Message

From: Scarano, Louis [Scarano.Louis@epa.gov]
Sent: 12/8/2020 6:37:41 PM
To: Le, Madison [Le.Madison@epa.gov]; OPPT NCD Managers [OPPT_NCD_Managers@epa.gov]
Subject: RE: OCSPP News for December 4, 2020
Attachments: PCRM_Nov_2020_NAM comments_SNUR.pdf

Madison:

This refers to the PCRM letter I gave you with a quick synopsis in an email I sent you on 12/4 at 1:38 pm.....here is what I put in the email and the comment letter is attached:

The letter is short (attached – two pages)....their three important points:

1. "In these five proposed SNURs, EPA does not specify required tests. Instead, it identifies "potentially useful information," .... we (PCRM) are concerned that submitters may still interpret these recommendations to refer to vertebrate animal tests. We urge EPA to clearly state its preference for NAMs by identifying specific alternatives and by directing potential SNUN submitters to its statutorily mandated List of Alternative Test Methods and Strategies".
2. PCRM points to vertebrate testing performed on cases mentioned in the SNUR batch....they then state: "While TSCA does not require EPA to review whether the submitters of these PMNs attempted to develop the information by means of alternative test methods or strategies before conducting new vertebrate animal testing, it does authorize EPA to do so....Reviewing compliance with TSCA section 4(h)(3) is an opportunity to communicate TSCA's voluntary testing provisions and EPA's preference for alternatives to PMN submitters....We request that EPA review compliance with TSCA section 4(h)(3) whenever the results of vertebrate animal testing are included with PMNs."
3. They then point to their own website for NAMs.... https://www.pcrm.org/ethical-science/animal-testing-and-alternatives/new-approach-methodologies

Regards,

Louis (Gino) Scarano, PhD
US EPA
Senior Advisor/Acting Branch Chief for Risk Assessment Branch 1 (RAB1)
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From: Le, Madison <Le.Madison@epa.gov>
Sent: Tuesday, December 08, 2020 1:20 PM
To: OPPT NCD Managers <OPPT_NCD_Managers@epa.gov>
Subject: FW: OCSPP News for December 4, 2020

From: Henry, Tala <Henry.Tala@epa.gov>
Sent: Tuesday, December 8, 2020 11:43 AM

To: Le, Madison <Le.Madison@epa.gov>; Camacho, Iris <Camacho.Iris@epa.gov>; Scarano, Louis <Scarano.Louis@epa.gov>
Subject: FW: OCSPP News for December 4, 2020

I would like to discuss the 2nd bullet under the TSCA heading below [PCRM comments on proposed SNURs] at the next (not today) NC Meeting.
Thx

Tala R. Henry, Ph.D.
Deputy Director
Office of Pollution Prevention & Toxics

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From: Rosen, Bailey <Rosen.Bailey@epa.gov>
Sent: Friday, December 4, 2020 4:46 PM
To: Bolen, Derrick <bolen.derrick@epa.gov>; Collazo Reyes, Yvette <CollazoReyes.Yvette@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; Dennis, Allison <Dennis.Allison@epa.gov>; Drinkard, Andrea <Drinkard.Andrea@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Giddings, Daniel <giddings.daniel@epa.gov>; Goodis, Michael <Goodis.Michael@epa.gov>; Hanley, Mary <Hanley.Mary@epa.gov>; Hartman, Mark <Hartman.Mark@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Hughes, Hayley <hughes.hayley@epa.gov>; Kaiser, Sven-Erik <Kaiser.Sven-Erik@epa.gov>; Keigwin, Richard <Keigwin.Richard@epa.gov>; Kochis, Daniel <Kochis.daniel@epa.gov>; Labbe, Ken <Labbe.Ken@epa.gov>; Layne, Arnold <Layne.Arnold@epa.gov>; Lieberman, Paige <Lieberman.Paige@epa.gov>; Messina, Edward <Messina.Edward@epa.gov>; Mills, Madeline <Mills.Madeline@epa.gov>; Nguyen, Khanh <Nguyen.Khanh@epa.gov>; OPS CSID CB <OPS_CSID_CB@epa.gov>; Pierce, Alison <Pierce.Alison@epa.gov>; Richmond, Jonah <Richmond.Jonah@epa.gov>; Siciliano, CarolAnn <Siciliano.CarolAnn@epa.gov>; Sullivan, Melissa <sullivan.melissa@epa.gov>; Tyler, Tom <Tyler.Tom@epa.gov>; Vendinello, Lynn <Vendinello.Lynn@epa.gov>; Vernon, Jennifer <Vernon.Jennifer@epa.gov>
Subject: OCSPP News for December 4, 2020

OCSPP News Round-Up

Special News on Chlorpyrifos

- E&E News 12/4; EPA may set new limits on farm chemical tied to brain damage
- Progressive Farmer 12/4; EPA Proposes Chlorpyrifos Safety Steps
- Courthouse News Service 12/4; EPA Proposes New Rules for Farmers Using Dangerous Insecticide
- EarthJustice 12/4; EPA Fumbles New Restrictions on Pesticide Linked to Brain Damage

TSCA

- Bloomberg Law 12/4; PFAS Power Lawyers Steer Multibillion-Dollar Litigation Boom
- Inside TSCA 12/3; Medical Group Urges EPA To Review Use Of NAM Tests In PMN Requests
- Inside TSCA 12/3; Trump critics seek to punt IST mandate to Biden
- EHS Daily Advisor 12/2; UPDATE: The Deadline for the Chemical Data Reporting Requirement Has Been Extended
- Spectrum News 12/3; Cuomo Approves Ban on PFAS in Food Packaging

Pesticides

- NPR's WHYY 12/3; Philly parks are going organic with ban on synthetic weed-killers
- Modern Farmer 12/1; EPA Draft Report Finds Glyphosate Harms Many Endangered Species
- EHS Daily Advisor 12/2; Recent Enforcement Demonstrates EPA Prioritization of FIFRA Compliance

Blog/OpEd/Other

- All Things Chemical Podcast 12/3; TSCA and Environmental Justice — A Conversation with Former OPPT Director Jeffery T. Morris, Ph.D.
- JD Supra (Arent Fox) 12/2; EPA Updates Draft Guidance on Plant Biostimulant Products
- JD Supra (Wiley Rein LLP) 12/2; EPA Releases Draft Final Plant Regulator Guidance
- Environmental Working Group 12/3; In Final Defense Bill, Too Little Progress on 'Forever Chemicals'
- The National Law Review (Bergeson & Campbell) 12/4; EPA Extends CDR Submission Deadline

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EPA may set new limits on farm chemical tied to brain damage
Marc Heller, E&E News
https://www.eenews.net/eenewspm/2020/12/04/stories/1063719971?utm_campaign=edition&utm_medium=email&utm_source=eenews%3Aeenewspm

EPA said today it may recommend new limits on the use of the pesticide chlorpyrifos but maintained that its risks to human health aren't clear enough to support stricter measures.

In a proposed interim decision that would continue the farm chemical's use, EPA said that some additional label restrictions would reduce the risk of exposure to infants and children.

The environmental agency continues to stand behind chlorpyrifos as safe for use, despite research linking it to brain damage in children and arguments from the agency's own moves during the Obama administration to ban it. The Trump administration scrapped that effort in one of former Administrator Scott Pruitt's first actions.

EPA considered "emerging new information" from laboratory animal and other studies and decided not to change the safety factors for the chemical, according to today's interim decision.

Today's interim decision echoes a human health risk assessment EPA released in September, adding information about proposed limits on uses (Greenwire, Sept. 23). Further revisions may follow, the agency said, based on recommendations from EPA's Federal Insecticide, Fungicide and Rodenticide Act Scientific Advisory Panel due this month.

