Message

From: Steven Gibb [skgibb@aol.com]
Sent: 12/5/2019 3:35:22 PM
To: rreindel@aflcio.org; Henry, Tala [Henry.Tala@epa.gov]; rengler@lawbc.com
Subject: Just fyi -- some past Bloomberg Articles on Worker Issues and TSCA

Hi all --

Looking forward to our 1:30 session on Monday at Salon K on Monday Dec. 11.

The articles below are just for background, not required reading.

Hopefully we'll get some good questions and have engaged audience members.

I'll go over the slides, have each of you introduce yourself and speak for 5-6 minutes on workers and TSCA and then open the floor.

If you could please arrive at Salon K by 1:15 p.m., that would help us get set up and organized.

Thank you again for your willingness to participate!

-Steve Gibb M.S.
202-422-5425

-----Original Message-----
From: Steven Gibb <skgibb@aol.com>
To: skgibb <skgibb@aol.com>
Sent: Thu, Sep 12, 2019 3:39 pm
Subject: occupational health articles and tSCA

EPA Overly Confident of Solvent's Safety, Advisers Warn

Posted Sept. 12, 2019, 2:40 PM

- Agency urged to acknowledge greater uncertainties about 1-bromopropane risk
- Advisers challenge EPA presumption that industrial workers always protected from solvent

The EPA doesn't have enough data about a widely used solvent's effects on the environment to support a conclusion that the chemical doesn't have the potential to harm wildlife, some agency advisers said Sept. 12.

The Environmental Protection Agency's Science Advisory Committee on Chemicals met Sept. 10-12 to critique the agency's draft evaluation of 1-bromopropane (1-BP), which is primarily used to clean grease and dirt off equipment used in many industries. The solvent also is released from building insulation panels.

The EPA's separate conclusions that some workplace exposures to 1-BP could pose too great a potential harm to employees may have been reasonable, several members of the committee said.

Still, it's possible the risk to workers is higher, because the EPA exaggerated the use of personal protective equipment, they said.

1-BP is among the first 10 chemicals in commerce that the EPA is evaluating to comply with the 2016 Toxic Substances Control Act amendments.

Response to Agency Signals

The panel's comments are relevant to companies and trade associations preparing to have the risks of at least 20 more chemicals evaluated starting the end of the year. The recommendations could signal the type of chemical risk data that manufacturers may want to provide to the agency.

Some companies, like BASF SE, and trade associations like the International Institute of Synthetic Rubber Producers Inc., may already be responding to such signals.

They have begun sending the EPA information about one or more of 20 chemicals they make or use that the agency is likely to start evaluating next year.

Lack of Ecological Data

The agency's use of "really only one study" to conclude that 1-bromopropane wouldn't pose unreasonable risks to wildlife was troubling, William Doucette, a Utah State University professor and aquatic chemist, said.

The agency's environmental risk conclusions are "really, really uncertain," said Daniel Schlenk, a professor of aquatic ecotoxicology and environmental toxicology at the University of California, Riverside. "These are huge data gaps that need to be filled by somebody."

The committee urged the EPA to acknowledge the uncertainty in the data.

It didn't tell the EPA to gather more environmental information before completing the 1-BP evaluation, Kenneth Portier, a biostatistician chairing the committee, said.

"We have the data that we have, and we try to evaluate it in the most comprehensive way," Stanley Barone, deputy director of the risk assessment division of the EPA's chemicals office, told the panel.

The Toxic Substances Control Act allows the agency to collect industry data, but the law's deadline for completing the first 10 risk evaluations didn't give the agency sufficient time to do so, he said.

Worker-Safety Presumption

Several committee members objected to an agency worker-safety assumption: The agency's draft risk evaluation of 1-BP says the EPA presumes "workers are properly trained and fitted on respirator use, and that they wear respirators for the entire duration of the work activity where there is potential exposure to 1-BP."

That applies to large industrial companies, Barone said. The agency presumes smaller companies, such as dry cleaners, tend not to use personal protective equipment, he said.

“Why one would presume 100% use of protective equipment?” Henry Anderson, a physician and University of Wisconsin-Madison professor, said.

“My experience is that PPE is generally not used and not used well,” James D. Blando, an associate professor at Old Dominion University in Norfolk, Va., said.

Does EPA Listen?

The effect of the committee’s advice on the EPA’s ongoing assessment is unclear.

This was the committee’s third meeting and the fourth draft risk evaluation it has critiqued. None of the committee’s recommendations has formally been submitted to the agency, and they aren’t binding.

In many cases, members of the panel didn’t completely agree with one another. Several advisers said the agency did “the best it could” given the lack of scientific information it had for 1-BP.

“Sometimes we don’t agree with their uncertainties, their assumptions, but [the EPA] laid them out, and I could follow them,” Portier said.

News

Booker Prodded EPA on How Solvent Analysis Omits Exposure Routes

Posted Aug. 22, 2019, 4:00 PM

- Air, water, land exposures to trichloroethylene won’t be in EPA’s coming risk evaluation
- Law allows agency to omit some exposures from chemical assessments, EPA maintains

The EPA’s forthcoming evaluation of a cancer-causing solvent’s risks is incomplete, ignoring ways people can be exposed through the air, water, and soil, according to assertions in congressional letters obtained by Bloomberg Environment.

