

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Comments of Safer Chemicals Healthy Families, Defend Our Health, and
Natural Resources Defense Council on Final Rules for Persistent,
Bioaccumulative and Toxic Chemicals Under TSCA Section 6(h)

Submitted via Regulations.gov (May 17, 2021)
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On March 16, 2021, the Environmental Protection Agency (EPA) requested additional public comments on five final rules issued by the previous Administration under section 6(h) of the Toxic Substances Control Act (TSCA).¹ These rules, promulgated on January 6, 2021², regulate five persistent, bioaccumulative, and toxic (PBT) chemicals that EPA determined met the criteria for expedited action under section 6(h).³ EPA's notice invites feedback on "whether there are further exposure reductions that could be achieved, including exposure reductions for potentially exposed or susceptible subpopulations and the environment." It also seeks input on compliance concerns, first raised by industry after finalization of the PBT rules, regarding the prohibition on processing and distribution of PIP (3:1) for use in articles and of these articles themselves.

Safer Chemicals Healthy Families, Defend Our Health, and Natural Resources Defense Council submit these comments in response to EPA's March 21 request. Our organizations are national and grassroots groups committed to assuring the safety of chemicals used in our homes, workplaces and the many products to which our families and children are exposed each day. We took a leadership role during the TSCA legislative process, advocating the most protective and effective legislation possible to reduce the risks of toxic chemicals in use today.

Added to TSCA by Congress in 2016, section 6(h) is based on the long-standing recognition by the scientific community, EPA and international bodies of the special dangers that PBTs pose to people and ecosystems as a result of their long-term presence, broad distribution and accumulation in living organisms and the natural environment. To address these dangers, section 6(h) creates a fast-track process for stringently restricting manufacture, use and disposal of chemicals determined by EPA to have PBT characteristics. These restrictions must reduce exposure to these PBTs to the extent practicable, thereby limiting further build-up in the environment and biota and the harmful long-term consequences that will result. Section 6(h) presumes that chemicals determined to be PBTs are harmful to the health and the environment and must be restricted without further risk evaluation or analysis of costs and benefits.

Section 6(h) identifies several exacting criteria that must be satisfied to justify PBT regulation. The five PBTs subject to the final rules satisfy all these criteria. They score high for both persistence and bioaccumulation or high for one and moderate for the other based on the 2012

¹ 86 Fed. Reg. 14398

² 86 Fed. Reg. 894 (PIP (3:1)).

³ These chemicals are 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP) (CASRN 732-26-3); decabromodiphenyl ether (decaBDE) (CASRN 1163-19-5); phenol, isopropylated phosphate (3:1) (PIP (3:1)) (CASRN 68937-41-7); pentachlorothiophenol (PCTP) (CASRN 133-49-3); and hexachlorobutadiene (HCBd) (CASRN 87-68-3).

Work Plan methodology that Congress incorporated in the TSCA amendments. EPA has demonstrated a reasonable basis to conclude that the five PBTs are toxic. And it has further shown that people and the environment are likely to be exposed to the PBTs and that exposure and release are significant and widespread.

As we show in these comments, we are disappointed that the final rules do not fully prevent buildup and accumulation of the five PBTs in people and the environment as required by Congress. We recommend several necessary strengthening changes in the rules to comply with the letter and intent of section 6(h).

We are also troubled by EPA's unwarranted use of enforcement discretion to delay compliance with the PIP (3:1) rule. Going forward, EPA must avoid further compromising important safeguards in the final rule against exposure to this highly persistent, accumulative and toxic substance.

Strengthening the Final PBT Rules

- Section 6(h)(4) directs EPA “to reduce exposure” to relevant PBTs “to the extent practicable.” Court decisions have held that, where used in a statute, the term practicable “imposes a clear duty on the agency to fulfill the statutory command to the extent that it is feasible or possible.” The term “feasible” in turn has been interpreted to mean technically and economically achievable – i.e. doable using available or foreseeable technology and without “massive dislocation” of the affected industry. Departing from this precedent, however, EPA construes “practicability” to allow consideration of costs, benefits, reasonableness and other factors that conflict with the plain meaning and core objectives of section 6(h). Applying these impermissible factors, EPA’s proposal exempts several uses of the 5 PBTs from restriction under section 6(h) without showing that restricting these uses is “impracticable.” This violates the plain language of section 6(h).
- In addition, EPA fails to justify these exemptions on the basis of the framework in section 6(g) of TSCA for exempting uses of a chemical from section 6(a) requirements. The section 6(g) criteria require specific findings that EPA has failed to make. They also require exemptions to include time limits and other conditions necessary to protect health and the environment. EPA must go back to the drawing board and apply the requirements of section 6(g) to all the uses of the five PBTs exempt from its final rule. We believe that many of these uses will not meet the high bar for use exemptions that section 6(g) sets and that the exemptions should be revoked.
- EPA has taken the position that no regulation of occupational exposure is warranted under section 6(h). However, section 6(h)(4) broadly directs EPA “to reduce exposure” to the 5 PBTs without differentiating between pathways of exposure or exposed subpopulations. As EPA’s use and exposure assessment confirms, workers have

significant exposure to the 5 PBTs (often at higher levels than the rest of the population) and these PBTs accumulate in their bodies, potentially harming them, their offspring and future generations.

- The final rules fail to impose any requirements on disposal of the 5 PBTs. Disposal is a major pathway for environmental release of PBTs and thus a significant contributor to their long-term buildup in biota and environmental media. EPA argues that it need not regulate disposal under section 6(h) in light of the waste management regime in the Resource Conservation and Recovery Act (RCRA). But the final rules do not address how and to what extent RCRA requirements apply to the 5 PBTs and why additional limitations on disposal are unwarranted to fulfill the requirements of section 6(h). Disposal is within the TSCA definition of “condition of use” and section 6(a) plainly authorizes regulation of disposal. Thus, EPA must now examine waste management practices for the five PBTs and revise the rules to impose additional restrictions on disposal to the extent practicable as required by section 6(h).
- Continued use of PBT-containing articles and products in commerce is also a substantial source of PBT exposure, as EPA itself finds for DecaBDE and PIP (3:1). However, EPA’s rules exempt articles in use based on a sweeping determination that restrictions would be “extremely burdensome” and “unreasonable.” EPA does not substantiate this assertion or conduct any analysis of options available under section 6(a) that would be effective in reducing exposure to PBTs contained in in-use articles. EPA must carefully examine these options and revise its final rules to place restrictions on use of PBT-containing articles to the extent practicable.

