton is author or co-author of over 100 peer-reviewed scientific publications and has held peer-reviewed grant support from the National Institutes of Health, EPA, Air Force Office of Scientific Research, Food and Drug Administration, and U.S. Fish and Wildlife Service. He previously served on the EPA Science Advisory Board Perfluorooctanoic Acid Risk Assessment Review Panel.

Matthew Longnecker, Sc.D., M.D
National Institute of Environmental Health Sciences

Dr. Longnecker, M.D., Sc.D., is the head of the Biomarker-based Epidemiology Group at the National Institute of Environmental Health Sciences (NIEHS). Dr. Longnecker received an M.D. from Dartmouth Medical School and completed a residency in internal medicine at Temple University Hospital in Philadelphia. After receiving a Sc.D. in Epidemiology from Harvard School of Public Health in 1989, he served as an Assistant Professor in the Department of Epidemiology at the University of California, Los Angeles, School Of Public Health. Since 1996, Dr. Longnecker has served as Adjunct Professor/ Associate Professor in the Department of Epidemiology, School of Public Health, University of North Carolina at Chapel Hill. He came to the NIEHS Epidemiology Branch in 1995, as a tenure-track investigator. Dr. Longnecker's research program is focused on the health effects of persistent organic pollutants (e.g., the DDT metabolite p,p'-DDE, and polychlorinated biphenyls). He is particularly interested in the effects of intrauterine exposure to persistent organic pollutants in relation to intrauterine growth,

preterm birth, birth defects, neurologic findings at birth, growth, neurodevelopment, intelligence, and hearing. Recently, Dr. Longnecker has completed and has ongoing a series of studies on perfluorinated alkyl substances in relation to reproductive and pediatric outcomes. In addition, he has begun studying the effects of early, low-level exposure to the nonpersistent pollutants, bisphenol A and organophosphate pesticides. Dr. Longnecker's research efforts have resulted in over 180 papers and book chapters to date. He has served as a leader for numerous national and international committees, such as for the Society for Epidemiologic Research and the International Society for Environmental Epidemiology, and has been on numerous national and international scientific advisory boards, including the EPA Science Advisory Board for the Perfluorooctanoic Acid Risk Assessment Review.

Angela Slitt, Ph.D.
University of Rhode Island

Dr. Slitt is an Associate Professor in the Department of Biomedical and Pharmaceutical Sciences at the University of Rhode Island. Dr. Slitt received her Ph.D. in Pharmacology and Toxicology from the University of Connecticut in 2000, and then served until 2004 as a postdoctoral fellow at the University of Kansas Medical Center. Dr. Slitt has been a faculty member at the University of Rhode Island since 2006. Dr. Slitt's graduate and postdoctoral training was heavily focused on liver biology and health, with a focus in the area of toxicology, and included research in nuclear receptors, biotransformation, and transporter expression. Her current research interests focus on how 1) expression of drug transporters affects chemical disposition and toxicity, 2) nutrition and intake of dietary antioxidants affects the expression of drug transporters, 3) liver disease (i.e., diabetes, cholestasis, and ethanol cirrhosis) affects transporter expression and chemical disposition, and 4) transporter expression affects cholesterol transport and susceptibility to gallstone formation. She has also recently investigated the effect of PFOS on caloric restriction in mice. Dr. Slitt is presently on the Editorial Board of *BMC Pharmacology and Toxicology, Journal of Biochemical and Molecular Toxicology*, and *Toxicology Methods and Mechanism*, and is an ad-hoc reviewer for numerous other journals. She is author or co-author of over 50 peer-reviewed scientific publications, and was recently awarded the University of Rhode Island Early Career Faculty Research Excellence Award.

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APPENDIX B: MEETING AGENDA

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AGENDA

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 21, 2014

Day 1 – PFOA Health Effects Document

8:30 AM	**Meeting Sign-In Begins**
9:00 AM	**Welcome, Goals of Meeting, and Introductions** David Bottimore, Versar, Inc.
9:15 AM	**Welcome by EPA and Overview of PFOA/PFOS Health Effects Documents** Elizabeth Doyle, Chief, EPA/OST/OW/HECD
9:30 AM	**Chair's Introduction and Review of Charge** Deborah Cory-Slechta, *Chair*
10:00 AM	**Discussion Session – "Round Table" General Overview Comments**
10:45 AM	*Break**
11:00 AM	**PFOA Discussion Session – Responses to Charge Questions:** Question 1: Strengths, Weaknesses, and Characterization of the Studies Selected Question 2: Additional References for Consideration Question 3: Conclusions on Human Epidemiology Data Question 4: Transparency and Characterization of Epidemiologic Data
12:15 PM	*Lunch**
1:15 PM	**PFOA Discussion Session – Response to Charge Questions:** Question 5: Cancer Classification Question 6: Pharmacokinetic Model Adjustments Question 7: Selected Parameters for Pharmacokinetic Model Question 8: Volume of Distribution (Vd) and Half-life Values
2:45 PM	*Break**
3:00 PM	**PFOA Discussion Session – Response to Charge Questions:** Question 9: Points of Departure and RfDs Question 10: RfDs and Applicability to Short-and Long-term Exposures Question 11: Uncertainty Factors Question 12: Other Suggestions for Improving the Document
5:00 PM	**Adjourn**

**Time for breaks and lunch are approximate and at the Chair's discretion.*

AGENDA

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 22, 2014

Day 2 – PFOS Health Effects Document

9:00 AM	**Recap of Day 1 and Agenda for Day 2** David Bottimore, Versar, Inc.
9:15 AM	**Chair's Review of Charge for Day 2** Deborah Cory-Slechta, *Chair*
9:30 AM	**Discussion Session – "Round Table" General Overview Comments**
10:00 AM	*Break**
10:15 AM	**PFOS Discussion Session – Responses to Charge Questions:** Question 1: Strengths, Weaknesses, and Characterization of the Studies Selected Question 2: Additional References for Consideration Question 3: Conclusions on Human Epidemiology Data Question 4: Transparency and Characterization of Epidemiologic Data
11:30 PM	*Lunch Break**
12:30 PM	**PFOS Discussion Session – Response to Charge Questions:** Question 5: Cancer Classification Question 6: Pharmacokinetic Model Adjustments Question 7: Selected Parameters for Pharmacokinetic Model Question 8: Volume of Distribution (Vd) and Half-life Values
2:15 PM	*Break**
2:30 PM	**PFOS Discussion Session – Response to Charge Questions:** Question 9: Points of Departure and RfDs Question 10: RfDs and Applicability to Short-and Long-term Exposures Question 11: Uncertainty Factors Question 12: Other Suggestions for Improving the Document
5:00 PM	**Adjourn**

**Time for breaks and lunch are approximate and at the Chair's discretion.*

EPA-HQ-2016-005679 06/14/2017

APPENDIX C: MEETING ATTENDEE LIST

ED_000915_Redeliver_PSTs-DD_00077515-00084

LIST OF OBSERVERS ATTENDING MEETING IN PERSON
August 21 and 22, 2014

External Peer Review Meeting on
EPA's Draft Health Effects Documents for
Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Name	Affiliation
Janet Anderson, Ph.D.	U.S. Air Force
Robert Bilott	Taft Stettinius & Hollister LLP
Norman Birchfield	U.S. EPA
John Butenhoff, Ph.D.	3M Company
Sue Chang, Ph.D.	3M Company
C-H Selene Chou, Ph.D.	Agency for Toxic Substances and Registry
Steven Chranowski	Chemistry Council of New Jersey
Joyce Donohue	U.S. EPA
Elizabeth Doyle	U.S. EPA
Colleen Flaherty	U.S. EPA
Maria Hegstad	Inside EPA
Gerald Kennedy	DuPont
La Rae Landers	Dept of the Navy BRAC PMO
Willington Lin	Public
Angela Lynch, Ph.D.	American Chemistry Council
Geary Olsen, Ph.D.	3M Company
Gloria Post, Ph.D.	New Jersey Department of Environmental Protection
Resha Putzrath, Ph.D.	Navy and Marine Corps Public Health Center
Jennifer Seed	U.S. EPA
Shalene Thomas	AMEC Environment & Infrastructure
Steve Via	American Water Works Association
Anthony Walters	United Science, LLC
Carol Wood	Oak Ridge National Laboratory

LIST OF OBSERVERS ATTENDING VIA PHONE
August 21 and 22, 2014

External Peer Review Meeting on
EPA's Draft Health Effects Documents for
Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Name	Affiliation
Matthew Bailor	Gilmore & Associates, Inc.
Victoria Binetti	U.S. EPA
Stuart Cagen, Ph.D.	Shell Health
Andrea Candara	New York State Department of Health
Tom Cleveland	Decatur Utilities
Jason Conder	ENVIRON International Corporation
Michelle Deveau	Health Canada
Stiven Foster	U.S. EPA
Helen Goeden	Minnesota Department of Health
Christopher Lau, Ph.D.	U.S. EPA
Anita Meyer, DABT	U.S. Army Corps of Engineers
Jonathan Naile, Ph.D.	Shell Health
Jessica Nelson	Minnesota Department of Health
Bridget O'Brien	U.S. EPA
Ramasamy Santhini	U.S. EPA
Robert Rickard	U.S. EPA
John Wambaugh	U.S. EPA
Carol Rowan West, Ph.D.	Massachusetts Department of Environmental Protection
Linda Wilson	New York State Office of the Attorney General
Virginia Yingling	Minnesota Department of Health
Tsedash Zewdie	Massachusetts Department of Environmental Protection

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Lalley, Cara
Sent: Mon 12/21/2015 7:13:19 PM
Subject: RE: New York Times - PFOA

Thanks- got it

From: Strong, Jamie
Sent: Monday, December 21, 2015 1:57 PM
To: Lalley, Cara <Lalley.Cara@epa.gov>
Subject: FW: New York Times - PFOA

From: Burneson, Eric
Sent: Monday, December 21, 2015 1:56 PM
To: Greene, Ashley <Greene.Ashley@epa.gov>; Loop, Travis <Loop.Travis@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Schollhamer, Mary <Schollhamer.Mary@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Lopez-Carbo, Maria <Lopez-Carbo.Maria@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Russell, Meredith <Russell.Meredith@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: RE: New York Times - PFOA

Deliberative Process / Ex. 5

From: Greene, Ashley
Sent: Monday, December 21, 2015 9:41 AM
To: Loop, Travis <Loop.Travis@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Schollhamer, Mary <Schollhamer.Mary@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Lopez-Carbo, Maria <Lopez-Carbo.Maria@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Russell, Meredith <Russell.Meredith@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Subject: RE: New York Times - PFOA

Hi Travis,

Attached is background information on PFOA/PFOS. Please let me know if you need any additional info or follow-up.

Thanks,
Ashley

From: Strong, Jamie
Sent: Friday, December 18, 2015 3:35 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Lopez-Carbo, Maria <Lopez-Carbo.Maria@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Russell, Meredith <Russell.Meredith@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: New York Times - PFOA

One additional bullet. Let us know if you want more info on the HA and history of the HA for Travis.

Thanks Eric

Jamie

From: Burneson, Eric
Sent: Friday, December 18, 2015 3:18 PM
To: Grevatt, Peter <Grevatt.Peter@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Lopez-Carbo, Maria <Lopez-Carbo.Maria@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>; Russell, Meredith <Russell.Meredith@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>
Subject: RE: New York Times - PFOA

Peter:

I agree that our response should highlight the UCMR 4 and Health advisories as the most recent in a number of steps EPA has taken to address PFOA/PFOS as follows:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

I am copying folks in TSC and OST for them to provide corrections, updates to the information above. But I think this can be the starting place for our response to these inquiries.

Eric Burneson, P.E.

Director of Standards and Risk Management

Office of Ground Water and Drinking Water

US Environmental Protection Agency

Phone: 202-564-5250

Fax: 202 564 3760

From: Grevatt, Peter
Sent: Friday, December 18, 2015 2:03 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Lopez-Carbo, Maria <Lopez-Carbo.Maria@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Greene, Ashley <Greene.Ashley@epa.gov>
Subject: Fwd: New York Times - PFOA

Deliberative Process / Ex. 5

Sent from my iPhone

Begin forwarded message:

From: "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>

Date: December 18, 2015 at 1:42:21 PM EST
To: "Loop, Travis" <Loop.Travis@epa.gov>
Cc: "Gilinsky, Ellen" <Gilinsky.Ellen@epa.gov>, "Lalley, Cara" <Lalley.Cara@epa.gov>, "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Wadlington, Christina" <Wadlington.Christina@epa.gov>, "Schollhamer, Mary" <Schollhamer.Mary@epa.gov>, "Behl, Betsy" <Behl.Betsy@epa.gov>
Subject: Re: New York Times - PFOA

OST can describe its drinking water advisory work, which is non regulatory, and OGWDW can describe their regulatory process actions.

Sent from my iPhone

On Dec 18, 2015, at 1:10 PM, Loop, Travis <Loop.Travis@epa.gov> wrote:

Folks

A New York Times reporter is doing a centerpiece story for the magazine on PFOA. One of the main assertions is that EPA is not doing anything to regulate this chemical in our water supply. I need good info on the history of our work on PFOA, the current landscape, and upcoming actions. Could I get this by Monday? Thanks.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]
From: Strong, Jamie
Sent: Fri 5/20/2016 4:54:07 PM
Subject: FW: Suggested Game Plan for May 23rd Webinar for States about the New HAs for PFOA and PFOS
PFOA-PFOS-OW HAs ASDWA 05 30 2016.ppt

Betsy,
Can you take a look?

Thanks,

Jamie

From: James Taft [mailto:jtaft@asdwa.org]
Sent: Friday, May 20, 2016 12:08 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Cc: Greene, Ashley <Greene.Ashley@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: RE: Suggested Game Plan for May 23rd Webinar for States about the New HAs for PFOA and PFOS

Eric, thanks much for that feedback. That approach sounds right on the money to me – we'll proceed accordingly and send one speaker's link to you. Jamie can send the Powerpoint slide to me – and, any time by noon-ish on Monday would be fine. Thank you.

Jim Taft

Executive Director

Association of State Drinking Water Administrators

1401 Wilson Blvd.

Arlington, VA 22209

Jtaft@asdwa.org

703-812-9507

From: Burneson, Eric [mailto:Burneson.Eric@epa.gov]
Sent: Friday, May 20, 2016 11:57 AM
To: Taft, Jim <jtaft@asdwa.org>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Cc: Greene, Ashley <Greene.Ashley@epa.gov>; Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Subject: RE: Suggested Game Plan for May 23rd Webinar for States about the New HAs for PFOA and PFOS

Jim: Thank you for making the arrangements for Monday's webinar with State Drinking Water Administrators and Health Officials. We appreciate the opportunity to interact with health scientists from the States to explain the basis for the PFOA and PFOS Health Advisories. The following is a suggested agenda for your consideration

2:00 – 2:05 Welcome and Introductions – Jim Taft

2:05 – 2:10 Opening Remarks – Betsy Southerland

2:10 – 2:40 PFOA/PFOS Health Advisory Presentation – Jamie Strong

2:40 – 2:55 Questions and Answers

2:55- 3:00 Closing Remarks

Regarding call in links. We plan to be in one conference room so multiple links for each of our presenters are not necessary. We also think your plans for muting/ raising hands works for us.

Please let us know who to send the power point presentation that Jamie will be using and when you need it by.

Thank you again for putting arrangements together quickly for this.

Eric Burneson, P.E.

Director of Standards and Risk Management

Office of Ground Water and Drinking Water

US Environmental Protection Agency

Phone: 202-564-5250

Fax: 202 564 3760

From: Taft, Jim [mailto:jtaft@asdwa.org]
Sent: Friday, May 20, 2016 8:24 AM
To: Grevatt, Peter <Grevatt.Peter@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Greene, Ashley <Greene.Ashley@epa.gov>
Subject: Suggested Game Plan for May 23rd Webinar for States about the New HAs for PFOA and PFOS

Good morning Peter and Eric --

Below is the information and link we sent to all states about Monday's webinar. We also shared this with ECOS and ASTHO and suggested they extend the invitation to their members. ***We'd like to send a separate link to all of the presenters.*** I'm assuming they would be you both, Betsy Behl, and Betsy Southerland. Is there anyone else that we should send a presenter link to?

In terms of logistics for Monday, we would suggest that we begin by globally muting everyone except the presenters. I can then welcome everyone, go over logistics, and then turn it over to you. After your remarks and those from OST, we can open it up to

questions. (Will OST be presenting or just answering questions as they arise?) For the Q & A portion, we can ask folks to electronically raise their hands and we can unmute them one-by-one or they can type questions into the questions box and we can read those off.

Please let me know if that general game plan sounds agreeable and confirm who will be speaking. Thank you.

****

Jim Taft
Executive Director
Association of State Drinking Water Administrators
1401 Wilson Blvd.; Suite 1225
Arlington, VA 22209
Jtaft@asdwa.org
Phone: 703-812-9507

Background Information for States about the New Health Advisories for the Perfluorinated Compounds

Join us for a webinar on May 23, 2016 at 2:00 PM EDT.

Register now!

https://attendee.gotowebinar.com/register/58262396347083521

EPA scientists and program managers will provide background information about the just-released Health Advisories for PFOA and PFOS as well as discuss implementation considerations and risk communication. There will also be opportunities for Q&A and discussion.

After registering, you will receive a confirmation email containing information about joining the webinar.

View System Requirements

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Southerland, Elizabeth
Sent: Fri 5/20/2016 3:12:18 PM
Subject: Re: media clips for PFOA PFOS

It is an honest to God major career accomplishment! Only a small percentage of people get that in a lifetime. I also think it will have long term risk assessment implications with more focus on breast milk transfer and data on lactating women.

Sent from my iPhone

On May 20, 2016, at 10:50 AM, Strong, Jamie <Strong.Jamie@epa.gov> wrote:

Thanks Betsy, it is really something to be proud of!

From: Southerland, Elizabeth
Sent: Friday, May 20, 2016 10:38 AM
To: Donohue, Joyce <Donohue.Joyce@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Cc: Behl, Betsy <Behl.Betsy@epa.gov>
Subject: Fwd: media clips for PFOA PFOS

What a difference you are making! My beloved WV has already switched 3 communities to new sources (Martinsburg, Parkersburg, Vienna). Also I am so glad you finally released it in response to Senator Schumer...

Sent from my iPhone

Begin forwarded message:

From: "Loop, Travis" <Loop.Travis@epa.gov>
Date: May 20, 2016 at 9:09:22 AM EDT
To: "Beauvais, Joel" <Beauvais.Joel@epa.gov>, "Gilinsky, Ellen" <Gilinsky.Ellen@epa.gov>, "Campbell, Ann" <Campbell.Ann@epa.gov>, "Gude, Karen" <Gude.Karen@epa.gov>, "Dennis, Allison" <Dennis.Allison@epa.gov>, "Fuld, John" <Fuld.John@epa.gov>, "Altieri, Sonia" <Altieri.Sonia@epa.gov>, "Duke, Nia" <Duke.Nia@epa.gov>, "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>, "Wadlington, Christina" <Wadlington.Christina@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Behl, Betsy" <Behl.Betsy@epa.gov>, "Harper, Ashley" <harper.ashley@epa.gov>

Subject: media clips for PFOA PFOS

Here is a compilation of media clips on PFOA PFOS. The biggest common error is referring to it as a standard.

Because they asked and had done some digging through data, we provided the list of 63 communities Joel did interviews with USA Today/Gannett and BuzzFeed. I have not seen those stories yet.

EPA sets health advisory level for lifetime exposure to **PFOA**

NEWS10 ABC - 19 hours ago

WASHINGTON (NEWS10) – The U.S. Environmental Protection Agency (**EPA**) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to **PFOA**. The **EPA**said the advisory is to provide Americans, including the most ...

EPA sets new level for chemical **PFOA** in drinking water

Albany Times Union - 12 hours ago

The **EPA's** long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of **PFOA** in public water systems and private wells. The contamination has been linked ...

EPA suggests tighter limits for **PFOA**, PFOS in drinking water

PhillyVoice.com - 3 hours ago

The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney cancers, as well as birth defects and liver damage. "**EPA** will continue sharing the latest science and information so that state and **...**

With New **EPA** Advisory, Dozens of Communities Suddenly Have Dangerous Drinking Water

The Intercept - 17 hours ago

The **EPA** announced new drinking water health advisory levels today for the industrial chemicals**PFOA** and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which **...**

EPA issues health advisory for long-term **PFOA** exposure

The Union Leader - 16 hours ago

"I am pleased that the **EPA** has answered my repeated requests and released the new health advisory standards for **PFOA** and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to ...

EPA issues **PFOA** health advisory

Nashua Telegraph - 8 hours ago

"The **EPA** has set the health advisory for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion and has recommended that when these two chemicals co-occur in the drinking water source, the sum of the ...

EPA Sets New Guidelines For **PFOA**, PFOS; Superfund Declared For Petersburgh

WAMC - 15 hours ago

In 2009, **EPA** set a short-term exposure guideline of 100 ppt for **PFOA** and PFOS. Perhaps due to a lack of long-term exposure guidlelines, state governments have not had consistent recommended levels. Vermont has acted under a 20 ppt threshold while ...

In Significant Reduction, **EPA** Sets Health Advisory For **PFOA** At 70 Parts Per Trillion

Vermont Public Radio - 18 hours ago

The **EPA** announced last year that it was looking at its health advisory level of 400 parts per trillion for **PFOA**, which was established in 2009. After the chemical was detected in North Bennington, the state of Vermont set a more conservative level **...**

EPA Releases New Health Guidelines for **PFOA**, PFOS Found in Drinking

Water

TWC News - 18 hours ago

The **EPA** has released new health guidelines for **PFOA** and PFOS found in drinking water. **PFOA**was the chemical found in the water supply in Hoosick Falls and Petersburgh. The new health advisory levels have been set to 70 parts per trillion. When first ...

EPA Announces Lifetime **PFOA** and PFOS Advisory Level

New Hampshire Public Radio - 13 hours ago

The **EPA** has announced a lifetime health advisory level for two chemicals that have contaminated water in Southern NH and at the former Pease Air Force Base. **PFOA** and PFOS are slippery, stable chemicals used since the 1940s in products like nonstick ...

EPA issues new federal standards for **PFOA** exposure

WCAX - 14 hours ago

There are new federal standards for exposure to **PFOA** and it's three times higher than the level Vermont is using.**PFOA** has been found in drinking water supplies in Bennington and Pownal. Officials believe the chemical came from old Teflon factories.

EPA Releases New 'Lifetime' **PFOA** Exposure Level Data

Patch.com - 14 hours ago

CONCORD, NH - The U.S. Environmental Protection Agency has issued new “lifetime drinking water health advisory levels” for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion (ppt), according to Jim Martin **...**

EPA releases drinking water health advisories for **PFOA** and PFOS

WaterWorld - 18 hours ago

WASHINGTON, May 19, 2016 -- Based on the latest science on two chemical contaminants called**PFOA** and PFOS, **EPA** has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals.

EPA Releases New **PFOA**, PFOS Guidelines

WAMC - 19 hours ago

“I am pleased that the **EPA** has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," New York U.S. Senator Charles Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh ...

EPA declares official standard for **PFOA**, PFOS contamination for lifetime exposure

WRGB - 19 hours ago

'**EPA's** assessment indicates that drinking water with individual or combined concentrations of**PFOA** and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of **...**

3 Arizona water systems afoul of new **EPA** water guidelines

azcentral.com - 9 hours ago

The agency's latest advisory drops the recommended limit of **PFOA** and PFOS in drinking water from 400 parts per trillion to 70 parts per trillion. The **EPA** cannot enforce that limit, as it is just a recommendation intended to advise water systems on how **...**

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

Wall Street Journal - 17 hours ago

On Thursday, the **EPA** declared that drinking water with **PFOA** concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The **EPA** has been reviewing ...

EPA sets new standards for contaminants

Eagle-Tribune - 1 hour ago

The state has been waiting for some time to hear from the federal **EPA** about its recommendations about acceptable levels of **PFOA** in drinking water, said DES spokesman Jim Martin on Thursday. The new data recommends no more than 70 parts per trillion, ...

New **EPA** Guidelines on PFCs Welcome – but Still Fall Short

Environmental Working Group (blog) - 15 hours ago

Today the Environmental Protection Agency issued a long-awaited drinking water health advisory for the perfluorinated chemicals **PFOA** and PFOS. But **EPA's** advisory falls far short of what's needed to fully protect public health, and it is not a legally ...

Air Force applies new **EPA** guidance

Air Force Link - 15 hours ago

The Air Force has been following a 2009 **EPA** issued short-term provisional health advisory level for **PFOA** at 400 parts per trillion and 200 ppt for PFOS. On May 19, the **EPA** released new lifetime exposure health advisories for PFOS at 70 ppt and for **PFOA ...**

Martinsburg shuts down water plant after **EPA** advisory

Herald-Mail Media - 11 hours ago

The **EPA** issued the stricter guidelines for the chemicals after years of pressure from public-health experts and advocacy groups. The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney ...

EPA releases new safety advisories for chemicals

Burlington County Times - 14 hours ago

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the **EPA** in 2009: 0.4 parts per billion for **PFOA** in drinking water, and 0.2 ppb for PFOS. Thursday's announcement **...**

EPA sets new level for contaminant found in drinking water

WMUR Manchester - 19 hours ago

H. "I will continue to monitor the increasing instances of potentially dangerous **PFOA** and PFOS levels in water resources in several communities across our state and ensure that the **EPA** is working with local officials and communities to take every **...**

'Do not drink' ordered for Vienna water after **EPA** issues C8 guidance

Charleston Gazette-Mail (subscription) - 15 hours ago

"Although it's a long overdue step in the right direction, the guideline is still too high as it allows unacceptable accumulation of **PFOA** to build up in the blood of people drinking it," said Robert Bilott, a longtime lawyer for residents who had their **...**

EPA Sets New Health Advisory for Toxic Chemicals in Drinking Water

NBC Bay Area - 15 hours ago

The agency set the advisory at 70 parts per trillion of human exposure to two perfluoronated compounds called PFOS and **PFOA**. That means people should not drink water with detections of the chemicals above that level. The new level is nearly six times ...

Amherst water tested for **PFOA**

Cabinet.com - May 19, 2016

After the presence of **PFOA** was detected in private wells in those towns, the DES declared a provisional safe exposure limit of 100 parts per trillion, which is the standard used by Maine. The **EPA** recommends avoiding short-term exposure to more than 400 ...

Federal **EPA** warns of high chemical levels in Martinsburg, Parkersburg and Vienna water sources

West Virginia MetroNews - 14 hours ago

WASHINGTON, D.C. — The federal **EPA** announced Thursday that water sources in Martinsburg, Parkersburg and Vienna contain the chemicals **PFOA** and PFOS at levels higher than previously recommended for public water systems. A ' do not drink' ...

Vermont Department of Health setting **PFOA** advisory level at 20 parts per trillion

NEWS10 ABC - 17 hours ago

Now that **EPA** has set a new advisory level of 70 parts per trillion for **PFOA** and PFOS

combined, the department says it will evaluate the hundreds of pages of supporting documents just released by**EPA** to assess how this differs from their current **...**

EPA Issues Tighter Limits for Chemical In Water

WILX-TV - 13 hours ago

The cancer-causing chemical **PFOA** has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of**PFOA** in recent years.

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

The Decatur Daily - 17 hours ago

The **EPA** advisory says some studies indicate long-term exposure to higher levels of **PFOA** and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune ...

Do not drink advisory issued for citizens of Vienna

WSAZ-TV - 14 hours ago

WOOD COUNTY, W.Va. (WSAZ) -- The Bureau for Public health has reviewed new information regarding **PFOA** and PFOS that the U.S. **EPA** released Thursday, and have decided to issue a Do Not Drink advisory for citizens of Vienna until additional testing ...

Amherst addresses **PFOA** contamination

WMUR Manchester - May 18, 2016

In Amherst, state environmental officials recently identified the former site of Textiles Coated International on Route 101-A as a likely source of **PFOA** contamination in nearby wells. “Why did this happen, and how is it allowed that we have industry **...**

West Morgan-East Lawrence water customers to receive health warning

The Decatur Daily - 7 hours ago

After the **EPA** on Thursday issued a health advisory, the West Morgan-East Lawrence Water and Sewer Authority said it will notify its 25,000 direct and indirect customers that their drinking water contains excessive amounts of two chemicals.

Newburgh water pollutant now more than twice level of new **EPA** guidelines

Times Herald-Record - 18 hours ago

Sean Maloney had been urging the **EPA** to expedite release of its updated guidelines. “I am pleased that the **EPA**has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS,” Schumer said in a ...

La Crosse releases drinking water advisory

WXOW.com - 13 hours ago

The contaminants are called Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (**PFOA**). The Environmental Protection Agency or **EPA** now wants municipal water supplies across the county to be tested for unregulated contaminants to be proactive ...

West Virginia communities altering their water sources after new

WHAG - 8 hours ago

... specifically in Martinsburg, Parkersburg and the town of Vienna, are altering their water sources after new **EPA**thresholds were released on Thursday. This comes after officials found raised levels of industrial chemicals of**PFOA** and PFOS in the water.

Doylestown Township shuts down contaminated well

The Intelligencer - 14 hours ago

It (**PFOA**) had not been on any chemical list that governs our permit," the director said. **PFOA** was first found in the Cross Keys well in 2014, the first year the **EPA** tested for the chemical, John said. "Had the **EPA** not looked for it, we wouldn't have **...**

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/**PFOA** from Water and **...**

Broadway World - 17 hours ago

The **EPA** issued two public health advisories today for perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. **EPA's** assessment indicates that drinking water with individual or combined concentrations of **PFOA ...**

Newest clips below: PoliticoPro; (Manchester) Union Leader; (all previously clips forwarded below that).

Politico Pro Energy

EPA SETS PFOA LIMIT: EPA today set its long-awaited PFOA limit at 70 parts per trillion. Scott Waldman reports the limit "applies to both long- and short-term exposure and could have a significant effect on water testing and lawsuits against industry. It is also lower than the current advisory of 100 parts per trillion that the EPA issued in many upstate communities facing exposure to the toxic chemical, which is used in the manufacturing of nonstick products." Communities from New England to West Virginia have been shown to have high levels of the chemical in their drinking water. The New York Times magazine did a deep dive into the chemical back in January.

Union Leader (New Hampshire)

http://www.unionleader.com/environment/epa-issues-health-advisory-for-long-term-pfoa-exposure--20160519

EPA issues health advisory for long-term PFOA exposure

By Kimberly Houghton on 5/19/16 at 4:51pm

Federal officials on Thursday issued a lifetime health advisory for the chemical perfluorooctanoic acid, which is being detected in some water sources in southern New Hampshire.

The U.S. Environmental Protection Agency has now identified 70 parts per trillion of PFOA as a new lifetime drinking water health advisory. Previously, the EPA had a 400 ppt PFOA advisory for short-term exposure.

The new advisory level is less than some levels of PFOA detected in the municipal public water supply wells operated by Merrimack Village District and provided to about 25,000 customers in the area.

At least one Village District well was found to have a PFOA level of 90 ppt, though that well is currently off-line. Ron Miner, superintendent of the district, was not immediately available for comment Thursday. Town Manager Eileen Cabanel directed questions to MVD.

Recently, the New Hampshire Department of Environmental Services began providing bottled water to about 200 properties throughout Litchfield, Merrimack and Amherst that have private wells detecting PFOA at 100 ppt or more. It will now begin offering bottled water to homeowners with PFOA at 70 ppt in light of the newest recommendations from EPA, according to a release.

The federal advisory level of 70 ppt was derived from a developmental toxicity study in mice, according to the EPA's advisory released on Thursday.

"This lifetime health advisory is based on the latest health effects information for noncancer and cancer effects for PFOA - the lifetime health advisory is therefore protective of the population at large," states the advisory.

Tests on monkeys, rats and mice discovered developmental effects, liver toxicity, kidney toxicity, immune effects and cancers such as liver cancer, testicular cancer and pancreatic cancer as a result of long-term PFOA exposure, according to the advisory.

"Water resources contaminated by PFOA have been associated with releases from

manufacturing sites, industrial sites, fire/crash training areas and industrial or municipal waste sites where products are disposed of or applied," it states.

Saint-Gobain Performance Plastics has been identified as the likely source of water contamination in Merrimack and surrounding areas, according to officials with DES. PFOA has also been discovered at the old Merrimack landfill and the former Textiles Coated International plant in Amherst.

To date, 73 private wells within Merrimack, Litchfield and Amherst have detected elevated levels of PFOA above 100 ppt.

"I am pleased that the EPA has answered my repeated requests and released the new health advisory standards for PFOA and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to know whether or not their water resources are safe.

"I will continue to monitor the increasing instances of potentially dangerous PFOA and PFOS levels in water resources in several communities across our state and ensure that the EPA is working with local officials and communities to take every action possible for the safety of all Granite State residents," she said.

4:23 PM

Associated Press

http://hosted.ap.org/dynamic/stories/U/US_DRINKING_WATER_CHEMICALS?SITE=AP&SECTI

EPA ISSUES TIGHTER LIMITS FOR INDUSTRIAL CHEMICAL IN WATER

By Michael Biesecker on 5/19/16 at 4:12pm

Federal regulators are tightening limits for human exposure to an industrial chemical used for decades in such consumer products as non-stick pans, stain-resistant carpets and microwave popcorn bags.

The cancer-causing chemical PFOA has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of PFOA in recent years.

Also at issue is the related chemical PFOS used in firefighting foam.

The Environmental Protection Agency issued the stricter standards for the chemicals on Thursday, following years of public pressure by advocacy groups. The agency said the new limits we prompted by recent scientific studies linking PFOA and PFOS to testicular and kidney cancers, as well as birth defects and liver damage.

4:12 PM

Wall Street Journal

http://www.wsj.com/articles/epa-issues-new-health-advisories-for-chemical-from-some-plastics-plants-1463687484

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

By Cameron McWhirter on 5/19/16 at 3:51pm

The Environmental Protection Agency announced new health advisories Thursday for perfluorooctanoic acid, a potentially toxic chemical, calling for water utilities across the nation to adhere to stricter guidelines than the agency had previously

recommended.

In recent months, state investigators in New York, Vermont and New Hampshire have found high levels of the chemical, known as PFOA, in drinking-water wells and groundwater near former and current chemical plants, alarming residents and raising concern about PFOA contamination in other parts of the country.

The Environmental Working Group, a Washington-based advocacy group that assesses chemicals in consumer products and the environment, sent a letter in late April to EPA Administrator Gina McCarthy urging the agency to set an enforceable drinking-water standard for the chemical and to force former manufacturers to disclose all sites in the U.S. where they used, made or dumped PFOA.

On Thursday, the EPA declared that drinking water with PFOA concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The EPA has been reviewing PFOA guidelines for months, and state environmental agencies have been setting their own guidelines. New York and New Hampshire both set limits of 100 parts per trillion, while Vermont had a stricter standard of 20 parts per trillion.

PFOA can be harmful to animals in high doses, causing tumors in the liver and other parts of the body, according to several scientific studies. A multiyear medical study in the 2000s of 70,000 people near a plant in West Virginia that made PFOA found "some suggestions" of "probable links" between high exposure to the chemical and illnesses, including cancer.

The agency Thursday also set a 70 parts per trillion guideline for perfluorooctane sulfonate, or PFOS, a chemical similar to PFOA that was used to make products stain resistant. PFOS has been found in studies to be harmful to the immune systems of animals.

For both chemicals, the guidelines are lifetime-exposure advisories.

The provisional health advisory for PFOS had been 200 parts per trillion. The EPA stated that if both chemicals were found in drinking water, the 70 parts per trillion limit applies for the two chemicals combined. The advisories are not regulations that can be enforced by the EPA, but health guidelines issued for water utilities, and state environmental and health agencies to consider.

"If these chemicals are found in drinking-water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope and source of contamination," according to an EPA statement. "They should also promptly notify consumers and consult with their state drinking-water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breast-fed or formula-fed infants."

Some state officials were quick to applaud the new guidelines. The New Hampshire Department of Environmental Services spokesman Jim Martin said his department would work to provide bottled water to any communities where drinking-water tests exceeded the 70 parts per trillion limit.

The Environmental Working Group said the new levels aren't strict enough and urged the agency to impose a legally enforceable limit.

Factories for decades used PFOA as a plastic coating and to make consumer products such as Teflon nonstick pans, waterproof jackets and pizza boxes. Former large manufacturers or users of PFOA, including 3M Co. and DuPont Co., agreed in 2006 to phase out PFOA production and use by December 2015. Public concern over PFOA has spread through upstate New York and New England since August 2014, when a resident of Hoosick Falls, N.Y., near the Vermont border, tested his drinking water and found high levels of the acid. The man was concerned because his father, a former employee of the town's plastics plant that used PFOA, died of cancer.

Saint-Gobain Performance Plastics, a subsidiary of Saint-Gobain SA of France, operates plants in Merrimack, N.H., and Hoosick Falls, N.Y., and used to operate a plant in North Bennington, Vt. Since last year, state investigators have found PFOA contamination near all three sites, and they cited the plants as potential sources.

A company spokeswoman said in a statement that, according to the EPA, the new advisory is "not a legally enforceable federal standard and is subject to change as new information becomes available." The company, however, believes the new guidelines will help "state and local governments to make consistent decisions concerning the levels of PFOA in drinking water," she said.

Shawn Dalton, 65, a retired communications manager who lives not far from the Merrimack plant, thought until Thursday that water from his well, which tested 73 parts per trillion for PFOA, was safe. Now he knows it is three parts above the new guideline. He was glad for the new guidelines, however, because it means he now can hold government officials and companies accountable, he said.

"At least now the federal government has put a stake in the ground," he said.

News 10 (ABC)

http://news10.com/2016/05/19/vermont-department-of-health-setting-pfoa-advisory-level-at-20-parts-per-trillion/

Vermont Department of Health setting PFOA advisory level at 20 parts per trillion

By Ali Stewart on 5/19/16 at 3:24pm

The Vermont Health Department says they evaluated all of the scientific information available at the time when setting Vermont's advisory level of 20 parts per trillion for PFOA in drinking water.

Now that EPA has set a new advisory level of 70 parts per trillion for PFOA and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by EPA to assess how this differs from their current advisory

level, and consider if any changes are warranted.

The department says they remain committed to protecting the health of Vermonters from these harmful chemicals.

3:29pm

Decatur Daily

http://www.decaturdaily.com/news/lawrence_county/epa-issues-advisory-on-chemicals-found-in-west-morgan-east/article_2d66630b-b85c-5f14-9c45-e11f422b8457.html

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

By Eric Fleischauer on 5/19/16 at 3:22pm

The Environmental Protection Agency today issued a health advisory for two chemicals that are found in the drinking water of West Morgan-East Lawrence Water Authority.

The lifetime advisory warns of adverse health effects for people exposed to drinking water with more than 70 parts per trillion of two chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to court documents, West Morgan-East Lawrence drinking water exceeds the EPA advisory limit for both chemicals.

The EPA advisory says some studies indicate long-term exposure to higher levels of PFOA and PFOS may result in adverse health effects, including developmental effects

to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune effects, thyroid effects and cholesterol changes.

The authority sells water to water departments in Vinemont, Falkville, Trinity, Town Creek and the West Lawrence Water Cooperative. About 25,000 people use water supplied by the authority, it has said in court documents.

West Morgan-East Lawrence in October filed a federal lawsuit alleging 3M Co. and its subsidiary, Dyneon LLC, and Daikin America Inc. released the chemicals into the Tennessee River. The lawsuit alleges the chemical entered the authorities water intake downstream of the companies.

Virtual-Strategy Magazine (Reprint from Business Wire)

http://www.virtual-strategy.com/2016/05/19/new-water-research-foundation-study-addresses-most-effective-methods-removing-pfospfoa-wa#axzz498AKvTCX

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

(See Business Wire story below)

3:02pm

Times Hearld-Record

http://www.recordonline.com/news/20160519/newburgh-water-pollutant-now-more-than-twice-level-of-new-epa-guidelines

Newburgh water pollutant now more than twice level of new EPA guidelines

By Leonard Sparks on 5/19/16 at 2:49pm

New federal health guidelines issued Thursday for the chemical that has shut down Newburgh's primary water supply are less than half the levels recorded in the city.

The Environmental Protection Agency is now urging action if levels of perfluorooctanoic acid or perfluorooctane sulfonate are above 70 parts per trillion, a significantly stricter standard than previously issued advisory guidelines of 100 parts per trillion for PFOA and 200 parts per trillion for PFOS.

Since its water was first tested in December 2013, Newburgh's Washington Lake has had levels of PFOS ranging from 140 to 170 parts per trillion.

While below the initial EPA guidelines, those levels spurred the closure of the lake on May 2, and Newburgh has been drawing water from its backup supply at Brown's Pond.

U.S. Sen. Charles Schumer and U.S. Rep. Sean Maloney had been urging the EPA to expedite release of its updated guidelines.

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS," Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause."

The Intercept

https://theintercept.com/2016/05/19/with-new-pfoa-drinking-water-advisory-dozens-of-communities-suddenly-have-dangerous-water/

WITH NEW DRINKING WATER ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS WATER

By Sharon Lerner on 5/19/16 at 2:36pm

The EPA announced new drinking water health advisory levels today for the industrial chemicals PFOA and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which were .4 ppb for PFOA and .2 ppb for PFOS. In areas where both PFOA and PFOS are present, the advisory suggests a maximum combined level of .07 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

The new federal standards may unify what has been an inconsistent official response to the presence of these perfluorinated chemicals, or PFCs, in drinking water. They will also instantaneously create official water contamination crises in dozens of cities and towns across the country.

According to the EPA's most recent data on unregulated drinking water contaminants, released in January, 14 drinking water systems around the country reported levels of PFOA that exceed the new federal threshold, while 40 reported PFOS above the new cutoff. In all, water systems in 18 states, as well as in Guam, are contaminated.

Some of these water systems have already begun to quietly address the problem. In Suffolk County, New York, where public drinking water wells show PFOS levels of .33 and .53 ppb, the contaminated water "has either been blended with other wells to reduce the level of the compound to non-detection or their use has been limited to the greatest extent possible," according to Kevin Durk, director of water quality and laboratory services for the Suffolk County Water Authority. Though he does not know the level of PFOS in the water that comes out of local taps, Durk wrote in an email that "it is a virtual certainty that levels of any detected chemical would have been reduced."

Similarly, the Security Water and Sanitation District in Colorado Springs has been struggling to clean up its contaminated water since 142 tests detected PFCs. The district has shut down seven out of 26 wells and is blending water to lower levels,

according to Roy Heald, the district's general manager.

But other water company operators have yet to lower their PFC levels. Steve Anderson, owner of the Oatman Water Company in Scottsdale, Arizona, where PFOS measured .2 and .23 in the most recent EPA testing, learned that the chemical was in his water only recently, after he received a call from the Arizona Department of Environmental Quality. Anderson, who suspects the PFOS originated from firefighting foam used by the nearby Oatman Fire Department, said he is "trying to come up with a solution."

Until today, there was a wide range of official opinion on the level of contamination that presented a health danger. The military, which is in the throes of a massive cleanup of 664 contaminated fire- and crash-training sites, has been using the EPA's older standards for PFOA and PFOS to guide its efforts and help determine who receives clean drinking water and remediation of contaminated private wells. (The Department of Defense did not responded to inquiries about how the new advisory levels would alter its cleanup plan.)

Others have set more stringent standards. On January 28, the EPA advised residents of Hoosick Falls, New York, not to use water with PFOA levels above .1 ppb. And a panel of scientists who spent years researching some 70,000 people whose water contained PFOA levels of at least .05 ppb, found probable links between that level of exposure and testicular cancer, kidney cancer, thyroid disease, preeclampsia, ulcerative colitis and high cholesterol. In 2010, New Jersey's Drinking Water Quality Institute calculated a safety limit of .04 for PFOA. Vermont currently has the lowest state drinking water limit for PFOA, .02 ppb.

The levels released today are based on numerous studies connecting the chemicals with health effects. For PFOS, the report notes, studies of lab animals exposed to the chemical reported "developmental effects (decreased body weight, survival, and increased serum glucose levels and insulin resistance in adult offspring), reproductive (mating behavior), liver toxicity (liver weight co-occurring with decreased cholesterol, hepatic steatosis), developmental neurotoxicity (altered spatial learning and memory), immune effects, and cancer (thyroid and liver)."

The report also acknowledged research on human populations that has found

associations between PFOS and immune suppression, thyroid disease, high cholesterol, and reduced fertility. It also acknowledged a possible connection between PFOS and bladder, colon, and prostate cancer.

For PFOA, the research included studies on monkeys, rats, and mice showing "developmental effects (survival, body weight changes, reduced ossification, delays in eye opening, altered puberty, and retarded mammary gland development), liver toxicity (hypertrophy, necrosis, and effects on the metabolism and deposition of dietary lipids), kidney toxicity (weight), immune effects, and cancer (liver, testicular, and pancreatic)."

The new health advisory for PFOA was also based on human studies, which showed "associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)." The EPA report noted that in humans "the developing fetus and newborn is particularly sensitive to PFOA-induced toxicity."

