Message

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Subject: OCSPP News for January 20, 2021

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Alexandra Dunn – assessing the accomplishments and opportunities ahead for the US EPA at transition

Terry Hyland, Chemical Watch

https://chemicalwatch.com/203853/big-interview-alexandra-dunn-assessing-the-accomplishments-and-opportunities-ahead-for-the-us-epa-at-transition

Alexandra Dunn took the reins at the head of the US EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) two years ago, promising a transparent, "no surprises" approach as the office worked to meet the stringent deadlines set out in the amended TSCA law.

Two years later, Ms Dunn says her office made great progress on that goal. She points to the agency's completion of the first ten risk evaluations under TSCA – with the last of the ten, for pigment violet 29 (PV29), released on 14 January – as one of the accomplishments she is most proud of.

"It's been an enormous effort," with hundreds of hours of outside peer review, innumerable studies, 22 public comment periods and reviews of some 46,000 responses, the outgoing assistant administrator said in a telephone interview. As a political appointee, Ms Dunn's tenure ends with President Trump's on 20 January. "I believe that we demonstrated that the TSCA risk evaluation process can be transparent and engaging" with all interested parties, she says.

And while the agency – and those TSCA reviews – have faced their share of criticism, many of the policies implemented will continue to shape the EPA's future actions.

These include a restructured OCSPP and a project management approach that will affect both existing and new substance evaluations, an effort to make completed risk evaluations more accessible and potential options to ease the workload for the agency's Science Advisory Committee on Chemicals (Sacc).

Risk management

One item Ms Dunn says she would have liked to have started sooner is a procedural rule to govern the risk management process under TSCA.

The 2016 Lautenberg Act amendments to TSCA give the agency one year to propose actions to mitigate any unreasonable risks after they've been identified in a risk evaluation, with one additional year to finalise those regulations.

"I know stakeholders would like to know more" about the risk management process, she says.

Six industry groups in July asked the agency to craft a rule to guide the TSCA process.

"We believe risk management offers a lot of approaches," Ms Dunn says. As an example, she points to the agency's recent rules on five persistent, bioaccumulative and persistent (PBT) substances, which included substance bans, as well as more gradual phase-outs to allow time to find substitutes for certain chemical applications.

"We don't make those choices in a vacuum," she says. "We try to fully understand how a chemical is used and what is possible and what timeframe is needed."

The EPA outlined the desire for a risk management rule in its autumn 2020 regulatory agenda, she says, with a start to the process as early as this May.

Managing new evaluations
People - Alex Dunn360

In addition to the risk management process, the agency is also in the early stages of evaluating potential risks for the next 20 substances, as well as manufacturer-requested reviews for the phthalates DINP and DIDP and a group of isomers used in fragrance ingredients.

To handle that workload, Ms Dunn says the OCSPP will "embrace a project management approach" that will allow anyone to see where the agency is in the process.

With stronger project management, the agency will be able to better meet its deadlines, while also providing greater opportunities for public comment, with less compressed review periods, she says.

Another effort still underway, Ms Dunn says, is the work to make TSCA risk evaluations – which can run into hundreds of pages – more accessible and easier to understand once they are finalised.

Sacc reviews
The agency also needs to ensure it utilises the Science Advisory Committee on Chemicals (Sacc) in an effective way, she says.

The independent committee met for a combined nine weeks as it reviewed the first ten chemicals, Ms Dunn says. If nothing changes for the next 20 reviews, she says, that would mean the scientific peer review of the next batch of evaluations will take 18 weeks.

"That's not really possible," she says.

One way to refine the Sacc review process that has been discussed, she says, is to borrow from the approach of the Scientific Advisory Panel (SAP) under the Federal Insecticide, Fungicide, and Rodenticide Act (Fifra) programme, where scientific advisers are asked broad, "more thematic questions" as opposed to "going chemical by chemical". Those discussions are "underway and will continue", she says.

New chemicals
The process for reviewing and approving new chemicals has evolved in a number of ways over the past few years, Ms Dunn says.

That included work to keep reviews of submitted pre-manufacture notices (PMNs) within the required 90 days and reduce the backlog of those overdue.

Ms Dunn says the agency has reduced their number from 400 when she took over the OCSPP to roughly 180 today. The office "is now focused on continuing" that reduction of overdue reviews, she says.

The office restructuring that took place in the autumn could also help improve the efficiency of reviews, she says. "Previously, career staff might have spent time on existing and new chemicals." With the office reorganisation, Ms Dunn says, "we created a new chemicals division dedicated to new chemicals."

The OCSPP also plans to hire more staff, she says. According to the agency, the office recently recruited 18 scientists to support TSCA implementation and plans to fill "more than 50 positions".

In future, Ms Dunn says she hopes the agency shares more information about the default assumptions it makes with new chemical submissions.

The EPA asks for information on discharge exposures, the new chemical's nature and toxicity and how it is handled through the manufacturing process, she says. If the agency doesn't receive information on those areas then "we have default assumptions that we put in" that can be conservative.

Going forward, she says, "there will be so much evolution" of the TSCA programme. "Our staff has proven to be dynamic and up to the challenge that everything Lautenberg offers."

Your right to know: How to find Toxics Release Inventory data for your community
Lisa Sorg, NC Policy Watch
http://pulse.ncpolicywatch.org/2021/01/18/your-right-to-know-how-to-find-toxics-release-inventory-data-for-your-community/#sthash.zQxhILZg.dpbs

Welcome to the Rabbit Hole, otherwise known as the Toxics Release Inventory. This is a tutorial to accompany a brief story that provides an overview of pollution released into North Carolina's environment in 2019.

The Toxics Release Inventory, administered by the EPA, collects data from industrial facilities for 770 chemicals, and reports the findings by state, city, county, Zip code, industry and chemical.

There are some data shortcomings: Not all toxic chemicals are included in the TRI and the data is self-reported. Nonetheless, the TRI is a valuable tool for communities to know who's polluting, which chemicals, and where they're going.

So grab a cup of coffee or tea (or favorite adult beverage, depending on your mood), and I'll show you in a series of steps and screenshots how to wrangle basic TRI information. Suggestion from someone who learned the hard way (me): Bookmark the various pages so you can trace your digital breadcrumbs. Sometimes if I haven't used the TRI for a while, I have to relearn the paths, and that's a pain.

The homepage of the TRI is straightforward. The EPA has a tutorial in English and Spanish at the bottom of the page, if you prefer video.

To search data for North Carolina, or any state, start at the Where You Live page. This is what it looks like. Notice you can even search smaller geographical areas, including tribal lands. The "Data to Display" includes total releases, land, air, water, population and a risk-screening score. That score is an estimate of potential human health risk from chronic exposures to TRI chemical releases and allows you to compare potential for risk across locations.

I've included an inset of the risk-screening score map and info so you know what it looks like. North Carolina ranks in the top third of states and U.S. territories in terms of risk. Not exactly something to brag about in the Chamber of Commerce newsletter.

Let's burrow farther down into the data to see more information about the major polluters in North Carolina. This is known as a factsheet, and it's what is shown after you hit "go" on the Where You Live page. It's a 30,000-foot view of total releases into the environment. The factsheet also lists the Top 5 facilities in terms of pollution releases and disposal.

You can also click on the names of the facilities for more information. Let's looks at International Paper, the Riegelwood Mill in Columbus County.

The facility report lists the address, map, public contact and compliance information.

Important: The compliance information is not always accurate. The NC Department of Environmental Quality has told me that because of an electronic communications glitch between the EPA and the state, some facilities appear to have violations when they actually don't. Contact DEQ to doublecheck.

At the top of the facility report page, you'll notice other areas to explore, such as chemicals, releases and transfers. Clicking on each of these reveals even more information about this paper mill.

"Chemicals" lists the names of those substances that the facility emits or discharges — and, this is an important point — are reportable under the TRI. Many chemicals, PFAS for example, were not reportable in 2019, but they were for 2020. So this time next year we will be able to see those releases.

There is also a column listing whether the chemical has been linked to harmful health effects or cancer.

This screenshot shows 10 of the 38 chemicals and compounds that the paper mill releases.

"Waste management" in the menu bar refers to how the facility disposes of their chemicals: recycling, treating, releasing and energy recovery.

Another interesting factoid on this page is a graph showing "non-production related waste from remedial actions and catastrophic or other one-time events." That's a long way of saying waste that was generated from accidents, spills and other ominous events. The graph doesn't tell us why the accident happened, but it's a starting point for asking DEQ for records and information.

International Paper reported some type of incident in 1996 that released 4,000 pounds (two tons) of chlorine dioxide into the air. The lime green bar represents 900 pounds of chlorine gas. Definitely not something you want to breathe.

The releases link is what you might think: Charts and graphs visualizing what has been released. This can show trends: Is the facility releasing more or less over time? Why or why not?

Next we'll explore transfers. This is a big deal from an environmental justice perspective, and a topic I'm exploring for a series to be published this year.

Transfers are exactly what they sound like: Moving waste from a facility to another. This could be a landfill, an injection well, an incinerating facility, storage, wastewater treatment plan or recycling center (copper and aluminum can be recycled.)

Chemours, for example, ships its PFAS-contaminated wastewater to Arkansas and Texas. And you'll be shocked — shocked, I say — that most of the communities receiving waste are either low-income or home to people of color. This applies even to household waste. Durham ships its trash to Sampson County, where the landfill is in an environmental justice community.

Back to chemicals: International Paper is opaque about its transfers. We know that a facility in Whiteville took some material but the other listing is "unreported transfer site." That leads to more questions, either for DEQ or the EPA, starting with "What is this site and why wasn't it reported?"

On a positive note, clicking on View Report for the Hazmat Emergency Response listing takes you to that facility's page. At the bottom, census data breaks down demographics within a three-mile radius of the Hazmat site. Another note of caution: Three miles can be instructive, but within that radius, the most vulnerable people could live closer to the site. When I work on stories like this, I actually visit the area to witness what numbers can only hint at.

OK, this is a lot to absorb, so I'll finish with one last section.

Release reports can be found at this link. I've found this section to be the most unwieldy. You can browse by facility, federal facility, such as military bases; chemical and industry. You can also search by state or Zip code. It's a lot, I know. Hang on, we're almost there.

Let's search for all 762 facilities reporting to the TRI in North Carolina. Click on Facility, and choose North Carolina for the Geographic Location. You can also choose the year. Then click Generate Report.

And this gawd-awful spreadsheet is what you get. Here's just a portion of it, sorted alphabetically, which is useful if you're looking for a particular facility.

You can also sort by amount with the up and down arrows at the top of each column. And if you're really motivated, you can also export this to Excel or Google Sheets and do your own analysis.

Here's what the spreadsheet looks like sorted by release amount. Painful, I know. And clicking on each facility takes you a page with more information, etc. etc. I told you it was a rabbit hole.

If you want more guidance or information about the TRI, I'm happy to share whatever I know (lisa@ncpolicywatch or @lisasorg on Twitter.) There are more ways to drill down and use other parts of the EPA's website (and DEQ's) to get information. All of this information is public, and the trick is viewing the data with a critical and patient eye. Data rarely answers all of your questions; instead it leads to more questions.