"Notwithstanding, EPA recognizes that the science is evolving on this topic, and that there may be new information available prior to the completion of registration review that may impact the agency's conclusions about these effects," EPA said.

Among possible new limits, EPA said it would add label restrictions to reduce risk to water supplies and might restrict chlorpyrifos use to 11 "high benefit" or "critical uses" in certain regions. Additional limits could be placed on its use in certain settings such as trash storage bins. And aerial spraying might be stopped to protect pesticide handlers, the agency said.

Chlorpyrifos remains a major insecticide for farmers, although it's been banned after this year in the nation's No. 1 agricultural state, California.

Between 2014 and 2018, about 5.1 million pounds was used in the United States on farms and other places, such as golf courses, EPA said. About half of the total was used on corn, alfalfa and soybeans, according to EPA.

The agency said the economic benefit of chlorpyrifos use in crop production ranges between $19 million and $130 million per year. It's especially valuable for sugar beet production in Minnesota and North Dakota, EPA said.

With a 60-day comment period, the review of chlorpyrifos and any new restrictions will fall to the Biden administration, which is likely to take a less favorable view on the pesticide. Congressional Democrats have called for a ban, which would pick up where the Obama administration left off.

The environmental group Earthjustice, supporting a ban on chlorpyrifos, criticized EPA's latest move.

"EPA is refusing to protect children from damage to their brains and learning disabilities," said Earthjustice Managing Attorney Patti Goldman in a statement. "Even with the new protections, the agency is still failing children, who will continue to be exposed to chlorpyrifos at levels that cause lifelong damage."

EPA Proposes Chlorpyrifos Safety Steps
Todd Neeley, Progressive Farmer
https://www.dtnpf.com/agriculture/web/ag/crops/article/2020/12/04/epa-proposes-safety-measures

OMAHA (DTN) -- EPA announced a proposal on Friday to improve the safety of using the insecticide chlorpyrifos. The proposal follows a draft risk assessment the agency released in September.

The EPA is proposing labeling amendments to limit applications associated with drinking water risks as well as requiring additional personal protection equipment and application restrictions to address handler risks.

The agency is also proposing spray drift mitigation in addition to use limitations and application restrictions to reduce exposure for off-target organisms.

Once the proposal is published in the Federal Register, the EPA will accept public comments for 60 days on the draft risk assessment and the additional proposal, according to a news release from the agency.

That assessment identified dietary risks in adults and children, as well as risks to professional handlers of the chemical. The EPA's draft assessment also identified potential adverse effects to mammals, birds, fish, and terrestrial and aquatic invertebrates.

EPA also is considering input from the September 2020 scientific advisory panel, which is set to release its report sometime this month.

Corteva announced in February 2020 that it was phasing out production of chlorpyrifos. The company cited falling demand for the product in the United States as the primary reason for the decision, but the chemical also has faced criticism and litigation over its health risks for decades.

EPA said in its risk assessment that with "limited remaining residential uses of chlorpyrifos, EPA found no risks of concern, including to children's health, when products are used according to the label instructions."

Chlorpyrifos is the main ingredient in what was Dow AgroSciences' -- now Corteva Agriscience's -- Lorsban insecticide. Corteva is a spinoff agricultural company from parent company DowDuPont, formed when Dow and DuPont merged in 2017.

First registered in 1965, chlorpyrifos is an organophosphate insecticide used in a broad range of crops, including corn, alfalfa, sugar beets, cotton, wheat, soybeans and peanuts. Chlorpyrifos targets a range of insects, such as aphids, armyworms, cutworms, bean leaf beetle, rootworm, spider mites, lygus, stink bugs and midges.

It has been available under several brand names, including Lorsban and Cobalt. Between 2012 and 2014, then-registrant Dow AgroSciences estimated to EPA that an average of 640,000 pounds were applied to an average of almost 800,000 corn acres per year.

In that same time period, the company reported that chlorpyrifos was the leading ingredient used to control wheat midge in wheat and that 600,000 pounds were used on roughly 1.6 million wheat acres per year, as well as an average of 105,000 pounds on 350,000 cotton acres per year.

EPA vowed to continue its re-registration of chlorpyrifos, ensuring that generic formulations of the chemical will remain legal to use in the years to come.

The agency recently has defended the chemical against legal challenges based on concerns about the neurodevelopmental effects it can have on people, particularly infants. In recent years, some states and countries have initiated bans on chlorpyrifos, such as Hawaii, California, New York, the UK and the EU.

In 2015, EPA proposed revoking all food residue tolerances for chlorpyrifos in response to a petition from the Natural Resources Defense Council and Pesticide Action Network North America, which would effectively end use of the chemical. But that decision was reversed in 2017 by Scott Pruitt, former administrator of the EPA.

Facing litigation and court orders over the move, EPA finalized its decision in July 2019 not to ban the insecticide. The decision was made as part of a court order issued on April 19, 2019, by the U.S. Court of Appeals for the Ninth Circuit in San Francisco.

EPA Proposes New Rules for Farmers Using Dangerous Insecticide
Alexandra Jones, Courthouse News Service
https://www.courthousenews.com/epa-proposes-new-rules-for-farmers-using-dangerous-insecticide/

WASHINGTON (CN) — The Environmental Protection Agency proposed new restrictions Friday on a dangerous insecticide that it opted not to ban outright last year.

Having long been considered a threat to childhood brain development, chlorpyrifos has been banned for indoor and residential use since 2001 but continues to be used on crops.

The EPA waited years to act on a petition by environmentalists seeking a full ban, only announcing that it would keep chlorpyrifos on the market after the Ninth Circuit set a deadline for it to make such a determination by July 2019.

Taking the next step in the regulatory review process on Friday, the agency said those who spray the chemical should be made to use additional personal protective equipment. Other proposals laid out in Friday's announcement include label amendments to address concerns about chlorpyrifos contaminating drinking water and efforts to mitigate "spray drift."

For the group Earthjustice, however, such actions fall short of what is needed. A complete ban of the pesticide is the only way to truly protect children and workers from its harms, the group said.

"EPA is refusing to protect children from damage to their brains and learning disabilitiessaid Earthjustice managing attorney Patti Goldman said in a statement. "Even with the new protections, the agency is still failing children, who will continue to be exposed to chlorpyrifos at levels that cause lifelong damage." In the Ninth Circuit case, Goldman made the case against the EPA's delays at oral arguments in March 2019.

The Ninth Circuit is expected to rule on the ban in the coming months. In the meantime, the EPA said in its Friday release that it will also consider recommendations from the Scientific Advisory Panel's September meeting after the group releases its report later this month.

"Depending on the SAP's conclusions, EPA may further revise the human health risk assessment," the EPA's release said. "After a thorough review of the best available science and carefully considering scientific peer review and public comments, EPA will then determine next steps in the registration review process for chlorpyrifos."

Several studies show chlorpyrifos cause cognitive problems in humans, including memory loss and trouble focusing. The problems are particularly pronounced for children, as exposure to the chemical can lead to long-term, irreversible IQ reduction, attention deficit disorder and autism. The adverse effects to human health prompted the EPA to ban the pesticide for household use in 2001.

The American Farm Bureau Federation has said the pesticide is a crucial component for farmers in protecting their crops and maximizing the efficiency of their operations. Still, some states have begun banning the chemical, with Hawaii leading the way in 2018 and New York and California following in 2019.