"Taken together," the report notes, "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." The exact phrasing was used in the PFOS report as well.

While calling the new level "a very long-overdue step in the right direction," Robert Bilott, an attorney overseeing a class-action suit over PFOA contamination near a DuPont plant in West Virginia, cautioned that "the new guideline is still too high, as exposures at even the new guideline level would allow PFOA to continue to build up to ever-increasing, unacceptable levels in human blood."

Bilott also noted that the new levels are informal guidelines, as opposed to enforceable regulatory limits. "If it was enforceable," he said, "the EPA could issue unilateral orders requiring the responsible party to clean it up."

WaterWorld

http://www.waterworld.com/articles/2016/05/epa-releases-drinking-water-health-advisories-for-pfoa-and-pfos.html

EPA RELEASES DRINKING WATER HEALTH ADVISORIES FOR PFOA AND PFOS

By (No author) on 5/19/16 at 2:42pm

Based on the latest science on two chemical contaminants called PFOA and PFOS, EPA has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals. These advisories will help local water systems and state, tribal and local officials take the appropriate steps to address PFOA and PFOS if needed.

EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations.

For many years, PFOA and PFOS were widely used in carpets, clothing, furniture fabrics, food packaging, and other materials to make them more resistant to water, grease, and stains. PFOA and PFOS were also used for firefighting at airfields and in a number of industrial processes. Between 2000 and 2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer. And EPA asked eight major companies to commit to eliminate their production and use of PFOA by the end of 2015 and they have indicated that they have met their commitments. While there are some limited ongoing uses of these chemicals, in recent years, blood testing data has shown that exposures are declining across the country.

For most people, their source of exposure to PFOA and PFOS has come through food and consumer products. But drinking water can be an additional source of exposure in the small percentage of communities where these chemicals have contaminated water supplies. This is typically a localized issue associated with a specific facility -- for example, in communities where a manufacturing plant or airfield made or used these chemicals.

If these chemicals are found in drinking water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope, and source of contamination. They should also promptly notify consumers and consult with their state drinking water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breastfed or formula-fed infants. There are a number of options available to water systems to lower concentrations of these chemicals in the drinking water supply.

EPA will continue sharing the latest science and information so that state and local officials can make informed decisions and take actions to protect public health. This is an important part of our broader effort to support states and public water systems as we work together to strengthen the safety of America's drinking water.

Business Wire

http://www.businesswire.com/news/home/20160519006484/en/Water-Research-Foundation-Study-Addresses-Effective-Methods

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

By (No author) on 5/19/16 at 2:44pm

The Water Research Foundation (WRF), a leading sponsor of research supporting the water community, has released findings of a study addressing effective methods for removing poly- and perfluoroalkyl substances (PFASs) from water and wastewater. The research report, Treatment Mitigation Strategies for Poly- and Perfluorinated Chemicals (WRF project #4322), contains results of an in-depth treatment study conducted on waters from 13 water and wastewater treatment plants in the United States. Additionally, WRF will be hosting a Webcast on June 2 addressing the project's results and has posted a State of the Science document on PFASs.

The research from project #4322 demonstrated that conventional treatment at

wastewater treatment plants and most drinking water treatment plants is ineffective at removing PFASs. Activated carbon and anion exchange can remove many PFASs but are less effective at removing shorter chain PFASs. The most effective treatment technologies are nanofiltration and reverse osmosis, which work even for the smallest PFASs studied.

The EPA issued two public health advisories today for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

"The research results from project #4322 will help the water community understand the best options for removing PFASs from water and wastewater, said Rob Renner, CEO of the Water Research Foundation. "This knowledge is especially important as the EPA continues the process of regulating these chemicals in water."

Poly- and perfluoroalkyl substances (PFASs) are a group of manmade chemicals with past and current uses in industrial processes and consumer products. PFASs are also commonly referred to as perfluorinated chemicals or PFCs. The most notable PFASs are PFOA and PFOS, but there are many others. PFASs are used in firefighting foams, coating for food packaging, ScotchGardTM and TeflonTM, among other products.

Exposure to PFASs can occur through use of products or consumption of food or water containing PFASs. PFASs do not break down easily and therefore persist in the environment. They are also soluble in water and can enter source waters through industrial releases, discharges from wastewater treatment plants, storm water runoff, release of firefighting foams, and land application of contaminated biosolids.

PFASs are a concern because they have been shown to have health effects in animal studies. Data from some human studies suggest that PFASs also affect human health. Additional research is ongoing in order to gain a better understanding of human health effects.

2:45pm

WRGB Albany (CBS)

http://cbs6albany.com/news/hoosick-falls-crisis/epa-declares-official-standard-for-pfoa-pfoh-contamination

EPA declares official standard for PFOA, PFOS contamination for lifetime exposure

By WRGB Staff on 5/19/16 at 2:19pm

The EPA has released official long- term exposure guidelines for PFOA, PFOS contamination.

Released documents state that concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

Vermont lists safe exposure levels at 20 parts per trillion, including babies and children.

Regional EPA originally set short term exposure as 100 ppt in Hoosick Falls.

'EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations. " , says the EPA in a released document.

2:27 PM

Vermont Public Radio

http://digital.vpr.net/post/significant-reduction-epa-sets-health-advisory-pfoa-70-parts-trillion#stream/0

In Significant Reduction, EPA Sets Health Advisory For PFOA At 70 Parts Per Trillion

By Howard Weiss-Tisman on 5/19/16 at 2:11pm

The Environmental Protection Agency on Thursday issued an updated health advisory for the suspected carcinogen PFOA.

The EPA says water that contains PFOA in levels at 70 parts per trillion should be considered unsafe to drink.

The EPA previously set its level at 400 ppt. The new, lifetime health advisory replaces that standard.

PFOA, a chemical that was used in a variety of manufacturing applications, has been found in water in North Bennington, Bennington and Pownal.

The contaminant has also been detected in New Hampshire and New York, and in other states around the country.

Vermont set its level at 20 parts per trillion.

(Reprint of Bucks County Courier Times story)

http://www.theintell.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_a404ad5d-a246-5ec2-9d1b-a9af8b6e70d5.html

EPA releases new safety advisories for chemicals

2:20 PM

Time Warner Cable News - Capital Region

http://www.twcnews.com/nys/capital-region/news/2016/05/19/epa-releases-new-pfoa-and-pfos-health-guidelines.html

EPA Releases New Health Guidelines for PFOA, PFOS Found in Drinking Water

By TWC News Web Staff on 5/19/16 at 1:46pm

The EPA has released new health guidelines for PFOA and PFOS found in drinking water.

PFOA was the chemical found in the water supply in Hoosick Falls and Petersburgh.

The new health advisory levels have been set to 70 parts per trillion.

When first tested at the St. Gobain facility in Hoosick Falls, the EPA measured the levels at 18,000 parts per trillion.

A filtration system has since been installed, eliminating traces of the chemical, making the water safe to use again in Hoosick Falls.

In Petersburgh, multiple homes have tested above the new acceptable levels.

Taconic Plastics is believed to be the source of contamination. Residents in the town have grown impatient with leaders as they await to learn when they can get blood tested.

The town even ran out of bottled water to give to residents over the weekend. That supply has since been replenished.

Also, PFOS levels in Washington Lake and Silver Stream are in the range of 145 to 150 parts per trillion.

Washington Lake used to supply Newburgh's drinking water, until the city found out about the continuing levels of PFOS.

The city switched to Brown's Pond as a drinking source, since almost no levels of PFOS were found in that water.

Newburgh is still working to determine where the PFOS contamination is coming from.

Senator Schumer on New Standards:

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS. Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause. The EPA's new guidance will go a long way in protecting public health and arming local officials with the most up-to-date information to keep our drinking water safe from harmful contaminates."

Bucks County Courier Times (also ran in the Intelligencer)

http://www.buckscountycouriertimes.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_97946008-1de8-11e6-83d3-334d7ea7ce37.html

EPA Releases New Safety Advisories for Chemicals

By Kyle Bagenstose on 5/19/16 at 2:00pm

The Environmental Protection Agency on Thursday released a long-awaited update to its drinking water advisories for unregulated chemicals perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).

According to prior testing data of public and private water supplies in Bucks and Montgomery counties, it appears the updated advisories could mean some drinking water in the area is contaminated with the chemicals at a level above what the EPA deems is safe to consume.

The chemicals already had contaminated about 100 public and private water wells near a trio of current and former military bases in the region: The former Naval Air Station Joint Reserve Base Willow Grove, Horsham Air Guard Station, and former Naval Air Warfare Center in Warminster.

The chemicals are suspected to have originated in firefighting foams used at the bases, and the military already has agreed to spend approximately $19 million to provide replacement water and install filtration systems for public water wells affected by the chemicals, and bottled water and hook-ups to public systems for homes with affected private wells.

But the number of wells now likely will increase.

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the EPA in 2009: .4 parts per billion for PFOA in drinking water, and .2 ppb for PFOS.

Thursday's announcement, however, set an advised limit of .07 ppb for PFOS and PFOA combined, in order to protect against health effects from a lifetime of exposure. In a worst case scenario, that means drinking water with .58 ppb of the chemicals (.39 ppb PFOA and .19 ppb PFOS) previously considered safe, now would be more than eight times the recommended limit.

After the chemicals first were discovered in some local public water supplies by a nationwide EPA testing program in 2013 and 2014, multiple public wells in the area were taken offline.

The Horsham Water and Sewer Authority removed two drinking water wells from its system in the summer of 2014 after PFOS was found at 1 and .7 ppb. Data from the testing program shows that three more wells also were contaminated with the chemicals at levels above the EPA's new advisory, with a combined .071 ppb, .123 ppb, and .14 ppb.

In a brief email Thursday, authority manager Tina O'Rourke said only two additional wells are above the .07 ppb level as of the most recent testing.

She added that the authority intends to take the wells offline and that existing agreements with the military allow for the authority to take action immediately.

The Warminster Municipal Authority, which previously removed three wells from its supply, also appears to have two more wells contaminated above the new level, with a combined .091 ppb and .09 ppb.

The Warrington Township Water Department previously removed a trio of wells that combined to form a single water source. Based on the EPA's data showing a combined .082 ppb, another well could also be above the new health advisory.

This news organization reached out to all three utilities to obtain the most recent testing information and will update this story as it receives responses.

Although unregulated, a growing body of science has established associations between PFOA and PFOS and a range of health effects, including a variety of cancers.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in a phone interview Thursday that the updated advisories reflect a review of available science and are intended to be protective for lifetime exposure to the chemicals for even vulnerable populations, such as nursing mothers and their children.

"These health advisories are scientific documents … the point is to provide the best available information to state and local authorities and drinking water system operators," Beauvais said. "They're calculated to reflect a margin or protection to the most sensitive populations."

Beauvais added that the next step for the chemicals is to be considered for a federal drinking water standard that can be enforced, as is the case with more well-known contaminants such as lead or arsenic. However, he was unable to say how long it might take for that decision to be made.

1:59 PM

Albany Times Union

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-

water-7716825.php

EPA Sets New Level for Chemical in Drinking Water

By Brendan J. Lyons on 5/19/16 at 1:17pm

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

The EPA's advisory level is well below the levels of PFOA that were detected in public water supplies over the past two years in Hoosick Falls, Petersburgh, North Bennington, Vt., and Merrimack, N.H.

In addition, health and environmental officials said tests have also revealed levels of PFOA in dozens of private wells in Rensselaer County that are much higher than the EPA's guideline.

Officials with the state Health Department and Department of Environmental Conservation could not immediately provide information Thursday about how many water systems in New York may contain PFOA, which has been used since the 1940s to make products such as nonstick coatings, such as Teflon, and heat-resistant wiring and other specialty products.

In 2009, the EPA established a guideline that a level of 400 parts per trillion is a safe level for "short-term" consumption of the water. Earlier this year, the EPA issued a provisional health advisory of 100 ppt. Meanwhile, other states have set far lower acceptable levels of PFOA in public water systems, including New Jersey, which has set a level of 40 ppt.

State Health Commissioner Dr. Howard A. Zucker in January said the state Health Department was reviewing its position on acceptable levels of PFOA in drinking water and would set a new safety limit within weeks. But the state did not issue a new advisory.

Robert A. Bilott, an Ohio attorney who is helping represent an estimated 3,500 people in a class-action lawsuit against DuPont, which manufactured and used perfluorinated chemicals such as PFOA in its products, has been urging the EPA for years to adopt a permanent health advisory for long-term exposure to PFOA in drinking water. Bilott has represented "tens of thousands of individuals in various communities across the country who have been injured because of the contamination of their drinking water with PFOA."

"The lower number and acknowledgement of the need to consider the combined amount of PFCs in water is a long-overdue step in the right direction, but the guideline is still too high, as it will allow ever-increasing, unacceptable levels of PFOA to continue to build up in the blood of those exposed," Bilott said.

Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

Bilott said the science panel's peer-reviewed report was paid for by DuPont and, as a result of the panel's findings, the company has to concede in the personal-injury lawsuits that PFOA causes cancer.

In Albany, numerous lawsuits were filed this year in U.S. District Court seeking class-action status on behalf of current and former Hoosick Falls residents, including some who allege they suffered serious health effects that could be linked to PFOA exposure.

According to the EPA, PFOA was detected in blood serum in 99 percent of the U.S. population between 1999 and 2012. However, the EPA said the levels of PFOA in human blood have been decreasing since U.S. companies began to phase out production of the chemical more than 10 years ago. Still, water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied, the agency said.

Thousands of people whose blood was tested in that area of the Ohio Valley had elevated levels of PFOA, including at levels as high as 40 parts per billion.

In Hoosick Falls, where hundreds of people signed up for state-sponsored blood tests in February, the results of those tests are expected to be released beginning next week.

In February, the state Department of Environmental Conservation asked two corporations, Saint-Gobain Performance Plastics and Honeywell International, to enter consent orders that would require them to clean up the remnants of the toxic chemical that polluted water supplies in and around Hoosick Falls.

The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations

in Rensselaer County, including the town of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

WAMC, Northeast Public Radio

http://wamc.org/post/epa-releases-new-pfoa-pfos-guidelines

EPA Releases New PFOA, PFOS Guidelines

By (No author) on 5/19/16 at 1:44pm

The U.S. Environmental Protection Agency has released new health advisories for PFOA and PFOS, the manufacturing chemicals at the center of water contamination crises in several communities in the region including Hoosick Falls, Petersburgh, and North Bennington. The guidelines released today lower the lifetime exposure from drinking water level to 70 parts per trillion. The level of PFOA in affected areas has been much higher than the new benchmark, leading communities to establish alternate water supplies. High exposure can result in cancer, birth defects and other diseases.

WMUR Manchester (ABC)

http://www.wmur.com/health/epa-sets-new-level-for-contaminant-found-in-drinking-water/39629266

EPA sets new level for contaminant found in drinking water

By Kirk Enstrom on 5/19/16 at 1:41pm

The Environmental Protection Agency has set new advisory levels for a contaminant that has been found in drinking water supplies in parts of New Hampshire.

The state Department of Environmental Services said Thursday that the EPA set a lifetime drinking water health advisory level for perfluorooctanoic acid at 70 parts per trillion.

The same level was set for a related chemical, perfluorooctane sulfonate. The EPA said that when both chemicals are present, the combined concentration shouldn't exceed 70 parts per trillion.

State environmental officials had been advising well water users whose water tested above 100 parts per trillion to drink bottled water instead.

PFOA was found earlier this year in groundwater near the Saint-Gobain Performance Plastics facility in Merrimack after that company conducted tests. The contaminant has since been found in private wells in Litchfield, Manchester, Bedford and other areas.

It was most recently found in Amherst near a former industrial site.

State environmental officials said they are working to review the scientific basis for the new levels. DES said it's also taking steps to provide bottled water to all known private well users who have detected PFOA or PFOS levels greater than 70 parts per trillion.

"The state of New Hampshire will take immediate action to expand distribution of bottled water in affected areas to those whose water supply falls under the new advisory," Gov. Maggie Hassan said.

DES said it plans to move quickly to develop emergency rules for groundwater cleanup and drinking water standards. There will be a public comment process before permanent rules are established.

DES has set up a website to discuss the PFOA investigation.

NEWS10 ABC

http://news10.com/2016/05/19/epa-issues-health-advisory-level-for-lifetime-exposure-to-pfoa/

EPA Sets Health Advisory Level for Lifetime Exposure to PFOA

By Joe Gullo on 5/19/16 at 1:21pm

The U.S. Environmental Protection Agency (EPA) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to PFOA.

The EPA says the advisory is to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime exposure to PFOA and PFOS from drinking water.

PFOA has been linked to serious health problems such as cancer.

Some local communities, including Petersburgh, Hoosick Falls, Bennington, and Pownal have had wells test positive for the chemical.

PFOA and PFOS have been used to make carpets, clothing, fabrics for furniture, paper packaging for food, and other materials that are resistant to water, grease, or stains. In 2006, the EPA says they asked eight companies using PFOA to phase out use and chemicals used to break down PFOA. Those companies have stated at the end of 2015, they phased out the use of PFOA.

According to the EPA, the establishment of the advisories follows an assessment from the latest peer-reviewed science to provide water system operators, and state, tribal, and local officials who have the primary responsibility of overseeing these systems.

Advisories issued by the EPA are designed to provide information on contaminants that can cause human health effects and are known or anticipated to occur in water.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

loop.travis@epa.gov

To: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Strong, Jamie
Sent: Fri 5/20/2016 2:50:35 PM
Subject: RE: media clips for PFOA PFOS

Thanks Betsy, it is really something to be proud of!

From: Southerland, Elizabeth
Sent: Friday, May 20, 2016 10:38 AM
To: Donohue, Joyce <Donohue.Joyce@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Cc: Behl, Betsy <Behl.Betsy@epa.gov>
Subject: Fwd: media clips for PFOA PFOS

What a difference you are making! My beloved WV has already switched 3 communities to new sources (Martinsburg, Parkersburg, Vienna). Also I am so glad you finally released it in response to Senator Schumer...

Sent from my iPhone

Begin forwarded message:

> **From:** "Loop, Travis" <Loop.Travis@epa.gov>
> **Date:** May 20, 2016 at 9:09:22 AM EDT
> **To:** "Beauvais, Joel" <Beauvais.Joel@epa.gov>, "Gilinsky, Ellen" <Gilinsky.Ellen@epa.gov>, "Campbell, Ann" <Campbell.Ann@epa.gov>, "Gude, Karen" <Gude.Karen@epa.gov>, "Dennis, Allison" <Dennis.Allison@epa.gov>, "Fuld, John" <Fuld.John@epa.gov>, "Altieri, Sonia" <Altieri.Sonia@epa.gov>, "Duke, Nia" <Duke.Nia@epa.gov>, "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Burneson, Eric" <Burneson.Eric@epa.gov>, "Wadlington, Christina" <Wadlington.Christina@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Behl, Betsy" <Behl.Betsy@epa.gov>, "Harper, Ashley" <harper.ashley@epa.gov>
> **Subject: media clips for PFOA PFOS**
>
> Here is a compilation of media clips on PFOA PFOS. The biggest common error is referring to it as a standard.
>
> Because they asked and had done some digging through data, we provided the list of 63 communities Joel did interviews with USA Today/Gannett and BuzzFeed. I have not seen those stories yet.

EPA sets health advisory level for lifetime exposure to **PFOA**

NEWS10 ABC - 19 hours ago

WASHINGTON (NEWS10) – The U.S. Environmental Protection Agency (**EPA**) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to **PFOA**. The **EPA**said the advisory is to provide Americans, including the most ...

EPA sets new level for chemical **PFOA** in drinking water

Albany Times Union - 12 hours ago

The **EPA's** long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of **PFOA** in public water systems and private wells. The contamination has been linked ...

EPA suggests tighter limits for **PFOA**, PFOS in drinking water

PhillyVoice.com - 3 hours ago

The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney cancers, as well as birth defects and liver damage. "**EPA** will continue sharing the latest science and information so that state and **...**

With New **EPA** Advisory, Dozens of Communities Suddenly Have Dangerous Drinking Water

The Intercept - 17 hours ago

The **EPA** announced new drinking water health advisory levels today for the industrial chemicals**PFOA** and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which **...**

EPA issues health advisory for long-term **PFOA** exposure

The Union Leader - 16 hours ago

"I am pleased that the **EPA** has answered my repeated requests and released the new health advisory standards for **PFOA** and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to ...

EPA issues **PFOA** health advisory

Nashua Telegraph - 8 hours ago

"The **EPA** has set the health advisory for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion and has recommended that when these two chemicals co-occur in the drinking water source, the sum of the ...

EPA Sets New Guidelines For **PFOA**, PFOS; Superfund Declared For Petersburgh

WAMC - 15 hours ago

In 2009, **EPA** set a short-term exposure guideline of 100 ppt for **PFOA** and PFOS. Perhaps due to a lack of long-term exposure guidlelines, state governments have not had consistent recommended levels. Vermont has acted under a 20 ppt threshold while ...

In Significant Reduction, **EPA** Sets Health Advisory For **PFOA** At 70 Parts Per Trillion

Vermont Public Radio - 18 hours ago

The **EPA** announced last year that it was looking at its health advisory level of 400 parts per trillion for **PFOA**, which was established in 2009. After the chemical was detected in North Bennington, the state of Vermont set a more conservative level **...**

EPA Releases New Health Guidelines for **PFOA**, PFOS Found in Drinking Water

TWC News - 18 hours ago

The **EPA** has released new health guidelines for **PFOA** and PFOS found in drinking water. **PFOA**was the chemical found in the water supply in Hoosick Falls and Petersburgh. The new health advisory levels have been set to 70 parts per trillion. When first ...

EPA Announces Lifetime **PFOA** and PFOS Advisory Level

New Hampshire Public Radio - 13 hours ago

The **EPA** has announced a lifetime health advisory level for two chemicals that have contaminated water in Southern NH and at the former Pease Air Force Base. **PFOA** and PFOS are slippery, stable chemicals used since the 1940s in products like nonstick ...

EPA issues new federal standards for **PFOA** exposure

WCAX - 14 hours ago

There are new federal standards for exposure to **PFOA** and it's three times higher than the level Vermont is using.**PFOA** has been found in drinking water supplies in Bennington and Pownal. Officials believe the chemical came from old Teflon factories.

EPA Releases New 'Lifetime' **PFOA** Exposure Level Data

Patch.com - 14 hours ago

CONCORD, NH - The U.S. Environmental Protection Agency has issued new “lifetime drinking water health advisory levels” for both perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS) at 70 parts per trillion (ppt), according to Jim Martin **...**

EPA releases drinking water health advisories for **PFOA** and PFOS

WaterWorld - 18 hours ago

WASHINGTON, May 19, 2016 -- Based on the latest science on two chemical contaminants called**PFOA** and PFOS, **EPA** has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals.

EPA Releases New **PFOA**, PFOS Guidelines

WAMC - 19 hours ago

“I am pleased that the **EPA** has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS," New York U.S. Senator Charles Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh ...

EPA declares official standard for **PFOA**, PFOS contamination for lifetime exposure

WRGB - 19 hours ago

'**EPA's** assessment indicates that drinking water with individual or combined concentrations of**PFOA** and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of **...**

3 Arizona water systems afoul of new **EPA** water guidelines

azcentral.com - 9 hours ago

The agency's latest advisory drops the recommended limit of **PFOA** and PFOS in drinking water from 400 parts per trillion to 70 parts per trillion. The **EPA** cannot enforce that limit, as it is just a recommendation intended to advise water systems on how **...**

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

Wall Street Journal - 17 hours ago

On Thursday, the **EPA** declared that drinking water with **PFOA** concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The **EPA** has been reviewing ...

EPA sets new standards for contaminants

Eagle-Tribune - 1 hour ago

The state has been waiting for some time to hear from the federal **EPA** about its recommendations about acceptable levels of **PFOA** in drinking water, said DES spokesman Jim Martin on Thursday. The new data recommends no more than 70 parts per trillion, ...

New **EPA** Guidelines on PFCs Welcome – but Still Fall Short

Environmental Working Group (blog) - 15 hours ago

Today the Environmental Protection Agency issued a long-awaited drinking water health advisory for the perfluorinated chemicals **PFOA** and PFOS. But **EPA's** advisory falls far short of what's needed to fully protect public health, and it is not a legally ...

Air Force applies new **EPA** guidance

Air Force Link - 15 hours ago

The Air Force has been following a 2009 **EPA** issued short-term provisional health advisory level for **PFOA** at 400 parts per trillion and 200 ppt for PFOS. On May 19, the **EPA** released new lifetime exposure health advisories for PFOS at 70 ppt and for **PFOA ...**

Martinsburg shuts down water plant after **EPA** advisory

Herald-Mail Media - 11 hours ago

The **EPA** issued the stricter guidelines for the chemicals after years of pressure from public-health experts and advocacy groups. The agency said the new limits were prompted by recent scientific studies linking **PFOA** and PFOS to testicular and kidney ...

EPA releases new safety advisories for chemicals

Burlington County Times - 14 hours ago

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the **EPA** in 2009: 0.4 parts per billion for **PFOA** in drinking water, and 0.2 ppb for PFOS. Thursday's announcement **...**

EPA sets new level for contaminant found in drinking water

WMUR Manchester - 19 hours ago

H. "I will continue to monitor the increasing instances of potentially dangerous **PFOA** and PFOS levels in water resources in several communities across our state and ensure that the **EPA** is working with local officials and communities to take every **...**

'Do not drink' ordered for Vienna water after **EPA** issues C8 guidance

Charleston Gazette-Mail (subscription) - 15 hours ago

“Although it's a long overdue step in the right direction, the guideline is still too high as it allows unacceptable accumulation of **PFOA** to build up in the blood of people drinking it,” said Robert Bilott, a longtime lawyer for residents who had their **...**

EPA Sets New Health Advisory for Toxic Chemicals in Drinking Water

NBC Bay Area - 15 hours ago

The agency set the advisory at 70 parts per trillion of human exposure to two perfluoronated compounds called PFOS and **PFOA**. That means people should not drink water with detections of the chemicals above that level. The new level is nearly six times ...

Amherst water tested for **PFOA**

Cabinet.com - May 19, 2016

After the presence of **PFOA** was detected in private wells in those towns, the DES declared a provisional safe exposure limit of 100 parts per trillion, which is the standard used by Maine. The **EPA** recommends avoiding short-term exposure to more than 400 ...

Federal **EPA** warns of high chemical levels in Martinsburg, Parkersburg and Vienna water sources

West Virginia MetroNews - 14 hours ago

WASHINGTON, D.C. — The federal **EPA** announced Thursday that water sources in Martinsburg, Parkersburg and Vienna contain the chemicals **PFOA** and PFOS at levels higher than previously recommended for public water systems. A ' do not drink' ...

Vermont Department of Health setting **PFOA** advisory level at 20 parts per trillion

NEWS10 ABC - 17 hours ago

Now that **EPA** has set a new advisory level of 70 parts per trillion for **PFOA** and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by**EPA** to assess how this differs from their current **...**

EPA Issues Tighter Limits for Chemical In Water

WILX-TV - 13 hours ago

The cancer-causing chemical **PFOA** has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of**PFOA** in recent years.

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

The Decatur Daily - 17 hours ago

The **EPA** advisory says some studies indicate long-term exposure to higher levels of **PFOA** and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune ...

Do not drink advisory issued for citizens of Vienna

WSAZ-TV - 14 hours ago

WOOD COUNTY, W.Va. (WSAZ) -- The Bureau for Public health has reviewed new information regarding **PFOA** and PFOS that the U.S. **EPA** released Thursday, and have decided to issue a Do Not Drink advisory for citizens of Vienna until additional testing ...

Amherst addresses **PFOA** contamination

WMUR Manchester - May 18, 2016

In Amherst, state environmental officials recently identified the former site of Textiles Coated International on Route 101-A as a likely source of **PFOA** contamination in nearby wells. “Why did this happen, and how is it allowed that we have industry **...**

West Morgan-East Lawrence water customers to receive health warning

The Decatur Daily - 7 hours ago

After the **EPA** on Thursday issued a health advisory, the West Morgan-East Lawrence Water and Sewer Authority said it will notify its 25,000 direct and indirect customers that their drinking water contains excessive amounts of two chemicals.

Newburgh water pollutant now more than twice level of new **EPA** guidelines

Times Herald-Record - 18 hours ago

Sean Maloney had been urging the **EPA** to expedite release of its updated guidelines. “I am pleased that the **EPA**has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals **PFOA** and PFOS,” Schumer said in a ...

La Crosse releases drinking water advisory

WXOW.com - 13 hours ago

The contaminants are called Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (**PFOA**). The Environmental Protection Agency or **EPA** now wants municipal water supplies across the county to be tested for unregulated contaminants to be proactive ...

West Virginia communities altering their water sources after new

WHAG - 8 hours ago

... specifically in Martinsburg, Parkersburg and the town of Vienna, are altering their water sources after new **EPA**thresholds were released on Thursday. This comes after officials found raised levels of industrial chemicals of**PFOA** and PFOS in the water.

Doylestown Township shuts down contaminated well

The Intelligencer - 14 hours ago

It (**PFOA**) had not been on any chemical list that governs our permit," the director said. **PFOA** was first found in the Cross Keys well in 2014, the first year the **EPA** tested for the chemical, John said. "Had the **EPA** not looked for it, we wouldn't have **...**

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/**PFOA** from Water and **...**

Broadway World - 17 hours ago

The **EPA** issued two public health advisories today for perfluorooctanoic acid (**PFOA**) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. **EPA's** assessment indicates that drinking water with individual or combined concentrations of **PFOA ...**

Newest clips below: PoliticoPro; (Manchester) Union Leader; (all previously clips forwarded below that).

Politico Pro Energy

EPA SETS PFOA LIMIT: EPA today set its long-awaited PFOA limit at 70 parts per trillion. Scott Waldman reports the limit "applies to both long- and short-term exposure and could have a significant effect on water testing and lawsuits against industry. It is also lower than the current advisory of 100 parts per trillion that the EPA issued in many upstate communities facing exposure to the toxic chemical, which is used in the manufacturing of nonstick products." Communities from New England to West Virginia have been shown to have high levels of the chemical in their drinking water. The New York Times magazine did a deep dive into the chemical back in January.

Union Leader (New Hampshire)

http://www.unionleader.com/environment/epa-issues-health-advisory-for-long-term-pfoa-exposure--20160519

EPA issues health advisory for long-term PFOA exposure

By Kimberly Houghton on 5/19/16 at 4:51pm

Federal officials on Thursday issued a lifetime health advisory for the chemical perfluorooctanoic acid, which is being detected in some water sources in southern New Hampshire.

The U.S. Environmental Protection Agency has now identified 70 parts per trillion of PFOA as a new lifetime drinking water health advisory. Previously, the EPA had a 400 ppt PFOA advisory for short-term exposure.

The new advisory level is less than some levels of PFOA detected in the municipal public water supply wells operated by Merrimack Village District and provided to about 25,000 customers in the area.

At least one Village District well was found to have a PFOA level of 90 ppt, though that well is currently off-line. Ron Miner, superintendent of the district, was not immediately

available for comment Thursday. Town Manager Eileen Cabanel directed questions to MVD.

Recently, the New Hampshire Department of Environmental Services began providing bottled water to about 200 properties throughout Litchfield, Merrimack and Amherst that have private wells detecting PFOA at 100 ppt or more. It will now begin offering bottled water to homeowners with PFOA at 70 ppt in light of the newest recommendations from EPA, according to a release.

The federal advisory level of 70 ppt was derived from a developmental toxicity study in mice, according to the EPA's advisory released on Thursday.

"This lifetime health advisory is based on the latest health effects information for noncancer and cancer effects for PFOA - the lifetime health advisory is therefore protective of the population at large," states the advisory.

Tests on monkeys, rats and mice discovered developmental effects, liver toxicity, kidney toxicity, immune effects and cancers such as liver cancer, testicular cancer and pancreatic cancer as a result of long-term PFOA exposure, according to the advisory.

"Water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas and industrial or municipal waste sites where products are disposed of or applied," it states.

Saint-Gobain Performance Plastics has been identified as the likely source of water contamination in Merrimack and surrounding areas, according to officials with DES. PFOA has also been discovered at the old Merrimack landfill and the former Textiles Coated International plant in Amherst.

To date, 73 private wells within Merrimack, Litchfield and Amherst have detected elevated levels of PFOA above 100 ppt.

"I am pleased that the EPA has answered my repeated requests and released the new health advisory standards for PFOA and (perfluorooctyl sulfonate) levels," U.S. Sen. Kelly Ayotte said in a statement on Thursday. "New Hampshire residents deserve to know whether or not their water resources are safe.

"I will continue to monitor the increasing instances of potentially dangerous PFOA and PFOS levels in water resources in several communities across our state and ensure that the EPA is working with local officials and communities to take every action possible for the safety of all Granite State residents," she said.

4:23 PM

Associated Press

http://hosted.ap.org/dynamic/stories/U/US_DRINKING_WATER_CHEMICALS?SITE=AP&SECTION

EPA ISSUES TIGHTER LIMITS FOR INDUSTRIAL CHEMICAL IN WATER

By Michael Biesecker on 5/19/16 at 4:12pm

Federal regulators are tightening limits for human exposure to an industrial chemical used for decades in such consumer products as non-stick pans, stain-resistant carpets and microwave popcorn bags.

The cancer-causing chemical PFOA has been found in the tap water of dozens of factory towns near industrial sites where it was manufactured. DuPont, 3M and other U.S. chemical companies voluntarily phased out the use of PFOA in recent years.

Also at issue is the related chemical PFOS used in firefighting foam.

The Environmental Protection Agency issued the stricter standards for the chemicals on Thursday, following years of public pressure by advocacy groups. The agency said the new limits we prompted by recent scientific studies linking PFOA and PFOS to testicular and kidney cancers, as well as birth defects and liver damage.

4:12 PM

Wall Street Journal

http://www.wsj.com/articles/epa-issues-new-health-advisories-for-chemical-from-some-plastics-plants-1463687484

EPA Issues New Health Advisories for Chemical Found Near Some Plastics Plants

By Cameron McWhirter on 5/19/16 at 3:51pm

The Environmental Protection Agency announced new health advisories Thursday for perfluorooctanoic acid, a potentially toxic chemical, calling for water utilities across the nation to adhere to stricter guidelines than the agency had previously recommended.

In recent months, state investigators in New York, Vermont and New Hampshire have found high levels of the chemical, known as PFOA, in drinking-water wells and groundwater near former and current chemical plants, alarming residents and raising concern about PFOA contamination in other parts of the country.

The Environmental Working Group, a Washington-based advocacy group that assesses chemicals in consumer products and the environment, sent a letter in late April to EPA Administrator Gina McCarthy urging the agency to set an enforceable drinking-water standard for the chemical and to force former manufacturers to disclose all sites in the U.S. where they used, made or dumped PFOA.

On Thursday, the EPA declared that drinking water with PFOA concentrations of 70 parts per trillion or more were not healthy for human consumption. In 2009, the agency issued a provisional guideline of 400 parts per trillion. The EPA has been reviewing PFOA guidelines for months, and state environmental agencies have been setting their own guidelines. New York and New Hampshire both set limits of 100 parts per trillion, while Vermont had a stricter standard of 20 parts per trillion.

PFOA can be harmful to animals in high doses, causing tumors in the liver and other parts of the body, according to several scientific studies. A multiyear medical study in the 2000s of 70,000 people near a plant in West Virginia that made PFOA found "some suggestions" of "probable links" between high exposure to the chemical and illnesses, including cancer.

The agency Thursday also set a 70 parts per trillion guideline for perfluorooctane sulfonate, or PFOS, a chemical similar to PFOA that was used to make products stain resistant. PFOS has been found in studies to be harmful to the immune systems of animals.

For both chemicals, the guidelines are lifetime-exposure advisories.

The provisional health advisory for PFOS had been 200 parts per trillion. The EPA stated that if both chemicals were found in drinking water, the 70 parts per trillion limit applies for the two chemicals combined. The advisories are not regulations that can be enforced by the EPA, but health guidelines issued for water utilities, and state environmental and health agencies to consider.

"If these chemicals are found in drinking-water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope and source of contamination," according to an EPA statement. "They should also promptly notify consumers and consult with their state drinking-water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breast-fed or formula-fed infants."

Some state officials were quick to applaud the new guidelines. The New Hampshire Department of Environmental Services spokesman Jim Martin said his department would work to provide bottled water to any communities where drinking-water tests exceeded the 70 parts per trillion limit.

The Environmental Working Group said the new levels aren't strict enough and urged the agency to impose a legally enforceable limit.

Factories for decades used PFOA as a plastic coating and to make consumer products such as Teflon nonstick pans, waterproof jackets and pizza boxes. Former large manufacturers or users of PFOA, including 3M Co. and DuPont Co., agreed in 2006 to phase out PFOA production and use by December 2015. Public concern over PFOA has spread through upstate New York and New England since August 2014, when a resident of Hoosick Falls, N.Y., near the Vermont border, tested his drinking water and found high levels of the acid. The man was concerned because his father, a former employee of the town's plastics plant that used PFOA, died of cancer.

Saint-Gobain Performance Plastics, a subsidiary of Saint-Gobain SA of France, operates plants in Merrimack, N.H., and Hoosick Falls, N.Y., and used to operate a plant in North Bennington, Vt. Since last year, state investigators have found PFOA contamination near all three sites, and they cited the plants as potential sources.

A company spokeswoman said in a statement that, according to the EPA, the new advisory is "not a legally enforceable federal standard and is subject to change as new information becomes available." The company, however, believes the new guidelines will help "state and local governments to make consistent decisions concerning the levels of PFOA in drinking water," she said.

Shawn Dalton, 65, a retired communications manager who lives not far from the Merrimack plant, thought until Thursday that water from his well, which tested 73 parts per trillion for PFOA, was safe. Now he knows it is three parts above the new guideline. He was glad for the new guidelines, however, because it means he now can hold government officials and companies accountable, he said.

"At least now the federal government has put a stake in the ground," he said.

News 10 (ABC)

http://news10.com/2016/05/19/vermont-department-of-health-setting-pfoa-advisory-level-at-20-parts-per-trillion/

Vermont Department of Health setting PFOA advisory level at 20 parts per trillion

By Ali Stewart on 5/19/16 at 3:24pm

The Vermont Health Department says they evaluated all of the scientific information available at the time when setting Vermont's advisory level of 20 parts per trillion for PFOA in drinking water.

Now that EPA has set a new advisory level of 70 parts per trillion for PFOA and PFOS combined, the department says it will evaluate the hundreds of pages of supporting documents just released by EPA to assess how this differs from their current advisory level, and consider if any changes are warranted.

The department says they remain committed to protecting the health of Vermonters from these harmful chemicals.

3:29pm

Decatur Daily

http://www.decaturdaily.com/news/lawrence_county/epa-issues-advisory-on-chemicals-

found-in-west-morgan-east/article_2d66630b-b85c-5f14-9c45-e11f422b8457.html

EPA issues advisory on chemicals found in West Morgan-East Lawrence drinking water

By Eric Fleischauer on 5/19/16 at 3:22pm

The Environmental Protection Agency today issued a health advisory for two chemicals that are found in the drinking water of West Morgan-East Lawrence Water Authority.

The lifetime advisory warns of adverse health effects for people exposed to drinking water with more than 70 parts per trillion of two chemicals, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). According to court documents, West Morgan-East Lawrence drinking water exceeds the EPA advisory limit for both chemicals.

The EPA advisory says some studies indicate long-term exposure to higher levels of PFOA and PFOS may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, liver damage, immune effects, thyroid effects and cholesterol changes.

The authority sells water to water departments in Vinemont, Falkville, Trinity, Town Creek and the West Lawrence Water Cooperative. About 25,000 people use water supplied by the authority, it has said in court documents.

West Morgan-East Lawrence in October filed a federal lawsuit alleging 3M Co. and its subsidiary, Dyneon LLC, and Daikin America Inc. released the chemicals into the Tennessee River. The lawsuit alleges the chemical entered the authorities water intake downstream of the companies.

Virtual-Strategy Magazine (Reprint from Business Wire)

http://www.virtual-strategy.com/2016/05/19/new-water-research-foundation-study-

addresses-most-effective-methods-removing-pfospfoa-wa#axzz498AKvTCX

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

(See Business Wire story below)

3:02pm

Times Hearld-Record

http://www.recordonline.com/news/20160519/newburgh-water-pollutant-now-more-than-twice-level-of-new-epa-guidelines

Newburgh water pollutant now more than twice level of new EPA guidelines

By Leonard Sparks on 5/19/16 at 2:49pm

New federal health guidelines issued Thursday for the chemical that has shut down Newburgh's primary water supply are less than half the levels recorded in the city.

The Environmental Protection Agency is now urging action if levels of perfluorooctanoic acid or perfluorooctane sulfonate are above 70 parts per trillion, a significantly stricter standard than previously issued advisory guidelines of 100 parts per trillion for PFOA and 200 parts per trillion for PFOS.

Since its water was first tested in December 2013, Newburgh's Washington Lake has had levels of PFOS ranging from 140 to 170 parts per trillion.

While below the initial EPA guidelines, those levels spurred the closure of the lake on May

2, and Newburgh has been drawing water from its backup supply at Brown's Pond.

U.S. Sen. Charles Schumer and U.S. Rep. Sean Maloney had been urging the EPA to expedite release of its updated guidelines.

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS," Schumer said in a statement. "Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause."

The Intercept

https://theintercept.com/2016/05/19/with-new-pfoa-drinking-water-advisory-dozens-of-communities-suddenly-have-dangerous-water/

WITH NEW DRINKING WATER ADVISORY, DOZENS OF COMMUNITIES SUDDENLY HAVE DANGEROUS WATER

By Sharon Lerner on 5/19/16 at 2:36pm

The EPA announced new drinking water health advisory levels today for the industrial chemicals PFOA and PFOS. The new levels — .07 parts per billion (ppb) for both chemicals — are significantly lower than standards the agency issued in 2009, which were .4 ppb for PFOA and .2 ppb for PFOS. In areas where both PFOA and PFOS are present, the advisory suggests a maximum combined level of .07 ppb. While the old levels were calculated based on the assumption that people were drinking the contaminants only for weeks or months, the new standards assume lifetime exposure and reflect more recent research.

The new federal standards may unify what has been an inconsistent official response to the presence of these perfluorinated chemicals, or PFCs, in drinking water. They will also instantaneously create official water contamination crises in dozens of cities and towns across the country.

According to the EPA's most recent data on unregulated drinking water contaminants, released in January, 14 drinking water systems around the country reported levels of PFOA that exceed the new federal threshold, while 40 reported PFOS above the new cutoff. In all, water systems in 18 states, as well as in Guam, are contaminated.

Some of these water systems have already begun to quietly address the problem. In Suffolk County, New York, where public drinking water wells show PFOS levels of .33 and .53 ppb, the contaminated water "has either been blended with other wells to reduce the level of the compound to non-detection or their use has been limited to the greatest extent possible," according to Kevin Durk, director of water quality and laboratory services for the Suffolk County Water Authority. Though he does not know the level of PFOS in the water that comes out of local taps, Durk wrote in an email that "it is a virtual certainty that levels of any detected chemical would have been reduced."

Similarly, the Security Water and Sanitation District in Colorado Springs has been struggling to clean up its contaminated water since 142 tests detected PFCs. The district has shut down seven out of 26 wells and is blending water to lower levels, according to Roy Heald, the district's general manager.

But other water company operators have yet to lower their PFC levels. Steve Anderson, owner of the Oatman Water Company in Scottsdale, Arizona, where PFOS measured .2 and .23 in the most recent EPA testing, learned that the chemical was in his water only recently, after he received a call from the Arizona Department of Environmental Quality. Anderson, who suspects the PFOS originated from firefighting foam used by the nearby Oatman Fire Department, said he is "trying to come up with a solution."

Until today, there was a wide range of official opinion on the level of contamination that presented a health danger. The military, which is in the throes of a massive cleanup of 664 contaminated fire- and crash-training sites, has been using the EPA's older standards for PFOA and PFOS to guide its efforts and help determine who receives clean drinking water and remediation of contaminated private wells. (The Department of Defense did not responded to inquiries about how the new advisory levels would alter its cleanup plan.)

Others have set more stringent standards. On January 28, the EPA advised residents of Hoosick Falls, New York, not to use water with PFOA levels above .1 ppb. And a panel of scientists who spent years researching some 70,000 people whose water contained PFOA

levels of at least .05 ppb, found probable links between that level of exposure and testicular cancer, kidney cancer, thyroid disease, preeclampsia, ulcerative colitis and high cholesterol. In 2010, New Jersey's Drinking Water Quality Institute calculated a safety limit of .04 for PFOA. Vermont currently has the lowest state drinking water limit for PFOA, .02 ppb.

The levels released today are based on numerous studies connecting the chemicals with health effects. For PFOS, the report notes, studies of lab animals exposed to the chemical reported "developmental effects (decreased body weight, survival, and increased serum glucose levels and insulin resistance in adult offspring), reproductive (mating behavior), liver toxicity (liver weight co-occurring with decreased cholesterol, hepatic steatosis), developmental neurotoxicity (altered spatial learning and memory), immune effects, and cancer (thyroid and liver)."

