Monday, June 24, 2019

The U.S. Environmental Protection Agency released on June 21, 2019, a proposed rule intended to reduce exposures to certain chemicals that are persistent, bioaccumulative, and toxic (PBT). EPA identified five chemicals pursuant to Section 6(h) of the Toxic Substances Control Act (TSCA): decabromodiphenyl ether (DecaBDE); phenol, isopropylated phosphate (3:1) (PIP (3:1)), also known as tris(4-isopropylphenyl) phosphate; 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); hexachlorobutadiene (HCBD); and pentachlorothiophenol (PCTP). The proposed rule would restrict or prohibit manufacture (including import), processing, and distribution in commerce for many uses of all of the chemicals except HCBD, for which EPA is proposing no regulatory action. For the other four chemicals, the proposed rule includes recordkeeping requirements, as well as additional downstream notification requirements for PIP (3:1). Publication of the proposed rule in the Federal Register will begin a 60-day comment period.

Background

Under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), TSCA Section 6(h) requires EPA to propose Section 6(a) regulatory action by June 22, 2019, on chemicals from the 2014 update of the TSCA Work Plan that meet the PBT requirements specified in Section 6(h). The proposed Section 6(a) rules must, pursuant to Section 6(h)(4), “address the risks” presented by the chemicals and reduce exposure “to the extent practicable.” EPA identified five PBT chemicals that meet the statutory criteria -- DecaBDE; PIP (3:1); 2,4,6-TTBP; HCBD; and PCTP.

What Action Is EPA Taking?

EPA is proposing to restrict or prohibit certain actions with respect to four of the five PBT chemicals subject to the rulemaking -- DecaBDE; PIP (3:1); 2,4,6-TTBP; and PCTP. As of the effective date of the final rule, affected persons would be required to maintain, for three years from the date the record is generated, ordinary business records that demonstrate compliance with the restrictions, prohibitions, and other requirements.

EPA states that the extent of exposure, the severity of the hazard, and thus the likely risk of these chemicals varies significantly. For example, according to EPA, the evidence suggests that human exposure to HCBD “is very limited due in large part to the high waste treatment efficiencies achieved by the chemical manufacturers.” Additionally, the amount and type of hazard information varies substantially, from relatively well studied chemicals (e.g., DecaBDE) to data-sparse chemicals (e.g., PCTP).

The proposed rule includes hazard summaries for each of the five PBT chemicals. According to the proposed rule, EPA “did not perform a systematic review of the literature to characterize the hazards of the five PBT chemicals, and instead performed a limited survey of the reasonably available scientific information.” EPA states that “[d]ue


to Congress’ direction in TSCA to expeditiously regulate PBTs on the 2014 Work Plan and because risk evaluations were not required by Congress, EPA prepared a fit-for-purpose summary of the hazards presented by the five PBT chemicals.” The proposed rule tabulates and briefly summarizes “[r]easonably available hazard information.” EPA requests comments making it aware of any more recent hazard information available. EPA notes that the hazard statements “are not based on a systematic review of the available literature and information may exist that could refine the hazard characterization.”

**DecaBDE**

EPA states that DecaBDE is a flame retardant that has been widely used in textiles, plastics, adhesives, and polyurethane foam. For DecaBDE, the proposed rule would prohibit the manufacture (including import), processing, and distribution in commerce of DecaBDE, and articles and products to which DecaBDE has been added except for the following:

- Manufacture, processing, and distribution in commerce for use in parts for new aircraft and aerospace vehicles, and distribution in commerce of the new vehicles containing such parts, for a period of three years;
- Manufacture, processing, and distribution in commerce for use in curtains in the hospitality industry, and the distribution of the curtains themselves, for a period of 18 months;
- Manufacture, processing, and distribution in commerce for use in replacement parts for the automotive and aerospace industries, and distribution in commerce of the replacement parts themselves;
- Processing for recycling and distribution in commerce for recycling of plastic that contained DecaBDE before the plastic was recycled (i.e., the plastic to be recycled is from articles and products that were originally made with DecaBDE), as long as no new DecaBDE is added during the recycling process; and
- Processing and distribution in commerce of articles and products made from recycled plastic that contained DecaBDE before the plastic was recycled, as long as no new DecaBDE was added during the recycling process or to the articles and products made from the recycled plastic.

