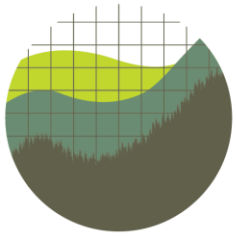

Institute *for*
Policy Integrity
NEW YORK UNIVERSITY SCHOOL OF LAW

October 28, 2019

VIA ELECTRONIC SUBMISSION

Attn: Cindy Wheeler, wheeler.cindy@epa.gov; Peter Gimlin, gimlin.peter@epa.gov

Re: Proposed Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), RIN 2070–AK34, Docket ID No. EPA–HQ–OPPT–2019–0080

The Institute for Policy Integrity ("Policy Integrity") at New York University School of Law[1] submits the following comments on the Environmental Protection Agency's Proposed Rule[2] addressing five persistent, bioaccumulative, and toxic chemicals under the Toxic Substances Control Act ("TSCA") ("Proposed Rule").[3]

Policy Integrity is a non-partisan think tank dedicated to improving the quality of government decisionmaking through advocacy and scholarship in the fields of administrative law, economics, and public policy. Policy Integrity supports EPA's efforts to regulate four persistent, bioaccumulative, and toxic chemicals in the agency's Proposed Rule. These comments suggest ways EPA can strengthen its proposal to do so. We also urge EPA to reexamine its decision not to regulate a fifth chemical, hexachlorobutadiene ("HCBD"). Specifically, we write to make the following comments:

1. For the four chemicals EPA proposes to regulate, EPA could strengthen the Proposed Rule by quantifying the benefits of regulation, to the extent such quantification is possible without falling behind TSCA's mandate to expedite regulating these chemicals. Where it is not feasible to monetize the benefits within that timeframe, the agency should consider conducting a breakeven analysis to describe the benefits of the Proposed Rule.
2. EPA fails to adequately analyze the benefits of regulating HCBD and fails to provide a reasoned explanation for its decision not to regulate HCBD.

[1] This document does not purport to present New York University School of Law's views, if any.

[2] Regulation of Persistent, Bioaccumulative, and Toxic Chemicals Under TSCA Section 6(h), Proposed Rule, 84 Fed. Reg. 36,728 (July 29, 2019).

[3] Toxic Substances Control Act, 15 U.S.C.A. §§ 2601–2692 (West, Westlaw Edge through P.L. 116-65) (to be codified at 15 U.S.C. §§ 2601–2692) (effective June 22, 2016).

I. EPA Should Quantify the Benefits of Its Proposed Regulations or Use a Breakeven Analysis for "DecaBDE," "PIP (3:1)," "2,4,6-TTBP," and "PCTP"

A. Background on the Proposed Rule

EPA has proposed to regulate the following four persistent, bioaccumulative and toxic chemicals: decabromodiphenyl ether (DecaBDE); phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); and pentachlorothiophenol (PCTP).[4] These chemicals have a variety of uses, including as fire retardants, plasticizers, fuel additives, and rubber manufacture components.[5]

EPA's authority to regulate here derives from TSCA § 6(h),[6] which instructs the agency to regulate persistent, bioaccumulative, and toxic chemicals.[7] This subsection requires the agency to take "expedited action"[8] and "reduce exposure to [such chemicals] to the extent practicable."[9] TSCA § 6(h) expressly states that the Administrator shall not be required to conduct risk evaluations before promulgating regulations.[10] But § 6(c)(2) provides that EPA should research and publish a "statement of effects" accompanying its regulations of toxics.[11] And EPA has interpreted the statute to require a statement of effects even for expedited chemicals.[12]

EPA has proposed varying degrees of regulation for four of the chemicals it considers in its proposal and has provided information under § 6(c)(2) for each. The information provided by the agency demonstrates that the regulations are beneficial to society. EPA relies on what are known as "qualitative benefits" as justification for regulating the four chemicals in its proposal. As EPA has explained, there are reports of serious environmental and health risks associated with these chemicals,[13] and EPA has data showing the points of exposure for the environment and humans.[14] EPA also explains in the Proposed Rule that reducing exposure to all four of these chemicals would benefit society.[15]

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[4] *See* 84 Fed. Reg. at 36,730 (summarizing the proposed regulations of each chemical).
[5] *Id.*
[6] *Id.* ("EPA is issuing this Proposed Rule to fulfill EPA's obligations under TSCA section 6(h) to take timely regulatory action on PBT chemicals . . ..").
[7] 15 U.S.C.A § 2605(h).
[8] *Id.* § 2605(h)(1).
[9] *Id.* § 2605(h)(4).
[10] *Id.* § 2605(h)(2).
[11] *Id.* § 2605(c)(2)(A).
[12] *See* 84 Fed. Reg. at 36,731 (providing an overview of TSCA § 6(c)(2) and EPA's efforts to provide a statement of reasonably available information).
[13] *See generally* ENVIRONMENTAL AND HUMAN HEALTH HAZARDS OF FIVE PERSISTENT, BIOACCUMULATIVE AND TOXIC CHEMICALS (2019) [hereinafter "HAZARDS REPORT"], https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0080-0519.
[14] *See generally* EXPOSURE AND USE ASSESSMENT OF FIVE PERSISTENT, BIOACCUMULATIVE AND TOXIC CHEMICALS (2019) [hereinafter "EXPOSURE REPORT"], https://www.regulations.gov/document?D=EPA-HQ-OPPT-2019-0080-0518.
[15] 84 Fed. Reg. at 36,755–56 (discussing health and environmental risks and benefits).

But the agency's statement of effects could be more robust if the agency quantified the benefits of its proposed regulations. EPA stresses that TSCA does not require risk evaluations for these chemicals[16] and EPA's position is that without a risk evaluation, the agency cannot estimate the extent to which its regulations reduce risk.[17] However, EPA does quantify the anticipated costs of the regulations.[18] The result is that the public and decisionmakers might get a relatively precise sense of the regulations' costs, but a relatively abstract understanding of the regulations' benefits.

Thus, to the extent possible within the required timeframe, EPA should provide either an estimate of the quantified benefits or provide a breakeven analysis to facilitate the public's understanding of the rule's benefits.

B. Background on Potential Benefits Analyses that EPA Could Use In the Proposed Rule

1. Qualitative Benefits

Qualitative descriptions of benefits, like the descriptions provided in the Proposed Rule, can help communicate regulatory upsides when quantification is infeasible.

Often agencies must rely on qualitative benefits when there is uncertainty over the magnitude of the benefits due to a lack of information. When an agency lacks the necessary data to quantify a given benefit, that does not mean that there is uncertainty about whether the benefits actually exist or that the benefits are small. In fact, some of the most substantial categories of monetized benefits of environmental regulation were at one time considered to be unquantifiable.[19] As the U.S. Court of Appeals for the D.C. Circuit has explained, "[t]he mere fact that the magnitude of [an effect] is uncertain is no justification for disregarding the effect entirely."[20] Stated differently, agencies can be justified in acting on qualitative benefits even when the effects of their decisions are "difficult, if not impossible, to quantify reliably."[21] Thus, Executive Order 12,866—the leading executive order on agency cost-benefit analysis[22]—makes clear that it is

[16] *See id.* at 36,746 (explaining that TSCA 6(h)(2), the provision for expedited chemicals, specifically provides that EPA is not required to conduct risk evaluations).
[17] *See id.* at 36,730 ("EPA did not perform risk evaluations for these chemical substances, nor did EPA develop quantitative risk estimates. Thus, EPA was not able to quantify the benefits of reducing human and environmental exposures . . .."); *see also* ECONOMIC ANALYSIS FOR PROPOSED REGULATION OF PERSISTENT, BIOACCUMULATIVE, AND TOXIC CHEMICALS UNDER TSCA SECTION 6(H) at 1-17 n.4 (2019) [hereinafter "ECONOMIC ANALYSIS"] (citing an inability to quantify welfare changes because of an inability to quantify marginal changes in risk without a risk evaluation).
[18] *See* 84 Fed. Reg. at 36,755 (estimating the costs of the proposed regulations and alternatives).
[19] *See* Richard L. Revesz, *Quantifying Environmental Benefits*, 102 CALIF. L. REV. 1423, 1436 (2014).
[20] Public Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209, 1219 (D.C. Cir. 2004).
[21] Am. Trucking Assocs., Inc. v. EPA, 175 F.3d 1027, 1052 (D.C. Cir. 1999), *rev'd on other grounds sub nom.* Whitman v. Am. Trucking Ass'ns, 531 U.S. 457 (2001).
[22] *See* Office of Mgmt. & Budget, Memorandum: Implementing Executive Order 13,771, Titled "Reducing Regulation and Controlling Regulatory Costs" pt. I1 (Apr. 5, 2017).