Industry released 39 million pounds of pollution into the environment last year, most of it into the air
Lisa Sorg, NC Policy Watch
https://www.ncpolicywatch.com/2021/01/18/industry-released-39-million-pounds-of-pollution-into-the-environment-last-year-most-of-it-into-the-air/

North Carolina industry released the least amount of air pollution last year — 21.5 million pounds — since 2003, according to federal data released last week. Releases to land were also at 16-year lows, but discharges to waterways — 8.1 million pounds — were the highest since 2015.

Releases for air, land and water totaled 39 million pounds.

The Toxics Release Inventory, administered by the EPA, collects data from industrial facilities for 770 chemicals. There are some data shortcomings: Not all toxic chemicals are included in the TRI and the data is self-reported. Nonetheless, the inventory can inform people about significant polluters in their communities. The reportable chemicals include those that can cause cancer or other chronic human illnesses; significant adverse acute human health effects and environmental harm.

The TRI lists all reporting facilities and their releases by state, Zip code, city or county. You can also search by facility, industry, and chemical. (Frankly, the website is a rabbit hole where you can get lost for hours.) To help, the EPA offers an instructional video on how to navigate the database. I've also laid out a step-by-step beginners' guide to gleaning the information.

Here are some summary data for North Carolina. All figures are for 2019, except where noted.

17 — Rank of North Carolina among 56 states and territories, in amount of pollutants released to the environment
762 — Number of facilities in North Carolina required to submit TRI reports to the EPA
58 — Number of facilities in Mecklenburg County, which has the most in the state
190,942 — Pounds of pollutants released in Mecklenburg County
55 — Number of facilities in Guilford County, which ranks second in the state
233,187 — Pounds of pollutants released in Guilford County

39 million — Pounds of pollutants released by all industries, onsite

21.5 million — Pounds released into the air
9.3 million — Pounds released onto the land
8.1 million — Pounds released into the water
17.9 million — Pounds of additional pollutants shipped offsite for treatment, recycling or disposal, all industries

5.13 million — Pounds of pollutants released by PCS Phosphate, in Beaufort, which ranks first in all releases to the environment in North Carolina
4.81 million — Pounds of pollutants released by CPI, an electric utility in Southport, which ranks second
3.23 million — Pounds of pollutants released onsite by Smithfield Tar Heel slaughter plant, in Tar Heel, which ranks third

127 million — Pounds of pollutants released by industries onsite, 2005, the largest amount in the past 15 years

Source: EPA Toxics Release Inventory, 2019

EPA data shows release of toxic chemicals down by 9% in mid-Atlantic region
Water Technology
https://www.watertechonline.com/industry/article/14195710/epa-data-shows-release-of-toxic-chemicals-down-by-9-in-midatlantic-region

The U.S. Environmental Protection Agency (EPA) has released its 2019 Toxics Release Inventory (TRI) National Analysis, which shows that EPA and companies that manage chemicals continue to make progress in preventing pollution. The report shows that between 2018 and 2019, total releases of TRI chemicals decreased by 9%.

For the first time in five years, industrial and federal facilities reported an increased number of new source reduction activities that aim to reduce or eliminate the amount of chemical-containing waste facilities create. Facilities also avoided releasing 89% of the chemical-containing waste they created and managed during 2019 into the environment by using preferred practices such as recycling, treatment and energy recovery.

Since 2018, releases of TRI chemicals in EPA's Mid-Atlantic Region decreased by 11.4 million pounds. Going back to 2007, releases have decreased by nearly 70% (270 million pounds) in the Region, compared to a 19% decrease nationally. This large decrease was driven by declining air releases, although releases to water, land and off-site disposal also decreased during this time. For 2019, 7% of facilities in the Mid-Atlantic Region reported implementing new source reduction activities. Source reduction reporting rates in the region were among the highest in the plastics/rubber manufacturing sector, where 14% of facilities reported source reduction activities.

"The Analysis of TRI data shows that facilities located in the Mid-Atlantic Region have continued the trend of decreasing the release of toxic chemicals," said EPA Regional Administrator Cosmo Servidio. "This data is a tool that can provide important information to the public on chemicals in their community as we work to reduce emissions."

The 2019 TRI National Analysis reflects TRI chemical waste management activities, including releases, that occurred during calendar year 2019 and therefore does not indicate any potential impacts of the COVID-19 public health emergency that began in the United States in early 2020. Due to the significant analysis of reported information, this summary and interpretation of the most recent TRI data is released approximately six months after the reporting deadline.

The Emergency Planning and Community Right-to-Know Act of 1986 helped create EPA's Toxics Release Inventory program. Today, nearly 22,000 facilities report annually on the use and quantities of more than 760 chemicals they release to the environment or otherwise manage as waste to the Toxics Release Inventory (TRI) program. EPA, states, and tribes receive TRI data from facilities in industry sectors such as manufacturing, mining, electric utilities, and commercial hazardous waste management. The Pollution Prevention Act also requires facilities to submit information on pollution prevention and other waste management activities of TRI chemicals.

To access the 2019 TRI National Analysis, including local data and analyses, visit: www.epa.gov/trinationalanalysis.

EPA report shows fewer toxic releases in Northeast Louisiana

Bonnie Bolden

https://www.thenewsstar.com/story/news/local/2021/01/14/epa-report-shows-fewer-toxic-releases-northeast-louisiana/4144618001/

Information published Wednesday by the Environmental Protection Agency shows total toxic releases in northeastern Louisiana fell by about 6% in 2019. The region is also home to the fifth-largest toxic chemical releaser in the state.

The 2019 Toxics Release Inventory National Analysis shows that figure on par with Region 6, which consists of Louisiana, Arkansas, New Mexico, Oklahoma and Texas.

In a review of national data, Ouachita Parish has the 40th highest toxic chemical release rate when compared to other counties.

TRI chemicals could post a threat to the environment or human health, and the EPA releases an annual report detailing the total amounts released, recycled, treated or used in energy recovery.

In a news release, the EPA notes that total releases in Region 6 — including air, water, land and off-site disposal — declined by 25.9 million pounds when compared to 2018, a reduction of 6%. They're also down 11% since 2007 across the region.

Conversely, TRI total releases in northeastern Louisiana increased by about 6% when compared to 2007.

Region 6 releases of TRI chemicals into the air decreased by 5.4 million pounds when compared to 2018. Decreases in chemical manufacturing, electric utilities and petroleum manufacturing are credited with the change.

The EPA works to get facilities to eliminate waste at the source. After that the goals are to recycle, use it for energy recovery, treatment or disposal/release. The final option is considered a last resort.

In 2019, 5% of Region 6 facilities reported new attempts to reduce waste at the source.

"Today's announcement underscores my commitment to helping communities and companies get the environmental information they need to prevent pollution and protect public health," said EPA Administrator Andrew Wheeler. "The progress made under the TRI program in 2019 is proof that a cleaner environment and economic growth go hand in hand."

In 2019, 43% of the waste tracked in Louisiana was recycled, 13% was used for energy recovery, 39% was treated, and 4% was released or disposed of.

Louisiana ranks third out of 56 states and territories the EPA tracks for TRI data for most total releases per square mile.

All five of the sites with the highest disposal rates are chemical companies.

Four of those are in a span from Baton Rouge to south of New Orleans commonly called Cancer Alley.

The fifth is ANGUS Chemical Co. in Sterlington.

2019 TRI National Analysis: Facilities Reporting in 2019 | Toxics Release Inventory (TRI) Program | US EPA

Know more about TRI releases around you

In northeastern Louisiana, 21 facilities tracked for TRI chemicals operate in 8 of the area's 12 parishes.

In 2019, a total of 12.47 million pounds of TRI chemicals were released by land, air and water.

The Majority came from ANGUS (68%) and Graphic Packaging International (23%).

Water, chemical rules on chopping block
E.A. Crunden & Hannah Northey, E&E News
https://www.eenews.net/greenwire/2021/01/20/stories/1063723039

President Biden on his first day in office is already taking aim at unraveling some of the Trump administration's most contentious rules, including wetlands protections, water permitting for the oil and gas sector, toxic chemical assessments, and emissions from waste sites.

That means significant wins for energy, chemical, waste and agricultural interests are now at risk.

Biden's chief of staff, Ron Klain, today will issue a "regulatory freeze memo" and pause any new regulations from moving forward, giving the new administration a chance to halt and review "midnight regulations" that the Trump administration tried to finalize in its last days, according to a White House fact sheet.

The practice has historically occurred at the beginning of a new administration, allowing the incoming team to review the rules indefinitely. Midnight rules are considered regulations that have been finalized since roughly the November election but may not have gone into effect. The Trump EPA sought to circumvent the process by claiming it had "good cause" to make several high-stakes rules on air quality and science transparency effective immediately (see related story).

According to the memo, all agencies, including EPA, will confer with the incoming director of the Office of Management and Budget before renewing regulatory activity.

The White House in a separate memo listed four dozen EPA rules that will be reviewed and possibly revamped.

The list includes the Trump administration's Navigable Waters Protection Rule, which took effect in June, pulling back federal protection for millions of miles of streams and acres of wetlands, and EPA's decision this summer to not set drinking water limits on perchlorate, a rocket fuel ingredient linked to fetal and developmental brain damage.

Biden's EPA will also review the newly minted Lead and Copper Rule — the first update to federal drinking water standards in nearly 30 years — which is already facing legal pushback and criticism among environmental groups that say it isn't strong enough, given that there is no safe level of exposure to lead, a powerful, brain-battering neurotoxin.

EPA estimates there are between 6 million and 10 million lead service lines nationwide (Greenwire, Jan. 5).

Another target for the Biden administration is a review of lead-dust hazard standards and the definition of lead-based paint. Environmental and public health advocates have repeatedly criticized the government's approach to lead regulation, and EPA tightened some lead standards for the first time in years last month (E&E News PM, Dec. 21, 2020).

Yet another regulation that is listed for a closer look: an Army Corps of Engineers rule aimed at streamlining a critical water permitting program for oil and gas pipelines.

The Army Corps of Engineers on Jan. 6 finalized changes to its nationwide permit program under Section 404 of the Clean Water Act, drawing applause from oil and gas trade associations. The rule won't take effect until 60 days after it's published in the Federal Register (Greenwire, Jan. 6).

Also primed for the Biden administration's review is EPA's final rule that limits states' ability to block energy projects under the Clean Water Act. Specifically, the rule limits the scope of state reviews — excluding issues like climate and air

pollution — under Section 401 of the landmark environmental law, according to an EPA official (Greenwire, June 1, 2020).

Chemical assessments, waste regs under scrutiny
Biden is also freezing a number of actions under the Toxic Substances Control Act (TSCA) seen by advocates as a boon to a range of industry interests.

A July 2017 rule establishing a process for conducting risk assessments under TSCA will be among those scrutinized. Former EPA Administrator Scott Pruitt gutted proposed Obama-era framework rules for TSCA and replaced them with the new approach, panned as a handout to the chemical industry. Environmental groups later sued over that move.

Specific actions taken on individual chemicals and set to be reviewed include a risk evaluation for methylene chloride, often used in paint strippers and classified as a likely carcinogen. That chemical is one of the first 10 chemicals reviewed under the overhauled TSCA; environmental groups have criticized EPA's methylene chloride assessment as too limited in scope (E&E News PM, Jan. 14).