The hazard statement states:

DecaBDE is toxic to aquatic invertebrates, fish, and terrestrial invertebrates. Data indicate the potential for developmental, neurological, and immunological effects, general developmental toxicity and liver effects in mammals. There was some evidence of genotoxicity. There was some evidence of carcinogenicity.

**PIP (3:1)**

PIP (3:1) is a flame retardant, a plasticizer, and an anti-compressibility and anti-wear additive. According to EPA, it is used in lubricants and hydraulic fluids and in the manufacture of other compounds. For PIP (3:1), also known as tris(4-isopropylphenyl) phosphate, the proposed rule would prohibit processing and distribution in commerce of the chemical substance and products containing the chemical substance, except for the following:

- Processing and distribution in commerce for use in aviation hydraulic fluid;
- Processing and distribution in commerce for use in lubricants and greases; and
- Processing and distribution in commerce for use in new and replacement parts for automobiles and other motor vehicles, and the distribution in commerce of the parts to which PIP (3:1) has been added.

In addition, the proposed rule would prohibit releases to water from the non-prohibited processing, distribution in commerce, and commercial use activities. Persons manufacturing, processing, and distributing PIP (3:1), and products containing PIP (3:1), in commerce would be required to notify their customers of these restrictions.

The hazard statement states:

PIP (3:1) is toxic to aquatic plants, aquatic invertebrates, sediment invertebrates and fish. Data indicate the potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, and heart in mammals.

**2,4,6-TTBP**

EPA states that 2,4,6-TTBP is an antioxidant that can be used as a fuel additive or lubricant additive, as an intermediate in the manufacture of other compounds, and as a waste fuel. For 2,4,6-TTBP, the proposed rule
would prohibit the distribution in commerce of 2,4,6-TTBP and products containing 2,4,6-TTBP in any container with a volume of less than 55 gallons for any use to prevent the use of 2,4,6-TTBP as a fuel additive or fuel injector cleaner by consumers and small commercial operations (e.g., automotive repair shops, marinas). According to the proposed rule, it is EPA’s intent that the 55-gallon container restriction will ensure the continued fuel additive or fuel injector cleaner use of this PBT only by commercial operators who have the capacity to protect their workers who may come into contact with 2,4,6-TTBP and whose workplaces are generally subject to the standards promulgated by the Occupational Safety and Health Administration (OSHA). The restriction also would prohibit processing and distribution in commerce of 2,4,6-TTBP, and products containing 2,4,6-TTBP, for use as an oil or lubricant additive, regardless of container size.

The hazard statement states:

2,4,6-TTBP is toxic to aquatic plants, aquatic invertebrates, and fish. Data indicate the potential for liver and developmental effects.

**HCBD**

HCBD is produced as a byproduct in the production of chlorinated solvents and has also been used in the past as an absorbent for gas impurity removal and as an intermediate in the manufacture of rubber compounds. For HCBD, EPA states that it has evaluated the uses of hexachlorobutadiene and is proposing no regulatory action.

The hazard statement states:

HCBD is toxic to aquatic invertebrates, fish, and birds. Data indicate the potential for renal, liver, and developmental effects in mammals. HCBD has been identified as a possible human carcinogen.

**PCTP**

PCTP is used in the manufacture of rubber compounds. For PCTP, the proposed rule would prohibit the manufacture (including import), processing, and distribution in commerce of PCTP, and products containing PCTP, unless in concentrations at or below one percent by weight.

The hazard statement states:

PCTP is toxic to protozoa, fish, terrestrial plants, and birds. Data for analogous chemicals (pentachloronitrobenzene and hexachlorobenzene) indicate the potential for liver effects in mammals and systemic (body weight) effects for PCTP in mammals (no repeated-dose animal or human epidemiological data were identified for PCTP).

