Expert Focus: What are the implications of the US EPA's expected final rule on persistent, bioaccumulative and toxic chemicals?

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Among many deadlines bearing down on the US EPA under TSCA, one relates explicitly to persistent, bioaccumulative and toxic (PBT) chemicals.

PBT chemicals have long been recognised to behave differently in the environment and in biological systems from non-PBT substances. The US Congress acknowledged this when amending TSCA in 2016 by crafting special provisions under the Regulation's Section 6(h) that were uniquely applicable to PBTs. Last July, the EPA proposed a rule that would implement the section, but this caused much controversy and led to comments from, among others, the retail, coatings and aerospace sectors and NGOs. It also raised several novel legal issues relating to TSCA's interpretation.

Nevertheless, the EPA must issue a final rule within 18 months of the proposal, that is to say by December 2020. This article focuses on the novel issues that have arisen and the implications of their resolution on affected stakeholders.

Background

PBT chemicals are known to remain in the environment and in biological systems for long periods of time. They thus pose unique challenges for chemical producers, users, product manufacturers, and regulators. In light of these unique and often challenging attributes, TSCA

Section 6(h) imposes specific requirements on the EPA to identify PBT chemicals for "expedited" action (meaning that TSCA Section 6(b) risk evaluations are not required) and to issue a final rule that addresses any risks the agency determines are presented by the chemicals and, as far as possible, reduces exposure.

In last July's proposed rule, the EPA identified five chemicals that meet the statutory criteria for PBT chemicals:

- 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);
- pentachlorothiophenol (PCTP) and
- hexachlorobutadiene (HCBD);

The EPA proposed restricting, or prohibiting certain actions, with respect to the first four. However, it proposed not regulating HCBD under TSCA Section 6(h). This was based on its view that measures already taken under other federal environmental and occupational authorities, such as the Clean Air Act and the Resource Conservation and Recovery Act, made appreciable further reductions in HCBD exposure not practicable.

The proposed rule includes hazard summaries for each of the five PBT chemicals, but no risk evaluations. Consistent with TSCA Section 6(h), however, the *Federal Register* notice says that

the EPA "did not perform a systematic review of the literature to characterise the hazards of the five PBT chemicals, and instead performed a limited survey of the reasonably available scientific information."

The agency noted that "[d]ue to Congress's 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 EPA admitted that these limited surveys only summarise reasonably available hazard information and that the hazard statements "are not based on a systematic review of the available literature and information may exist that could refine the hazard characterisation."

For three of the four PBT chemicals for which the EPA determined regulation was necessary under TSCA Section 6(h), the agency proposed to prohibit manufacture – including import, processing, and distribution in commerce – of the substances in products and manufactured articles. Limited exceptions apply. For 2,4,6-TTBP, it proposed to prohibit distribution of products containing the substance in containers with a volume of less than 55 gallons and processing or distributing the substance in commerce for use as an oil and lubricant additive. This restriction would effectively eliminate the use of the chemical as a retail fuel additive, or fuel injector cleaner, by consumers.

Key issues and implications

Before outlining the key issues raised in the rulemaking, one topic on which many stakeholders agreed, and noted in their comments on the rule, was the considerable stakeholder engagement the EPA conducted in preparing its proposed rule. The agency obtained input from

businesses, experts and other potentially impacted stakeholders. It also hosted a public meeting and devoted significant energy to obtaining stakeholder views. The EPA is to be commended for its efforts.

The EPA can be expected to address several key issues in the final rule, the outcome of which will have significant implications.

Presumptive compliance with existing regulation:

The EPA has proposed largely refraining from regulating commercial uses of the chemicals and instead relied on other laws to address exposure to them. These include:

- the Resource Conservation and Recovery Act;
- the Clean Air Act; and
- the Occupational Safety and Health Act.

In deferring to other statutory authorities to address potential exposure opportunities that may pose a risk, commenters have both supported and criticised the agency.

Industry stakeholders found the presumption of compliance appropriate, while others claimed the approach was inconsistent with TSCA. The EPA's reliance upon other federal authorities is an important and recurrent theme in its TSCA implementation approach and a reasonable interpretation of the law. The agency's interpretation of the phrase "to the extent practicable" in TSCA section 6(h) relies, in part, on its presumptive compliance approach in proposing not to regulate in areas otherwise covered by the RCRA, CAA, and Osha. It is expected that in the final

rule the EPA will continue to rely upon this presumptive compliance approach. To do otherwise would almost certainly impose extraordinary and unreasonable burdens on itself and regulated stakeholders. It would also result in much more regulation of existing uses of these chemicals.

Forbearance in regulating uses of products containing the PBTs:

The EPA expressly noted in the proposed rule that it would "not generally propos[e] to use its TSCA section 6(a) authorities to regulate commercial use of products containing the PBT chemicals." In other words, it chose not to prohibit the continued use of existing products and articles that contain any of the identified PBT chemicals. The agency said in the proposal that such regulation would not be practicable and would be extremely burdensome. Assuming the final rule reflects this interpretation, industrial stakeholders can take comfort in the fact that they will largely avoid any commercial impact with respect to existing inventories of products that use or articles that contain the PBTs at issue. The EPA's focus would be on newly manufactured products and articles. This is good news for the automotive and aerospace industries, among others. If the final rule retreats from this position, current uses of the PBT chemicals could be subject to restriction. Stakeholders may wish to consider this possible, but unlikely, outcome.

