# Regulating Risk from Toxic Substances

*Best Practices for Economic Analysis of Risk Management Options Under the Toxic Substances Control Act*

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**July 2021**
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Policy Integrity gratefully acknowledges the research assistance of Scott Greenberg and Brandon Ho, as well as the editing assistance of Jeff Hannan, in preparing this report.

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# Executive Summary

In 2016, Congress amended the Toxic Substances Control Act (TSCA) through the Lautenberg Act, with the aim of spurring the Environmental Protection Agency (EPA) to issue more expansive and protective regulations of harmful chemicals. The new statutory framework provides a three-step process for evaluating and controlling the risks of chemicals currently in use: prioritization, risk evaluation, and risk management. After finding during the prioritization process that a chemical *may* present an unreasonable risk, EPA must conduct a risk evaluation to assess its hazards, including to especially vulnerable populations. If the agency's risk evaluation finds that the chemical does indeed pose unreasonable risks, EPA must then issue a risk management rule that eliminates the unreasonable risks.

During the Trump administration, EPA completed risk evaluations for ten chemicals but did not issue any risk management rules. These ten risk evaluations have numerous problems, including the exclusion of certain chemical uses and exposure pathways, and several are subject to pending court challenges brought by environmental, health, and labor groups as well as state and local governments. The Biden administration is planning to issue risk management rules for three of these ten chemicals, as EPA believes their risk evaluations to be acceptable, while simultaneously revising the remaining seven risk evaluations to better account for the total risks posed by those chemicals.

Under the 2016 Lautenberg Act, EPA is required to consider the health and environmental benefits as well as the economic costs of regulation when deciding how to control chemicals that pose an unreasonable risk. Accordingly, this report identifies best practices for EPA to follow when assessing the costs and benefits of potential risk management options. Specifically, we recommend that any such analysis should include consideration of 1) benefits of regulating below the "unreasonable" risk level, 2) benefits from reducing exposures that may fall under the jurisdiction of other statutes, 3) benefits from reducing harms to vulnerable subpopulations, 4) unquantified benefits, 5) substitution effects, and 6) distributional consequences. Robust cost-benefit analyses that incorporate these elements will satisfy EPA's statutory obligations and aid the agency in selecting the risk management approaches that will be most welfare-enhancing. Finally, we recommend that EPA rely on cost-effectiveness metrics only when choosing between risk management options that offer similar net benefits.

# I. Regulating Under the Amended TSCA: Statutory Framework and Current Implementation

Originally enacted in 1976, TSCA requires EPA to regulate chemicals that are harmful to human health and the environment.[1] However, the agency rarely used the law to regulate chemicals on the market after the US. Court of Appeals for the Fifth Circuit vacated EPA's 1989 regulation of asbestos in the case *Corrosion Proof Fittings v. EPA*.[2] In part to combat this inaction, Congress passed the Lautenberg Act in 2016, which revised TSCA to strengthen EPA's regulatory authority and establish clear processes and timelines for identifying, assessing, and managing chemicals in commerce that present unreasonable risks.[3]

Under the amended statute, regulation of chemicals currently in use is a three-step process.[4] The first stage is prioritization, where chemicals are designated as low or high priority. The next stage is risk evaluation, where EPA determines whether a chemical's risks are reasonable or unreasonable.[5] Finally, EPA issues risk management rules to eliminate, at a minimum, those risks found to be unreasonable.