**Potential Exposures that EPA Is Not Proposing to Regulate**

EPA states that in general, there are some activities or exposures that it is not proposing to regulate, even though the Exposure and Use Assessment identified exposures or potential exposures. One of these is disposal. According to EPA, under the Resource Conservation and Recovery Act (RCRA), “there are comprehensive regulations governing the disposal of hazardous and non-hazardous wastes.” EPA notes that it is also not generally proposing to use its TSCA Section 6(a) authorities to regulate commercial use of products containing the PBT chemicals. EPA states:

For example, EPA is not proposing to prohibit the continued commercial use of articles or products that contain DecaBDE or PIP (3:1), such as commercial aircraft. Such a prohibition would not be practicable; to the contrary, it would be extremely burdensome, necessitating the identification of products containing DecaBDE or PIP (3:1), and the disposal of countless products, such as televisions and computers, that would have to be replaced with new products. If the continued commercial use of vehicles containing DecaBDE or PIP (3:1) were prohibited, it would result in widespread economic impacts and disruption in the channels of trade while the prohibited parts or fluids were identified and replaced. EPA believes that, for most products containing the PBT chemicals, it would be either extremely burdensome, for vehicles, or unreasonable, because of the low concentrations of PCTP in golf balls, for example, and, thus, impracticable to prohibit or otherwise restrict the continued commercial use of the products.

EPA is not proposing to regulate occupational exposure directly through mandated controls such as engineering controls or use of personal protective equipment (PPE). According to the proposed rule, EPA “expects there is compliance with federal and state laws, such as worker protection standards, unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will prevent occupational exposures that are capable of causing injury from occurring.” EPA acknowledges that OSHA has not established permissible exposure limits (PEL) for any of the five PBT chemicals, but states that under Section 5(a)
of the Occupational Safety and Health Act of 1970 (OSH Act), “each employer has a legal obligation to furnish to each of its employees a place of employment that [is] free from recognized hazards that are causing or are likely to cause death or serious physical harm.” EPA “expects that employers will require, and workers will use, appropriate PPE consistent with 29 CFR 1910.132, taking into account employer-based assessments, in a manner sufficient to prevent occupational exposures that are capable of causing injury.”

Reasonably Ascertainable Economic Consequences of the Proposed Rule

Overview of Cost Methodology

According to the proposed rule, EPA has evaluated the potential costs of the proposed and primary alternative regulatory actions for the PBT chemicals. EPA estimated costs of the proposed rule based on the assumption that under regulatory limitations on the PBT chemicals, processors that use the regulated chemical in their products would switch to available alternative chemicals to manufacture the product, or to products that do not contain the chemical. EPA states that approaches for the analysis of each regulated chemical varied according to whether the focus was on chemical substitutes or product substitutes, depending on the uses for each chemical. For DecaBDE and PCTP, EPA assessed the costs based on chemical substitutes only. For PIP (3:1) and 2,4,6-TTBP, EPA assessed the costs based on product substitutes where product information was more substantial than information on chemical substitutes alone.

EPA estimated substitution costs on the industry level using the price differential between the cost of the chemical (or chemical product) and identified substitutes. EPA estimated costs for rule familiarization and recordkeeping based on burdens estimated for other similar rulemakings. EPA annualized costs over a 25-year period. According to EPA, other potential costs include, but are not limited to, those associated with testing, reformulation, release prevention, imported articles, and some portion of potential revenue loss. EPA discusses these costs only qualitatively, however, due to lack of data availability to estimate quantified costs. More details of this analysis are presented in “Economic Analysis for Proposed Regulation of Persistent, Bioaccumulative, and Toxic Chemicals under TSCA section 6(h)” (Economic Analysis), which will be available in Docket EPA-HQ-OPPT-2019-0080 at https://www.regulations.gov when the proposed rule is published in the Federal Register.

Estimated Costs of Proposed and Primary Alternative Regulatory Actions

According to EPA, total quantified annualized industry costs for the proposed rule is $43.1 million (at both three percent and seven percent discount rates). Total quantified annualized industry costs for the primary alternative regulatory action are $414 million (at both three percent and seven percent discount rates). The proposed rule provides the following costs for each PBT chemical:

- DecaBDE -- Total quantified annualized industry costs for the proposed rule under both the proposed and the primary alternative regulatory actions are zero;
- PIP (3:1) -- Total quantified annualized industry costs for the proposed rule are $34.7 million (at both three percent and seven percent discount rates), and $38.1 million (three percent discount rate) or $37.6 million (seven percent discount rate) for the primary alternative regulatory action;
- 2,4,6-TTBP -- Total quantified annualized industry costs for the proposed rule under both the proposed and the primary alternative regulatory actions are $8.4 million (at both three percent and seven percent discount rates);
- HCBD -- The proposed action is not to regulate; therefore, there is no industry cost associated. For HCBD, the annualized costs to industry associated with the primary alternative regulatory action are estimated to total $368 million (at both three percent and seven percent discount rates); and
- PCTP -- Total quantified annualized industry costs for the proposed rule are $0.03 million (at both three percent and seven percent discount rates), and negligible for the primary alternative regulatory action.