The incoming administration will also freeze rules for five chemicals under TSCA targeting persistent, bioaccumulative and toxic (PBT) chemicals — toxic substances that build up in the environment and pose a risk to the public.

Another hot-button item on the agenda is chlorpyrifos, a controversial pesticide linked to severe health effects including brain development damage in children. In a proposed interim decision in December, EPA doubled down on supporting the chemical's usage and said expanding label restrictions would limit the pesticide's impacts. Congressional Democrats have supported a ban on chlorpyrifos, as has the group Earthjustice, and advocates anticipate Biden will crack down on the chemical (E&E News PM, Dec. 4, 2020).

In a blow to the waste industry, Biden's team is also freezing an amendment to emissions guidelines for solid waste landfills. Those sites will be a target for the incoming administration due to methane emissions, and the industry has long speculated that a Biden presidency would mean stricter landfill regulations.

An additional move targeting disposal regulations concerns rules for coal combustion residuals from electric utilities. The Trump administration repeatedly sought to aid coal-fired power plants, including through easing regulations around disposing of coal ash, which often sits in unlined pits and is known to contaminate groundwater. The Utility Solid Waste Activities Group and other industry interests favored such rules, which are likely to be rolled back under new EPA leadership (Greenwire, Oct. 16, 2020).

Environmental advocates will also breathe a sigh of relief over the incoming administration's move to revisit financial responsibility requirements for the hardrock mining industry under Superfund law. EPA said in 2018 that it would not require the industry to "establish and maintain evidence of financial responsibility" for relevant sites. Critics of that move say such requirements are important to ensure responsibility for future cleanup in the case of toxic contamination (Greenwire, Nov. 30, 2020).

Democrats promise 'assertive' oversight of IRIS programme
Kelly Franklin, Chemical Watch
https://chemicalwatch.com/204312/democrats-promise-assertive-oversight-of-iris-programme

Democratic members of the US Congress have pledged to take an "assertive" oversight approach to the EPA's Integrated Risk Information System (IRIS) programme and have called on the agency to make changes to restore public confidence in its chemical assessments.

The press for reforms – including a call to resume abandoned IRIS reviews, like for formaldehyde – is far from the first time that politicians have weighed in on the controversial programme. But with the balance of power in Congress now shifted in the Democrats' favour, it provides an early glimpse into the types of policies the party might press the EPA to pursue.

"Political obstruction" within the Trump administration's EPA has impeded the programme's ability to produce IRIS assessments, according to a joint statement by Senator Tom Carper (D–Delaware), top Democrat on the Senate Environment and Public Works (EPW) Committee, and Congresswoman Eddie Bernice Johnson (D–Texas), who chairs the House of Representatives' science committee.

The two lawmakers called on the agency to:

review the IRIS assessments that have been suspended or discontinued since December 2018, including for formaldehyde, and determine a path to get them "back on track";
"quickly rescind rules and other policies that restrict the use of the best available science";
remove "arbitrary limits" on the volume of work conducted under IRIS;
increase transparency on the progress of assessments; and
replace the survey process currently used for determining priorities with a "collaborative" process that considers the needs of programme offices and regional offices in determining which substances to assess.
The recommendations came alongside the release of a Government Accountability Office (GAO) report assessing the programme's progress in adopting reforms in recent years.

Like other recent reports from the nonpartisan agency, the latest – 'Chemical assessments: Annual EPA survey inconsistent with leading practices in programme management' – says that IRIS has made progress toward improvement, but issues remain.

The GAO recommended that the EPA should make more information publicly available about the status of chemical assessments. It also should refine its survey process "to facilitate the collection of quality information" in determining programme priorities.

The agency, however, disagreed with at least some of the recommendations, according to the report. The EPA already maintains a high level of transparency and "implementing the recommendation would create an additional reporting and management burden that would slow the development of assessments", it states.

The EPA also pointed to a September 2020 memorandum that reflects how it has been gathering feedback to improve its chemical assessments nomination process, according to the report.

Nonetheless, Ms Johnson said the GAO's finding "demonstrates yet again the extent to which the outgoing EPA leadership has sought to undermine IRIS by imposing ill-conceived and opaque processes, obstructing the progression of chemical assessments, and failing to provide the programme with political support."

"Our committees will maintain an assertive oversight posture … to ensure that IRIS is quickly revitalised and restored to its vital role within EPA's scientific framework," she added.

Biden Moves Presage 'Aggressive' Chemicals Stance (Corrected)
Pat Rizzuto, Bloomberg Law
https://news.bloomberglaw.com/environment-and-energy/biden-day-1-moves-presage-far-more-aggressive-chemicals-stance?context=search&index=0

- 13 of 48 environment rules under review deal with chemicals
- Environmental justice lens at play in several of them

More than a quarter of the Trump-era EPA rules and decisions the Biden administration will review deal with chemicals, signaling the agency's oversight of potentially dangerous substances will be top priority.

Thirteen of the 48 Trump-era environment and public health rules and actions President Joe Biden's administration announced Wednesday it will review involve decisions the Environmental Protection Agency made about pesticides or actions on commercial chemicals implementing the Toxic Substances Control Act.

"We would expect a Biden administration to take a far more aggressive approach to implementation of TSCA," said Tom Berger, a partner in Keller and Heckman LLP's Washington and Indianapolis offices.

That includes a broader view of a chemical's "conditions of use," he said. Under TSCA, that term means the ways EPA decides how "a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of."

The more uses the EPA examines, the greater chance it could find potential health or environmental problems it needs to control.

Environmental Justice

"It shows the Biden administration is aware that the last administration's actions utterly failed to protect human health from toxic chemicals including pesticides," said Eve Gartner, an attorney focused on toxics and health at Earthjustice, a nonprofit public interest environmental law group.

Low income neighborhoods and communities of color are disproportionately exposed to chemicals and pesticides, so focusing on toxic substances "is an integral part of his environmental justice commitment," she said.

Seven of the 11 TSCA-related rules and decisions being reviewed focus on regulations restricting commercial and industrial chemicals. The chemicals are methylene chloride, a sometimes deadly solvent; lead, which damages children's IQ; and five toxic chemicals that remain for years in the environment and build up in the food chain.

Rules that control chemicals that can harm people are "the heart of TSCA," Gartner said. And whether these rules truly protect people who've been exposed to higher-than-average chemical exposures for decades is of central importance, she said.

Chlorpyrifos, Pesticides Spray Zones

The EPA's decision to allow the continued use of chlorpyrifos, a neurotoxic pesticide, and a rule that shrank pesticide spray exclusion zones, potentially exposing farm workers to greater amounts of pesticide drift, also are included in the 13 rules and decisions.

Lynn Bergeson, managing partner of Bergeson and Campbell PC, which specializes in chemical policies, saw the selected TSCA rules and policies as focusing on the entire process EPA has used to examine and regulate chemicals.

But an environmental justice "lens" will find many problems, she said, ticking off criticisms the agency's process has received. These include little focus on how the risks that potentially exposed or susceptible subpopulations face due to factors including age, sex, ethnicity, and preexisting health conditions.

"Perhaps this is why the process is under review," Bergeson said.

(Clarifies in second paragraph that action covers pesticides; also corrects number of TSCA rules in seventh paragraph.)

Democrats Blame Politics for Problems in EPA's Chemical Analyses

Pat Rizzuto, Bloomberg Law

https://news.bloomberglaw.com/environment-and-energy/democrats-blame-politics-for-problems-in-epas-chemical-analyses?usertype=External&bwid=00000177-1bf6-d667-a577-7ffed75a0001&qid=7044922&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve_nl%3A71&source=newsletter&item=headline&region=digest&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzctMWJmNi1kNjY3LWE1NzctN2ZmZWQ3NWEwMDAxIiwic2lnIjoidWJ

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EPA program to protect health seen remaining at risk
Democrats urge incoming EPA to toss Trump policies
Multiyear setbacks in completing certain EPA chemical analyses are delaying needed health protections, a federal watchdog report said Tuesday.

But top House and Senate Democrats say the blame lies squarely on "political interference" by Scott Pruitt, the Environmental Protection Agency's former administrator, and outgoing Administrator Andrew Wheeler.

The EPA didn't immediately respond to the Democrats' allegations, and it rejected many of report's recommendations.

The Government Accountability Office (GAO) issued a report describing problems within the EPA's Integrated Risk Information System, or IRIS program. The result, it said, is that the program takes years to release few chemical assessments.

IRIS' assessments examine chemicals' health hazards and the amounts of them that may be harmful. EPA regions, regulatory offices, and states combine those details with other information to decide if a chemical or pollutant should be cleaned up, have its air or water emissions restricted, or dealt with in some other way.

The delays affect people, according to the GAO, the investigative arm of Congress.

"EPA's ability to effectively fulfill its mission of protecting public health and the environment depends on understanding the universe of chemicals in or considered for commerce and producing timely assessments of the risks posed by those chemicals," it said.

The delays also spur states to conduct their own examinations that reach different conclusions about how toxic the same chemical is, the GAO said.

Echo Earlier Conclusions
The report's concerns echo similar conclusions GAO has reached since 2009, when it first included IRIS among its list of federal programs "most in need of transformation." IRIS remains on that high-risk list.

The GAO also makes recommendations, such as increasing the public information about IRIS reports. Some of these suggestions are similar to those its made in years past.

But the report also points to improvements the program has made since 2009.

The EPA's response, included in the report, disagreed with many recommendations. The IRIS program already has made many strides in becoming more transparent. And many of the GAO's suggestions would add additional procedures that would further delay IRIS analyses, the EPA said.

'Inconvenient' Science Buried
House Science, Space, and Technology Committee Chairwoman Eddie Bernice Johnson (D-Texas) and Sen. Tom Carper of Delaware , the top Democrat on the Senate's Environment and Public Works Committee, requested the report.

The Trump administration, which vacates power Wednesday, has spent the past four years interfering with IRIS' ability to fulfill its mandate, Johnson said in a statement.

It also "silenced the experts and buried 'inconvenient' science that highlighted unsafe chemicals," said Carper (D-Del.) in that statement.

"I am confident that the Biden administration will allow science to be its guide," Carper said.

He urged EPA's incoming leadership to follow the reports recommendations and make the other changes needed to restore confidence in its health assessments, policies, and rules.

The two Democrats also urged incoming EPA appointees to revoke many policies put in place during the Trump administration.

EPA Denies Revised TSCA Petition Seeking To Ban Water Fluoridation
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/epa-denies-revised-tsca-petition-seeking-ban-water-fluoridation

EPA has rejected a court-ordered request from anti-fluoridation groups to reconsider its denial of their 2016 petition asking the agency to ban drinking water fluoridation because of concerns about potential neurotoxic effects, saying TSCA does not require it to reconsider such actions and it is declining to exercise its discretion to do so.

"Nothing in section 21, or TSCA more broadly, requires EPA to reopen the record for a section 21 petition and/or reconsider the agency's final action to deny the petition," the agency's Jan. 19 letter to petitioners' attorney states. "EPA declines to exercise its discretion to reopen the administrative record and reconsider the February 17, 2017 petition denial. Instead, EPA is exercising its discretion to allocate its resources to most effectively implement TSCA requirements, including significant new requirements from the 2016 amendments, by prioritizing review of existing chemical substances grounded in risk-based considerations."