The report also acknowledged research on human populations that has found associations between PFOS and immune suppression, thyroid disease, high cholesterol, and reduced fertility. It also acknowledged a possible connection between PFOS and bladder, colon, and prostate cancer.

For PFOA, the research included studies on monkeys, rats, and mice showing "developmental effects (survival, body weight changes, reduced ossification, delays in eye opening, altered puberty, and retarded mammary gland development), liver toxicity (hypertrophy, necrosis, and effects on the metabolism and deposition of dietary lipids), kidney toxicity (weight), immune effects, and cancer (liver, testicular, and pancreatic)."

The new health advisory for PFOA was also based on human studies, which showed "associations between PFOA exposure and high cholesterol, increased liver enzymes, decreased vaccination response, thyroid disorders, pregnancy-induced hypertension and preeclampsia, and cancer (testicular and kidney)." The EPA report noted that in humans "the developing fetus and newborn is particularly sensitive to PFOA-induced toxicity."

"Taken together," the report notes, "the weight of evidence for human studies supports the conclusion that PFOA exposure is a human health hazard." The exact phrasing was used in the PFOS report as well.

While calling the new level "a very long-overdue step in the right direction," Robert Bilott, an attorney overseeing a class-action suit over PFOA contamination near a DuPont plant in West Virginia, cautioned that "the new guideline is still too high, as exposures at even the new guideline level would allow PFOA to continue to build up to ever-increasing, unacceptable levels in human blood."

Bilott also noted that the new levels are informal guidelines, as opposed to enforceable regulatory limits. "If it was enforceable," he said, "the EPA could issue unilateral orders requiring the responsible party to clean it up."

WaterWorld

http://www.waterworld.com/articles/2016/05/epa-releases-drinking-water-health-advisories-for-pfoa-and-pfos.html

EPA RELEASES DRINKING WATER HEALTH ADVISORIES FOR PFOA AND PFOS

By (No author) on 5/19/16 at 2:42pm

Based on the latest science on two chemical contaminants called PFOA and PFOS, EPA has released drinking water health advisories to provide the most up-to-date information on the health risks of these chemicals. These advisories will help local water systems and state, tribal and local officials take the appropriate steps to address PFOA and PFOS if needed.

EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations.

For many years, PFOA and PFOS were widely used in carpets, clothing, furniture fabrics, food packaging, and other materials to make them more resistant to water, grease, and stains. PFOA and PFOS were also used for firefighting at airfields and in a number of industrial processes. Between 2000 and 2002, PFOS was voluntarily phased out of

production in the U.S. by its primary manufacturer. And EPA asked eight major companies to commit to eliminate their production and use of PFOA by the end of 2015 and they have indicated that they have met their commitments. While there are some limited ongoing uses of these chemicals, in recent years, blood testing data has shown that exposures are declining across the country.

For most people, their source of exposure to PFOA and PFOS has come through food and consumer products. But drinking water can be an additional source of exposure in the small percentage of communities where these chemicals have contaminated water supplies. This is typically a localized issue associated with a specific facility -- for example, in communities where a manufacturing plant or airfield made or used these chemicals.

If these chemicals are found in drinking water systems above these levels, system operators should quickly conduct additional sampling to assess the level, scope, and source of contamination. They should also promptly notify consumers and consult with their state drinking water agency to discuss appropriate next steps. Public notification is especially important for pregnant or nursing women because of the impact these chemicals can have on the development of fetuses and breastfed or formula-fed infants. There are a number of options available to water systems to lower concentrations of these chemicals in the drinking water supply.

EPA will continue sharing the latest science and information so that state and local officials can make informed decisions and take actions to protect public health. This is an important part of our broader effort to support states and public water systems as we work together to strengthen the safety of America's drinking water.

Business Wire

http://www.businesswire.com/news/home/20160519006484/en/Water-Research-Foundation-Study-Addresses-Effective-Methods

New Water Research Foundation Study Addresses Most Effective Methods for Removing PFOS/PFOA from Water and Wastewater

By (No author) on 5/19/16 at 2:44pm

The Water Research Foundation (WRF), a leading sponsor of research supporting the water community, has released findings of a study addressing effective methods for removing poly- and perfluoroalkyl substances (PFASs) from water and wastewater. The research report, Treatment Mitigation Strategies for Poly- and Perfluorinated Chemicals (WRF project #4322), contains results of an in-depth treatment study conducted on waters from 13 water and wastewater treatment plants in the United States. Additionally, WRF will be hosting a Webcast on June 2 addressing the project's results and has posted a State of the Science document on PFASs.

The research from project #4322 demonstrated that conventional treatment at wastewater treatment plants and most drinking water treatment plants is ineffective at removing PFASs. Activated carbon and anion exchange can remove many PFASs but are less effective at removing shorter chain PFASs. The most effective treatment technologies are nanofiltration and reverse osmosis, which work even for the smallest PFASs studied.

The EPA issued two public health advisories today for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS), each at 70 parts per trillion. EPA's assessment indicates that drinking water with individual or combined concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

"The research results from project #4322 will help the water community understand the best options for removing PFASs from water and wastewater, said Rob Renner, CEO of the Water Research Foundation. "This knowledge is especially important as the EPA continues the process of regulating these chemicals in water."

Poly- and perfluoroalkyl substances (PFASs) are a group of manmade chemicals with past and current uses in industrial processes and consumer products. PFASs are also commonly referred to as perfluorinated chemicals or PFCs. The most notable PFASs are PFOA and PFOS, but there are many others. PFASs are used in firefighting foams, coating for food packaging, ScotchGardTM and TeflonTM, among other products.

Exposure to PFASs can occur through use of products or consumption of food or water containing PFASs. PFASs do not break down easily and therefore persist in the

environment. They are also soluble in water and can enter source waters through industrial releases, discharges from wastewater treatment plants, storm water runoff, release of firefighting foams, and land application of contaminated biosolids.

PFASs are a concern because they have been shown to have health effects in animal studies. Data from some human studies suggest that PFASs also affect human health. Additional research is ongoing in order to gain a better understanding of human health effects.

2:45pm

WRGB Albany (CBS)

http://cbs6albany.com/news/hoosick-falls-crisis/epa-declares-official-standard-for-pfoa-pfoh-contamination

EPA declares official standard for PFOA, PFOS contamination for lifetime exposure

By WRGB Staff on 5/19/16 at 2:19pm

The EPA has released official long- term exposure guidelines for PFOA, PFOS contamination.

Released documents state that concentrations of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure.

Vermont lists safe exposure levels at 20 parts per trillion, including babies and children.

Regional EPA originally set short term exposure as 100 ppt in Hoosick Falls.

'EPA's assessment indicates that drinking water with individual or combined concentrations

of PFOA and PFOS below 70 parts per trillion is not expected to result in adverse health effects over a lifetime of exposure. These levels reflect a margin of protection, including for the most sensitive populations. " , says the EPA in a released document.

2:27 PM

Vermont Public Radio

http://digital.vpr.net/post/significant-reduction-epa-sets-health-advisory-pfoa-70-parts-trillion#stream/0

In Significant Reduction, EPA Sets Health Advisory For PFOA At 70 Parts Per Trillion

By Howard Weiss-Tisman on 5/19/16 at 2:11pm

The Environmental Protection Agency on Thursday issued an updated health advisory for the suspected carcinogen PFOA.

The EPA says water that contains PFOA in levels at 70 parts per trillion should be considered unsafe to drink.

The EPA previously set its level at 400 ppt. The new, lifetime health advisory replaces that standard.

PFOA, a chemical that was used in a variety of manufacturing applications, has been found in water in North Bennington, Bennington and Pownal.

The contaminant has also been detected in New Hampshire and New York, and in other states around the country.

Vermont set its level at 20 parts per trillion.

(Reprint of Bucks County Courier Times story)

http://www.theintell.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_a404ad5d-a246-5ec2-9d1b-a9af8b6e70d5.html

EPA releases new safety advisories for chemicals

2:20 PM

Time Warner Cable News - Capital Region

http://www.twcnews.com/nys/capital-region/news/2016/05/19/epa-releases-new-pfoa-and-pfos-health-guidelines.html

EPA Releases New Health Guidelines for PFOA, PFOS Found in Drinking Water

By TWC News Web Staff on 5/19/16 at 1:46pm

The EPA has released new health guidelines for PFOA and PFOS found in drinking water.

PFOA was the chemical found in the water supply in Hoosick Falls and Petersburgh.

The new health advisory levels have been set to 70 parts per trillion.

When first tested at the St. Gobain facility in Hoosick Falls, the EPA measured the levels at

18,000 parts per trillion.

A filtration system has since been installed, eliminating traces of the chemical, making the water safe to use again in Hoosick Falls.

In Petersburgh, multiple homes have tested above the new acceptable levels.

Taconic Plastics is believed to be the source of contamination. Residents in the town have grown impatient with leaders as they await to learn when they can get blood tested.

The town even ran out of bottled water to give to residents over the weekend. That supply has since been replenished.

Also, PFOS levels in Washington Lake and Silver Stream are in the range of 145 to 150 parts per trillion.

Washington Lake used to supply Newburgh's drinking water, until the city found out about the continuing levels of PFOS.

The city switched to Brown's Pond as a drinking source, since almost no levels of PFOS were found in that water.

Newburgh is still working to determine where the PFOS contamination is coming from.

Senator Schumer on New Standards:

"I am pleased that the EPA has heeded my call to release updated drinking water health advisories for the highly-toxic chemicals PFOA and PFOS. Communities like Hoosick Falls, Petersburgh and Newburgh understand all too well the uncertainty and anxiety that contamination from these chemicals can cause. The EPA's new guidance will go a long way in protecting public health and arming local officials with the most up-to-date information to keep our drinking water safe from harmful contaminates."

Bucks County Courier Times (also ran in the Intelligencer)

http://www.buckscountycouriertimes.com/news/local/epa-releases-new-safety-advisories-for-chemicals/article_97946008-1de8-11e6-83d3-334d7ea7ce37.html

EPA Releases New Safety Advisories for Chemicals

By Kyle Bagenstose on 5/19/16 at 2:00pm

The Environmental Protection Agency on Thursday released a long-awaited update to its drinking water advisories for unregulated chemicals perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS).

According to prior testing data of public and private water supplies in Bucks and Montgomery counties, it appears the updated advisories could mean some drinking water in the area is contaminated with the chemicals at a level above what the EPA deems is safe to consume.

The chemicals already had contaminated about 100 public and private water wells near a trio of current and former military bases in the region: The former Naval Air Station Joint Reserve Base Willow Grove, Horsham Air Guard Station, and former Naval Air Warfare Center in Warminster.

The chemicals are suspected to have originated in firefighting foams used at the bases, and the military already has agreed to spend approximately $19 million to provide replacement water and install filtration systems for public water wells affected by the chemicals, and bottled water and hook-ups to public systems for homes with affected private wells.

But the number of wells now likely will increase.

Up until Thursday, the military had been gauging its response using short-term, provisional health advisories for the chemicals set by the EPA in 2009: .4 parts per billion for PFOA in drinking water, and .2 ppb for PFOS.

Thursday's announcement, however, set an advised limit of .07 ppb for PFOS and PFOA combined, in order to protect against health effects from a lifetime of exposure. In a worst case scenario, that means drinking water with .58 ppb of the chemicals (.39 ppb PFOA and .19 ppb PFOS) previously considered safe, now would be more than eight times the recommended limit.

After the chemicals first were discovered in some local public water supplies by a nationwide EPA testing program in 2013 and 2014, multiple public wells in the area were taken offline.

The Horsham Water and Sewer Authority removed two drinking water wells from its system in the summer of 2014 after PFOS was found at 1 and .7 ppb. Data from the testing program shows that three more wells also were contaminated with the chemicals at levels above the EPA's new advisory, with a combined .071 ppb, .123 ppb, and .14 ppb.

In a brief email Thursday, authority manager Tina O'Rourke said only two additional wells are above the .07 ppb level as of the most recent testing.

She added that the authority intends to take the wells offline and that existing agreements with the military allow for the authority to take action immediately.

The Warminster Municipal Authority, which previously removed three wells from its supply, also appears to have two more wells contaminated above the new level, with a

combined .091 ppb and .09 ppb.

The Warrington Township Water Department previously removed a trio of wells that combined to form a single water source. Based on the EPA's data showing a combined .082 ppb, another well could also be above the new health advisory.

This news organization reached out to all three utilities to obtain the most recent testing information and will update this story as it receives responses.

Although unregulated, a growing body of science has established associations between PFOA and PFOS and a range of health effects, including a variety of cancers.

Joel Beauvais, deputy assistant administrator for the EPA's Office of Water, said in a phone interview Thursday that the updated advisories reflect a review of available science and are intended to be protective for lifetime exposure to the chemicals for even vulnerable populations, such as nursing mothers and their children.

"These health advisories are scientific documents … the point is to provide the best available information to state and local authorities and drinking water system operators," Beauvais said. "They're calculated to reflect a margin or protection to the most sensitive populations."

Beauvais added that the next step for the chemicals is to be considered for a federal drinking water standard that can be enforced, as is the case with more well-known contaminants such as lead or arsenic. However, he was unable to say how long it might take for that decision to be made.

1:59 PM

Albany Times Union

http://www.timesunion.com/local/article/EPA-sets-new-level-for-chemical-in-local-water-7716825.php

EPA Sets New Level for Chemical in Drinking Water

By Brendan J. Lyons on 5/19/16 at 1:17pm

The U.S. Environmental Protection Agency on Thursday issued a lifetime drinking water health advisory of 70 parts per trillion for human exposure to the man-made chemical, perfluorooctanoic acid, or PFOA.

The EPA's long-awaited action comes as health and environmental officials in New York, Vermont and New Hampshire are grappling with the discovery of elevated levels of PFOA in public water systems and private wells. The contamination has been linked to factories that used PFOA in their manufacturing processes, in some cases dating back decades.

"Where these chemicals are detected above the advisory levels, we're recommending the water system operators go back and do confirmatory testing," said Joel Beauvais, deputy assistant administrator for the EPA's Office of Water. "We're also recommending that systems promptly provide notice to residents and users of water systems."

Beauvais said the EPA's recommendation is based on toxicity studies in mice.

The EPA's advisory level is well below the levels of PFOA that were detected in public water supplies over the past two years in Hoosick Falls, Petersburgh, North Bennington, Vt., and Merrimack, N.H.

In addition, health and environmental officials said tests have also revealed levels of PFOA in dozens of private wells in Rensselaer County that are much higher than the EPA's guideline.

Officials with the state Health Department and Department of Environmental Conservation could not immediately provide information Thursday about how many water systems in New York may contain PFOA, which has been used since the 1940s to make products such as nonstick coatings, such as Teflon, and heat-resistant wiring and other specialty products.

In 2009, the EPA established a guideline that a level of 400 parts per trillion is a safe level for "short-term" consumption of the water. Earlier this year, the EPA issued a provisional health advisory of 100 ppt. Meanwhile, other states have set far lower acceptable levels of PFOA in public water systems, including New Jersey, which has set a level of 40 ppt.

State Health Commissioner Dr. Howard A. Zucker in January said the state Health Department was reviewing its position on acceptable levels of PFOA in drinking water and would set a new safety limit within weeks. But the state did not issue a new advisory.

Robert A. Bilott, an Ohio attorney who is helping represent an estimated 3,500 people in a class-action lawsuit against DuPont, which manufactured and used perfluorinated chemicals such as PFOA in its products, has been urging the EPA for years to adopt a permanent health advisory for long-term exposure to PFOA in drinking water. Bilott has represented "tens of thousands of individuals in various communities across the country who have been injured because of the contamination of their drinking water with PFOA."

"The lower number and acknowledgement of the need to consider the combined amount of PFCs in water is a long-overdue step in the right direction, but the guideline is still too high, as it will allow ever-increasing, unacceptable levels of PFOA to continue to build up in the blood of those exposed," Bilott said.

Three years ago, a science panel released the results of a multiyear study that examined PFOA exposure and health risks in several Ohio Valley communities, where PFOA, also known as C8, was emitted since the 1950s from the Washington Works plant in Parkersburg, W.Va. The panel found probable links between PFOA exposure and high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension.

Bilott said the science panel's peer-reviewed report was paid for by DuPont and, as a result of the panel's findings, the company has to concede in the personal-injury lawsuits that PFOA causes cancer.

In Albany, numerous lawsuits were filed this year in U.S. District Court seeking class-action status on behalf of current and former Hoosick Falls residents, including some who allege they suffered serious health effects that could be linked to PFOA exposure.

According to the EPA, PFOA was detected in blood serum in 99 percent of the U.S. population between 1999 and 2012. However, the EPA said the levels of PFOA in human blood have been decreasing since U.S. companies began to phase out production of the chemical more than 10 years ago. Still, water resources contaminated by PFOA have been associated with releases from manufacturing sites, industrial sites, fire/crash training areas, and industrial or municipal waste sites where products are disposed of or applied, the agency said.

Thousands of people whose blood was tested in that area of the Ohio Valley had elevated levels of PFOA, including at levels as high as 40 parts per billion.

In Hoosick Falls, where hundreds of people signed up for state-sponsored blood tests in February, the results of those tests are expected to be released beginning next week.

In February, the state Department of Environmental Conservation asked two corporations, Saint-Gobain Performance Plastics and Honeywell International, to enter consent orders that would require them to clean up the remnants of the toxic chemical that polluted water supplies in and around Hoosick Falls.

The DEC said its preliminary investigation determined the two corporations, and possibly others, are the "parties responsible" for the presence of high levels of PFOA that were discovered two years ago in the village's public water supply. The chemical has since been detected in private wells in and around the village and at other locations in Rensselaer County, including the town of Petersburgh.

Saint-Gobain operates two plants in Hoosick Falls, including a McCaffrey Street facility the company has owned since 1999. That plant is a few hundred yards from the village's water-treatment plant and has been a focus of the contamination.

PFOA, a man-made chemical, was discovered in Hoosick Falls' water system by a resident, Michael Hickey, who began researching the issue because of what he believed was a high rate of cancer in the village where he grew up. His father, John, who worked at the Saint-Gobain plant for decades, died of kidney cancer in 2013. Hickey paid to have samples of village water tested for PFOA and notified village officials in 2014 that the tests showed the levels of the chemical found in the system exceeded federal health advisories.

Saint-Gobain, which said it learned of the pollution in December 2014, has voluntarily funded the distribution of bottled water and said it will pay for the installation of a long-term water filtration system at the village's water treatment plant. The state has been installing individual filter systems at residences and businesses that have private wells with PFOA contamination.

In 2006, the EPA reached an agreement with DuPont and other manufacturers to stop producing or using PFOA, although DuPont continued producing PFOA because the agreement did not call for the end of production of the chemical until 2015. The EPA settlement with DuPont came less than a year after DuPont agreed to pay $10.25 million in civil penalties to settle the complaint brought by the EPA regarding the company's PFOA pollution in the Midwest. At the time, it was the largest civil administrative penalty ever obtained by the EPA under federal environmental statutes.

WAMC, Northeast Public Radio

http://wamc.org/post/epa-releases-new-pfoa-pfos-guidelines

EPA Releases New PFOA, PFOS Guidelines

By (No author) on 5/19/16 at 1:44pm

The U.S. Environmental Protection Agency has released new health advisories for PFOA and PFOS, the manufacturing chemicals at the center of water contamination crises in several communities in the region including Hoosick Falls, Petersburgh, and North Bennington. The guidelines released today lower the lifetime exposure from drinking water level to 70 parts per trillion. The level of PFOA in affected areas has been much higher than the new benchmark, leading communities to establish alternate water supplies. High exposure can result in cancer, birth defects and other diseases.

WMUR Manchester (ABC)

http://www.wmur.com/health/epa-sets-new-level-for-contaminant-found-in-drinking-water/39629266

EPA sets new level for contaminant found in drinking water

By Kirk Enstrom on 5/19/16 at 1:41pm

The Environmental Protection Agency has set new advisory levels for a contaminant that has been found in drinking water supplies in parts of New Hampshire.

The state Department of Environmental Services said Thursday that the EPA set a lifetime drinking water health advisory level for perfluorooctanoic acid at 70 parts per trillion.

The same level was set for a related chemical, perfluorooctane sulfonate. The EPA said that when both chemicals are present, the combined concentration shouldn't exceed 70 parts per trillion.

State environmental officials had been advising well water users whose water tested above 100 parts per trillion to drink bottled water instead.

PFOA was found earlier this year in groundwater near the Saint-Gobain Performance

Plastics facility in Merrimack after that company conducted tests. The contaminant has since been found in private wells in Litchfield, Manchester, Bedford and other areas.

It was most recently found in Amherst near a former industrial site.

State environmental officials said they are working to review the scientific basis for the new levels. DES said it's also taking steps to provide bottled water to all known private well users who have detected PFOA or PFOS levels greater than 70 parts per trillion.

"The state of New Hampshire will take immediate action to expand distribution of bottled water in affected areas to those whose water supply falls under the new advisory," Gov. Maggie Hassan said.

DES said it plans to move quickly to develop emergency rules for groundwater cleanup and drinking water standards. There will be a public comment process before permanent rules are established.

DES has set up a website to discuss the PFOA investigation.

NEWS10 ABC

http://news10.com/2016/05/19/epa-issues-health-advisory-level-for-lifetime-exposure-to-pfoa/

EPA Sets Health Advisory Level for Lifetime Exposure to PFOA

By Joe Gullo on 5/19/16 at 1:21pm

The U.S. Environmental Protection Agency (EPA) announced a lifetime drinking water health advisory of 70 parts per trillion for human exposure to PFOA.

The EPA says the advisory is to provide Americans, including the most sensitive populations, with a margin of protection from a lifetime exposure to PFOA and PFOS from drinking water.

PFOA has been linked to serious health problems such as cancer.

Some local communities, including Petersburgh, Hoosick Falls, Bennington, and Pownal have had wells test positive for the chemical.

PFOA and PFOS have been used to make carpets, clothing, fabrics for furniture, paper packaging for food, and other materials that are resistant to water, grease, or stains. In 2006, the EPA says they asked eight companies using PFOA to phase out use and chemicals used to break down PFOA. Those companies have stated at the end of 2015, they phased out the use of PFOA.

According to the EPA, the establishment of the advisories follows an assessment from the latest peer-reviewed science to provide water system operators, and state, tribal, and local officials who have the primary responsibility of overseeing these systems.

Advisories issued by the EPA are designed to provide information on contaminants that can cause human health effects and are known or anticipated to occur in water.

Travis Loop

Director of Communications
Office of Water

U.S. Environmental Protection Agency

202-870-6922

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To: Harper, Ashley[harper.ashley@epa.gov]; Behl, Betsy[Behl.Betsy@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]
From: Lalley, Cara
Sent: Tue 4/5/2016 4:23:29 PM
Subject: RE: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

Betsy- I suggest the following for an answer. Please edit at will. Thanks

Deliberative Process / Ex. 5

From: Harper, Ashley
Sent: Tuesday, April 05, 2016 11:07 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: FW: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

Please answer this question from reporter:

•□□□□□□□□ When EPA will be issuing the final health advisories for chronic exposure to these two chemicals? Also, will they be issued together?

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

From: Wadlington, Christina
Sent: Tuesday, April 05, 2016 10:39 AM
To: Schollhamer, Mary <Schollhamer.Mary@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: RE: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

I'll take #2 but #1 is for OST

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

From: Schollhamer, Mary
Sent: Tuesday, April 05, 2016 10:21 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

DDL tomorrow at 2pm.

•□□□□□□□□ When EPA will be issuing the final health advisories for chronic

exposure to these two chemicals? Also, will they be issued together?•□□□□□□□□
On a related note, while EPA made a decision Jan. 28 at Hoosick Falls, NY to advise residents against consuming drinking water exceeding 0.1 ppb of PFOA, elsewhere, other locations have been deferring to EPA's provisional health advisory of 0.4 ppb. Is EPA taking any action to advise those communities not to consume drinking water that exceeds 0.1 ppb of PFOA? Are EPA's regional offices investigating or giving notice to communities where drinking water is reported at PFOA levels of 0.1 ppb or higher?

Mary G Schollhamer

Acting Deputy Director of Communications

Office of Water

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Office: 202-564-5759

Mobile: 202-853-5317

schollhamer.mary@epa.gov

From: Daguillard, Robert
Sent: Tuesday, April 05, 2016 10:01 AM
To: Schollhamer, Mary <Schollhamer.Mary@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: MARY ACTION; INSIDE EPA; DDL 4/6: PFOA and PFOS

Good morning, The reporter's deadline is tomorrow at 2 PM. Please send response back to Dale Perry. -----Original Message-----From: Suzanne Yohannan Enesta, I'm continuing to cover PFOA and PFOS issues, and wanted to know if you could tell me when EPA will be issuing the final health advisories for chronic exposure to these two chemicals? Also, will they be issued together? On a related note, while EPA made a decision Jan. 28 at Hoosick Falls, NY to advise residents against consuming drinking water exceeding 0.1 ppb of PFOA, elsewhere, other locations have been deferring to EPA's provisional health advisory of 0.4 ppb. Is EPA taking any action to advise those communities not to consume drinking water that exceeds 0.1 ppb of PFOA? Are EPA's regional offices investigating or giving notice to communities where drinking water is reported at PFOA levels of 0.1 ppb or higher? Thanks. Suzanne YohannanInside EPA

To: Behl, Betsy[Behl.Betsy@epa.gov]
Cc: Lalley, Cara[Lalley.Cara@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Tue 4/5/2016 3:07:12 PM
Subject: FW: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

Please answer this question from reporter:

•□□□□□□□□ When EPA will be issuing the final health advisories for chronic exposure to these two chemicals? Also, will they be issued together?

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | harper.ashley@epa.gov

From: Wadlington, Christina
Sent: Tuesday, April 05, 2016 10:39 AM
To: Schollhamer, Mary <Schollhamer.Mary@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>; Harper, Ashley <harper.ashley@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: RE: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

I'll take #2 but #1 is for OST

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

From: Schollhamer, Mary
Sent: Tuesday, April 05, 2016 10:21 AM
To: Lalley, Cara <Lalley.Cara@epa.gov>; Wadlington, Christina <Wadlington.Christina@epa.gov>
Cc: Loop, Travis <Loop.Travis@epa.gov>
Subject: MEDIA INQUIRY; INSIDE EPA; PFOA and PFOS [DDL 4/6, 2pm]

DDL tomorrow at 2pm.

•□□□□□□□□ When EPA will be issuing the final health advisories for chronic exposure to these two chemicals? Also, will they be issued together?•□□□□□□□□ On a related note, while EPA made a decision Jan. 28 at Hoosick Falls, NY to advise residents against consuming drinking water exceeding 0.1 ppb of PFOA, elsewhere, other locations have been deferring to EPA's provisional health advisory of 0.4 ppb. Is EPA taking any action to advise those communities not to consume drinking water that exceeds 0.1 ppb of PFOA? Are EPA's regional offices investigating or giving notice to communities where drinking water is reported at PFOA levels of 0.1 ppb or higher?

Mary G Schollhamer

Acting Deputy Director of Communications

Office of Water

U.S. Environmental Protection Agency

Office: 202-564-5759

Mobile: 202-853-5317

schollhamer.mary@epa.gov

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To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Mon 3/28/2016 6:26:47 PM
Subject: QA for PFOA PFOS
PFOA-PFOS QA not in state-utility fact sheet 3-28-16.docx

Please look at these and let me know which office questions belong to

To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Harper, Ashley
Sent: Mon 3/28/2016 1:30:54 PM
Subject: QAs for PFOA/PFOS
PFOA-PFOS QA not in state-utility fact sheet 3-25-16.docx

The QAs for you to look at again.

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Evans, Crystal[Evans.Crystal@epa.gov]
Cc: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Tue 3/22/2016 2:09:35 PM
Subject: FW: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
PFOA-PFOS-OW HAs ADMIN BRIEF 03 23 16 final.ppt

Crystal, please make 15 copies of the presentation above and bring to Jamie Strong. thanks

From: Behl, Betsy
Sent: Tuesday, March 22, 2016 8:20 AM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

This is the final version including Travis's slides from yesterday. Ready to go! Thanks Octavia.

From: Conerly, Octavia
Sent: Tuesday, March 22, 2016 6:51 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: FW: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Good morning All,

Here's the version that Karen already sent to the Administrator's office late last night. If this version is not the correct one, please let me know ASAP. Colleen, I know you said you wanted to change a number.

Octavia Conerly

Special Assistant to the Office Director

Office of Science and Technology

1200 Pennsylvania Ave. NW MC 4304T

Room 5231H

Washington, DC 20460

EMAIL: conerly.octavia@epa.gov

PHONE: (202) 566-1094

FAX: (202) 566-0441

From: Gude, Karen
Sent: Monday, March 21, 2016 9:21 PM
To: Klasen, Matthew <Klasen.Matthew@epa.gov>
Cc: Campbell, Ann <Campbell.Ann@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>
Subject: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Matt,

Hi. Attached please find the materials for the 3/23 Administrator briefing on PFOA/PFOS.

Thanks,

Karen

To: Conerly, Octavia[Conerly.Octavia@epa.gov]
From: Strong, Jamie
Sent: Tue 3/22/2016 1:18:57 PM
Subject: FW: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
PFOA-PFOS-OW HAs ADMIN BRIEF 03 23 16 final.ppt

Typo on slide 2.

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Subject: FW: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

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Washington, DC 20460

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PHONE: (202) 566-1094

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Subject: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Matt,

Hi. Attached please find the materials for the 3/23 Administrator briefing on PFOA/PFOS.

Thanks,

Karen

To: Behl, Betsy[Behl.Betsy@epa.gov]; Flaherty, Colleen[Flaherty.Colleen@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]
Cc: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
From: Conerly, Octavia
Sent: Tue 3/22/2016 10:51:29 AM
Subject: FW: Administrator's Briefing: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
PFOA-PFOS-OW HAs ADMIN BRIEF 03 18 16 AA draft.ppt

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To: Strong, Jamie[Strong.Jamie@epa.gov]
From: Behl, Betsy
Sent: Mon 3/21/2016 4:26:43 PM
Subject: FW: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
PFOA-PFOS-OW HAs ADMIN BRIEF 03 18 16 AA draft.ppt

These are the latest slides

From: Behl, Betsy
Sent: Friday, March 18, 2016 7:33 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Subject: FW: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

From: Behl, Betsy
Sent: Friday, March 18, 2016 10:41 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>; Donohue, Joyce <Donohue.Joyce@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: FW: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Betsy: This is the final draft for Joel of the briefing for the administrator. It includes all comments from other offices with the exception of Travis (final slide on the Roadmap).

Deliberative Process / Ex. 5

I think it is very good and I hope he likes it!

Betsy

From: Conerly, Octavia
Sent: Thursday, March 17, 2016 1:12 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Does Joel have the slides for this briefing? I have not seen any email. They are due to the Administrator tomorrow.

Subject: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
Location: Alm Conference Room

Start: Wed 3/23/2016 1:30 PM
End: Wed 3/23/2016 2:30 PM

Recurrence: (none)

Meeting Status: Accepted

Organizer: Personal Address / Ex. 6
Required Attendees: Southerland, Elizabeth; Behl, Betsy; Flaherty, Colleen; Strong, Jamie; Donohue, Joyce; Grevatt, Peter; Clark, Becki; Burneson, Eric; Henry, Tala; Cleland-Hamnett, Wendy; Conerly, Octavia; Miller, Gregory; Etzel, Ruth; Scozzafava, MichaelE; Cooke, Maryt; Vaught, Laura; Gilinsky, Ellen; Fritz, Matthew; Klasen, Matthew; Burke, Thomas; Thomas, Russell; Wambaugh, John; Slotkin, Ron; Rodgers, Ryan; Carter, Donnell; Sampson, Jamaal; Vitalien, Christal; EPAVTC; MCClain, Mike; Meiburg, Stan; Purchia, Liz; Nancy Grantham (Grantham.Nancy@epa.gov); Distefano, Nichole; Rupp, Mark; Beauvais, Joel; Stanislaus, Mathy; Barry Breen (Breen.Barry@epa.gov); Rennert, Kevin

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SCt: Liel Azoolin
Ct: Crystal Penman, 202-564-3318

Staff:
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Liz Purchia, Nancy Grantham (OPA)
Nichole Distefano, Mark Rupp (OCIR)
Joel Beauvais, Ellen Gilinsky, Elizabeth Southerland, Betsy Behl, Colleen Flaherty, Jamie Strong, Joyce Donohue, Peter Grevatt, Becki Clark, Eric Burneson (OW)
Tom Burke, Russell Thomas, John Wambaugh (ORD)
Mathy Stanislaus, Barry Breen (OLEM)
Laura Vaught, Kevin Rennert (OP)

Optional:
Octavia Conerly (OW)
Ruth Etzel, Greg Miller (OCHP)
Michael Scozzafava, Mary Cooke (OLEM)
Tala Henry, Wendy Cleland-Hamnett (OCSPP)

Conference Code/ Ex. 6

To: Behl, Betsy[Behl.Betsy@epa.gov]
From: Strong, Jamie
Sent: Fri 3/18/2016 2:09:54 PM
Subject: RE: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
PFOA-PFOS-OW HAs ADMIN BRIEF 03 18 16.ppt

Check it out...

From: Behl, Betsy
Sent: Friday, March 18, 2016 8:57 AM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: FW: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

jamie. can you do that? then I think we are done

From: Southerland, Elizabeth
Sent: Friday, March 18, 2016 8:56 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Yep, change the equation.

From: Behl, Betsy
Sent: Friday, March 18, 2016 8:53 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

The value given in the exposure factors handbook is the adjusted body weight (they don't break it down by body weight and dw intake). How about we change the equation?

From: Southerland, Elizabeth
Sent: Friday, March 18, 2016 8:41 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Conerly, Octavia <Conerly.Octavia@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and

Perfluorooctanoic Acid (PFOA)

Looks great! My only comments are as follows:

Deliberative Process / Ex. 5

From: Behl, Betsy
Sent: Thursday, March 17, 2016 6:49 PM
To: Conerly, Octavia <Conerly.Octavia@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Subject: RE: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Betsy:

Deliberative Process / Ex. 5

<< File: PFOA-PFOS-OW HAs ADMIN BRIEF 03 17 16.ppt >>
Jamie or Colleen may also have edits.

From: Conerly, Octavia
Sent: Thursday, March 17, 2016 1:12 PM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
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Recurrence: (none)

Meeting Status: Accepted

Organizer: Personal Address / Ex. 6
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Ct: Crystal Penman, 202-564-3318

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Octavia Conerly (OW)
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Tala Henry, Wendy Cleland-Hamnett (OCSPP)

Conference Line: 866-299-3188 / Conference Code/ Ex. 6

To: Behl, Betsy[Behl.Betsy@epa.gov]; Flaherty, Colleen[Flaherty.Colleen@epa.gov]
From: Strong, Jamie
Sent: Fri 3/18/2016 12:49:29 PM
Subject: FW: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
PFOA-PFOS-OW HAs ADMIN BRIEF 03 18 16.ppt

Deliberative Process / Ex. 5

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Betsy:

Deliberative Process / Ex. 5

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Tala Henry, Wendy Cleland-Hamnett (OCSPP)

Conference Line: 866-299-3188 / Access Code: **Conference Code/ Ex. 6**

To: Conerly, Octavia[Conerly.Octavia@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]; Flaherty, Colleen[Flaherty.Colleen@epa.gov]
Cc: Southerland, Elizabeth[Southerland.Elizabeth@epa.gov]
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Betsy:

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Subject: Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Does Joel have the slides for this briefing? I have not seen any email. They are due to the Administrator tomorrow.

Subject:	Meeting Re: Health Advisories for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)
Location:	Alm Conference Room
Start:	Wed 3/23/2016 1:30 PM
End:	Wed 3/23/2016 2:30 PM
Recurrence:	(none)
Meeting Status:	Accepted
Organizer:	**Personal Address / Ex. 6**
Required Attendees:	Southerland, Elizabeth; Behl, Betsy; Flaherty, Colleen; Strong, Jamie; Donohue, Joyce; Grevatt, Peter; Clark, Becki; Burneson, Eric; Henry, Tala; Cleland-Hamnett, Wendy; Conerly, Octavia; Miller, Gregory; Etzel, Ruth; Scozzafava, MichaelE; Cooke, Maryt; Vaught, Laura; Gilinsky, Ellen; Fritz, Matthew; Klasen, Matthew; Burke, Thomas;

Thomas, Russell; Wambaugh, John; Slotkin, Ron; Rodgers, Ryan; Carter, Donnell; Sampson, Jamaal; Vitalien, Christal; EPAVTC; MCClain, Mike; Meiburg, Stan; Purchia, Liz; Nancy Grantham (Grantham.Nancy@epa.gov); Distefano, Nichole; Rupp, Mark; Beauvais, Joel; Stanislaus, Mathy; Barry Breen (Breen.Barry@epa.gov); Rennert, Kevin

******Please DO NOT forward this calendar invitation. You may "Accept" or "Decline" the invitation but DO NOT respond with questions or concerns. If you do have any questions or concerns about this invitation please contact the Scheduling Office at scheduling@epa.gov . ******

SCt: Liel Azoolin
Ct: Crystal Penman, 202-564-3318

Staff:
Deputy Meiburg, Matt Fritz (OA)
Liz Purchia, Nancy Grantham (OPA)
Nichole Distefano, Mark Rupp (OCIR)
Joel Beauvais, Ellen Gilinsky, Elizabeth Southerland, Betsy Behl, Colleen Flaherty, Jamie Strong, Joyce Donohue, Peter Grevatt, Becki Clark, Eric Burneson (OW)
Tom Burke, Russell Thomas, John Wambaugh (ORD)
Mathy Stanislaus, Barry Breen (OLEM)
Laura Vaught, Kevin Rennert (OP)

Optional:
Octavia Conerly (OW)
Ruth Etzel, Greg Miller (OCHP)
Michael Scozzafava, Mary Cooke (OLEM)
Tala Henry, Wendy Cleland-Hamnett (OCSPP)

Conference Line: 866-299-3188 / Access Code: **Conference Code/ Ex. 6**

To: Conerly, Octavia[Conerly.Octavia@epa.gov]; Behl, Betsy[Behl.Betsy@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]; Harper, Ashley[harper.ashley@epa.gov]; Lalley, Cara[Lalley.Cara@epa.gov]
From: Flaherty, Colleen
Sent: Wed 3/9/2016 3:35:13 PM
Subject: Revised PFOA/PFOS briefing
PFOA-PFOS-OW HAs ADMIN BRIEF 030916.ppt

Octavia, as discussed – this version includes Travis's edits to the last slide.

Colleen M. Flaherty | Deputy Director

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 564-5939 | ✉ flaherty.colleen@epa.gov

To: Wadlington, Christina[Wadlington.Christina@epa.gov]
Cc: Lalley, Cara[Lalley.Cara@epa.gov]; Strong, Jamie[Strong.Jamie@epa.gov]; Huff, Lisa[Huff.Lisa@epa.gov]
From: Harper, Ashley
Sent: Fri 3/4/2016 8:24:23 PM
Subject: Please Review these QsAs for PFOA PFOS
QA PFOA PFOS Master List 3 4 16 v2 (JBS).docx
PFOA-PFOS HAs_press release_draft 3-4-16 v2.docx

Hello Christina,

Deliberative Process / Ex. 5

The press release I sent you this morning will also change significantly BUT if you could address the highlighted sections for now.

Thanks,

Ashley

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Behl, Betsy[Behl.Betsy@epa.gov]
From: Strong, Jamie
Sent: Tue 6/21/2016 1:08:44 PM
Subject: RE: PFOA/PFOS Webcast
PFOA-PFOS-OW HAs 06 13 2016 FINAL.ppt

No I have no info from AWWA or Eric. I assumed I would do the presentation I have been doing for folks. Attached here.

From: Behl, Betsy
Sent: Tuesday, June 21, 2016 9:05 AM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: FW: PFOA/PFOS Webcast

Is there a plan for this?

From: Burneson, Eric
Sent: Thursday, June 09, 2016 3:07 PM
To: Scott Biernat <biernat@amwa.net>
Cc: svia@awwa.org; Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: PFOA/PFOS Webcast

Yes we have flexibility. Lets make it the 27th at 1:00.

From: Scott Biernat [mailto:biernat@amwa.net]
Sent: Thursday, June 09, 2016 2:49 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: svia@awwa.org; Behl, Betsy <Behl.Betsy@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: Re: PFOA/PFOS Webcast

Thanks Eric,

If you have the flexibility, could I push back for one of the 1:00 times? Although doable, 11:00 is a bit early for our west coast participants if we can avoid it.

We can take care of the Webcast logistics.

-Scott

On Jun 9, 2016, at 2:28 PM, "Burneson, Eric" <Burneson.Eric@epa.gov> wrote:

Scott: We can make all of these dates/times work although our preference is for the 11:00 time on June 29.

Also I have been assuming that you will take care of the webcast logistics. Jamie has a slide deck that typically requires about 30 minute or so to run through then we can take questions.

Eric Burneson, P.E.

Director of Standards and Risk Management

Office of Ground Water and Drinking Water

US Environmental Protection Agency

Phone: 202-564-5250

Fax: 202 564 3760

From: Scott Biernat [mailto:biernat@amwa.net]
Sent: Wednesday, June 08, 2016 9:57 AM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: svia@awwa.org
Subject: PFOA/PFOS Webcast

Good Morning Eric,

Apologies for the delay in getting this sorted. The dates/times that fall in the windows you suggested and floated to the top for AMWA and AWWA are.

June 29 at 1 p.m. ET (preferred)

June 27 at 1 p.m. ET
June 29 at 11 a.m. ET

Thanks,

Scott

Scott Biernat

Director of Regulatory Affairs

Association of Metropolitan Water Agencies (AMWA)

1620 I St. NW, Suite 500

Washington, DC 20006

p: 202-331-2820

http://www.amwa.net

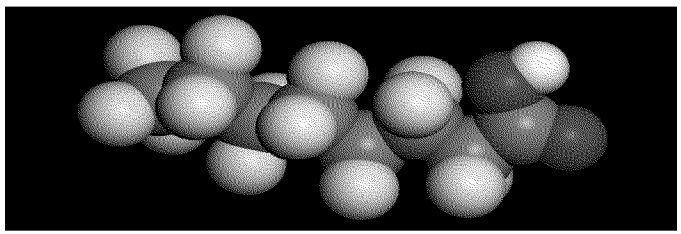
AMWA is the definitive voice for the largest publicly owned drinking water systems in the United States on regulatory, legislative and security issues, as well as a leadership resource for senior water executives. Member-utilities collectively serve more than 130 million people with safe drinking water.

Lifetime Health Advisories (HA) for Perfluorooctane Sulfonate (PFOS) and Perfluorooctanoic Acid (PFOA)

Office of Water
Office of Science and Technology
June 13, 2016

Background-Chemical Characteristics

- PFOS and PFOA are two chemicals in a large group (hundreds) of manmade chemicals called perfluoroalkyl substances (PFAS).
- PFAS have varying carbon chain lengths and have many uses, including as surfactants and to make products more resistant to stains, grease, and water.
- PFOS and PFOA both have 8 carbon atoms and are resistant to biodegradation, photolysis and hydrolysis.
- PFOS and PFOA are the terminal degradation products formed from longer chain commercial, biodegradable precursors.
- Both chemicals have similar environmental fate and transport processes.
  - They are stable in the environment, including in water.
  - Low volatility, but adsorb to airborne particulates and can be transported long-range.
  - Mobile in water and soils.
  - Bioaccumulate across trophic levels.



Background-Physiological Behavior

- Both chemicals are very persistent in the human body.
  - PFOA half-life in blood serum: 2.3 years (general population)
  - PFOS half-life in blood serum: 5.4 years (occupational exposure)

- Six CDC National Health and Nutrition Examination Surveys (NHANES) analyzed PFAS in blood serum between 1999 and 2012.
  - PFOA and PFOS were detected in 99.7% and 99.9% of the U.S. population.
  - Serum concentrations declined over this period:
    - PFOA (geometric mean) concentration from 5.2 µg/L to 2.12 µg/L.
    - PFOS (geometric mean) concentration from 30.4 µg/L to 6.31 µg/L.

Previous and Current Uses: Industrial and Consumer Products

PFOA

- Cooking surfaces (Teflon)
- Fire fighting foams
- Toothpaste, Shampoos, cosmetics
- Polishes and waxes
- Electronics
- Lubricants/surfactants/emulsifiers
- Pesticide
- Plumbing Tape
- Food containers and contact paper
- Textiles (Gore-Tex) and Leather
- Paints, varnishes, sealants
- Cleaning products
- And more…

PFOS

- Metal plating and finishing
- Fire fighting foams
- Photograph Development
- Semiconductor industry
- Aviation Fluids
- Flame repellants
- Packaging Papers
- Oil and Mining
- Stain repellants on carpets and upholstery (e.g. Stainmaster, ScotchGard)
- Cleaning products
- Paints, varnishes, sealants
- Leathers, textiles
- And more…

U.S. Production

- PFOS and PFOA are the two PFAS that have been produced in the largest amounts in the U.S since 1950. Both PFOA and PFOS have been phased out of production in the U.S. and replaced by shorter chain PFAS or other compounds.
  - In 2000-2002, PFOS was voluntarily phased out of production in the U.S. by its primary manufacturer, 3M. EPA has issued regulations to require notification before any new future manufacturing, including importation of PFOS and its precursors. A limited set of existing uses are not subject to these regulations because they were ongoing at the time of the regulation.
  - In 2010, eight companies entered into a voluntary agreement to phase out production of PFOA and longer chain chemicals that degrade to PFOA by the end of 2015. There are notice requirements for use on imported carpets and some specialty uses are ongoing.