"essential to consider" the "qualitative measures of costs and benefits that are difficult to quantify."[23]

2. Quantification and Monetization

Though qualitative analyses can be very useful and are sometimes necessary, quantification, and if possible, monetization, facilitate the comparison of a rule's cost and benefits. Without quantification, decisionmakers and the public could overly discount that individual action's potential positive contribution.[24] In contrast, monetization allows decisionmakers and the public to weigh the costs and benefits of an action and compare alternatives using the common metric of money, a traditional analysis that most people are familiar with and comfortable with performing. Monetizing benefits, therefore, better informs the public and helps "bring[] those effects to bear on [the agency's] decisions."[25]

For these reasons, although EPA is not required to conduct risk evaluations for chemicals whose regulation is expedited under TSCA, because the agency quantified costs, the agency should endeavor to provide estimates of the quantified benefits and monetize regulatory benefits when and if EPA possesses enough information to make those estimates.

For background, when sufficient information exists, EPA would follow these steps to quantify the benefits of a chemical regulation (in whatever order EPA deems best):

- First, EPA would look at the environmental and health hazards associated with the chemical.[26] Frequently, the agency relies on non-human animal studies to reach these conclusions.[27]
- Second, EPA would estimate the extent to which the population is exposed to the chemical.[28]
- Third, the agency would determine how different dose quantities are linked to that environmental or health harm—the "dose-response relationship."[29]
- Fourth, EPA would multiply the exposure by the dose response relationship factor, in order to gain an understanding of the risk a chemical poses to the public.
- Fifth, the agency estimates how much its regulation will reduce exposure and thus risk.

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[23] Exec. Order. No. 12,866, 58 Fed. Reg. 51,735 (Oct. 4, 1993). *See also* KENNETH J. ARROW ET AL., BENEFIT-COST ANALYSIS IN ENVIRONMENTAL, HEALTH, AND SAFETY REGULATION: A STATEMENT OF PRINCIPLES 8 (1996).
[24] *See* Revesz, *supra* note 19, at 1428 (discussing a tendency among judges to discount unquantified benefits, leading to suboptimally lax regulations).
[25] Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, 462 U.S. 87, 96 (1983) (emphasis added).
[26] RICHARD L. REVESZ ET AL., ENVIRONMENTAL LAW AND POLICY 73–74 (4th ed. 2019) (excerpting Alon Rosenthal et al., *Legislating Acceptable Cancer Risk from Exposure to Toxic Chemicals*, 19 ECOLOGY L.Q. 269 (1992)).
[27] *Id.* at 74–75.
[28] *Id.* at 78–79. This is usually expressed in units of milligrams of the toxic per kilogram of body weight per day.
[29] *Id.* at 76–77. For example, this might be expressed in units of increased lifetime probability of a health harm per milligram of toxic per kilogram of body weight per day of exposure.

- Sixth, for ease of comparison to costs, the agency would monetize this reduced risk, or benefit.

Following these steps will lead to an estimate of the monetized benefits for the regulation.

3. Breakeven Analysis

If benefit monetization is not feasible on an expedited timeline, EPA should consider conducting a breakeven analysis.[30] Breakeven analyses help the public and decisionmakers evaluate regulations by identifying the necessary benefits a regulation would have to produce to recoup the regulation's cost. [31] Breakeven analyses are useful when the agency is unsure about the full extent of the rule's benefits because the analysis does not demand a full understanding of all the benefits or a risk evaluation.[32] Rather than quantifying all benefits precisely, the agency need only make a reasoned estimate about whether the benefits will be above or below one number: the anticipated cost of the rule. Because EPA has already quantified costs of the rule, a breakeven analysis would help the public put those costs in context.

Here, given the relatively low annual costs EPA attributes to regulating each of the four chemicals in the Proposed Rule, even modest reductions in health risks would ensure the regulations' societal upsides surpass anticipated costs.

If EPA cannot quantify benefits or perform a breakeven analysis for a particular chemical, EPA should explain precisely what information the agency lacks to perform those analyses.

C. EPA Should Quantify the Benefits of Its Proposed Regulations to Further Strengthen its Proposed Rule

As discussed above, given that EPA has interpreted TSCA to require a statement of effects for expedited chemicals and has quantified the costs of regulation as an effect, quantifying benefits will help the public understand the agency's proposed regulations. This section applies the above principles and discusses the information EPA would need to quantify and monetize the benefits associated with each of its chemical regulations.

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[30] *See* Revesz, *supra* note 19, at 1426 (describing breakeven analysis).

[31] *See, e.g.*, DEPT. OF HEALTH AND HUMAN SERVS., DEEMING TOBACCO PRODUCTS TO BE SUBJECT TO THE FOOD, DRUG, AND COSMETIC ACT, AS AMENDED BY THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT; REGULATIONS RESTRICTING THE SALE AND DISTRIBUTION OF TOBACCO PRODUCTS AND REQUIRED WARNING STATEMENTS FOR TOBACCO PRODUCT PACKAGES AND ADVERTISEMENTS 115–16 (2016) (applying a breakeven analysis to determine whether tobacco regulations were justified); U.S. DEPT. OF JUSTICE, REGULATORY IMPACT ASSESSMENT FOR NATIONAL STANDARDS TO PREVENT, DETECT, AND RESPOND TO PRISON RAPE UNDER THE PRISON RAPE ELIMINATION ACT 157–63 (PREA) (2012) (explaining the breakeven analysis used to justify the regulation's standards).

[32] Cass R. Sunstein, *The Limits of Quantification*, 102 CAL. L. REV. 1369, 1387 (2014) (discussing how an agency could use breakeven analysis to evaluate an environmental regulation when quantification is infeasible).

1. DecaBDE

For DecaBDE, the agency proposes banning "manufacture (including import), processing, and distribution in commerce."[33] According to EPA, regulating DecaBDE will entail roughly $155,000 per year in quantified costs.[34] On the benefits side, EPA explains that DecaBDE is "associated with developmental neurological effects, developmental immunological effects, general developmental toxicity, and thyroid and liver effects in mammals, as well as with toxicity in aquatic organisms."[35] In addition, EPA explains that "[e]xposures to humans and the environment would thus decrease as a result of the proposed regulatory action, and thus there would be benefits to health and the environment."[36] EPA should, where time permits, provide a more robust analysis of these benefits, along the following lines:

a. Benefit Quantification

EPA should capitalize on the information it has already gathered for cost quantification to quantify benefits. The agency has already estimated the volume of products containing DecaBDE broken down by type of use, ranging from wire and cable rubber casings to textiles.[37] In its economic analysis, EPA uses this information to determine substitution cost by estimating how many pounds of DecaBDE industry will need to replace: 724,787 pounds per year. [38] The number of pounds of DecaBDE to be replaced as a result of the regulation is identical to the number of pounds that will no longer be produced as a result of the regulation.

Thus, EPA has already calculated that its regulation will cause a decrease of 724,787 pounds of toxic DecaBDE per year. This quantified benefit represents removing the total volume of annual imports, the primary source of DecaBDE.[39] The number of pounds removed adds context to EPA's regulation, and the agency should include the figure when discussing the regulation's benefits, rather than only discussing qualitative benefits.

In addition, there are two main categories of quantified benefits that EPA could estimate.