The denial, which government officials have long signaled, will presumably return the issues to Judge Edward Chen of the U.S. District Court of Northern California, who has presided over petitioners' challenge to EPA's 2017 denial of the original petition.

After the conclusion of a two-week trial last summer, Chen ordered petitioners to re-submit their petition augmented with new research that had become available since the original petition was filed and to EPA to consider it.

Chen issued the directions and set the case in abeyance over petitioners' and EPA's objections, citing a series of benefits (/node/225676) from his plan, including giving the plaintiffs a new opportunity to bolster their standing in the case and allowing the National Toxicology Program (NTP) to advance a long-awaited monograph on fluoride's neurodevelopmental risks.

"I'm just saying [the upcoming NTP study is] another reason why it makes sense, frankly, to spend this time allowing the agency to take a second look [at a new petition and] allowing plaintiffs to straighten out the standing issue [in a new petition], which I also think is very serious," Chen said during an Aug. 6 status conference in the case, Food & Water Watch, Inc., et al. v. EPA.

"And then, if we have to come back here, if the agency does not take any action and the plaintiffs decide they want to take it up there'll be a mechanism [for that]," Chen added.

While plaintiffs and Justice Department (DOJ) attorneys for EPA raised concerns with his position, Chen appeared reluctant to rule de novo on whether fluoridating drinking water poses neurodevelopmental risks and expressed "serious" concerns about plaintiffs' standing to sue.

But he also declined to rule on the case as it stands, as EPA urged, suggesting he also has concerns after hearing plaintiffs' evidence at trial. It appears, however, that he will have to reconsider the issues.

Resource Constraints

EPA in its denial letter, filed with the court Jan. 19, offers a series of reasons for its denial of the revised petition in addition to its discretion.

For example, the agency's letter details the extensive time and resource constraints that its toxics office is working under to evaluate and write risk management rules for more than 30 chemicals in its existing chemicals program following Congress' 2016 reform of the Toxic Substances Control Act (TSCA), with EPA arguing that it "must allocate its resources to meet these new resource-intensive statutory requirements and deadlines."

EPA adds that the petitioners' 2020 submissions "do not support diverting significant resources to reopen the 2016 Petition and reconsider the petition denial."

The agency also raised again one of its arguments at trial last June that the petitions do not satisfy "the legal requirements necessary for EPA to initiate a proceeding for a [TSCA] section 6(a) rulemaking because, among other deficiencies, the scientific evidence submitted for evaluating the risk of neurotoxic effects from exposure to fluoride is insufficient for EPA to reach an informed risk determination. Section 21 petitions should include a well-supported risk assessment fit for informing EPA's risk determination under TSCA."

EPA expands its argument by suggesting that section 21 citizen's petitions do not provide a vehicle for the public to request risk evaluations and subsequent risk management rules.

"EPA-conducted risk evaluations can be initiated in only one of two ways -- upon EPA's designation of a chemical substance as a high-priority substance, or in response to a request for risk evaluation by a manufacturer of the chemical substance . . . The purposes of the prioritization process are (1) to ensure that the Agency's priorities for risk evaluation and risk management are grounded in risk-based considerations and (2) to provide the public and interested stakeholders with an opportunity to provide relevant information. . . . If a petitioner could circumvent the prioritization process and unilaterally compel a TSCA risk evaluation through section 21, the purpose and intent of these statutory provisions would surely be frustrated."

EPA also reiterates trial arguments that the evidence petitioners submitted, even augmented by evidence provided at trial and in NTP's updated draft monograph, is "insufficient for reaching an informed risk determination."

The agency describes the overall evidence of neurotoxic effects at the recommended fluoridation level in the United States of 0.7 milligrams fluoride per liter of water as "inconsistent and unclear," adding that "it is premature and inappropriate to rely upon either" of two epidemiology studies that petitioners focus on in the request "for quantitative analysis."

EPA adds that because the NTP monograph remains in draft form and under peer review by the National Academy of Sciences, it does "not justify reconsideration at this time."

"While the science on this issue develops and, particularly, without the final NTP monograph, reconsidering the petition denial at this time would not be a prudent use of EPA's resources. Reconsideration would divert significant resources from ongoing risk evaluations and rulemakings the Agency is already undertaking, as well as other high priority work within the Office of Pollution Prevention and Toxics," it adds. -- Maria Hegstad (mhegstad@iwpnews.com)

GAO Faults Wheeler's IRIS Review, Fueling Calls For Biden To Undo Reforms
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/gao-faults-wheeler-s-iris-review-fueling-calls-biden-undo-reforms

A new Government Accountability Office (GAO) report says EPA Administrator Andrew Wheeler's review of the Integrated Risk Information System (IRIS) risk-assessment program was implemented without "sufficient guidance or criteria," drawing calls from Democrats for the Biden administration to quickly undo Wheeler's changes.

Top Democrats on the House science committee and the Senate environment committee jointly released the GAO report on Jan. 19 as part of a call for EPA under President-elect Joe Biden to scrap reforms Wheeler imposed on the influential but troubled IRIS program that were widely seen as sidelining it.
"The IRIS program is the gold standard for chemical toxicity assessments around the world, but the Trump Administration has spent the past four years interfering with the program's ability to fulfill its mandate," Rep. Eddie Bernice Johnson (D-TX), who chairs the House science panel, said in a joint Jan. 19 statement with Sen. Tom Carper (D-DE).

GAO's report, conducted at Carper and Johnson's request, finds IRIS "has not produced timely chemical assessments, and most of its 15 ongoing assessments have experienced delays."

The report delves into the new "survey" process Wheeler implemented in mid-2018, requiring program and regional office leaders to review and prioritize chemicals already on IRIS' agenda for continuation in the program or to add new chemicals.

It found that the changes were made "without providing sufficient guidance or criteria, raising questions about its ability to meet EPA user needs," and that the survey "was not supported by quality information."

Wheeler's changes to IRIS have been blamed for stalling several long-pending chemical assessments and have been seen as a way to sideline the program in favor of Toxic Substance Control Act (TSCA) evaluations, which often target the same types of chemicals that have long been the domain of the IRIS program.

But many critics of the IRIS program have welcomed the shift away from IRIS and its conservative, hazard-based assessments to TSCA, which evaluates risks from select conditions of use.

However, former Trump EPA General Counsel Matt Leopold expects that the Biden administration will revitalize IRIS, bringing it closer to parity with TSCA as an avenue for assessing risks posed by toxic substances.

Based on GAO's findings, Johnson and Carper -- who will take over as chairman of the Senate Environment and Public Works Committee on Jan. 20 -- are calling on the incoming EPA leadership to eliminate Wheeler's survey process and to address a host of other concerns including those that began before the Trump administration.

Those include recommendations that officials remedy long-standing productivity and transparency concerns that have left IRIS on GAO's list of "high-risk" federal programs for years; complete the IRIS handbook which was recently released for public comment and peer review; review the assessments that have been suspended and discontinued since December 2018, such as the formaldehyde assessment, and determine the best course to get high-priority assessments "back on track" and assert the Administrator's commitment to getting IRIS "back on its path to address recommendations from GAO and the National Academies" among other steps.

'Assertive Oversight Posture'

"EPA must take certain essential actions -- such as eliminating the flawed annual survey process criticized by GAO and reviewing the suspensions and discontinuations of assessments such as formaldehyde since 2018 -- to restore IRIS's ability to properly support the Agency's mission. Our Committees will maintain an assertive oversight posture during the 117th Congress to ensure that IRIS is quickly revitalized and restored to its vital role within EPA's scientific framework," Johnson says.

Carper adds that Trump officials "did everything possible to starve [IRIS] of resources . . . I encourage the incoming leadership at EPA to heed the recommendations of this report and make the other changes needed to restore confidence in EPA's health assessments, policies, and rules to protect human health and the environment."

It is unlikely that the Biden EPA will be able to make significant changes to the IRIS program, whether targeting Trump-era issues or longer-standing ones, until an assistant administrator has been nominated to head the Office of Research

and Development (ORD), which oversees IRIS. That post is often one of the last roles selected at EPA; has been unfilled since 2012.

And while science groups are already calling on the incoming administration to move more quickly than its predecessors on selecting an ORD chief, IRIS' future depends not only on leadership but also decisions about how the program will complement -- or not -- the toxics office's TSCA program for evaluating existing chemicals.

"I think that they need to do some serious thinking about the relationship between IRIS and the TSCA program. The TSCA program has a very, very heavy risk evaluation workload on chemicals," one former EPA official tells Inside TSCA.

"Over time a lot of the chemicals that used to be handled by IRIS will, one way or another, be handled by TSCA. So, the question is, what is the continuing role of IRIS and is there some category of chemicals that really belong with IRIS rather than TSCA and what are they? What are the resources required to deal with those chemicals, bearing in mind however you slice it the scientific resources for the TSCA program need to be much bigger. It would be a shame if the new administration just reflexively tries to reinflate IRIS without doing a careful analysis of what the science needs are within the administration."

GAO Findings

When EPA introduced Wheeler's IRIS process, officials indicated they would conduct new surveys annually to update IRIS' chemical-assessment agenda. However, GAO finds that when EPA conducted the process a second time in 2019, there was "a significant decline in survey participation between 2018 and 2019," but "EPA did not indicate whether the agency has assessed the quality of information generated by the survey."

More specifically, the report concludes that since 2018, "the IRIS draft development process has improved, especially in communication and transparency efforts ... but "ORD's survey was not supported by quality information--particularly explicit criteria on how ORD selected chemical nominations for inclusion in the IRIS Program's list of assessments in development and information about how the IRIS Program's work was prioritized. Providing that information to program and regional offices would have communicated how their nominations are selected and prioritized, allowing them to better utilize the nomination process to communicate needs that the IRIS Program can meet."

The report contains five recommendations for EPA; the agency partially agreed with two of them and disagreed with three.

EPA disagreed with GAO recommendations that ORD provide more public information about where IRIS assessments are in the development process, stating that it "already maintains a high level of transparency and that implementing the recommendation would create an additional reporting and management burden that would slow the development of assessments," according to GAO.

EPA also disagreed with GAO's recommendation for EPA program and regional office leaders to provide staff guidance on how and which chemicals to nominate for inclusion in IRIS, telling GAO that it has made changes "to the latest nominations process as articulated in a September 2020 memorandum that described the two-phase process for regional offices and National Program Managers. We have noted the memorandum's release in our report. We do not believe the memorandum addresses our recommendation."

Finally, the agency disputed GAO's recommendation that it evaluate its survey process to ensure it provides useful information, saying it "already obtained useful feedback on ways to improve the clarity and transparency of its nominations process from program and regional office senior leadership, as reflected in its September 2020 memorandum. We adjusted the language of the recommendation to acknowledge that EPA has started an evaluation process, but we believe that ongoing assessment of the annual survey process is warranted."