Preventing Unjustified Delays in Compliance that Weaken Essential Prohibitions on the Presence of PIP (3:1) in Articles

- Following the promulgation of EPA’s final rule for PIP (3:1) on January 6, industry groups raised – for the first time – concerns about the difficulty of eliminating it from articles subject to the rule’s restrictions. Industry has now claimed that it is impossible to remove PIP (3:1) from these articles by the rule’s effective date without catastrophic economic consequences. Yet the regulated community has been on notice of EPA’s intention to regulate PIP (3:1) under TSCA since 2014 and made no effort to alert the Agency to its concerns until after a final rule was in place 7 years later. It is unfathomable why well-staffed industry associations based in Washington DC should be excused from reading the Federal Register, filing comments and responding to EPA’s requests for information – elementary tasks that our underfunded organizations and other commenters had no trouble performing during the PBT rulemaking.
- EPA’s Acting Assistant Administrator for Chemical Safety and Pollution Prevention has acknowledged that, “[d]espite EPA’s extensive outreach, most stakeholders contacting EPA after the rule was finalized did not comment on the proposal or otherwise engage with the Agency on the PIP (3:1) rulemaking, and do not appear

to have previously surveyed their supply chains to determine if PIP (3:1) was being used.”

- Despite industry’s inexcusable negligence, on March 8, 2021, EPA issued a No Action Assurance effectively suspending the rule’s prohibitions on the processing and distribution of PIP (3:1) for use in articles for 180 days. We believe this application of enforcement discretion was unwarranted under EPA policies in light of industry’s extreme lack of diligence in tracking, let alone complying with, these prohibitions and the risk of harm to health and the environment in delaying compliance, which EPA inexplicably ignored when issuing its No Action Assurance. EPA’s reliance on enforcement discretion in this instance rewards industry for ignoring the rulemaking process and sets a precedent that will weaken future compliance with environmental laws.
- Our groups strongly oppose the exercise of enforcement discretion to further extend the rule’s compliance date for PIP (3:1)-containing articles. This mechanism is not only unjustified under EPA policy but deprives the public of the opportunity to comment and seek judicial review.
- Any further extension should thus be accomplished through rulemaking to amend the PBT rule in accordance with TSCA section 6(d), which requires that rules under section 6(h) take effect “as soon as practicable.” We have seen no evidence to date that the current compliance date (as extended by six months through the No Action Assurance) is “impracticable” and urge EPA to reaffirm that date until and unless industry can make a compelling case for more time under section 6(d).
- Similarly, we oppose revising the PBT rule to exempt PIP (3:1)-containing articles, as some industry representatives have suggested. The current record provides no basis to conclude that these articles meet the stringent criteria for use exemptions in section 6(g) and excluding them from PBT restrictions would defeat the purposes of section 6(h).
- In fact, EPA has failed to justify under section 6(g) the several exclusions now included in the PIP (3:1) rule. These exclusions should be reexamined in light of the section 6(g) criteria and either removed from the final rule or narrowed to strengthen protection of health and the environment.

I. EPA MUST MAKE SEVERAL NECESSARY STRENGTHENING CHANGES IN THE RULES TO COMPLY WITH THE LETTER AND INTENT OF SECTION 6(h)

A. Congress Placed Stringent Restrictions on PBTs Because of Their Long-Term Build-Up in the Environment and Accumulation in Biological Systems

The serious and unique threats posed by PBTs to human health and the environment have long been recognized by EPA and other authorities. As EPA states in its March 17 notice, “PBT chemicals are of particular concern in the Agency’s efforts to protect human health and the

environment because they are toxic and remain in the environment for long periods of time and can build up or accumulate in the body.”⁴

It is broadly accepted that the special characteristics of PBTs dictate a comprehensive, multi-media strategy to reduce exposure and release – and thus potential accumulation in biological systems and the environment – to the lowest levels possible. This is the goal of section 6(h). It creates an expedited rulemaking process for imposing restrictions on chemicals determined by EPA to possess PBT properties using stringent criteria. Reflecting a sense of urgency, rules imposing these restrictions must be proposed no later than June of 2019 and finalized 18 months thereafter. Section 6(h)(2) states that, in contrast to other chemicals, EPA is not “required to conduct risk evaluations” on PBTs subject to section 6(h). This demonstrates that Congress presumed PBTs to be harmful and believed a risk determination is unnecessary to justify eliminating their presence in commerce and the environment. Section 6(h) is explicit about this objective: it unconditionally calls for EPA “to reduce exposure to [a PBT] substance to the extent practicable.”

B. The Five Substances Subject to EPA’s Proposal Meet the TSCA Criteria for Regulation under Section 6(h)

Section 6(h)(1) provides that its requirements apply to chemicals that (1) are identified in the 2014 update of the TSCA Work Plan for Chemical Assessments and scored high for both persistence and bioaccumulation, or high for one and either high or moderate for another, based on EPA’s 2012 Work Plan methodology, (2) do not fall within statutory exclusions for metals and certain previous regulatory actions, and (3) were not the subject of timely industry requests for risk evaluations as described in section 6(h)(5). As EPA has demonstrated, the five chemicals targeted for restriction under section 6(h) all scored high or moderate for persistence and bioaccumulation properties using the 2012 Workplan methodology.⁵ Moreover, none of the five chemicals is a metal and EPA has excluded two PBTs for which industry has requested that the Agency conduct TSCA risk evaluations.

Under section 6(h)(1)(A), EPA must also have a “reasonable basis to conclude” that a chemical meeting the criteria for persistence and bioaccumulation is “toxic.” To meet this requirement, EPA must identify data or some other basis to conclude that the chemical can cause one or more acute or chronic adverse effects in people or animal species. Using the criteria and methodology in its 2012 Work Plan Methods Document, EPA screened the five PBTs subject to its proposal for “hazard” based on human health and environmental toxicity concerns. All five received “high” or “moderate” hazard scores.

⁴ 86 Fed. Reg. 14398

⁵ Describing provisions that form the basis for section 6(h), the House Report on the TSCA legislation states that “[t]he Committee hopes the Administrator will rely on its TSCA Work Plan Chemicals Methods Document published in February 2012 in identifying PBT candidate substances for listing.” H.R Report 114–176, 114 Cong, 1st Sess, June 23, 2015, at 27.

No evidence in the record contradicts EPA's determination that the five chemicals qualify as PBTs under section 6(h). As the Agency concludes, "information EPA has collected and reviewed in developing this proposal provides no basis to call into question the scoring for persistence, bioaccumulation, and toxicity performed in 2014 for these five PBT chemicals pursuant to the screening process described in the TSCA Work Plan Chemicals: Methods Document."⁶

Finally, under section 6(h)(1)(B), EPA must determine that exposure to the chemical under the conditions of use is "likely" to the general population, a potentially exposed or susceptible population or the environment. This determination must be made on the basis of a "use and exposure assessment." Again, however, the analysis EPA conducts need not be extensive or comprehensive. Since EPA must only show that the occurrence of exposure is "likely," it is not required to characterize the nature, magnitude and duration of exposure or even to document actual exposure.