First, EPA anticipates that industry will save money by switching to a substitute chemical more affordable than DecaBDE, resulting in savings of $726,900 per year.[40] This is a monetized benefit of the rule that EPA should factor into its analysis. Rather than considering these savings as quantified benefits, however, EPA assumes the substitution cost of regulation is zero.[41] EPA explains that the agency takes this approach as a "conservative approach due to the large amount

[33] 84 Fed. Reg. at 36,730.
[34] ECONOMIC ANALYSIS, *supra* note 17, at 4-46 tbl. 4-50.
[35] 84 Fed. Reg. at 36,755.
[36] *Id.*
[37] ECONOMIC ANALYSIS, *supra* note 17, at 2-4 to 2-7.
[38] *Id.* at 4-8 tbl. 4-4. This is the annual estimate for years beginning at year 1.5 of the rule.
[39] ECONOMIC ANALYSIS, *supra* note 17, at 2-7, 2-9 (discussing domestic distributors' commitment to end production of DecaBDE and its steep decline in production as well as quantifying the annual number of imports of DecaBDE).
[40] ECONOMIC ANALYSIS, *supra* note 17, at 4-8 tbl. 4-4.
[41] *Id.* at 4-5.

of uncertainty that surrounds the price estimates."[42] But EPA seems to have followed a reasoned process in estimating prices and does not explain why the results are so uncertain as to render them null.[43] In any event, because the agency has requested more information from industry about the costs of regulation, EPA is likely to receive more information about cost savings soon. The agency should update its estimate of the cost in light of information received, and if its analysis still projects benefits, EPA should count that as a benefit of the rule.

Moreover, even if uncertainty is a significant concern, valuing uncertain benefits as zero contravenes the instructions of the Office of Management and Budget's Circular A-4[44] guidance for dealing with uncertainty. When analyses are uncertain, Circular A-4 urges agencies to conduct quantitative assessments of uncertainty[45] or use averages from distributions of potential outcomes.[46] Nowhere does Circular A-4 authorize agencies to ignore benefits completely because of uncertainty. EPA's own guidelines on economic analyses recommend other ways of dealing with uncertainty, such as including a narrative description of an economic analysis's uncertainty,[47] running tests based on alternative assumptions,[48] or testing how sensitive an analysis's results are to changed parameters.[49] Again, nowhere does EPA endorse ignoring benefits because they are uncertain.

In sum, EPA should include the cost savings as benefits of the regulation, and subtract the savings from the anticipated cost of the regulation. Because the anticipated savings from the regulation are $726,900 annually relative to an anticipated cost of $155,000 annually,[50] the regulation ought to result in net benefits based on these numbers alone.

Second, given the amount of information EPA already has at its disposal, EPA should translate the information it has about how much DecaBDE would be reduced into at least a partial estimate of the environmental and health benefits that can be monetized. Though EPA is not required to conduct a risk evaluation and thus should not be required to conduct any additional studies or pull together a full risk evaluation, given the amount of information EPA already has

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[42] *Id.*
[43] *Id.* at A-1 (explaining the process used to make price estimates).
[44] Office of Mgmt. & Budget, CIRCULAR A-4 (2003).
[45] *Id.* at 39–42.
[46] *Id.* at 42. *See also* Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin., 538 F.3d 1172, 1190, 1200 (9th Cir. 2008) (finding agency reasoning arbitrary and capricious where agency argued that benefits of carbon dioxide reductions were "too uncertain to support their explicit valuation and inclusion" in a regulatory cost-benefit analysis); Pub. Citizen v. Fed. Motor Carrier Safety Admin., 374 F.3d 1209, 1219 (D.C. Cir. 2004) ("The mere fact that the magnitude of [an effect] is *uncertain* is no justification for *disregarding* the effect entirely.") (emphasis in original).
[47] *See* EPA, GUIDELINES FOR PREPARING ECONOMIC ANALYSES 11-10 (2010), *available at* https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf ("In many cases, only a narrative description of the impact of errors in assumptions is possible.").
[48] *Id.* at 11-11.
[49] *Id.*
[50] ECONOMIC ANALYSIS, *supra* note 17, at 4-46 tbl. 4-50.

about DecaBDE, it would be reasonable for EPA to use that information to provide estimates at each of the following steps:

1. Calculate the health effects and hazards associated with exposure to DecaBDE and estimate associated monetary harms. EPA can perform this step because it already has significant information at its disposal with respect to hazards linked to DecaBDE. The agency has examined 19 studies[51] of environmental hazards and at least 69 studies[52] of health hazards associated with DecaBDE, linking the chemical to aquatic toxicity[53] and health hazards such as developmental and reproductive toxicity, neurotoxicity, genotoxicity, and cancer.[54] These hazards have associated monetary costs. For example, the typical case of cancer costs about $132,165, according to EPA.[55] Cancer, in turn, can result in premature death, or $8.96 million in costs per death, according to EPA's value of a statistical life.[56] A full risk evaluation is not necessary for this step, as EPA already has information about the hazards posed by DecaBDE and, in some cases, monetized values associated with those hazards. If EPA lacks studies showing the monetized damages of some health or environmental hazards that are associated with DecaDBE, then EPA should say so and explain that its monetization thus understates the harms linked to the chemical.

2. Estimate current environmental exposure to particular doses of DecaBDE. EPA can provide at least an estimate for this step because it has reasonable estimates of the population's current exposure to specific dose levels of DecaBDE. EPA has at least one study that breaks down exposure by age, in milligrams of DecaBDE per kilogram of body weight per day.[57] Several biomonitoring studies have measured environmental and human exposure as well.[58] Even if these studies are imperfect or involve some level of uncertainty, they could provide a valuable quantified reference point for public exposure. A risk evaluation is not necessary for this step as EPA already has the information needed to prepare an estimate of dose exposure.

3. Calculate the connection between exposure and health effects. The majority of the DecaBDE health studies establish both the lowest dose (measured in milligrams of DecaBDE per kilogram of body weight per day taken into the body) at which adverse effects are observed and a

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[51] HAZARDS REPORT, *supra* note 13, at 7.
[52] *Id.* at 14.
[53] *Id.* at 7.
[54] *Id.* at 14–15.
[55] *See* EPA, COST OF ILLNESS HANDBOOK at II.1-26 tbl. II.1-4 (2007). Total Lifetime Costs in 1996 Dollars is $82,581.16. *CPI Inflation Calculator*, BUREAU OF LABOR STATISTICS, https://www.bls.gov/data/inflation_calculator.htm (last visited Oct. 19, 2019).
[56] *See* EPA Guidelines, *supra* note 47, at B-1 (providing the central estimate Value of a Statistical Life as $7.4 million in 2006 USD). $7.4 million in 2006 USD, accounting for inflation, is $8.96 million in 2018 USD. *CPI Inflation Calculator*, Bureau of Labor Statistics, https://www.bls.gov/data/inflation_calculator.htm (last visited Oct. 19, 2019).
[57] *See* EXPOSURE REPORT, *supra* note 14, at 112 tbl. 4-33.
[58] *Id.* at 112–13. *See also, e.g.*, Hermann Fromme et al., *Human Exposure to Polybrominated Diphenyl Ethers (PBDE), as Evidenced by Data from a Duplicate Diet Study, Indoor Air, House Dust, and Biomonitoring in Germany*, 35 ENV'T INTERNAT'L 1125 (2009); Andreas Sjodin et al., *Polybrominated Diphenyl Ethers and Biphenyl in Serum: Time Trend Study from the National Health and Nutrition Examination Survey for Years 2005/06 Through 2013/14*, 53 ENVTL. SCI. & TECH. 6018 (2019); Chuanlong Zhou et al., *Legacy Polybrominated Diphenyl Ethers (PBDEs) Trends in Top Predator Fish of the Laurentian Great Lakes (GL) from 1979 to 2016: Will Concentrations Continue to Decrease?*, 53 ENVTL. SCI. & TECH. 6650 (2019).

lower dose at which no adverse responses are observed.[59] Moreover, EPA has already summarized these ranges across studies.[60] According to many toxicology and policy experts, EPA should assume that any exposure to a toxic chemical represents a risk, even very low doses.[61] EPA should then plot the health effects associated with different doses of the chemical in what is known as the dose-response relationship.[62] In the case of liver cancer, EPA has already established a dose-response curve.[63] Thus for at least some health hazards, EPA already has the information needed to provide an estimate here, though it is important to understand that this would underestimate the benefits because many other health hazards would remain unquantified.