EPA partially agreed with the remaining two recommendations, that ORD should issue criteria for how it determines which nominations for assessments it adds to the IRIS agenda and that EPA should include IRIS "assessment needs, how the program is being resourced, and other metrics, in its strategic plans." -- Maria Hegstad (mhegstad@iwpnews.com)

EPA Finalizes PFAS SNUR Guide Unchanged, Days After Comments Close

Diana DiGangi, Inside TSCA

https://insideepa.com/tsca-news/epa-finalizes-pfas-snur-guide-unchanged-days-after-comments-close

EPA has finalized without changes its guidance defining "surface coatings" subject to its significant new use rule (SNUR) for some per- and polyfluoroalkyl substances (PFAS), just one business day after the close of comments on a draft version and despite calls from environmentalists and others to clarify or broaden several provisions.

EPA released the final guidance on Jan. 19, the first business day after the Jan. 15 deadline for comments on the draft version. And despite environmentalists' criticisms of that draft, including that the White House unduly narrowed its scope during inter-agency review, EPA made no substantive changes to the final version of the guide.

"Comment period on draft version closed on Friday. . . . EPA issued the final today: Zero changes made. No way did they even look at the comments," one environmentalist tells Inside TSCA.

Even though EPA in September enacted a new rule that requires the agency to follow a formal notice-and-comment process when crafting some guidance documents, the SNUR guide appears not to be subject to that mandate because it is not labeled "significant" -- allowing officials to complete work on it just a day before President-elect Joe Biden's inauguration.

But the same procedure would also allow the incoming Biden administration to quickly rework its interpretation of the SNUR, potentially addressing arguments by environmental groups in their comments that the guidance's definition of "surface coatings" is so narrow that it conflicts with the PFAS rule's text.

"The final guidance does not fix the problems we were concerned about in our comments. The SNUR guidance is really problematic and, as we said in our comments, unlawful because it's contrary to the SNUR itself," said Bob Sussman, a former top EPA official in the Clinton and Obama administrations who worked with the group Safer Chemicals Healthy Families (SCHF) on its Jan. 15 comments on the guide.

The guidance is designed to aid implementation of EPA's SNUR for the PFAS subgroup termed long-chain perfluoroalkyl carboxylate chemical substances (LCPFACs), which are widely used in consumer, commercial and other products.

It specifically aims to define "surface coatings" subject to the rule and uses a test based on whether the coating will have "direct contact with humans or the environment" during normal use or reuse -- language that according to a "redline" version of the guide was added by the White House during review of much broader draft language that EPA crafted.

Environmentalists and some former EPA staff have attacked the White House's definition as overly narrow, with several groups arguing in comments that both the "direct contact" standard and the refusal to consider disposal contradict the language of the SNUR.

Environmentalists' Criticism

For instance, SCHF writes in its comments that the SNUR includes "no qualification that the article and its components must be 'in direct contact with humans or the environment.' To add this limitation is thus not authorized by the SNUR itself and is unlawful."

And the Environmental Defense Fund (EDF) wrote in its Jan. 15 letter that "individually and in combination, these criteria serve to increase ambiguity and confusion over when the SNUR will apply, which was already increased by EPA's unwarranted decision to limit the SNUR to articles with surface coatings containing LCPFAC substances."

EDF relates its criticisms more broadly back to what it says are flaws in the SNUR itself, which was initiated by the Obama administration in 2015, languished, and was then revived but narrowed in scope by the Trump administration, after Congress set a deadline for a final version in the fiscal year 2020 defense authorization act.

"We noted that EPA failed to recognize that articles have a lifecycle, including production, distribution, use, recycling and/or disposal," EDF writes. "Sadly, these same flaws in the SNUR extend to and indeed are made worse by language in the Draft Compliance Guide that even further narrows the applicability of the SNUR by establishing narrow criteria limiting which surface coatings would be subject to it."

It says that under the guide, "[a] company could claim that the SNUR does not apply, for example, to inhalation of dust generated by activities such as drilling, sanding, or grinding a coated article, arguing that such exposure is not from "direct contact" with the coating."

EDF adds that similar scenarios could arise when LCPFACs are "released from a coating into various media such as air or water, through leaching, erosion, abrasion, wear and tear or similar 'natural' mechanisms, arguing that those exposures would also not be from 'direct contact' with the surface coating itself."

Even outside of the written comments, environmentalists and industry attorneys alike have raised concerns over whether the guide is workable.

Larry Culleen, an environmental attorney at the law firm Arnold & Porter, told Inside TSCA that the new test "seems to exclude consideration of exposures that might occur only during deliberate misuse or disposal of the article at the end of its useful life."

Culleen noted in his legal analysis of the guidance that it would limit the SNUR's application to "to only those surfaces to which humans or the environment will ordinarily be in direct contact," echoing EDF's criticism.

And Betsy Southerland, a former top career official at EPA who is now a member of the Environmental Protection Network (EPN), said that this exclusion violates EPA's responsibilities under the 2016 amendments to the Toxic Substances Control Act (TSCA).

"It's very clear under new TSCA, that you're supposed to look at cradle to grave aspects of toxic chemical exposure," Southerland told Inside TSCA. "So you're supposed to look at the disposal aspect as well as use, as well as the cradle stage, the manufacturing." -- Diana DiGangi (ddigangi@iwpnews.com)

Groups Say Phthalate Scopes Give Biden Chance To Extend TSCA's Reach
Maria Hegstad, Inside TSCA
https://insideepa.com/tsca-news/groups-say-phthalate-scopes-give-biden-chance-extend-tsca-s-reach

Environmentalists are urging the incoming Biden administration to expand the scope of two pending TSCA evaluations for a pair of phthalates to consider vulnerable subpopulations and other issues that they charge were unlawfully excluded, saying they provide a chance to overhaul past practices and expand the reach of future evaluations.

"The risk evaluations that are now underway present an opportunity for EPA to reconsider its past practices and to conduct the comprehensive, health-protective risk evaluations that TSCA requires," the groups, long critical of the Trump EPA's approach to conducting risk evaluations, state in their joint Jan. 11 comments. "To do so, significant changes to the draft scopes are needed. We urge EPA to publish revised scopes, or problem formulation documents that address the deficiencies," they say.

In particular, they say EPA's proposed scopes for the pair of phthalate evaluations industry has requested that EPA conduct under the Toxic Substances Control Act (TSCA) are "fundamentally flawed," arguing that the agency has

"illegally excluded relevant" susceptible groups, ignored multiple exposure sources as well as advice to assess phthalate chemicals as a larger group, and needs to order testing.

Groups signing the joint comments crafted by Earthjustice include Alaska Community Action on Toxics, Breast Cancer Prevention Partners, Center for Environmental Health, Defend Our Health, Learning Disabilities Association of America, Natural Resources Defense Council, and Safer Chemicals Healthy Families.

Their comments are on EPA's draft scope documents for diisodecyl phthalate (DIDP) and diisononyl phthalate (DINP), two phthalate chemicals widely used as plasticizers in the production of plastics and plastic coatings to increase flexibility.

Manufacturers represented by the American Chemistry Council (ACC) asked EPA to conduct the two assessments. Since the deadline on the proposed scope of those assessments was on Jan. 11, it will fall to the incoming Biden administration will finalize the documents.

The groups argue that EPA's scope document "illegally excludes relevant potentially exposed or susceptible subpopulations" (PESS) that TSCA requires be given special consideration in the evaluation because the scopes do not explicitly include developing fetuses as part of the subpopulations.

The environmentalists' calls for EPA to formally identify certain groups as PESS in these evaluations is just the latest such push, which the groups hope will eventually drive stricter controls on evaluated chemicals.

For example, Earthjustice and community groups from the Gulf Coast region in Texas and Louisiana unsuccessfully urged the Trump EPA to account for the particular risks that communities adjacent to petrochemical facilities in the region faced from the next 20 chemicals has prioritized for evaluation.

But a leading industry lawyer said recently he expects the incoming Biden administration to give higher priority to considering risks for such vulnerable subpopulations when conducting TSCA reviews, given President-elect Joe Biden's pledges to address environmental justice concerns.

"I think they'll bring that to bear in the context where the statute requires that EPA take into consideration sensitive subpopulations when assessing risk and in choosing ways to evaluate chemicals," Larry Culleen, a partner at Arnold and Porter, said recently.

Developing Fetuses

The groups point to "strong evidence that the developing fetus is exposed to multiple phthalates, and the fact that prenatal phthalate exposure can lead to catastrophic health outcomes, the developing fetus should be explicitly considered a potentially exposed or susceptible subpopulation. A failure to evaluate the developing fetus as such will lead to a vast underestimation of risk to the most susceptible life stage to phthalate exposure."

The groups also argue EPA should explicitly consider racial and ethnic minorities, particularly those of lower socio-economic status, as studies have indicated they have greater phthalate body burdens, particularly poor, minority individuals who also live near chemical facilities.

While the comments acknowledge that in the proposed scopes, "EPA stated that communities surrounding major sources of those chemicals may be considered as potentially exposed or susceptible subpopulations," they say TSCA requires the agency to formally identify these communities as potentially exposed or susceptible subpopulations and "must also consider not only those communities' increased exposure but also their heightened susceptibility to DIDP and DINP as a result of both intrinsic and extrinsic susceptibility factors."

As critics have called on EPA to do in most if not all of the first 10 evaluations of existing chemicals that it has completed since Congress reformed TSCA in 2016, the groups are also urging the agency to use its expanded authority under

sections 4 and 8 of the law to require companies to test and submit more data about the chemicals, while also calling on EPA to use its authority in the Emergency Planning and Community Right-To-Know Act (EPCRA) to add DIDP and DINP to the annual Toxic Release Inventory (TRI) reporting requirements.

"To the extent EPA is missing information relevant to the DINP or DIDP risk evaluations, it must use all statutory tools at its disposal to generate or obtain relevant data to inform those risk evaluations. If it fails to do so and instead relies on surrogate data and proxy models, it will violate its directive under TSCA to consider all reasonably available information."

But environmentalists also note that "[n]either DINP, DIDP, nor phthalate esters -- the chemical class to which DINP and DIDP belong--are listed on the TRI, even though they meet the criteria for listing. . . . EPA should list phthalate esters as a category on the TRI both because doing so will allow it to satisfy its statutory mandate under TSCA to obtain reasonably available information and because communities deserve to know when chemicals that EPA recognizes as hazardous and toxic are released in their midst. At the very least, EPA must list DINP and DIDP on the TRI. EPA has long known that the toxicity of these phthalates makes it appropriate to list them -- it proposed to add a DINP category to the TRI over twenty years ago based on DINP's liver, kidney, and developmental toxicity."

Data gleaned from TRI reporting will allow EPA to identify those communities most exposed to DIDP and DINP production and processing, the groups add.

Additional Exposures

The groups also raise a number of concerns about EPA's approach to considering exposures to the pair of phthalates, ranging from workers' oral exposures, exposures to microplastics in landfill leachate and its failure to aggregate exposures as necessary, an ongoing concern for the groups in EPA"s existing evaluations to date.