Under the Work Plan Methods Document, the five PBTs have already been screened and scored for "exposure":⁷ this should constitute adequate evidence of potential exposure under section 6(h)(1)(B). Moreover, in compliance with the statute, EPA has supplemented this screening process with an Exposure and Use Assessment on the five PBTs which summarizes available information on their manufacturing (including importing), processing, distribution in commerce, use, and disposal. The Assessment documents numerous significant pathways of human exposure and environmental release and shows that both the general population and numerous vulnerable subpopulations are exposed to the 5 PBTs, often at high levels. Thus, EPA has satisfied this final criterion for PBT regulation under section 6(h).

C. The Restrictions that the Final Rules Place on the Five PBTs Violate TSCA Because They Fail to Achieve the Greatest Practicable Reduction in Exposure and Release

Restrictions on PBTs identified in accordance with section 6(h)(1) must comply with section 6(h)(4). Under this provision, EPA must impose requirements that "reduce exposure to [the PBT] to the extent practicable."⁸ The final rules misinterpret this statutory command and, as a consequence, exempt numerous uses of the 5 PBTs from regulation based on factors that are inconsistent with the wording and intent of section 6(h).

Congress sought to assure that the restrictions imposed under section 6(h) result in the largest possible reductions in exposure by humans and biota that are achievable in practice. The statute directs EPA to achieve this goal using the range of restrictions listed in section 6(a). These restrictions cover the entire life-cycle of the chemical and enable EPA to regulate all pathways of exposure. The section 6(a) requirements most effective in reducing human

⁶ 84 Fed. Reg. 36734 (July 29, 2019).

⁷ *Id.*

⁸ While earlier drafts of the legislation used the phrase "to the maximum extent practicable," the legislative history indicates that this phrase was considered synonymous with the phrase "to the extent practicable" included in the enacted legislation and thus the deletion of "maximum" did not change EPA's obligations. Congressional Record – Senate 3517 (June 7, 2016).

exposure and environmental release are a prohibition on manufacturing, processing and distribution in commerce (§6(a)(1)), a prohibition on any manner or method of commercial use (§6(a)(5), and a prohibition or restriction on any manner or method of disposal (§6(a)(6)(B)). These prohibitions should be default requirements under section 6(h). If EPA selects less stringent requirements, it should justify them on the basis of “practicability.”

According to the Merriam-Webster dictionary, the term “practicable” means “capable of being put into practice or of being done or accomplished.” The dictionary lists as synonyms achievable, attainable, doable, feasible, possible, realizable, viable, and workable. Court decisions have held that, where used in a statute, the term practicable “imposes a clear duty on the agency to fulfill the statutory command to the extent that it is feasible or possible.” *Defenders of Wildlife v. Babbitt*, 130 F. Supp. 2d 121, 131 (D.D.C. 2001). *Fund for Animals v. Babbitt*, 903 F. Supp. 96, 105 (D.D.C.1995) (“Obviously, the phrase ‘to the maximum extent practicable’ does not permit an agency unbridled discretion. It imposes a clear duty on the agency to fulfill the statutory command to the extent that it is feasible or possible.”)

Since “practicable” is synonymous with “feasible,” court cases construing this term in other laws shed light on how EPA should interpret its obligations under section 6(h). In *American Textile Manufacturers Institute, Inc. v. Donovan (Cotton Dust)*, 452 U.S. 490 (1981), the Supreme Court held that “feasible” in section 6(b)(5) of the Occupational Safety and Health Act (OSH Act) means “capable of being done.” *Id.* at 509. Therefore, the Court determined, the OSH Act did not mandate cost-benefit analysis because “Congress itself defined the basic relationship between costs and benefits, by placing the ‘benefit’ of worker health above all other considerations save those making attainment of this ‘benefit’ unachievable.” *See also Friends of Boundary Waters Wilderness v. Thomas*, 53 F.3d 881, 885 (8th Cir. 1995) (“feasible” means “physically possible”).

Lower courts have divided feasibility into two components: technological feasibility and economic feasibility. This distinction was first articulated in *American Iron & Steel Institute v. OSHA*, 577 F.2d 825, 832 (3d Cir. 1978) and elaborated on in *United Steelworkers v. Marshall*, 647 F.2d 1189, 1264 (D.C. Cir. 1980). According to these decisions, the technology to meet a standard must be “either already in use or has been conceived and is reasonably capable of experimental refinement and distribution within the standard’s deadlines.” The decisions also hold that cost alone is not the measure of a standard’s economic feasibility. Rather, a standard will be deemed economically feasible “if it does not threaten ‘massive dislocation’ to, or imperil the existence of the industry.” *Id.* at 1265.

In accordance with these decisions, EPA should apply a two-fold test in determining “practicability” under section 6(h). First, is the elimination of exposure to a PBT technically achievable? And second, is it within the economic capability of the industry – i.e. able to be achieved without causing massive dislocation or threatening the industry’s viability? EPA’s final rules do not apply this two-fold test but instead “interpret[] this requirement as generally directing the Agency to consider such factors as achievability, feasibility, workability,

and reasonableness.”⁹ While “achievability” and “feasibility” can be equated with “practicability”, “reasonableness” cannot. To use this term as the basis for restricting exposure to PBTs allows EPA to reject requirements that are technically and economically achievable merely because, in the Agency’s subjective judgment, they are not “reasonable.” This opens the door to circumventing section 6(h)’s overriding goal of eliminating PBTs from commerce and the environment by determining that the costs of restricting PBTs are excessive or the benefits insubstantial. Congress precluded such determinations by how it framed section 6(h) EPA also interprets section 6(h) to incorporate section 6(c)’s directive to consider costs, benefits and other economic factors under section 6(h) in determining practicability:¹⁰

EPA’s approach to determining whether particular prohibitions or restrictions are practicable is informed in part by a consideration of certain other provisions in TSCA section 6, such as TSCA section 6(c)(2)(A) which requires the Administrator to consider health effects, exposure, and environmental effects of the chemical substance; benefits of the chemical substance; and the reasonably ascertainable economic consequences of the rule. In addition, pursuant to TSCA section 6(c)(2)(B), in selecting the appropriate TSCA section 6(a) regulatory approach to take, the Administrator is directed to “factor in, to the extent practicable” those same considerations.