4. *Connect the dose-response relationship with each group's current exposure to gain an understanding of the baseline risks already posed by the chemical to the population.* If the agency has a dose-response curve, as it does in the case of DecaBDE-induced liver cancer, EPA can apply it to information about public exposure to estimate the risk that is already faced by the population. Because EPA has estimates showing exposure of DecaBDE among the population, the agency can plot these doses on its dose-response curve and determine the probability of a health harm associated with the dose. Across the population, EPA can determine, for example, the number of cancer cases per year associated with exposure to DecaBDE. A risk evaluation is not necessary for this step as EPA already has the information needed to conduct this step.

5. Connect the reduction in the amount of environmental exposure to observed doses. EPA should examine how much a reduction of 724,787 pounds of DecaBDE will reduce current average doses of DecaBDE. EPA has several studies that show how a specific amount of environmental exposure can lead to specific exposure doses, including from textiles, for example.[64] EPA also has estimates of how many pounds of DecaBDE will cease to be produced for various specific uses, including textiles.[65] EPA should use this information to provide an estimate showing how exposure would be affected by the regulation.

6. *EPA should monetize each reduced risk.* EPA has information which would allow it to at least partially monetize the value of reducing DecaBDE-associated risks through the regulation. For example, if the regulation's reduction of DecaBDE will avoid a certain number of cancer cases

[59] *See id.* at 16–31 (listing the NOAEL and LOAEL for each study). These studies are in non-human animals, but the agency routinely converts such results into dose levels for humans through dividing by safety factors. REVESZ ET AL., *supra* note 26, at 76.
[60] *See, e.g.*, HAZARDS REPORT , *supra* note 13, at 14 (discussing the LOAEL and NOAEL ranges for short-term toxicity, subchronic toxicity, and chronic toxicity).
[61] *See, e.g.*, INTERNAT'L PROGRAM ON CHEM. SAFETY, GUIDANCE DOCUMENT ON EVALUATING AND EXPRESSING UNCERTAINTY IN HAZARD CHARACTERIZATION 1-2 (2014) (providing methods to evaluate uncertainty of RfDs); NAT'L ACAD. OF SCI., SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 8 (2009) (finding that noncancer effects do not necessarily have a threshold); Al McGartland et al., *Estimating the Health Benefits of Environmental Regulations*, 357 SCIENCE 457, 458 (2017) (arguing against threshold methodology); Jessica A. Wignall et al., *Standardizing Benchmark Dose Calculations to Improve Science-Based Decisions in Human Health Assessments*, 122 ENVTL. HEALTH PERSP. 499, 503 (2014) (finding that NOAELs correspond to a risk of up to 10%).
[62] *Id.*
[63] *See* HAZARDS REPORT, *supra* note 13, at 14 (referencing the cancer slope plasm for liver neoplasms and carcinomas).
[64] *See* EXPOSURE REPORT, *supra* note 14, at 112–13.
[65] *See* ECONOMIC ANALYSIS, *supra* note 17, at 4-8 tbl. 4-4. 650,090 pounds of DecaBDE will no longer be produced for textiles.

per year, EPA should multiply the number of avoided cases by the value of avoiding a single case of cancer. The sum of monetized benefits for each health harm would constitute the health benefits of the regulation. To the extent a similar calculation is possible for environmental harms, EPA should conduct such an analysis as well.

If EPA cannot perform any one of the steps listed above, EPA should explain that and provide a specific reason for why the specific step cannot be performed.

b. Breakeven Analysis

If the above method is not feasible within EPA's statutory timeline, EPA should consider conducting a breakeven analysis.[66]

In the proposed rule, EPA asserts that the DecaBDE regulation will cost $155,000 per year. Assuming that estimate is accurate (and assuming that cost savings do not already outweigh those costs),[67] the proposed regulation of DecaBDE must yield at least $155,000 in annual benefits to break even.[68] As discussed above, the agency has examined 19 studies[69] of environmental hazards and at least 69 studies[70] of health hazards associated with DecaBDE, linking the chemical to aquatic toxicity[71] and health hazards such as developmental and reproductive toxicity, neurotoxicity, genotoxicity, and cancer.[72] Thus, EPA could look at the costs of regulating DecaBDE in comparison to the benefits of avoiding these hazards. For example, EPA could include a breakeven analysis of cancer avoidance, as DecaBDE has carcinogenic properties.[73] The EPA Cost of Illness handbook presents the total lifetime cost of a "typical" cancer as $132,165.12.[74] To break even, EPA's proposed regulation of DecaBDE would therefore have to prevent 1.2 cases of cancer per year. For context, there were 1,735,350 new cancer cases in the U.S. in 2018, [75] meaning that the regulation would have to prevent a very small percentage of all cancer cases. Thus, even without considering any of the non-cancer benefits of regulating DecaBDE, the regulation need only have an extremely modest effect on the cancer rate in the U.S. to break even.

These numbers alone put the modest costs of EPA's proposed regulation into context with the significant costs of harms associated with DecaBDE. But that breakeven analysis provides only a lower bound of the regulation's benefits, because the regulation will avert more harms than just cancer. For example, because cancer can lead to premature death, the rule could also save lives.

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[66] Revesz, *supra* note 19, at 1426 (describing breakeven analysis).
[67] *See supra* notes 40–50 and accompanying text.
[68] ECONOMIC ANALYSIS, *supra* note 17, at 4-8.
[69] HAZARDS REPORT, *supra* note 13, at 7.
[70] *Id.* at 14.
[71] *Id.* at 7.
[72] *Id.* at 14–15.
[73] *See* 84 Fed. Reg. at 36,744 (referring to carcinogenicity of DecaBDE).
[74] *See supra* note 55.
[75] *See* Cancer Facts & Figures 2018, Am. Cancer Soc'y, https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2018.html (last visited Oct. 3, 2019).

Using EPA's value of a statistical life of $8.96 million,[76] the rule must save roughly 0.02 lives annually, or one life every 50 years, to break even.

2. PIP (3:1)

For PIP (3:1), EPA proposes banning "processing and distribution in commerce," as well as prohibiting certain kinds of release and requiring notifications to customers.[77] According to EPA, regulating PIP (3:1) will entail $34.8 million per year in quantified costs.[78] On the benefits side, EPA explains that PIP (3:1) "is a neurotoxicant and aquatic toxicant with high persistence and high potential for bioaccumulation"[79] that is associated with "the potential for reproductive and developmental effects, neurological effects and effects on systemic organs, specifically adrenals, liver, ovary, and heart in mammals."[80] And according to EPA, the regulation will decrease "occupational exposures, if workers are unprotected" as well as "exposures to the environment . . . and thus there would be benefits to health and the environment."[81] EPA should provide a more robust analysis of these benefits, along the following lines:

a. Benefit Quantification

The steps to quantifying benefits of PIP (3:1) are the same as those for quantifying DecaBDE. This section discusses the information EPA has about PIP (3:1). For more explanation of each step, refer to the section on DecaBDE above.