"In the Draft Phthalate Scopes, EPA outlines plans to evaluate risk from exposure to each phthalate across defined conditions of use, but fails to consider real-world, foreseeable combinations of exposures across conditions of use. Instead, EPA evaluates consumer exposures in isolated categories, assuming that exposures to product categories like toys, furniture, and vinyl flooring are mutually exclusive. In addition, EPA understates the extent of phthalate exposures across different consumer uses by failing to examine relevant sources of phthalate exposures . . . EPA also fails to consider exposures across both occupational and consumer settings, a likely scenario for workers who live in homes with products or building materials that contain DINP and DIDP, such as vinyl flooring."

Perhaps more broadly, the groups call on EPA to heed advice in the National Academy of Science's 2008 report, "Phthalates and Cumulative Risk," which urges EPA and others to assess similar phthalates as a class.

They argue that this approaches also best comports with revised TSCA and makes sense, given the fact that EPA chose several additional phthalates as among its ongoing batch of 20 chemicals that it is evaluating before ACC asked the agency to consider DIDP and DINP as well.

"In order to comply with TSCA, EPA should evaluate the seven phthalates that are currently undergoing risk

evaluation as a class. EPA's traditional approach of conducting risk assessments on individual chemicals will not account for real world exposures to phthalates and will underestimate risk posed to workers, ONUs, the general population, and potentially exposed or susceptible subpopulations. Assessment of phthalates individually will underestimate risk because exposure to multiple phthalates is widespread in the United States, and phthalates contribute towards common adverse health outcomes, increasing the likelihood of cumulative adverse health impacts." -- Maria Hegstad (mhegstad@iwpnews.com)

Biden plans to elevate newly-tapped OSTP chief
Inside TSCA
https://insideepa.com/tsca-takes/biden-plans-elevate-newly-tapped-ostp-chief

President-elect Joe Biden has nominated his choices to lead the White House Office of Science and Technology Policy (OSTP) while elevating the office to a cabinet-level position for the first time, a move that will lend added weight as OSTP works to implement new mandates to coordinate PFAS and green chemistry research government-wide.

Biden Jan. 15 nominated Eric Lander to serve as OSTP director and Presidential Science Advisor and Alondra Nelson to serve as OSTP's deputy director, according to a statement from the transition team.

Lander was a principal leader of the Human Genome Project and is the founding director of the Broad Institute of MIT and Harvard. During the Obama administration, he served as external co-chairman of the President's Council of Advisors on Science and Technology (PCAST).

Nelson is president of the Social Science Research Council, a nonprofit organization linking social science research to policy and a professor at the Institute for Advanced Study, in Princeton, NJ, with research interests in science, technology, social inequality, and race.

House science committee chairman Eddie Bernice Johnson (D-TX) praised their selection while also applauding Biden's decision to "elevate the position of OSTP Director to be included in his Cabinet. I am thrilled to turn the page to a new era in which we can be confident that, once again, science, facts, and data are at the forefront of decision making at all levels across our government."

Elevating OSTP is one of a number of steps Biden is expected to take early in his administration to bolster the role of science in his decisions. For example, several sources have said Biden will sign an executive order protecting the scientific integrity of EPA and other federal agencies that use science in the course of their work.

And elevating the office will likely add weight as OSTP works to implement recent congressional mandates in the National Defense Authorization Act to establish two chemical-focused programs.

The legislation, which Congress codified after overriding President Donald Trump's veto, directs OSTP to create and lead an interagency body to coordinate federal per- and polyfluoroalkyl substances (PFAS) research while also requiring OSTP, together with officials from EPA and several other agencies, to create a first-time interagency group "with responsibility to coordinate federal programs and activities" in support of "sustainable chemistry."

The sustainable chemistry language comes from standalone legislation long pushed by Sen. Chris Coons (D-DE) which he had sought unsuccessfully to attach to other, previous legislation, including the 2016 Lautenberg bill that reformed the Toxic Substances Control Act.

Biden also named Frances H. Arnold and Maria Zuber to serve as the external co-chairs of PCAST and Kei Koizumi as OSTP's chief of staff.

CHEMICALS FOUND IN EVERYDAY OBJECTS COULD CAUSE MORE SEVERE CASES OF COVID-19

Emily Arnsten, News @ Northeastern

https://news.northeastern.edu/2021/01/14/chemicals-found-in-everyday-objects-could-cause-more-severe-cases-of-covid-19/

A group of chemicals called PFAS (per- and polyfluoroalkyl substances), colloquially known as "forever chemicals" because of their lengthy degradation time, are nearly inescapable. Commonly used to repel water and reduce the friction on surfaces, they're found in raingear, lotion, non-stick pans, dental floss, food packaging, surgical gowns, electronics, and the foam used to fight fires.

Now, a new study shows that people with elevated levels of PFAS in their blood—most often a result of exposure to contaminated drinking water or food—could have more severe cases of COVID-19. Of the 323 COVID-19 patients

screened in the study, more than half of those seriously ill with the disease had elevated levels of a particular type of PFAS—known as PFBA—in their blood.

Phil Brown, director of the Social Science Environmental Health Research Institute and university distinguished professor of sociology and health sciences, explains how PFAS could cause more severe cases of COVID-19 and reduce the effectiveness of the vaccine. Photo by Ruby Wallau/Northeastern University

"These chemicals interfere with the immune system," says Phil Brown, a university distinguished professor of sociology and health sciences at Northeastern who studies the effects of PFAS on people's health. "PFAS have been shown to suppress B cells, which are very important for producing antibodies."

On top of that, effects of PFAS on the immune system have also been associated with an overactive immune system. "Cytokine storm" is one effect of COVID-19 seen in more severe cases.

Cytokines are the proteins that activate the self-destruct button in infected cells, which is usually a good strategy for protecting healthy cells from infection. But if cytokines flood the body in a "storm," the immune system mistakenly attacks all cells instead of only those infected with the virus, says Brown, who is also the director of the Social Science Environmental Health Research Institute at Northeastern, as well as co-director of the Institute's PFAS Project Lab.

In COVID-19 patients, that rapid cell death can cause a huge loss of tissue, especially in the lungs where the virus accumulates. As the tissue breaks down, the air sacs in the lungs become leaky and fill with fluid, ultimately leading to pneumonia, a major cause of death among COVID-19 patients.

"It's like overdosing on your immune system," says Brown, who intends to incorporate COVID-19 research into his ongoing study about the health effects of high levels of PFAS in drinking water.

The negative consequences PFAS have on the immune system can also reduce the efficacy of vaccines, Brown explains. Suppressed immune systems are less likely to respond to inoculations.

"Another concern here is that you wouldn't necessarily know that the vaccine might not work unless you were testing for [PFAS]," he says. Even though the chemicals are widespread—97 percent of Americans have some level of PFAS in their blood—it's not routinely checked for or considered during vaccination.

The Centers for Disease Control and Prevention is currently investigating whether heightened levels of PFAS cause more severe cases of COVID-19 or have any effect on the vaccine. "In the past, when we saw that children had antibody levels that were below the level of protection, we just gave the child another booster vaccination," said Phillippe Grandjean, lead author of the study on PFAS and COVID, in an interview with Chemistry Magazine.

"I would think that this option needs to be considered also for the [coronavirus] vaccines, but I would first like to see data on corona antibody levels in people with different levels of PFAS exposure," Grandjean continued.

Of all the PFAS, the chemical known as PFBA—found in carpets, stain-resistant clothing, eye shadow, and bike lubricant, to name only a few products—is considered by some to be one of the least harmful because it circulates in the blood for less time than other PFAS. But it tends to congregate in the lungs, which is why researchers believe it has such adverse effects on COVID-19 patients. Indeed, many chemicals that leave the body even sooner, such as BPA, have many documented health effects, so that short duration is not necessarily related to less hazard, Brown says.

The consequences of PFAS extend far beyond just COVID-19. The chemicals are also associated with liver malfunction, preterm births, hypertension, thyroid disease, and a variety of cancers including prostate, pancreatic, and ovarian cancer, Brown says.

"Most of the uses of PFAS aren't essential," he says. "We want all these products to slip and slide easier. Teflon pans or dental floss, for example. But we've been cooking with cast iron pans and using dental floss that doesn't have PFAS in it for decades, and they've worked just fine. We need to get back to that."

Pesticides Drift Rule Under Review by Incoming Biden Administration
Fatima Hussein, Bloomberg Law
https://news.bloomberglaw.com/environment-and-energy/pesticides-drift-rule-under-review-by-incoming-biden-administration?context=search&index=1

- Pesticide rule on list of agency review items
- NY Court temporarily halted implementation

An EPA rule that shrinks pesticide spray exclusion zones, potentially exposing farm workers to greater amounts of chemical drift, will be up for review by the incoming Joe Biden administration, according to a statement it issued just ahead of the new president's inauguration.

Promulgated by the outgoing Trump administration, the pesticide drift rule is one of dozens of agency actions that will be reviewed under a coming Executive Order titled, "Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis."

In December, U.S. District Judge Lewis J. Limanin the Southern District of New York temporarily halted the Environmental Protection Agency's implementation of the measure that worker safety advocates said increases health risks.

That case, filed by a farmworkers' coalition in December, has since been consolidated with an earlier case filed by the states of New York, California, Illinois, Minnesota, and Maryland. Liman's order remains in effect.

During the Obama administration, the EPA directed applicators to stop spraying within 100 feet of a person, even if that person is outside the farm's property boundary. The Trump-era rule reduced the distance to just 25 feet.

The farmworkers' petition challenged three aspects of the EPA's final rule: the rollback of a provision requiring the exclusion zone to apply to those off the target property; the elimination of protection for people who aren't employees of the agricultural firm and who are on an easement on the property; and the rollback of the provision mandating a 100-foot buffer for pesticides sprayed in the form of small droplets that are more susceptible to drift.

Its opponents argued the rule wasn't made with adequate justification or factual support. They added that it was issued despite the agency's receipt, during the public comment period, of evidence showing serious human health risks that may result from reducing the zone.

The EPA's proposal received 126 comments. Three mass mail or signature campaigns had more than 28,000 written comments and signatures from state pesticide regulatory agencies and associations, farmworker advocacy organizations, and public health associations.

Is Roundup Safe to Use on Vegetables? Here's What You Should Know
Stephanie Osmanski, Green Matters
https://www.greenmatters.com/p/is-roundup-safe-vegetable-garden

Glyphosate is an herbicide that's made many headlines for causing both legal and health crises nationwide. Roundup is a brand name version of a glyphosate-based herbicide produced by Monsanto, and although it's the most commonly used herbicide, many are left wondering what's safe and what's not when it comes to glyphosate with its long history of controversies.

Is Roundup safe to use in a vegetable garden? Here's what gardeners and farmers alike should know beforehand.

What is Roundup?
Roundup is the brand name of an herbicide, the main ingredient of which is isopropylamine salt of glyphosate. It's been used as a weed and poison ivy killer since it was first introduced in 1974. So, how does it work? According to National Geographic, glyphosate internally blocks the proteins that are essential to weed growth.

National Geographic says Roundup is used in over 160 countries, with 1.4 billion pounds of the chemicals used annually. Roundup is not just used to treat dandelions and poison ivy, though — many farmers treat crops with Roundup to avoid weeds cropping up in the first place. According to the USDA, nearly all of the corn, cotton, and soy grown in the U.S. has been treated with glyphosate.