The letters from Sen. Cory Booker (D-N.J.) to the Environmental Protection Agency last year—and the agency’s response this May—discuss the scope of the EPA’s evaluation of the health and environmental risks of trichloroethylene, or TCE.

New Jersey is home to 150 Superfund sites, according to the EPA. TCE is considered one of the most common contaminants found at waste sites because of its long-time use as a machine degreaser for industrial parts at factory and military sites.

The solvent is among 10 chemicals the EPA is evaluating for safety. The agency's preliminary conclusions about TCE's potential to injure people or the environment are to be released for public comment and review by a science advisory committee later this year.

Booker—who since writing the letter announced he is running for president—raised his concerns as EPA was mapping out what exposures would be considered in its draft TCE analysis.

Omitted Exposure Routes

Booker asked then-acting Administrator Andrew Wheeler last August to reconsider the EPA's plans to omit from its trichloroethylene risk evaluation health problems that might occur if the general population is exposed to the solvent through air, water, and land.

Booker asked whether—as the EPA decided to omit these exposure routes—the agency had considered "the disproportionately harmful impact that decision would have on vulnerable communities around the United States, including low-income communities, communities of color, and indigenous communities."

The 2016 Toxic Substances Control Act amendments required the agency to consider chemical risks to vulnerable, highly exposed communities, the senator wrote.

Role of Other Statutes

"EPA does not expect to include those exposure pathways in the TSCA risk evaluations," Alexandra Dapolito Dunn, assistant administrator for chemical safety and pollution prevention, said in her May 2019 response to Booker. Both letters were obtained by Bloomberg Environment through the Freedom of Information Act.

The agency plans to exercise its discretion to omit exposure routes that are regulated by other EPA-administered statutes, Dunn said. "This approach enables EPA to use resources efficiently, avoid duplicating regulatory efforts, and meet tight statutory deadlines," Dunn wrote.

Booker's letter says "to ignore certain exposure pathways because the risks may be able to be managed by other environmental statutes such as the Clean Air Act and Clean Water Act is deeply concerning given the efforts by your agency to roll back or eliminate many regulations promulgated under those statutes."

Booker's office didn't immediately reply to an Aug. 22 inquiry for his thoughts on the agency's decision. Nor did the agency provide requested details about the scope of the forthcoming TCE assessment or its planned release.

His criticisms about the narrow scope of EPA's risk evaluation also have been voiced by some members of the EPA's Science Advisory Committee on Chemicals, other scientists, and environmental, health, and labor groups on other draft EPA safety evaluations.

Some of those environmental advocacy groups are pursuing legal action on the completeness of EPA's exposure route analysis.

Trade associations—including the American Chemistry Council, American Forest & Paper Association, and the Battery Council International—have backed the agency's approach to the scope of its risk evaluations.

Trichloroethylene

Trichloroethylene's many applications include being used to make adhesives, batteries, and carpet cleaners, and to clean machinery.

Between 100 million and 250 million pounds of TCE were made in or imported into the U.S. by companies including Axiall Corp, Olin Corp., and Superior Oil Co. in 2015, according to EPA data.

More 2.1 million pounds of TCE were released into the air or water or disposed of in 2017, according to the EPA. The solvent also has been found at at least 1,051 of 1,854 Superfund sites, according to the Agency for Toxic Substances and Disease Registry. It can pose risks to workers in buildings above such sites because it seeps into indoor air from the ground below.

Trichloroethylene can cause cancer and other health problems at sufficient levels of exposure, according to the EPA.

Degreaser Could Harm Workers, Consumers, EPA Finds (2)

Posted Aug. 9, 2019, 9:55 AMUpdated Aug. 9, 2019, 3:26 PM

- Exposure may harm some consumers, workers, their children
- Draft conclusions based in part on presumptions previously challenged

Some uses of a common degreaser would need to be controlled because the chemical poses too much risk of harming workers and consumers, the agency said in a draft risk evaluation released Aug. 9.

Workers cleaning electrical equipment and consumers dabbing spots on furniture to remove stains are among those who could encounter health and reproductive problems from their exposure to the chemical, a solvent called 1-bromopropane.

Companies including Albemarle Corp.; Chemtura Corp., now called Lanxess; Phoenix Chemical Co. Inc., now the Polymer Solutions Group; Superior Oil Co. Inc.; and Wego Chemical Group made or imported 25.9 million pounds of 1-bromopropane in 2015, the most recent year that industry had to report production data to the EPA.

Identified on business documents as CAS No. (106-94-5), 1-bromopropane is among 10 chemicals that the Environmental Protection Agency is evaluating under the 2016 Toxic Substances Control Act (TSCA) amendments. It is used in many commercial and some household cleaning applications.

The EPA's Science Advisory Committee on Chemicals will critique the agency's draft risk evaluation at a Sept. 10-12 meeting.

Public comments on the draft document must be submitted by Aug. 30 for consideration by that advisory panel. The EPA, however, will consider all comments submitted by Oct. 11.