EPA Fumbles New Restrictions on Pesticide Linked to Brain Damage
Erin Fitzgerald, EarthJustice
https://earthjustice.org/news/press/2020/epa-fumbles-new-restrictions-on-pesticide-linked-to-brain-damage

WASHINGTON, D.C. — Today the Environmental Protection Agency (EPA) proposed new restrictions on chlorpyrifos, a widely used neurotoxic pesticide, as it released its revised human health risk assessment.
Chlorpyrifos, which belongs to a class of pesticides called organophosphates, is acutely toxic and associated with neurodevelopmental harms in children. Prenatal exposures to chlorpyrifos are linked to lower birth weight, reduced IQ, loss of working memory, attention disorders, and delayed motor development. It is also unsafe for workers even with the most protective equipment.

The following statement comes from Earthjustice Managing Attorney Patti Goldman, who leads the legal fight to ban chlorpyrifos:

"EPA is refusing to protect children from damage to their brains and learning disabilities. Even with the new protections, the agency is still failing children, who will continue to be exposed to chlorpyrifos at levels that cause lifelong damage."

EPA is proposing label amendments to address drinking water contamination and requiring additional personal protective equipment for workers. It is also calling for spray drift mitigation rules. However, only banning the pesticide can truly protect children and workers from a pesticide that is widely recognized as unsafe.

Last September, EPA said it rejected extensive scientific evidence that even low levels of the pesticide chlorpyrifos damage children's brains.

The 9th Circuit Court of Appeals is set to rule on a chlorpyrifos ban in the next weeks or months.

PFAS Power Lawyers Steer Multibillion-Dollar Litigation Boom
Ellen M. Gilmer, Bloomberg Law
https://news.bloomberglaw.com/environment-and-energy/pfas-power-lawyers-steer-multibillion-dollar-litigation-boom

- Lawsuits over 'forever chemicals' sprouting up nationwide
- Big Law, plaintiffs' firms, government, nonprofits involved

Legions of lawyers are working behind the scenes on multibillion-dollar litigation over a class of human-made chemicals known as PFAS—a legal snarl so vast it's drawn comparisons to the groundbreaking lawsuits against the tobacco industry.

Chemical companies, water utilities, and the U.S. government face a surge of legal challenges related to contamination from per- and polyfluoroalkyl substances. Nicknamed "forever chemicals" for their ability to build up and linger in the environment and human bodies long after exposure, PFAS are commonly used in cookware, rugs, and other household items.

Federal and state regulators have been slow to respond to scientific research shedding light on health hazards linked to some types of the ubiquitous chemicals. Most action in recent years has instead played out in the courts, as litigants seek to make someone pay for the damage they say PFAS has wrought. Legal analysts say the cases could ultimately cost companies billions of dollars.

Behind the scenes are insider lawyers from private firms, career government attorneys, and advocates from the environmental community who are filing PFAS-focused lawsuits, honing defenses, and hashing out settlements that will ripple across the legal landscape.

One PFAS lawyer's story was even given the Hollywood treatment, with actor Mark Ruffalo playing the determined defense-turned-plaintiffs' attorney Rob Bilott, who's led a legal fight against DuPont over contaminated water in the Ohio River Valley. The litigation is widely credited with launching the PFAS liability battles taking place today.

Others in the PFAS ranks haven't achieved the same celebrity status, but they're driving cases with long-term impacts, shaping both legal precedent and potential settlement values. Here are some to watch:

Michael A. London, Plaintiffs' Attorney
Douglas & London PC attorney Michael A. London is at the center of two of the highest-profile PFAS battles in the country. The New York-based lawyer serves as co-lead counsel for plaintiffs in an Ohio multidistrict litigation, or MDL, that stems from the same contamination Bilott began litigating years ago. London started working with Bilott as follow-up cases began proliferating against DuPont in 2012 and 2013.

London plays the same role, co-lead counsel, in a ballooning MDL in South Carolina that features nationwide claims about PFAS in firefighting foam.

"The general themes are the same," London said. "What the defendants knew, and when they knew it, really is a liability issue that cuts across all cases."

As one of the top plaintiffs' attorney in the South Carolina litigation, London is charged with "juggling everybody's interests"—water utilities, airports, states, individual plaintiffs, and others—to present a united front in streamlined MDL proceedings against manufacturers, suppliers, and distributors of firefighting foam. The goal: to make at least a little progress on plaintiffs' claims each day.

"What did you to today to advance that case? Oh, you didn't do anything? Well, you better go do something," he said, recounting the internal dialogue he says is critical to managing complex litigation. The plaintiffs are hoping to get some bellwether cases set for trial as soon as late 2021, he said.

London's previous work has centered on pharmaceuticals rather than environmental torts. His deep dive into PFAS contamination issues is starting to hit home; he bought a carbon filter for his house's water supply to quell his own exposure concerns.

Dana Nessel, State Attorney General
As plaintiffs' attorneys fan out across the country to take up compelling PFAS cases, other lawyers remain focused on what's going on closer to home. Michigan Attorney General Dana Nessel (D) has been one of the most active state-level lawyers pursuing claims against PFAS manufacturers and users.

"What we really pride ourselves on in Michigan, more than anything else, is our natural resources, our water," she told Bloomberg Law. "And yet, you have communities all over the state now who don't have clean, safe drinking water, and I found that to be an outrage."

Nessel, a lifelong Michigander, campaigned on PFAS contamination before taking office in January 2019, accusing her predecessors of being beholden to the chemical industry. Former Attorney General Bill Schuette (R) refused to sue chemical companies, despite bipartisan public pressure.

"It was one of the things really that drove me to run for office," she said.

Michigan regulators have since set aggressive drinking water rules for certain types of PFAS, and are investigating more than 100 sites across the state. Nessel, meanwhile, has filed a series of lawsuits against 3M Co., E.I. du Pont de Nemours & Co., the Chemours Co., and hired outside firms to spearhead the litigation.

Her office reached a $70 million settlement with clothing maker Wolverine World Wide Inc. earlier this year over PFAS contamination linked to a former manufacturing site. Nessel said she's taking aim at both manufacturers and users of PFAS because "there's not just one component where the blame lies."

"I subscribe to the belief that, 'You made the mess, you clean it up,'" she said. "It shouldn't be the taxpayers that have the burden of paying for remediation."

Christina Falk, Federal Lawyer
Justice Department lawyer Christina Falk is on the other side of the PFAS fight, helping the U.S. government fend off claims that it should be on the hook for contamination around military bases.

Falk is on the team of top defense lawyers for the South Carolina litigation that features hundreds of cases about aqueous film-forming foam, or AFFF, a specialized firefighting material that often contains types of PFAS.

As the assistant director of the Justice Department's environmental torts section, she is the sole federal lawyer on the defendants' coordination committee for the case, a powerful group otherwise dominated by corporate defense attorneys. She's responsible for making sure the U.S. government's interests don't get lost in the mix.

"This MDL is particularly unusual because a lot of times an MDL will involve one particular location with many parties in it," she said. "In this instance, the locations are literally across the United States, so the interests are very varied; the facts are different."

Falk has worked in the environmental torts section for 30 years, racking up experience in other high-profile matters, including litigation over contaminated water in Flint, Mich., and at the Camp Lejeune military base in North Carolina.

Close attention to PFAS from Congress, the Environmental Protection Agency, Defense Department, and other corners of government doesn't affect the way she and her colleagues approach the case, she said. "We're plowing along as we normally would," she said.

Jonathan Kalmuss-Katz, Environmental Lawyer
Earthjustice lawyer Jonathan Kalmuss-Katz is leading the charge in an often overlooked PFAS litigation front: disposal of the chemicals.

"Historically a lot of the attention has been, how do we get this out of our drinking water?" he said. "There has been relatively little attention paid to, how can we safely dispose of the PFAS that already surround us?"