Application of statutory exemptions to articles and replacement parts:

Under TSCA, the EPA is directed by Section 6(h) to issue rules pursuant to TSCA Section 6(a). It must do this in accordance with TSCA Section 6(c)(2), which exempts replacement parts and articles from Section 6 prohibitions and restrictions unless certain conditions are met. There are

several aspects of the proposed rule that raise interesting questions pertinent to the application of these exemptions.

TSCA Section 6(c)(2)(D) exempts replacement parts for complex durable goods and complex consumer goods, unless the agency finds that the replacement parts "contribute significantly" to the risk the EPA found in its risk evaluation of the subject chemical substance.

Similarly, under TSCA Section 6(c)(2)(E), articles containing a targeted chemical substance are subject to restriction "only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation" conducted by the EPA under TSCA Section 6(b).

The agency says in the proposal that it interprets Section 6(h) to require it to issue a rule under Section 6(a) to satisfy Section 6(h) requirements "using the regulatory prohibitions and other restrictions identified in TSCA section 6(a)(1)-(7)" and applying Section 6 provisions in a way that is consistent with Section 6(h), "but not applying those provisions of TSCA section 6(c) [the exemptions] that conflict with TSCA section 6(h), in the sense that those provisions assume the existence of a TSCA section 6(b) risk evaluation ..." In other words, the EPA interprets TSCA as allowing the elimination of these statutory exemptions even in the absence of a risk evaluation and any meaningful record evidence that the replacement part or article contributes to the identified risk that the agency is seeking to regulate. The EPA invited public comment on its construction of the law in the proposed rule.

A number of commenters to the consultation expressed significant concern with the EPA's interpretation. Some argued that because the agency had elected not to conduct risk evaluations, the exemptions for replacement parts and articles are all the more necessary. The absence of any record evidence that the EPA had attempted to assess how replacement parts "contribute significantly" to a risk, or how PBT substances in articles must necessarily be restricted to "address the identified risks from exposure to the chemical substance or mixture" in an article where no risk evaluation was conducted is counterintuitive. Given the lack of statutory clarity regarding the relevance of the article and replacement part exemptions for TSCA Section 6(h) rules where there has been no risk evaluation, the EPA's legal interpretation seems uncertain and would benefit from greater explanation in the final rule's preamble discussion.

The resolution of this issue, in particular, could have significant implications for importers of articles containing the substances and, of course, current users dependent upon replacement parts. In crafting the article exemption language, Congress showed a desire to impose restrictions on articles only to the extent necessary to address risks arising from exposure to the substances from articles, and to restrict replacement parts if they are found to "contribute significantly" to an identified risk. This explicit Congressional intent imposes, according to some, a higher burden on the EPA to justify with record evidence the elimination of these exemptions than is reflected in the rulemaking record.

Resolution of this issue in the final rule will have an especially significant impact on importers of articles and users dependent upon replacement parts containing the PBT substances. One

outcome is the restored applicability of these exemptions such that importers would be allowed to import articles into the US, and replacement parts would not be prohibited to the extent now contemplated under the proposed rule. This is a result that industrial interests would welcome.

The EPA's final rule is expected to be issued in December. Stay tuned to this important, precedent-setting initiative.

The PBTs and their risk management details

decaBDE:

A flame retardant that has been widely used in textiles, plastics, adhesives and polyurethane foam. The agency says that it is an aquatic toxicant, with data indicating it has potential for developmental, neurological and immunological effects, liver effects, and carcinogenicity. It has proposed to prohibit its manufacture, import, processing and distribution in commerce, with the following exceptions:

- in new aircraft and aerospace vehicles, for a period of three years;
- in curtains for use in the hospital industry for 18 months;
- in replacement parts for the automotive and aerospace industries; and
- in certain recycling applications where the plastic to be recycled was originally made with decaBDE, as well as the articles and products made from these materials.

PIP (3:1):

A flame retardant, a plasticiser, and an anti-compressibility and anti-wear additive. It is used in lubricants and hydraulic fluids and in the manufacture of other compounds. The EPA has determined that it is an aquatic toxicant, with potential for reproductive, developmental and neurological effects, as well as impacts on systemic organs. It is seeking to prohibit the processing and distribution in commerce of the substance, and products containing it, with the exception of:

- aviation hydraulic fluid;
- lubricants and greases; and
- for use in new and replacement parts for the automotive industry.

The rule also proposes to impose customer notification requirements, and prohibit releases to water from the remaining commercial activities.

2,4,6-TTBP:

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. The identified hazards associated the substance include aquatic toxicity, with potential liver and developmental effects.

The rule looks to:

- prohibit the processing and distribution of the substance, or products containing it, for use as an oil or lubricant additive in containers of any size; and
- prohibit the distribution of the substance, or products containing it, in any container with a volume under 55 gallons. This is in order to "effectively prevent" the substance's use as a fuel additive for fuel injector cleaner by consumers and small commercial operations, such as auto repair shops or marinas.

PCTP:

Used in the manufacture of rubber compounds. The agency has determined it to be toxic to protozoa, fish, terrestrial plants and birds. Data for analogous substances indicate potential for liver and reproductive effects.

The proposal looks to prohibit the manufacture, processing and distribution in commerce of the substance, or products containing it, in concentrations above 1% by weight.

HCBD:

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. The EPA has found it to be toxic to aquatic

invertebrates, fish and birds, and to be a possible human carcinogen. Data also indicate potential for renal, reproductive and developmental effects.

However, the EPA says it has evaluated the conditions of use of the substance and is proposing to take no action on it because the exposures are already regulated under other environmental laws.