- Production is still ongoing in other countries, and thus, importation of products containing both compounds is possible.

Environmental Occurrence Examples

- Manufacturing sites
  - DuPont, Diakin, 3M, Ashai, Clarient, etc.
- Industrial use sites
  - Dispersion processors including Saint-Gobain sites (Hoosick Falls)
  - Glass/Cloth Coating
  - Manufacturing and Formulating Coating Products
  - Metal Coating
  - Additives
  - Film and Film Coating Manufacturing
  - Impregnated Felt Cloth
  - Fluoropolymer Fiber Production
- Industrial and municipal waste sites
  - Landfills
  - Waste water treatment plants (Industrial and Municipal)
  - Land application of biosolids
- Fire/crash training areas
  - FAA airports
  - Federal Facilities

Process for Development of Lifetime HAs

- **2014 Public Panel Peer Review**
  - Followed EPA's 2013 *Conflict of Interest Review Process for Contractor-Managed Peer Reviews of EPA HISA and ISI Documents.*
    - Three Federal Register Notices: 1) released draft documents for 60-day public comment period and solicited panel nominations, 2) published interim list of panel members for public comment, and 3) announced final panel and meeting details.
  - Panel included 7 experts in the following areas: epidemiology, toxicology (liver, immune, neurological and reproductive and developmental effects), membrane transport, risk assessment, pharmacokinetic models, and mode-of-action for cancer and noncancer effects.
  - Public comments on the draft documents were provided to the panel prior to the panel meeting in August 2014.

Summary of Health Effects

- PFOA and PFOS health effects information is available from animal studies and human epidemiology studies.
- Animal studies were used quantitatively to develop candidate RfDs. Human epidemiology studies were used as additional supporting lines of evidence.
- Studies indicate that PFOA and PFOS exposure results in multiple health effects including: developmental effects, effects on serum lipids and total cholesterol, liver and kidney effects, immune effects, reproductive effects, and cancer.
- Under EPA's Cancer Guidelines there is *suggestive* evidence of carcinogenic potential for both PFOA and PFOS.
  - PFOA-Positive association for kidney and testicular cancers from epidemiology literature and liver, testicular, and pancreatic tumors in rats.
  - PFOS-No positive associations from epidemiology literature and evidence of liver adenomas and thyroid in rats (lacked dose-response).

Reference Dose (RfD) Selection

- EPA modeled average serum values using a peer-reviewed pharmacokinetic model (rat, mouse, and monkey) developed by EPA ORD.
  - **PFOA:** EPA modeled data from 6 studies for effects on development (delayed ossification and accelerated puberty, pup body weight; adult body and kidney weight); liver; and immune system.
  - **PFOS:** EPA modeled data from 6 studies for effects on development (pup body weight, neurodevelopment, pup survival) and liver.

- For both PFOA and PFOS, the RfDs based on multiple adverse effects resulting from short-term and longer-term exposures fall within a narrow range.

- EPA selected the most sensitive RfD based on developmental effects to calculate a health advisory protective for the general population and sensitive lifestages.

Critical Studies Selected as Basis for RfDs

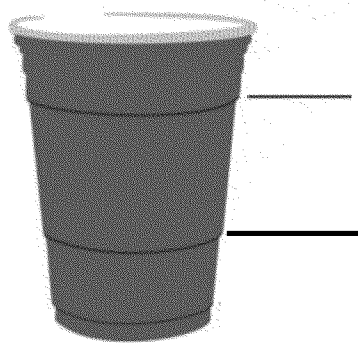
- PFOA
  - Lau et al., 2006
    - Developmental toxicity study
    - Dosing throughout pregnancy gestational days 1-17; pups sacrificed at weaning (e.g., lactational exposure included)
  - Decreased ossification in proximal phalanges and accelerated puberty in male pups
  - RfD derived from a LOAEL and a total uncertainty factor of 300
  - **RfD = 0.00002 mg/kg/d**
- PFOS
  - Luebker et al., 2005b
    - 2-generation reproductive toxicity study
    - Dosing premating and throughout pregnancy and lactation for 2 generations
  - Decreased body weight and weight gain in pups
  - RfD derived from a NOAEL and a total uncertainty factor of 30
  - **RfD = 0.00002 mg/kg/d**

Support from Human Epidemiology Studies

- There is a significant body of epidemiology data for PFOA and PFOS.
- The epidemiology data provide support for the identification of hazards observed following exposure to PFOA and PFOS in the animal studies and for their human relevance (i.e., developmental effects including low birth weight).
- Because of uncertainties associated with use of the epidemiological data they were not used quantitatively in the derivation of the HA at this time. EPA used the epidemiological data as a line of evidence to support the assessment.

PFOA	PFOS
• Increased serum lipids (C8 Panel) • Increased liver enzymes and decreased bilirubin • Low birth weight • Immunological effects (suppressed vaccine response) • Pregnancy induced hypertension (C8 Panel) • Thyroid disorders (C8 Panel) • Ulcerative colitis (C8 Panel) • Cancer (testes, kidney) (C8 Panel)	• Increased serum lipids • Low and mean birth weight • Immunological effects (suppressed vaccine response) • Thyroid effects

Relative Source Contribution (RSC)



RSC of 80%-Exposure is primarily from drinking water; reserve 20% of RfD to account for exposure through other sources (e.g., dust, air, soil, etc.)

RSC of 20%-Exposure is primarily through other sources (e.g., dust, air, soil, etc.); reserve 20% of RfD to account for exposure via drinking water.

- EPA derived an **RSC of 20% for PFOA and PFOS** for the national HA based on available occurrence information and considering the environmental persistence of these compounds
  - CDC data provide evidence of broad exposure to PFAS from multiple sources.
  - Currently, diet is the major source of PFOA and PFOS:
    - Food products including fish, snack foods, vegetables grown in contaminated soils, and meat and dairy products from exposed grazing animals
    - Food packaging products and use of Teflon cookware
  - Contaminated drinking water
  - Indoor dust is another major source (especially to children) from treated carpets and furniture/textiles in homes, offices, automobiles.
  - Other sources of legacy exposure or exposure to precursors: soils, air, clothing, cosmetics, cleaning materials, etc.

Lifetime HA Calculation for PFOA and PFOS

$$\text{Lifetime HA} = \frac{\text{RfD} \times \text{RSC}}{\text{DWI/BW}}$$

Where:

HA = Health Advisory

RfD = Reference Dose [0.00002 mg/kg/d]

RSC = Relative Source Contribution [20%]

DWI/ BW = DWI adjusted by BW for lactating women [0.054 L/kg]

$$\text{Lifetime HA} = \frac{0.00002 \text{ mg/kg/d} \times 0.2}{0.054 \text{ L/kg}}$$

Lifetime HA = 0.00007 mg/L

= 0.07 µg/L

Lifetime HA and Application

- **The Lifetime HAs are based on developmental effects resulting from exposures that occur during pregnancy and lactation (nursing) and are protective for all other health effects (non-cancer and cancer) that may occur during a lifetime of exposure to these chemicals in drinking water.**
  - For developmental effects, a single exposure at a critical time in development may produce an adverse outcome, i.e., repeated exposure is not a necessary prerequisite for toxicity to be manifested (US EPA 1991). These effects (i.e., low birth weight) can impact an individual over a lifetime.

- PFOA and PFOS are extremely persistent in both the human body and the environment; thus, even a short-term exposure results in a body burden that persists for years and can increase if additional exposure occurs later.

Lifetime HA and Application

- Because the critical effects identified are developmental effects and can potentially result from a short-term exposure during a critical period of development, the Lifetime HAs apply to both short term (weeks to months), such as the time periods during pregnancy and nursing and bottle feeding, as well as chronic (lifetime) exposure scenarios.

- Because the RfDs for both PFOA and PFOS are based on developmental effects and are numerically identical, where these chemicals co-occur in drinking water at the same time, we recommend that the HA be applied to the sum of the concentrations of PFOA and PFOS.
  - EPA has not evaluated the toxicity of other PFAS at this time.

Appendix-Additional Slides

Candidate RfD Values – PFOA

Selected Quantification Results from Critical Studies

Reference	Endpoint	PK-HED (mg/kg/day)	UF_H	UF_A	UF_L	UF_S	UF_D	Total	RfD (mg/kg/day)
Palazzolo et al. 1993	rat liver effects	0.0044 (NOAEL)	10	3	1	1	1	30	0.00015
Dewitt et al. 2008	mouse immune effects	0.0054 (NOAEL)	10	3	1	10	1	300	0.00002
Lau et al. 2006	**mouse delayed ossification and early male puberty**	**0.0056 (LOAEL)**	**10**	**3**	**10**	**1**	**1**	**300**	**0.00002**
Butenhoff et al., 2004	rat adult body and kidney weight	0.0064 (LOAEL)	10	3	10	1	1	300	0.00002
Wolfe et al 2007 (17 days)	mouse pup body weight	0.0115 (LOAEL)	10	3	10	1	1	300	0.00004
Wolfe et al 2007 (11 days)	mouse pup body weight	0.0134 (LOAEL)	10	3	10	1	1	300	0.00004

Candidate RfD Values – PFOS

Selected Quantification Results from Critical Studies									
Reference	**Endpoint**	**PK-HED (mg/kg/day)**	**UF_H**	**UF_A**	**UF_L**	**UF_S**	**UF_D**	**Total**	**RfD (mg/kg/day)**
Seacat et al. 2002	monkey liver effects	0.0031 (NOAEL)	10	3	1	1	1	30	0.0001
Seacat et al. 2003	rat liver effects	0.0013 (NOAEL)	10	3	1	1	1	30	0.00004
Lau et al. 2003	rat pup survival	0.0014 (NOAEL)	10	3	1	1	1	30	0.00005
Butenhoff et al. 2009	rat neuro effects	0.00084 (NOAEL)	10	3	1	1	1	30	0.00003
Luebker et al. 2005b	**rat pup weight**	**0.00051 (NOAEL)**	**10**	**3**	**1**	**1**	**1**	**30**	**0.00002**
Luebker et al. 2005a	rat pup weight	0.0016 (LOAEL)	10	3	3	1	1	100	0.00002

To: Huff, Lisa[Huff.Lisa@epa.gov]; Behl, Betsy[Behl.Betsy@epa.gov]; Buckley, Katherine[Buckley.Katherine@epa.gov]
From: Strong, Jamie
Sent: Wed 6/1/2016 3:01:41 PM
Subject: RE: Australia PFC Discussion
PFOA-PFOS-OW HAs 06 01 2016 FINAL.ppt

With revised cover slide, my apologies. Last version I promise. I will bring copies.

Jamie

From: Strong, Jamie
Sent: Wednesday, June 01, 2016 10:23 AM
To: Huff, Lisa <Huff.Lisa@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Buckley, Katherine <Buckley.Katherine@epa.gov>
Subject: RE: Australia PFC Discussion
Importance: High

please use this version

<< File: PFOA-PFOS-OW HAs 06 01 2016 FINAL.ppt >>

From: Huff, Lisa
Sent: Wednesday, June 01, 2016 9:31 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Buckley, Katherine <Buckley.Katherine@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: Australia PFC Discussion

Betsy and Katherine,
I see that slide 16 has written in red for OGWDW edits - I need a chance to look at this but have meetings until 11:00 and will do so after that.

Lisa Foersom Huff

Associate Branch Chief
Targeting and Analysis Branch
Standards and Risk Management Division
Office of Groundwater and Drinking Water
U.S. EPA
EPA East Bldg. Rm. 2331 C
202-566-0787

From: Behl, Betsy
Sent: Tuesday, May 31, 2016 7:42 PM
To: Buckley, Katherine <Buckley.Katherine@epa.gov>
Cc: Huff, Lisa <Huff.Lisa@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: Australia PFC Discussion

Kathrine,

Attached is a presentation that I will provide at the meeting tomorrow on the derivation of the health advisory. Please let me know if you would rather I bring paper copies to the meeting.

Thanks, Betsy << File: PFOA-PFOS-OW HAs Australian Delegation 06 01 2016 FINAL.ppt >>

-----Original Appointment-----
From: Behl, Betsy **On Behalf Of** Buckley, Katherine
Sent: Thursday, May 26, 2016 4:04 PM
To: Strong, Jamie
Subject: FW: Australia PFC Discussion
When: Wednesday, June 01, 2016 1:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB31107-1/Ronald-Reagan-Building; DCRoomRRB31107-2/Ronald-Reagan-Building; DCVideoRRBTandbergOITA/Ronald-Reagan-Building

-----Original Appointment-----
From: Buckley, Katherine
Sent: Thursday, May 26, 2016 12:37 PM
To: Buckley, Katherine; Cooke, Maryt; Scozzafava, MichaelE; Gaines, Linda; Kloss, Christopher; Kloss, Sarah; Cunningham, Lisa Bradford; Flowers, Lynn; Vandenberg, John; Bahadori, Tina; vanDrunick, Suzanne; Impellitteri, Christopher; Behl, Betsy; Huff, Lisa; Doa, Maria; Henry, Tala
Cc: Hillger, Robert; Jennings, Lynne; LaVay, Maggie; Doroski, Brenda; Koo-Oshima, Sasha; Morris, Jeff
Subject: Australia PFC Discussion
When: Wednesday, June 01, 2016 1:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB31107-1/Ronald-Reagan-Building; DCRoomRRB31107-2/Ronald-Reagan-Building; DCVideoRRBTandbergOITA/Ronald-Reagan-Building

Dear EPA Colleagues -

Below is a draft agenda for the Australian DOD meeting taking place on June 1 from 1-3pm on PFC contamination. Thanks much to all the EPA offices for their engagement and participation in this meeting!

Call- In Number:
1-866-299-3188
Access Code 202-564-6426

Suggested Tentative Agenda on June 1:
1-1:10pm Introductions
1:10-1:20pm Introduction of Australian PFC contamination experiences and treatment processes (Hartog)
1:20-1:40pm ORD - PFC-related research - (Lynn Flowers, John Vandenberg, Suzanne VanDrunick)
1:40-2:00pm OW - Health Advisory - (Betsy Behl and Linda Huff)
2:00-2:20pm OLEM - Overview of EPA Engagement on Remediation of Emerging Contaminants - w/examples from around US
(Mary Cooke and Mike Scozzafava)
2:20-2:30pm R3 Discussion of Remediation work at Willow Grove and Horsham and Warminster (TBC - by teleconference line)
2:30-2:45pm OCSPP - (TBC)
2:45-3:00pm Q&A
3:00pm Wrap Up

Australian DOD Visitors:
David Hartog
Assistant Director Remediation
PFC Environmental Management Program
Infrastructure Division (ID)
Estate & Infrastructure Group (E&IG)
Department of Defence

Ms Stacey Hannon
Director PFC Environmental Management Program
Infrastructure Division (ID)
Estate & Infrastructure Group (E&IG)
Department of Defence

Topics:
The Australian DOD visitors are hoping to visit several United States Department of Defense sites which are affected by PFC contamination, similar to their Australian Defense sites. We have directed them to USDOD for coordination of potential site visits as USDOD is the lead on this. Further to these site visits, the Australian team will be in Washington DC and plans to meet with EPA. The intent for the meeting is to have an informal discussion on matters such as, lessons learnt, policies, public consultation, health assessments, analytical chemistry, monitoring and remediation of PFC contamination.

Thanks again to all and please let me know if you have any questions.

Best wishes,
Katherine

Katherine Buckley
Eurasia and Pacific Program Manager
US EPA - OITA
Tel: 202-564-6426

To: Huff, Lisa[Huff.Lisa@epa.gov]; Behl, Betsy[Behl.Betsy@epa.gov]; Buckley, Katherine[Buckley.Katherine@epa.gov]
From: Strong, Jamie
Sent: Wed 6/1/2016 2:23:02 PM
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please use this version

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Sent: Wednesday, June 01, 2016 9:31 AM
To: Behl, Betsy <Behl.Betsy@epa.gov>; Buckley, Katherine <Buckley.Katherine@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>
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Associate Branch Chief
Targeting and Analysis Branch
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U.S. EPA
EPA East Bldg. Rm. 2331 C
202-566-0787

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Sent: Tuesday, May 31, 2016 7:42 PM
To: Buckley, Katherine <Buckley.Katherine@epa.gov>
Cc: Huff, Lisa <Huff.Lisa@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: Australia PFC Discussion

Kathrine,

Attached is a presentation that I will provide at the meeting tomorrow on the derivation of the health advisory. Please let me know if you would rather I bring paper copies to the meeting.

Thanks, Betsy << File: PFOA-PFOS-OW HAs Australian Delegation 06 01 2016 FINAL.ppt >>

-----Original Appointment-----
From: Behl, Betsy **On Behalf Of** Buckley, Katherine
Sent: Thursday, May 26, 2016 4:04 PM
To: Strong, Jamie
Subject: FW: Australia PFC Discussion
When: Wednesday, June 01, 2016 1:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB31107-1/Ronald-Reagan-Building; DCRoomRRB31107-2/Ronald-Reagan-Building; DCVideoRRBTandbergOITA/Ronald-Reagan-Building

-----Original Appointment-----
From: Buckley, Katherine
Sent: Thursday, May 26, 2016 12:37 PM
To: Buckley, Katherine; Cooke, Maryt; Scozzafava, MichaelE; Gaines, Linda; Kloss, Christopher; Kloss, Sarah; Cunningham, Lisa Bradford; Flowers, Lynn; Vandenberg, John; Bahadori, Tina; vanDrunick, Suzanne; Impellitteri, Christopher; Behl, Betsy; Huff, Lisa; Doa, Maria; Henry, Tala
Cc: Hillger, Robert; Jennings, Lynne; LaVay, Maggie; Doroski, Brenda; Koo-Oshima, Sasha; Morris, Jeff
Subject: Australia PFC Discussion
When: Wednesday, June 01, 2016 1:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: DCRoomRRB31107-1/Ronald-Reagan-Building; DCRoomRRB31107-2/Ronald-Reagan-Building; DCVideoRRBTandbergOITA/Ronald-Reagan-Building

Dear EPA Colleagues -

Below is a draft agenda for the Australian DOD meeting taking place on June 1 from 1-3pm on PFC contamination. Thanks much to all the EPA offices for their engagement and participation in this meeting!

Call- In Number:

Conference Code/ Ex. 6

Suggested Tentative Agenda on June 1:
1-1:10pm Introductions
1:10-1:20pm Introduction of Australian PFC contamination experiences and treatment processes (Hartog)
1:20-1:40pm ORD - PFC-related research - (Lynn Flowers, John Vandenberg, Suzanne VanDrunick)
1:40-2:00pm OW - Health Advisory - (Betsy Behl and Linda Huff)
2:00-2:20pm OLEM - Overview of EPA Engagement on Remediation of Emerging Contaminants - w/examples from around US
(Mary Cooke and Mike Scozzafava)
2:20-2:30pm R3 Discussion of Remediation work at Willow Grove and Horsham and Warminster (TBC - by teleconference line)
2:30-2:45pm OCSPP - (TBC)

2:45-3:00pm Q&A
3:00pm Wrap Up

Australian DOD Visitors:
David Hartog
Assistant Director Remediation
PFC Environmental Management Program
Infrastructure Division (ID)
Estate & Infrastructure Group (E&IG)
Department of Defence

Ms Stacey Hannon
Director PFC Environmental Management Program
Infrastructure Division (ID)
Estate & Infrastructure Group (E&IG)
Department of Defence

Topics:
The Australian DOD visitors are hoping to visit several United States Department of Defense sites which are affected by PFC contamination, similar to their Australian Defense sites. We have directed them to USDOD for coordination of potential site visits as USDOD is the lead on this. Further to these site visits, the Australian team will be in Washington DC and plans to meet with EPA. The intent for the meeting is to have an informal discussion on matters such as, lessons learnt, policies, public consultation, health assessments, analytical chemistry, monitoring and remediation of PFC contamination.

Thanks again to all and please let me know if you have any questions.

Best wishes,
Katherine

Katherine Buckley
Eurasia and Pacific Program Manager
US EPA - OITA
Tel: 202-564-6426

To: Miller, Gregory[Miller.Gregory@epa.gov]
From: Strong, Jamie
Sent: Wed 3/16/2016 1:23:11 PM
Subject: FW: slides for administrator briefing on PFOA/S
PFOA-PFOS-OW HAs ADMIN BRIEF 03 15 16.ppt

From: Behl, Betsy
Sent: Tuesday, March 15, 2016 7:30 PM
To: Foos, Brenda <Foos.Brenda@epa.gov>
Cc: Flaherty, Colleen <Flaherty.Colleen@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: slides for administrator briefing on PFOA/S

Please let us know if you have comments

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0788

room 5233H

To: Flaherty, Colleen[Flaherty.Colleen@epa.gov]
From: Strong, Jamie
Sent: Tue 3/15/2016 6:57:51 PM
Subject: RE: slides
PFOA-PFOS-OW HAs ADMIN BRIEF 031416 cf-JMD.ppt

Sorry this one

From: Strong, Jamie
Sent: Tuesday, March 15, 2016 2:49 PM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: slides

Changes in red.

From: Flaherty, Colleen
Sent: Tuesday, March 15, 2016 1:45 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: slides

Deliberative Process / Ex. 5

From: Strong, Jamie
Sent: Tuesday, March 15, 2016 1:36 PM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: slides

Here are Joyce's changes.

From: Flaherty, Colleen

Sent: Tuesday, March 15, 2016 12:06 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: slides

Colleen M. Flaherty | Deputy Director

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 564-5939 | ✉ flaherty.colleen@epa.gov

To: Flaherty, Colleen[Flaherty.Colleen@epa.gov]
From: Strong, Jamie
Sent: Tue 3/15/2016 6:49:15 PM
Subject: RE: slides
PFOA-PFOS-OW HAs ADMIN BRIEF 031416 cf-JMD.ppt

Changes in red.

From: Flaherty, Colleen
Sent: Tuesday, March 15, 2016 1:45 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: slides

Deliberative Process / Ex. 5

From: Strong, Jamie
Sent: Tuesday, March 15, 2016 1:36 PM
To: Flaherty, Colleen <Flaherty.Colleen@epa.gov>
Subject: RE: slides

Here are Joyce's changes.

From: Flaherty, Colleen
Sent: Tuesday, March 15, 2016 12:06 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: slides

Colleen M. Flaherty | **Deputy Director**

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 564-5939 | ✉ flaherty.colleen@epa.gov

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Mon 3/14/2016 3:18:50 PM
Subject: slides
PFOA-PFOS-OW HAs ADMIN BRIEF 031416.ppt

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Fri 3/4/2016 8:06:52 PM
Subject: RE: Take a look at these Qs and As
QA PFOA PFOS Master List 3 4 16 JBS.docx

Deliberative Process / Ex. 5

From: Harper, Ashley
Sent: Friday, March 04, 2016 1:12 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: Take a look at these Qs and As

Hey Jamie, can you please take a look at these. We have added some more since last you looked

Ashley S. Harper | **Communications Specialist**

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | ✉ harper.ashley@epa.gov

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Fri 2/26/2016 8:35:24 PM
Subject: Q&A PFOA PFOS
QA PFOA PFOS Sent to Jamie for revision 2 26 16 .docx

Deliberative Process / Ex. 5

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Sat 2/13/2016 6:44:16 PM
Subject: Fwd: Q&A for PFOS and PFOA for review
New additional QandA from Cara JBS021016 LH 2 12.docx
ATT00001.htm
QandA PFOA PFOS 011916 LH 2 12 16.docx
ATT00002.htm

Sent from my iPhone

Begin forwarded message:

From: "Huff, Lisa" <Huff.Lisa@epa.gov>
Date: February 12, 2016 at 5:58:39 PM EST
To: "Strong, Jamie" <Strong.Jamie@epa.gov>
Cc: "Christ, Lisa" <Christ.Lisa@epa.gov>, "Wadlington, Christina" <Wadlington.Christina@epa.gov>
Subject: RE: Q&A for PFOS and PFOA for review

Jamie,

I reviewed the Qs and As and made some comments in track changes. There are still some unanswered questions that it is noted should be directed to other offices e.g. OLEM.

Christina is working on risk communication materials for PFOA and PFOS too so I'm cc'g her to share info and make sure there isn't anything contradictory in these Qs and As from what she is developing (particularly Q10-13).

Lisa Foersom Huff

Associate Branch Chief

Targeting and Analysis Branch

Standards and Risk Management Division

Office of Groundwater and Drinking Water

U.S. EPA

EPA East Bldg. Rm. 2331 C

202-566-0787

From: Strong, Jamie
Sent: Wednesday, February 10, 2016 11:22 AM
To: Huff, Lisa <Huff.Lisa@epa.gov>
Subject: Q&A for PFOS and PFOA

Lisa,

Have you all had a chance to look at the Q&As Ashley Harper, HECD comms, sent to you? Our comms package is due to go up the chain next week I believe.

Thanks,

Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Wed 2/10/2016 4:19:28 PM
Subject: RE: Please review the questions
New additional QandA from Cara JBS021016.docx

Haven't talked to Lisa Huff. I will ask her. Here are my responses, most are for other folks. Rick Stevens in HECD is the biosolids person to talk to about that question. Sorry not much help.

From: Harper, Ashley
Sent: Tuesday, February 09, 2016 2:50 PM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: Please review the questions

Jamie, please review these questions and answer the ones that HECD can, afterward I will send them down to OGWDW. Have you had a chance to talk to Lisa Huff? I haven't heard anything from them so I am not even sure she got them!

From Cara:

Hi Ashley,

Deliberative Process / Ex. 5

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | harper.ashley@epa.gov

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Wed 2/3/2016 6:05:31 PM
Subject: RE: briefing with admin on PFOA PFOS
APPENDIX F Briefing Memo PFOA PFOS 02032016.docx

From: Harper, Ashley
Sent: Wednesday, February 03, 2016 11:01 AM
To: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: briefing with admin on PFOA PFOS

No, because you haven't had the chance to review the memo. I have re-attached the memo for you.

Ashley S. Harper | Communications Specialist

Health and Ecological Criteria Division | Office of Water

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW, Washington, DC 20460

☎ Phone: (202) 566-0532 | harper.ashley@epa.gov

From: Strong, Jamie

Sent: Wednesday, February 03, 2016 9:18 AM
To: Harper, Ashley <harper.ashley@epa.gov>
Subject: briefing with admin on PFOA PFOS

Ashley,
Did we submit this yet?

Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Fri 1/29/2016 7:34:08 PM
Subject: FW: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses
PFOA Media Inquiries_1.28.16.cw2.docx

From: Wadlington, Christina
Sent: Thursday, January 28, 2016 1:00 PM
To: Burneson, Eric <Burneson.Eric@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Will do. Thanks Eric.

I will send forward the attached.

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

From: Burneson, Eric
Sent: Thursday, January 28, 2016 12:46 PM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>
Cc: Lalley, Cara <Lalley.Cara@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: Re: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Deliberative Process / Ex. 5

Sent from my iPhone

On Jan 28, 2016, at 12:14 PM, Wadlington, Christina <Wadlington.Christina@epa.gov> wrote:

Thanks Cara, I updated this with your most recent comments.

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

From: Wadlington, Christina
Sent: Thursday, January 28, 2016 12:02 PM

To: Lalley, Cara <Lalley.Cara@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Cara,

Attached is a draft response based on our discussion. Please let me know if this works.

Greg,

Do you think we should add anything about UCMR4? If not, we can leave out.

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

From: Lalley, Cara
Sent: Thursday, January 28, 2016 11:29 AM
To: Carroll, Gregory <Carroll.Gregory@epa.gov>; Wadlington, Christina

<Wadlington.Christina@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: RE: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Thanks, Greg. Christina, I am concerned that there are two different answers to the same question:

Apparently this Q&A is answering the AP question to Region 2:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

From: Carroll, Gregory
Sent: Thursday, January 28, 2016 11:07 AM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Christina:

I looked this over, mostly from a UCMR standpoint, and have only a couple of comments:

Deliberative Process / Ex. 5

Bottom-line: No specific edits to propose.

Greg

From: Wadlington, Christina
Sent: Thursday, January 28, 2016 10:36 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Provided is a document that consolidates all the PFOA inquiries received in the last few days. These include input from Region 2.

Can you please review asap? Our deadline is 1130am. I apologize for the quick turnaround.

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

<PFOA Media Inquiries_1.28.16.cw.docx>

To: Lalley, Cara[Lalley.Cara@epa.gov]
From: Strong, Jamie
Sent: Thur 1/28/2016 4:29:48 PM
Subject: Re: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

I sent comments on the HA text.

From: Lalley, Cara
Sent: Thursday, January 28, 2016 11:28 AM
To: Carroll, Gregory; Wadlington, Christina; Christ, Lisa; Huff, Lisa; Hautman, Dan
Cc: Burneson, Eric; Strong, Jamie
Subject: RE: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Thanks, Greg. Christina, I am concerned that there are two different answers to the same question:

Apparently this Q&A is answering the AP question to Region 2:

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

From: Carroll, Gregory
Sent: Thursday, January 28, 2016 11:07 AM
To: Wadlington, Christina <Wadlington.Christina@epa.gov>; Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: RE: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Christina:

I looked this over, mostly from a UCMR standpoint, and have only a couple of comments:

Deliberative Process / Ex. 5

Bottom-line: No specific edits to propose.

Greg

From: Wadlington, Christina
Sent: Thursday, January 28, 2016 10:36 AM
To: Christ, Lisa <Christ.Lisa@epa.gov>; Huff, Lisa <Huff.Lisa@epa.gov>; Carroll, Gregory <Carroll.Gregory@epa.gov>; Hautman, Dan <Hautman.Dan@epa.gov>
Cc: Burneson, Eric <Burneson.Eric@epa.gov>; Lalley, Cara <Lalley.Cara@epa.gov>
Subject: Consolidated Media Inquires; due TODAY 1130AM, PFOA and Region 2 Responses

Provided is a document that consolidates all the PFOA inquiries received in the last few days. These include input from Region 2.

Can you please review asap? Our deadline is 1130am. I apologize for the quick turnaround.

Christina Wadlington

Communications Director

Office of Ground Water and Drinking Water

U.S. Environmental Protection Agency

Tel: 202.566.1859

Email: wadlington.christina@epa.gov

To: Harper, Ashley[harper.ashley@epa.gov]
From: Strong, Jamie
Sent: Wed 1/20/2016 1:25:17 PM
Subject: Q&As PFOA and PFOS
QandA PFOA PFOS 011916.docx

Here is the first crack at this…Joyce weighed in on a few.

Jamie

Jamie Strong, Chief Human Health Risk Assessment Branch

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0056

fax: 202.566.1140

To: Wathen, John[Wathen.John@epa.gov]
Cc: Behl, Betsy[Behl.Betsy@epa.gov]
From: Strong, Jamie
Sent: Tue 1/19/2016 1:26:06 PM
Subject: FW: PFOA HESD for final internal agency review
PFOA Post External Review 010816.docx
PFOA PFOS EPR REPORT AUG 2014.pdf

And PFOA

From: Behl, Betsy
Sent: Friday, January 08, 2016 10:46 AM
To: Cantilli, Robert <cantilli.robert@epa.gov>; Fegley, Robert <Fegley.Robert@epa.gov>; Foos, Brenda <Foos.Brenda@epa.gov>; Cooke, Maryt <Cooke.Maryt@epa.gov>; 'Focazio, Michael' <mfocazio@usgs.gov>; Henry, Tala <Henry.Tala@epa.gov>
Cc: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>; Clark, Becki <Clark.Becki@epa.gov>; Thomas, Russell <Thomas.Russell@epa.gov>; Burneson, Eric <Burneson.Eric@epa.gov>; Strong, Jamie <Strong.Jamie@epa.gov>
Subject: PFOA HESD for final internal agency review
Importance: High

Many thanks to you all for your review of our PFOS document. We are expecting comments by Monday January 11, so that we can keep to our schedule to publish final HAs. As you can imagine, the recent report of PFCs in drinking water in Hoosick Falls, NY and articles in the press have heightened interest in EPA finalizing these HAs as well as our timetable.

Attached above is the final draft PFOA Health Effects Support Document (HESD) for your review. This is the second and last HESD for PFCs which we requesting you to review. Like the PFOS document, this document has been spell checked but has not been through a final technical edit. We plan to address your comments and have then have a final technical edit done prior to the issuance of the Health Advisories (HAs). We are also attaching the external peer review comments, for your information.

This HESD provides the key science support for the point of departure for PFOA that will be used in the HA calculation. OW would like to release the HAs in March, which is coming up fast. This is our plan for internal review of all the PFC documents:

•□□□□□□□□ PFOS HESD: begins internal review 12/17/2015. **Comments due 1/11/2016**

•□□□□□□□□ PFOA HESD: begins internal review 1/8/2016. Comments due 1/29/2016 (3 weeks) (current document)

•□□□□□□□□ PFOA and PFOS HAs: begin internal review late January/early February. Comments due 2 weeks later.

Many thanks in advance for your comments, Betsy

Elizabeth (Betsy) Behl, Director

Health and Ecological Criteria Division, 4304-T

Office of Science and Technology, Office of Water

United States Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington DC 20460

phone: 202.566.0788

Peer Review Summary Report

External Peer Review of EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

November 17, 2014

Peer Reviewers:

James V. Bruckner, Ph.D.
Deborah A. Cory-Slechta, Ph.D.
Jamie C. DeWitt, Ph.D.
Jeffrey W. Fisher, Ph.D.
William L. Hayton, Ph.D.
Matthew P. Longnecker, Sc.D, M.D
Angela L. Slitt, Ph.D.

Contract No. EP-C-13-010
Task Order 2013-06

Prepared for:
U.S. Environmental Protection Agency
Office of Science and Technology/Office of Water
Health & Ecological Criteria Division
1200 Pennsylvania Avenue, NW (MC4304T)
Washington, DC 20460

Prepared by:
Versar, Inc.
6850 Versar Center
Springfield, VA 22151

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EXECUTIVE SUMMARY

Versar, Inc. (Versar), a contractor for the Environmental Protection Agency (EPA), coordinated an external peer review of EPA's draft health effects documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS), and organized a two-day public peer review meeting in Arlington, Virginia on August 21 and 22, 2014. The peer review of EPA's draft health effects documents was initiated with a pre-meeting written peer review managed by Versar and conducted by seven independent expert peer reviewers. The role of the peer reviewers was to evaluate the scientific and technical merit of the draft documents and provide their responses to 12 charge questions. Peer reviewers were charged only with evaluating the quality of the science included in EPA's draft health effects documents and were not charged with making any regulatory recommendations or reaching consensus in either their deliberations or written comments. The two-day peer review meeting, which directly followed the written peer review period, was held to discuss the scientific basis supporting EPA's draft health effects documents and to provide members of the public with an opportunity to observe the peer reviewer deliberations.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. In addition, EPA provided background information on the draft documents and approach used in the development of the documents. Following opening remarks by Versar and EPA, the peer reviewers began their discussions on the PFOA draft document, moderated by the Chair, Dr. Deborah Cory-Slechta. The discussions centered on individual responses to EPA's 12 charge questions. Additionally, some comments submitted to the public docket prior to the meeting were also discussed. The second day of the meeting began with brief remarks from Versar followed by discussions focusing on the PFOS draft document.

The reviewers began the discussion on the first day with the recognition of the significant amount of data that is available for both PFOA and PFOS and thus to be considered by the EPA for incorporation into the document and for the ultimate derivation of reference dose (RfD) values. In general, the reviewers commended EPA in doing a very good job of pulling together this significant and extensive body of information and of condensing it into its most critical pieces for the derivation of RfD values. This was especially the case given that there is significant human and animal data available for both chemicals, as well as inconsistencies in the data.

The reviewers did offer numerous suggestions for improving the documents, many of which are applicable to both PFOA and PFOS. In general, the suggestions relate to the statement of the problem and defining the database that was utilized, clarity and ease of presentation, and transparency of the reports, as well as to issues of modeling, use of human data, and liver weight increases as the most sensitive endpoint. These comments are summarized below, but please note that this does not reflect a consensus or group perspective.

- All reviewers agreed that it would be extremely useful to include an opening section of the document describing in some detail the literature that was reviewed. More specifically, this would include a description of the dates that were included in the

literature review, whether requirements for peer-reviewed materials were imposed, and what criteria were used in eliminating studies from consideration. This would assist in identifying studies that should potentially have been included. Many additional studies of importance were suggested for review at the meeting by the peer reviewers.

- The reviewers also agreed that there are some significant studies that have been published recently on PFOA and PFOS that may be relevant, and these should be included in the documents during the current revisions.
- Reviewers also felt that the Tables in the documents could be made much more useful to readers with the addition of columns that included more study details. This would minimize the amount of back-and-forth to the text that was required to assess conclusions.
- Additionally, there was a strong agreement that the Hazard Identification section of the documents should include a more systematic review of study strengths and limitations. These were noticeably absent in the human studies, where all studies were considered equivalent but also applicable to animal studies.
- Reviewers also felt that each Chapter should include introductory paragraphs, as well as concluding paragraphs, that would provide better integration of the material across the Chapters, as well as summarize the conclusions arrived at from the text in the Chapter. This would also facilitate the ability of readers to follow the presentations provided in Chapter 5 of the derivation of RfDs.
- As pointed out at the peer review meeting, the authors would be well advised to base these documents on the new documents being produced by EPA's National Center for Environmental Assessment (NCEA) for the Integrated Risk Information System (IRIS) program. While the reviewers recognize that the PFOA and PFOA health effect documents will not be used specifically for the same purpose, they will still likely be held to the same standards of presentation, clarity and transparency and thus, the new NCEA formats provide good models to follow.
- With respect to content of the documents, there was initial confusion around some of the modeling outcomes and assumptions based on values that were provided in the documents. However, following explanation from EPA personnel in response to clarifying questions from the reviewers at the peer review meeting, it became clear that there were errors in these values and once these were corrected, concerns about the specific values used in some modeling were allayed.
- Even with the corrections to the modeling, there were residual concerns among reviewers based on toxicokinetic properties of these chemicals, with respect to applying the same candidate RfD values to both short and long-term exposures, which in animal studies ranged from 11 to 182 days with reviewers expressing a need for this to be re-considered.
- There were mixed comments by reviewers with respect to the decision not to use human data in the derivation of RfD values. All reviewers generally agreed that the rationales provided for the exclusion of the human data were not actually appropriate, as it is certainly not the case that such use would be precluded by the fact that there were

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multiple and not sole exposures to either PFOA or PFOS. There was discussion as to the possibility of whether human data could be utilized in these assessments, and that ranged from an opinion that these data would not be useful to the view that it might be possible to use these data, despite the absence of information on route of exposure. Collectively, the range of opinions suggests that the issue should be revisited, and that appropriate rationales should be provided for the decision that is reached in the revised version.

- For both PFOA and PFOS, the RfDs were ultimately based on increases in liver weights in animal studies. There was significant discussion among reviewers as to the appropriateness of this endpoint for the derivation of the RfDs. That range of opinion spanned from an interpretation that these did constitute adverse effects in that they are a direct effect of a chemical exposure, whereas other reviewers saw these as adaptive effects. Collectively, the range of opinions suggests that the issue should be revisited, and that appropriate rationales should be provided for the decision that is reached in the revised version.

Following the meeting, peer reviewers were given additional time to complete their individual written reviews, which were submitted to Versar upon completion. These final written comments are contained in Sections III, IV, V of this report and fall into three categories: general impressions, responses to charge questions, and specific observations. Written peer review comments, as well as comments submitted to the docket by members of the public, will be considered by EPA as it revises the draft documents.

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I. INTRODUCTION

I.1 Background on Draft Health Effects Documents

On February 28, 2014, the EPA's Office of Water (OW) announced in the Federal Register the release of the draft health effects documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS) for purposes of public comment (scientific views) and peer review (http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf). The draft documents and charge questions were prepared by the Health and Ecological Criteria Division (HECD), within EPA's OW, in order to support future regulatory evaluations and decisions. EPA will consider the public comments and peer reviewer comments when revising the documents. Once the PFOA and PFOS health effects documents are finalized, they will be utilized to develop lifetime health advisory values for each chemical. PFOA and PFOS are listed on the third Contaminant Candidate List (CCL3)[1] and both chemicals are currently being monitored under the third Unregulated Contaminant Monitoring Rule (UCMR3)[2].

I.2 Peer Review Process

Consistent with guidelines for the peer review of highly influential scientific assessments, Versar, an EPA contractor, was tasked with assembling six to seven scientific experts to evaluate the draft PFOA and PFOS documents. The purpose of the peer review was to provide a documented, independent, and critical review of the draft health effects documents, and identify any necessary improvements to the documents prior to being published. In assembling these peer reviewers and coordinating the peer review, Versar was charged with evaluating the qualifications of peer review candidates, conducting a thorough conflict of interest (COI) screening process, independently selecting the peer reviewers, distributing review materials, maintaining contact with the peer reviewers, organizing and hosting the public peer review meeting, and developing a final peer review report.

The peer review selection process was initiated with a three-week public nomination period that was held from February 28, 2014 to March 21, 2014, as documented in the Federal Register on February 28, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-02-28/pdf/2014-04455.pdf). During this period, members of the public were able to nominate scientific experts with knowledge and experience in one or more of the following areas: (1) epidemiology, (2) toxicology (liver effects, immunotoxicity, neurotoxicity, developmental and reproductive toxicology, etc.), (3) membrane transport, (4) human health risk assessment, (5) pharmacokinetic models, and (6) mode-of-action for cancer and noncancer effects. Concurrently, Versar conducted an independent search for qualified scientific experts to augment the list of publically-nominated candidates. In total, Versar evaluated 29 interested and available candidates who were either nominated by the public (n=18) or identified by Versar (n=11).

[1] CCL3 is a list of contaminants that are currently not subject to any proposed or promulgated national primary drinking water regulations, that are known or anticipated to occur in public water systems, and which may require regulation under the Safe Drinking Water Act (SDWA). Additional information about the CCL3 can be found at the following website: http://water.epa.gov/scitech/drinkingwater/dws/ccl/ccl3.cfm.

[2] EPA uses the Unregulated Contaminant Monitoring (UCM) program to collect data for unregulated contaminants suspected to be present in drinking water. Results from UCMR3 can be examined as they become available at the following website: http://water.epa.gov/lawsregs/rulesregs/sdwa/ucmr/ucmr3/.

Versar considered and screened all 29 candidates against the selection criteria described in the Federal Register dated February 28, 2014, which included: (1) having demonstrated expertise in the areas described above, based on information in their submitted resume, biographical sketch and/or current publications, (2) being free of any COI and the appearance of the lack of impartiality, and (3) being available to participate in-person in a two-day peer review meeting in the Washington DC area in the July or August 2014 timeframe. Following the screening process, Versar narrowed the list of potential reviewers to 15 candidates and provided to EPA the names of the candidates selected by Versar to be on the interim list. Additionally, information on the 15 candidates, including their professional affiliations, expertise, education, and professional experience were provided for the interim list and published in the Federal Register on April 30, 2014 (http://www.gpo.gov/fdsys/pkg/FR-2014-04-30/pdf/2014-09888.pdf). The Federal Register also requested the public to submit relevant information or documentation on the interim list of candidates that Versar should consider during the evaluation process of selecting the final six to seven reviewers.

Following the close of the public comment period on the interim list of potential reviewers, Versar re-evaluated each interim candidate's credentials to select the experts who, collectively, provided expertise spanning the multiple subject matter areas covered in the draft documents and provided a balance of perspectives. In addition, Versar evaluated the availability of each candidate to ensure all final peer reviewers were available on the same days for the meeting in the selected timeframe. Once the evaluation process was completed, Versar narrowed the interim list of 15 candidates and selected the seven final peer reviewers. In addition, Versar selected Dr. Deborah Cory-Slechta as Chair of the peer review meeting due to her expertise in toxicology as well as her strong record of chairing and participating in peer review panels, scientific meetings, and workshops. A list of the final seven peer reviewers who participated in this review is provided below. In addition, each reviewer's biographical sketch is included in Appendix A.

Following the selection process, Versar distributed EPA's draft PFOA and PFOS documents and 12 charge questions (see Section II) to the peer reviewers. The peer reviewers were asked to evaluate the scientific and technical merit of the draft documents and provide their responses to the 12 charge questions. This included evaluating the appropriateness of the quality, accuracy, and relevance of the data in the documents. Peer reviewers were not charged with making any regulatory recommendations or reaching consensus in either their written comments or public deliberations. In addition to being provided the draft documents and charge questions, comments submitted to EPA's public docket (Docket ID number EPA–HQ–OW–2014–0138) during each document's 60-day public comment period were provided to the peer reviewers ahead of the meeting for their consideration. Also, a brief summary of the public comments was developed by Versar and provided to the reviewers. However, peer reviewers were not asked to evaluate or respond to comments submitted to the docket.