Kalmuss-Katz and other advocates are working to change that. Earthjustice sued the Defense Department in February on behalf of community groups concerned about the impacts of PFAS incineration in their regions. The groups say the agency failed to consider the environmental and public health impacts of the disposal method.

"There are communities surrounding these incinerators that are suffering the consequences of the Defense Department's incineration," he said, adding that Black and Latino neighborhoods are disproportionately affected.

Kalmuss-Katz has a decade of experience in environmental law and has been with Earthjustice for two years, focusing on toxic exposure and health issues. While environmental nonprofits have been busy lobbying for PFAS laws and regulations, the incineration case is one of their few forays into the litigation side of the issue.

That's because these groups generally focus on using environmental statutes as legal tools to push policymakers to craft more protective laws and regulations—rather than pursuing personal injury claims and other torts. Congress has been slow to act on PFAS, leaving few "hooks" for federal litigation, Kalmuss-Katz said.

The Earthjustice case hangs on one of those few hooks, alleging the Pentagon violated the National Environmental Policy Act by not considering the impacts of its decision to incinerate PFAS. And more legal action is likely on the horizon, Kalmuss-Katz said.

"When you think about the magnitude of the PFAS problems that our country is facing right now, it's issues like this that are the reason that environmental lawyers go to law school," he said.

Michael A. Olsen, Corporate Defense Attorney
3M, DuPont, and other companies facing PFAS-related litigation have turned to the nation's biggest law firms to lead their defense.

Mayer Brown LLP partner Michael A. Olsen is one of the top players on that side. The Chicago-based lawyer began representing 3M in individual cases in 2018, and is now quarterbacking the defense strategy in the complex firefighting foam MDL in South Carolina.

He serves as defendants' co-lead counsel in the case, coordinating the work of lawyers for dozens of different companies and other entities facing claims.

Olsen is an expert in complex tort litigation, and helps lead Mayer Brown's Litigation & Dispute Resolution practice and its Mass Tort & Product Liability practice. He works on several high-profile issues in addition to PFAS, including litigation over asbestos, medical devices, and college student athlete concussions.

Olsen didn't respond to interview requests for this story. In a video on his firm's site, he described his approach in an unrelated case to earning the trust of a big client during yearslong proceedings.

"It's essential to have trust," he said. "And the way you build that trust is through the depth of the relationship—keeping the client apprised of what's going on, and making sure they have the faith in what you're doing, and why you're doing it, and how you're doing it."

—With assistance from Alex Ebert.

Medical Group Urges EPA To Review Use Of NAM Tests In PMN Requests
Jeremy Bernstein, Inside TSCA
https://insideepa.com/tsca-news/medical-group-urges-epa-review-use-nam-tests-pmn-requests

A group of physicians is urging EPA to review industry compliance with voluntary provisions in TSCA encouraging submitters of pre-manufacture notices (PMNs) to first use non-animal test methods when developing data they submit to the agency to justify their requests for approving new chemical uses.

In Nov. 19 comments on proposed Significant New Use Rules (SNURs) for five new chemicals, the Physicians Committee for Responsible Medicine (PCRM) asked the agency to ensure PMN submitters are complying with the voluntary provisions in section 4(h)(3) of the Toxic Substances Control Act (TSCA) requiring use of so-called New Approach Methodologies (NAMs) whenever they include results from animal testing in their submissions.

"We request that EPA review compliance with TSCA section 4(h)(3) whenever the results of vertebrate animal testing are included with PMNs," PCRM said in its comments.

The group says such a review could help ensure compliance with the voluntary provisions for the use of NAMs under TSCA.

Such calls underscore the growing focus EPA and some of its stakeholders are placing on the use of NAMs. Driven in part by language in TSCA section 4(h), which Congress inserted into the law when it reformed it in 2016, EPA and others have

been seeking to increase use of NAMs. EPA Administrator Andrew Wheeler issued a directive to the agency last year to reduce animal testing by 30 percent by 2025 and eliminate it by 2035.

In addition to section 4(h)(3), section 4(h)(2) requires EPA to "develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine or replace vertebrate animal testing" within two years of the reformed TSCA's June 2016 enactment.

Within that strategic plan, TSCA section 4(h)(2)(C) directs EPA to develop "a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies . . . that do not require new vertebrate animal testing and are scientifically reliable . . ."

But reflecting the difficulty in moving to such approaches, agency officials are struggling to develop and approve NAMs for use under TSCA in the face of a series of fundamental policy and technical issues -- including what part of a chemical evaluation they should be used for -- that could hamper the agency's efforts going forward.

For example, during a recent EPA webinar on NAMs, representatives of EPA, PCRM and other groups debated how such methods should be used in TSCA evaluations and how the agency could ease their development and use.

"From an organization that promotes the use of NAMs, we want them to be used," Kristie Sullivan, PCRM's vice president of research policy, told the webinar. "The whole purpose of this nomination process is to share these strategies so they can be used by EPA, and more widely."

Proposed SNURs

PCRM's comments respond to proposed SNURs EPA published in the Federal Register in October that sought comment on agency plans to regulate five new chemicals or new uses of existing chemicals.

The agency says in the proposal that it has preliminarily determined that while the intended conditions of use are not likely to present unreasonable risks, it is designating other "reasonably foreseen" conditions of use, as well as certain other circumstances, as significant new uses that require submission of significant new use notifications (SNUNs) and agency review.

The agency also included language encouraging PMN submitters to consult with officials, pursuant to section 4(h), "on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data."

"EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h)," the Federal Register notice says.

But PCRM urges the agency to go further, asking that it review all PMNs where submitters rely on animal data.

"In these five proposed SNURs, EPA does not specify required tests. Instead, it identifies as 'potentially useful information,' the results of aquatic toxicity, eye and skin irritation/corrosion, and specific target organ toxicity testing," the group says.

In addition, the group notes that EPA encourages SNUN submitters to consult with the agency before performing any testing.

"While PCRM generally supports this approach, which allows this information to be derived from alternative test methods and strategies (i.e. New Approach Methodologies or NAMs) that reduce vertebrate animal testing, we are concerned that submitters may still interpret these recommendations to refer to vertebrate animal tests."

"We urge EPA to clearly state its preference for NAMs by identifying specific alternatives and by directing potential SNUN submitters to its statutorily mandated List of Alternative Test Methods and Strategies."

It notes that in the case of one of the PMNs subject to these proposed SNURs, the results of acute toxicity testing in rats and fish and dermal irritation testing in rabbits were included.

"While TSCA does not require EPA to review whether the submitters of these PMNs attempted to develop the information by means of alternative test methods or strategies before conducting new vertebrate animal testing, it does authorize EPA to do so."

For example, it says, the PMN submitter might have considered using the Collaborative Acute Toxicity Modeling Suite to screen for acute oral toxicity, the Fish Embryo Acute Toxicity test and threshold approach to evaluate acute toxicity to fish, and the reconstructed human epidermis test to evaluate the potential for skin irritation.

"Reviewing compliance with TSCA section 4(h)(3) is an opportunity to communicate TSCA's voluntary testing provisions and EPA's preference for alternatives to PMN submitters. Over time, this would lead submitters to consider such alternatives before conducting vertebrate animal tests," the group says. -- Jeremy Bernstein (jbernstein@iwpnews.com)

Trump critics seek to punt IST mandate to Biden
Inside TSCA
https://insideepa.com/tsca-takes/trump-critics-seek-punt-ist-mandate-biden

The incoming Biden administration appears to be facing the prospect of reconsidering an Obama-era regulation that requires facilities to consider use of inherently safer chemicals and other technologies (IST) and other requirements in order to prevent industrial incidents.