1. Calculate the health effects and hazards associated with exposure to PIP (3:1) and estimate associated monetary harms. EPA can perform this step because it already has significant information about PIP (3:1), including more than 70 studies for environmental toxicity and more than 20 studies on human health hazards. [82] In addition to association with aquatic toxicity,[83] PIP (3:1) is linked to neurotoxicity, developmental and reproductive toxicity, genotoxicity, and premature mortality.[84] EPA should discuss the monetary costs associated with these hazards, including $132,165 per case of cancer,[85] a possible outcome of genotoxicity,[86] and $8.96 million, the value of a statistical life.[87] Describing the costs associated with the hazards of PIP (3:1) does not require a risk evaluation. If EPA can monetize some but not all of the hazards associated with

[76] *See supra* note 56.
[77] 84 Fed. Reg. at 36,730.
[78] ECONOMIC ANALYSIS, *supra* note 17, at 4-46 tbl. 4-50.
[79] 84 Fed. Reg. at 36,756.
[80] *Id.* at 36,744.
[81] *Id.*
[82] HAZARDS REPORT, *supra* note 13, at 51–52, 63–64 (environmental and human health study summaries, respectively).
[83] *Id.* at 51.
[84] *Id.* at 63–64.
[85] *See supra* note 55.
[86] EPA considers genotoxicity as an indicator for carcinogenicity. *See Risk Assessment for Carcinogenic Effects* (last updated Jan. 21, 2017), https://www.epa.gov/fera/risk-assessment-carcinogenic-effects (discussing genotoxicity as one of three broad categories of data collected when determining carcinogenicity).
[87] *See supra* note 56.

PIP (3:1), EPA should say so and explain that its monetization thus understates the harms linked to the chemical.

2. Estimate current environmental exposure to particular doses to PIP (3:1). In contrast to DecaBDE, there are relatively few exposure studies of PIP (3:1).[88] EPA did, however, identify one study by the Environment Agency of the United Kingdom and Wales that estimated daily human dose in a variety of scenarios.[89] EPA should consider using this study, which the agency refers to as "authoritative,"[90] to estimate average levels of the exposure that the U.S. population already experiences. In addition, the agency references dose studies of a surrogate chemical for PIP (3:1),[91] triphenyl phosphate, TPP.[92] Given that EPA has selected TPP as its surrogate chemical for PIP (3:1), the agency should consider relying on TPP dose estimates to make PIP (3:1) estimates. Even if these studies are imperfect or involve some level of uncertainty, they could provide a valuable quantified reference point for public exposure. If EPA cannot use information from any of these studies as estimates of U.S. doses, EPA should explain its reasoning.

3. Calculate the connection between exposure and health effects. As with DecaBDE, EPA has many studies of doses and responses on which to base a dose-response curve.[93] This information would allow EPA to establish the risk of adverse health effects at each dose or exposure level.

4. *Connect the dose-response relationship with each group's current exposure to gain an understanding of the baseline risks already posed by the chemical to the population.* Using information from the previous steps, EPA can then use a constructed dose-response curve to estimate exposures/doses in the population. This will provide the level of risk that the population already faces from PIP (3:1).

5. Connect the reduction in the amount of environmental exposure to observed doses. To calculate substitution costs of its proposed regulation, EPA has already quantified the amount of PIP (3:1) that will no longer be produced: 3,230,000 gallons annually.[94] This reduction constitutes a 75% reduction in the amount of PIP (3:1) produced each year.[95] EPA should include this number in its description of the benefits of the proposed regulation. Furthermore, EPA should use its studies of doses associated with different uses of PIP (3:1) or TPP[96] to estimate the reduced exposures that come from reducing gallons of PIP (3:1) within specific types of use,[97] all data that EPA has. Based on this information, EPA can estimate the reduced dose resulting from its proposed regulation, and thus the reduced risk associated with the regulation.

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[88] EXPOSURE REPORT, *supra* note 14, at 198–200.
[89] *Id.* at 195.
[90] *Id.* at 198 (referring to "the authoritative sources presented in Section 6.9," the section in which the U.K. study is discussed).
[91] *Id.* at 10, 198 (explaining TPP was chosen because of its similar chemical structure, similar use, and availability of data, and referencing exposure studies for TPP).
[92] *See id.* at 10 (discussing the selection of TPP as a surrogate for PIP (3:1)).
[93] HAZARDS REPORT, *supra* note 13, at 51–62, 63–70 (environmental and human health studies, respectively).
[94] ECONOMIC ANALYSIS, *supra* note 17, at 4-19 tbl. 4-13.
[95] *See id.* at 4-16 tbl. 4-11 (showing the total production of PIP (3:1), 4,330,000 gallons, by use).
[96] *See* EXPOSURE REPORT, *supra* note 14, at 198 (saying that many studies of TPP exposures could be used to model exposures of PIP (3:1) through the CEM model or IEC-CU model).
[97] *See* ECONOMIC ANALYSIS, *supra* note 17, at 4-19 tbl. 4-13 (listing the reduction in PIP (3:1) by use).

6. *EPA should monetize each reduced risk.* EPA should translate the reduced risk into monetary benefits. For example, reducing exposure to PIP (3:1) will likely reduce cases of cancer and premature mortality, valued at $132,165 per cancer case[98] and $8.96 million per death.[99] EPA should multiply the number of avoided hazards, such as cancer cases, by the cost of the hazardous outcome to estimate the annualized benefits of the rule. Although these examples have focused on health hazards, EPA should follow the same steps to monetize the benefits associated with reducing environmental hazards.

If EPA lacks adequate information at any step in the process of quantifying benefits for either type of hazard, EPA should explain what information it lacks and why that information is necessary.

b. Breakeven Analysis

If quantifying the benefits is not feasible within EPA's statutory timeline, EPA should consider conducting a breakeven analysis.[100]

In the case of PIP (3:1), to recoup annual costs, EPA's proposed regulation of PIP (3:1) must yield at least $34.8 million in annual benefits.[101] As discussed above, the agency has examined more than 70 studies for environmental toxicity and more than 20 studies on human health hazards. [102] PIP (3:1) is linked to aquatic toxicity,[103] neurotoxicity, developmental and reproductive toxicity, genotoxicity, which can lead to cancer, and premature mortality.[104] Accordingly, EPA could look at the costs of regulating PIP (3:1) in comparison to the benefits of avoiding these hazards. For example, EPA could include a breakeven analysis of cancer avoidance. Assuming the typical cost of a cancer case is $132,165,[105] preventing 263 cancer cases annually would make up for the costs of the regulation. Again, there were 1,735,350 new cancer cases in the U.S. in 2018, meaning that the regulation would only have to prevent a small percentage of all cancer cases to break even.[106]

Of course, the regulation could prevent less than 263 cancer cases and still break even, because the regulation will have more benefits than preventing cancer. For example, because PIP (3:1) is linked to premature mortality,[107] EPA could evaluate the Proposed Rule in terms of lives saved. Using the statistical value of a human life of $8.96 million,[108] the regulation need only prevent 3.88 deaths per year to break even.

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[98] *See supra* note 55.
[99] *See supra* note 87.
[100] *See* Revesz, *supra* note 19, at 1426 (describing breakeven analysis).
[101] ECONOMIC ANALYSIS, *supra* note 17, at 4-8.
[102] HAZARDS REPORT, *supra* note 13, at 51–52, 63–64 (environmental and human health study summaries, respectively).
[103] *Id.* at 51.
[104] *Id.* at 63–64.
[105] *See supra* note 55.
[106] *See* Cancer Facts & Figures, *supra* note 75.
[107] HAZARDS REPORT, *supra* note 13, at 63–64.
[108] *See supra* note 87.

3. 2,4,6-TTBP

For 2,4,6-TTBP, EPA proposes banning distribution in commerce of containers holding less than 55 gallons, in order to effectively prohibit certain uses by consumers and small commercial operations not regulated by the Occupational Safety and Health Administration.[109] According to EPA, regulating 2,4,6-TTBP will entail $8.96 million per year in quantified costs.[110] On the benefits side, EPA explains that 2,4,6-TTBP "is persistent and bioaccumulative, and has been associated with liver toxicity and reproductive and developmental effects in mammals."[111] EPA states that the proposed "rule is expected to reduce consumer exposures to 2,4,6-TTBP and occupational exposure in certain industries, if workers are unprotected, as well as releases to the environment from consumer use, and thus, there would be benefits to health and the environment."[112] EPA should attempt to provide a more robust analysis of these benefits, along the following lines:

a. Benefit Quantification

There are two main categories of benefits that EPA could estimate:

First, as with DecaBDE, EPA's analysis of substitution costs for 2,4,6-TTBP includes costs of regulation while ignoring benefits.[113] Specifically, while EPA anticipates that substituting other products for fuel additives containing 2,4,6-TTBP will cost industry $8.4 million annually, EPA also anticipates that substituting other products for fuel injector cleaner containing 2,4,6-TTBP will save industry $2,896,900 annually.[114] The agency, however, treats these anticipated benefits as zero, citing uncertainty.[115] As with EPA's DecaBDE analysis, however, the agency seems to have used a reasoned method to estimate substitution costs and does not explain why the uncertainty renders the benefits null.[116] Because the agency has solicited information from industry with respect to cost[117] and will likely receive that information, EPA should be able to produce an estimate of costs going forward. Any savings predicted by that analysis should accordingly be considered quantified benefits.