Versar managed the pre-meeting peer review period, which provided the peer reviewers approximately two months to evaluate the draft health effects document and complete their written reviews. Following receipt of the peer reviewers' draft comments, Versar compiled the comments into a pre-meeting peer review report and distributed them to the peer reviewers and

EPA to prepare for the public peer review meeting. These preliminary responses to the charge questions formed the basis of reviewer discussions on Days 1 and 2 of the public meeting.

Peer Reviewers:

James V. Bruckner, Ph.D.
University of Georgia

Deborah A. Cory-Slechta, Ph.D.
University of Rochester School of Medicine and Dentistry

Jamie C. DeWitt, Ph.D.
East Carolina University

Jeffrey W. Fisher, Ph.D.
U.S. Food & Drug Administration

William L. Hayton, Ph.D.
The Ohio State University

Matthew P. Longnecker, Sc.D, M.D
National Institute of Environmental Health Sciences

Angela L. Slitt, Ph.D.
University of Rhode Island

I.3 Peer Review Meeting

On August 21 and 22, 2014, Versar convened a public peer review meeting in Arlington, Virginia. This meeting was held to discuss the scientific basis supporting EPA's draft health effects documents and to provide members of the public with an opportunity to observe the peer reviewer deliberations. The meeting followed both the documents' public comment period, during which members of the public were able to submit written comments, and the pre-meeting written peer review period, during which the seven selected peer reviewers evaluated EPA's draft health effects documents and provided preliminary comments in response to the charge questions.

Versar managed the pre-meeting registration period, which allowed members of the public to register to attend the meeting in person or remotely via teleconference and/or webinar. Members of the public were able to register online, via Versar's registration website (http://peerreview.versar.com/epa/pfoa/) as well as by telephone, email, or U.S. mail. In advance of the meeting, Versar provided all registered attendees with pre-meeting handouts, which included the agenda and logistics information.

On the first day of the meeting, Versar began by providing information on the overall peer review process and introducing the peer reviewers. In addition, EPA provided background

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information on the draft documents and approach used in the development of the documents. Following opening remarks by Versar and EPA, the peer reviewers began their discussions on the PFOA draft document, which centered on individual responses to EPA's 12 charge questions. The remainder of the day was dedicated to discussions on the PFOA document, which were moderated by the Chair, Dr. Deborah Cory-Slechta. The second day of the meeting began with brief remarks from Versar followed by discussions focusing on the PFOS draft document. Approximately 23 public observers attended the peer review meeting in person and 21 observers attended the meeting via teleconference and/or webinar. Please see Appendix B for the meeting agenda and Appendix C for a list of public attendees.

Following the public peer review meeting, peer reviewers were given additional time to complete their individual written reviews. These final written comments are contained in Sections III, IV, and V of this report. Written peer review comments, as well as comments submitted to the EPA docket by members of the public, will be considered by EPA as it revises the draft health effects documents.

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II. CHARGE TO REVIEWERS

PFOA and PFOS are environmentally persistent organic fluorocarbons (PFC) that have been identified in ambient waters, ground water, drinking water, and biosolids. They are metabolically inert but have the ability to bind to and interact with a variety of biomolecules leading to responses in living organisms. Both compounds have a substantial database of epidemiological, pharmacokinetic, toxicological and mechanistic studies. The two documents submitted for peer review include health assessment chapters that will be used 1) to provide information to drinking water treatment plant operators regarding the significance of monitoring results with respect to potential health outcomes and 2) to determine whether the perfluorinated compounds currently being monitored at Public Drinking Water Systems require regulation. The health information at that time will be accompanied with chapters on environmental fate, occurrence at public drinking water systems and occurrence in other media. The quantitative aspects of the Health Assessment documents will also be used to develop lifetime Health Advisories for both compounds.

Charge Questions

1. Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

2. Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

3. The OW concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment of the OW characterization of the data.

4. Please comment on the transparency and characterization of the epidemiological data.

5. The OW has concluded that the cancer classifications for PFOA and PFOS are most consistent with respective classifications of suggestive evidence for carcinogenicity as described the EPA Guidelines for Carcinogen Risk Assessment (pp. 2-56, 2-57). Please comment on the strengths and weaknesses of this classification.

6. Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

7. Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

8. The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

9. A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

10. The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days, and occur at comparable human equivalent dose (HED) levels. The current, draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

11. In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.

12. Please describe any suggestions you have for improving the clarity, organization, and/or transparency of the draft documents.

III. GENERAL IMPRESSIONS

James V. Bruckner

PFOA-specific comments

This is one of the most comprehensive Health Effects Documents I have reviewed. The clarity and accuracy of accounts of pertinent research reports/publications are excellent. It is obvious considerable time and efforts were devoted to its composition. If anything, the amount of detail is so great that it is difficult to distill the mass of information on each topic and capture its "essence". This is likely the result of directions the authors were given for writing the document. Some topics in the Hazard Identification section do have summarizing sentences, in which the key/critical studies and their finding(s) are integrated and conclusions reached. It would be very helpful to devote much more attention to this for more topics, perhaps as an addition to Section 4.4 Hazard Characterization.

I do have a real problem with the scientific basis and soundness of certain conclusions in the document. The primary effect of PFOA in different species is increased absolute and/or relative liver weight. These are quite modest, reversible, non-specific effects that usually are not considered toxicologically significant. Livers of mice and rats dosed with PFOA typically exhibited hypertrophy characterized by increased peroxisomes, numerous mitochondria, reduced rough endoplasmic reticulum (RER), proliferation of smooth endoplasmic reticulum (SER), and increased autophagosomes or lipid-like droplets. Such morphological changes, particularly those in RER and SER, are manifestations of microsomal enzyme induction. This is considered adaptive, rather than adverse. Hall et al. (2012) points out that activation of a battery of genes involved in xenobiotic metabolism and transport serve to maintain homeostasis by enhancing the systemic elimination of the foreign chemical. Although PFOA is very poorly metabolized, it does persistently induce microsomal enzymes and the accompanying hepatocellular morphological changes. Upregulation of genes responsible for biliary excretion may be beneficial, since excretion of bilirubin, bile acids and conjugates of toxic chemicals/metabolites would be enhanced.

There are substantial qualitative and quantitative differences in responses of rodents and humans to PPARα activation. Therefore, many of the PFOA-induced alterations in lipid metabolism/homeostasis and associated biological processes in mice will be absent or an order of magnitude less pronounced at comparable doses in humans. Many of PFOA's effects on the liver of rodents are dependent on PPARα activation, though some effects appear to be PPARα-independent. Studies in PPARα-knockout mice show activation of other nuclear receptors by PFOA, including PXR, CAR, LXRA and FXR. Bjork et al. (2011) observed markedly lower transcriptional responses of PPARα, PXR, CAR and FXR to PFOA in cultured human than in cultured rat hepatocytes. These more subtle effects lead the investigators to conclude the changes in human cells reflected an adaptive metabolic remodeling rather than overt metabolic dysregulation, or disorder occurring in rat cells. The PFOA document's authors should go into detail discussing and summarizing the relative toxicological significance of non-PPARα effects in rodents versus humans.

It is important to recognize that clearly adverse effects of PFOA are seen. Lovelass et al. (2008), Cui et al. (2009) and others have seen focal necrosis and degenerative changes in the liver of mice and rats given relatively high doses of PFOA, as well as modest elevations in serum (hepatic) enzyme activities. Wolf et al. (2008a) observed a variety of degenerative structural changes in the liver of PPARα-null mice dosed with PFOA. Sakr et al. (2007a,b) and Olsen and Zobel (2007) reported associations between serum PFOA levels and slightly elevated serum enzyme activities in some occupationally-exposed populations. The increases in enzymes may have been attributable to factors other than PFOA. In light of the foregoing, it would be preferable to utilize hepatic morphological changes in rodents and/or elevated serum enzymes as the critical effect(s), rather than increased liver weight. These are clearly adverse effects seen in both rodents and humans.

An international panel of experts (Hall et al., 2012) opined that an increase in liver weight of ≤ 150%, at doses of chemical that do not produce structural or biochemical evidence of hepatocellular damage, would not be considered adverse. Absolute and relative liver weights were not increased as much as 50% by most PFOA doses in the majority rodent and monkey studies. Perkins et al. (2004), for example, reported dose-dependent increases in liver/body weight in rats fed 1, 10, 30 and 100 ppm PFOA for 13 weeks of 0, 10, 30, and 41%, respectively. Butenhoff et al. (2002) measured increases of 17, 21 and 37.5% and relative liver weight in monkeys given 3, 10 or 30/20 mg PFOA/kg/day for 26 weeks, respectively. Liver hypertrophy of this magnitude does not warrant such a low RfD. By adhering to EPA policies of calculating a $BMDL_{10}$ and using multiple UFs, regardless of the (lack of) severity of the critical effect and relatively low level of concern about other potential health effects, the end result is a vanishingly low RfD (i.e. 0.00002 mg/kg/day). A great deal of time and effort were spent on the PFOA hazard assessment, toxicokinetic modeling and extrapolations, dose metric and POD considerations, etc. Despite all of these scientifically-credible exercises and deliberations, the end result (RfD) seems to this reviewer to have been preordained-- to be extremely low.

Logic expressed on page 5-6, in support of use of liver weight gain as a critical effect and biomarker of loss of hepatocellular homeostasis seems flawed. As pointed out in the second paragraph, liver weight changes were not observed in PFOA-treated mice with a humanized PPARα receptor. It is noted that changes in gene products that modulate lipid metabolism do occur in these mice. EPA argues that this supports adoption of increased liver weight as a biomarker/critical effect. It has not been established that these changes in gene expression are adverse, or whether they are sufficient in magnitude to significantly alter lipid metabolism. It would be expected that repeated dosing with enough of a molecule (i.e., PFOA) that resembles a fatty acid would affect expression of such genes. Reversible changes in total cholesterol, bile acids, bilirubin, etc. have been observed. It has not been established, however, whether mild fluctuations in these indices are detrimental. No increases in mortality from cerebrevascular disease or ischemic heart disease have been found in PFOA-exposed humans. How then does the concurrence of alteration of expression of such genes and of liver weight gain support the latter as toxicologically-significant effect that should be prevented by setting the RfD low enough?

PFOS-specific comments

This Health Effects Document, like that for PFOA, is quite comprehensive. Its descriptions of the many studies of PFOS are clear, quite complete, and apparently quite accurate. As with the

PFOA document, so much detail is given about many studies in the Hazard Identification section, that is difficult to compare study designs/dosage regimens/species/indices/findings/etc. and to draw conclusions. The summary tables for single and multiple studies, however, are quite helpful in this regard. It would also be very useful to have more summary statements or paragraphs at the end of each topic. These should address the scientific importance of findings, their relevance to humans; and their impact on the weight of evidence on an issue.

The hazard characterization section (4.4) is, for the most part, inclusive and balanced in its presentation and integration of findings of the more important studies in each subject area. This is true for both non-cancer and cancer effects in humans and animals. It concerns me, however, that the document's authors do not focus in the remainder of the document on science (i.e., the candidate critical effects and their relevance to human health), but merely choose the most sensitive end-points and stress how similar the RfDs are after dosimetry modeling estimates and adjustments. I am not sure how this similarity of derived points of departure and other values, calculated from dissimilar endpoints, supports or validates the final RfD.

I recommend that an additional section be written, in which the primary adverse effects of PFOS are discussed-- in terms of their relative toxicological significance, their apparent mechanism(s), their relevance to humans, their likelihood in realistic exposure scenarios, and implications of altered experimental indices to actual organ dysfunction.

I am quite concerned about the increased rat pup mortality in several studies at relatively low maternal doses, but not about reversible liver weight changes or centrilobular hypertrophy. Is the decreased pup survival in several studies at relatively low maternal doses of PFOS relevant to humans?-- Is the dose-response curve steep, as suggested by Luebker et al. (2005a), such that there would be less concern about sub-threshold doses? -- What is the most likely mode of action (pulmonary surfactant or maturation, dietary, hormonal)? -- Is decreased survival PPARα-related? -- Is the mechanism in rats relevant to other species? -- Does pup mortality occur in other species at comparable doses? -- Might there be a dose-dependent alteration of maternal-fetal partitioning of PFOS?

Deborah A. Cory-Slechta

Both documents, although the PFOA document to some degree more than PFOS, overall are more of a tabulation of studies than a critical review of studies from which a rationale is presented for a choice of studies to model and from which to derive associated RfDs. The Executive summaries are too abbreviated and do not include sufficient rationale, description and detail to provide the reader with an understanding of how decisions described in Chapter 5 were made. Since in some cases, this will be the only sections read, they could provide a more informative summary.

It would be very helpful to provide a section up front that describes all of the parameters of the literature search, including the years that are included in the document review, as well as descriptions of criteria for studies that were included vs. those that were excluded. In addition, it should be indicated whether there was a criterion that studies be peer-reviewed. This is particularly important given the voluminous size of the data base that has accumulated for these

two chemicals. Given that revisions will be done and that such documents do not get updated with any frequency, it would be good to attempt to include as much of the new pertinent literature as possible.

The section on Toxicokinetics in the documents present studies in detail, but no real conclusions; this is true of most of the sections in these documents. Chapters 3 and 4 in particular read like tabulations of studies rather than critical reviews and because of that, the documents seem disjointed and Section 5, i.e., derivation of values, tend to be difficult to read through and require constant searching back to the original chapters in which they are described. It is critical to identify the strengths and weaknesses of the various studies, and which were given weight to use in the final determinations. It would be helpful if Sections 3, 4 and 5 included an introductory paragraph describing the goal of the chapter, and that each ends with an overall summary with conclusions. The tables in these chapters also would benefit from the inclusion of additional information that ultimately permits comparisons within the Table and does not require continually returning to the text to recall the species, sample sizes, etc.

In the sections on Hazard Identification, it is useful that studies are summarized by target organ, but there are almost no conclusions and no discussions of strengths or weaknesses of studies and therefore their use or not in future decisions. In fact, one is left with the impression that all studies are equal, especially in the section describing human studies. Within Chapter 4, the sub-sections entitled "evaluative and integrative" are actually neither. Data are presented simply as positive or negative with no real discussion of the strengths and limitations and what was concluded overall. For this reason, Chapter 5 is also lacking. It provides very little in the way of rationale and conclusions. Thus, the transparency of the process is really insufficient.

Jamie C. DeWitt

The information presented throughout the documents appears to be accurate (with one minor exception noted in Table 1 of these comments) and is presented clearly. For PFOA, a reference dose (RfD) of 0.00002 mg/kg/day was determined and evidence of carcinogenicity is considered suggestive with a human equivalent dose (HED) of 0.58 mg/kg/day. The RfD was based on changes in liver weight reported as a common denominator in four rodent (three rat and one mouse) studies and carcinogenicity was based on a limited number of epidemiology studies linking kidney and testicular tumors with exposure and evidence of tumor induction in the liver, testes, and pancreas (the "tumor triad") in rats. For PFOS, a RfD of 0.00003 mg/kg/day was determined and evidence of carcinogenicity is considered suggestive but with insufficient evidence to determine human carcinogenic potential. The RfD was based on developmental neurotoxicity and changes in liver weight.

While the carcinogenicity assessment seems appropriate for the two compounds given the limitations of the data sets, changes in liver weight as a basis of both of the RfDs is questionable in terms of its significance to exposed humans. Exposure to these agents increases liver weight and hepatocellular hypertrophy in rodents (and the definition of these endpoints as "adverse" or "toxic" also is contentious); this has been demonstrated across various rodent strains and under myriad exposure paradigms. However, there is no consensus in the scientific community regarding the mechanism by which exposure to these compounds increases liver weight and

induces hepatocellular hypertrophy in rodents and whether any of the putative mechanisms are sufficient to induce hepatotoxicity in exposed humans. Proposed mechanisms include peroxisome proliferator activated receptor alpha (PPARα) activation, activation of other nuclear receptors, peroxisome proliferation (which may or may not be dependent on PPARα activation), and oxidative stress. Humans can certainly respond to PPARα agonists (i.e., fibrate drugs are used as hypolipidemic agents) and a handful of epidemiological studies of highly exposed human populations have reported associations between PFOA/PFOS and alterations in liver enzymes, but the clinical relevance of the changes to the liver enzymes reported for these studies is uncertain. These liver-related changes in humans generally occur at higher doses than required to induce changes in the livers of rodents, which occurs at relatively lower doses than other observed effects. Therefore, a critical endpoint that occurs at very low doses in rodents, has no agreed upon mechanism that may or may not be relevant in humans at relatively high doses, may not be the best choice for the basis of a RfD. Liver weight change has been reported to occur in several species, including non-human primates, and at low doses, it may be an adaptive response and not a toxicological response. While this response may be protective of human health because it is common following low dose exposure to PFOA or PFOS, other endpoints may be more relevant to humans, especially endocrine system effects, including changes to thyroid hormones and mammary gland development, and immune system effects. Endocrine and immune system effects have been reported in exposed humans, suggesting that such endpoints may operate via a mechanism that is more relevant to humans than mechanisms related to changes in liver weights.

In addition, the one developmental neurotoxicity study used, in part, for the PFOS RfD is only weakly supported by additional studies in rodents or other species and is based on behavioral responses that could be influenced by factors other than direct effects on the nervous system. Additional confirmatory studies are necessary for this observation to be considered a critical effect of PFOS exposure.

Finally, while well-written overall, the documents lacked an overall critical analysis or depth required of a risk assessment. Why specific studies were included or not should be better explicated in the text.

Jeffrey W. Fisher

The document was well written in terms of balance and presenting information. Summary statements are needed for chapters; a synthesis/analyses of the data are needed in some cases. A more critical evaluation of the human and non-human responses to PFOA/PFOS is required to justify not using human or non-human primate data. A rationale for the modeling approaches is needed given the more recent PBPK models that are available.

William L. Hayton

The literature that pertains to the health effects of PFOA and PFOS is large and presents a major challenge to accurately summarize and analyze it and develop an RfD for PFOA and PFOS. Reported health effects in animals and humans, sometimes contradictory, include exposure-associated changes in serum cholesterol, lipids, uric acid, and thyroid hormones, obesity-related

metabolism, immune system function, and effects on reproduction, development of the mammary gland, the nervous system, and behavior. Target organ effects (e.g., liver, kidney) have been reported, as well as associations of PFOA and PFOS exposure with testicular, prostate and kidney cancer. Studies in several laboratory animal species have added the complications of interspecies comparisons and extrapolation of findings to humans. In humans, there have been a Phase I clinical trial of PFOA, and epidemiological studies of populations exposed to PFOA and PFOS occupationally and in communities with and without water supplies contaminated with PFOA and PFOS. The draft documents have accurately presented in summary form the results of many animal and human studies and used pharmacokinetic methods to link PFOA and PFOS exposure rates to internal dose metrics such as serum concentration. While the overall effort is commendable, there are two issues that the draft documents raise: 1) the literature cited does not include many apparently relevant published works. The cut-off date for cited literature was early 2013 (this should be indicated in the documents), but commenter's noted a number of pertinent publications in 2011 and 2012 that were not cited, and there have appeared several highly pertinent papers since the cut-off date, and 2) while the descriptions of individual studies are generally clear and accurate, there is a lack of independent, critical analysis of the studies and a lack of synthesis of results from multiple studies common to a particular health effect.

Matthew P. Longnecker

The PFOA and PFOS documents achieve the goal of identifying RfDs that are well founded. My main criticism is that the rationale for not using the human data to provide a POD needs to be strengthened.

For example, in the PFOA document, on page 5-19, first paragraph below the table, it says "human data … lack the exposure information for dose-response modeling." This statement is logically inconsistent with techniques that were used to estimate HED on the basis of serum concentration, as given on page 5-17, near the bottom. Or, in some cases, such as in the C8 study, the exposure estimates that were calculated based on water district were sufficiently good that a dose-response analysis would be possible. In other words, because many human studies have serum concentration of PFOA or reasonable estimated exposure values, the corresponding HED could be estimated, and hence the dose-response could be modeled. Granted, some assumptions would be needed, but the methods could be serviceable (see response to item 3 below). (Some of the above also applies to pages 5-1 and 5-2). More compelling arguments for not basing the POD on human data are, e.g., that: 1) the low probability that humans are 1,000 times more sensitive to PFOA than other species (the number is based on the last column in table 5-9 compared with PFOA values in the C8 study and background exposed populations), especially given the relatively tight agreement between LOAEL (average serum concentration basis) among other species, 2) the possibility that the observed associations in humans were due to unmeasured confounding factors or reverse causality, and 3) other weaknesses in the epidemiologic data such as inconsistent results across studies (selected outcomes), unreplicated findings, or associations with clinical chemistry results for which corresponding adverse clinical correlates (i.e., morbidity) are not clearly established.

Angela L Slitt

The documents provide a very thorough evaluation of PFOA and PFOS studies. It is logically organized, presenting findings in a way that the reader can understand the findings related to human, monkey, and rodents. The organization of the document allows the reader to easily find information about each species within the subchapters and summarizes key points in table form. PFOA is a well-studied compound, with a substantial amount of toxicokinetic and endpoint studies in rodents. Mechanistic data describing the role of membrane transporters to understand gender differences in PFOA elimination in rats is fairly well written. Little data exist regarding contribution of membrane transporters to PFOS disposition and elimination. The documents thoroughly describe species differences in PPAR-alpha signaling that might contribute to observed endpoints in rats, but not humans or monkeys. Overall, both documents are very thorough and provide a reliable basis for PFOS and PFOA evaluation.

For PFOA toxicokinetics, mechanisms of PFOA transport are important for understanding species differences in response to PFOA exposure, with focus placed on kidney. Figure 3-2 in the PFOA document does not adequately present the localization of renal transporters with relationship to their contribution to the urine compartment or renal reabsorption. A very nice diagram showing the subcellular localization of renal transporters presented by Klaassen and Aleksunes (Pharmacol Rev. 2010 Mar;62(1):1-96) clearly depicts the contribution of various transporters to filtrate or blood. This is an easier diagram to put PFOA elimination into context than the one presented. Contribution of membrane transporters to species differences in PFOA excretion Section 3 (specifically 3.4.1) would be put in better context if a table could be generated to compare Km and Vmax values for PFOA for various transporters, with specific focus on species information for OATPs and OATs. Data regarding information on contribution for OATps in liver accumulation of PFOS and PFOA is lacking, with specific regard to species differences. As PFOS is a likely candidate for hepatic uptake transport, understanding a mechanism to explain species differences in hepatic effects possibly due to difference in hepatic exposure is critical. Understanding impact species specific regulation of OATp expression in liver (e.g. whether species difference in PPAR-alpha signaling contributes) is also important in putting rodent distribution data into context.

Increased liver weight is considered to be a critical effect, but how increased liver weight relates to the observed human and monkey health effects needs to be further explained. First, use of liver weight alone might not be substantiate of an effect for point of departure compared to other liver effects observed at higher concentrations, such as increased serum ALT or AST.
The studies that have evaluated these endpoints are well conducted. In layman terms, if someone is walking around with an increased liver weight, is he or she at risk for disease? Will his/her life span be shortened? To increase transparency of the document, a more comprehensive explanation is needed to justify why increased liver weight should be considered as a critical endpoint for human health.

However, it should be noted for future consideration that there are a few publications in mice that do also ascribe liver weight changes in increased lipid accumulation along with increased expression of genes that contribute to fatty liver disease. This is considered to be a gap in knowledge for the field. Will relatively low dose PFOS exposures associated with hepatic

steatosis have other endocrine related effects known to be associated with NAFLD (insulin resistance, impaired glucose tolerance)? Emerging studies are evaluating whether PFOS induces hepatic steaosis and whether it is a PPAR-α mediated effect. For example a study performed by Wan et al. (2012) administered 0, 1, 5 or 10 mg/kg/day PFOS to adult male CD-1 mice for 3, 7, 14 or 21 days. Histological analysis of liver sections, and biochemical/molecular analysis of biomarkers for hepatic lipid metabolism were assessed. Overall, the study reported that PFOS-administration induced hepatic steatosis in a time- and dose-dependent manner. The study also shows a high correlation between liver weight and lipid content. Increased expression of a lipogenic target (CD36/FAT) was observed at 5 and 10 mg/kg PFOS. A second study by Bijland et al. (2011) illustrated that PFOS administration increased liver weight (+ 107%, $p < 0.0001$), which was accompanied by an increased hepatic TG content (+ 192%, $p < 0.0001$, respectively) in E3L.CETP mice on a C57Bl/6 background. At the age of 8–10 weeks, mice were fed a semisynthetic Western-type diet, containing 0.25% (wt/wt) cholesterol, 1% (wt/wt) corn oil, and 14% (wt/wt) bovine fat for 4 weeks in three independent experiments. Upon randomization according to body weight, plasma TC, and TG levels, mice were fed a Western-type diet without or with PFOS (0.003%, ~3 mg/kg/day) for 4–6 weeks. In summary, there is evidence that administration of relatively low PFOS doses to mice can result in hepatic lipid accumulation in the absence of overt "wasting."

Data is lacking as to whether higher species, such as monkeys or humans will also develop PFOS-induced steatosis, which is confounding. Studies have profiled gene expression in wild-type and PPARα-null mice administered PFOS, finding that there is pathology and gene expression consistent with lipid-promoting effects in liver that are independent of PPARα, as they are observed in PPARα-null mice (Rosen et al., 2010). Limitations to the studies are that they did not specifically quantify hepatic lipid content, but inferred that the PFOS-induced vacuolization in liver pathology observed was potentially related to triglycerides. Studies by Bjork et al. (2011) comparing rat and human primary hepatocytes treated with PFOS (25 μM) demonstrated that human hepatocytes were slightly less responsive to the induction of lipid oxidation and synthesis genes, as well as induction of carbohydrate metabolism. It should be noted that the hepatocytes from the study are from a single human donor, the hepatocyte lipid content was not determine, and hepatocyte culture conditions were standard and not optimized to induce steatosis. In summary, the current literature is lacking robust information regarding whether PFOS, which highly concentrates in liver, has a steatotic-inducing effect in human or monkey liver. The evidence in PPARα-null mice indicates that it might have some PPARα independent effects related to hepatic fat accumulation. Because evidence for hepatic lipid content in PPARα-null mice after PFOA or PFOS has been described only by pathology, more robust studies are needed to conclude whether the effects can occur independent of PPARα and the observed increased liver weight is due not only to hypertrophy due to nuclear receptor activation, but lipid accumulation. However, this reviewer is noting this as a concern for the future and area where a gap in knowledge exists.

Moreover, because the reviewer is noting a concern for hepatic fat accumulation that exists in the absence of PPARα, it should be appreciated that traditional markers, such as AST and ALT have poor prognosis for NAFLD or toxicant associated steatohepatitis. Most patients with NAFLD are asymptomatic and the disease is often diagnosed following findings of elevated aminotransferases, especially when combined with other features of metabolic syndrome. These

abnormal liver function tests usually require the physician to distinguish between NAFLD and alcoholic fatty liver disease (AFLD). Some have suggested that a serum AST/ALT ratio >1 are indicative of AFLD. Other possible signs of AFLD include elevated HDL-cholesterol with hypertriglyceridemia. While most diagnoses of NAFLD may result from altered liver function tests, normal serum aminotransferase tests can be seen in patients with both steatosis and NASH (Ipekci, et al., 2003; Mofrad, et al., 2003). Indeed, it is reported that two-thirds of NASH patients may have normal aminotransferase levels at any given time (Oh, et al., 2008; Delgado, 2008; Wieckowska and Feldstein, 2008). Kunde et al. investigated the accuracy of NASH diagnosis by serum ALT in women undergoing gastric bypass surgery (Kunde, et al., 2005). They compared two different reference laboratory cutoffs for "normal" ALT levels, the previous guideline of 30U/L, and new lower level of 19U/L that was suggested to aid in the diagnosis of NAFLD. Importantly, the authors reported that the diagnostic utility of serum ALT remained poor even at the new lower cutoff. Sensitivity and specificity of serum ALT levels were found to be 42% and 80% (ALT > 30U/L) versus 74% and 42% (ALT > 19U/L). These and other studies (Lizardi-Cervera, et al., 2006; Amarapurkar and Patel, 2004; Amarapurka, et al., 2006; Chen, et al., 2006; Fracanzani, et al., 2008; Sorrentino, et al., 2004; Mofrad, et al., 2003; Uslusoy, et al., 2009) illustrate the need for a more effective diagnostic measure for NAFLD, especially the NASH stage. In sum, use of ALT and AST elevation to base the point of departure must be taken into context because they are poor prognostic markers for increased liver accumulation, NAFLD, or even NASH. Use of ALT and AST might not be an appropriate biomarker for measurement of PFOA or PFOS-induced adverse effects on liver and should be considered as a gap in our knowledge for future work.

In the review panel discussion, there was discussion regarding a publication by Hall et al. (2012), which summarized the outcome of a workshop regarding liver hypertrophy and hepatocarcinogenesis. Overall, the workshop concluded that "hepatomegaly as a consequence of hepatocellular hypertrophy without histologic or clinical pathology alterations indicative of liver toxicity was considered an adaptive and a non-adverse reaction". This conclusion is taken in the context of hepatic hypertrophy caused by nuclear receptor activation. This differs from others that have concluded in mouse NTP studies where correlations between liver weight increases and histological parameters and carcinogenesis were assessed, the authors concluded that ''the best single predictor of liver cancer in mice was hepatocellular hypertrophy'' (Allen et al. 2004). Based on the conclusions presented in Hall et al. (2012), increased liver weight might not be considered an appropriate POD because of lack of overt toxicity and hepatomegaly being considered an adverse effect. It should be noted that this reviewer still has concerns regarding this conclusion for PFOS and PFOA because the pathology described in PPARα-null mice reflect increased hepatic lipids and not hepatomegaly due to nuclear receptor activation that is described in this opinion publication. If one considers the pathology examples of hypertrophy presented in Hall et al. (2012), it is quite different from the pathology described for PFOS and PFOA. For clarity, the document should try to delineate the cellular components that are contributing to increased liver weight caused by PFOA and PFOS administration, if such a publication exists (e.g. how much of the liver is associated with protein/peroxisome proliferation increase versus lipid increase). Because the literature is not clear regarding what exactly in the liver is causing increased liver weight, studies documenting hepatic lipid accumulation should not be currently considered for POD. Given the recent opinion cited by Hall et al. (2012), it is

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recommended that studies documenting liver damage, such as ALT and AST elevation be currently used as the POD.

The documents often have redundancy in information, especially in regard to hormone effects (there are very similar write ups in sections about effects on thyroid hormone) and metabolic/cardiovascular disease risk factors (e.g. lipid endpoints).

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IV. RESPONSE TO CHARGE QUESTIONS

Charge Questions

Question 1. Please comment on the strengths, weaknesses, and characterization of the studies selected as key for quantification.

James V. Bruckner

PFOA-specific comments
The document's authors have done a good job describing and integrating the findings of the numerous studies in which liver weight gain was observed. Although there is a consensus about the effect and the dosage required to elicit it in different species, this reviewer does not believe it should be utilized, as described above. There are several clearly adverse effects such as elevated serum (hepatic) enzyme activities, focal hepatocellular necrosis, bile duct degeneration and fibrosis, etc. These effects are generally seen in response to relatively high PFOA doses, so the PODs will be higher than with liver weight increase. Alternatively, a human endpoint such as elevated serum cholesterol could be considered. See responses to Charge Question 3.

PFOS-specific comments
There have been a substantial number of well-conducted toxicological studies of PFOS. My major concern, as expressed above, is its potential to cause adverse effects in children. Other than that, PFOS doesn't appear to produce effects other than those anticipated from a repetitive, cumulative dose of an 8-carbon fatty acid.

Deborah A. Cory-Slechta

In general, it appears that, at least with respect to the animal studies, the choices are appropriate both in the case of PFOA and PFOS. The derivation of the RfDs/RfCs are based on studies of sufficient strength, duration and represent the most sensitive endpoints.

Having said that, in both documents, the reader is forced to that conclusion with no real assistance from the text itself. There is virtually no discussion of the strengths and weaknesses of the studies overall. Human study outcomes for the most part are simply enumerated, although an occasional statement will be made about a limitation (usually) of one of those studies. There is no discussion in the human studies of the power to detect effects, the sample sizes, etc. Much weight seems to be given to occupational studies in some cases, being used to essentially dismiss effects in a community cohort as the same effect was not seen in occupationally exposed workers, when in fact finding effects in a population with seemingly longer, albeit lower exposure levels actually makes the outcome more robust. Also, population studies with smaller sample sizes that nevertheless find significant effects are in fact more compelling and suggest robust effects which can be detected even with a small sample size. This deficiency is manifest in statements such as those in the PFOS document (p. 5-1) that 'in most cases the findings are suggestive and not conclusive of an effect'.

There is a bit more discussion of the animal studies in both documents, at least with respect to methods, but as with the human studies, there is little text addressing which studies represent stronger studies or what the weaknesses are. From these increase liver weight has been chosen as the endpoint from which to derive RfDs. This reviewer does not have an issue with that choice, as while it has been described as adaptive by some, it represents a response to an involuntary exposure with a direction of effect that is potentially associated with adverse consequences. The fact that it is reversible when exposure ends seems irrelevant as reversal of exposure is not happening in the human environment.

Jamie C. DeWitt

Strengths: The studies selected as key for quantification were generally well-conducted studies, employing a range of doses and sample sizes large enough for detecting statistical differences. Additionally, the doses associated with LOAELs for the identified critical endpoints were not associated with signs of overt or systemic toxicity in the animal models and nearly all of the studies measured serum and/or tissue concentrations of the parent compounds.

Weaknesses: No obvious experimental design weaknesses were noted in any of the studies selected as key for quantification.

Characterization: The studies selected as key for quantification for PFOA are all rodent studies while at least one study selected for PFOS quantification includes a non-human primate study. It is therefore surprising that the PFOA database does not include, as a study key for quantification, the Butenhoff et al. 2002 study of non-human primates. Additionally variability in putative mechanisms among species was not adequately addressed in the characterization of the selective studies, although all of the selective studies were descriptive and not mechanistic.

Jeffrey W. Fisher

PFOA and PFOS: Data bases are massive and both need to be updated. Several human studies and a few non-human primate toxicity studies are available. The authors need to explain why these studies are not adequate for causality (dose-response).

William L. Hayton

An advantage to assessment of health effects for both PFOA and PFOS is the large amount of published work that informs the topic. While the draft health-effects documents have summarized the results of many pertinent studies, the literature reviewed was not comprehensive, which projects an appearance of weakness. The documents do not state whether the intention was to include all relevant health-effects literature, or to be selective and summarize those studies judged to be most relevant. Such a statement at the beginning of the documents would be helpful; a cut-off date for the literature review would also frame expectations of readers. If the intention was to be selective, a description of selection criteria would help allay concerns of readers about papers that were not included. If the intention was to comprehensively review all the PFOA and PFOS health-effects literature, then it appears that

more work should be done to include omitted works. Public comments list a number of works to consider for inclusion.

A general, albeit minor weakness of the literature is that PFOA and PFOS serum concentrations in control animals were not measured for many studies – they were likely non-zero and, since there is no information on how high they were, it is possible that baseline health-effects metrics were affected and that dose-response relationships were affected, especially in the low dose range. It is perhaps worthwhile to mention this shortcoming somewhere in the health effects documents.

Matthew P. Longnecker

EPA may want to consider the article by AP Hall et al. 2012, about liver hypertrophy. The defense of increased liver weight as the POD (or a POD) could be strengthened by evaluating the evidence in the context of Hall's Figure 9, where evidence regarding hepatoxicity and toxic mechanisms are also considered. In this case, the possibility of an unknown mechanism exists that could be relevant to humans, and long-term exposure could have effects that have not yet been detected. See Hall page 986, where it defines adverse as: "…affects [response] to an additional environmental challenge". Thus, an adverse effect, via an unknown mechanism, by this definition is possible and has not been studied in animals or humans.

While AP Hall's article is not all that supportive of using increased liver weight as a point of departure (unless certain criteria are met), they are focused on animal studies, especially those done in rodents. If increased relative liver weight were to occur in a human population, I suspect that it would be considered an adverse outcome, whether or not there was evidence of hepatotoxicity or a specific mechanism. Note also that for PFOA, in monkeys, there was an increase in relative liver weight with chronic exposure (PFOA document, page 4-66), so increase in liver weight in the animal experiments may be relevant to humans.

An additional comment of relevance here pertains to whether the human data support hepatoxicity. While there are studies that report elevated liver function tests in subjects with higher serum concentrations of perfluorakyl substances, these elevations do not clearly support the presence of toxicity. Again, AP Hall's discussion of what constitutes evidence of hepatoxicity is relevant here, and takes into account the number of LFTs elevated, the specific LFTs involved, and the magnitude of their elevation.

Finally, as discussed at the meeting, for the PFOA document on page 5-23 ("RfD Selection"), and the PFOS document on page 5-26 ("RfD selection"), I suggest minor editorial changes to deemphasize the "consistency of response" point and instead focus a little more on how the RfD is robust to choice of POD endpoints. If the selection of RfD does not hinge on increased liver weight as a POD, it will be more defendable.

Transparency might be increased by saying why (more clearly, or more clearly by implicit reasoning) the Macon et al. 2011 study, in which the LOAEL was 0.01 mg PFOA/kg from GD10 to GD17, based on delayed mammary gland development, was not considered as a POD, and why the Hines et al. 2009 study, in which the LOAEL was 0.01 mg PFOA/kg from GD1 to

GD17, based on various outcomes, was not considered as a POD. The PFOS studies with low LOAELs were considered in the dose-response assessment (no suggestions for improvement there).

Angela L Slitt

My response is basically the same as my General Impressions above.

The documents provide a very thorough evaluation of PFOA and PFOS studies. It is logically organized, presenting findings in a way that the reader can understand the findings related to human, monkey, and rodents. The organization of the document makes allows the reader to easily find information about each species within the subchapters and summarizes key points in table form. PFOA is a well-studied compound, with a substantial amount of toxicokinetic and endpoint studies in rodents. Mechanistic data describing the role of membrane transporters to understand gender differences in PFOA elimination in rats is fairly well written. Little data exist regarding contribution of membrane transporters to PFOS disposition and elimination. The documents thoroughly describe species differences in PPAR-alpha signaling that might contribute to observed endpoints in rats, but not humans or monkeys. Overall, both documents are very thorough are provide a reliable basis for PFOS and PFOA evaluation.

For PFOA toxicokinetics, mechanisms of PFOA transport are important for understanding species differences in response to PFOA exposure, with focus placed on kidney. Figure 3-2 in the PFOA document does not adequately present the localization of renal transporters with relationship to their contribution to the urine compartment or renal reabsorption. A very nice diagram showing the subcellular localization of renal transporters presented by Klaassen and Aleksunes (Pharmacol Rev. 2010 Mar;62(1):1-96) clearly depicts the contribution of various transporters to filtrate or blood. This is an easier diagram to put PFOA elimination into context than the one presented. Contribution of membrane transporters to species differences in PFOA excretion Section 3 (specifically 3.4.1) would be put in better context if a table could be generated to compare Km and Vmax values for PFOA for various transporters, with specific focus on species information for OATps and OATs. Data regarding information on contribution for OATps in liver accumulation of PFOS and PFOA is lacking, with specific regard to species differences. As PFOS is a likely candidate for hepatic uptake transport, understanding a mechanism to explain species differences in hepatic effects possibly due to difference in hepatic exposure is critical. Understanding impact species specific regulation of OATp expression in liver (e.g. whether species difference in PPAR-alpha signaling contributes) is also important in putting rodent distribution data into context.

Increased liver weight is considered to be a critical effect, but how increased liver weight relates to the observed human and monkey health effects needs to be further explained. In layman terms, if someone is walking around with an increased liver weight, is he or she at risk for disease? Will his/her life span be shortened? To increase transparency of the document, a more comprehensive explanation is needed to justify why increased liver weight should be considered as a critical endpoint for human health.

Use of humanized PPARα mice are a sexy tool to delineate species differences in effects associated with peroxisome proliferation. For transparency, the document should acknowledge the limitations of that model. Specifically, lack of response may not necessarily correlate to a lack of response for human PPARα because of species differences in binding to cogate DNA elements (e.g. a human receptor may have lower binding capacity to mouse DNA due to structural differences and species differences in co-activator/co-repressor interactions). Wording in the documents using these mice should acknowledge this limitation.

The documents often have redundancy in information, especially in regard to hormone effects (there are very similar write ups in sections about effects on thyroid hormone) and metabolic/cardiovascular disease risk factors (e.g. lipid endpoints).

Question 2. Please provide citations (and, where possible, pdfs or hard copies) for any references you suggest EPA consider adding to the document. Describe where you suggest these references be incorporated.

James V. Bruckner

PFOA-specific comments
Fabrega, F. et al. (2014). PBPK modeling for PFOS and PFOA: Validation with human experimental data. Toxicol. Lett. On line. (Hard copy available)

Stahl, T., Mattern D and Brunn, H. (2011). Toxicology of perfluorinated compounds. Environ. Sci. Europe 23: 38-60.

Hall, A. P., et al. 2012. Liver hypertrophy: A review of adaptive (adverse and non-adverse) changes- Conclusions from the 3rd International ESTP Expert Workshop. Toxicol. Pathol. 40: 971-994.

Bjork, J. A., Butenhoff, J. L., and Wallace, K. B. 2011. Multiplicity of nuclear receptor activation by PFOA and PFOS in primary human and rat hepatocytes. Toxicology 228: 8-17.

PFOS-specific comments
No additional references were located.

Deborah A. Cory-Slechta

For both PFOA and PFOS, the document should include a description of the process through which studies were identified and how they were processed for inclusion or not. It is not clear what the exact dates of the studies examined included, i.e., what the cut-off date was for these studies. This makes it difficult to evaluate whether there are missing studies. That said, this reviewer is not aware of any specific omissions in the peer-reviewed literature other than those that were discussed at the face-to-face meeting.

Jamie C. DeWitt

Granum, B., Haug, L.S., Namork, E., et al. 2013. Pre-natal exposure to perfluoroalkyl substances may be associated with altered vaccine antibody levels and immune-related health outcomes in early childhood. J Immunotoxicol. 10:373–379; Looker, C., Luster, M.I., Calafat, A.M., et al. 2014. Influenza vaccine response in adults exposed to perfluorooctanoate and perfluorooctanesulfonate. Toxicol. Sci. 138:76–88.

Any time the Grandjean et al. (2012) findings related to PFAS and vaccine responses are discussed, these references could/should be discussed as well as they report related findings in human populations. Although they also are confounded by multiple PFAS (as was the Grandjean et al. study), they lend additional support to immunotoxicity as an endpoint worthy of consideration. However, it is noted that these references were published after the cutoff date for consideration for inclusion in the document.

Lopez-Espinosa, M.J., et al. 2012. Thyroid function and perfluoroalkyl acids in children living near a chemical plant. Environ.Health Perspect. 120:1036–1041. This study is missing from the discussion of thyroid hormone disruption. It reports a positive correlation between hypothyroidism and PFOA in children from the C8 population aged 1-17.

Corsini E., et al. 2011. In vitro evaluation of the immunotoxic potential of perfluorinated compounds (PFCs). Toxicol. Appl. Pharmacol. 250:108-116. Corsini E. et al. 2012. In vitro characterization of the immunotoxic potential of several perfluorinated compounds (PFCs). Toxicol. Appl. Pharmacol. 258:248-255.These studies are in vitro/ex vivo studies of human-derived cells that provide evidence that in vitro measures of immunocompetence in mice may be relevant to the human experience.

Jeffrey W. Fisher

For completeness sake, at least, please update lab animal studies conducted since 2012.

William L. Hayton

A review of PFOA health-effects literature (GB Post et al. (2012) Environ. Res. 116: 93-117) provides an excellent, in-depth discussion of many issues covered in the PFOA health effects document. Consider citing this review in the document.

The literature on PFOA and PFOS toxicokinetics (Section 3) has been comprehensively covered in the health effects documents, with the notable omission of Wambaugh et al., Dosimetric Anchoring of *In Vivo* and *In Vitro* Studies for Perfluorooctanoate and Perfluorooctanesulfonate. Toxicol. Sci. 136:308-327, 2013. This paper informed a significant part of the health effects documents.