However, there is no indication in TSCA that Congress intended the framework for analysis in section 6(c) to govern PBT requirements under section 6(h). Moreover, EPA’s proposed PBT rules recognized that other provisions of TSCA section 6 should be applied only when they are “consistent with the direction in TSCA section 6(h)”, not when they “conflict with TSCA section 6(h).”¹¹ To balance PBT restrictions against costs, benefits, other economic impacts and the magnitude of human and environmental exposure would “conflict” with the goals and express wording of section 6(h) and effectively nullify its unique approach to restricting PBTs.¹²

The final rules exempt several uses of the 5 PBTs from restriction on a wide variety of grounds, including unreasonableness, limited exposure, high cost, compliance burdens, enforcement difficulty and lack of benefits. However, these considerations are precluded under section 6(h) and do not mean that elimination of the PBT use is “impracticable.” As shown above, to meet this standard, EPA must show that prohibiting the use is technically impossible or economically unachievable – a determination that EPA fails to make explicitly for any of the PBT uses that it exempts from regulation. Nor can EPA justify use exemptions on the ground that it believes a particular use results in insubstantial exposure since it may be practicable (and thus required) to eliminate even low exposures of PBTs. Moreover, since section 6(h) expressly precludes risk evaluations, EPA has no basis under the law to make a risk-based judgment that a pathway of exposure is too insignificant to require restriction.

⁹ 86 Fed. Reg. 897

¹⁰ Id.

¹¹ 84 Fed. Reg. 36733

¹² If the 6(c) factors were used to determine the appropriate level of regulation for PBT chemicals, section 6(h)(4) be “mere surplusage.” *Dunn v. Commodity Futures Trading Comm’n*, 519 U.S. 465, 472 (1997). Moreover, where two different statutory provisions are potentially applicable to an agency’s action, “the specific trumps the general.” *United States v. Wenner*, 351 F.3d 969, 975 (9th Cir. 2003) (explaining that “[s]pecific terms prevail over the general in the same or another statute which otherwise might be controlling”)

We urge EPA to reinterpret “practicability” in light of its plain meaning, caselaw and the purposes of section 6(h). It should then reexamine the exemptions in the final rule under this revised definition and propose to eliminate those that can no longer be justified.

D. EPA Cannot Exempt Uses of the five PBTs from Section 6(g) Restrictions Except in Accordance with the Exemption Criteria and Other Requirements in Section 6(g)

To the extent exemptions from PBT restrictions are warranted, they should be based on the framework in section 6(g) of TSCA. Although our organizations underscored the applicability of section 6(g) in their comments on the proposed rules, EPA chose not to apply its exemption criteria in its final section 6(h) rules. We believe this was a mistake. By its terms, section 6(g) is applicable to rules under section 6(a) and such rules include PBT regulations under section 6(h). Section 6(g) does not conflict with the language and goals of section 6(h) but complements them and, unlike section 6(c), should therefore be incorporated in EPA’s decision-making on PBTs. Section 6(g)(1) provides that:

The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that—

- (A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;
- (B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or
- (C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

Section 6(g)(2) requires that, when proposing an exemption, EPA “shall analyze the need for the exemption and shall make public the analysis and a statement describing how the analysis was taken into account.” However, the rulemaking record for the PBT rules lacks such an analysis and thus fails justify EPA’s exemptions under the criteria in section 6(g). For example, there is no demonstration that the exempted uses are “critical or essential” and lack a “technically and economically feasible safer alternative”; that their elimination would “significantly disrupt the national economy, national security, or critical infrastructure”; or that compared to alternatives, they provide “a substantial benefit to health, the environment, or public safety.” In fact, it is doubtful that several of the exemptions in the proposed rule could be shown to meet these criteria.

Section 6(h) also requires important conditions on exemptions that EPA’s proposed rule fails to impose. For example, section 6(g)(3) directs EPA to establish “a time limit on any exemption . . . on a case-by-case basis.” This time limit assures that the exemption is in effect no longer than necessary and that industry has maximum incentives to develop alternatives to the regulated chemical so it can be phased out of the use as soon as possible. However, EPA’s rules generally

do not place time limits on exemptions. Similarly, section 6(g)(4) directs EPA to condition exemptions on recordkeeping, monitoring, reporting and other requirements “necessary to protect health and the environment while achieving the purposes of the exemption.” However, the EPA rules include recordkeeping requirements but generally lacks other conditions that would restrict exposure and release.

EPA must go back to the drawing board and justify any use exemptions on the basis of the requirements of section 6(g). For each use under consideration for exemption, EPA should prepare an analysis under section 6(g)(2) evaluating whether the use meets the exemption criteria in section 6(g)(1). For those exemptions that EPA can justify under these criteria, EPA must comply with section 6(g) by imposing a meaningful time limit and other conditions necessary to protect health and the environment and assure progress in phasing out the exempt use.

E. EPA Lacks any Basis to Conclude that Worker Exposure Is Exempt from Section 6(h) and that No Restrictions on Worker Exposure are Needed

The final PBT rules, like the proposals, do not “directly regulate occupational exposures in industrial settings. As explained in the proposed rule, as a matter of policy, EPA assumes compliance with federal and state requirements, such as worker protection standards, unless case-specific facts indicate otherwise.”¹³ On its face, this exclusion is unwarranted. Section 6(h)(4) broadly directs EPA “to reduce exposure” to the 5 PBTs. There is no scientific or legal basis to exempt workers – a subpopulation with significant exposure -- from a broad statutory mandate intended to prevent the buildup of PBTs in people and the environment.

EPA justifies its approach on the ground that it “assumes compliance with other federal requirements, including OSHA standards and regulations [and] does not read TSCA section 6(h)(4) to direct EPA to adopt potentially redundant or conflicting requirements.”¹⁴ However, only one of the 5 PBTs is subject to OSHA occupational health standards and, despite EPA’s assertions, there is little information in the record demonstrating “that employers are using engineering and process controls and providing appropriate personal protective equipment (PPE) to their employees consistent with [OSHA] requirements.”¹⁵

In previous rulemakings under TSCA section 6, EPA has found that respirators and other personal protective equipment are difficult to wear throughout a shift, even where legally required, due to several factors, including discomfort, improper seals for respirators, the need to reduce contamination when exiting a work area, and interference with work duties. Additionally, Safety Data Sheets (SDS) and directions for safe use are often misunderstood or ignored, and employers often fail to provide adequate training in a language or dialect that is easy to understand and furnish adequate equipment to their workers.¹⁶ For these reasons, if a chemical presents a significant risk, OSHA manages that risk using the “hierarchy of controls,” under which hazard elimination, substitution, engineering and administrative controls are all prioritized

¹³ 86 Fed. Reg. 900

¹⁴ Id.

¹⁵ 86 Fed. Reg. 901.

¹⁶ Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7481 (Jan. 19, 2017).

over the use of PPE.¹⁷ Thus, there is no basis for EPA to presume that, because of industry practice and OSHA regulations, employees exposed to the 5 PBT chemicals are adequately protected by the use of PPE.