## A. Prioritization

The prioritization process is governed by TSCA § 6(b)(1)[6] and EPA's Procedures for *Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act*.[7] The statute requires EPA to designate a chemical as high priority if the agency determines that the chemical "may present" an unreasonable risk of injury to health or the environment.[8] Chemicals found not to meet this criterion must be designated as low priority, though a low priority designation can be revised later based on new information.[9]

To guide EPA in making priority designations, Congress included a list of statutory factors to consider, including the substance's "hazard and exposure potential," its "conditions of use" (or significant changes in those conditions), and the volume in which it is manufactured or processed (or significant changes in that volume).[10] EPA also looks to whether the chemical is a known carcinogen or otherwise highly toxic to human health, as well as whether it persists in the environment.[11] Additionally, lawmakers barred EPA from considering costs or other non-risk factors in the prioritization process.[12]

The primary objective of the prioritization process is to direct the agency's resources to chemicals that pose the "greatest hazard and exposure potential first."[13] In designating a substance as a high or low priority, EPA regulations require evaluation of the chemical as a whole and not on a use by use basis.[14] The agency also has authority to designate entire categories of chemicals as high priority,[15] which can alert industry to potential regulations on a class of substances.

The first ten risk evaluations conducted after passage of the 2016 Lautenberg Act did not undergo this prioritization process; they were selected from the 2014 TSCA Work Plan, which had already identified numerous chemicals that posed serious hazards.[16] Congress specified that the agency must, in designating high-priority substances, give preference to chemicals that were listed on the work plan either because of their persistence and bioaccumulation or because they are human carcinogens with "high acute and chronic toxicity."[17]


## B. Risk Evaluation

Once EPA designates a chemical as high priority, it must immediately initiate a risk evaluation for the substance.[18] The risk evaluation process is governed by TSCA § 6(b)(4)[19] and EPA's *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (hereinafter "Risk Evaluation Procedures").[20] The purpose of a risk evaluation is to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use."[21] Potentially exposed or susceptible subpopulations are groups "who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects . . . such as infants, children, pregnant women, workers, or the elderly."[22] Conditions of use are "the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[23] EPA is statutorily forbidden from "consider[ing] costs or other nonrisk factors" at the risk evaluation stage.[24]

As the first step in the evaluation process, EPA must publish the scope of its inquiry.[25] Under EPA's Risk Evaluation Procedures, EPA first identifies the "the potentially exposed or susceptible subpopulations EPA expects to consider, the ecological receptors, and the hazards to human health and the environment the Agency plans to evaluate."[26] It then develops a conceptual model that describes "the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance—from manufacturing, processing, distribution in commerce, storage, use, to release or disposal."[27] The scope also includes "a description of the reasonably available information and the science approaches that the Agency plans to use" as well as plans for peer review.[28] Within three months of initiating a risk evaluation, EPA must publish the draft scope, followed by a 45-day public comment period. Within six months of beginning a risk evaluation, EPA must publish its final scope.[29]

Once the scope is finalized, EPA's Risk Evaluation Procedures require the agency to complete a risk evaluation with the following components: a hazard assessment, an exposure assessment, a risk characterization, and a risk determination.[30] Hazards include, but are not limited to, the "potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, and cardiovascular impacts, and neurological impairment."[31] In the exposure assessment, EPA examines the "likely duration, intensity, frequency, and number of exposures under the conditions of use."[32] The risk characterization then integrates these assessments into "quantitative and/or qualitative estimates of risk for the identified populations."[33] The agency's Risk Evaluation Procedures also require EPA to examine the chemical's hazardousness for vulnerable subpopulations, using "an appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, [and] models representing health effects to the population."[34] While EPA has discretion over what specific methods and approaches it uses to determine a chemical's risk, both TSCA itself and EPA's Risk Evaluation Procedures require the agency to use the "best available science."[35]

The entire risk evaluation process must be completed within three years of its initiation, subject to a six-month extension.[36] If EPA concludes that a chemical presents an unreasonable risk of injury, the agency must proceed to risk management. As of July 2021, EPA had completed risk evaluations for ten chemicals,[37] and had begun risk evaluations for an additional 22 chemicals.[38]

Although EPA did make progress in completing risk evaluations during the Trump administration, environmental, labor, and public health organizations, state and local governments, and EPA's own scientific advisors raised numerous concerns with the agency's procedures for determining whether a chemical poses an unreasonable risk.[39] Two major areas of dispute have been 1) whether EPA must consider all of a chemical's conditions of use in a single risk evaluation, and 2) whether TSCA requires EPA to consider exposure routes that fall under the purview of other environmental statutes or other federal laws.