Commenter's have suggested a number of references to consider with regard to Section 4 Hazard Identification. Many recent publications report on toxicity associated with PFOA/PFOS exposure. For the Dose-Response Assessment (Section 5) it is desirable to focus on those toxicities that have occurred at the lowest PFOA/PFOS exposures. For PFOA, the literature that is used in Section 5 to determine an RfD was published prior to 2009 (Tables 5-8 – 5-11). The benchmark response chosen based on the Section 4 literature was a 10% increase in liver weight, which was the biological response that occurred at the lowest PFOA exposure; it was acknowledged that this response "… is a biomarker for systemic exposure in rodents, rather than a biomarker of adversity …" (p. 5-6). More recent studies of hazard have identified potential adverse effects that result from, or are associated with, PFOA exposures that are lower than the LOAEL for a 10% increase in liver weight. For example, adverse effects on fetal, neonatal and early childhood stages of development may occur at lower exposures than does liver weight gain, which suffers in addition from not being a biomarker of adversity, and which therefore raises a question about the validity of any RfD based upon it. Macon et al. 2011 reported an LOAEL for delayed mammary gland development of 0.01 mg/kg administered to pregnant CD-1 mice during GD10 – GD17. As this relatively brief exposure was well below that required for steady state, it is possible that had the dams been at steady state at the time of conception (about 9 weeks of exposure) a much lower LOAEL may have been observed; i.e., a much lower dose

rate at steady state would have produced the same exposure to the fetal pups as did the 0.01 mg/kg administered to the dams during GD10 – GD17. The steady state situation is more relevant to adverse effects in humans than is a brief exposure.

Matthew P. Longnecker

I suggest you include the following citation and include a discussion of the evidence presented: Paula I. Johnson, Patrice Sutton, Dylan S. Atchley, Erica Koustas, Juleen Lam, Saunak Sen, Karen A. Robinson, Daniel A. Axelrad, and Tracey J. Woodruff. The Navigation Guide—Evidence-Based Medicine Meets Environmental Health: Systematic Review of Human Evidence for PFOA Effects on Fetal Growth. Environ Health Perspect; DOI:10.1289/ehp.1307893 (in press and available through the journal's website).

Based on the meta-analysis in this paper, the evidence that PFOA is associated with lower birthweight is consistent. Thus, the rationale for not basing the POD on the human data needs to be strengthened, as noted above. The Johnson et al. report could be discussed in the section on anthropometric endpoints that begins on p 4-22.

The relationship between birthweight and PFOA or PFOS may be confounded because glomerular filtration (and hence excretion of the compounds) is proportional to birthweight, as discussed in:

Morken NH, Travlos GS, Wilson RE, Eggesbø M, Longnecker MP. Maternal glomerular filtration rate in pregnancy and fetal size. PLoS One. 2014 Jul 8;9(7):e101897

In the PFOA document, on page 4-18, you might want to also cite:

Taylor KW, Hoffman K, Thayer KA, Daniels JL. Polyfluoroalkyl chemicals and menopause among women 20-65 years of age (NHANES). Environ Health Perspect. 2014 Feb;122(2): 145-50.

The Taylor et al., like the Knox et al. report (already cited in the PFOA document) is from a large-cross sectional study. Both studies, in their discussion sections, note that the association of PFOA or PFOS concentration in serum with age at menopause could be expected because postmenopausal women have lost a route of excretion for the compound and will have higher serum concentrations on that basis. It would be worth noting this possible explanation in the PFOA document on page 4-18, and in the PFOS document on page 4-8.

Additional data are available on the potential carcinogenicity of PFOA:

- Steenland K, Woskie S. Cohort mortality study of workers exposed to perfluorooctanoic acid. Am J Epidemiol. 2012;176(10):909-17.
- Barry V, Winquist A, Steenland K. Perfluorooctanoic acid (PFOA) exposures and incident cancers among adults living near a chemical plant. Environ Health Perspect. 2013;121(11-12):1313-8
- Hall AP et al. Toxicol Pathol 2012:40:971-94. (About liver hypertrophy.)

The Steenland and Barry reports could be discussed in Section 4.1.2, on pages 4-28 and 4-29, respectively.

Angela L. Slitt

1) Evidence is presented for PFOA and PFOS as substrates for the related OATp1d1 in zebra fish. Establishing whether PFOS is an OATp transporter substrate is needed to better understand PFOS accumulation in liver. This study suggests that it might be. The following finding should be included in the PFOS document in Section 3.2.3 and the PFOA document in Section 3.0:
    a. Popovic M, Zaja R, Fent K, Smital T. Toxicol Appl Pharmacol. 2014 Interaction of environmental contaminants with zebrafish organic anion transporting polypeptide, OATp1d1 (Slco1d1).

2) This publication presents the finding that PFOS inhibits Pgp, Mrp1, and Mrp4 activity. The following finding should be included in the PFOS document in Section 3.2.3 and the PFOA document in Section 3.0:
    a. Dankers AC1, Roelofs MJ, Piersma AH, Sweep FC, Russel FG, van den Berg M, van Duursen MB, Masereeuw R. Toxicol Sci. 2013 Dec;136(2):382-91. Endocrine disruptors differentially target ATP-binding cassette transporters in the blood-testis barrier and affect Leydig cell testosterone secretion in vitro.

3) PFOS induced ABC transporters in grey mullets.
    a. de Cerio OD1, Bilbao E, Cajaraville MP, Cancio I. Gene. 2012 Apr 25;498(1):50-8. Regulation of xenobiotic transporter genes in liver and brain of juvenile thicklip grey mullets (Chelon labrosus) after exposure to Prestige-like fuel oil and to perfluorooctane sulfonate.

4) These are new publications regarding epidemiology findings for PFOS and PFOA exposure and serum lipids:
    a. Fitz-Simon N, Fletcher T, Luster MI, Steenland K, Calafat AM, Kato K, Armstrong B. Epidemiology. 2013 Jul;24(4):569-76. doi: 10.1097/EDE.0b013e31829443ee. Erratum in: Epidemiology. 2013 Nov;24(6):941.
    b. Starling AP, Engel SM, Whitworth KW, Richardson DB, Stuebe AM, Daniels JL, Haug LS, Eggesbø M, Becher G, Sabaredzovic A, Thomsen C, Wilson RE, Travlos GS, Hoppin JA, Baird DD, Longnecker MP. Perfluoroalkyl substances and lipid concentrations in plasma during pregnancy among women in the Norwegian Mother and Child Cohort Study. Environ Int. 2014 Jan;62:104-12.
    c. Fu Y, Wang T, Fu Q, Wang P, Lu Y. Associations between serum concentrations of perfluoroalkyl acids and serum lipid levels in a Chinese population. Ecotoxicol Environ Saf. 2014 Aug;106:246-52.
5) These are publications regarding PFOS exposure and hepatic steatosis:
    a. Lv Z, Li G, Li Y, Ying C, Chen J, Chen T, Wei J, Lin Y, Jiang Y, Wang Y, Shu B, Xu B, Xu S. Glucose and lipid homeostasis in adult rat is impaired by early-life exposure to perfluorooctane sulfonate. Environ Toxicol. 2013 Sep;28(9):532-42. doi: 10.1002/tox.20747. Epub 2011 Aug 24. PMID: 23983163 Select item 22484034

b. Wan HT, Zhao YG, Wei X, Hui KY, Giesy JP, Wong CK. PFOS-induced hepatic steatosis, the mechanistic actions on β-oxidation and lipid transport. Biochim Biophys Acta. 2012 Jul;1820(7):1092-101. doi: 10.1016/j.bbagen.2012.03.010. Epub 2012 Mar 28. PMID: 22484034 [PubMed - indexed for MEDLINE] Free Article
c. Bijland S, Rensen PC, Pieterman EJ, Maas AC, van der Hoorn JW, van Erk MJ, Havekes LM, Willems van Dijk K, Chang SC, Ehresman DJ, Butenhoff JL, Princen HM. Perfluoroalkyl sulfonates cause alkyl chain length-dependent hepatic steatosis and hypolipidemia mainly by impairing lipoprotein production in APOE*3-Leiden CETP mice. Toxicol Sci. 2011 Sep;123(1):290-303. doi: 10.1093/toxsci/kfr142. Epub 2011 Jun 24.

Question 3. The OW concluded that the human epidemiology data for PFOS/PFOA do not provide adequate quantifiable dose-response information for use as the basis of a candidate RfD because of uncertainty regarding the routes, levels and timing of exposures plus the confounding influences of other PFCs present in serum. Please comment of the OW characterization of the data.

James V. Bruckner

PFOA-specific comments
The document's authors have done a good job summarizing and accurately characterizing the epidemiology literature for various endpoints in Section 4.4 - Hazard Characterization. It is true there are a number of confounding factors that make estimation of PFOA exposures difficult. The EPA might consider, however, utilization of reverse dosimetry modeling. There is a reasonable body of data on serum PFOA levels, which could be used to estimate a range of PFOA exposures that would result in such internal doses.

PFOS-specific comments
I agree that human epidemiology data do not provide an adequate basis for calculation of a RfD or RfC. A reverse dosimetry modeling approach, however, could be used to estimate a range of PFOS exposures that could have resulted in measured body burdens. The human data might then be utilized in the risk assessment.

Deborah A. Cory-Slechta

It is not clear that such an assertion should be used in the construction of this document. It is not clear why the route of exposure should be raised to a concern in the calculations, in fact in the human environment, there are exposures from multiple routes, no doubt and thus this is consistent with human environmental exposures. Further, if there is data on serum levels, it should reflect that cumulative exposure across exposure routes. Indeed, at the end, the goal is to arrive at an RfD based on serum levels. There is, moreover, no guarantee that there is no contamination in studies in animals from food, glassware etc.

Furthermore, in many epidemiological studies in which mixed exposures are the norm, controlling for other exposures is utilized to address this concern and to therefore make conclusions about individual exposures. In point of fact, in every single human study, there will invariably be other exposures and not a single exposure, and thus this strategy essentially says that no human studies can ever be used for any risk assessments. The stated rationales for not using human data based on these statements is not adequate. This is why it is important as well to evaluate the strengths and weaknesses of each of the studies in terms of whether appropriate controlling for other known exposures was carried out and sample sizes sufficient etc. to arrive at some conclusions with respect to their ultimate usability in constructing RfDs.

Jamie C. DeWitt, Ph.D..

While the OW characterization of the epidemiological data for PFOA/PFOS is, technically, true, it also is somewhat misguided. Almost any epidemiological database will contain uncertainty regarding the routes, levels, and timing of exposures and will have confounding influences of other compounds. Very few epidemiological studies are free from these uncertainties, but when similar observations and conclusions are reached from multiple studies with these types of uncertainties, the database becomes useful for determining a candidate RfD or other value relevant to human health. What is particularly valuable about the PFOA/PFOS database is that it is relatively extensive in that it includes data not only from occupationally-exposed humans, but from people highly exposed to environmental concentrations of PFOA/PFOS and from people in the general population who have detectable concentrations of these compounds. Additionally, for establishing an RfD, do all of these uncertainties need to be absent? In other words, do animal studies used to derive RfDs lack these uncertainties?

What is missing from the OW characterization of the epidemiological data is a thorough evaluation concerning hepatotoxicity and developmental toxicity reported in human populations and how these endpoints are relevant to or related to animal studies.

Jeffrey W. Fisher

The use of non-human and human data is very important for interpreting exposure extrapolations from rats. I am not an epidemiologist so I cannot comment with authority on the epidemiology data for dose-response. Justify why human data are not suitable for use in the analysis of the health hazards of PFOA and PFOS.

William L. Hayton

There are a number of epidemiological studies that have been based on large numbers of subjects chronically exposed (over decades in some studies) to the subject compounds over a broad range of intakes. Steady state serum concentrations have also been available for quantification of the systemic exposure. While the route, levels and timing of the exposures may have been uncertain, the long half-lives of PFOA and PFOS in humans and the long periods of exposure to them indicate that 1) subject serum concentrations were generally at steady state, and 2) daily fluctuations in the amount and timing of the exposure would not produce much day-to-day fluctuation in the serum concentration of PFOA/PFOS. These consequences of the long exposure period and long half-life indicate that variability in the route and level of exposure would not have led to a measured serum concentration that was unrepresentative of the subjects' long-term average serum concentration. The serum concentration then should be relatively stable over time and it should reflect an integrated measure of the individual's exposure to PFOA and PFOS.

The serum concentration is a quantitative measure of systemic exposure to the subject chemicals, and is arguably a better metric of exposure than are intake rate. The over-all rate of intake (R) that produces a particular steady state serum concentration (Css) can readily be

calculated from the clearance (CL) of the chemicals, which is about 0.08 mL/d/kg body weight: R = Css x CL. The calculated rate of intake would represent all intake routes.

Confounding influences of other PFCs and indeed other chemicals and life-style factors such as smoking, diet, alcohol use, etc. would have to be considered, as is generally the case with epidemiological studies. Methodology exists for dealing with such influences.

Thus it appears that the epidemiological results should be used in the RfD determination. Their strength is that uncertainties associated with extrapolation from laboratory animal studies are avoided. Health effects that are positively associated with serum PFOA/PFOS concentration and that are observed in large populations of subjects should seriously be considered as potentially arising from PFOA/PFOS exposure. If mode of action studies in lab animals or in vitro studies support a cause-effect relationship, then the threshold serum concentration could inform the calculation of the RfD.

Matthew P. Longnecker

As noted in the General Impressions section above, the human studies with data on plasma or serum concentrations of PFOA and PFOS, especially for several categories of such levels, could be used to estimate dose-response information. However, there are other reasons why the human data may not be useful for setting the RfD (see above). Either PK or PBPK models might be useful for estimating the dose that human are exposed to; an advantage of a PBPK model is that it could incorporate information about routes and timing of exposure. Estimates of the contribution of various routes are available (e.g., Haug et al. 2011; Lorber & Egeghy 2011), and exposure trends could be assumed and evaluated in sensitivity analyses. Some occupational studies had data that allowed an estimate of serum levels, or measured them directly. Several reports show estimated exposure based on serum concentrations of PFOA or PFOS (Locissano et al. 2013; Lorber & Egeghy 2011; Thompson et al. 2010). With respect to confounding, the assessment of how likely this is could be informed by: 1) the correlation of serum concentration of PFOA, PFOS, and other compounds of this type in a particular study population (or in a series of studies), and 2) whether the other compound(s) has been associated with the particular outcome being considered. If the correlation is low or the other compound has not been associated with the outcome, concern about confounding may not be strongly justified. Without additional consideration of data that address these points, it may be premature to assume confounding would be a problem.

Angela L. Slitt

Strengths of the studies: Several studies, which all demonstrate a positive association between serum PFOA and/or PFOS and cholesterol or LDL levels are based on drinking water as a route of exposure. These studies are in agreement with Nelson et al., 2010, which was analyzing data from the 2003-4 NHANES study. Steenland et al., 2009 (*Environ Health Perspect*. Jul 2009; 117(7): 1083–1088) as part of the C8 Health Project collected data on 69,030 subjects with findings that serum PFOA was higher for males, those consuming local vegetables, and those using well water rather than public water, and *lower for those using bottled water.* The estimated response rate for participants >20 years of age was 81% and mean serum PFOA

concentration was 83 ng/l. Subjects were eligible to participate in the C8 Health Project if they had consumed drinking water for at least one year before 3 December 2004 supplied by Little Hocking Water Association (Ohio), City of Belpre (Ohio), Tuppers Plains Chester Water District (Ohio), Village of Pomeroy (Ohio), Lubeck Public Service District (West Virginia), Mason County Public Service District (West Virginia), or private water sources within these areas that were contaminated with PFOA. Subjects were also eligible if they could document that they had either worked in a contaminated water district or went to school there for at least one year. From this population, which the route of exposure is considered to be primarily via drinking water, serum lipids were analyzed with regard to PFOA levels and a positive correlation was observed for all serum lipids except HDL. Frisbee further characterized this cohort, analyzing 12, 476 children and adolescents included in the C8 Health Project, finding an increase in total cholesterol.

A recent epidemiology study (Fitz-Simon et al., 2013), not included in the current documents, described positive associations between PFOA and PFOS in serum LDL cholesterol. This study examined a study population that consisted of 560 adults living in parts of Ohio and West Virginia where public drinking water had been contaminated with PFOA. They had participated in a cross-sectional study in 2005-2006, and were followed up in 2010, by which time exposure to PFOA had been substantially reduced. Overall, the findings demonstrate a positive association between serum PFOA and PFOS levels and serum and LDL cholesterol.

Weaknesses: The studies did not appear to analyze PFOS or PFOA levels in drinking water from the participants analyzed and did not analyze data based on the length of exposure.

Question 4. Please comment on the transparency and characterization of the epidemiological data.

James V. Bruckner

PFOA-specific comments
See comments above.

PFOS-specific comments
The document's authors have done a good job describing and summarizing the designs and findings of the epidemiology studies.

Deborah A. Cory-Slechta

The PFOA document in particular and to some extent the PFOS document present all of the epidemiological studies but do not actually evaluate them; there is not a consistent indication of individual strengths and limitations of the studies, failures or not to adequately control potential confounding variables. Furthermore, there is no 'power analysis' type of evaluation, i.e., some of these studies included very small sample sizes and thus their power to actually detect effects may be limited, and yet they all appear to be weighted basically the same, i.e., studies with very small sample sizes with obviously extremely limited power to detect any effects appear to be considered the same as those with extremely large sample sizes. Studies with small sample sizes that nevertheless do find an effect of PFOA or PFOS actually suggest a robust type of effect.

The discarding of positive associations in human epidemiological studies because they do not produce frank clinical disease seems inappropriate and inconsistent with other EPA documents. For example, p. 4-3 in the PFOS document states that only a small number of ALT values were outside the normal range making the results difficult to interpret in terms of health. Physiological changes that are moving in the wrong direction, even if sub-clinical at the time, are still adverse effects. Are actual clinical diagnoses required for an adverse effect? This is especially the case given that the ranges of normal across populations are extremely broad.

The latter also raises the question of the cumulative toxicity of PFOA and PFOS and whether any consideration is being given to this.

Another such example is in the PFOS document, where it actually refers to a statistically significant, but not toxicologically significant effect (p.4-38); what does that mean? Also, p. 5-4 appears to dismiss any changes in thyroid function since no evidence of clinical hypothyroidism actually occurred. This whole approach with the human studies seems quite inconsistent with the reliance on increased liver weight in the absence of clinical pathology as the endpoint in the human studies.

Jamie C. DeWitt

It is not obviously or abundantly clear how the OW characterized the epidemiological data for either PFOA or PFOS. The studies were well-described, but the contribution of particular studies

to the overall assessment was not. The results of studies described in the hazard characterization section (4.4) need to be better characterized. For example, in the PFOA risk assessment:

- An increase in serum lipids associated with PFOA/PFOS exposure in humans is discussed as a risk factor for cardiovascular disease in humans; however, no evidence of increased cardiovascular disease has been observed in human populations. Additionally, serum lipids typically are decreased in animal models after PFOA/PFOS exposure, which is thought to be associated with/typical of exposure to agents that activate PPARα. If humans are known to respond to PPARα activators (i.e., fibrate drugs), why would the results between humans and animal models be discordant? This should be discussed.
- Several epidemiological studies reporting changes in liver enzymes clearly state that the clinical relevance of the changes in enzymes is unknown. Therefore, stating that the human studies "suggest effects on the liver as indicated by increases in liver enzymes" amounts to a mischaracterization of the data.
- No direct evidence of hepatotoxicity has been reported in epidemiological studies. This should be discussed.
- More in-depth characterizations are needed for the additional sections of the hazard characterization, with the exception of the thyroid section, which was well-described.

For example, in the PFOS risk assessment: Similarly to the PFOA risk assessment, the hazard characterization section needs to better discussion differences and similarities between effects reported in humans and effects reported in animal models.

Jeffrey W. Fisher

I am not an epidemiologist, but it appears to be adequate. Better characterization of the pros and cons of the human analyses and interpretation of the outcomes would be helpful.

William L. Hayton

The characterization of the individual epidemiological studies presented seems to be adequate. Public comments have identified the need to distinguish positive and negative associations with statistical significance, which seems to be a fair criticism. As noted in the response to Question 2, there are relevant studies that have not been described in the health-effects documents that ought to be considered and this includes some epidemiological studies. Most of the cited epidemiological studies have focused on healthy adults – workers exposed occupationally, residents of communities with or without contaminated water. These populations might be expected to be less sensitive to adverse effects than would early life stages and particular disease populations. Studies of potentially more sensitive populations would be desirable. The Frisbee et al. (2010) study of children 1-11.9 years and adolescents 12-17.9 years showed significant positive associations with serum lipid levels. Studies such as this one would be informative.

Matthew P. Longnecker

Please see the long paragraph above, under General Impressions, and some of the comments in response to item #2 above. Another point that the authors may want to consider is that studies that examine external exposure in relation to health outcomes may have special advantages in the case of PFOA and PFOS. While in general it is considered best to have a measure of exposure that is based on a biomarker of internal exposure, this may be problematic for several outcomes for PFOA and PFOS, because of the possibility of confounding or reverse causality that would not be an issue if an external estimate of exposure were used. For example, in Steenland K, Zhao L, Winquist A. A cohort study of workers exposed to PFOA. Occup Environ Med. 2014 Jun;71 Suppl 1:A55, when an external estimate of exposure was used for the Washington Works employees, no association with elevated cholesterol was found. The Viera et al. (2013) results are based on external estimates of exposure, whereas the similar study by Barry et al. (2013) are based on serum levels or estimates based on serum levels. The fact that association with kidney cancer is present in the Viera study decreases concern that the association was due to reverse causality. Steenland et al. 2012 used an external estimate of exposure to study cancer mortality and also found an association with kidney cancer. Lundin et al. (external estimate of exposure) had no cases of kidney cancer, though their study was also small.

Angela L. Slitt

The epidemiology data is well described and a thorough read. The data would be put in better context for the reader if there are average serum concentrations or ranges for the studies summarized in tables in addition to other key pieces of information.

A recent publication should be included in the document for consideration. Simon N, Fletcher T, Luster MI, Steenland K, Calafat AM, Kato K, Armstrong B. Epidemiology. 2013 Jul;24(4):569-76. doi: 10.1097/EDE.0b013e31829443ee.

Question 5. The OW has concluded that the cancer classifications for PFOA and PFOS are most consistent with respective classifications of suggestive evidence for carcinogenicity as described the EPA Guidelines for Carcinogen Risk Assessment (pp. 2-56, 2-57). Please comment on the strengths and weaknesses of this classification.

James V. Bruckner

PFOA-specific comments
I agree with EPA's choice of "Suggestive Evidence for Carcinogenicity." Epidemiological findings in occupationally-exposed and general populations to date are equivocal. Increases in Leydig cell tumors and liver adenomas have been reported in high-dose male rats. Increased incidences of pancreatic cell hyperplasia/adenomas and ovarian stromal hyperplasia/adenoma have been observed in female rats. More studies are necessary to confirm/expand these findings, and to assess carcinogenic potential in other species. Most mutagenicity and genotoxicity assays have been negative. Thus, there is some, but not undue cause for concern about the human carcinogenic potential of PFOA.

PFOS-specific comments
The document's authors have adequately and convincingly presented evidence for classifying PFOS as "suggestive of carcinogenicity."

Deborah A. Cory-Slechta

The classification of both PFOA and PFOS evidence for carcinogenicity as suggestive seems consistent with the clear limitations in the available data bases. In addition, the animal studies are limited to one species and mutagenicity does not occur in response to PFOA.

Jamie C. DeWitt

This classification is appropriate for both PFOA and PFOS given the epidemiological evidence, which is somewhat limited for PFOA and quite limited for PFOS. For PFOA, there is an association between kidney and testicular cancer, but there are limited data in animal models for these cancers and there is uncertainty that the mechanism of PFOA-induced carcinogenicity in animal models is applicable to humans. Studies of PFOS have the same limitations, but epidemiological studies have failed to find an association between PFOS exposure and cancer.

Jeffrey W. Fisher

I did not review the cancer studies for PFOA and PFOS.

William L. Hayton

The classification of "suggestive" is not unreasonable. The epidemiological studies, while showing apparent associations between PFOA exposure and cancer incidence in testicle and kidney as well as other tissues, do not provide a cause-effect relationship. However, they certainly do raise a concern about the carcinogenicity of the subject substances. Studies in animals have demonstrated conclusively that PFOA causes liver cancer in rats but the MOA that involves PPAR activation is absent in humans and it has been concluded that PFOA and PFOS cannot be carcinogenic in humans via this mechanism.

An EPA SAB panel (2006) consideration of this question resulted in a majority of the panel members favoring a classification of "likely to be carcinogenic" for PFOA. Board members acknowledged the PPAR MOA argument against causation of cancer in humans, but also found evidence that liver cancer in rats administered PFOA may also have had a MOA independent of PPAR activation. Recent epidemiological studies have added to the weight of evidence for an association between PFOA/PFOS exposure and cancer. Therefore a classification of "likely" is also not unreasonable to this reviewer. Lacking expertise in the nuances of applying the EPA's classification scheme, it is difficult for this reviewer to argue in favor of either "suggestive" or "likely".

Matthew P. Longnecker

The classification as "suggestive evidence for carcinogenicity" for both PFOA and PFOS is consistent with the guidelines put forth in the EPA Guidelines for Carcinogen Risk Assessment (2005). There are few pertinent data, including some suggestive but weak human evidence. There is clearly not enough evidence to classify these agents as likely human carcinogens.

Angela L. Slitt

Overall, the assessments for each PFOS and PFOA appear to be consistent with the EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a).

Strengths: Both classifications use evidence from human studies as guidance.

PFOS: The limited data that exist regarding PFOS and cancer were presented, the classification for PFOS under the EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005a) is currently consistent with the suggestive evidence of carcinogenic potential descriptor. This assessment is reasonable, given that it is based on two studies that show a slight increase in adenomas that occurred in males and females.

PFOA: There is conflicting evidence regarding PFOA exposure and cancer risk. However, several human studies have found associations between PFOA exposure and elevation of cancer of the bladder and kidney. This is also supported by a chronic bioassay in rats, which demonstrated that PFOA was tumorigenic.

Question 6. Significant interspecies differences in pharmacokinetics exist for both PFOA and PFOS. Adjusting for interspecies differences was an important step in developing candidate RfDs given the totality of the human and animal data. Please comment on the strengths and weaknesses of the pharmacokinetic model adjustments to accommodate the impact of albumin binding and renal tubule transporters in determining average serum values.

James V. Bruckner

PFOA-specific comments
The adjustments made to accommodate the influence of albumin binding and saturable renal tubular resorption of PFOA seem reasonable. I would defer, however, to someone with more experience in providing for these processes in PBPK models.

PFOS-specific comments
The PBPK model adjustments to estimate human equivalent doses appear to be appropriate. I defer to someone more qualified on the subject.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

Jamie C. DeWitt

Several PK models have been reported in the literature for these compounds and are relatively well described in the documents. The documents assert that the existing PK models do not consider the impact of renal tubule transporters and albumin binding; while, many of the existing models appropriately predict serum concentrations in humans and other species, but they are mostly based on empirical models. Please explain the weaknesses of such empirical models.

Additionally, numerous studies for both compounds report serum and tissue concentrations in humans and other species, which can be compared to existing models. Both documents present a revised model that amounts to a reanalysis of data from studies that report serum concentrations. A more thorough discussion of the improvements made by the reanalysis is needed to better understand if the improved model adequately estimates or predicts the clearance rate and other parameters for which confidence is low. Alternatively, the publication (Wambaugh et al., 2013) that thoroughly describes the reanalysis could be referenced.

Jeffrey W. Fisher

Serum protein binding: Both PFOA and PFOS are highly bound in serum proteins across species, thus model adjustments seem trivial for interspecies extrapolation. Steady-state conditions can be assumed to estimate the free fraction (e.g., 2% based on paper by Han et al., 2003 for humans). I did not find a discussion about the half-life of serum proteins, which may have some influence on the 'apparent' serum half-life of PFOA and PFOS. The estimated fraction of free PFOA or PFOS is important for describing urinary and fecal elimination in rats (and other species) and the plasma concentrations of total PFOA and PFOS. Thus, the model predicts total PFOA and PFOS in serum or plasma, but the free fraction estimates drive the gradual clearance of total BPA from plasma or serum by describing clearance of free.

Renal reabsorption: The renal reabsorption hypothesis involving species specific and sometimes gender specific transporters to describe the pharmacokinetic data represents sound judgment. This departure from normal allometric scaling is suggestive of active transport processes. Few PBPK models explicitly describe transporters with drugs or chemicals, although the field is moving in this direction. Thus, the approach used for PFOA and PFOS is adequate, that is, a hypothesis was evaluated by employing empirical PK-based kinetic analyses. Because the mechanistic details are missing for each species/gender, scaling of this biological phenomenon is not possible at this time. This is not a weakness, but represents the state of the science.

William L. Hayton

A very important strength of the documents is the attempt to deal with the interspecies differences in pharmacokinetics so that adverse effects across species are compared on the basis of internal, systemic exposure to PFOA and PFOS, instead of basing comparisons on the administered mg/kg dosages. PFOA and PFOS have complicated pharmacokinetics that have proven difficult to model. While a relatively simple one-compartment model appears adequate to analyze single, low doses, this model fails when it is extended to higher doses and repeated doses. Nonlinearities appear associated with saturable plasma protein binding and with saturation of transporters thought to be involved in the reabsorption of the compounds from renal filtrate.

A weakness of the pharmacokinetic model adjustments is the lack of robustness of the models. Despite the extensive efforts of talented pharmacokineticists, development of a model that scales across species and handles a range of dosages and a variety of administration routes has proven elusive. The two compartment model of Andersen et al. (2006) has formed the basis of the model used in the draft documents. The model incorporates saturable resorption of PFOA and PFOS from renal tubular filtrate. While protein binding is known to be saturable (fraction free increases with concentration), the model uses a species-specific but constant free fraction. Model parameter values for mouse, rat and monkey were used to predict reasonably well measured serum concentrations after a fixed daily dosing regimen, Tables 5-6 – 5-8 for PFOA and 5-8 and 5-10 for PFOS. This agreement between predicted and measured serum concentrations gives confidence that the model-calculated AUC values and final serum concentrations associated with adverse health effects (or in the case of liver weight, biological marker of exposure) are realistic and a basis for estimation of RfD. While the model used

appears adequate for the purpose, the model parameters that were used have some markedly non-physiological values. (Information subsequently provided at the reviewers meeting explained some of the departure from expected physiological values, as discussed in a following section.)

Matthew P. Longnecker

For PFOA and PFOA, the MCMC model results (predicted final serum value) were compared to the measured final serum values, and the agreement was fairly good. For PFOS, the MCMC model results were compared to those from Loccisano et al. (2012b) and were found to be similar, which is also reassuring. Because the PBPK models of PFOA and PFOS are empirical, and have been shown to give results that agree reasonably well with observed data, the adjustments to accommodate the impact of albumin binding and renal tubule transporters are not critical. More data on albumin binding and renal tubule transporters might allow improved understanding of the pharmacokinetics of these compounds, but may not necessarily cause substantial improvements in the empirical predictions from current models.

Angela L. Slitt

The current weakness of the models is that data on species differences in PFOA and PFOA for various key transporters is limited and the document is also using mRNA data for various transport proteins to explain gender differences in urinary elimination. First, with regard to PFOS accumulation in the liver compartment, it is necessary to compare affinity of human versus rat for OATp mediated transport. This alone is tricky because of species differences in OATps. If PFOS-induced liver effects are related to PFOS accumulation in liver, it is would be helpful to understand whether a lower affinity of human OATp1b1 and 1b3 compared to rat OATp1a1 predicts lower hepatic PFOS accumulation. More is known about PFOA, but a similar argument can be made for PFOA. In addition, more comprehensive, controlled assessment of renal transporter affinity for PFOA and PFOS is needed to better model the species difference in urinary elimination.

The document often speculates about PFOA or PFOS regulation of transporter expression, but some papers cited (Cheng and Klaasen) do not have enough data at the protein level to support whether these differences in transporter expression are the drivers of toxicokinetic differences between males and females.

Question 7. Table 5-5 in the PFOA document and Table 5-7 in PFOS document list the parameters used for the ORD pharmacokinetic models that provide the final serum and AUC values for calculating the internal dose point of departure for the RfD calculation. Please comment on the strengths and weaknesses of the selected parameters.

James V. Bruckner

PFOA-specific comments
Despite the complexities and unknowns involved in plasma protein binding and renal tubular functions (i.e., glomerular filtration, basolateral tubular excretion and resorption, and apical tubular excretion and resorption), it is necessary to: (a) simply model only for saturable tubular resorption; and (b) use a range, or distribution of parameter values consistent with existing kinetic data. Unfortunately, optimization sometimes results in selection of physiological parameters that are not biologically-realistic, or plausible.

PFOS-specific comments
The parameters used in the modeling are biologically plausible.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

One unclear component of Table 5-7 in the PFOA document is the column labeled Species/Strain Used for prediction, which in every case is the same as the column labeled Species/Strain and is not otherwise adequately explained.

Jamie C. DeWitt

It is not clear that the parameters in Table 5-5 in the PFOA document and Table 5-7 in the PFOS document are from the Andersen et al. 2006 PK model or if they are parameters used in the reanalysis of the data. This needs to be better explained in both documents. Additionally, all of the units in the tables need to be explained and re-checked for accuracy.

Jeffrey W. Fisher

The authors should entertain the calculation of data derived AUC (e.g. Table 5-6) to compare to the model derived AUC, just as was done with measurement of total PFOA in serum. This works for the animal studies. The choice of using the empirical model over the more recent physiological models may be a weakness and our understanding of transporters advance.
The evolution of chemical-specific PBPK models for use in risk assessment and regulatory applications has repeated itself several times. This is, the first empirical non-physiological model(s) or PBPK models contain hypotheses generating ideas and later models test some of

these hypotheses, especially if additional experimental data become available. In the case of PFOA and PFOS, the EPA selected not to use the most recent PBPK models for PFOA and PFOS, but instead use a computational empirical based model (Andersen et al. 2006) that was the first attempt to quantitatively interpret the kinetics of PFOA and PFOS across species of laboratory animals. The authors did publish their model (Wambaugh et al., 2013). The authors chose not to use a human model because a lack of information for Bayesian analyses. The justification for their extrapolation methods should be stated and the published reference for the model should be cited.

Model parameter distributions (Bayesian analyses) appear to be biologically implausible in some cases, covering many orders of magnitude. The authors should discuss this issue and check the units of model parameters in Tables.

Both model parameters tables need to include a description of what the parameter represents and cite a figure. The figures showing the Andersen et al. 2006 model do not show all the model parameters and have different nomenclature.

The Andersen et al. 2006 paper is a critical paper offering a quantitative explanation for the PFOA and PFOS kinetic data sets.

William L. Hayton

In the "Pharmacokinetic Model Approach" sections of the documents, it is not made sufficiently clear that the parameter values in Table 5-5 (PFOA) and Table 5-7 (PFOS) were from re-fitting the published data, rather than using parameter values from the original literature reports.

PFOA Table 5-5, p. 5-12

Body Weight and Cardiac Output values are reasonable and typical.

k_a values for mouse and monkey seem extremely large; absorption half-lives would be on the order of 10 seconds, which is physiologically unrealistic. All of an oral dose would be absorbed within a minute, mimicking a rapid i.v. bolus dose. Serum concentration-time profiles may not be sensitive to these values, however so they are not disconcerting for the intended use of the models. The rat values appear reasonable.

V_{cc} values appear reasonable. The total steady-state volume of distribution value [$V_{ss} = V_{cc} \times (1 + R_{v2:v1})$] compares favorably with one-compartment V_d values for CD1 mouse, but V_{ss} values for the other columns (species) appear too large, due to the large $R_{v2:v1}$ values.

k_{12} values vary a lot across the columns, suggesting that k_{12} may be highly correlated with another parameter (e.g., $R_{v2:v1}$).

$R_{v2:v1}$ values also vary a lot across the columns.

T_{maxc} values are consistent across the columns; expressed in Gm/hr, they seem very large. For example, 2032 Gm/hr (4.91 moles x 414 Gm/mole) for the CD1 mouse. Even on a kg body weight basis could mouse renal tubules resorb 2 kg PFOA per hour? This maximum rate of resorption must far exceed the rate of filtration of PFOA at the glomerulus. (Clarification at the reviewers meeting explained this apparent departure from physiological reality. The units had been mis-specified in Tables 5-5 and 5-7. They were in fact micromole per hour

and micromolar for T_{maxc} and k_T instead of molar based. Thus T_{maxc} mouse value was 2 mg/hr, which is physiologically plausible.)

k_T values are the concentration in glomerular filtrate that half saturates the resorption transporters. Expressed in mg/mL, they seem large, much larger than the urine concentration that would be expected; e.g., for CD1 mouse, k_T is 15 mg/mL where free serum concentrations (Free x C_{serum}) would be about 0.3 µg/mL with 10 mg/kg in the mouse. So the transporter would not become saturated except at extreme doses. The value used by Andersen et al. (2006) for monkey was 0.00001 mg/mL. Unit specified in Tables 5-5 and 5-7 should be µM, not M.

Free fraction values measured in vitro are 0.01 or less at low PFOA serum concentrations (Table 3-1). The Free values for rat seem much higher than the measured values.

Q_{filc} is defined as a fraction of blood flow (renal or cardiac output?) to the filtrate (bottom of p. 5-11) but has units of flow in Table 5-5.

V_{filc} values are much smaller than the 0.01 L value used by Andersen et al. (2006), although Andersen et al. state that the model output is insensitive to this parameter and that their value was assumed.

PFOS Table 5-7, p. 5-15

Body Weight and Cardiac Output values are reasonable and typical.

k_a values for female mouse and monkey seem extremely large – see comment above for PFOA.

V_{cc} values appear reasonable. See comment above for PFOA.

k_{12} values vary a lot across the columns, suggesting that k_{12} may be highly correlated with another parameter.

$R_{v2:v1}$ values appear reasonable and consistent with other reports of V_{ss} values for PFOS.

T_{maxc} values are highly variable across the columns and seem much higher than physiological reality would allow. See comment above for PFOA.

k_T values are physiologically unrealistic and highly variable across columns. See comment above for PFOA.

Free fraction values have been measured in vitro and are 0.01 or less at low PFOS serum concentrations (Table 3-1, p. 3-3). The Free values in Table 5-7 are consistent with the measured values.

Q_{filc} is defined as a fraction of blood flow (renal or cardiac output?) to the filtrate (bottom of p. 5-14) but has units of flow in Table 5-7.

V_{filc} values are much smaller than the 0.01 L value used by Andersen et al. (2006), although Andersen et al. state that the model output is insensitive to this parameter and that their value was assumed.

While the parameter values for the pharmacokinetic models predict reasonable serum concentrations that generally agree with measured values (Tables 5-6 – 5-8 for PFOA and Tables 5-8 and 5-10 for PFOS), their high interspecies variability suggest that the models may be unreliable for prediction of internal exposures after other intake regimens and during a depuration phase.

Matthew P. Longnecker

Please see the answer to the previous question.

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Angela L. Slitt

The parameters included appear to be appropriate, but this lies outside of my area of expertise.

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Question 8. The volume of distribution (Vd) and half-life values are critical in the derivation of the interspecies uncertainty factor applied in derivation of candidate RfDs from a NOAEL, LOAEL or a BMDL. The available data for both values are provided in Section 3.5.2 and 3.5.3 of both documents. Please comment the strengths and weaknesses of the values selected.

James V. Bruckner

PFOA-specific comments
The adult male rat data of Kemper (2003), from which the rat half-life and clearance (CL) were obtained, appear to be solid. It is reasonable to select the human half-life of 2.3 years reported by Bartell et al. (2010), as their study population included equal numbers of males and females. Division of the rat CL by the human CL to yield a value of 219 is fine. I did not examine the publication of Bartell et al. (2010) to evaluate their data or methodology used to derive a human half-life of 2.3 years. Therefore, I am uncertain about its accuracy.

PFOS-specific comments
I would again defer to someone with more expertise.

Deborah A. Cory-Slechta

This falls outside my area of expertise and therefore no significant comments are provided. However, at the face-to-face meeting there was significant discussion regarding the modeling, including clarifications from Dr. Wambaugh that were found by those panel members with expertise to clarify these issues and these particular issues were considered adequately addressed.

Jamie C. DeWitt

While the overview of the individual studies that calculated Vd and half-life for each compound was detailed and complete, the rationale and analysis concerning *why* particular values were selected were insufficient. Additionally, as addressed in Charge Question 6, the rate of clearance/elimination likely contributes to the differences in half-life that are not associated with differences in the Vd. Therefore, a 3-fold uncertainty factor for species differences in pharmacodynamics (UF_A) was utilized for both compounds. What was the justification for using a UF_A of 3? The section on UF application needs a more thorough discussion regarding the choice of this value given differences in clearance. If the section on model adjustment (a suggestion in Charge Question 6) is better described, this comment may no longer be applicable.

Jeffrey W. Fisher

The use of this non-compartmental method should be justified. Why not use a PBPK model? Assuming steady state in the humans does allow for calculation a human equivalent serum concentration associated with a laboratory animal concentration. In what region of the exposure-dose range would nonlinearity occur in humans? Some type of discussion is needed

about the assumptions of this methodology and why it was used. I would like to see statements about if the NOAEL, LOAEL, and a BMDL doses are in the linear range for kinetics.

The authors should use the Bayesian analysis for animal studies to inform the UF. Use percentiles to explore Vd and half-life to support UF values. I did not see any attempt to use distribution information generated from the model beyond the central tendency or mean values. Please state why this is the case. It seems that the distribution information generated from the Bayesian analysis could be used to support UF development.

William L. Hayton

PFOA-specific comments

For male rat, the Kemper (2003) study appears to be the best source of pharmacokinetic parameter values, which were obtained by a model-independent analysis of serum concentration-time data from rats that were dosed by oral gavage at dosages of 0.1, 1.0, 5.0 and 25 mg/kg. In addition, there was a 1.0 mg/kg dosage administered intravenously, and a 0.1 mg/kg oral gavage dose with an extended sampling time. Each treatment used four animals. The CL and $t_{1/2}$ values appeared to be independent of dosage and route of administration. It would therefore be reasonable to average all 6 mean values for each parameter to give an over-all mean of 24 determinations. The average (n=24) values for male rat were CL = 0.0209 L/kg/d and $t_{1/2}$ = 7.83 d. These values can be used to calculate a V_d value ($t_{1/2}$ x CL / ln 2), which is 0.236 L/kg.

It is not apparent on p. 5-20 why a V_d value of 0.17 was used with half-life to calculate CL_{rat} when Kemper (2003) reported CL values and not $t_{1/2}$ values. (At the peer review meeting, it was clarified that the data of Kemper (2003) were re-analyzed and as a result the parameter values in the health effects documents differ somewhat from those published with the data in the original reports.)

The CL_{human} value was taken to be 0.00014 L/kg/d. There are no direct measurements of this parameter. Thompson et al. (2010) assumed that the intake rate of PFOA for subjects using PFOA-contaminated water was 91% of the PFOA in 1.4 L/d of water. This intake rate was used along with a PFOA half-life of 2.3 years to calculate a V_d value of 0.17 L/kg. This is the same value that was used in the health effects document for the rat (p. 5-20). The V_d values available in mouse, rat and monkey are about 0.2 L/kg, so the $V_{d,human}$ set at 0.17 L/kg is not unreasonable but it lacks the certainty of the rat V_d value.

The health effects document used a $t_{1/2}$ for PFOA in human of 839.5 d (2.3 years), which seems to be toward the low end of the range of values that have been reported. Along with Vd = 0.17 L/kg one arrives at CLhuman = ln 2 x 0.17 / 839.5 = 0.00014 L/kg/d.

The ratio CL_{rat} / CL_{human} calculated using the mean CL_{rat} from Kemper (2003) would be 0.0209 / 0.00014 = 149, which is about twice the value calculated on p. 5-21. This difference arises from the calculation of CL_{rat} using the $V_{d,human}$ and a half life of 11.5 d instead of using the CL_{rat} directly from Kemper (2003). The mean half life from Kemper (2003) was 7.8 d.

The CL_{mouse} / CL_{human} ratio is accurate, using Lou et al. (2009) data. A calculation for monkey is not shown.

PFOS-specific comments
Chang et al. (2012) appears to be the best source of pharmacokinetic parameter values for mouse, rat and monkey. Butenhoff and Chang (2007) is given as the reference for a 48-day half-life in rat; this is a final report, internal to 3M. The Chang paper gives half-life values for male and female Sprague-Dawley rat at 2 mg/kg and 15 mg/kg. The average V_d for the four groups of three/group was 0.71 L/kg. This is higher than the 0.23 L/kg value used in the draft document (p. 5-23). The 0.71 L/kg value is also higher than values for mouse, monkey and human, which are closer to the 0.23 L/kg value used in the draft document. The draft document ought to acknowledge this difference; it may be that the value in the 3M report is lower than the published value; Chang was a co-author for both sources. The Chang et al. (2012) paper gives CL_{rat} values that are 0.0051 L/h/kg for female (similar for 2 and 15 mg/kg doses) and for males, 0.022 and 0.011 L/h/kg for the 2 and 15 mg/kg doses. A single average value for CL_{rat} would be 0.011 L/h/kg, about 3 times the value used for the UF_A calculation in the draft document. The male value is about 2-3 times the female value and it may be appropriate to calculate a different UF_A value for each sex. Using the single CL_{rat} averaged across two doses and both sexes (0.011 L/H/kg) would give a CL_{rat} / CL_{human} ratio of 0.011 / 0.000081 = 135 and a UF_A = 407, substantially higher than the value of 123 in Table 5-15.

The UF_A values calculated for mouse and monkey appear to be in line with the literature values for PFOS CL values in these species.