Again, even if the uncertainty is meaningful, ignoring the upsides projected by EPA's analysis while emphasizing the downsides projected by the same analysis departs from the Office of Management and Budget's guidance and EPA's own guidelines with respect to handling

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[109] 84 Fed. Reg. at 36,730.
[110] ECONOMIC ANALYSIS, *supra* note 17, at 4-46 tbl. 4-50.
[111] 84 Fed. Reg. at 36,756.
[112] *Id.*
[113] *See id.* at 4-27 tbl. 4-24 & 4-5 (laying out the anticipated savings associated with substituting another chemical for fuel injector cleaner, and explaining EPA's overall approach of treating anticipated benefits as zero).
[114] *See id.* at 4-27 tbl. 4-24 (number obtained by multiplying 4,910,000 gallons by anticipated saving per gallon of $0.59).
[115] *Id.*
[116] *See id.* at 4-23 (explaining the cost estimate methodology, relying on substitute products, without citing any reason the analysis should be particularly unreliable).
[117] 84 Fed. Reg. at 36,755.

uncertainty.[118] Instead, EPA should include the anticipated savings as an offset of the anticipated costs. Subtracting the annual savings of $2,896,900 from the annual costs of $8.4 million yields $5,503,100 in costs. This is the appropriate number against which to measure the rule's other benefits discussed below.

Second, given the amount of information EPA already has at its disposal, EPA should translate the information it has about how much 2,4,6-TTBP would be reduced into at least a partial estimate of the environmental and health benefits that can be monetized. Though EPA is not required to conduct a risk evaluation and thus should not be required to conduct any additional studies or pull together a full risk evaluation, given the amount of information EPA already has about 2,4,6-TTBP, it would be reasonable for EPA to use that information to provide at least estimates at each of the following steps:

1. Calculate the health effects and hazards associated with exposure to 2,4,6-TTBP and estimate the associated monetary harms. EPA has reviewed seven studies on environmental hazards and ten studies on health hazards linked to 2,4,6-TTBP. These studies link 2,4,6-TTBP to aquatic toxicity,[119] and to neurological and developmental toxicity, as well as cancer.[120] As with other chemicals, EPA should explain the costs associated with these hazards in justifying its regulation, including its own monetization of the costs of a typical cancer case, $132,165,[121] and the value of avoided premature death, $8.96 million.[122] The agency does not need to conduct a risk evaluation to explain the typical costs associated with these hazards. If EPA can monetize some but not all of the hazards associated with 2,4,6-TTBP, EPA should say so and explain that its monetization thus understates the harms linked to the chemical.

2. Estimate current environmental exposure to particular doses of 2,4,6-TTBP. EPA has reviewed two data sets associated with the existing daily doses of 2,4,6-TTBP experienced by the population.[123] EPA could use these data sets to estimate exposure in the population to 2,4,6-TTBP. If the agency cannot use these data sets to make an estimate, the agency should explain why.

3. Calculate the connection between exposure and health effects. EPA should model the dose-response data unless the agency can show that the data are not amenable to this analysis.

4. *Connect the dose-response relationship with each group's current exposure to gain an understanding of the baseline risks already posed by the chemical.* The agency should map the estimated exposures of the population onto the dose response curve to determine the over-all risk the public faces from 2,4,6-TTBP.

5. Connect the reduction in the amount of environmental exposure to observed doses. As with the other chemicals EPA proposes to regulate, EPA has already estimated the volume of fuel with 2,4,6-TTBP that will no longer be produced as a result of the regulation: 120 million gallons

[118] *See supra* notes 44–49and accompanying text.
[119] HAZARDS REPORT, *supra* note 13, at 71.
[120] *Id.* at 73.
[121] *See supra* note 85.
[122] *See supra* note 56.
[123] EXPOSURE REPORT, *supra* note 14, at 221–22.

annually.[124] EPA should include this quantified reduction in its description of benefits. Where EPA has less information translating specific routes of exposure to 2,4,6-TTBP into human does, EPA can use default data based on other similar chemicals. Defaults are recommended by the National Academy of Sciences in Science and Decisions as an appropriate way to fill in data gaps to ensure that risks are not inappropriately set to zero.[125]

6. *EPA should monetize each reduced risk.* EPA should use the dose-response to calculate decreased risk, unless the agency can show that it is not possible.

If EPA cannot perform any one of the steps listed above, EPA should explain that and provide a specific reason for why the specific step cannot be performed.

b. Breakeven Analysis

If benefit monetization is not feasible on an expedited timeline, EPA should consider conducting a breakeven analysis. With $8.4 million of costs annually, the regulation would need to provide benefits that break even with $8.4 million annually. 2,4,6-TTBP is carcinogenic,[126] and the typical cost of cancer is $132,165.[127] Thus, according to EPA's stated cost number, the regulation must prevent about 64 cases of cancer per year, significantly less than 0.01% of cases in the U.S. in 2018.[128] With costs of $5,503,100, the proposed regulation must prevent roughly 42 cases of cancer per year. As with the other proposed regulations, the regulation of 2,4,6-TTBP need yield only modest benefits to break even.

The numbers suggest that EPA's proposed regulation of 2,4,6-TTBP can be justified based on cancer avoidance alone. Additionally, the rule could save lives. Using EPA's value of a statistical life of $8.96 million,[129] the rule must save less than one life per year to break even.

4. PCTP

For PCTP, EPA proposes banning "manufacture (including import), processing, and distribution in commerce" of products that contain more than 1 percent of the chemical by weight.[130] According to EPA, regulating PCTP will entail $108,000 per year in quantified costs.[131] On the benefits side, EPA explains that PCTP is "persistent, bioaccumulative, and an aquatic toxicant"[132] that is associated with the "potential for liver effects in mammals and systemic (body weight) effects . . . in mammals."[133] EPA explains that the "proposed regulatory action would

[124] ECONOMIC ANALYSIS, *supra* note 17, at 4-27 tbl. 4-24.
[125] *See* NAT'L ACAD. OF SCI., *supra* note 61, at 7–8.
[126] *See* HAZARDS REPORT, *supra* note 13, at 73 (discussing 2-year carcinogenicity study).
[127] *See supra* note 85.
[128] *See supra* note 106 and accompanying text.
[129] *See supra* note 56.
[130] 84 Fed. Reg. at 36,730.
[131] ECONOMIC ANALYSIS, *supra* note 17, at 4-46 tbl. 4-50.
[132] 84 Fed. Reg. at 36,756.
[133] *Id.* at 36,744.

decrease dermal and inhalation PCTP exposures in workers involved in the manufacture of golf balls, if the workers are unprotected, and decrease releases of PCTP to the environment.[134] Decreased releases to the environment would eventually result in a decrease of exposures in the general population and of consumption of contaminated food.[135] According to EPA, reducing PCTP in this way "would have benefits for the environment and potential benefits to health for workers, if they are unprotected."[136] EPA should consider providing a more robust analysis of these benefits, along the following lines:

a. Benefit Quantification

EPA has less information at its disposal about PCTP than it does about the other chemicals it proposes to regulate.[137] Nevertheless, EPA cites studies linking PCTP to aquatic toxicity,[138] genotoxicity, [139] and premature mortality.[140] In summarizing the benefits of the regulation, EPA should include the costs associated with these hazards, such as the typical cost of a case of cancer, $132,165,[141] and the statistical value of a human life, $8.96 million.[142] Describing these costs does not require a risk evaluation.