Section 6(h) requires EPA to reduce worker exposure to the PBTs to the lowest level that is technically and economically achievable. Because section 6(h) is not risk-based and does not require a risk evaluation, the goal of exposure reduction should be to eliminate exposure and thereby prevent the accumulation of the PBT in the bodies of workers and its resultant buildup in future generations and the environment. EPA should thus revise the 5 final PBT to reduce worker exposure to the extent practicable

F. The Final Rules Fail to Reduce Disposal and Environmental Release of the PBTs to the Extent Practicable

The final rules include an exemption for “disposal of any chemical substance, or products and articles that contain the chemical substance, including importation, processing and distribution-in-commerce for purposes of disposal.” To justify this exclusion, EPA relies on its earlier position that, “as a general matter, disposal is adequately regulated under the authority of the Resource Conservation and Recovery Act (RCRA) which governs the disposal of hazardous and non-hazardous wastes, and it is not practicable to impose additional requirements under TSCA on the disposal of the PBT chemicals in the proposed rule.”¹⁸

Disposal is a major pathway for environmental release of PBTs and thus a significant contributor to their long-long buildup in biota and environmental media. Moreover, EPA’s broad obligation under section 6(h)(4) to “reduce exposure . . . to the extent practicable” plainly encompasses environmental as well as human pathways of exposure. Section 6(h) directs EPA to select requirements to reduce exposure from the list of prohibitions and other restrictions in section 6(a), and this list includes a “requirement prohibiting or otherwise regulating any manner or method of disposal.” To categorically exclude disposal from section 6(h) is thus unjustified under TSCA.

EPA’s reliance on RCRA to assure safeguards against unsafe disposal of the 5 PBTs is unwarranted. RCRA does not embody a “one size fits all” approach to waste disposal. Some wastes are tightly managed as “hazardous” under the cradle-to-grave system in Subtitle C. But the universe of wastes deemed “hazardous” is only a small portion of all wastes subject to RCRA. Non-hazardous waste is governed by the less restrictive provisions of Subtitle D, which generally establish minimum standards for landfills but defer to states for implementation and enforcement. Individual non-hazardous wastes are rarely subject to specific management requirements under Subtitle D and there is no basis for assuming that disposal of these wastes by generators, transporters and landfill operators under the Subtitle is controlled to the greatest extent practicable. EPA has not analyzed the status of the 5 PBTs under RCRA in any detail and provides no evidence that generation and disposal of wastes and related environmental releases are controlled to the extent required by section 6(h).

¹⁷ OSH, Ctrs. for Disease Control & Prevention, updated Jan. 13, 2015, <https://www.cdc.gov/niosh/topics/hierarchy/>.

¹⁸ 86 Fed. Reg. 900.

Thus, EPA should revise the five final rules to fully identify and analyze current waste disposal practices and requirements for the 5 PBTs and impose all further restrictions on waste disposal that are practicable.

G. There Is No Basis for Excluding In-Use Articles Containing a PBT from Regulation under Section 6(h)

The final rules exempt “distribution in commerce of any chemical substance, or products and articles that contain the chemical substance, that has previously been sold or supplied to an end user, i.e., an individual or entity that purchased or acquired the finished good for purposes other than resale.”¹⁹ Here too, EPA seeks to impose a blanket exclusion from regulation under section 6(h) that has no basis in TSCA.

TSCA gives EPA broad regulatory authority over “articles” in commerce. The directive in section 6(h)(4) to “reduce exposure . . . to the extent practicable” plainly encompasses articles which are a source of PBT exposure. TSCA provides tools to address such articles. The restrictions authorized by section 6(a) include a “requirement prohibiting or otherwise regulating any manner or method of commercial use” (§ 6(a)(5)) and broad public notice, replacement and repurchase requirements for substances and mixtures in commerce (§ 6(a)(7)). EPA can apply these requirements to PBTs under section 6(h)(4).

EPA’s categorical rejection of regulating end-use articles is not accompanied by any economic analysis of the impacts of such regulation or any evaluation of specific options for reducing exposure to PBTs in such articles. For example, rebate programs that offer incentives for replacing existing products with new models have been used successfully in the home appliance sector and other industries. Companies and local governments have also created recycling incentive programs to encourage consumers to properly dispose of batteries, smartphones and other products. Public notice programs could advise consumers how to use PBT-containing articles in a way that minimizes exposure and release. All these remedies are authorized under section 6(a) and would be “practicable” in many instances but have been categorically rejected by EPA. In reexamining the final rules, EPA must assess how to reduce exposure from end-use articles and products to the extent practicable under section 6(h).

II. EPA Should Refuse to Provide More Time for Complying with the PIP (3:1) Article Prohibitions or to Exempt Covered Articles from the Rule and Should Reexamine the Existing PIP (3:1) Exemptions

Following the promulgation of EPA’s final rule for PIP (3:1) on January 6, industry groups raised – for the first time – concerns about the difficulty of eliminating it from articles subject to the rule’s restrictions. Industry has now claimed that it is impossible to remove PIP (3:1) from these articles by the rule’s effective date without catastrophic economic consequences. Yet the regulated community has been on notice of EPA’s intention to regulate PIP (3:1) under TSCA since 2014 and failed to alert the Agency to its concerns until after a final rule was in place 7 years later.

¹⁹ 86 Fed. Reg. 900.

Despite industry's inexcusable negligence, on March 8, 2021, EPA issued a No Action Assurance effectively suspending the rule's prohibitions on the processing and distribution of PIP (3:1) for use in articles for 180 days. We believe this application of enforcement discretion was unwarranted in light of industry's extreme lack of diligence in tracking, let alone complying with, these prohibitions and the risk of harm to health and the environment in delaying compliance.

Our groups strongly oppose the use of enforcement discretion to further extend the rule's compliance date for PIP (3:1)-containing articles. Any further extension should be accomplished through rulemaking to amend the PBT rule in accordance with TSCA section 6(d), which requires that rules under section 6(h) take effect "as soon as practicable." We have seen no evidence to date that the current compliance date (as extended by six months through enforcement discretion) is "impracticable" and urge EPA to reaffirm that date until and unless industry can make a compelling case for more time under section 6(d).

Similarly, we oppose revising the PBT rule to exempt PIP (3:1)-containing articles. The current record provides no basis to conclude that these articles meet the stringent criteria for use exemptions in section 6(g) and excluding them from PBT restrictions would defeat the purposes of section 6(h). In fact, EPA has failed to justify under section 6(g) the several exemptions now included in the PIP (3:1) rule and these exemptions should be reexamined in light of the section 6(g) criteria.

A. Industry Ignored Repeated Opportunities Over Seven Years to Express Concerns about Prohibiting PIP (3:1)-containing Articles

The long history of EPA scrutiny of PIP (3:1) demonstrates that industry knew, or had ample reason to know, that significant restrictions would likely be imposed on articles containing this substance long before EPA's final PBT rule.