State, labor and environmental petitioners Dec. 3 asked a federal appellate court to stay litigation over the Trump administration's so-called Risk Management Plan (RMP), which reversed the IST and other requirements in the Obama regulation, so that President-elect Joe Biden and his administration can decide whether to restore the requirements.

"EPA will soon be transitioning to a new presidential administration," the petitioners tell the court in an unopposed Dec. 3 motion to govern and for additional abeyance.

"Given past experience, it is reasonable to expect that the incoming administration will want to review the 2019 RMP Rule and EPA's reconsideration denials, and determine whether to defend those actions or change course, the latter of which would likely involve a request for additional abeyance pending agency review."

EPA says it is not opposing the group's motion for an additional stay of the case, which is pending before the U.S. Court of Appeals for the District of Columbia Circuit.

The suit, Air Alliance Houston, et al. v. EPA, challenges EPA's November 2019 rule undoing the Obama-era policy that strengthened RMP safety requirements for chemical facilities.

The Trump EPA 2019 rule significantly scaled back the January 2017 rule, rescinding the Obama administration's major accident prevention program provisions, retracting mandates that would have required third-party audits after an incident, consideration of ISTs, a root-cause analysis after an incident or a near miss and broad public disclosure of documents after an incident.

The D.C. Circuit previously stayed the litigation until Dec. 3 to give litigants time to consider a separate suit they filed contesting the agency's denial of an administrative petition for reconsideration that critics of the rollback filed with EPA urging it to undo the action.

Both suits were subsequently consolidated in Air Alliance Houston. The petitioners include 13 environmental and community groups, 16 mostly Democratic-led states, the District of Columbia and two local governments, and the United Steelworkers (USW).

"Given that the litigation regarding the 2019 RMP Rule and the reconsideration denials have now been consolidated, Petitioners need additional time to coordinate on briefing these consolidated cases in order to determine how to best present the issues and avoid duplicative arguments," the petitioners say in their motion.

They note that the issues they are raising are complex involving multiple regulations of the Clean Air Act's (CAA) RMP. They ask for the case to be stayed until March 20, at which time the parties should file an additional motion.

They cite as an example that the action under challenge reversed a rule EPA promulgated after multiple years of work. "Due to the unusual circumstances of the rulemaking history in this litigation, Petitioners seek the requested additional time in the interest of efficiency, to attempt to preserve the resources of all parties during the transition, and to ensure that the new administration can participate in planning an appropriate motion to govern for these proceedings," according to the filing.

UPDATE: The Deadline for the Chemical Data Reporting Requirement Has Been Extended
Lisa Whitley Coleman, EHS Daily Advisor
https://ehsdailyadvisor.blr.com/2020/12/the-deadline-for-the-chemical-data-reporting-requirement-is-approaching/

Update: The EPA recently published a final rule extending the Toxic Substances Control Act's (TSCA) Chemical Data Reporting (CDR) deadline to January 29, 2021. The previous deadline was November 30, 2020.

The Toxic Substances Control Act (TSCA) of 1976 provides regulatory authority to the EPA to regulate the distribution and use of chemicals in industry. Section 8 (a) establishes the CDR rule, requiring reports every 4 years.

Complying with CDR reporting requirements requires intensive file reviews. Businesses are advised to conduct reviews with legal counsel in place to preserve privileged communications and ensure they are positioned to respond quickly in the event reporting deficiencies are discovered.

The Basics
Meeting CDR guidelines requires companies that manufacture or import chemical substances for commercial purposes to report certain information to the EPA if the chemical substances are on the TSCA Inventory list and are produced in quantities of 25,000 pounds or more at any one location during any of the 4 years in the reporting period. For certain chemicals that are considered more toxic, the reporting threshold is reduced to 2,500 pounds.

There are several exemptions to the reporting requirements, including highly technical exemptions from the premarket notification requirements of TSCA Section 5.

Use and exposure information must be based on data for the principal reporting year, which is currently 2019.

What Information Is Required?
The data that must be reported on chemicals on the TSCA Inventory include information that is known or obtainable about:

- Chemical identity and structure
- Manufacturing data
- Use
- Exposure
- Disposal
- Health and environmental effects

Overcoming Hurdles

Occasionally, end users encounter roadblocks such as chemical suppliers claiming confidentiality over the ingredient list of a chemical when the chemical is used to manufacture other substances.

The EPA requires "reasonably ascertainable" information about certain chemicals to be reported, so it is important to understand the EPA's definition of "reasonably ascertainable." This is a vague term for which the EPA has provided some guidance.

1. Companies must "ascertain details regarding the processing and use of chemical substances that they manufacture through reasonable inquiries within the full scope of their organizations, not just based on the specific knowledge of management and supervisory personnel; however, the standard does not necessarily require that the manufacturer conduct an exhaustive survey of all employees."
2. "Reasonably ascertainable information may include information contained in marketing studies, sales reports, customer surveys, or Safety Data Sheets in the business' files," according to pillsburylaw.com.

This type of information is reported on the EPA's Form U, which requires the use of specific and complex codes. All the chemicals at each facility are reported on one Form U and are submitted electronically through the EPA's Central Data Exchange (CDX). It is recommended that companies hire contractors with specialized knowledge in this area if they do not have this expertise in-house.

2020 Changes

Earlier this year, the EPA amended the CDR rules. These changes include clarifying "the upfront substantiation of Confidential Business Information (CBI), the scope of the byproduct exemption, and the specific information to be provided for different use scenarios," according to Pillsbury Law. The changes also broadened the definition of a "small manufacturer" and increased the sales threshold from $40 million to $120 million under its first size standard and from $4 million to $12 million under its second size standard. The amended definition classifies a manufacturer as small "if its total annual sales, when combined with those of its parent company (if any), are less than $120 million, and it manufactures/imports under 45,400 kilograms of a chemical," according to Pillsbury Law. "Furthermore, a manufacturer/importer is considered 'small' if its total annual sales, when combined with those of its parent company (if any), are less than $12 million, regardless of the quantity of substances manufactured/imported."

Some chemicals must now be reported regardless of size, so some manufacturers that have not previously been required to report may now have reporting requirements due to these amendments.

Best Practices

Conduct CDR reviews using in-depth file reviews and systemwide procedures designed as an internal compliance review so that any compliance deficiencies are quickly discovered and corrected. According to Pillsbury Law, some of the common deficiencies generally encountered include:

- "Evidence of non-compliance in CDR reporting from past reporting cycles";
- "Misapplication of the exemptions from the PMN requirement in connection with the past manufacture or import of chemicals not listed on the TSCA Inventory";
- "Failure to comply with the terms of Significant New Use Rules or Section 5(e) Consent Orders, for chemicals whose manufacture or import is subject to special restrictions";
- "Failure to properly complete TSCA Import Certifications"; and
- "General systemic non-compliance with TSCA due [to] corporate governance shortcomings or the unsettled nature of the law."

When deficiencies are discovered, companies must choose whether to disclose noncompliance issues under the EPA's Audit Policy, which provides substantial relief from penalties for companies that voluntarily report and correct violations. It is important to note there is only a 21-day window for making violations reports, and companies doing so must have a plan for how to return to compliance and prevent a recurrence.

Certain types of Section 5 TSCA violations have immediate quarantine requirements for some distribution products, which can cause contract violations and supply chain disruptions, possibly leading to third-party litigation.

The penalties for noncompliance with TSCA can be severe—the EPA can seek up to $40,576 per day in civil penalties for each violation and up to $50,000 per day in criminal fines. These penalties are calculated per chemical. Because many products contain multiple chemicals, the fines can quickly escalate.