Moreover, EPA's regulation requires that no product contain more than 1% PCTP by weight.[143] According to the agency, PCTP in the U.S. comes from impurities in ZnPCTP, a compound used to make golf ball cores.[144] To calculate substitution costs, EPA estimates that 94,982 pounds of 98% ZnPCTP will be converted to 99% ZnPCTP. [145] As a rough estimate, this proposed rule could result in a reduction of PCTP of roughly 1% of 94,982 pounds, or roughly 950 pounds of PCTP reduced annually.[146] EPA should include this number to better quantify the benefits of its regulation.

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[134] *Id.*
[135] *Id.*
[136] *Id.*
[137] *See* EXPOSURE REPORT, *supra* note 14, at 232–33 (describing EPA's failure to identify studies of PCTP in monitoring data, measuring existing exposure, or modeling intake).
[138] HAZARDS REPORT, *supra* note 13, at 75–76.
[139] *Id.* at 77–78.
[140] *Id.*
[141] *See supra* note 85.
[142] *See supra* note 87.
[143] 84 Fed. Reg. at 36,760.
[144] ECONOMIC ANALYSIS, *supra* note 17, at 1-3.
[145] *Id.* at 4-10 tbl. 4-7. This is a reduction of ZnPCTP in golf balls, the only use of PCTP. *Id.*; *see also* 3-9 (describing ZnPCTP as the only source of PCTP, and golf balls as the only use of ZnPCTP).
[146] Although EPA does not know what percent of the impurities of ZnPCTP is PCTP, the agency takes the conservative approach of assuming that 100% of the impurities are attributable to PCTP; similarly, our rough estimate assumes that the reduction of impurities is fully PCTP. *See* ECONOMIC ANALYSIS *supra* note 17, AT 4-9 to 4-10 ("While the concentration at which PCTP appears (as an impurity) in ZnPCTP is not known, EPA assumes that ZnPCTP sold at a purity level of 99% would allow for a maximum of 1% concentration of PCTP.").

b. Breakeven Analysis

If benefit monetization is not feasible on an expedited timeline, the agency should consider performing a breakeven analysis. To break even, the proposed regulation must yield at least $108,000 in benefits annually. PCTP is associated with genotoxicity,[147] which can lead to cancer,[148] and premature mortality.[149] With a typical cost of a cancer case of $132,165 and a statistical value of human life at $8.96 million, the regulation must prevent less than one case of cancer or one death annually to exceed costs. Thus, it would be reasonable to conclude that the costs of the regulation will break even with the benefits.

II. EPA Has Failed to Provide a Reasoned Explanation for Its Failure to Regulate HCBD

Although EPA has proposed to regulate four of the persistent, bioaccumulative, and toxic chemicals it considered, the agency has declined to regulate hexachlorobutadiene (HCBD).[150] The agency announces this decision despite strong evidence, borne out by more than 50 studies analyzed by EPA, that HCBD exposures pose threats to the environment as well as to health, including risks such as genotoxicity, neurological damage, developmental and reproductive harm, cancer, and premature mortality.[151]

EPA's decision not to regulate HCBD must comply with the Administrative Procedures Act,[152] which forbids arbitrary and capricious agency action.[153] Under the arbitrary and capricious standard, an agency must "examine the relevant data" and "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made."[154] Courts will reverse where an examination of the agency's explanation makes clear that the agency failed to consider "an important aspect of the problem."[155] In addition, a "serious flaw undermining" the agency's cost-benefit analysis "can render the rule unreasonable." [156]

EPA's analysis is flawed in two major ways. First, EPA only considers a total ban on HCBD and does not adequately consider regulatory alternatives. Second, in evaluating a total ban on HCBD, EPA does not account for the benefits of effectively banning the potentially toxic substances HCBD is used to produce, such as perchloroethylene, trichloroethylene, and carbon tetrachloride. These chemicals cause numerous health harms themselves and are known or likely

[147] HAZARDS REPORT, *supra* note 13, at 77–78.
[148] *See supra* note 86.
[149] HAZARDS REPORT, *supra* note 13, at 77–78.
[150] 84 Fed. Reg. at 36,753.
[151] *See* HAZARDS REPORT, *supra* note 13, at 33, 36 (summarizing the studies of environmental hazards and health hazards respectively).
[152] 5 U.S.C. § 706(2)(A).
[153] *Id.*
[154] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983).
[155] *Id. See also* F.C.C. v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009).
[156] Nat'l Ass'n of Home Builders v. EPA, 682 F.3d 1032, 1040 (D.C. Cir. 2012).

carcinogens.[157] Instead, the agency performs a lopsided analysis that considers only the costs to industry of banning HCBD's products, without even a qualitative description of the potential upsides of banning chemicals under investigation as toxics themselves.

A. EPA Has Not Adequately Considered the Regulatory Alternatives to a Full Ban of HCBD

In the United States, HCBD is produced only as a byproduct to make other things: 1) chlorinated solvents typically used in industrial-level cleaning[158] and 2) rubber compounds and fluorinated lubricants.[159] Chlorinated solvents may themselves be toxic and are undergoing separate, independent risk evaluations under TSCA § 6(b), the regulatory track for non-expedited toxics.[160]

Because HCBD is eliminated by incineration and is thus not released, most HCBD enters the environment through fugitive emissions, according to EPA.[161] Thus, HCBD is currently regulated and monitored under Clean Air Act §112 as a hazardous air pollutant, as well as under the Clean Water Act and the Resource Conservation and Recovery Act.[162] Because of this, EPA determines that "[t]aking into account the many existing controls on activities that might affect exposures to HCBD, the only meaningful further reductions that might be achieved would be by prohibiting manufacture of HCBD."[163] EPA is "not aware" of any alternative ways to produce chlorinated solvents, so the agency evaluates the cost of an HCBD ban as effectively banning the production of chlorinated solvents.[164] After considering a full ban on HCBD, EPA proposes that regulation is not practicable, due to the burdensome effect a ban would have on the production of chlorinated solvents.[165]

But TSCA's statement of effects, which EPA has interpreted as applicable to expedited chemicals, requires EPA to consider at least one or more alternative regulatory approaches to its

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[157] AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, PUBLIC HEALTH STATEMENT FOR PERCHLOROETHYLENE 3–4 (2015), *available at* https://www.atsdr.cdc.gov/ToxProfiles/tp18-c1.pdf (linking the chemical to cancer); AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY, PUBLIC HEALTH STATEMENT FOR TRICHLOROETHYLENE 4 (2015), *available at* https://www.atsdr.cdc.gov/ToxProfiles/tp19-c1.pdf (discussing health effects including cancer); OXY OCCIDENTAL CHEMICAL CORP., PRODUCT STEWARDSHIP SUMMARY CARBON TETRACHLORIDE 2–3 (2017), *available at* https://www.oxy.com/OurBusinesses/Chemicals/ResponsibleCare/Documents/Carbon%20tetrachloride.pdf (describing health and environmental harms of carbon tetrachloride).

[158] *Chlorinated Solvents*, THE WORKER HEALTH PROTECTION PROGRAM, http://www.worker-health.org/chlorinatedsolvents.html (last visited Oct. 19, 2019).

[159] ECONOMIC ANALYSIS, *supra* note 17, at 2-25.

[160] 84 Fed. Reg. at 36,753.

[161] *Id.*

[162] *Id.*

[163] *Id.*

[164] ECONOMIC ANALYSIS, *supra* note 17, at 4-2.

[165] 84 Fed. Reg. at 36,753.

proposed regulation.[166] Consideration of "less restrictive, yet easily administered" regulatory alternatives is also required to withstand arbitrary and capricious review.[167]

EPA's exclusive focus on a total ban of HCBD does not meet this standard. The agency does not adequately explain why there is no middle ground alternative between current practices and banning HCBD. For example, studies have suggested that workers may be occupationally exposed to HCBD.[168] EPA could presumably reduce exposure in the work place by restricting, rather than fully banning, the production of HCBD. In its current proposal, EPA seems to dismiss this possibility by asserting that employers already have a responsibility to make workspaces safe for employees under OSHA.[169] But EPA also acknowledges that OSHA has not established permissible exposure limits for any of the five chemicals at issue in the Proposed Rule, including HCBD.[170] Surely a regulation from EPA could protect employees and lead to benefits.