EPA states that it based total annualized Agency costs associated with implementation of the proposed rule on its best judgment and experience with other similar rules. For the proposed regulatory action, EPA estimates it will require three full-time equivalents (FTE) at $465,000 per year. For the primary alternative regulatory option, EPA estimates 3.5 FTE at $543,000. Total quantified annualized social costs for the proposed rule are $43.5 million (at both three percent and seven percent discount rates). Total quantified social costs for the proposed rule under the primary alternative regulatory action are $415 million (at both three percent and seven percent discount rates).

Issues for Comment
EPA requests comment on all aspects of the proposed rule, including the proposed regulatory actions for each of the PBT chemicals, the primary alternative regulatory actions, and any other options that EPA has considered or should consider. In particular, EPA requests comment on its proposed determinations with respect to whether exposure is likely and whether EPA’s proposed regulatory actions achieve the statutory directives to “address the risks of injury to health and the environment that the Administrator determines are presented by the chemical substance and [...] reduce exposure to the substance to the extent practicable.” EPA also requests comment on all aspects of the Economic Analysis accompanying the proposed rule. According to the proposed rule, in taking final action, following review of comments, EPA may require exposure reductions beyond those proposed here, or may reduce the scope of the proposed exposure reductions.

Commentary

We commend EPA for meeting another deadline under new TSCA, in this case a rather imposing one that required EPA to propose regulations on certain PBT chemicals within three years after enactment. While we applaud EPA’s ability to issue a timely proposal, we note with chagrin the very tight deadline imposed on EPA by Congress and the fact that no risk evaluation was required to be developed in producing the proposal. Regulating chemicals in commerce is a complex undertaking that requires adequate time and understanding to allow for informed decision-making. The limitations that EPA points out in its hazard, exposure, and risk understanding should be of concern to stakeholders. Nonetheless, statutory deadlines and requirement are just that, legal requirements that EPA is obliged to meet.

The proposed regulation is likely to produce comments in opposition to the approach outlined, particularly with regard to EPA’s proposal largely to refrain from regulating commercial use of the chemicals and to rely on other laws such as RCRA and the OSH Act concerning areas falling under their scope. While we are sympathetic to the concept that specific areas are best regulated by the statute that is specifically crafted and intended to oversee that area, we are well aware that this is not the view that some stakeholders hold when considering the effect of the TSCA Amendments. Another aspect that will be interesting to watch as it plays out is EPA’s approach to and the forthcoming comments on the requirement in TSCA Section 6(h)(4) that EPA’s Section 6(a) regulation “reduce exposure to the substance to the extent practicable.” Interestingly, EPA uses an extent practicable argument in part when explaining its proposal not to regulate in areas otherwise covered by RCRA and the OSH Act.

Additional Resources

As noted above, EPA will open the docket for the proposed rule, Docket ID EPA-HQ-OPPT-2019-0080 at https://www.regulations.gov, when it publishes the proposed rule in the Federal Register. In 2016, EPA established public dockets for each of the five PBT chemicals to facilitate receipt of information on exposure and use that may be useful to EPA’s rulemaking effort:

- DecaBDE --;
- PIP (3:1) -- Docket ID EPA-HQ-OPPT-2016-0730;
- 2,4,6-TTBP -- Docket ID EPA-HQ-OPPT-2016-0734;
- HCBD -- Docket ID EPA-HQ-OPPT-2016-0738; and
- PCTP -- Docket ID EPA-HQ-OPPT-2016-0739.

On Thursday, September 7, 2017, EPA hosted a webinar, “Use Information for Persistent, Bioaccumulative, and Toxic (PBT) Chemicals Under TSCA Section 6(h).” The webinar provided background on the requirements for PBT chemicals under amended TSCA and explained to interested parties the process for gathering use and exposure information for the five PBT chemicals. EPA has posted the meeting agenda and its presentation.

EPA conducted letter peer reviews of exposure and hazard information for the five PBT chemicals. EPA also accepted written comments on the charge questions and other documents to be considered by the peer reviewers. These materials are available online in Docket ID EPA-HQ-OPPT-2018-0314.

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