2014 Workplan Update. PIP (3:1) was a high priority for EPA before the 2016 TSCA amendments. As EPA notes in its final rule,²⁰ in the 2014 Update to the TSCA Work Plan for Chemical Assessments, PIP (3:1) scored high (3) for hazard (based on neurotoxicity in mammals and aquatic toxicity); high (3) for exposure (based on use as a flame retardant in industrial and consumer products); and high (3) for persistence and bioaccumulation (based on high environmental persistence and high bioaccumulation potential). The overall score for PIP (3:1) was high (9).

Early Characterization of PIP (3:1) Use and Exposure. On October 11, 2016, shortly after the new law took effect, EPA announced that PIP (3:1) was one of 5 PBTs selected for restriction under section 6(h). Following this announcement, EPA began collecting exposure and use information on the 5 PBTs. In August 2017, the Agency posted a [document](#) entitled *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Phenol, isopropylated, phosphate (3:1)*. The document identified flame retardants as a major application of PIP (3:1) and explained that these retardants --

²⁰ 86 Fed. Reg. 899.

are used predominantly in four major areas: electronics and electrical devices, building and construction materials, furnishings, and transportation. They are also used in adhesives, lubricants, oils, paints, epoxy resins, and plasticizers. Commonly treated electronics are TVs, computers/computer accessories, phones, washers and dryers, circuit boards, electrical cables, and other various household appliances. For building and construction materials, treated products include insulation materials, paints and coatings, wood products, roofing components, composite panels, and fixtures. Home/Office furnishing such as foam upholstery, curtains, carpets, and any fabrics that house them may also contain phenol, isopropylated, phosphate (3:1). Fabrics, foams, carpets, electrical equipment, and bumpers in airplanes, trains, and automobiles also contain flame retardants (p. 9).

Our organizations retained the Healthy Building Network (HBN) to further research the use profile of PIP (3:1) and its findings were submitted in [comments](#) filed with EPA on January 12, 2018. Using information submitted under EPA's Chemical Data Reporting (CDR) rule and other public sources, HBN identified the major producers and importers of PIP (3:1) and described their product lines, reporting that "flame retardants [containing PIP 3:1] are used in many types of plastics not included in EPA's Preliminary Information, including: PVC, cellulosic resins, EPDM, High Impact Polystyrene (HIPS), Poly(phenylene oxide)/HIPS alloys, polycarbonate, polycarbonate/ABS alloys, rigid polyurethane, and thermoplastic polyurethane" (p. 12). HBN and our organizations were invited to meet with EPA to discuss these HBN findings in greater detail.

2018 Use and Exposure Assessment. On May 25, 2018 (83 Fed. Reg. 24305), EPA announced the availability of a draft *Exposure and Use Assessment of Five Persistent, Bioaccumulative and Toxic Chemicals* (Exposure and Use Assessment). To assure the completeness and accuracy of its findings, the Agency requested public comment on the draft and convened a peer review panel to provide feedback. The draft [Exposure and Use Assessment](#) notes that "EPA communicated with dozens of companies, industry groups, chemical users, and other stakeholders to aid in identifying and verifying conditions of use of PIP (3:1)" (p. 107). The draft explains that, "[a]s reported to the 2016 CDR, the types of processes using PIP (3:1) include incorporation into articles, use as a chemical processing or manufacturing aid, and incorporation into a formulation, mixture or reaction product" (id.). The draft presents a detailed breakdown of PIP (3:1)'s uses throughout its life cycle, including addition to "various industrial products where it acts as both a plasticizer and flame retardant." The draft also describes in detail the articles which contain PIP (3:1):

The "complex articles" category encompasses road vehicles for passengers and goods such as cars and trucks, and machinery, mechanical appliances, electrical and electronic articles such as computers and drills. The "plastic articles" category encompasses consumer products made of both hard and soft plastics, which include PIP (3:1) as a flame retardant or plasticizer, including toys intended for children's use, and furniture and furnishings, including furniture coverings such as computer casing and foam in furniture or mattresses (p. 110).

If EPA had overlooked any PIP (3:1) uses, commenters had ample opportunity in 2018 to bring them the Agency's attention.

2019 Proposed Rule. EPA's proposed PBT [rule](#), published on July 29, 2019, again highlighted the breadth of PIP (3:1)'s use profile:

PIP (3:1) is used as a plasticizer, a flame retardant, an anti-wear additive, and/or an anti-compressibility additive in hydraulic fluid, lubricating oils, lubricants and greases, epoxy coatings for decks of marine shipping vessels, coatings for pipes and insulation in construction, adhesives and sealants for insulation, and articles.

84 Fed. Reg. 36736. The proposal specifically enumerated the large number of articles containing PIP (3:1):

PIP (3:1) has been identified as a possible component in plastic products and articles, including children's products, automotive, and aerospace products (Ref. 7). PIP (3:1) also is added to articles as a plasticizer or flame-retardant additive in plastic components, adhesives and sealants, and paints and coatings. Use of PIP (3:1) in complex articles (such as in casings of electronics or components of automobiles), plastic articles including furniture and furnishings, and toys intended for children's use, has been identified.

Id.

After reviewing PIP (3:1)'s diverse uses, EPA proposed "to prohibit the processing and distribution in commerce of PIP (3:1), and products containing the chemical substance" except for three discrete use categories that would be exempt from the rule. 84 Fed. Reg. 36749. Although raising concern about the availability of substitutes for PIP (3:1) in the exempted use categories, EPA emphasized that "[m]anufacturers have described alternative chemicals that are available for the functional applications of PIP (3:1) as a plasticizer, flame retardant, and anti-wear additive" and it concluded that "viable substitutes are available for many of the uses of PIP (3:1)." 84 Fed. Reg. 36751.

According to EPA's economic impact analysis, the estimated cost of eliminating and replacing PIP (3:1) in the prohibited use categories would be modest. The analysis projected that total quantified annualized industry costs for the proposed PIP (3:1) would be \$34.7 million (at both 3% and 7% discount rates) and \$38.1 million (3% discount rate). 84 Fed. Reg. 36755.

To assure that these cost estimates were reasonable, EPA "request[ed] comment on potential costs of reformulation with substitute chemicals in the uses that are proposed to be restricted or prohibited" as well as on "the time it may take for reformulation that would meet the current performance standards." Id.

EPA explicitly considered how much lead time industry should receive before the prohibitions on processing and distribution in commerce of PIP (3:1) and products containing it would take effect. It determined that there was "no information indicating that a compliance date of 60 days after publication of the final rule is not practicable for the activities that would be prohibited, or that additional time is needed for products to

clear the channels of trade.” Nonetheless, EPA “request[ed] comment on whether additional time is needed for products to clear the channels of trade.” 84 Fed. Reg. 36749.