Companies Using Solvent

The EPA examined just a few of the uses for 1-bromopropane (1-BP), including degreasing metal parts, making adhesives work more quickly, removing stains from clothes, and being an ingredient in mold killers.

The agency, however, focused particular attention on the solvent's potential to increase the risk of cancer and its potentially harmful effects on fertility and reproduction.

Laboratory animals exposed to 1-BP can be less fertile, give birth to fewer offspring, or bear fewer healthy offspring. Health problems that lab animals experience are presumed to predict potential human health concerns.

The EPA also examined many different ways 1-bromopropane is produced and used. It found that thousands of employees could face undue risk.

The workplace risks that it identified were most likely to occur at downstream companies that purchase the solvent.

Workers at companies that spray 1-bromopropane onto equipment, dip metal parts into it, or use it to make foam cushions are among those that could face too great a health risk from the solvent, according to the EPA.

But employees at companies that make or import 1-bromopropane don't face undue risks, the agency found.

Consumers, Developmental Risks

The agency said it doesn't know how many consumers could be exposed to products containing 1-bromopropane. It concluded, however, that children born to consumers using products made with 1-bromopropane could be at risk.

Consumer products that could be problematic include those that use 1-bromopropane to clean furniture or coins and auto-care products.

This is the first draft risk evaluation that the EPA has released that found consumers could face too much risk from products that contain 1-bromopropane on store shelves.

Initial Responses, Previous Concerns

The EPA's conclusions in the draft assessment rely on several presumptions that the Science Advisory Committee on Chemicals has challenged in previous meetings examining three other draft chemical assessments EPA prepared.

These include that the agency choose not to examine airborne and other routes of exposure. The agency presumes the Clean Air Act and other regulations adequately prevent any health or environmental risks.

Many committee members also have faulted the EPA's presumption, in previous chemical assessments, that workers can reliably be protected by constantly wearing personal protective equipment (PPE) such as respirators.

Yet, the draft 1-bromopropane assessment presumes exposed workers would use personal protective equipment, and that the equipment would be "universally effective," said Richard Denison, lead senior scientist with the Environmental Defense Fund.

For example, the EPA's presumption that chemical manufacturing workers would not be harmed by the solvent depends on the workers using protective equipment. Only when workers would wear protective gear and still be exposed to too much 1-bromopropane does the agency presume the solvent poses an unreasonable risk.

Yet, within its own document, the agency acknowledged that few studies discuss the use of respirators for individuals working with 1-BP, he said. The EPA assumes respirator use for workers while elsewhere acknowledging it has no supporting evidence, Denison said.

The agency's preliminary findings may change, according to Alexandra Dapolito Dunn, the EPA's assistant administrator for chemical safety and pollution prevention.

Even if they don't change, the agency faces a challenge, she has said. There will be a lag time between when the agency announces its final risk conclusions and the time it can decide what regulations would best reduce risky exposures.

Three Flame Retardants' Use Is Dropping, Controlled, EPA Says (1)

Posted June 28, 2019, 11:48 AMUpdated June 28, 2019, 3:14 PM

- Three persistent, toxic flame retardants don't warrant further controls, according to EPA
- International efforts underway to reduce reliance

Three flame retardants that most countries are striving to eliminate don't pose enough concerns to warrant regulatory controls, the EPA said June 28.

The Environmental Protection Agency released its preliminary conclusion after spending 2 1/2 years examining the health and environmental risks of the flame retardants. The agency refers to the chemicals by either of two names: hexabromocyclododecane (HBCD), and the cyclic aliphatic bromide cluster.

The flame retardants are primarily used for insulation in homes and commercial buildings and in welding solder paste, but also are found in automobile replacement parts.

"EPA concludes that HBCD does not present an unreasonable risk of injury to health for workers, occupational non-users, consumers, and the general population by inhalation, oral, or dermal exposure under all conditions of use within the scope of the risk evaluation," including vulnerable populations such as children and the elderly, the agency found.

The agency based that conclusion on examining some, but not all, ways people and the environment could be exposed to the flame retardants.

The EPA evaluated imports of the flame retardants; their use to make insulating panels, solder paste, car replacement parts; and the distribution, disposal, and recycling of products containing the chemicals.

The agency did not examine risks that could occur from exposure to the flame retardants in places where they are no longer being used, in products such as car dashboards and commercial or consumer textiles. Nor did it examine exposures that could occur as such products are disposed or recycled, or that firefighters might incur in buildings where these products burn.

Comments are invited on the EPA's draft risk evaluation 60 days after it appears in the Federal Register. The agency's analysis also will be critiqued by a panel of science advisers July 29-Aug. 2.

Initial Reaction

The American Chemistry Council, the primary voice of the chemical industry, commended the agency for releasing the documents, which it plans to review.

Environmental organizations criticized the agency's efforts.

"Since day one the Trump EPA has worked tirelessly to NOT protect the American people from exposure to dangerous toxic chemicals—whether it's chlorpyrifos, perchlorate, PFAS, lead, or asbestos the chemical office has looked for every way possible to cut corners, create delays, downplay risks, and ignore the best science," Daniel Rosenberg, an attorney with the Natural Resources Defense Council, said by email.