Matthew P. Longnecker

The PBPK model of Loccisano et al. 2013 (for humans) can be used to calculate a volume of distribution for PFOA of 177 ml/kg, which is very close to the value of 170 ml/kg based on Thompson et al.'s 2010 one-compartment model . For PFOS, the corresponding value from the PBPK is 280 ml/kg, compared with the value of 230 ml/kg used in the Health Effects Document. This 22% difference could have an impact on some calculations. (Note: the PBPK model-based volumes of distribution were calculated by Marc-Andre Verner of the University of Montreal. He had calculated these values in the course of a separate project.)

For humans, the half-life data all depend on the assumption that ongoing exposure is negligible compared to baseline exposure, a reasonable assumption in most of the populations used to estimate half-life. While the Seals et al. (2011) gave estimates that were slightly different for PFOA in some cases, the methods employed in this study were not as strong as for Bartell et al. (2010) or the Burris et al. studies (2000; 2002). The agreement within species for the half-life estimates for PFOS are reassuring. The animal data on the half-life of PFOA are relatively sparse (2 rat studies that agreed reasonably well, 1 mouse study, 1 monkey study). For PFOA, the UF_As and RfD that were calculated based on the half-lives (expressed as clearance) would not have been substantially altered by alternate choices for specific values. The same is true for PFOS.

Angela L. Slitt

Strengths of the available data is that for the several species thorough evaluated, the half-life values are very consistent. For example, the several human studies cited report a range in calculated PFOS half-life in humans to be 4.1-8.67 years, two studies putting monkeys at 110-132 days, and rat generally has a narrow range with 3 out of 4 values provided ranging from 39.8-48.2 days for PFOS. An inconsistency is the Chang et al., 2012 describing a half-life of females of 66.7 days when in general female rodents may have faster elimination of PFOS.

Question 9. A variety of endpoints and studies were used to compare points of departure and the resultant RfDs for both PFOA and PFOS. In addition, comparisons were provided across RfD outcomes based on the model outputs compared to those for the NOAEL, LOAEL and BMDL points of departure. The range of candidate RfDs derived from the different points of departure is fairly narrow. Please comment on the strengths, weaknesses and transparency of this analysis.

James V. Bruckner

PFOA-specific comments
The procedure used to calculate PODs adheres to standard EPA guidelines and policy. The presentation of their derivation is clear, concise and transparent. It is certainly interesting that the range of PODs and resulting candidate RfDs is so narrow. Nevertheless, as discussed previously, I do not agree with their selection.

PFOS-specific comments
See my comments under General Impressions.

Deborah A. Cory-Slechta

While it is the case for both PFOA and PFOS that values from different points of departure are fairly narrow, the transparency of the analyses in neither case is clear. There is no rationale described even as to why these analyses were done on all of the studies, what was the primary study and how others related to that etc., i.e., this presentation does not follow the typical presentation format of IRIS documents in either its presentation of rationales and strategies, nor in the conclusions that it reaches. In both cases, it is only the single sentence indicating that modeling from one particular study will be protective of effects at other studies using higher exposures. This section in both documents needs introductory paragraphs that describe the specific strategy, choices of studies and the rationales for those choices.

As noted in response to Charge Question 3, the rationale for discarding the human epidemiological studies is not sufficient and requires rationale other than that stated and therefore, the question of using the human data remains open. As noted in response to Charge Question 1, in this reviewer's opinion, the increased liver weight can be justified as a departure point for assessment of RfDs, but as discussed at the face-to-face meeting, additional text supporting this choice is needed.

Jamie C. DeWitt

This particular section contained inadequate detail on why particular studies *were* or *were not* chosen. For example, immunotoxicity as an endpoint was not chosen for PFOS, based on "*in vitro* measures of immunocompetence on mice may not be relevant to the human experience and limited human data from epidemiology studies are inconclusive regarding the immunotoxicity of PFOS in humans"; however, the breadth of data from in vitro/ex vivo immunotoxicity studies for PFOS were not thoroughly discussed (please see Charge Question #2 for two additional in vitro studies).

For both compounds, an increase in absolute liver weight was selected as an endpoint as it was a common *effect* [sic] in both short and long term studies. However, the toxicological relevance of an increase in absolute liver weight was not discussed other than to indicate that it was a sign of altered homeostasis. Further, the co-occurrence of increases in absolute liver weight with other toxicologically-relevant endpoints (i.e., immunotoxicity and/or reproductive/developmental toxicity) is not a toxicologically valid justification for the use of liver weight as an endpoint for an RfD. Therefore, the analysis was not sufficiently transparent to deduce its relative strengths and weaknesses. Certainly, choosing an endpoint that occurs across species and occurs at relatively low doses will likely be protective of exposed humans; however, will it be a defensible endpoint? As currently written, the choice of this endpoint for an RfD is not adequately defended.

Jeffrey W. Fisher

I did not review the toxicity data.

William L. Hayton

For PFOA, a 10% increase in liver weight was selected as the metric for effect, which was "… not made based on toxicity but on the desire to find a common denominator against which to evaluate dose-response across studies and justified by the fact that other adverse effects accompanied the LOAEL for increased liver weight in some cases." The lowest serum concentration associated with an increase in liver weight was calculated for female mouse to be 20.33 mg/L (p. 5-16, PFOA document). These data are referenced to DeWitt (2008); this paper has only summary information on liver weights, all of which exceeded 20% weight gain, going as high as 70%; and it is not apparent in PFOA document how these liver weight gains were used to estimate an LOAEL for 10% liver weight gain.

Many of the animal studies of hazard assessment were conducted under conditions where the duration of the exposure was relatively short compared with the half-life, and steady state had not been achieved. It is not apparent how the NOAEL and LOAEL values from such studies were adjusted to account for the non-steady state situation. For example, the 20.33 mg/L PFOA concentration associated with a 10% increase in liver weight (Table 5-9) emanated from a 15 day drinking water exposure to 0.94 mg/kg/day that resulted in an average serum exposure of 20.33 mg/L (0 – 29.7 mg/L over 15 d, Tables 5-7, 5-9). For a fixed daily dose, the time to 90% steady state for mouse would be about 63 days (3.3 x half life, which was 19 days), and after 15 days the serum concentration would only be about 15% of its steady-state value. This seems to suggest that the RfD would have been over-estimated by a factor of 7, since the 0.94 mg/kg/day at steady state would have produced a serum concentration of about 150 mg/L, not 20.33 mg/L. This analysis is based upon the behavior expected from one-compartment model pharmacokinetics. As discussed on p.5-9 of the PFOA document, the steady-state serum concentration of PFOA is achieved in a much shorter time than one-compartment model kinetics would predict. Whether the target-site steady-state concentration of PFOA also occurs in a much shorter time than one-compartment model kinetics would predict (3.3 x half life) is apparently unknown.

Matthew P. Longnecker

This part of the document seemed especially strong and transparent. The agreement between methods was reassuring. The weaknesses and assumptions were well discussed. Please see the minor editorial comment on this issue given for Charge Question 1, above.

Angela L. Slitt

The RfD Point of Departure was based on animal studies that include monkey and rat.

Question 10. The RfDs for PFOS and PFOA are derived from the modeled steady state serum concentrations and their association with effects that include short term and longer term exposures with associated diverse effects. The studies considered included effects due to exposure durations that ranged from 11 to 182 days, and occur at comparable human equivalent dose (HED) levels. The current, draft RfDs do not include an uncertainty factor for study duration because of the apparent concordance HEDs despite duration differences. Given this pattern of response, is it appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures?

James V. Bruckner

PFOA-specific comments
I do not believe it is appropriate to conclude that the candidate RfDs are applicable to both short-term and lifetime exposures. Steady-state is apparently achieved in monkeys within 4 - 6 weeks (Butenhoff et al., 2002). Steady-state likely takes considerably longer in humans. Thus, RfDs for shorter periods of exposure should be based upon results of studies of similar duration.

PFOS-specific comments
I do not believe the candidate RfDs, as calculated, are applicable to different durations of exposure.

Deborah A. Cory-Slechta

While initially believing that it was appropriate conclusion for PFOA and PFOS, based on the correspondences in RfDs across short and longer term exposure, discussion at the face-to-face meeting made clear that this approach is not reasonable and requires additional consideration.

Jamie C. DeWitt

This approach may be appropriate given the relative similarity of serum concentrations attained regardless of study duration, i.e., steady state in serum is attained after a relatively short period of exposure. This appears to be consistent across studies with various species of animal models. However, the document authors might need to reconsider given what we may or may not know about liver hypertrophy. In the Hall et al. (2012) paper on liver hypertrophy (discussed during the public meeting), increase in liver weight is an adaptive response that may not be adverse UNLESS weight increases >150% over a three month or longer period may. Following this large and prolonged increase in weight, the end result may be a hepatocarcinogenic response. However, none of the studies contained in the documents indicate that longer term exposures increase liver weight to this degree.

Jeffrey W. Fisher

The departure from K=CXT (Haber's law) should be based on the toxicity endpoints of concern and what is known about dose-exposure kinetics/responses for these chemicals and other chemicals that target the same endpoint, not that the HED values are comparable. The NAS

AEGL committee only considered primary irritation for inhaled chemicals as an endpoint that was independent of duration of exposure. There is an SOP if needed for reference.
The time to steady state should be included in a table for the lab animals. Toxicity studies conducted for less than 30 days (perhaps?) are not at steady state for the pharmacokinetics of PFOA. Thus the measured serum levels would be different than at steady state. The shorter the duration of the toxicity test, the more impact this could have on extrapolation to chronic exposures in humans. My personal preference would be to use PBPK models for all species and consider only long term exposures for extrapolation to humans.

William L. Hayton

This depends in part on how quickly the PFOA/PFOS concentrations at sites of toxicity come to steady state. Since the Vd for these chemicals is small (~ 0.3 L/kg) it seems likely that the concentrations in tissues rise in pseudo equilibrium with the rise in serum concentration. That said, the half lives are relatively long due to the very small clearance ($t_{1/2} = \ln 2 \times V_d / CL$). If one-compartment kinetics apply, then a guideline for time to 90% steady state is 3.3 $t_{1/2}$. For studies that expose animals for a period of time shorter than 3.3 $t_{1/2}$, the serum concentration would not be at steady state and the internal systemic exposure (serum concentration) would be less than what it would be if the exposure were longer than 3.3 $t_{1/2}$. This effect would seem to lead to overestimation of the intake rate that was associated with a particular internal exposure and associated biological endpoint. For example, the $t_{1/2}$ of PFOS in mouse is about 36 days and 3.3 $t_{1/2}$ is 120 days. Consider a 28-day exposure using a fixed daily dose that produced an LOAEL of "X" mg/kg/day. On Day 28, the body level would only be 42% of the steady state level, and the average body level over the 28-day period would be about 21% (approximating the increase as linear and not exponential). The true LOAEL would be 0.21 "X" mg/kg/day; i.e., intake of 0.21 "X" mg/kg/day would produce a body level at steady state that was the same as the average body level produced by X mg/kg/day administered over 28 days. The time to 90% steady state for a fixed intake rate is quite long; from the literature in the health effects documents, the times in the following table were calculated. From this line of reasoning, exposure times less than two half-lives begin to significantly overestimate intake rates associated with particular endpoints. This analysis is based upon the behavior expected from one-compartment model pharmacokinetics. As discussed on p.5-9 of the PFOA document, the steady-state serum concentration of PFOA is achieved in a much shorter time than one-compartment model kinetics would predict. Whether the target-site steady-state concentration of PFOA also occurs in a much shorter time than one-compartment model kinetics would predict (3.3 x half life) is apparently unknown.

	CL		Vd		$t_{1/2}$		Time to 90% steady state	
	[mL/d/kg]		[mL/kg]		[d]		[d]	
Species	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS	PFOA	PFOS
Mouse	6.6	5	180	265	19	36	63	120
Rat - Male	23	16	273	947	8.4	40	28	92
Rat - Female	776	5.2	150	476	0.13	66	0.43	218
Monkey	6.3	1.4	190	238	27	121	89	400
Human	0.085	0.08	170	230	1378	2000	12.5 yr	18 yr

In addition, this line of reasoning may be incorrect if the assumption of one-compartment kinetics is incorrect. For multi-compartment models the serum concentration and target organ/tissue could come to their pseudo steady state levels relatively quickly while slowly equilibrating (deep) sites slowly approached steady state. Simulation with PBPK models for PFOS and PFOA may help answer this question.

Associated with the uncertainty introduced by exposures that were shorter than the time to achieve steady-state concentration at the target site is the exposure time required for the adverse effect to be expressed. While some adverse effects may occur immediately and directly in proportion to the concentration of PFOA or PFOS at the target site, other adverse effects may be slow to become manifest. These "indirect adverse response" behaviors are well known in the drug action arena; e.g., certain antidepressant drugs require several weeks exposure to the target site before the effect of the drug appears. This lag time is not associated with pharmacokinetics (time to steady state) but with indirect-response pharmacodynamics. It could be argued that uncertainty factors are needed for both pharmacokinetics (pre-steady state condition) and pharmacodynamics (or toxicodynamics) to account for possible indirect response behavior.

Matthew P. Longnecker

EPA might want to consider using an uncertainty factor for duration, for two reasons. First, the monkey data for PFOS used for the point of departure were from a study where the duration of exposure was relatively short-term relative to the half-life, and it appeared that duration of dose affected liver and other adverse outcomes detected at higher doses, and no monkey data were used in the POD for PFOA. Second, questions raised by Drs. Hayton and Fisher at the peer-review meeting made me less comfortable with the calculations that used average serum concentration derived from the AUC and duration of dosing to compare with humans, who are more likely to be near steady-state.

Angela L. Slitt

Yes, but this lies outside of my area of expertise.

Question 11. In addition to using the average serum values from animal studies to calculate internal doses for humans, the animal to human extrapolation can be accomplished by dividing animal average serum values by the human to animal clearance ratios to project a human average serum point of departure in units of mg/L serum. Please provide recommendations for applying uncertainty factors to the extrapolated average human serum values to determine serum-based thresholds that are protective for humans. A NOAEL expressed in average human serum units would be useful in interpreting NHANES population monitoring data.

James V. Bruckner

PFOA-specific comments
No comment.

PFOS-specific comments
No comment.

Deborah A. Cory-Slechta

In initial response to charge questions, I found it difficult to understand specifically what this charge question was asking for a response to: Does this refer to the data in Table 5-10 for PFOA? Wouldn't you include animal to human UF values at the least. Since the data for the studies listed in the Table is not clear as to their duration (columns are needed for this information, or add to the Study box), it is not clear whether a UF for study duration is warranted. It is not clear how sex differences are being accommodated in any of these.

At the face-to-face meeting, however, with some additional input from EPA, it was clear to all that there was no need to do such derivations from animal to human, which could instead be derived directly from the human data and thus presumably this is no longer an issue.

Jamie C. DeWitt

Would this approach take into account differences between animal studies that have a defined exposure duration and data from NHANES, where exposure duration is assumed to be continuous (although it may not be), if exposure duration does not appear significantly impact serum concentrations? Additionally, how would the half-life estimations from the Seals et al. (2011) study, which contained two half-life estimations based on concentration and time, impact this approach?

Jeffrey W. Fisher

Again, is the system linear in the exposure/dose ranges of interest? I would try to determine an UF by exploring a range of predicted human serum levels. Attempt to use 5,50, and 95% for animal serum concentrations with a 5,50, and 95% CL values in the animals and for the human perhaps use two CL values representing a high and low. The idea is to use as much information

as you can to determine the possible range of values. This will help guide the selection of uncertainty values.

William L. Hayton

This calculation is equivalent to dividing the animal dosage by the CLhuman, assuming that the animal serum concentration is at steady state ($C_{ss,animal}$) maintained by a constant dose rate (DR).

$$C_{ss,animal} / CL_{human} \div CL_{animal} = CL_{animal} * C_{ss,animal} / CL_{human} = DR / CL_{human}$$

This calculation would give the steady-state serum concentration in human that would be produced by the animal dose rate. (I will have to study this to understand the question; the calculation does not make sense to me.)

At the peer review meeting, the aim of this calculation was clarified. Authors desired a way to calculate a steady-state serum concentration ($C_{ss,human}$) that would result from the human equivalent dose rate (HED) administered until steady state. The appropriate calculation would be:

$$C_{ss,human} = HED / CL_{human}$$

Matthew P. Longnecker

The proposed division by animal clearance ratios does not make sense to me. The average serum values from animal studies is already taking pharmacokinetic variability in blood levels during the observation period into account, and human blood levels will be relatively constant. Thus, it would make sense to directly compare the POD estimated average serum concentrations from animal models to the blood levels in NHANES. With respect to uncertainty factors that would be need consideration for this approach, it seems that UF_H, UF_L (For LOAEL and HED_{LOAEL}), UF_D, and the component of UF_A that takes pharmacodynamics into account would all still be applicable.

Angela L. Slitt

This is outside of my area of expertise.

Question 12. Please describe any suggestions you have for improving the clarity, organization, and/or transparency of the draft documents.

James V. Bruckner

PFOA and PFOS-specific questions
See specific observations.

Deborah A. Cory-Slechta

While the EPA authors are aware of updates in the IRIS process, it might be very helpful to look at some of the new documents coming through that process for guidance as to the levels of critique and evaluation that are now included in these documents. They also include an introductory chapter focused specifically on the literature searches and literature that is included vs. excluded.

The Executive summary does not provide sufficient rationale and descriptions to lead a reader through the steps to what is concluded and reads more like an abstract than an Executive Summary. Since this may be the only section read by many reviewers, it is important that it provide a succinct journey through the process. Here again, the new IRIS documents (e.g., trimethylbenzene) could provide a useful template.

Chapters 3, 4 and 5 could each benefit from an opening paragraph describing what the section's goals are, and integration and conclusion sections at the end that establish the basis for the presentation in Chapter 5. Currently the Hazard Identification studies generally treat all studies as of equal strength/power, which is certainly not the case. These chapters should present that kind of critical and transparent assessment as it ultimately serves as the basis for decisions that are made.

The inclusion of sections on in Vitro data did not ultimately seem particularly relevant in the outcome for these compounds and could be significantly shortened to add more to Chapter 4 on study strengths and weaknesses. However, where pertinent, it would probably be more useful to break that section up and insert test where it follows an in vivo discussion.

Tables could be considerably improved and made far more useful to the reader for comparative assessments. As of now, they require going back and forth to the text to capture additional details of the studies, e.g., sample sizes, species etc. and could benefit the reader significantly with those additions. For the human assessments, it is equally important to include these details in the chapter as well as a column of study strengths and limitations.

While charge questions ask whether the appropriate studies were chosen as key studies, this reviewer does not remember that that term was even used in the documents, certainly no explicit mention was made as to which studies were considered key studies. This would seem to be a section that should be included in Chapter 4 more explicitly. Chapter 5 of both documents, more so PFOA, are confusing as almost all studies are subjected to modeling, for reasons that are

never presented in sufficient detail and simply followed by statements that a selected study (not really well presented in Chapter 4 as a selected study) will protect against other adverse effects.

Jamie C. DeWitt

The documents lack a critical analysis of differences between findings of epidemiological studies and findings of animal models. As stated in the comments to Charge Question #3, what is particularly valuable about the PFOA/PFOS database is that it is relatively extensive in that it includes data not only from occupationally-exposed humans, but from people highly exposed to environmental concentrations of PFOA/PFOS, and from people in the general population who have detectable concentrations of these compounds.

Critical to this analysis is a discussion of concordance and lack of concordance between human data and animal model data. For example, immunotoxicological findings appear to be consistent between humans and rodent models whereas serum lipids are not. How do these differences impact the overall confidence in the database and derivation of the RfD?

All of the sections related to the PK models developed by ORD need additional information for clarity and transparency. As written, it is not clear that the PK values presented throughout the document actually represent a reanalysis of existing data from studies that reported serum concentrations. The Wambaugh et al. (2013) study could be referenced to shorten this exercise as this publication provides details on the reanalysis of existing data.

Justifications for choosing or not choosing particular values or endpoints need to be more thoroughly detailed throughout both documents, especially for endpoints that appear to occur in both experimental animal models and exposed humans (i.e., thyroid hormone disruption and immunotoxicity).

Jeffrey W. Fisher

These documents represent an enormous undertaking to describe studies with PFOA and PFOS. Keep the same writing style for reporting studies. This was very good. A synthesis of the most important studies is needed and some statements about why other studies are not used by EPA. It is easy to get lost in the document because of its size, but if there was an analysis or synthesis section for the key toxicity studies and another for PK modeling rationale, it would help readers.

William L. Hayton

It would be helpful to use one set of units for test article amount and concentration. The draft documents use ng/mL, µg/mL, µg/L, ppb, ppm, and µM for PFOA/PFOS concentration in water, diet, and serum. It would be more straightforward to use one concentration term, preferably ng/mL, and perhaps µg/mL in addition as necessary. But making comparisons among ng/mL, ppm, and µM is a distraction.

In Section 3 of both documents, it would be helpful to include a summary table of primary pharmacokinetic parameter values for the species included in this section. Tables 3-17 – 3-20 in

the PFOS draft document are a good start. In the PFOA document, Table 3-23 lacks CL values, and Tables 3-24 and 3-25 lack V_d values. For the pharmacokinetic model analyses presented, primary parameters values could be limited to CL, Vd_{ss}, and half life (see table in response to question 10). The CL and V_{dss} values should be normalized to body weight. Where there are multiple models for a species, there should be separate entries for each study. Where there are multiple dosages for a species, there should be separate entries for each dosage. For the PBPK models, V_{dss} values are not available and therefore should not be included. Such a table would be helpful to show consistency or lack thereof among studies and would facilitate selection of the best available values for CL and V_{dss} for use in a human PK model that would predict steady-state serum concentration from intake (dosing) rate and, conversely, predict intake rate from steady-state serum concentration. These predictions are probably the primary reason to include a pharmacokinetics section in the documents.

The pharmacokinetic sections of both documents lack example graphs of serum concentration-time data on semilog coordinates for PFOA and PFOS. Inclusion of a few representative graphs would help the reader evaluate the consistency of the data used to generate the pharmacokinetic parameter values, and where model-based equations have been fitted to the data, the scatter of the measured concentrations around the model-predicted line would be informative as to the goodness of fit and the validity of the model and its parameters.

Matthew P. Longnecker

I can see advantages to treating this more like a systematic review of the literature, where the specific search algorithm for included articles is laid out, as are the range of dates of publication to be considered, and any other selection criteria applied for articles considered. In these documents, while the review of earlier literature appears to be comprehensive, after some point there must have been some decision making about which of the more recent articles to include.

The EPA has many guidelines about how data like these are to be evaluated, yet in the document few, if any, references to these guidelines were cited. Because so many guidelines exist, it could help readers if the authors cited specific places in critical documents that provide guidance for specific decisions.

Angela L. Slitt

The document reads very well. Although not included in the RfD determination, including a table of the observed human effects along with serum concentrations in Section 5.0 would put Tables 5-2 and 5-3 into context. Some sort of layman explanation to help understand why only non-human exposures are being included would be helpful to the general public.

V. SPECIFIC OBSERVATIONS

James V. Bruckner

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
3-11	5, lines 7-11	It is stated that the PFOA concentration in bile increased by a factor of 12.5 with the increase in PFOA dose from 12.5 to 25 umol/kg in wild-type mice and 19.5 in PPARα-null mice. These factors should be 2.8 for wild-type and 6.1 for PPARα-null mice. The document's authors may want to rethink their interpretation of the data. The results for the wild-type mice do suggest saturation of transport from liver to bile ducts, but the PPARα-null results do not, indicating a role for PPARα in this process. In contrast to the foregoing, the findings of Lou et al. (2009) (p. 3-11, pgr. 2) indicate their highest dose of PFOA is cleared from the blood of mice more rapidly than lower doses, suggesting saturation of hepatic and/or renal reuptake transporters. What is the relative importance of biliary and renal elimination of PFOA?
3-12	3, lines 2-4	It should also be stated that upregulation of MRP3&4 and the OATs may be <u>beneficial</u>, due to increased biliary excretion of bile acids, bilirubin, conjugated metabolites of toxic chemicals, etc.
3-14	1 & 2	It might be stated that the findings of Hinderliter (2004) support those of Han (2003), in regards to development of female rats.
3-14& 3-15		It is problematic to try to compare values in Table 3-14 with values referred to at the end of the second paragraph on p. 3-17. Whole pup and pup serum PFOA levels decrease between PND 1&18 for each dosage in the table. It would be preferable to include another table showing the PFOA levels with body weight taken into account. Table 3 – 14 and other tables should include the species in the title. It would also be helpful to include some details of the experimental protocol in the footnotes.
3-20		It would be useful at the end of this section (Distribution During Pregnancy and Lactation) to summarize the primary findings, or conclusions that can be drawn from the data that were presented.
3-23	4, line 2	It should be emphasized that urinary excretion of PFOA was substantially higher in female than male rats.
3-28	2, line 4	Replace "receptors" with "transporters".
3-28	6	Did 10 uM PFOA inhbit PAH and estrone uptake to a greater extent than 100 uM PFOA?
3-29	3 & 4	It is not clear what Yang et al. (2009) concluded about the role of OATp1a1 in the uptake of PFOA from glomerular filtrate.
3-32	3 & 4	These two summary paragraphs are very helpful.
3-37	1, line 1	Should "adsorption" be "absorption"?

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
4-7 & 4-9	Tables 4-1 & 4-2	Tables 4-1 and 4-2 are quite helpful in integrating the results of studies of occupationally-exposed populations.
4-13		A concluding sentence should be added to summarize the findings of a lack of association of PFOA with diabetes, metabolic syndrome, etc.
4-32		The NOAEL and/or LOAEL for this study should be stated at the end of the paragraph.
4-34	2	Is the LOAEL for liver effects 1 ppm in the study of Loveless et al. (2008)?
4-38	1	Include the meaning of the abbreviation "mPPARα".
4-39		Inclusion of the table for Minata et al. (2010) would be useful to help readers better comprehend the study findings.
4-40		A table of short-term LOAELs and NOAELs should be added here or in Section 5.
4-47	2	It is hard to believe, judging from the slight difference in mean values and their standard deviations, that absolute and relative liver weights are significantly higher than controls in the 1 mg/kg/day group.
4-67	2, line 5	Insert "absolute" before "liver weight".
4-69	1, lines 1 & 2	It might be worthwhile to point out that the actual study by Butenhoff et al. was conducted prior to 2004.
4-73		A summary sentence (or two) should be added at the end of the Mutagenicity and Genotoxicity section.
4-83		A summary paragraph should be included at the end of the Immunotoxicity section.
4-101	1, line 14	Insert the word "some" before "occupational studies". In order to present a more balanced perspective of findings in occupational studies, the following sentences could be added at the end of the paragraph: "Olson and Zobel (2007) examined groups of male workers at 3 fluorochemical production facilities. Serum PFOA concentrations were not associated with total cholesterol, LDL or HDL in workers at these facilities."
4-102	4	It should be stated that the increases in serum enzyme activity in workers were quite modest/small. The following sentence should be added at the end of the paragraph: "Emmett et al. (2006), however, found no association between serum PFOA and liver or renal enzymes".
4-103	2, line 2	Change "apoptotic or necrotic damage of" to "apoptosis or necrosis of". Apoptosis and necrosis are types of cell death, not damage/injury.
4-103	3, line 1	It is true that PFOA may interfere with the biliary excretion of other compounds that are transported by the same transporters. Upregulation of the genes for these transporters, however, may be beneficial in that the excretion of bile acids, bilirubin and conjugates

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
		of toxic chemicals/metabolites may be hastened.
4-103	4, line 2	I would avoid the word "critical" until the section on Dose-Response Assessment.
4-103	4	Increases in absolute and relative liver weights were dose-dependent (Cui et al., 2009; Elcombe et al., 2010; Wolf et al., 2008a)
4-103	5	It is important to distinguish between effects of PFOA on rough and smooth endoplasmic reticulum (RER and SER). RER content was diminished, but there was a proliferation of SER.
4-104	2, line 5	This last line should be amended to read "that PFOA has some effects of unknown toxicological significance that appear to be independent of PPARα activation.
4-104	4, line 3-5	The meaning of the sentence is not clear. Has something been omitted?
4-105	3, line 3	Add "of offspring" between "abilities" and "at 6 and 18". Include Fei and Olsen's (2011) finding of no association between prenatal PFOA exposure and behavioral or coordination problems in children at age 7.
4-109	3	The species (i.e., mice) studied by White et al. (2009) and by Wolf et al. (2007) should be stated.
4-111	4, line 2	Replace "examine" with "determine whether there was".
4-112	2, lines 1 & 2	The first sentence is misleading and should be rewritten. Butenhoff et al. (2012) did not see a significant increase in liver adenomas or carcinomas. Biegel et al. (2001) reported an increased incidence of hepatic adenoma but not carcinoma.
4-112	2, line 13	What is hepatic cystoid degeneration?
4-114	2, line 3	Insert "decreased" before "apoptosis".
4-115	5, line 2	What is meant by "PRAR exposures"?
4-116		There is no mention of PFOA-induced changes in expression of genes (e.g., cell cycle control, peroxisomes biogenesis, inflammation, etc.) that are PRARα-dependent. There is no mention of the role of PRARα or peroxisomes in oxidative injury and carcinogenesis.
4-120	1, lines 11 & 12	Insert "these" between "that" and "hormones".
4-121	3	It would be helpful to give the PFOA dosages of White et al. (2007) and one or two other studies, so the reader will have some idea of the magnitude of PFOA exposure required to alter mammary gland development.
5-1		RfD: Omit the word "wealth" from the bullet pertaining to epidemiology studies. There have been relatively few epidemiology studies of PFOA-exposed populations.

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
5-2	1, lines 2-6	Another obvious point should be made here, mainly that occupational exposures result in much higher plasma PFOA levels and body burdens than do environmental exposures. Thus, it would be anticipated that adverse effects would be more apparent in PFOA facility workers.
5-2	1, line 5	Include the words "in some instances" between the words "shown" and "between". Otherwise, it appears from this paragraph the serum PFOA concentrations are consistently/usually associated with the various maladies.
5-2	3, line 8	Insert "failure to attain" between the words "with" and "developmental".
5-7	2, line 4	Insert the word "rodent" between "between" and "species"
5-19	1, line 1	Insert "from some studies" between "data" and "have".

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
3-2	5, lines 2 & 3	It is stated here that "the ratio of PFOS identified in serum and liver tissue are similar". Do the authors mean that PFOS concentrations in the serum and liver are similar?
3-2	6	How does PFOS distribute between plasma lipoproteins and proteins/albumin?
3-5	1, lines 9& 10	How much lower were milk PFOS levels than serum levels?
3-7	1, line 2	Oral and gavage are redundant.
3-16	Figure 3-1	This figure nicely illustrates relative PFOS levels in dams and fetuses/pups over time.
3-19	1,line 3	Insert "groups" between "day" and "on".
3-21	1, line 10	Substitute "longer" for "slower".
3-23	2	It is not clear who conducted the human PBPK modeling nor which model they used.
4-21	2, lines 1-3	What did the 2nd monkey die from?
4-26	3, line 3	The word "concentrations" should be replaced by "doses".
4-39	1	Does an increase in motor activity on PND 17, but no such effect on PND 13, 21 or 61, constitute a toxicologically-significant effect?
4-56	2, lines 1 & 2	It is stated that "taken together, these studies suggest a PPARα-independent mechanism…" Of the studies reviewed to this point in the document, only that of Abbott et al. (2009) supports this premise. Qazi et al. (2009), Rosen et al. (2010) and other groups of investigators have reported other PPARα-independent effects of PFOS.
4-60	2, lines 15-17	Is oxidative damage likely to be operative to a significant extent at lower PFOS doses?

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
4-61	2, line 4	What is meant by "The concentration…"?
4-61	4, line 2	Change "dose of exposure is" to "levels of exposure are".
4-62	1, lines 2 & 3	What did Olsen et al. (2003) find correlation between?
4-62	3, lines 4 & 5	Identify the species (i.e., rat) studied by Chang et al. (2009) and Stein et al. (2012).
4-62	5	The liver of rats and monkeys was examined for histopathological changes, but the histological changes should not be considered lesions nor pathological.
4-68	4, lines 5 & 6	The elevated incidence of hepatocellular adenomas/ carcinomas was almost entirely due to adenomas. Only 1 of 60 high-dose female rats exhibited carcinoma.
4-69	5, lines 3 & 4	It is stated here that there was no increase in hepatocellular proliferation detected in the subchronic study of Seacat et al. (2003). It is stated previously on page 4-69 that "the data for PFOS are adequate to support some but not all key events…" I assume that cell proliferation is thought to be a missing event. Seacat et al. (2003) reported that the average hepatocyte proliferation index was not increased, but that some animals exhibited mild increases. It is clear in the current document that PFOS is not as potent a PPARα inducer as PFOA.
5-4	2 & 5, line 7	Again the terms "histopathological" and "lesions" are misnomers.
5-4	3, line 9	What is meant by a "biologically significant decrease in survival" at 0.8 mg/kg?

Deborah A. Cory-Slechta

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
Chapter 5		The text of Chapter 5 in the PFOA document (and other places) continues to state that a 10% increase in liver weight would not be an adverse effect, but merely a denominator for loss of homeostasis. On what basis was this conclusion derived? What is the support for this statement? It appears that benchmark dosing was applied to studies that had liver weight as the common denominator, but does this accommodate the lowest NOAELS and LOAELS observed for any endpoint in the long duration studies? Use of just studies with the common denominator because they provide replication ignores the fact that some other effect may occur at lower levels but simply hasn't been evaluated in as many studies as focused on PPARa-based targets. If this isn't the case, then the text should clearly address this.
5-7	2	States that the $BMDL_{10}$ values all fall below the experimental LOAELs. So, what does that mean, is there some conclusion that is supposed to be reached from this? IF so, please state it.
5-13	1	States "Generally these values were similar." What does similar mean? What is acceptable in this context?
5-16	3	States that the half-life value Bartell et al. (2010) was sued for half-life because it seemed more relevant to scenarios where exposure result from ingestion of contaminated drinking water by members of the general population. This rationale does not appear to consider the potential different strengths and weaknesses of the other potential studies. Is it necessarily the case that general population is more important than occupational studies? The rationale needs to be described in greater detail. Virtually no rationale is provided for the choice of the Thompson et al. (2010) study for a volume of distribution value.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
1-1	4	There are similar concerns for the PFOS document. Loose terminology should be eliminated, e.g., what is a 'finding of note' as used in the executive summary for PFOS.
Executive summary		The PFOS executive summary is of limited utility; for many readers this may be as much of the document as they read; as currently written it is not clear or transparent nor does it sufficiently explain how it arrived at an RfD.
3-3	Table 3-1	Couldn't a sentence essentially substitute for Table 3-1; it really isn't useful.
3-25	1	Loose terminology should be eliminated, e.g., what is "generally good"
3-26	Figure 3-7	Figure 3-7 has no explanation of what is the black vs. gray line.
All tables		There is a need to improve all of the tables; they should always include study name/year, sample size and exposure duration information on them; this would make all of the comparisons easier to evaluate and not require the reader to continue to go back and forth to the text.
4-4	Table 4-1	For example, table 4-1 has only study name and year, but what really matters is also exposure duration and sample sizes, because the comparisons of outcomes in the Table depend upon the power of the study to detect effects at the very least.
4-9	Table 4-2	The same comment applies to Table 4-2 and any others with this intended purpose.
4-11	Table 4-3	Table 4-3 needs sample sizes, exposure duration etc.
4-24	Table 4-7	Tables that summarize a significant amount of data from a single study (e.g., 4-7) should include the study authors and year in the Table title so it doesn't have to be searched for.
		In several instances in the PFOS document, adverse effects early that appear to be reversed at a later age are discounted with the suggestion that they therefore do not matter; given our increasing understanding of the importance of early changes in terms of epigenetic changes, this is no longer appropriate and in fact, misleading.
5-16	Table 5-8	What do the parentheses signify?
5-17	Table 5-9	What do the parentheses signify?

Jamie C. DeWitt

Specific Observations for *Health Effects Document for Perfluorooctanoic Acid*		
Page	**Paragraph**	**Comment or Question**
4-102	2 & 3	DeWitt et al. 2009 also included data on triglyceride levels in C57BL/6 mice exposed to PFOA for 15 days; triglyceride levels were dose-responsively decreased.

Jeffrey W. Fisher

No specific observations.

William L. Hayton

Specific Observations for *Health Effects Document for Perfluorooctanoic acid*		
Page	**Paragraph**	**Comment or Question**
1-2	Last, line 5	Delete "in"; should read "… in rats was analyzed …"
3-2	1, lines 6-8	Assumption that fecal excretion represented unabsorbed PFOA is problematic; suggest rephrasing this sentence.
3-3	Table 3-1	Protein binding is important for PK modeling, where the fraction unbound (fup) is the important parameter, not the fraction bound. Suggest listing fup values rather than percent bound.
3-6	Last, line 3	"concentration" should be "dose rate"
3-8	2, line 4	In addition to liver, kidney, and blood, other tissues are prominent. E.G., Table 42 of Kemper shows that in male at 1 mg/kg, t=Tmax, GI tract, GI contents, muscle, bone and skin contained a greater percentage of dose than did the kidney.
3-8	2, line 8	"Blood to kidney" should be "kidney to blood"
3-8	2, line 10-11	In Kemper, Tables 44-45, blood to kidney ratios are not 10 or higher in males.
3-8	2	This paragraph reports both percent of dose found in tissues, and concentrations found in tissues. But Tables 3-4 and 3-5 present only the former. When presenting tissue concentrations, please make it clear that those data are not shown.
3-18	Last, line 3	"were" is repeated.
3-19	1, line 1	Technically incorrect to say that the level peaked at PND7; that was the earliest sample time. The peak may have occurred before PND7.
3-19	Table 3-15	The last dose was on GD17; strange that at 1 and 3 mg/kg the serum concentration increases from PND7 to PND14.
3-22	4	Last sentence is garbled.
3-22	4, 5	Agree that biliary elimination is possible, but it could be that chloestyramine binds PFOA and PFOS in the GI tract lumen after they passively diffuse from the blood to the gut. There seems to be no direct evidence of biliary elimination, e.g., bile collected from treated animals.
3-23	Last, line 4	Should be Table 3-18.
3-34	Last, line 9	Should be "nonlinear least squares"
3-35	Table 3-23	Column 2, "Adsorption" should be "Absorption"
3-38 3-38	2 Figure 3-7	The arrow from Gut to Liver appears to point in the wrong direction; it should represent biliary excretion of PFOA from Liver to Gut.
3-43	Last line	"… indicating the absence of active excretion in human kidneys." This does not follow from the observation of renal clearance being about 0.001% of GFR. A plasma free fraction of 0.001 would

Specific Observations for *Health Effects Document for Perfluorooctanoic acid*		
Page	**Paragraph**	**Comment or Question**
		account for the CLr being 0.1% of GFR, and passive tubular reabsorption would make it 0.001% of GFR since urine flow is about 1% of GFR. Other scenarios are possible that do not invoke the absence or presence of active excretion.
3-44	Table 3-24	Should report all data values with three significant figures. For example, Lambda z values have only one sig. fig., while $T_{1/2}$ values have 5-6.
3-46	2	This reviewer does not follow the derivation and use of a value for volume of distribution with regard to intake rate and serum concentration of PFOA. If the subjects were at steady state, the body burden would have to be known. At steady state, the serum concentration would be independent of the volume of distribution, so any V value ought to match the intake rate to the steady state serum concentration.
4-9	1	Log transformed concentration was 1.51 and 1.48 ng/mL – are these the logarithms? IE, are the actual concentrations 10^1.51 = 32 and 10^1.48 = 30 ng/mL?
4-20	2, line 8	Anderson here is spelled Andersen in the reference list.
4-30	1, line 9	prostrate should be prostate.
4-31	4, line 10	decreased should be decrease.
4-112	1	It would be helpful to restate the serum concentrations for the Eriksen and Vieira studies, or refer reader to p. 4-29 where they are provided.
4-112	1, line 9	Delete "for".
4-112	2, line 12	Delete "were".
4-118	4	Delete "of actions" after MOAs
4-120	3	The broad range of half lives could also be due to person-to-person variability in the free fraction of PFOA in serum (fup). This is the case for highly bound drugs; e.g., warfarin.
5-1	3	Pharmacokinetic is misspelled.
5-1	5	Disagree – exposure assessment based on the human data is feasible. In fact, the serum concentrations are a better measure of exposure than are intake measures as they reflect all intake pathways and eliminate bioavailability and pharmacokinetic influences on internal exposure.
5-12	Last	Table numbers should be 5-6, 5-7, and 5-8.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
3-5	3	The low CSF : serum concentration ratio could also be due to an export transporter that pumps PFOS out of the CSF and/or to extensive serum protein binding, where only the free serum concentration of PFOS is in equilibrium with the free PFOS concentration in the CSF.
3-22	2	The free fraction used for the model is much larger than that determined experimentally, Table 3-1; this should be pointed out in the text.
3-22 3-23	2 Figure 3-5	The arrow from Gut to Liver appears to point in the wrong direction; it should represent biliary excretion of PFOS from Liver to Gut.
3-24	4	Anderson should be Andersen.
4-26	4	"concentrations" should be "dosages".
5.2	3	Should note for many of these studies, that steady state may not have been achieved due to the long half-life of PFOS. Half-life values from Section 3 are: mouse, 37 days; rat male, 40 days and female 64 days; monkey, 120 days. Using a one-compartment PK model, the time to 90% steady state is 3.3 half lives.
5-5	3	The NOAEL for liver effects in rats of 0.072 mg/kg/day is not consistent with p. 5.4, para. 2, which states that lesions of the liver <u>were</u> observed in male rats after 104 weeks at this dosage.
5-7	2	For female rat, the PFOS half life is about 60 d and the period of gestation is about 20 d or one-third of a half life. If PFOS is administered to the dam only during gestation at a fixed daily dose, the serum concentration of PFOS would rise from 0 to 21% of the steady-state serum concentration that the fixed dose rate would produce at steady state. The exposure of the fetus during gestation would average only about 10% of the exposure that would have occurred if the dam had received PFOS for 4 half-lives (240 days) prior to mating. BMDs based on such a fixed dose could be elevated by as much as a factor of 10 compared with the steady state situation. Steady state would be the relevant situation for humans. For the Luebker study (Table 5-3) the serum concentration during gestation would have increased from about 38% to 50% of the eventual steady state concentration.

Matthew P. Longnecker

Specific Observations for *Health Effects Document for Perfluorooctanoic*		
Page	**Paragraph**	**Comment or Question**
3-28	1st complete	Should the end of the sentence be "increase the transporters" rather than "increase the receptors"?
3-30	2nd complete	L 3, would insert "transfected" between "OAT3" and "cells"
3-39	1st complete	Next to last sentence: I doubt that Olsen assumed the major source of exposure was drinking water in the occupational study
3-41	4th complete	In the first formula listed, the plus sign should be an equal sign
4-9	1st complete	L 3 from bottom: the values of 1.51 and 1.48 given are probably better described as geometric means.
4-16	2nd complete	L 3 from bottom: would insert "draw" after "blood"
4-21	2nd complete	L 5: the value of 6.78 ug/L is a water level, not a serum level; this issue recurs on P 4-23, paragraph at bottom
4-30	1st complete	L 8: should read "exposure categories" rather than "cancer categories"?
4-37	Table	Would note dose of PFOA somewhere in table or footnote
4-55	Last para	L 3: should the ">" be a "<"?
4-79	Last para	Last sentence: should "50 and 25" be "50 and 250"?
4-80	1st complete	The last sentence does not accurately describe the table. E.G., the CD4+CD8+ cells decreased at the 47.21 mg/kg/d dose
4-82	Next to last para	Last sentence: the 37.5 mg/kg/dose is not mentioned earlier, so this is a little confusing.
4-85	Last para	L 2: should "0.5" be "0.05"?; Same issue for L 5.
4-89	4th para	How long were the animals dosed?
4-110	3rd complete para	L 5: should "serum" be "blood"?
4-113	3rd complete para	L 1: insert "in" before "liver cells"
5-4	Last para	Were the criteria for inclusion in Table 5.2 the same as for Table 5.1?
5-12	Para below table	8-6, 8-7, and 8-8 should be 5-6, 5-7, and 5-8
5-16	Last line	I do not see in the Thompson et al. (2010) study any mention of using exposure data from NHANES to calibrate the volume of distribution. Other sources of data were used, where the water had been contaminated.
5-17	1st formula	"/day" should be deleted from "0.17 $L/kg_{bw}/day$"
5-20	Table 5-12	The first three values in the UF_{total} column need to be corrected; they should be 21900, 219000, and 21900
5-21	Paragraph above table	Last sentence: UF_L should be UF_H
5-21	Last sentence	UD_S should be UF_S

Specific Observations for *Health Effects Document for Perfluorooctanoic*		
Page	**Paragraph**	**Comment or Question**
5-27	Calculations	The text says the body weight conversions should be based on the ¾ power. If so, the HED formulas are incorrect, and the HED should be 1.99 x 0.0254 = 0.0506, the dosimetric adjustment factor should be 0.0254, and the CSF should be 1.57. All the figures here should be checked as should the paragraph on P 5-28. The HED is 2,530-fold greater than the RfD, not 29,000.