2021 Final Rule. No one could claim that EPA’s proposal hid the ball on how the PBT rule would affect use of PIP (3:1) in the manufacture and distribution of articles. The proposal was crystal clear about the broad range of article uses that would be prohibited, the types of articles impacted by this prohibition, the availability of substitutes, the estimated costs of implementation and the timeframe for compliance. Moreover, the proposal invited comments on all these issues.

Remarkably, while EPA received comments on several aspects of the rule, industry was silent on the proposed prohibitions on PIP (3:1)-containing articles and offered no information that called into question the scope of these prohibitions or the proposed deadline for compliance. As a result, while the final rule expanded the exempted use categories and clarified certain requirements, the prohibitions on PIP (3:1)-containing articles and related compliance deadline were essentially the same as in the proposal. Moreover, the rule preamble reiterated that “EPA believes there are viable substitutes for PIP (3:1), except for the specified processing and distribution in commerce activities excluded from the final rule” and lowered the Agency’s estimates of annualized compliance costs to \$23.6 million at a 3% discount rate and \$22.8 million at a 7% discount rate annualized over 25 years. 86 Fed. Reg. 907.

EPA’s Recognition of the Industry’s Total Lack of Diligence. While recommending a 180-day suspension of the March 8, 2021 compliance date for articles subject to the PIP (3:1) rule, the Acting Assistant Administrator for Chemical Safety and Pollution Prevention underscored that “[s]takeholder outreach during the development of the proposed and final rule was extensive, and stakeholder input is reflected in the provisions of the proposed and final rule.”²¹ She added that:

Despite EPA’s extensive outreach, most stakeholders contacting EPA after the rule was finalized did not comment on the proposal or otherwise engage with the Agency on the PIP (3:1) rulemaking, and do not appear to have previously surveyed their supply chains to determine if PIP (3:1) was being used. Several have indicated that they did not understand that articles can be regulated under TSCA, and that, because PIP (3:1) is not regulated by other authorities, there was a lack of awareness relative to its presence in the supply chain. Absent timely input from these stakeholders, in the final rule EPA determined that PIP (3:1) was not widely present in complex articles outside the aerospace and automotive sectors. While some commenters on the proposed rule indicated that PIP (3:1) may be present in articles, their comments were very general and did not identify specific uses or

²¹ Memorandum from Michal Freedhoff, Acting Assistant Administrator for OCSPP, to Larry Starfield, Acting Assistant Administrator Office of Enforcement and Compliance Assurance, *Request for No Action Assurance Regarding the Prohibition of Processing and Distribution of Phenol Isopropylated Phosphate (3:1), PIP (3:1), for Use in Articles and PIP (3:1)-containing Articles under 40 CFR 751.407(a)(1)*, March 8, 2021.

concerns with the March 8, 2021 compliance date. EPA held a number of follow-up calls with these stakeholders and requested information specific to PIP (3:1)'s presence in articles. No additional information was provided by stakeholders in these follow-up calls and meetings.

The industry groups who ignored EPA's PBT rulemaking but now seek to delay or avoid compliance include such sophisticated and well-funded trade associations as the Semiconductor Industry Association, the National Association of Manufacturers, the Air-conditioning, Heating, and Refrigeration Institute, the Retail Industry Leaders Association and the Association of Equipment Manufacturers. As [reported](#) by INSIDE EPA, a senior executive with the National Association of Manufacturers claimed that these groups were unaware of EPA's 7-year effort to restrict PIP (3:1) because it was not being regulated in the European Union (EU):

Jones says she first saw concerns raised about the rules "a month ago at most. . . . At the time, no one else had even said a peep about PIP."

That is in part because of the five PBTs that EPA identified, PIP is the only one not already subject to significant regulatory limits in other countries, in particular the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) program.

"Usually, on any of these things you get word of it via Europe and what's happening with REACH," she says.

The idea that US industry depends on the EU to alert it to EPA regulatory actions would be laughable if it were not so alarming. Why well-staffed industry associations based in Washington DC should be excused from reading the Federal Register, filing comments and responding to EPA's requests for information – elementary tasks that our organizations and other commenters had no trouble performing during the PBT rulemaking – is unfathomable.

B. EPA Has Improperly Applied Enforcement Discretion to Extend the Compliance Dates for the PIP (3:1) Rule

EPA uses enforcement discretion – the forbearance of penalties and compliance orders for violations of rules and statutes -- sparingly and only in extraordinary circumstances. In its [Covid-19 enforcement discretion guidance](#), EPA emphasized that "entities should make every effort to comply with their environmental compliance obligations" and that relief from these obligations is available only where "compliance is not reasonably practicable" because external events "constrain the ability of regulated entities to carry out" their responsibilities.

In this case, EPA itself has recognized that industry is unable to carry out the PIP (3:1) prohibitions not because unexpected external events made compliance impossible but because industry ignored EPA's rulemaking, made no effort to anticipate the difficulty of

compliance and sat on its hands until after the PBT rule was promulgated. To grant enforcement discretion in such circumstances would reward industry for its gross negligence and absence of good faith and set a precedent that undermines compliance with environmental laws.

Moreover, the Covid-19 guidance indicates that, as a prerequisite for enforcement discretion, “EPA expects all regulated entities to continue to manage and operate their facilities in a manner that is safe and that protects the public and the environment.” Surprisingly, the March 9 No Action Assurance glosses over the public interest in preventing exposure to PBTs, asserting that the “Assurance would not jeopardize the Agency’s efforts to ensure the protection of health and the environment under TSCA.”²² While EPA notes that the Assurance does not affect the rule’s limits on water discharges and requirement to notify downstream customers, it is the rule’s prohibitions on processing and distributing articles that most directly prevent exposure to PIP (3:1) and the No Action Assurance will allow such exposure to continue to occur.

PIP (3:1) scored “high” for human health hazard in the 2014 TSCA Workplan and the preamble to the final rule indicates that available data demonstrate its “potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, and heart in mammals.”²³ Continued processing, distribution and use of articles containing large quantities of PIP (3:1) because of the No Action Assurance will prolong exposure and risks to health throughout the substance’s life-cycle. Moreover, the 2014 Workplan also scored PIP (3:1) “high” for persistence and bioaccumulation. Thus, its continued presence in articles while the Assurance is in effect will add to PIP (3:1)’s buildup and distribution in the bio-sphere and environment, with long-term harmful effects on the food chain, wildlife and people. These are the very concerns on which section 6(h) of TSCA is based and provide the basis for its directive to “reduce exposure” to regulated PBTs “to the extent practicable.” The law’s stringent deadlines for implementing section 6(h) underscore the importance Congress attached to this objective. It is troubling that EPA gave no weight to these considerations in determining that the “public interest” warranted delaying the rule’s effective date.