Learn more about the EPA's CDR requirements.

Cuomo Approves Ban on PFAS in Food Packaging
Nick Reisman, Spectrum News
https://spectrumlocalnews.com/nys/buffalo/ny-state-of-politics/2020/12/03/cuomo-approves-ban-on-pfas-in-food-packaging-

A ban on the usage of PFAS chemicals in food packaging was approved this week by Gov. Andrew Cuomo.

PFAS chemicals have been found in food packaging as well as in food containers used for takeout orders at restaurants.

"When we buy food from the grocery store or takeout from a restaurant, we assume that product is safe for our families," said Assemblywoman Pat Fahy, a Democrat from the Albany area who backed the bill. "PFAS — a dangerous and cancer-causing class of chemicals commonly used in everyday food packaging — however, is anything but safe for New Yorkers. The short-chain PFAS most commonly used in food packaging has been shown to have similar toxicity to long-banned long-chain PFAS."

The measure bans perfluoroalkyl and polyfluoroalkyl, considered potential carcinogens, making New York the latest and the largest state in the country have enacted a ban behind Maine and Washington state.

"I'm thrilled to see these dangerous chemicals banned in food packaging and the public health — especially that of our children — protected as a result," said Sen. Brad Hoylman, a Democrat from Manhattan who sponsored the bill in his chamber.

Restaurants and food distributors will have time to adjust to the new ban. The measure will take effect at the end of 2022.

Philly parks are going organic with ban on synthetic weed-killers
Taylor Allen, NPR's WHYY
https://whyy.org/articles/philly-parks-are-going-organic-with-ban-on-synthetic-weed-killers/

Synthetic weed-killers will soon be a substance non-grata in Philadelphia parks and public spaces.

In a unanimous vote, City Council Thursday passed legislation banning herbicides linked to health conditions such as cancer, asthma and learning disabilities on all city-owned land.

The Healthy Outdoor Public Spaces bill sponsored by Councilmember Cindy Bass applies to all city parks, trails, recreation centers and playgrounds. These parcels of public land are now maintained with chemicals including glyphosate and 2, 4-D, a common pesticide linked by a growing body of scientific research to harmful impacts on humans and the environment.

The World Health Organization's International Agency for Research on Cancer described glyphosate in 2015 as "probably carcinogenic to humans."

In addition to the ban on certain chemicals, the legislation requires the city's Department of Parks and Recreation to document the usage of any pesticide and report back annually to City Council.

A recent study by the U.S. Environmental Protection Agency declared that glyphosate is not a carcinogen and presents no threat to human health when the chemical is used according to the label. But public health advocates believe protections should be in place because of the difficulty in guaranteeing correct usage and exposure levels. The chemical can be especially harmful to children, whose playful explorations can put them at risk of higher levels of exposure.

"Children play close to ground where pesticides settle, they put their hands in their mouths and breathe more rapidly than adults increasing inhalation exposures," said Sarah Evans, an assistant professor of environmental medicine and public health at the Icahn School of Medicine at Mount Sinai.

Under the legislation passed Thursday, the regulation will go into effect over the next three years. Beginning in July, the Department of Parks and Recreation will be required to report pesticide use publicly. In 18 months, the law will prohibit certain toxic chemicals on all city property except golf courses and athletic fields, which must comply by the end of 2022.

The city must also develop an organic land management plan that includes regular soil testing and selection of planting.

Dr. Linda Stern spent most of her career at the Philadelphia Veterans Affair Medical Center where she treated veterans exposed to Agent Orange, a dangerous chemical weapon that includes 2, 4-D, one of the banned herbicides.

"There are no established safe levels of herbicides," Stern said, commending City Council for the bill's passage. "Health alarms have been demonstrated at very low levels and they can even be passed to future generations."

According to research by the Black Institute, a New York-based racial justice think tank, Black and Hispanic communities are statistically more affected by the chemicals.

"Every single time a chemical-based herbicide is sprayed in Philadelphia, environmental racism is being manifested in our communities," Ryan Dougherty, an organizer with the group, said.

Deep health disparities are well-documented in Philadelphia, with some Black and brown neighborhoods experiencing much higher levels of childhood asthma and other ailments than white neighborhoods.

The bill passed without the support of the city's Department of Parks & Recreation.

Parks and Rec officials argue the ordinance will make it more difficult to manage the health and ecology of Philadelphia's natural lands. In particular, the bill doesn't come with adequate funding attached. The department already faces a $12.5 million budget reduction because of the pandemic.

"The known alternatives to herbicides are far less effective and far more costly, so our already-stretched capacity to manage invasive plants would be greatly reduced," Commissioner Kathryn Ott Lovell said.

An amendment to the bill made before it passed does allow Parks and Rec to use a synthetic herbicide if approved through a waiver.

The department still isn't happy with that, calling it "impractical" and would not allow staff to carry out routine park maintenance.

As a response to the public's concern about the potential dangers of the synthetic herbicides, the department will not use any within 50 feet of play equipment, post signs in advance that there will be applications of the synthetic herbicides, and institute a pilot program on selected sites to test how well organic pest management products work.

Mayor Jim Kenney has not spoken publicly about the legislation. Following Thursday's City Council vote, environmental advocates urged him to sign the bill into law.

"Organic land management is a safe and effective alternative to spraying toxic chemicals in our parks and playgrounds. This change is well worth it to ensure that children and adults alike can safely enjoy outdoor spaces in the city, especially during the COVID-19 pandemic," said Pennsylvania Public Interest Research Group advocate Emma Horst-Martz. "We encourage Mayor Kenney to sign this bill into law and look forward to continued action to reduce the use of toxic chemicals across Philadelphia."

EPA Draft Report Finds Glyphosate Harms Many Endangered Species
Dan Nosowitz, Modern Farmer
https://modernfarmer.com/2020/12/epa-draft-report-finds-that-glyphosate-harms-many-endangered-species/

Much of the debate over glyphosate, the herbicide from Bayer-Monsanto, has revolved around its effects on human health.

While Bayer-Monsanto will be paying billions of dollars to settle thousands of cases alleging that glyphosate causes cancer, the news lately is not about humans—it's about animals and their habitats. The Environmental Protection Agency this week released a draft of its findings on how glyphosate affects endangered or otherwise at-risk animals, plants, and their habitats. Those findings are not great, if you're a fan of glyphosate.

While the EPA has maintained that glyphosate is, when used according to its label, not carcinogenic, the agency has been working on figuring out whether glyphosate is dangerous to plants and animals for months. The EPA updated how it does this analysis earlier this year, using data to indicate how a pesticide is actually used, rather than based on how the label says it should be used.

These new findings say that glyphosate, when combined with common surfactants (which help the herbicide coat leaves more evenly), is "likely to adversely affect" a whopping 93 percent of the plants and animals it examined. As for habitats that serve as homes for these at-risk plants and animals, the findings say that glyphosate is likely to have a negative effect on 96 percent of them.

Chronic exposure to glyphosate, finds the report, can inhibit a vital enzyme in many plants, without which they can experience cell death. For animals, chronic and acute exposure (exposure over an extended period of time, or a lot all at once) can result in reduced body and organ weights.

Glyphosate is one of the world's most popular herbicides; around 280 million pounds of it are used on agricultural land, mostly corn, soy, and cotton. But a further 21 million pounds are used for non-agricultural reasons; you can find it at Home Depot, and it's pretty popular for landscaping and home gardening.

If the report goes through the comment period as written, the EPA would have to work with other agencies, like the Fish and Wildlife Service and the National Marine Fisheries Service, to come up with a plan for protection measures. Those might include limiting glyphosate's use in certain areas, or general limitations on its use.