On the first issue, TSCA stipulates that EPA must evaluate whether a chemical poses an unreasonable risk under its "conditions of use."[40] The statute defines a "condition of use" as "the circumstances . . . under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[41] In its Risk Evaluation Procedures, EPA sought to leave itself discretion to determine the "circumstances" that constitute the "conditions of use" for each chemical on a case-by-case basis.[42] While the statute does task the agency with identifying the circumstances that constitute a chemical's conditions of use, EPA sought to preemptively *exclude* a number of known conditions of use from risk evaluations.[43] In addition, it asserted that "legacy" uses and associated disposal which it defined as those "associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution" are not conditions of use.[44]

EPA sought to preemptively *exclude* a number of known conditions of use from risk evaluations.

Many stakeholders objected to EPA's attempt to exclude known conditions of use from a risk evaluation and to narrowly define the term "conditions of use," arguing that doing so violated TSCA and could obscure the true risks of a chemical. In a subsequent lawsuit over EPA's Risk Evaluation Procedures, the U.S. Court of Appeals for the Ninth Circuit found that, while EPA is responsible for identifying *how* a substance is being manufactured, used, and so forth, its own regulation does not afford it the discretion to consider only a subset of such conditions in a risk evaluation.[45] In other words, EPA must consider all identified conditions of use in a risk evaluation,[46] which the agency did not do for its first ten risk

evaluations.[47] The Ninth Circuit also specifically held that the 2016 Lautenberg Act requires EPA to consider so-called "legacy" uses of a chemical in risk evaluations,[48] which has prompted EPA to rework its approach to chemicals like asbestos that have multiple such uses.[49]

The second major issue, whether EPA can exclude exposure routes from risk evaluations because they are under the jurisdiction of other federal statutes, is still being litigated.[50] TSCA exempts chemicals in some products from its definition of "chemical substance,"[51] and chemical exposures that are governed by the statute may also be subject to control through other laws, such as the Clean Air Act, the Clean Water Act, or the Occupational Safety and Health Act. During the Trump administration, most of EPA's risk evaluations excluded certain exposure pathways when assessing whether a substance poses an unreasonable risk of harm, under the theory that EPA was not obligated to consider them because they could be addressed through other laws.[52]

However, the statute specifies that EPA should refer a substance to another agency for regulation only after determining both "that the [chemical] . . . presents an unreasonable risk of injury to health or the environment" and "that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator."[53] Similarly, for regulation under other statutes that EPA does administer, TSCA instructs the agency to use these other laws only after determining "that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws."[54] Thus, EPA cannot know whether it is appropriate to use a different legal mechanism for controlling a chemical until *after* it assesses the relevant exposure routes through a risk evaluation conducted under TSCA.[55]

**EPA assumed that workers would use personal protective equipment when evaluating their exposure risk, even though such equipment may not be available or deployed adequately.**

This issue and other problems with EPA's risk evaluations have led to litigation over four of the first ten risk evaluations; the chemicals at issue in the suits are methylene chloride,[56] 1,4-dioxane,[57] asbestos,[58] and cyclic aliphatic bromide cluster (HBCD).[59] The pending challenges allege that the agency made numerous errors in assessing chemical risk—ranging from flawed estimates of carcinogenicity to unsupported assumptions about workers' use of personal protective equipment that are meant to be assessed in the risk management stage. For example, in its methylene chloride risk evaluation, EPA assumed that workers would use personal protective equipment when evaluating their exposure risk, even though such equipment may not be available or deployed adequately.[60] The agency also chose a numeric estimate of how much inhaling the substance would increase cancer risk that was far less protective than the figures it had used in past risk assessments or those currently used by OSHA.[61]