"The draft risk evaluations are more of the same," he said.

"By ignoring potential sources of exposure and assuming protections that don't exist, the Trump EPA is violating TSCA and putting the public at continued risk for contamination and harm from these toxic chemicals," Rosenberg said.

The EPA's assessment of hexabromocyclododecane is among the first 10 the agency is required to conduct under the 2016 Toxic Substances Control Act (TSCA) amendments.

The Chemical Abstracts Service numbers for two of the flame retardants are 25637-99-4 and 3194-55-6, but none is available for the third.

Lawsuits

The EPA's environmental review flagged potential risks to land-based mammals, but the agency said its approach used cautious assumptions that allowed it to conclude that HBCDs' environmental risks were negligible.

The agency also found that workers wearing protective gear like gloves and masks were safe but that some occupational risks remain if personal protective equipment isn't used.

After public comment and scientific peer review, if the EPA determines that the flame retardants don't pose an "unreasonable risk," that finding can be challenged in court.

The final conclusion also would have implications for states wanting to regulate the flame retardants, as they would be prevented from regulating any specific uses the federal EPA looked at and deemed acceptable.

International Actions

Production and use of the chemicals has been steadily falling over the last decade, as substitutes become available.

Concerns about the flame retardants' ability to persist in the environment and build up in the food chain—combined with their potential to harm the nervous system, reproduction, and development in people and wildlife—has prompted most countries to work towards eliminating them.

Of the countries that are party to the Stockholm Convention, 171 of the 188 nations agreed in 2013 to move toward eliminating the flame retardants. The global treaty controls chemicals that persist, build up in the food chain, are toxic, and travel across the globe far from where they were made or used.

The U.S. is among the few developed countries that never ratified the convention, but domestic manufacture of the flame retardants has ceased, the EPA said.

The Chemtura Corp., now part of Lanxess, told the agency it stopped making the flame retardants in 2015, the EPA said. The Albemarle Corp. stopped producing HBCD in 2016 and doesn't intend to resume making it, the EPA said. The Dow Chemical Co. told the agency in a Dec. 21, 2017, email that stopped making the flame retardants in the U.S. in November 2017.

Many downstream industries—including electronics and textile manufacturers—that formerly used the flame retardants have stopped doing so, the EPA said.

For example, automobile makers no longer use the chemicals except in about 155 replacement parts, the EPA said.

Given that at one time millions of pounds per year were manufactured, EPA says "reductions in environmental and biological concentrations will likely occur gradually over a period of time for this persistent and bioaccumulative compound."

—With assistance from Steven Gibb.

Frequent Foes Unite to Urge EPA to Boost Chemical Data Gathering

Posted June 28, 2019, 5:01 AM

- Critics, backers of EPA's handling of chemicals law agree that EPA should demand data
- Democratic senators have asked EPA to describe data-gathering policies

The EPA should use its legal powers to get exposure and other data from chemical companies, according to representatives of organizations that normally disagree over how the agency implements the nation's primary chemicals law.

The EPA "has yet to use that authority even one time" since the Toxic Substances Control Act was overhauled in 2016, said Michal Freedhoff, director of oversight for Democrats on the Senate Environment and Public Works Committee.

The Environmental Protection Agency's decision not to use that authority is "egregious" and shows the agency is failing to implement the TSCA amendments as Congress intended, Freedhoff said at a June 24 event titled "TSCA: Three Years Later."

Industry attorneys and EPA science advisers also are urging the EPA to collect more data to inform its chemical decisions.

Data Analysis

These varied voices are referring to a major change Congress made in 2016 when it amended the nation's primary industrial chemicals law.

Republicans and Democrats agreed in those amendments that the EPA should be able to demand toxicity, exposure, or other chemical data from companies, even though those studies can be costly.

The combination of basic "physical chemical" data that shows how a chemical moves through the body and the environment—combined with toxicity data—allow the agency to determine if that chemical could be hazardous.

Exposure data allow the EPA to assess if communities, workers, wildlife, plants, or the ozone layer, for example, would be harmed by a hazardous chemical.

Exposure information is particularly helpful to the EPA in assessing how chemicals are used in the workplace and other settings, and what risks those "conditions of use" pose when weighing possible regulations.

The EPA didn't reply to repeated email requests for comment on whether it plans to require companies to provide the agency existing or newly generated information on their chemicals.

'New Chemical Bias'

The EPA now has the authority to require companies that make and import chemicals to provide data, Lynn Bergeson, managing partner with Bergeson & Campbell PC, which represents chemical companies.

"We urge it to use that authority," she said at the TSCA forum organized by the Environmental Law Institute, George Washington University, and Bergeson & Campbell.

The EPA's data gathering approach doesn't treat new, yet-unmanufactured chemicals the same as compounds already in commerce, said Bergeson, whose law firm manages the TSCA New Chemicals Coalition. Through that coalition, chemical manufacturers share information on how the agency assesses new compounds.

The EPA seeks toxicity and other information from companies that want to make a new chemical that's never been produced before, she said. But the agency isn't asking for the same information about chemicals already on the market.

That preserves a long-standing "new chemical bias" the agency wrestled with even before TSCA was amended, she said.