Is Roundup safe for vegetable gardens?
The active ingredient in Roundup, glyphosate, kills weeds and any plant it comes in contact with. According to SF Gate, "Although [Roundup] can quickly kill sprayed plants, it's generally safe to use around vegetable gardens when applied in accordance with the instructions. Glyphosate doesn't move very far in the soil and tends to break down in days to weeks."

In order to safely use Roundup around your vegetable garden, you can use Roundup to prepare the bed of the garden, taking care to follow the instructions from the label. SF Gate recommends waiting three full days after the last application of Roundup before planting vegetables in your garden. Check your Roundup bottle's label, as different products have different wait and application times.

How long after using Roundup can I plant vegetables?
According to SF Gate, gardeners should wait three full days after the final application of Roundup Weed & Grass Killer Super Concentrate before planting vegetables. This wait time is different for each individual Roundup and herbicide product, so make sure to consult the label for instructions.

Are Roundup containers recyclable?
The EPA maintains that pesticide containers should not be reused, but they can be recycled. According to Earth 411, pesticide containers such as Roundup are recyclable, if taken care of properly. These containers cannot be tossed in your curbside recycling bin, as they need to undergo specific treatment in order to be recycled into repurposed plastic.

This treatment requires Roundup and other pesticide containers to be triple-rinsed, then processed or shipped to facilities specifically equipped to properly recycle the type of plastic the container is made of. To recycle your Roundup or other pesticide container, check your state and municipal regulations on recycling pesticide containers.

Can Roundup kill a tree?
According to Hunker, Roundup can be used to kill "unwanted or damaged trees." Of course, before using any herbicide to kill of a tree, you should check with your local Agriculture Extension Offices, which may have regulations in place about using herbicides to eradicate trees, especially healthy ones.

According to the Hunker tutorial, to kill a tree with Roundup, you'd mix a high concentration of Roundup with water and using a spray tank, pour the mixture into cut wedges of the tree trunk. If the tree trunk is completely saturated, then the Roundup will cause the tree to die.

Are Roundup fumes harmful?
Despite being declared a "probable carcinogen" in 2015 by an international agency, glyphosate-based products like Roundup are still on the shelves at stores. Aside from being linked to cancer, glyphosate has also been linked to antibiotic resistance and hormone disruption that may even cause infertility.

Many public court cases have claimed that glyphosate caused cancer in Roundup-using patrons. As many as 42,000 plaintiffs claimed glyphosate-based herbicides caused their cancer as of Oct. 30, 2019. To date, the highest amount any plaintiff has been awarded in a case against Roundup is $2 billion dollars (which was later reduced to $87 million via

appeal by Bayer). The court ruled Bayer had failed to publicize to consumers that the ingredients in Roundup were possible carcinogens.

As a direct result of the many public court cases, Costco dropped Roundup and other glyphosate-based herbicides in January 2019. Because of the harmful effects of glyphosate, the EPA has been planning to restrict weed-resistance herbicides. Even certain school districts in the U.S. have introduced plans to use alternative products and even ban the ingredient from being used on school grounds.

Many lawsuits in recent years have come from consumers who claim that exposure to Roundup caused their cancers. Roundup has been linked to increased risk of bladder cancer, non-Hodgkin Lymphoma, prostate, and kidney cancer, and has been found to induce breast cancer cell growth. Glyphosate exposure has also been tied to cancer in dogs.

Although Roundup may be OK around vegetables, you may want to stay away from it altogether.

Public interest groups sue EPA for re-approving controversial herbicide dicamba
KTTN
https://www.kttn.com/public-interest-groups-sue-epa-for-re-approving-controversial-herbicide-dicamba/

Public-interest groups are suing the Environmental Protection Agency over the agency's re-approval of products containing dicamba, a herbicide controversial for its tendency to drift into neighboring fields and damage farmers' crops and homeowners' gardens.

Last fall, the EPA green-lighted dicamba use for five years, the third time the agency registered dicamba products.

George Kimbrell, legal director at the Center for Food Safety, said last summer a federal court found the Trump administration's 2018 approval of dicamba unlawful, noting the EPA had failed to consider the adverse impacts to farmers and the environment before granting approval. "And yet five months later, right before the election, they went back and re-approved this same product," Kimbrell observed. "So we're back in court fighting to prevent those harms from again occurring."

The latest lawsuit seeks to stop the nationwide use of dicamba during this year's growing season.

The EPA decides when and how much dicamba farmers can spray on their crops, but Kimbrell noted some states are enacting tougher restrictions. Arkansas has banned farmers from spraying the herbicide after May 25, and Illinois and Indiana have passed similar cut-off dates.

Over the past few years, dicamba sprayed atop soybean and cotton crops has caused drift damage to millions of acres. In Arkansas, thousands of complaints over the herbicide have been lodged and farmers have sued the makers of dicamba products for damages.

Kimbrell added dicamba use has created a harmful cycle for growers. "It's not all remedied by money," Kimbrell contended. "You have farmers that are losing the right to plant the crop of their choice, and having to buy these genetically engineered seeds defensively and plant them because they know they're going to be hit by drift and their crops are going to be damaged." He believes dicamba products are a linchpin of an unsustainable industrial food system and pointed to recent studies showing human exposure to dicamba can increase the risk of developing numerous cancers, including acute and chronic lymphocytic leukemia.

"They're a monocultural crop system that is harming the environment and harming American farmers, on behalf of agrochemical companies to sell more pesticides that then go onto our food and into the environment," Kimbrell asserted.

The EPA said its five-year registration of dicamba products for use on genetically modified soybean and cotton crops meets the regulatory standard of causing no unreasonable adverse effects to either human health or the environment.

Fluoropolymers Are Vital for Life in the 21st Century

Jay West, Bloomberg Law OpEd

https://news.bloomberglaw.com/environment-and-energy/fluoropolymers-are-vital-for-life-in-the-21st-century?usertype=External&bwid=00000176-fce1-d345-a777-feeb06da0001&qid=7044922&cti=FGOV&uc=1320000080&et=NEWSLETTER&emc=neve_nl%3A23&source=newsletter&item=headline&region=digest&access-ticket=eyJjdHh0IjoiTkVWRSIsImlkIjoiMDAwMDAxNzYtZmNlMS1kMzQ1LWE3NzctZmVlYjA2ZGEwMDAxIiwic2lnIjoiZDhuMkh3QW92dXB4d0o3QUxxakdEWnFDTktJPSIsInRpbWUiOiIxNjExMTQ0MDc1IiwidXVpZCI6IlpabElVSE5SZWVLajloeHZMMU1maUE9PUVPL0N1MzhQdXZkVGswV2lhWFc3Snc9PSIsInYiOiIxIn0%3D

Jay West, senior director at the American Chemistry Council and executive director of the Performance Fluoropolymer Partnership, asserts that a subset of PFAS chemicals, used in many everyday consumer products, has a well-established safety profile and do not present a significant concern for human health or the environment and should be differentiated from other PFAS.

Several technologies rely on a versatile group of materials called fluoropolymers, including the cell phones and tablets you use to communicate every day, the fuel cell and solar cell technologies used to implement global sustainability efforts, and even the Covid-19 testing equipment used right now around the world to save lives.

The members of the Performance Fluoropolymer Partnership are dedicated to the responsible production, use, and management of these chemistries. We proudly work to produce high-quality products that provide significant value and unique benefits to our customers, and at the same time are protective of human health and the environment.

We read with great interest a Bloomberg Law article examining a study that that calls for broad restriction on the use of fluoropolymers. We want to take this opportunity to set the record straight on the safety of these vital chemistries.

Importance of Fluoropolymers

Fluoropolymers are specialty materials that can simultaneously impart strength, durability, heat and chemical resistance, and high performance electrical insulation. This unique combination of properties extends the life span of components, improves fire safety, increases data transmission speeds, and enables the creation of the smaller, more powerful, more integrated electronic products the market demands. They are critical to life in the 21st century, enabling technologies such as semiconductors, renewable energy, conventional and battery-powered vehicles, medical devices, and energy exploration and production.

To be sure, fluoropolymers are part of the broad family of fluorinated chemistries known as per- and polyfluoroalkyl substances, or PFAS. There is much confusion in the news and the public regarding PFAS, as they are often lumped together and not differentiated. Fluoropolymers have well-established safety profiles and do not present a significant concern for human health or the environment.

Low Concern

In fact, peer reviewed research demonstrates that they meet internationally recognized criteria to be considered "Polymers of Low Concern" (PLC) for potential risk to human health and the environment. The PLC criteria serve as a valuable tool for understanding the physical and chemical properties of polymers and are intended to facilitate polymer hazard assessments.

Key findings from this peer-reviewed research on fluoropolymers include:

Fluoropolymers have thermal, chemical, photochemical, hydrolytic, oxidative, and biological stability;

Fluoropolymers are practically insoluble in water and not subject to long-range transport;

Due to their high molecular weight, fluoropolymers cannot cross the cell membrane;

Fluoropolymers are not bioavailable or bioaccumulative; and

No adverse reproductive, developmental, or other toxic effects have been documented in patients with permanently implantable medical devices containing PTFE, a commercially important fluoropolymer.

These findings are important to this conversation and differentiate fluoropolymers from other PFAS chemistries.

While we agree that life cycle analyses (LCA) of substances and their alternatives are important as suggested in the above-mentioned study, PLC criteria are a tool intended to assess the potential hazards of polymers themselves, distinct from any LCA. This is important to ensure policymakers and the public have confidence in the products that are being produced with these chemistries.

Indeed, the PLC concept is a broadly applicable tool to evaluate all polymers (not just fluoropolymers) and is widely accepted today by many regulatory authorities.

Science-Based Decisions

We support strong, science-based chemical regulations that are protective of human health and the environment, and it's important for regulators and the scientific community to understand the facts when addressing fluoropolymers. Unfortunately, though, there has been growing pressure to regulate all PFAS as a single class.

We do not support attempts to regulate all PFAS as a class, as different types of PFAS have different properties and different health and environmental profiles. It is neither scientifically accurate nor appropriate to regulate all PFAS as if they were a single substance.

Furthermore, in Europe and the U.S., many fluoropolymers have been evaluated by regulators such as the European Food Safety Agency and the Food and Drug Administration, as well as other organizations that evaluate products for public safety, such as the U.S. Pharmacopeia and NSF International.

Many fluoropolymers meet the requirements for direct food and potable water contact, and pharmaceutical and medical applications. Permission for those uses is only granted if there is sufficient scientific data to demonstrate that the substance is safe for its intended use. We support these rigorous review processes.

Given their important contribution to our daily lives, it is vital that questions about the safety and environmental profile of fluoropolymers are properly addressed.

This column does not necessarily reflect the opinion of The Bureau of National Affairs, Inc. or its owners.

Sustainable Chemistry Research and Development Act Passed as Part of National Defense Authorization Act
Bergeson & Campbell TSCA Blog
https://www.lawbc.com/regulatory-developments/entry/sustainable-chemistry-research-and-development-act-passed-as-part-of-nation

On December 28, 2020, the House overrode President Trump's veto and passed the National Defense Authorization Act for Fiscal Year 2021 (H.R. 6395) by a vote of 322 to 87, and the Senate passed the bill on January 1, 2021, by a vote of 81 to 13. Subtitle E of Title II of the Act (Subtitle E) includes the text of the bipartisan Sustainable Chemistry Research and Development Act of 2019. Subtitle E will establish an interagency working group led by the Office of Science and Technology Policy (OSTP) to coordinate federal programs and activities in support of sustainable chemistry (also called green chemistry).