Given these concerns regarding the risk evaluations, the Biden administration has pledged to revisit seven of the ten completed risk evaluations under the Trump Administration.[62] These include methylene chloride, 1,4-dioxane, carbon tetrachloride (CCl4), trichloroethylene (TCE), perchloroethylene (PCE or perc), 1-bromopropane (1-BP) and n-methylpyrrolidone (NMP).[63] This process is expected to extend into 2022 and could involve a new round of public comment and peer review.[64]

## C. Risk Management

When EPA finds that a chemical presents an unreasonable risk, the agency must at least regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk."[65] Added as part of the 2016 Lautenberg Act amendments to TSCA, this requirement is a departure from the original text of TSCA, which had instead directed EPA "to protect adequately against [unreasonable] risk using the least burdensome requirements."[66] This change was made, among other reasons, to alleviate the perceived evidentiary burdens on the agency following the Fifth Circuit's decision in *Corrosion Proof Fittings*.[67] In EPA's view, the Fifth Circuit opinion imposed an infeasible amount of analysis in order to demonstrate that a regulation was the "least burdensome" option.[68]

As discussed in more detail in Part II of this report, the amended statute requires EPA to consider multiple factors in deciding how to regulate a substance. These include the substance's health and environmental effects, the benefits of its use, and the economic consequences of controlling it, all of which can be encompassed in a cost-benefit analysis. After considering these factors, the Administrator's regulatory options include restrictions on manufacture or distribution, warnings or other informational requirements, record keeping obligations, and restrictions on commercial uses or disposal.[69]

While the 2016 Lautenberg Act stipulates that risk management rules must at least eliminate unreasonable risks, it does not preclude EPA from promulgating controls that further reduce health and environmental harms below this level.[70] Therefore, EPA should have discretion to further reduce risks if a cost-benefit analysis indicates that the benefits of doing so outweigh the costs. In amending TSCA, Congress expressly rejected the prior statute's requirement that EPA regulate chemicals in the "least burdensome" manner, instead seeking to give EPA greater flexibility in deciding how stringently to control toxic chemicals as long as it at least eliminates the unreasonable risks it identified.[71] Regulating to reduce risk

below the unreasonable risk level is consistent with this legislative history as well as scientific studies of toxic chemicals, which have demonstrated that the vast majority of these substances have harmful effects even at very low exposures.[72]

The first risk management rule for a risk evaluation completed under the 2016 amendments, for methylene chloride, was due to be proposed in June 2021.[73] As noted above, EPA has recently stated that it intends to revisit the risk evaluations for methylene chloride and six other chemicals to determine if revisions are needed, which will delay the agency's promulgation of risk management rules for these substances.[74] However, EPA does intend to propose risk management regulations shortly for three chemicals, "chrysotile asbestos, pigment violent 29 (PV29), and the cluster of flame retardants termed HBCD," as their risk evaluations were deemed sufficient to proceed without undertaking substantial new analysis.[75]

**When EPA finds that a chemical presents an unreasonable risk, the agency must at least regulate "to the extent necessary so that the chemical substance or mixture no longer presents such risk."**

# II. Cost-Benefit Considerations in the 2016 Lautenberg Act

The 2016 Lautenberg Act made major changes to the way EPA is to consider the costs and benefits of regulation for substances already in use.[76] As noted above, EPA is now required to conduct risk evaluations for existing chemicals without consideration of costs.[77] If EPA finds that a chemical poses an unreasonable risk to health and the environment, the agency must regulate use of the substance in order to at least eliminate the unreasonable risk.[78]

The statute sets out several factors that EPA must consider "to the extent practicable" when deciding how to regulate a chemical that poses an unreasonable risk of harm.[79] These include: 1) the effects of the chemical on health and the magnitude of human exposure, 2) the effects of the chemical on the environment and the magnitude of environmental exposure, 3) the benefits of the chemical for various uses, and 4) the reasonably ascertainable economic consequences of the rule.[80] In determining the economic consequences, EPA is instructed to consider three subfactors: a) the likely effect of the rule on the national economy, small businesses, technological innovation, the environment, and public health, b) the costs and benefits of the rule and at least one regulatory alternative, and c) the cost effectiveness of the rule and at least one regulatory alternative.[81] When examining these factors, EPA must base its analysis on information that is reasonably available to the agency.[82]