The alleged bias refers to new chemicals facing tougher safety standards before they can get on the market, while older chemicals can remain in commerce under the sometimes untested presumption that they're safe. People concerned by this alleged bias argue that it hinders the entry of possibly safer chemicals into commerce.

In most other TSCA implementation efforts besides data requests, the "EPA has faithfully implemented what's in the law," Bergeson said.

June Deadline

Members of the EPA's Science Advisory Committee on Chemicals also urged the agency to require companies to provide more data.

Workplace monitoring data, inhalation toxicity, and skin-sensitization tests are types of information the agency could get from companies to evaluate worker exposure risks as TSCA requires the agency to do, said panelists critical of the agency's draft risk evaluation of Pigment Violet 29 during a June 18-21 meeting.

In addition, five Democratic senators who backed the TSCA amendments in 2016 voiced strong concerns about the agency's decisions not to request data, in a June 20 letter to EPA Administrator Andrew Wheeler.

The letter referred to the agreement by Republicans and Democrats to increase EPA's data-gathering authorities as "one of the areas of greatest bipartisan consensus in TSCA reforms."

"It is impossible to ensure the safety of chemicals and protect human health and the environment without having solid information about a chemical's risks," said Sens. Tom Udall (D-N.M.), Cory Booker (D-N.J.), Ed Markey (D-Mass.), Jeff Merkley (D-Ore.), and Sheldon Whitehouse (D-R.I.).

They gave EPA until the end of June to answer a series of questions about its data-gathering policies.

Chemical manufacturers and product makers also should be offering and generating new information to submit to EPA, Bergeson said.

"Business needs to be more engaged," she said. "We are all challenged to help move the needle forward. We don't have to wait for EPA to do it all."

Lag Time in EPA Action on Toxic Chemicals May Worry Public (1)

Posted June 24, 2019, 4:08 PMUpdated June 24, 2019, 4:28 PM

- EPA's upcoming evaluations likely to find some uses pose unreasonable risks
- People may worry about exposure during lag before EPA controls

The EPA may soon identify situations in which a chemical poses unreasonable risks, but not act to reduce exposure until several years later, which could spark concerns among the public, the agency's top chemicals official said June 24.

Environmental Protection Agency officials anticipate receiving questions from members of the public during the lag between risk findings and controls. But they haven't announced specific risk communication plans for addressing such concerns.

The EPA over the next few months plans to release its preliminary conclusions on whether specific uses of nine chemicals pose an unreasonable risk, with final decisions due by June 2020.

"It's possible and quite likely we'll find unreasonable risks under some conditions of use," said Alexandra Dapolito Dunn, the EPA's assistant administrator for chemical safety and pollution prevention.

Once the EPA identifies these risks, the 2016 Toxic Substances Control Act amendments give it two-and-a-half years to reduce them.

"If unreasonable risks are found for workers, would workers be comfortable knowing it will take two-and-a-half years to figure out how to manage their risks?" Dunn said at a June 24 event titled "TSCA: Three Years Later."

Agency, Companies Challenged

The EPA will have to figure out how to communicate such risks to affected populations, and explain what it's doing to figure out how to protect them, Dunn said at the forum, which was organized by the Environmental Law Institute, George Washington University, and Bergeson and Campbell PC.

Companies will also be affected by the EPA deciding that the way a chemical is made, used, or disposed of is too risky, Lynn Bergeson, managing partner with Bergeson and Campbell PC, told Bloomberg Environment.

The EPA's unreasonable risk finding—even if preliminary—is likely to start discussions within companies about whether to stop using that chemical in the risky manner the agency identifies, she said.

Dunn said exposure reduction methods the EPA proposed in a regulation it issued June 21 that would control five persistent, bioaccumulative, and toxic chemicals offer insight into future strategies the agency will use to control chemical exposures, and thereby risks.

The EPA's exposure reduction tools include limiting the concentration of a chemical in products, limiting uses of the chemical, and restricting manufacturing and import volumes, she said.

The nine draft risk evaluations the EPA plans to release this summer address asbestos, 1-bromopropane, carbon tetrachloride, 1,4-dioxane, the three flame retardants known as the cyclic aliphatic bromide cluster, methylene chloride, n-methylpyrrolidone, perchloroethylene, and trichloroethylene.

News

More Data, Logic Needed for Chemical Risk Findings, EPA Told (1)

Posted June 21, 2019, 12:56 PMUpdated June 21, 2019, 6:02 PM

- EPA needs more data, clearer rationale to persuade advisers a chemical is 'safe'
- Advisers detail types of information needed in future chemical risk evaluations

EPA must back its conclusions that a chemical is safe enough to forgo regulation with sufficient data and a clear rationale—elements that were missing in its first analysis of a pigment, agency science advisers said June 21.

The Science Advisory Committee on Chemicals needed more information to have confidence in the agency's conclusion that a chemical called Pigment Violet 29 didn't pose an unreasonable risk of injuring people or the environment, said panel member Charles Barton, an independent industry consultant.

Under the nation's primary chemicals law, regulatory controls are only applied to compounds that pose an unreasonable risk.