For these reasons, we believe that EPA’s March 8 No Action Assurance was unjustified and strongly oppose the use of enforcement discretion to excuse further delays in compliance beyond the ongoing 180 day period.

²² Id.

²³ 86 Fed. Reg. 899. As the preamble notes, “studies presented in the document entitled ‘Environmental and Human Health Hazards of Five Persistent, Bioaccumulative and Toxic Chemicals (Hazard Summary)’ (Ref. 8) Demonstrate these hazardous endpoints.”

C. Any Further Compliance Date Extension Must Occur Through Rulemaking and Meet the Criteria in TSCA Section 6(d)

Since any additional exercise of enforcement discretion would be unwarranted, the effective date for the PIP (3:1) requirements can only be further extended through rulemaking to amend the PBT rule. It is in the public interest to conduct rulemaking for this purpose because it would include a notice-and-comment process and allow for judicial review. In such a rulemaking, EPA would need to justify an extended effective date under section 6(d) of TSCA. This provision states that a rule under section 6(a) of TSCA (which includes PBT restrictions under section 6(h)) must contain an effective date which is “as soon as practicable but not later than 5 years after the date of promulgation.”

EPA has already found that a 60-day compliance deadline is “practicable” based on the availability of substitutes for PIP (3:1) and the low costs of compliance. The burden is thus on industry to provide concrete evidence that the PIP (3:1) article prohibitions cannot practicably be implemented within 8 months of promulgation (the compliance deadline resulting from the 180-day No Action Assurance plus the initial 60-day compliance period) and, if not, to identify the minimum amount of time required assuming maximum diligence in complying with the rule. In its statements and submissions to date, industry has not begun to meet this burden and, until and unless it makes a compelling case for more time based on a showing of impracticability, an additional extension of the compliance deadline would be unjustified.

D. EPA Should not Amend the PBT Rule to Exempt Processing and Distribution of the Articles Now Subject to the Rule’s Prohibitions

According to [media reports](#), industry intends to “ask EPA to greatly scale back Trump-era TSCA limits on processing or distributing products made with the flame retardant phenol, isopropylated phosphate (3:1), or PIP, raising new requests for critical-use exemptions along with legal arguments that the current rules are unlawfully strict.” EPA should reject such exemption requests and refuse to weaken the current rule.

As noted above, exemptions from the PBT rules must comply with section 6(g)(1) of TSCA and thus must be based on an analysis finding that the exempted use “is a critical or essential use for which no technically and economically feasible safer alternative is available” or that compliance with the rule would “significantly disrupt the national economy, national security, or critical infrastructure.” Although EPA did not apply these criteria in its section 6(h) rulemaking, as noted above, it did find that suitable substitutes for PIP (3:1) in article applications are available, that transitioning to these substitutes across the supply chain would not be burdensome and that the overall costs of this transition would be small. These findings would preclude granting exemptions under section 6(g).

If industry now presents evidence that it failed to offer in the rulemaking, it must overcome EPA’s previous findings and meet its burden of demonstrating the absence of “technically and economically feasible alternatives” for PIP (3:1) and establishing that its

now-prohibited article uses are “critical or essential.” Moreover, even if industry could carry this burden, any exemptions would need to include time limits under section 6(g)(3) and conditions “necessary to protect health and the environment” under section 6(g)(4). Given the exposure prevention goals of section 6(h) and EPA’s determinations that PIP (3:1) is “high” in persistence, bioaccumulation and toxicity, such conditions would need to include stringent controls on environmental release and human exposure through PIP (3:1)’s life-cycle.²⁴

E. The Exemptions in the PIP (3:1) Final Rule Must be Reexamined under the Use Exemption Framework in Section 6(g)

As described in EPA’s March 17 notice,²⁵ the PIP (3:1) final rule contains exclusions for:

- Use in photographic printing articles before January 1, 2022;
- Use in aviation hydraulic fluid in hydraulic systems and use in specialty hydraulic fluids for military applications;
- Use in lubricants and greases;
- Use in new and replacement parts for the aerospace and automotive industries;
- Use as an intermediate in the manufacture of cyanoacrylate glue;
- Use in specialized engine air filters for locomotive and marine applications;
- Use in sealants and adhesives before January 6, 2025; and
- Recycling of plastic that contained PIP (3:1) before the plastic was recycled, and the articles and products made from such recycled plastic, so long as no new PIP (3:1) is added during the recycling or production process.

Although EPA explained the basis for these exclusions, it did not justify them using the use exemption framework in section 6(g), which is applicable to section 6(h) as discussed above. Thus, EPA made no finding that each excluded use “is a critical or essential use” and “no technically and economically feasible safer alternative is available” or that elimination of the rule would “significantly disrupt the national economy, national security, or critical infrastructure.” Moreover, except in two instances, EPA did not set time limits for the exclusions or establish conditions “necessary to protect health and the environment,” as required by sections 6(g)(3) and (g)(4). Thus, the exclusions do not comply with TSCA and must be reexamined under the use exemption framework in section 6(g).

Conclusion

²⁴ According to INSIDE EPA, industry plans to argue that restrictions under section 6(h) “must be justified by a finding that they ‘contribute significantly to the risk, identified in a risk evaluation,’ of the chemical.” This argument is precluded by the plain language of section 6(h)(2), as EPA concluded in the preamble to the final rule: “EPA does not believe that TSCA section 6(h) contemplates a new evaluation of any kind, given that evaluations to determine risks are now addressed through the TSCA section 6(b) risk evaluation process and that TSCA section 6(h)(2) explicitly provides that no risk evaluation is required.” 86 Fed. Reg. 898.

²⁵ 86 Fed. Reg. 14400.

EPA's final PBT rules must be reexamined and modified to comply with section 6(h) of TSCA. Revised rules must include additional requirements to prevent buildup and accumulation of the PBTs in people and the environment, and EPA must fully implement its obligation under TSCA section 6(h) to reduce exposure to the extent practicable. Exclusions from the rules that are unjustified under the plain language of section 6(h) or the exemption criteria in section 6(g) must be removed.

Our organizations are deeply concerned by EPA's No Action Assurance delaying compliance with the PIP (3:1) rule's prohibition on its use in numerous articles. This exercise of enforcement discretion is unjustified in light of industry's gross negligence in responding to the PBT rulemaking and the priority Congress placed on reducing exposure to harmful PBTs. Any further compliance extensions should be accomplished through rulemaking applying the directive in section 6(d) to implement the rule "as soon as practicable." EPA should not weaken the rule by granting additional exemptions.

We appreciate the opportunity to submit these comments on EPA's final PBT rules.

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