TSCA therefore requires EPA to consider "the costs and benefits of the . . . regulatory action," as well as the other "primary alternative regulatory actions considered."[83] Such an analysis will necessarily encompass many of the other factors listed in the statute, such as potential benefits to public health and the environment and potential welfare losses from eliminating a chemical's use, including costs to businesses.[84]

Additionally, Executive Order 12,866 requires agencies to assess the costs and benefits of all "significant" regulations, which includes those likely to have "an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities."[85] As many, if not all, TSCA risk management rules will likely have effects that meet this standard, EPA will need to conduct an analysis of the rules' costs and benefits to comply with Executive Order 12,866.[86]

# III. Best Practices for Assessing the Costs and Benefits of TSCA Risk Management Rules

Given the statutory requirement for EPA to consider the costs and benefits of its toxic substance regulations and the requirement for all significant rules to undergo a cost-benefit analysis under Executive Order 12,866,[87] this section sets out seven recommendations for conducting such cost-benefit analyses under TSCA:

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| 1 | EPA should consider the benefits of reducing risks below the level deemed unreasonable. |
| 2 | EPA should consider the benefits of reducing risks within the scope of other federal statutes. |
| 3 | EPA should consider the increased susceptibility or exposure of certain subpopulations in estimating the benefits of risk reductions. |
| 4 | EPA should consider unquantified benefits when selecting among risk management options. |
| 5 | EPA should consider potential substitution effects when selecting among risk management options. |
| 6 | EPA should consider distributional consequences when selecting among risk management options. |
| 7 | EPA should rely on cost-effectiveness analysis only when deciding between two options with similar net benefits. |

## A. EPA Should Consider the Benefits of Reducing Risks Below the Level Deemed "Unreasonable"

When evaluating regulatory options for managing the risks of toxic chemicals, EPA should consider all the benefits of each option. Specifically, even when EPA has previously deemed certain chemical risks to be "reasonable," it should still account for the differing extents to which available regulatory options would reduce these risks.

As mentioned above, TSCA requires EPA to make an initial determination of whether a chemical substance poses an "unreasonable risk of injury to health or the environment."[88] The determination of which risks are "unreasonable" is legally important, because EPA is required to regulate chemical substances at least to the extent necessary to prevent unreasonable risks.[89]

However, as noted above in Part I.C, the requirement to eliminate unreasonable risk is merely a floor, not a ceiling, on the stringency of EPA's risk management rules. Thus, when assessing the "costs and benefits" of available regulatory options,[90] EPA should consider the health and environmental benefits of *all* risk reductions associated with each option, including for risks that are below the unreasonable risk level.

In addition to being permissible under TSCA, considering the benefits of all foreseeable risk reductions is consistent with longstanding executive orders and guidance documents on regulatory cost-benefit analysis.[91] Under EPA's Guidelines for Preparing Economic Analyses, the agency must assess "*all* identifiable costs and benefits."[92] Similarly, Executive Order 12,866 states that agencies "deciding whether and how to regulate . . . should assess *all* costs and benefits of available regulatory alternatives" and "should select those approaches that maximize net benefits."[93] Executive Order 13,563 reaffirms that agencies should maximize net benefits and, like Executive Order 12,866, defines benefits expansively to include "potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity."[94] Since TSCA does not bar EPA from considering all benefits from risk reductions, the agency should comply with these Executive Orders by including all foreseeable benefits in cost-benefit analyses for risk management options.