The committee's inaugural meeting critiqued the first of 10 draft risk evaluations it's expected to review this summer under the 2016 amendments to the Toxic Substances Control Act.

Although the Environmental Protection Agency needed to better support its final conclusions, the committee did give the agency credit for its publicly available summary of a confidential study on developmental impacts that BASF SE voluntarily provided the agency to help it evaluate the pigment's toxicity.

Basics Missing

Getting basic information the committee needs about whether the pigment could move within human or animals' bodies wouldn't be too onerous, but is important, said Concepcion Jimenez-Gonzalez, a panel member and GlaxoSmithKline Plc scientist.

The amount and type of scientific evidence the EPA will need to make a decision about risk will vary with each chemical it reviews, said panel member Mark Johnson, director of toxicology for the U.S. Army Public Health Center.

But ranked on a five-point scale—with five being the highest level of confidence—the committee had a roughly 1.5 confidence level that the pigment would not pose an unreasonable risk based on the agency's risk evaluation, said committee Chairman Kenneth Portier, a biostatistician and independent consultant from Atlanta.

For this particular chemical, the EPA needed to address whether the pigment gets absorbed into living organisms. If not, the agency should address the size and shape of its particles and if they would irritate workers lungs, the committee said.

Setting the 'Right Precedent'

The committee described physical, chemical, exposure, and toxicity data that could be useful for this and future chemical assessments that TSCA requires the agency to conduct.

Workplace monitoring data, inhalation studies, and information from cellular tests that show whether and how a chemical moves through the body are among the types of data the agency should seek, according to Sheri Blystone who works on regulatory affairs and product safety at the SNF Holding Co., a chemical manufacturer.

If the agency can't answer basic questions, it should explain how uncertain it is about the chemical's potential to injure people or the environment, several committee members said.

Using more tables and charts also could help summarize information, they said. For example, including logic models that map out questions the agency asked and answered in reaching its conclusions would be useful, Portier said.

It is strongly recommended that the agency better support its conclusions in future evaluations, said Barton, whose consulting business is based in Alpharetta, Ga.

"We want to set the right precedent," added Kathleen Gilbert, a microbiology and immunology professor at the University of Arkansas for Medical Sciences.

Confidential Business Information

One challenge the agency faces, and likely will continue to face, is how it should handle commercially valuable information companies voluntarily provide the agency for assessments.

The same chemical often is sold in many countries. A manufacturer of that chemical may have paid a significant amount of money to generate toxicity and other data to meet the registration requirements in some countries or regions like the European Union. If details of that information become public, other companies could benefit without having helped pay for the data.

The results of health and safety studies must be publicly available, Christina Franz, an attorney and senior director at the American Chemistry Council, told the committee in public comments June 20. But the "commercially valuable and competitive details" of the information should be protected from disclosure, she said.

The EPA can justify a company's need to keep certain information out of the public arena, Blystone said in summarizing remarks from several panel members. But, "it's important to give the public as much information as possible," she said.

Panelists praised the summary of BASF toxicology data the EPA released, saying it accurately reflected the Pigment Violet 29's potential to harm reproduction or development.

Next Steps

The agency scientists that evaluated the risks of the pigment need to discuss the committee's comments and read its full report, before deciding how to proceed, said Garrett Jewett, EPA's team lead for the assessment. The agency is striving to issue its final risk evaluation by December, he added.

Nine more draft chemical risk assessments are slated to come before the committee over the next few months. Those analyses will address: asbestos; 1-bromopropane; carbon tetrachloride; 1,4-dioxane; the three flame retardants known as the cyclic aliphatic bromide cluster (HBCD); methylene chloride; n-methylpyrrolidone; perchloroethylene; and trichloroethylene.

Precedent-Setting Critique of EPA's Chemical Review Launched (1)

Posted June 19, 2019, 3:57 PMUpdated June 19, 2019, 4:39 PM

- EPA's Science Advisory Committee on Chemicals critiques agency's first chemical risk evaluation
- Agency approaches, committee's critique to shape future analyses, regulations

Some EPA science advisers chafed June 19 at the black-and-white call the agency made when it decided a reddish-purple pigment doesn't pose unreasonable risks of injuring people or the environment.

The Environmental Protection Agency's conclusion is an "all or nothing" statement, said Henry Anderson, a member of the agency's Science Advisory Committee on Chemicals.

It would seem more accurate to give the public circumstance-based conclusions that described, for example, whether releases of the chemical from smokestacks would pose unreasonable risks or a statement that worker's risks are controlled by Occupational Safety and Health Administration (OSHA) requirements, Anderson, a physician and adjunct professor at the University of Wisconsin-Madison, said.

Stan Barone, deputy director for the chemical office's risk assessment division at EPA, said the Toxic Substances Control Act requires the agency to conclude whether specific ways a chemical is used, or its "conditions of use," pose an unreasonable risk.

The EPA is exploring different ways it could describe the varied risks a chemical poses, he said. But the agency wants to avoid making its risk evaluations so lengthy they become difficult to read, Barone said.

For example, one approach the agency tried resulted in 22 different statements to describe the risks one chemical would pose under one use scenario, he said. Any single chemical may have multiple uses.