Recent Enforcement Demonstrates EPA Prioritization of FIFRA Compliance
Lisa Whitley Coleman, EHS Daily Advisor
https://ehsdailyadvisor.blr.com/2020/12/recent-enforcement-demonstrates-epa-prioritization-of-fifra-compliance/

On October 15, 2020, the EPA announced a settlement with Electrolux Home Products Inc. in the amount of $6,991,400 to resolve alleged violations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Electrolux, headquartered in Charlotte, North Carolina, was charged with importing approximately 420,000 air conditioners and dehumidifiers containing filters treated with an unregistered nanosilver, "which were labeled and marketed with pesticidal claims," including "antibacterial filter," and "helps eliminate bacteria in the air that can make breathing difficult," according to the EPA.

The EPA alleged that Electrolux "imported unregistered pesticides in violation of section 12(a)(1)(A) of FIFRA and failed to file the required Notice of Arrival in violation of section 12(a)(2)(N) of FIFRA."

The EPA said Electrolux imported these products 141 different times between January 11 and May 12, 2020, across 6 different EPA regions at 11 different entry ports, including Los Angeles/Long Beach, California; San Francisco, California; Jacksonville, Florida; Savannah, Georgia; Chicago, Illinois; Boston, Massachusetts; Worcester, Massachusetts; Wilmington, North Carolina; New York/Newark, New Jersey; Columbus, Ohio; and Norfolk, Virginia.

FIFRA requires all pesticide products to be registered with the EPA before distribution or sale within the United States.

"FIFRA also requires importers to submit a Notice of Arrival (NOA) to EPA prior to the arrival of pesticide products," according to Taft Stettinius & Hollister LLP, a law firm founded in Cincinnati, Ohio. "EPA determined that Electrolux failed to submit the required NOA and that the air conditioners, dehumidifiers, and the nanosilver pesticide used to treat the filters were all unregistered pesticides. EPA, therefore, concluded that Electrolux's importation and intended sale of the dehumidifiers and air conditioners violated FIFRA. As a result, EPA worked closely with U.S. Customs and Border Protection (CBP) to detain approximately 420,000 of Electrolux's products and prevent them from entering U.S. commerce."

Because Electrolux failed to file NOAs on the 141 shipments, it violated FIFRA.

In addition to the hefty fine, before the release of the detained products, Electrolux was required to agree to remove the unregistered filters treated with nanosilver and to remove any advertising claims related to petrocide benefits from all its products—those detained and those already in the United States.

"Electrolux's consent agreement serves as a notice to the regulated community that FIFRA compliance is one of EPA's top enforcement priorities during the COVID-19 pandemic," according to the Taft Law Firm. "EPA continues to pursue severe civil and criminal penalties to ensure all pesticide products on the market comply with FIFRA's strict requirements."

The EPA press release confirms Taft's assessment.

"The sale and distribution of unregistered pesticides may pose risks to human health and the environment," according to the EPA. "If EPA has not reviewed reliable data about the how the pesticide product works and what kinds of exposures may impact the user, then the risk to the consumer and the environment is unknown and use of the product is potentially unsafe. Additionally, consumers may be misled to believe a pesticide product provides public health benefits that it may not.

"Before EPA can register a pesticide, the agency must determine that no unreasonable adverse effects on human health and the environment will occur when the pesticide product is used according to its label directions," continues the EPA. "The only nanosilver pesticides that are currently registered with the EPA are approved solely for incorporation into textiles to protect those articles themselves from antimicrobial pests such as mold and bacteria that can cause deterioration, discoloration or odors. No nanosilver pesticide is registered with the EPA for use in home appliances to disinfect the ambient air or protect the health of the user."

The Electrolux website contains no information regarding the settlement. The EPA states, as of the settlement date, that Electrolux had brought 500,000 dehumidifiers and air conditioners back into compliance.

Visit the EPA FIFRA website for more information about the Act's regulations.

TSCA and Environmental Justice — A Conversation with Former OPPT Director Jeffery T. Morris, Ph.D.
Bergeson & Campbell All Things Chemical Podcast

This week I sat down with Dr. Jeff Morris, immediate past Director of EPA's Office of Pollution Prevention and Toxics (OPPT), the EPA office that regulates industrial chemicals. Jeff is now a principal of Jeff Morris Solutions LLC, a consulting firm helping entities navigate the complexities of industrial chemical regulation. While at EPA, Jeff directed the Agency's implementation of the 2016 amendments to the Toxic Substances Control Act (TSCA), the U.S. law regulating industrial chemicals, and headed the office most immediately impacted by the significant changes brought about by the Lautenberg amendments.

In our discussion, we look back on Jeff's leadership of the Office of Pollution Prevention and Toxics and its accomplishments in implementing Lautenberg, which policies the current Administration has implemented that should continue, and how the new Administration should and can do more using TSCA to address social inequities and achieve the goals of environmental justice. Jeff discusses his recent articles on this important topic, as well as the important role international collaboration plays in understanding both the commercial promise and chemical profile of nanomaterials.

ALL MATERIALS IN THIS PODCAST ARE PROVIDED SOLELY FOR INFORMATIONAL AND ENTERTAINMENT PURPOSES. THE MATERIALS ARE NOT INTENDED TO CONSTITUTE LEGAL ADVICE OR THE PROVISION OF LEGAL SERVICES. ALL LEGAL QUESTIONS SHOULD BE ANSWERED DIRECTLY BY A LICENSED ATTORNEY PRACTICING IN THE APPLICABLE AREA OF LAW.

EPA Updates Draft Guidance on Plant Biostimulant Products

Karen Ellis Carr, JD Supra (Arent Fox)

https://www.jdsupra.com/legalnews/epa-updates-draft-guidance-on-plant-57792/

This updated guidance follows an earlier version EPA released for public comment in March 2019.

Last week, EPA released an updated guidance document aimed at assisting developers of plant biostimulant products regarding what products and product claims fall within, and without, EPA's jurisdiction under the federal pesticide regulatory regime, FIFRA. This updated guidance follows an earlier version EPA released for public comment in March 2019.

EPA regulates pesticides pursuant to its authority under the Federal Insecticide, Rodenticide, and Fungicide Act (FIFRA). Under FIFRA, the definition of "pesticide" includes a "plant regulator" — a substance or mixture of substances intended "through physiological action, for accelerating or retarding the rate of growth or rate of maturation or for otherwise altering the behavior of plants or the produce thereof." 7 U.S.C. § 136(v). Products meeting the definition of a plant regulator are subject to regulation by EPA as pesticides, unless they meet one of several enumerated exclusions, including plant nutrients and trace elements (e.g. fertilizers), plant inoculants, soil amendments, and vitamin hormone products. Id. Generally, pesticides must clear EPA's registration process under FIFRA before they may be distributed or sold in the United States.

Plant biostimulants are, as EPA notes, "an increasingly popular category of products containing naturally-occurring substances and microbes that are used to stimulate plant growth, enhance resistance to plant pests, and reduce" stress from non-biological sources (e.g., climate). These products can promote increased water and nutrient use efficiency and can be useful tools in meeting sustainability goals. But neither FIFRA nor any other federal statute provides a regulatory definition for "plant biostimulant," which has sometimes made it difficult for developers to ascertain whether their products fall within EPA's scope of regulation under FIFRA. In an effort to provide additional clarity, EPA's updated draft guidance:

1. provides examples of products and product claims EPA would consider to be plant regulators and plant regulator claims;
2. provides examples of products and claims that it would not consider plant regulators or plant regulator claims, including examples of claims tied to a specific exclusion (e.g., plant nutrient) and "generic" claims;
3. identifies specific substances that the agency could potentially recognize as plant regulators based on their mode of action; and
4. outlines the agency's potential regulatory approach to products that may have multiple modes of action, (i.e., products with both plant regulator and non-plant regulator modes of action).