Specific Observations for *Health Effects Document for Perfluorooctane Sulfonate*		
Page	**Paragraph**	**Comment or Question**
1-1	2nd	1st sentence: would revise for clarity. Do you mean uncertainties exist about whether PFOS-induced peroxisome proliferation is involved in causing PFOS-induced hepatic lesions?
1-1	3rd	1st sentence: would revise for clarity; the occupational studies were done at PFOS production plants, but to my knowledge there are no residential populations that have been studied for health effects who lived near PFOS production plants. (Mid-Ohio valley factory was a source of PFOA.) In the 2nd sentence, I do not believe that exposure was mainly through contaminated drinking water in any of these studies.
4-66	2nd	The earlier summary of the Bloom et al. study (P 4-10) said the results were not statistically significant, whereas here the interpretation appears to be that the study found an association. The interpretation does not seem consistent across the two sections.
5-17	Below table	L 3: the word "terminal" should be deleted from this sentence
5-20	1st formula	The "/day" should come out of "0.23 L/kg bw/day"
5-26	L 2 from bottom	This should be 35 ug/L not 35 mg/L

Angela L. Slitt

No specific observations.

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APPENDIX A: PEER REVIEWER BIOSKETCHES

ED_000915_Redeliver_PSTs-DD_00085780-00075

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 21 and 22, 2014

LIST OF PEER REVIEWERS

James Bruckner, Ph.D.
University of Georgia

Deborah Cory-Slechta, Ph.D. (chair)
University of Rochester School of Medicine and Dentistry

Jamie DeWitt, Ph.D.
East Carolina University

Jeffrey Fisher, Ph.D.
U.S. Food & Drug Administration

William Hayton, Ph.D.
The Ohio State University (Emeritus)

Matthew Longnecker, Sc.D., M.D
National Institute of Environmental Health Sciences

Angela Slitt, Ph.D.
University of Rhode Island

BIOGRAPHICAL SKETCHES OF PEER REVIEWERS

James Bruckner, Ph.D.
University of Georgia

Dr. Bruckner is Professor of Pharmacology and Toxicology at the University of Georgia College of Pharmacy. He is also Professor in the Department of Physiology and Pharmacology at the University of Georgia College of Veterinary Medicine. He received his Ph.D. in Toxicology from the University of Michigan in 1974. He has previously held faculty positions at the University of Kansas and the University of Texas Medical School at Houston. He is actively engaged in graduate education and in federally-funded research projects. Dr. Bruckner's research focus is on the toxicology and toxicokinetics of solvents, drug-solvent interactions at occupational exposure levels, and toxicokinetic bases for susceptibility of children to insecticides and other chemicals. Dr. Bruckner has published more than 200 journal articles, book chapters, and abstracts. He has also served on a variety of expert panels and committees for the EPA, National Institutes of Health, National Aeronautics and Space Administration, Agency for Toxic Substances and Disease Registry, Food and Drug Administration, and the National Academy of Sciences.

Deborah Cory-Slechta, Ph.D. (chair)
University of Rochester School of Medicine and Dentistry

Dr. Cory-Slechta is a Professor in the Department of Environmental Medicine and the Department of Pediatrics at the University of Rochester School of Medicine and Dentistry, where she also serves as co-director of the Behavioral Sciences Facility Core and director of the Animal Behavior Core. Dr. Cory-Slechta received her Ph.D. from the University of Minnesota in 1977 and worked as a junior staff fellow of the National Center for Toxicological Research beginning in 1979. She was appointed to the faculty of the University of Rochester Medical School in 1982 and was appointed Chair of the Department of Environmental Medicine and Director of the NIEHS Environmental Health Sciences Center at the University of Rochester in 1998. From 2000 to 2002, she was the Dean for Research and Director of the AAB Institute for Biomedical Sciences. Following her appointment as Dean, she served from 2003 to 2007 as the Chair of the Department of Environmental and Occupational Medicine at Robert Wood Johnson Medical School and as Director of the Environmental and Occupational Health Sciences Institute, a joint Institute of the Robert Wood Johnson Medical School and Rutgers. Dr. Cory-Slechta's research has focused largely on environmental neurotoxicants as risk factors for behavioral disorders and neurodegenerative disease. These research efforts have resulted in over 170 papers and book chapters to date. Dr. Cory-Slechta has served on numerous national research review and advisory panels, including committees of the National Institutes of Health, the National Institute of Environmental Health Sciences, the Food and Drug Administration, the National Center for Toxicological Research, the Environmental Protection Agency, the National Academy of Sciences, the Institute of Medicine, and the Agency for Toxic Substances and Disease Registry, Centers for Disease Control. In addition, Dr. Cory-Slechta has served on the editorial boards of several journals including *Environmental Health Perspectives*, *Neurotoxicology*, *Toxicology*, *Toxicological Sciences*, *Fundamental and Applied Toxicology*, *Neurotoxicology* and *Teratology*, and *American Journal of Mental Retardation*. She has held the elected positions of President of the Neurotoxicology Specialty Section of the Society of Toxicology, President of the Behavioral Toxicology Society, and been named a Fellow of the American Psychological Association. She also previously served on the EPA Science Advisory Board Perfluorooctanoic Acid Risk Assessment Review Panel.

Jamie DeWitt, Ph.D.
East Carolina University

Dr. DeWitt is an Assistant Professor in the Department of Pharmacology and Toxicology at the Brody School of Medicine at East Carolina University (ECU). She is affiliated with The Harriet and John Wooten Laboratory for Alzheimer's and Neurodegenerative Diseases Research and holds an adjunct appointment in the ECU Department of Public Health. Dr. DeWitt received her Ph.D. in Environmental Science and Neural Science from the School of Public and Environmental Affairs and Program in Neural Science at Indiana University in 2004. She also completed postdoctoral training in Developmental Cardiotoxicity at Indiana University-Bloomington and in Immunotoxicology at EPA through a cooperative training agreement with the University of North Carolina at Chapel Hill. Dr. DeWitt's main research focus is on how toxicants found in the environment can lead to neurodevelopmental and neurodegenerative disorders via disruption of the developing immune system. Much of her past research has

involved the immunotoxicity of perfluorooctanoic acid (PFOA) and related polyfluroalkyl substances (PFASs). Dr. DeWitt has published seven peer reviewed research articles, three review papers and two book chapters that address the biological effects of PFOA, as well as one paper on the effects of PFOS on immune function. Her publications describe effects as well as underlying mechanisms following adult and developmental exposure. Her research experience and publication record (more than 25 peer reviewed manuscripts, 6 review articles, 9 book chapters) extend beyond the effects of PFAAs and working with rodent models. She is currently editing a book on the general toxicity of PFASs and is a current member of the mechanistic working group for Monograph 110 of the International Agency for Research on Cancer, which will include an assessment of PFOA. She is on the editorial boards of the *Journal of Immunotoxicology* and the *Journal of Environmental Toxicology and Health* and has reviewed grants for the Department of Defense and the National Institute of Occupational Safety and Health. She has also been manuscript reviewer for more than 20 journals. Dr. DeWitt is the current president of the North Carolina chapter of the Society of Toxicology and the Junior Councilor for the Immunotoxicology Specialty Section of the Society of Toxicology. She also was awarded the Outstanding Young Investigator Award from the Immunotoxicology Specialty Section in 2013.

Jeffrey Fisher, Ph.D.
U.S. Food & Drug Administration

Dr. Fisher is a Research Toxicologist at the U.S. Food and Drug Administration (FDA), National Center for Toxicological Research. He was formerly a Professor in the Department of Environmental Health Science, College of Public Health at the University of Georgia (UGA). He joined UGA in 2000 and served as Department Head of the Department of Environmental Health Sciences from 2000 to 2006 and Director of the Interdisciplinary Toxicology Program from 2006-2010. Prior to joining UGA, he spent most of his career at Wright Patterson Air Force Base (AFB), where he was Principal Investigator and Senior Scientist in the Toxics Hazards Division and Technical Advisor for the Operational Toxicology Branch. Dr. Fisher's research interests are in the development and application of biologically based mathematical models to ascertain health risks from environmental, food-borne and occupational chemical exposures. Dr. Fisher's modeling experience includes working with chlorinated and non-chlorinated solvents, fuels, pesticides, perchlorate and bisphenol A. He has developed physiologically-based pharmacokinetic (PBPK) models for use in cancer risk assessment, estimating lactational transfer of solvents, understanding in utero and neonatal dosimetry, quantifying metabolism of solvent mixtures and developing biologically motivated models for the hypothalamic-pituitary-thyroid axis in rodents and humans. Dr. Fisher has published over 140 papers on pharmacokinetics and PBPK modeling in laboratory animals and humans. He has served on several national panels and advisory boards for the DoD, ATSDR, USEPA and non-profit organizations. He was a U.S. delegate for the North Atlantic Treaty Organization. Dr. Fisher served on the International Life Sciences Institute Steering Committee, which evaluated chloroform and dichloroacetic acid using EPA-proposed Carcinogen Risk Guidelines. He is Past President of the Biological Modeling Specialty Section of the Society of Toxicology, reviewer for several toxicology journals, and was Co-Principal Investigator on a National Institutes of Health (NIH)-supported workshop on Mathematical Modeling at the University of Georgia in the fall of 2003. Dr. Fisher was also a member of the National Academy of Sciences subcommittee on Acute Exposure

Guideline Levels (AEGLs) from 2004-2010 and Science Advisory Board (SAB) for the US EPA (2007-2010). He is an ad hoc EPA SAB member for dioxin and perchlorate. Dr. Fisher is a Fellow of the Academy of Toxicological Sciences, an associate editor for Toxicological Sciences, and on the editorial board of *Journal of Environmental Science and Health Part C Environmental Carcinogenesis & Ecotoxicology Reviews*.

William Hayton, Ph.D.
The Ohio State University (Emeritus)

Dr. Hayton is a Professor Emeritus in the College of Pharmacy at The Ohio State University. Dr. Hayton received a Ph.D. in Pharmaceutics from the State University of New York at Buffalo in 1967. He was a member of the Washington State University College of Pharmacy faculty for 19 years, rising to Chair of the Pharmacology/Toxicology Graduate Program in 1982 and Acting Dean at the College of Pharmacy in 1987. In 1990, he transferred to the Ohio State University as Chair of the Division of Pharmaceutics, where he later served as Associate Dean for the Graduate Programs and Research until his retirement in 2010. Dr. Hayton's expertise is pharmacokinetics, particularly construction and validation of mathematical models that describe or explain the kinetics of complex biological systems. One recent research interest is characterization of the Fc receptor-mediated transport and catabolism of albumin and IgG in wild type and FcR knockout mice. A second recent project is the quantitative modeling of the female hypothalamus-pituitary-gonad (HPG) axis in the female rainbow trout (Oncorhynchus mykiss). The model is based on and integrates the biology of gonadotropin, estrogen, androgen and maturational hormone signaling systems, and it includes key intermediate steps in the signaling pathways; viz., gonadotropin and sex steroid synthesis, hormone receptors and their corresponding mRNA levels. Dr. Hayton's expertise extends to interspecies scaling of pharmacokinetic model parameter values and xenobiotic metabolism. Dr. Hayton is author or co-author of over 100 peer-reviewed scientific publications and has held peer-reviewed grant support from the National Institutes of Health, EPA, Air Force Office of Scientific Research, Food and Drug Administration, and U.S. Fish and Wildlife Service. He previously served on the EPA Science Advisory Board Perfluorooctanoic Acid Risk Assessment Review Panel.

Matthew Longnecker, Sc.D., M.D
National Institute of Environmental Health Sciences

Dr. Longnecker, M.D., Sc.D., is the head of the Biomarker-based Epidemiology Group at the National Institute of Environmental Health Sciences (NIEHS). Dr. Longnecker received an M.D. from Dartmouth Medical School and completed a residency in internal medicine at Temple University Hospital in Philadelphia. After receiving a Sc.D. in Epidemiology from Harvard School of Public Health in 1989, he served as an Assistant Professor in the Department of Epidemiology at the University of California, Los Angeles, School Of Public Health. Since 1996, Dr. Longnecker has served as Adjunct Professor/ Associate Professor in the Department of Epidemiology, School of Public Health, University of North Carolina at Chapel Hill. He came to the NIEHS Epidemiology Branch in 1995, as a tenure-track investigator. Dr. Longnecker's research program is focused on the health effects of persistent organic pollutants (e.g., the DDT metabolite p,p'-DDE, and polychlorinated biphenyls). He is particularly interested in the effects of intrauterine exposure to persistent organic pollutants in relation to intrauterine growth,

preterm birth, birth defects, neurologic findings at birth, growth, neurodevelopment, intelligence, and hearing. Recently, Dr. Longnecker has completed and has ongoing a series of studies on perfluorinated alkyl substances in relation to reproductive and pediatric outcomes. In addition, he has begun studying the effects of early, low-level exposure to the nonpersistent pollutants, bisphenol A and organophosphate pesticides. Dr. Longnecker's research efforts have resulted in over 180 papers and book chapters to date. He has served as a leader for numerous national and international committees, such as for the Society for Epidemiologic Research and the International Society for Environmental Epidemiology, and has been on numerous national and international scientific advisory boards, including the EPA Science Advisory Board for the Perfluorooctanoic Acid Risk Assessment Review.

Angela Slitt, Ph.D.
University of Rhode Island

Dr. Slitt is an Associate Professor in the Department of Biomedical and Pharmaceutical Sciences at the University of Rhode Island. Dr. Slitt received her Ph.D. in Pharmacology and Toxicology from the University of Connecticut in 2000, and then served until 2004 as a postdoctoral fellow at the University of Kansas Medical Center. Dr. Slitt has been a faculty member at the University of Rhode Island since 2006. Dr. Slitt's graduate and postdoctoral training was heavily focused on liver biology and health, with a focus in the area of toxicology, and included research in nuclear receptors, biotransformation, and transporter expression. Her current research interests focus on how 1) expression of drug transporters affects chemical disposition and toxicity, 2) nutrition and intake of dietary antioxidants affects the expression of drug transporters, 3) liver disease (i.e., diabetes, cholestasis, and ethanol cirrhosis) affects transporter expression and chemical disposition, and 4) transporter expression affects cholesterol transport and susceptibility to gallstone formation. She has also recently investigated the effect of PFOS on caloric restriction in mice. Dr. Slitt is presently on the Editorial Board of *BMC Pharmacology and Toxicology, Journal of Biochemical and Molecular Toxicology*, and *Toxicology Methods and Mechanism*, and is an ad-hoc reviewer for numerous other journals. She is author or co-author of over 50 peer-reviewed scientific publications, and was recently awarded the University of Rhode Island Early Career Faculty Research Excellence Award.

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APPENDIX B: MEETING AGENDA

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AGENDA

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 21, 2014

Day 1 – PFOA Health Effects Document

8:30 AM	**Meeting Sign-In Begins**
9:00 AM	**Welcome, Goals of Meeting, and Introductions** David Bottimore, Versar, Inc.
9:15 AM	**Welcome by EPA and Overview of PFOA/PFOS Health Effects Documents** Elizabeth Doyle, Chief, EPA/OST/OW/HECD
9:30 AM	**Chair's Introduction and Review of Charge** Deborah Cory-Slechta, *Chair*
10:00 AM	**Discussion Session – "Round Table" General Overview Comments**
10:45 AM	*Break**
11:00 AM	**PFOA Discussion Session – Responses to Charge Questions:** Question 1: Strengths, Weaknesses, and Characterization of the Studies Selected Question 2: Additional References for Consideration Question 3: Conclusions on Human Epidemiology Data Question 4: Transparency and Characterization of Epidemiologic Data
12:15 PM	*Lunch**
1:15 PM	**PFOA Discussion Session – Response to Charge Questions:** Question 5: Cancer Classification Question 6: Pharmacokinetic Model Adjustments Question 7: Selected Parameters for Pharmacokinetic Model Question 8: Volume of Distribution (Vd) and Half-life Values
2:45 PM	*Break**
3:00 PM	**PFOA Discussion Session – Response to Charge Questions:** Question 9: Points of Departure and RfDs Question 10: RfDs and Applicability to Short-and Long-term Exposures Question 11: Uncertainty Factors Question 12: Other Suggestions for Improving the Document
5:00 PM	**Adjourn**

**Time for breaks and lunch are approximate and at the Chair's discretion.*

AGENDA

External Peer Review Meeting on EPA's Draft Health Effects Documents for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Crystal City Marriott at Reagan National Airport
1999 Jefferson Davis Highway
Arlington, VA, 22202-3526

August 22, 2014

Day 2 – PFOS Health Effects Document

9:00 AM	**Recap of Day 1 and Agenda for Day 2** David Bottimore, Versar, Inc.
9:15 AM	**Chair's Review of Charge for Day 2** Deborah Cory-Slechta, *Chair*
9:30 AM	**Discussion Session – "Round Table" General Overview Comments**
10:00 AM	*Break**
10:15 AM	**PFOS Discussion Session – Responses to Charge Questions:** Question 1: Strengths, Weaknesses, and Characterization of the Studies Selected Question 2: Additional References for Consideration Question 3: Conclusions on Human Epidemiology Data Question 4: Transparency and Characterization of Epidemiologic Data
11:30 PM	*Lunch Break**
12:30 PM	**PFOS Discussion Session – Response to Charge Questions:** Question 5: Cancer Classification Question 6: Pharmacokinetic Model Adjustments Question 7: Selected Parameters for Pharmacokinetic Model Question 8: Volume of Distribution (Vd) and Half-life Values
2:15 PM	*Break**
2:30 PM	**PFOS Discussion Session – Response to Charge Questions:** Question 9: Points of Departure and RfDs Question 10: RfDs and Applicability to Short-and Long-term Exposures Question 11: Uncertainty Factors Question 12: Other Suggestions for Improving the Document
5:00 PM	**Adjourn**

**Time for breaks and lunch are approximate and at the Chair's discretion.*

EPA-HQ-2016-005679 06/14/2017

APPENDIX C: MEETING ATTENDEE LIST

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LIST OF OBSERVERS ATTENDING MEETING IN PERSON
August 21 and 22, 2014

External Peer Review Meeting on
EPA's Draft Health Effects Documents for
Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Name	Affiliation
Janet Anderson, Ph.D.	U.S. Air Force
Robert Bilott	Taft Stettinius & Hollister LLP
Norman Birchfield	U.S. EPA
John Butenhoff, Ph.D.	3M Company
Sue Chang, Ph.D.	3M Company
C-H Selene Chou, Ph.D.	Agency for Toxic Substances and Registry
Steven Chranowski	Chemistry Council of New Jersey
Joyce Donohue	U.S. EPA
Elizabeth Doyle	U.S. EPA
Colleen Flaherty	U.S. EPA
Maria Hegstad	Inside EPA
Gerald Kennedy	DuPont
La Rae Landers	Dept of the Navy BRAC PMO
Willington Lin	Public
Angela Lynch, Ph.D.	American Chemistry Council
Geary Olsen, Ph.D.	3M Company
Gloria Post, Ph.D.	New Jersey Department of Environmental Protection
Resha Putzrath, Ph.D.	Navy and Marine Corps Public Health Center
Jennifer Seed	U.S. EPA
Shalene Thomas	AMEC Environment & Infrastructure
Steve Via	American Water Works Association
Anthony Walters	United Science, LLC
Carol Wood	Oak Ridge National Laboratory

LIST OF OBSERVERS ATTENDING VIA PHONE
August 21 and 22, 2014

External Peer Review Meeting on
EPA's Draft Health Effects Documents for
Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonate (PFOS)

Name	Affiliation
Matthew Bailor	Gilmore & Associates, Inc.
Victoria Binetti	U.S. EPA
Stuart Cagen, Ph.D.	Shell Health
Andrea Candara	New York State Department of Health
Tom Cleveland	Decatur Utilities
Jason Conder	ENVIRON International Corporation
Michelle Deveau	Health Canada
Stiven Foster	U.S. EPA
Helen Goeden	Minnesota Department of Health
Christopher Lau, Ph.D.	U.S. EPA
Anita Meyer, DABT	U.S. Army Corps of Engineers
Jonathan Naile, Ph.D.	Shell Health
Jessica Nelson	Minnesota Department of Health
Bridget O'Brien	U.S. EPA
Ramasamy Santhini	U.S. EPA
Robert Rickard	U.S. EPA
John Wambaugh	U.S. EPA
Carol Rowan West, Ph.D.	Massachusetts Department of Environmental Protection
Linda Wilson	New York State Office of the Attorney General
Virginia Yingling	Minnesota Department of Health
Tsedash Zewdie	Massachusetts Department of Environmental Protection

To: Behl, Betsy[Behl.Betsy@epa.gov]
From: Strong, Jamie
Sent: Tue 1/19/2016 12:52:10 PM
Subject: RE: Pfoa

John just stopped by, he would like the HESDs. I will send this morning.

From: Behl, Betsy
Sent: Saturday, January 16, 2016 11:20 AM
To: Southerland, Elizabeth <Southerland.Elizabeth@epa.gov>
Cc: Strong, Jamie <Strong.Jamie@epa.gov>
Subject: Re: Pfoa

Deliberative Process / Ex. 5

Sent from my iPhone

On Jan 16, 2016, at 7:29 AM, Southerland, Elizabeth <Southerland.Elizabeth@epa.gov> wrote:

Deliberative Process / Ex. 5

Sent from my iPhone

Begin forwarded message:

From: "Beauvais, Joel" <Beauvais.Joel@epa.gov>
Date: January 15, 2016 at 10:15:44 PM EST
To: "Grevatt, Peter" <Grevatt.Peter@epa.gov>, "Southerland, Elizabeth" <Southerland.Elizabeth@epa.gov>, "Behl, Betsy" <Behl.Betsy@epa.gov>, "Gilinsky, Ellen" <Gilinsky.Ellen@epa.gov>
Subject: FW: Pfoa

From: Enck, Judith
Sent: Friday, January 15, 2016 2:55 PM
To: **Personal Phone / Ex. 6** Fritz, Matthew <Fritz.Matthew@epa.gov>; Meiburg, Stan <Meiburg.Stan@epa.gov>; Beauvais, Joel <Beauvais.Joel@epa.gov>; Gilinsky, Ellen <Gilinsky.Ellen@epa.gov>; Stanislaus, Mathy <Stanislaus.Mathy@epa.gov>; Burke, Thomas <Burke.Thomas@epa.gov>

Subject: Pfoa

Below is some of the media from yesterday's community meeting. Also attached are the two letters from New York State. We had a very productive meeting today with ny doh and ny dec. call me with any questions. Judith

Concerned citizens pack Hoosick Falls water hearing

EPA leader says action should be taken to find out about contamination

By Brendan J. Lyons Updated 7:26 am, Friday, January 15, 2016

Albany Times Union

Hoosick Falls

Residents in this factory village packed the high school Thursday night to learn more about a dangerous chemical that contaminated their water system and stoked fears about whether it's caused what many believe is a high rate of unusual and aggressive forms of cancer.

"I'm very, very sorry that you have been going through this," Judith Enck, U.S. Environmental Protection Agency regional administrator, told the audience. "I'm sorry that we don't know how long you have been drinking contaminated water. ... No medical studies or surveys have been done in Hoosick Falls. Action should be taken to protect your health."

The focus of the contamination has been a Saint-Gobain Performance Plastics manufacturing plant. The small factory, the village's largest employer with about 125 workers, is on a hill overlooking the Hoosick River, about 400 yards from village well fields. The company owns a second plant in the village with about 75 workers.

The standing-room-only meeting took place hours after the state Department of Environmental Conservation and state Health Department jointly called on the EPA to add Saint-Gobain's McCaffrey Street plant "and other possible sources of contamination" in the village to the federal Superfund program and "undertake a full environmental investigation to address the sources of contamination."

Enck, who organized the informational meeting, has urged village leaders to warn residents to stop drinking the water and limit other exposure. Mayor David B. Borge had previously said it was a "personal choice" whether to consume the water, which comes from underground wells serving about 4,500 consumers.

Elevated levels of the toxic chemical, perfluorooctanoic acid, or PFOA, were

found in the system in 2014 by Michael Hickey, a former village trustee whose father died of cancer. Hickey sent water samples to a Canadian lab that reported levels of PFOA that the EPA later said are not safe for human consumption.

The audience applauded loudly when David Engel, a lawyer for a grassroots citizens group formed to help educate residents about the pollution, referred to Hickey as a "hero."

Saint-Gobain officials said there has been no determination on the source of the contamination, but the McCaffrey Street plant they bought in 1999 used PFOA for decades, and levels as high as 18,000 parts per trillion were found in the groundwater under the plant. EPA's guideline is 400 PPT for short-term exposure, which many health officials and experts say is not strict enough.

"The use of PFOA in our facilities in the past was limited to small amounts that were present in some of the raw materials that were supplied to us by others," said Dina Silver Pokedoff, company spokeswoman. "In December 2014, we eliminated altogether the use of PTFE (polytetrafluoroethylene) containing PFOA in our Hoosick Falls facility."

The firm's decision to stop using PFOA at its Hoosick Falls plants took place the same month that Saint-Gobain told the EPA that PFOA had been found in the public water system.

The state Health Department last month issued a fact sheet to residents downplaying the health risks of the toxic chemical. But Thursday, the state took a stronger stand and called on the EPA to set stricter standards on the acceptable levels of PFOA in drinking water. The state also said it would begin "an investigation of the incidence of cancer among village residents."

Hoosick Falls has had number of manufacturing plants dating to the early 1800s, including other plants that used PFOA or similar synthetic chemicals. In the last three months, the Times Union has interviewed current and former residents who suspect the drinking water may have caused cancer or other serious effects for themselves or relatives.

Sarah Armour, whose mother, Janice Marie Polacek, was born and raised here, told the Times Union her family was suspicious when Polacek, a non-smoker, died at 42 from brain cancer.

"She was only 39 years old when she began to have horrible headaches and dizzy spells," Armour said. "A CT scan of her brain showed a huge mass that turned out to be a metastasis from an extremely rare and aggressive form of cancer, carcinoma of the thymus. She underwent radiation, chemotherapy, and even a tumor debulking open chest surgery, but ultimately died ... I recall when she was first diagnosed, my father saying something about a plant near her childhood home that he suspected might have contributed to her unlikely development of cancer. Even back then, over 25 years ago, he knew something was not right about it."

The EPA's Enck said government agencies need to determine the source and extent of water pollution, including if it has contaminated private wells.

"A very detailed study of groundwater is needed in Hoosick Falls to know what we are dealing with and how to best address it," she told the audience. "There also needs to be sampling in the Hoosic River."

Dr. Marcus E. Martinez, who runs a family medical practice here, said he and his father, who opened the practice in 1956, have noted rare and aggressive forms of cancer in patients, as well as thyroid diseased and other health problems.

PFOA is a man-made chemical used to make non-stick and other household and commercial products that are heat-resistant and repel grease and water. Under a deal with the EPA, major PFOA makers began phasing out its use in 2006. PFOA exposure has been linked to increased health effects, including testicular and kidney cancer and thyroid disease.

Last week, village trustees voted to have temporary filters installed on the water system. A long-term plan to install a charcoal filter system expected to remove PFOA from the water is set to be done later this year. Saint-Gobain has offered to pay to install and maintain the filter, and has also paid for residents to get free water from a local supermarket.

Julia DiCorleto, a general manager who oversees Saint-Gobain's Hoosick Falls plants, said the soil-testing it did around the McCaffrey Street plant showed low levels of PFOA in the soil, which may indicate water pollution came from a source other than their plant. But the company's tests also showed extremely high levels of PFOA in the groundwater under the plant site, which includes an aquifer believed to feed the village's underground well system.

Saint-Gobain officials said their decision to help the village does not represent any acknowledgement of responsibility for the PFOA pollution.

A science panel formed as a result of class-action litigation in the Ohio Valley with DuPont, one of the primary manufacturers of PFOA, conducted a comprehensive study of the health effects of exposure and concluded the chemical has a "probable link" to six diseases: kidney cancer; testicular cancer; ulcerative colitis; thyroid disease; preeclampsia/pregnancy-induced hypertension; and medically diagnosed high cholesterol.

Last fall, one of the first cases to go to trial resulted in a $1.6 million judgment for a woman who lost a kidney attributed to PFOA exposure. Five other cases in the litigation may go to trail beginning this year.

Photos: Cindy Schultz

Image 1/15

Judith Enck, Environmental Protection Agency Regional Administrator for Region 2, addresses questions on PFOA contamination in the village of Hoosick Falls

water system on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 2/15

High school senior Anna Wysocki, 17, poses her question about PFOA contamination in the water system during a public meeting on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 3/15

Residents attend a public meeting about PFOA contamination in the village's water system on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Photo: Cindy Schultz

Image 4/15

Suzanne DiDonato poses her question about PFOA contamination in the water system during a public meeting on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 5/15

Toxicologist Dr. Mark Maddaloni addresses questions on PFOA contamination in the village of Hoosick Falls water system on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 6/15

Toxicologist Dr. Bob Michaels speaks during a public meeting to address PFOA contamination in the village of Hoosick Falls water system on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 7/15

High school senior Jeff Brewer, 17, poses his question about PFOA contamination in the water system during a public meeting on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 8/15

Judith Enck, Environmental Protection Agency Regional Administrator for Region 2, center with microphone, addresses questions on PFOA contamination in the village of Hoosick Falls water system on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 9,10/15

Scores attend the EPA's informational hearing on the Hoosick Falls water system (Cindy Schultz/Times Union)

Image 11/15

A standing-room only audience attends a public meeting about PFOA contamination in the village's water system on Thursday, Jan. 14, 2016, at Hoosick Falls Central School in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Photo: Cindy Schultz

The Hoosic River flows through the village where PFOA contamination is in the water system on Thursday, Jan. 14, 2016, in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 13/15

Downtown where PFOA contamination is in the water system on Thursday, Jan. 14, 2016, in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Image 14/15

Downtown where PFOA contamination is in the water system on Thursday, Jan. 14, 2016, in Hoosick Falls, N.Y. (Cindy Schultz / Times Union)

Hundreds gather at meeting to discuss contaminated Hoosick Falls water

News10.com

By Lindsay Nielsen Published: January 14, 2016, 9:54 pm Updated: January 15, 2016, 7:18 am

HOOSICK FALLS, N.Y. (NEWS10) – The people of Hoosick Falls expressed their concerns over contaminated water to environmental officials on Thursday.

“Could we have acted sooner and saved lives in Hoosick Falls?” high school senior Connor McCart wondered.

The municipal water in the Village of Hoosick Falls has tested positive for a chemical called PFOA. Samples near Saint-Gobain Performance Plastics showed levels were 45 times higher than what’s considered safe.

But whispers of contamination started years ago.

"I was, like, 6-years old, 7-years old, as a joke, 'Don't eat the fish out of the river because the water's bad,'" McCart said.

On Thursday night, hundreds gathered for an informational meeting where Michael Hickey was dubbed a hero. His father died of kidney cancer three years ago. Suspicious, Hickey tracked down a lab and bought a special kit in 2014. The water test came back positive for PFOA.

"I also didn't want to see anybody else go through what we went through," Hickey said.

Now the Environmental Protection Agency has recommended a temporary filtration system be put in place until a permanent one is completed in October. But a Hoosick Falls High School senior had another idea.

"What monetary aid can be given to the village to acquire a new water source such as contracting with Troy and the Tomahanock Reservoir or Bennington and their source, Morgan Springs?" she asked.

The EPA informed people that the journey is far from over.

"More private well sampling is still needed in the area," EPA Regional Director Judith Enck said. "A study needs to be done to investigate the nature and the extent of the contamination and to identify all of the sources of the contamination," she said.

PFOA is believed to cause cancers and other illnesses.

Dr. Marcus Martinez organized the meeting because he believes cancer in the village is linked to the contamination.

The New York State Department of Health will be looking at cancer rates. The department is encouraging residents to participate in blood testing to identify levels of PFOA.

wnyt.com

EPA addresses concerns about contaminated water in Hoosick Falls

Anna Meiler

Updated: 01/15/2016 4:26 AM

Created: 01/14/2016 5:38 PM

HOOSICK FALLS - Hundreds of people in Hoosick Falls packed an auditorium

Thursday night as the EPA explained the water they've been drinking has a cancer-causing chemical in it.

The EPA says they don't know for how long or at what level the water has been contaminated, but it very well could be years, even decades. And they may have never found out if it wasn't for one man who decided to test the water himself.

When John Hickey died from kidney cancer in 2013, his son Michael started searching for answers.

“It’s always been stated around here that we seem to have a high rate of cancer,” said Hickey.

He took it upon himself to take samples of the municipal water. Test results showed high levels of a manufactured chemical called PFOA. The EPA says more than 400 parts per trillion is unsafe to consume. Tests in Hoosick Falls showed more than 600 parts per trillion in the water.

“One sample came back at 18,000 parts per trillion. So, that led the EPA to make a very clear, strong public statement they should not drink the water,” said Judith Enck with the EPA.

The EPA says the contamination is linked to the Saint Gobain plant where Michael’s dad worked for thirty years.

Dr. Marcus Martinez says PFOA can cause kidney and liver cancers and can have reproductive and developmental effects.

“Birth defects, cranial facial deficits have been reported as far as cleft lip, cleft pallet," said Dr. Martinez.

For Dr. Martinez, raising awareness of this problem has become a personal battle.

“I was diagnosed with cancer last year so it's changed my life a lot,” he said.

It's because of Michael Hickey and Dr. Martinez the EPA is taking action, informing hundreds of people how to protect themselves. They say to drink and cook with bottled water.

“We’re brushing our teeth with bottled water, cleaning with bottled water,” said village resident, McKenzie Bradley.

But, the EPA says bathing shouldn't be a big concern for most people.

“For children or people with rashes or abrasions they should take really short showers and really short baths and crack the window open,” said Enck.

Michael wishes his community knew about this years ago, but Dr. Martinez says he's a hero for future generations.

“For all the lives that may be saved going forward he's responsible for all that,” he said.

The EPA is launching an investigation to find the source of the contamination which they say could take many years.

A temporary filtration system will be installed by the end of next month, but until then people need to continue using bottled water for drinking and cooking. Every resident can receive five gallons of free bottled water a day. It's important to stress that boiling the tap water will not make it safer.

The law firm Weitz and Luxenberg had representatives at the meeting. They're teaming up with famed environmentalist Erin Brockovich to possibly pursue legal action on behalf of those residents.

Time Warner News

EPA Addresses Potentially Harmful Chemical in Hoosick Falls Water Supply

By Tanja Rekhi

Thursday, January 14, 2016 at 11:22 PM EST

It was standing room only, just minutes into a meeting Hoosick Falls residents have anticipated for months.

"As a mother, I can only imagine what it's been like for all the parents in this community," EPA regional administrator Judith Enck said.

Some questions were finally answered after amounts of perfluorooctanoic acid, otherwise known as PFOA, above the acceptable amount were found in village drinking water.

"There was a comprehensive study done of about 70,000 people who drank PFOA-contaminated water for about a year," Enck said, "and the study showed elevated levels of certain types of cancers, thyroid disease, problems with pregnancy."

While state agencies don't know where the man-made chemical found in non-stick pans, carpets and fire fighting foam is coming from, four times the acceptable amount have been found in the ground water at the Saint Gobain plant. Several other locations are over the limit as well.

"We don't know how long people have been drinking contaminated water, and we don't know what the levels were," Enck said.

Saint Gobain has been paying for residents to pick up five gallons of water a day at Tops Market, but some say that isn't enough.

"Some of these families are just too big and they need more," resident Brian LaPoint said, "because, I mean, now they're saying you're not even supposed to bathe in it."

The EPA says the water isn't safe to drink, cook or brush teeth with. They recommend taking quick showers with the windows cracked open.

"The EPA has recommended that senior citizens, or people with disabilities who can't get out to the market every day and pick up their five gallons of water, should have bottled water delivered to their home," Enck said.

State agencies will be gathering blood samples and studying cancer rates while Saint Gobain pays for a filtration system, but a long-term fix will take years -- and many hope it isn't too late.

"Ever since hearing about the tainted water, it just leaves me to believe, you know, am I one of those people who is starting to have onset symptoms of drinking the water?" LaPoint asked.

People with private wells can get them tested for PFOA by the State Department of Health by emailing beei@health.ny.gov or calling 518-402-7860. For more information, log on to www.EPA.gov/aboutEPA/Hoosick-Falls-water-contamination.

Times Union

State wants Hoosick Falls site on federal Superfund list; water meeting is tonight

Updated 4:45 pm, Thursday, January 14, 2016

HOOSICK FALLS — The Environmental Protection Agency hosts a meeting tonight to hear community concerns about Hoosick Falls' drinking water.

The meeting begins at 6 p.m. at the Hoosick Falls High School auditorium on Route 22.

Environmental Protection Agency Regional Administrator Judith Enck will speak at the forum hosted by Healthy Hoosick Water.

Enck, EPA staff, and others also will share information and answer questions, as the EPA continues to gather information on the perfluorooctanoic acid contamination of the drinking water supply.

In a development late this afternoon, the state departments of Environmental Conservation and Health want the EPA to add the Saint-Gobain Performance Plastics Corp. plant and other possible sources of contamination in Hoosick Falls to the National Priorities List under the federal Superfund program and investigate contamination sources.

Times Union

DOH, DEC asks EPA to take action on Hoosick Falls water

By Casey Seiler, Capitol bureau chief on January 14, 2016 at 5:25 PM

The state departments of Environmental Conservation and Health want the federal Environmental Protection Agency to add the Saint-Gobain Performance Plastics Corp. plant and other possible sources of contamination in Hoosick Falls to the National Priorities List under the federal Superfund program, and investigate contamination sources.

As the TU's Brendan Lyons reported as part of a series of stories on the situation in Hoosick Falls, the EPA last month issued a statement warning residents not to drink or cook with village water because of elevated levels of a toxic chemical, perfluorooctanoic acid or "PFOA," that was used since the 1940s to manufacture industrial and household products such as non-stick coatings and heat-resistant wiring — including at a factory near the village water treatment plant.

The state Health Department only recently changed its stance on the safety of the village's water: In early December, DOH handed out a "fact sheet" to residents stating "health effects are not expected to occur from normal use of the water."

Researchers say a "probable link" exists between PFOA and a range of ailments in humans, including various types of cancer.

The release from the two state agencies came out less than two hours before EPA was scheduled to hold a town meeting with the community.

The full release from the state agencies, which oddly does not mention DOH's recent turnaround in its assessment of the water's safety:

The New York State Department of Environmental Conservation (DEC) and Department of Health (DOH) today called on the U.S. Environmental Protection Agency (EPA) to add the Saint-Gobain Performance Plastics Corporation McCaffrey Street Plant and other possible sources of contamination in Hoosick Falls to the National Priorities List (NPL) under the federal Superfund program and to undertake a full environmental investigation to address the sources of contamination. In addition, the state, Saint-Gobain Performance Plastics Corporation and the Village of Hoosick Falls (Village) are collaboratively working on an agreement to install water treatment systems to remove hazardous

chemicals from the Village's water supply. To view the state's letters, click here and here.

Health Commissioner Dr. Howard Zucker said, "As soon as the Department of Health was notified of the contamination, we immediately began working with all parties in a collaborative manner to gather more data on the problem and work on solutions to reduce people's exposure to PFOA. I look forward to working with DEC, EPA and the Village of Hoosick Falls to address the sources of contamination."

Acting DEC Commissioner Basil Seggos said, "It is imperative that all levels of government work collaboratively to protect public health and the environment in situations such as this. DOH is working to develop a long-term solution for the Village's public water supply and we must ensure the extent of contamination is identified and cleaned up. I urge the EPA to take vigorous action on the federal level to regulate PFOA and quickly add this site to the National Priorities List so the resources of the federal Superfund program can be used to advance these next steps."

State Calls for National Priorities Listing & Urges Federal Action on PFOA

NPL listing permits EPA to use the resources of the federal Superfund to investigate and clean up hazardous substances. Listing also enables EPA to issue an order requiring a responsible party or parties to clean up the site if that becomes necessary. The source, or sources, of PFOA to the Village's public water system has not been confirmed. Through the federal Superfund program, all potential sources and responsible parties will be evaluated.

The state also called on the EPA to take stronger national actions to address Perfluorooctanoic acid (PFOA) contamination. In a letter to EPA Administrator Gina McCarthy, DEC and DOH requested that EPA lower its health advisory for PFOA in drinking water to take into account the most current scientific evidence and adopt a protective maximum contaminant level. This letter also called upon EPA to expeditiously list PFOA as a hazardous substance under the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) to facilitate the cleanup of contaminated groundwater and other media. Further, the letter asks EPA to review the remaining uses of PFOA under the Toxic Substance Control Act and curtail them whenever less toxic alternatives are available.

DOH Continues to Monitor Water to Ensure Public Health Safety

PFOA was detected in the Village's public drinking water in 2014. Although the use of PFOA is being phased out, it is still used to make household and commercial products that resist heat, and repel oil, stains, grease, and water. This includes nonstick cookware, surface coatings for stain-resistant carpets and fabric, and paper and cardboard food packaging. Studies of people have associated exposure to PFOA with an increased risk for several health effects. This includes associations with effects on the liver, immune system, thyroid gland, cholesterol levels, blood pressure during pregnancy, and kidney and testicular cancer.

After PFOA was detected in the water supply, DOH worked closely with the Village to provide technical advice and assistance for water sampling and to evaluate water treatment options to eliminate health risks. Because the levels of PFOA in public water were higher than the EPA health advisory level, DOH determined that people should reduce their exposure by avoiding the use of tap water for drinking and cooking. In addition, DOH continues to monitor private wells and will have more results very soon.

State Undertakes Cancer Registry & Biomonitoring Studies

In response to public concern, DOH has also begun an investigation of the incidence of cancer among Village residents, using data from the DOH Cancer Registry. The agency will also offer a PFOA biomonitoring study for residents of the Hoosick Falls area. This study will measure PFOA in blood to provide information on exposure. Detailed information about the project will be shared with area residents prior to the start of the project.

DOH will continue to provide technical advice and assistance to the Village, to protect the health of the affected residents. The agency has been testing water samples since first notified of the contamination, and will continue to test private wells.

Looking down on Carey Ave. the Saint-Gobain Performance Plastics plant is seen in the background in Hoosick Falls. (Paul Buckowski / Times Union)

BENNINGTON BANNER

State calls on EPA to list Saint-Gobain, other Hoosick Falls, NY sites on Superfund list

State wants EPA to list Saint-Gobain at a Superfund site

By Edward Damon

Posted: 01/14/2016 05:53:54 PM EST

HOOSICK FALLS, N.Y. >> Two state agencies have asked the Saint-Gobain Performance Plastics site, a potential source of a chemical that has contaminated the village's water supply, be among those added to the National Priorities List (NPL) of Superfund sites.

The state has also called on the federal Environmental Protection Agency (EPA) to lower the health advisory for the chemical, which has been linked to cancer and other diseases, and announced health officials will study cancer rates in the village and surrounding area.

The joint announcement, made by the state's Department of Environmental

Conservation (DEC) and Department of Health (DOH) Thursday afternoon, is the latest among efforts to address Perfluorooctanoic acid (PFOA), a manmade, toxic chemical once used to make non-stick coatings.

It also came just hours before a well-attended meeting in the village, hosted by local group Healthy Hoosick Water.

"A very detailed study of groundwater is needed in Hoosick Falls to know what we are dealing with and how to best address it," Judith Enck, regional administrator of EPA Region II, told a standing-room only crowd of hundreds in the high school auditorium.

Such an effort would take years, she said, but in the meantime, "providing safe drinking water has to be taken care of immediately."

Residents should not drink the tapwater, Enck said, until a solution is in place.

Officials say a granulated activated carbon (GAC) filter would bring the chemical "below detactable levels." A temporary filter is expected to be online by Februrary, and a "permentant" filter by October.

Saint-Gobain has agreed to fund both projects and to continue paying for bottled water at the local Tops Friendly Market.

Enck said those who need more than five gallons a day should contact the village. She also said the company will pay to deliver water to seniors, people with disabilities and others who need it.

Residents packed the municipal building's meeting chambers Tuesday where they peppered village board members with questions. Among them, whether new wells should replace the three which lie some 500 yards from the Saint-Gobain site, where PFOA samples were 40 times greater than the EPA's recommended levels of 400 parts per trillion.

Enck told attendees that a full investigationis needed to determine the full extent of the PFOA "plume" in the groundwater.

Enck said the EPA doesn't believe PFOA, which is no longer used, was manufactured in the village. But the chemical was a component of the PTFE once used at 14 McCaffrey St. and 1 Liberty St.. Both are currently owned by the Saint-Gobain Corporation and Enck said, "it's quite possible other facilities in Hoosick Falls used it as well."

Eugene Leff, deputy commissioner of the state DEC, said the request to the EPA is the first step in starting a cleanup.

"Ultimately, the vast resources of the Superfund will be available," he said.

Walter Mugdan, the EPA's regional superfund director, said "an initial sampling program" would begin in a couple of months. It's a necessary step to support the