If the agency concludes any use of a chemical poses an unreasonable risk, the agency must take action to regulate that risk, Barone said.

'Historic'

The draft risk evaluation the TSCA Science Advisory Committee on Chemicals is reviewing involves Pigment Violet 29. The sole U.S. manufacturer is Sun Chemical Corp., in Goose Creek, S.C.

About 90% of the chemical is used on site to make other chemicals, Jafrul Hasan, an agency branch chief, told the committee.

That leaves about 60,000 pounds that get shipped elsewhere for such uses as car paints and coatings, plastic and rubber products used primarily by the automotive and industrial carpeting industries, and less than two percent for commercial printing and consumer uses, he said.

Despite the limited production and use of the pigment, the EPA's evaluation of it is "historic," Daniel Rosenberg, an attorney with the Natural Resources Defense Council, told the committee during a public comment period.

EPA's decisions can pre-empt states from taking regulatory action on chemicals in all 50 states, he said.

"For the first time ever under TSCA—if EPA determines that a chemical does not pose an unreasonable risk—then states will be prohibited from taking regulatory action," Rosenberg said.

No industry representatives spoke June 19.

But the Auto Alliance submitted comments previously that the Pigment Violet 29 risks evaluation and review by the committee will likely set precedents for future agency evaluations.

The alliance represents the BMW Group, Ford Motor Co., Porsche Cars North America, Toyota, and other car manufacturers.

Insufficient Information

In comments before the panel, Jennifer McPartland, a senior scientist with the Environmental Defense Fund, said the EPA didn't have enough information about the pigment's toxicity or exposure to reach its "no unreasonable risk" conclusion.

Nor did the agency have the "best available science" TSCA requires, she said.

The EPA lacked details on how the pigment moves through the environment and into the food chain as well as information on the chemical's effects following long-term exposures, McPartland said. The agency also didn't have documentation of the amount of Pigment Violet 29 released into the environment and population exposures.

The advisory committee—established by the 2016 TSCA amendments—will meet through June 21.

Next Steps

It also will critique nine other chemical risk assessments in the coming months.

Two or three more draft risk evaluations will be released by June 28, Alexandra Dapolito Dunn, EPA's assistant administrator for chemical safety and pollution prevention, told the committee June 18.

Jeffery Morris, director of the EPA's chemicals office, invited the committee to point out during those reviews broader scientific issues the agency should address.

For example, if the EPA decides it needs chemical or other manufacturers to provide additional toxicity and exposure data to understand the risks a chemical may pose, TSCA requires the agency to seek that information using a step-wise or "tiered" approach in which simpler—often cheaper—information is requested before more complex, expensive information.

Workers Will Die Unless EPA Bans Solvent, Advocates Say

Posted June 10, 2019, 6:00 AM

- Training workers to safely use a deadly solvent won't work, say occupational physicians, others
- Most fatalities from methylene chloride between 1980 and 2018 were of workers

More laborers working with a toxic solvent will die while the EPA reconsiders the strategy to protect them, occupational physicians, advocates, and researchers predict.

At least three workers exposed to the paint stripping solvent, methylene chloride, died since 2017 when the Environmental Protection Agency proposed a rule(RIN:2070–AK07) to ban consumer and most commercial uses, said Jonathan Kalmuss-Katz, a staff attorney working on labor issues at Earthjustice.

Separate research released in April showed that 83 people died from methylene chloride exposure over nearly four decades.

"Now, tragically we'll see how many die" while the agency revisits its previous conclusion that workers faced unreasonable risks, and decides how it may reduce those risks, Kalmuss-Katz said June 5. He referred to a change the EPA made March 27 when it issued a final rule that banned consumer—but not workplace—uses of paint strippers made with the solvent.

Instead, the agency floated an idea (RIN:2070-AK48) to develop a training, certification, and limited access program to protect contractors, furniture strippers, antique restorers, and other workers who use methylene chloride to strip paints and other coatings. The EPA said the change in course was spurred by small businesses and other groups, who say they rely on the solvent.

Paint and coating removal products with methylene chloride will only be available to commercial users who are trained and certified to show they can use the chemical so that it doesn't present unreasonable risks, the agency told Bloomberg Environment in a June 6 email.

While some businesses supported training, most comments on the agency's training program, which were due May 28, rejected the training strategy and supported the agency's originally proposed commercial ban.

83 Deaths

"No one should be poisoned at work—EPA needs to follow the science and move forward with a commercial ban," said Veena Singla, a researcher at the University of California, San Francisco.

Singla pointed to recent research she and other scientists displayed at the American College of Medical Toxicology meeting in April and included in comments submitted to the EPA. Eighty-three people died from methylene chloride exposure between 1980 to 2018, according to that research.

Most of those deaths, 87%, occurred on the job.

"Specifically, paint removers have been responsible for the most fatalities, 63%, of all methylene chloride product types," the researchers said.

The Toxic Substances Control Act requires the agency to protect the public—including highly exposed individuals such as workers—from unreasonable risks that chemicals can pose, Earthjustice and other groups said in comments they submitted to EPA about its training proposal.

Alternatives 'Totally Ineffective'

Others, however, said the strippers are needed and supported training.