Consider a second example: Most states control HCBD through air pollution, water pollution, or waste management regulations, but their standards of strictness vary.[171] EPA could consider how regulating aspects of manufacture, processing, and distribution might bring the standards in laxer states closer to those of more stringent states.

Yet another example: HCBD could be regulated in the context of production for uses other than making chlorinated solvents. EPA acknowledges that some of the sites that produce HCBD do not produce chlorinated solvents.[172] EPA further acknowledges that the agency does not understand why HCBD is produced on these sites.[173] EPA should investigate this issue before determining that the only way to further reduce exposure is a full ban on HCBD.

Along similar lines, EPA's economic analysis mentions that HCBD is produced not only to make chlorinated solvents, but also to make rubber compounds and fluorinated lubricants.[174] But EPA mentions this second use nowhere in its Proposed Rule. Limiting the use of HCBD to make rubber compounds and fluorinated lubricants could be a way of regulating HCBD without affecting its use in producing chlorinated solvents. This regulatory approach would offer an alternative to a total ban on HCBD.

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[166] *See* 15 U.S.C. § 2605(c)(2)(C) (requiring the consideration of alternatives).
[167] Cin. Bell Tel. Co. v. FCC, 69 F.3d 752, 761 (6th Cir. 1995).
[168] EXPOSURE REPORT, *supra* note 14, at 126–27.
[169] 84 Fed. Reg. at 36,745 (saying that EPA is not regulating occupational exposure through mandated controls such as engineering controls or use of personal protective equipment because of OSHA and employers' resultant "legal obligation to furnish to each of its employees a place of employment that are [*sic*] free from recognized hazards that are causing or are likely to cause death or serious physical harm").
[170] *Id.*
[171] *See* ECONOMIC ANALYSIS, *supra* note 17, at 1-10, 1-11 to 1-12 tbl. 1-10 (listing states with regulations and varying standards).
[172] *Id.* at 2-27.
[173] *See id.* ("EPA notes that some companies that produce HCBD do not manufacture the solvents are the same site; the reason for HCBD production at these sites is not clear.").
[174] *Id.* at 2-25.

B. EPA Must Account for the Benefits of Banning Chlorinated Solvents in Evaluating a Full Ban on HCBD

Although EPA acknowledges that banning HCBD would reduce exposure to the toxic chemical,[175] EPA nowhere makes any attempt to quantify the benefit of this reduction, through a breakeven analysis or other means. For reasons similar to those discussed regarding the four other chemicals above, EPA should consider quantifying the benefits of reduced exposure to HCBD. If quantification is infeasible, EPA should conduct a breakeven analysis.

But EPA's analysis has issues beyond a lack of quantification. EPA fails to adequately assess the effects that banning HCBD would have upon the production of chlorinated solvents, such as perchloroethylene, trichloroethylene, and carbon tetrachloride—potential toxic chemicals in their own right. [176] The agency quantifies the costs of banning chlorinated solvents,[177] while making no attempt to quantify or qualitatively describe the benefit of reduced exposure to chlorinated solvents.[178] After this lopsided analysis, EPA conclusively states that the cost of a ban would be too high.[179] Such an incomplete and conclusory analysis is arbitrary and capricious.[180]

EPA's reasons for neglecting to fully consider the dangers of chlorinated solvents, and the associated benefits with banning them, are unpersuasive. As part of its justification for ignoring the effects of banning chlorinated solvents, EPA notes that the agency is currently investigating chlorinated solvents on a non-expedited regulatory track under TSCA § 6(b).[181] There may be some merit to evaluating a ban on chlorinated solvents separately under that provision, which allows more time to promulgate rules, and requires risk evaluations.[182] But so far, only one of the scope documents for risk evaluation of these chlorinated solvents—of which there are three—mentions HCBD.[183] And even the scope document that mentions HCBD only does so in passing

[175] *See id.* at 5-13 (discussing "benefits of reduced exposure to HCBD").
[176] 84 Fed. Reg. at 36,753.
[177] ECONOMIC ANALYSIS, *supra* note 17, at 4-41.
[178] *See id.* at 5-13 to 5-15 (describing the benefits of regulation and nowhere describing the benefits of reduced exposure to chlorinated solvents).
[179] 84 Fed. Reg. at 36,753.
[180] United Techs. Corp. v. Dep't of Def., 601 F.3d 557, 562 (D.C. Cir. 2010) (courts "do not defer to the agency's conclusory or unsupported suppositions." (quotations marks omitted)); *accord* NetCoalition v. SEC, 615 F.3d 525, 539 (D.C. Cir. 2013); *see also* Ctr. for Biological Diversity v. Nat'l Highway Traffic Safety Admin., 538 F.3d 1172, 1198 (9th Cir. 2008) (explaining that an agency is not permitted to "put a thumb on the scale" by under- or overvaluing key effects).
[181] 84 Fed. Reg. at 36,753.
[182] 15 U.S.C.A. § 2605(b)(3).
[183] *See* SCOPE OF THE RISK EVALUATION FOR CARBON TETRACHLORIDE 58 (2017), *available at* https://www.epa.gov/sites/production/files/2017-06/documents/ccl4_scope_06-22-17.pdf (mentioning that "small volumes of" hexachlorobutadiene are produced in the chlorination of hydrocarbons). HCBD is mentioned nowhere in the other two scope documents. *See generally* SCOPE OF THE RISK EVALUATION FOR PERCHLOROETHRYLENE (2017), *available at* https://www.epa.gov/sites/production/files/2017-06/documents/perc_scope_06-22-17.pdf; SCOPE OF THE RISK EVALUATION FOR TRICHLOROETHYLENE (2017), *available at* https://www.epa.gov/sites/production/files/2017-06/documents/tce_scope_06-22-17.pdf.

and gives no indication that HCBD will play an important role in the risk evaluation.[184] This lack of mention suggests that EPA will fail to consider the associated hazard of HCBD in its risk evaluations of chlorinated solvents. EPA should not allow analysis of the hazardous use of HCBD to fall through the cracks in this way.

Furthermore, it does not seem as though EPA investigated whether HCBD-free production methods for chlorinated solvents exist.[185] The agency merely states that it is "not aware" of such methods, with no reference to any underlying investigation or solicitation for comment.[186] EPA should at least solicit such information from industry before concluding that a ban on HCBD would entail a ban on chlorinated solvents.

Conclusion

In sum, EPA has provided compelling evidence justifying its proposal to regulate DecaBDE, PIP (3:1), 2,4,6-TTBP, and PCTP. Because EPA has quantified costs in its statement of effects, the agency should also quantify the benefits of regulation and, where such quantification is not possible in the given time period, perform a breakeven analysis. If quantification is not possible, EPA should explain why by specifying exactly what piece of information is missing and why that information is necessary.

Furthermore, the agency should reevaluate its decision not to regulate HCBD. EPA's explanation is insufficient because it only considers a full ban. In addition, the analysis is lopsided because it considers the costs but not the benefits of effectively banning chlorinated solvents. The agency's current HCBD analysis thus fails the standards of arbitrary and capricious review.[187]

Respectfully,

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[184] *See* SCOPE OF THE RISK EVALUATION FOR CARBON TETRACHLORIDE 58 (2017) (mentioning that "small volumes of" hexachlorobutadiene are produced in the chlorination of hydrocarbons).
[185] *See* ECONOMIC ANALYSIS, *supra* note 17, at 4-2, (claiming EPA is "not aware of any other methods of production for these solvents," without reference to any inquiry into the question).
[186] *See id.*; *see also* 84 Fed. Reg. at 36,756 (referencing the effective ban on chlorinated solvents as the reason not to regulate without soliciting comment).
[187] Policy Integrity has submitted copies of the cited references in this comment letter to the docket separately.