This document is important reading for developers of plant biostimulant products; it provides valuable insight into EPA's thinking regarding how products are categorized under its plant regulator authority and an opportunity for stakeholders to provide comment to EPA on its approach.

EPA Releases Draft Final Plant Regulator Guidance
Keith Matthews, JD Supra (Wiley Rein LLP)
https://www.jdsupra.com/legalnews/epa-releases-draft-final-plant-98470/

On November 30, 2020, the U.S. Environmental Protection Agency (EPA) published a Federal Register notice announcing the availability of the draft final guidance on label claims for plant regulators, including plant biostimulants (Pesticides; Updated Draft Guidance for Pesticide Registrants on Plant Regulator Products and Claims, Including Plant Biostimulants; Notice of Availability and Request for Comment, 85 Fed. Reg. 76562). The draft guidance is available here. EPA is requesting comment on the draft final Plant Regulator guidance until December 30, 2020. EPA has stated that it "anticipates finalizing this guidance in January 2021." EPA's stated accelerated time frame for producing the final Plant Regulator guidance places a premium on effective participation in the public comment period that will end December 30.

EPA initially released a draft Plant Regulator guidance for comment in March 2019. I discussed the initial EPA draft Plant Regulator guidance in a March 28, 2019 Wiley Alert, "EPA Releases Draft Guidance on Acceptable Label Claims for Plant Biostimulants." This previous Alert explained the regulatory conundrum that results in some biostimulants potentially being regulated as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), while other biostimulants can be marketed without being subject to onerous regulation as pesticides. EPA's 2019 draft Plant Regulator guidance was intended to provide clarity to product developers as to the types of claims that would make a product subject to regulation as a pesticide.

For the most part, three of the tables included in the 2019 draft Plant Regulator guidance were useful in describing specific label and marketing claims that would render products either subject to regulation as plant regulator biostimulants or not subject to regulation as plant regulators. A fourth table, however, purported to identify substances that, if included in a biostimulant product, would categorically render that product subject to regulation as a plant regulator ("Table 4. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having Modes of Action that Trigger Regulation Under FIFRA as a Pesticide," EPA 2019 draft Plant Regulator guidance at pages 10-11). EPA's Table 4 included a number of substances that, while they are active ingredients in some EPA-registered products, are also currently contained in biostimulant products for which plant regulator claims are not made and that are not currently regulated or registered under FIFRA as plant regulators. A fair reading of EPA's draft guidance is that EPA could take the position that it would consider any product containing one of these substances to be regulable as a plant regulator notwithstanding the claims that are made for the product.

Inclusion of Table 4 engendered substantial comment on the draft Plant Regulator guidance (see docket EPA-HQ-OPP-2018-0258 at www.regulations.gov). In the draft final Plant Regulator guidance, EPA removes Table 4 and replaces it with discussions of (1) "Substances that have no other use than as plant regulators or pesticides;" (2) "Substances that may have plant regulator and non-plant regulator activity;" and (3) "Regulatory approaches for substances and products that have multiple plant regulator and non-plant regulator modes of action." (Draft Final Plant Regulator Guidance at pages 11-15.)

Given the very shortened timeline that EPA has indicated regarding its intent to issue the final Plant Regulator guidance, agricultural inputs producers, growers, and individuals and entities interested in the production and use of biostimulant products must not fail to provide input on the draft guidance. In particular, EPA's discussions of substances that it concludes have no uses other than as plant regulators and that may have both plant regulator and non-plant regulator uses, and its discussion of its intended regulatory approaches to such substances likely will be of significant concern to many biostimulants producers. While it is always important to submit concise, substantive, and well-supported comments to administrative dockets, given the fact that EPA has indicated that it will issue the final guidance within three weeks of the December 30 close of the comment period, the necessity to do so here is even more important.

Preparation of comments that adequately convey the substance of the comment and preserve the commenter's procedural rights will be of the utmost importance.

In Final Defense Bill, Too Little Progress on 'Forever Chemicals'
Environmental Working Group
https://www.ewg.org/release/final-defense-bill-too-little-progress-forever-chemicals

WASHINGTON – A House-Senate conference committee today approved a final version of the National Defense Authorization Act for FY 2021, which both houses will vote on before it goes to the White House for President Trump's signature or veto. Here is the statement of Scott Faber, EWG's senior vice president of government affairs, on the NDAA provisions concerning the toxic fluorinated "forever chemicals" known as PFAS.

We're grateful that the NDAA once again seeks to address the PFAS contamination crisis by banning some Defense Department uses of PFAS, by expanding PFAS research and by accelerating efforts to develop PFAS-free firefighting gear and firefighting foams. The bill also requires the Defense Department to warn nearby farmers if their irrigation water may be contaminated.

But the NDAA falls far short of what's needed to address the contamination crisis facing our service members and neighboring communities. PFAS have been confirmed in the groundwater of 328 military installations and are suspected in the groundwater at hundreds of other bases.

Tragically, this bill will do little to clean up the existing legacy contamination at bases and nearby communities and does nothing to hold polluters or the Pentagon accountable when they fail to act to protect us. What's more, the bill fails to expand PFAS blood testing to all service members, even though growing evidence suggests that the PFAS in our blood make vaccines less effective.

The bill also fails to ensure that legacy firefighting foams are properly disposed of. Although we are pleased that legislators recognize the need to make PFAS a priority, this NDAA fails to do so.

Our service members take enormous risks to protect us. Sadly, too many members of Congress are afraid to take political risks to protect them. Some would rather protect the polluters than the people who risk their lives to protect our nation.

By contrast, President-elect Biden has pledged to make the PFAS pollution crisis a top priority. In particular, Biden has pledged to designate PFOA and PFOS, the most notorious PFAS chemicals, as hazardous substances under the federal Superfund law, which will accelerate the cleanup process at military bases and ensure that polluters pay their fair share of cleanup costs. He has also pledged to end the use of PFAS in many everyday consumer products and to quickly establish a national drinking water standard for PFAS in tap water.

EPA Extends CDR Submission Deadline
Lynn L. Bergeson, The National Law Review (Bergeson & Campbell)
https://www.natlawreview.com/article/epa-extends-cdr-submission-deadline

On November 25, 2020, EPA announced the amendment of the Toxic Substances Control Act (TSCA) Chemical Data Reporting (CDR) regulations by extending the submission deadline for 2020 reports. CDR submissions are now due on January 29, 2021. According to EPA, this is the final extension, and it only applies to 2020 submissions. CDR regulations require manufacturers of certain chemical substances included on the TSCA Chemical Substance Inventory to report data on the manufacturing, processing, and use of chemical substances.

To assist chemical manufacturers and processors with submitting CDR data, Bergeson & Campbell, P.C.'s (B&C®) affiliate The Acta Group (Acta®) developed CDR Cross-Check™, an ingenious and cost-efficient tool to identify whether a company's chemicals are subject to CDR and at what reporting threshold. CDR Cross-Check will identify:

- Whether the chemical is listed as active or inactive;
- Whether the chemical was subject to specific TSCA regulatory actions in 2016;
- Whether the chemical is exempt; and
- What the reporting thresholds are based on the updated data released by EPA on May 29, 2020.

Visit the CDR Cross-Check page on the Acta website for a sample report and information on how to use CDR Cross-Check.

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And while you're reading.... Remember to shoot your coworkers a shooting star!