Overview

No later than 180 days after enactment, an interagency working group will be convened to oversee the coordination of federal programs and activities in support of sustainable chemistry. To be terminated ten years after the date of the enactment, the working group would be co-chaired by the Director of OSTP and a representative from the U.S. Environmental Protection Agency (EPA), the National Institute of Standards and Technology (NIST), the National Science Foundation (NSF), or the U.S. Department of Energy (DOE), as selected by the Director of OSTP.

Implementation

Subtitle E also includes a roadmap for the working group to follow no later than two years after the date of enactment. According to Subtitle E, the working group will have to consult with relevant stakeholders, including industry and academia representatives, national labs, the federal government, and international entities, to develop and update, as necessary, a consensus definition of "sustainable chemistry" that will guide the activities under Subtitle E. In addition, the working group will develop a working framework of attributes characterizing, and metrics for assessing, sustainable chemistry. In developing the framework, the working group shall:

Seek advice and input from stakeholders (including business and industry representatives; the scientific community; the defense community; the defense community; state, tribal, and local governments; non-governmental organizations (NGO); and other appropriate organizations);

Consider existing definitions of, or frameworks characterizing and metrics for assessing, sustainable chemistry already in use at federal agencies;

Consider existing definitions of, or frameworks characterizing and metrics for assessing, sustainable chemistry already in use by international organizations of which the United States is a member; and

Consider any other appropriate existing definitions of, or frameworks characterizing and metrics for assessing, sustainable chemistry.

As part of Subtitle E's implementation roadmap, the working group will assess the state of sustainable chemistry in the United States as a key benchmark from which progress under described activities can be measured, including assessing key sectors of the U.S. economy, key technology platforms, commercial priorities, and barriers to innovation. Subtitle E would require the working group to coordinate and support federal research, development, demonstration, technology transfer, commercialization, education, and training efforts in sustainable chemistry, including budget coordination and support for public-private partnerships, as appropriate. In addition to these measures, the working group will be responsible for identifying any federal regulatory barriers to, and opportunities for, federal agencies facilitating the development of incentives for development, consideration, and use of sustainable chemistry processes and products. The working group will also identify major scientific challenges, roadblocks, and hurdles to transformational progress in improving the sustainability of the chemical sciences.

Report to Congress

No later than two years after the date of enactment, the working group will be responsible for the submission of a report to certain Senate and House Committees. The report will include summaries of federally funded sustainable chemistry activities and financial resources, as well as an assessment of the current state of sustainable chemistry in the United States and recommendations for future program activities. In addition to submitting the report to Congress, the working group will also be responsible for submitting it to the Comptroller General of the United States for consideration in future Congressional inquiries.

Limitations

Funding under Subtitle E will be available only for pre-competitive activities and will not be used to promote the sale of or to disparage a specific product, process, or technology. Agencies participating in the working group may, however, facilitate and support, through financial, technical, or other means, the creation of partnerships between higher education institutions, NGOs, consortia, or companies across the value chain in the chemical industry.

Other limitations include prohibiting the use of funds to: (1) support or expand a regulatory chemical management program at an implementing agency under a state law; (2) construct or renovate a building or structure; or (3) promote the sale of or disparage a specific product, process, or technology.

Commentary

Subtitle E of the Act is a long-overdue initiative to coordinate efforts between and among federal departments and agencies (collectively, Agencies) to fund and promote sustainable chemistry. It will take some effort for the new interagency group to create a workable definition of sustainable chemistry and associated metrics. Perhaps the consensus standard (ANSI/NSF 355) developed in 2010 can provide a starting point for such metrics.

One of the major challenges is how to weight different endpoints that are identified. For example, should a climate change endpoint be given equal weight to aquatic toxicity? Alternatively, will endpoints not be weighted, effectively making all identified endpoints equally important? It will also take effort for Agencies to identify current funding and to ensure that there is not duplicative funding -- although given the dearth of federal research funding going to green or sustainable chemistry, this may not be a significant issue.

Subtitle E of the Act puts EPA's Green Chemistry Challenge (formerly the Presidential Green Chemistry Challenge) on more solid footing as the Act directs EPA to "incentivize or recognize actions that advance sustainable chemistry products, processes, or initiatives, including through the establishment of a nationally recognized awards program." The Act also puts a greater emphasis on training and education, another area of effort that has languished within federal Agencies.

Perhaps most intriguing to B&C clients is the requirement that Agencies "identify any Federal regulatory barriers to, and opportunities for, Federal agencies facilitating the development of incentives for development, consideration and use of sustainable chemistry processes and products." As we have written on many occasions, it is B&C's view that EPA's implementation of the Toxic Substances Control Act (TSCA) creates a bias against new chemicals, putting new, greener chemistry technologies at a disadvantage in commercial markets. In our view, EPA has the necessary authority under both TSCA and the Pollution Prevention Act to consider environmental and health benefits of new chemicals when making a decision about the necessity of issuing controlling regulations for new chemicals. Subtitle E of the Act now requires that EPA consider whether its current practices are a barrier (or incentive) to new, sustainable chemistry technologies.

We are optimistic that Subtitle E of the Act will increase focus on federal research and development and raise awareness of the benefits of more sustainable chemistry, and are hopeful that it will also put novel sustainable chemistry on (at least) an equal regulatory playing field when compared to incumbent, less sustainable options.

EPA Issues Final Compliance Guide Addressing Surface Coatings under PFAS SNUR
Lynn L. Bergeson & Carla N. Hutton, B&C TSCA Blog
http://www.tscablog.com/entry/epa-issues-final-compliance-guide-addressing-surface-coatings-under-pfas-sn

On January 19, 2021, the U.S. Environmental Protection Agency (EPA) announced the availability of a final compliance guide that outlines which imported articles are covered by EPA's July 2020 final significant new use rule (SNUR) that prohibits companies from manufacturing, importing, processing, or using certain long-chain per- and polyfluoroalkyl substances (PFAS) without prior EPA review and approval. The final guide is "the official compliance guide for imported articles that may contain long-chain perfluoroalkyl carboxylate chemical substances as part of a surface coating." Specifically, the guide provides additional clarity on what is meant by a "surface coating," identifies which entities are regulated, describes the activities that are required or prohibited, and summarizes the notification requirements of the final SNUR. EPA states that there "are no significant changes between the final guidance document and the draft document, which was released for public comment in December." More information on the draft compliance guide is available in our December 14, 2020, memorandum, "EPA Publishes Draft Compliance Guide Addressing Surface Coatings under PFAS SNUR." Comments on the draft guide were due January 15, 2021.

EPA Confirms Widespread PFAS Contamination of Pesticides, Announces "Investigation," Stops Short of Action to Protect Public
Beyond Pesticides Blog
https://beyondpesticides.org/dailynewsblog/2021/01/epa-confirms-widespread-pfas-contamination-of-pesticides-announces-investigation-stops-short-of-action-to-protect-public/

(Beyond Pesticides, January 20, 2021) The U.S. Environmental Protection Agency has confirmed that PFAS (per and polyfluorinated alykyl substances) 'forever chemicals' are contaminating containers that store pesticide products, and subsequently the products themselves. The confirmation comes after preliminary testing from the watchdog group Public Employees for Environmental Responsibility (PEER) found PFAS in the widely used mosquito pesticide Anvil 10+10. In response EPA announced further investigation and said, "EPA understands the need to provide guidance to states, tribes, and other users as they prepare to purchase mosquito control products for 2021 and will provide more

information as it continues its investigation. EPA will update the following webpage with information as it becomes available: https://www.epa.gov/pesticides/pfas-packaging."

"EPA's discovery has opened a Pandora's Box of health risks," stated PEER Science Policy Director Kyla Bennett, PhD, whose testing of the insecticide first raised the alarms, according to the EPA statement. "Shipping containers may be a significant source of PFAS exposure through the entire U.S. agricultural sector."

According to EPA, high-density polyethylene (HDPE) containers used to store and transport pesticides are commonly treated with fluoride in order to create a "chemical barrier" that will "prevent changes in chemical composition." The fluorinated container is supposed to be more stable, and "less permeable, reactive, and dissolvable."

Testing so far has been limited to one pesticide product supplier (likely the company Clarke, maker of Anvil 10+10), but resulted in detection of 9 different PFAS chemicals at levels the agency has not yet released. Earlier testing found PFAS chemicals well above safety limits established by states, as well as EPA's health advisory.

Although the agency cautions that recent testing is not a direct measure of levels likely to be found in the environment, advocates note that repeated spraying of contaminated products are likely to result in significant non-point source pollution. Because of its nature as a 'forever chemical,' PFAS does not break down in the environment, and any pollution becomes cumulative.

There are also indications that fluorinated HDPE containers may have other storage uses, such as food packaging. EPA announced that it is subpoenaing the company that fluorinates HDPE containers under the Toxic Substances Control Act, but has done little else from a regulatory standpoint. States with stocks of Anvil 10+10 in HDPE barrels are being to encouraged to "red tag that inventory and hold for now." It is unclear what, if any further actions will be taken by the agency.

"This development only underlines how inadequate and haphazard EPA's approach to this emerging contaminant has been," added Dr. Bennett of PEER, pointing to the more substantive regulatory approach being pursued in Europe. "All unnecessary uses of PFAS need to be banned."

Contamination of a toxic product with other harmful chemicals is glaringly problematic for public health and the environment. Mixtures of different chemicals can result in synergy that may increase or decrease the toxicity of a pesticide, or result in other changes to its characteristic, for example making it easier to penetrate through skin or plant material.

Past contamination scandals have plagued the pesticide manufacturing process. For example, DuPont was subject to a series of lawsuits two decades ago after its Benlate fungicide was contaminated with the toxic herbicide atrazine following quality control problems at its production plant. The Vietnam era chemical Agent Orange was contaminated with the dioxin TCDD (2,3,7,8 tetrachlorodibenzodioxin), produced as a by-product of its manufacture.

Contamination of widely used storage and transportation containers with chemicals that have been linked to cancer, liver damage, birth and developmental problems, reduced fertility, and asthma is a scandal without compare. It is unclear how long such a practice has been commonplace without any regulatory oversight. What is certain is that the next administration will have a massive challenge ahead in getting an adequate handle on the depth and scope of PFAS contamination. President Biden's pick for EPA Administrator, Michael Regan, has taken action against PFAS in his home state of North Carolina. Advocates are urging that this past experience will inform a stricter regulatory approach against PFAS and other toxic chemicals and pesticides under EPA's purview.

Join Beyond Pesticides in urging the incoming administration to restore science to its rightful place. In light of serious weakening of the agency over the last four years, and years of corporate influence before that, help call on the agency to halt new pesticide registrations. This will provide time for EPA to review the science supporting existing registrations and confirm to the public it is not manipulated or corrupt. See Beyond Pesticides' Action of the Week archive for more ways to engage with the incoming administration.

All unattributed positions and opinions in this piece are those of Beyond Pesticides.

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