Businesses must use strippers made with methylene chloride because paints and coatings have improved so much over the past 50 years that alternative formulations—ones without the solvent—are often "totally ineffective," Benco Sales Inc., an industrial stripper manufacturer, told the EPA.

Banning methylene chloride strippers "would greatly reduce recyclability of durable products that are able to be refinished and reused, and would adversely affect small businesses," the company said.

The Halogenated Solvents Industry Alliance Inc. supports the agency's ban on consumer sales of methylene-based strippers and its idea to limit access to professional and commercial users who have been trained to use the products responsibly, said Faye Graul, the alliance's executive director.

A methylene chloride worker-training program that the U.K.'s Health and Safety Executive (HSE) developed could be a template for what the EPA could use, the alliance said.

U.K. Training Program

That program teaches workers about methylene chloride's health risks, and how ensuring adequate ventilation or other actions can reduce risks, Dave Arden, from HSE's Chemicals Regulation Division, said by email.

Workers also learn about available substitutes and non-chemical means to remove coatings, which can be less hazardous, he said. Only professional users who are in possession of an HSE certificate of competence can legally purchase and use methylene chloride-based paint strippers, he said.

The U.K. agency doesn't have data on the effectiveness of its training program, Arden said.

But the Environmental Defense Fund, which backs a commercial ban, told the EPA that the U.K.'s program isn't effective.

As evidence, it cited a criminal enforcement case HSE announced in January. The director of a U.K. company, Abel Ltd., was sentenced to 10 months in prison for selling methylene chloride paint strippers online without ensuring the purchasers were certified.

HSE didn't immediately reply to a request to clarify whether that incident showed the program wasn't working or showed it was, because the company director was sent to jail.

Thirty European countries have banned methylene chloride paint strippers, and their workers are using alternatives, the Environmental Defense Fund said.

Burns, Coma, Cancer, Death

Exposure to short-term, high concentrations of methylene chloride can cause slowed reaction times, impaired gait, coma, fluid buildup in the lungs, skin blistering or burns, seizures, and death, according to the Centers for Disease Control and Prevention.

Chronic exposure is "reasonably anticipated" to cause cancer, according to the Department of Health and Human Services.

The consumer ban the EPA issued was the first TSCA regulation prohibiting some uses of a chemical that the agency had issued since 1991, when the U.S. Court of Appeals for the Fifth Circuit in *Corrosion Proof Fittings v. EPA* overturned the agency's 1989 rulemaking that would have banned multiple uses of asbestos.

Disputed EPA Policy Clouds Second Set of New Chemical Rules

Posted April 16, 2019, 2:41 PM

- Designated uses of 11 chemicals would need to be reviewed, approved by EPA
- Strategy helps speed entry of new chemicals into commerce

The EPA has proposed a second batch of new chemical rules using an interpretation of the chemicals law disputed by environmental organizations.

The Environmental Protection Agency interprets the 2016 Toxic Substances Control Act amendments as allowing it to let a new chemical enter commerce even if some manufacturing methods or uses of that chemical might pose an undue risk.

Those potentially worrisome manufacturing methods or uses—allowing a worker to inhale a chemical that may harm lungs, for example—can be controlled through significant new use rules and compliance with existing worker safety or other laws, according to the agency. On April 15, it posted proposed new use rules for 11 new chemicals.

The strategy also helps speed the entry of new chemicals into commerce, Greg Schweer, chief of the EPA's new chemicals branch, said during a recent chemicals conference.

The Natural Resources Defense Council, however, maintains the agency's interpretation of TSCA violates that law. The 2016 TSCA amendments require the agency to consider and manage any unreasonable "intended, known, or reasonably foreseen" risks of a new chemical before it can be sold, the environmental group says.

"EPA continues to skirt Congress's requirement that it consider foreseeable uses of a new chemical before approving its use. EPA is not ensuring that new chemicals put into products—and to which workers may be exposed—are unlikely to pose an unreasonable risk, as the law requires," Daniel Rosenberg, an NRDC attorney told Bloomberg Environment.

"It's too early to say for certain whether there will be litigation, but Nancy Beck and the Trump EPA are definitely refusing to implement TSCA as Congress wrote it," he said. Nancy Beck, principal deputy assistant administrator in the EPA's chemicals and pesticides office, formerly worked for the American Chemistry Council, making her a frequent target for critics of the agency's current chemical policies.

Significant New Use Rules

Under the proposed rules, neither chemical manufacturers nor processors could use any of the 11 chemicals in ways that the agency is concerned about unless the company requested and got the agency's permission.

For example, many of the rules would prohibit any manufacture, processing, or use of a chemical in ways that could allow workers or other people to inhale it. Many rules also bar the release—above specific concentrations—of a chemical into water.

Unlike many regulations the EPA proposes, new use rules go into effect when they are proposed.

The idea is to require any company to give the EPA the opportunity to review any manufacturing method or use of a new chemical that raises concerns.

That makes even proposed significant new use rules "immediately protective across the supply chain," Bergeson and Campbell PC said in a recent memo.

The 11 new chemicals, many of which are identified by generic names, will be used for purposes that include making plastic, adhesives, and metalworking fluid.