**Even when EPA has previously deemed certain chemical risks to be "reasonable," it should still account for the differing extents to which available regulatory options would reduce these risks.**

Most importantly, a considerable body of scientific research suggests that there are health and environmental benefits from reducing risks below the level deemed unreasonable at the risk evaluation stage. For example, EPA determines whether a risk from a carcinogenic substance is reasonable or unreasonable based on whether it increases the probability of developing cancer above a certain level. The agency has thus far set that level at a range of 1 in 1,000,000 to 1 in 10,000,[95] but this has varied depending on the subpopulation exposed.[96] For example, in its risk evaluation for 1,4-dioxane, the agency set the level at 1 in 10,000 for industrial and chemical workers but at 1 in 1,000,000 for consumers.[97]

However, as noted, scientific studies have demonstrated that there is no threshold below which carcinogens pose no risk.[98] The same is true for many other types of noncarcinogenic pollutants.[99] Because these substances cause harm even at low doses of exposure, EPA should value the benefits of reducing risk below the unreasonable risk level set during the risk evaluation stage.

As one example, in EPA's final risk evaluation for TCE published in November 2020, the agency found that none of TCE's conditions of use would pose an unreasonable risk to the environment, even though it determined that the chemical would pose an unreasonable risk to human health in some circumstances.[100] EPA reached this conclusion by modeling the exposure of aquatic and sediment-dwelling organisms to TCE and comparing these amounts to "concentrations of concern," which EPA describes as "threshold concentrations below which adverse effects on aquatic life are expected to be minimal."[101]

However, even if the environmental risks of TCE are "reasonable," they are not nonexistent. EPA's risk evaluation excluded numerous studies and datasets showing TCE can accumulate in ecosystems and pose a risk to terrestrial and aquatic organisms.[102] In fact, the agency's own prior risk assessments have noted that TCE could harm the environment. For instance, when EPA assessed the risks of TCE used for dry cleaning spot removers and commercial aerosol degreasing in 2016, it noted that "there is potential for TCE exposures to ecological receptors;" in a subsequent proposed rule to restrict these uses, it included reduced environmental risks of TCE as a qualitative benefit to the rule.[103] EPA should similarly consider such environmental benefits when formulating regulations under TSCA and in accompanying cost-benefit analyses, even where these risks have been deemed by EPA to be reasonable at the risk evaluation stage.

In sum, TSCA requires EPA to choose a regulatory option that is at a minimum sufficient to eliminate all unreasonable risks from a chemical substance. The statute also, however, requires the agency to consider the costs and benefits of available risk-management options. And a regulation that both eliminates unreasonable risks and incrementally reduces "reasonable" risks may have greater net benefits than one that merely eliminates unreasonable risks. Accordingly, EPA's cost-benefit analyses for risk-management alternatives should include the health and environmental benefits of risk reductions below the level deemed to present an unreasonable risk.

## B. EPA Should Consider the Benefits of Reducing Risks Within the Scope of Other Federal Statutes

EPA's restrictions on a chemical under TSCA may lead to indirect reductions in exposure beyond the pathways and uses identified in the risk evaluation. This can occur if EPA does not account for the risks of a chemical governed by other environmental laws or laws administered by another federal agency. While there are currently disagreements about whether EPA should consider these risks at the evaluation stage, the agency should at a minimum consider the ancillary benefits of reducing them when conducting a cost-benefit analysis at the risk management stage.[104]

When EPA determines that a chemical for which it finds unreasonable risk is also governed by other federal laws, TSCA provides mechanisms permitting EPA to refer aspects of the risk to another agency for regulation or to choose to reduce a chemical's risks through another statute that EPA administers.[105] This statutory authority is intended to facilitate control of chemical harms through the most appropriate legal avenue. If EPA refers a chemical risk for regulation under another law, either inside or outside the agency, and the chemical exposure at issue is subsequently controlled through these alternative means, EPA is prohibited from acting to reduce that same risk.[106] The agency is obligated, however, to control any unreasonable risks that remain.[107] This provision of TSCA is intended to ensure that all unreasonable risks associated with the chemical are eliminated, while avoiding duplicative federal efforts to control the same chemical risks.

As discussed in Part I.B, in many of its most recent risk evaluations, EPA has relied on the fact that a chemical exposure *could be* controlled under other laws to eliminate those exposure pathways from consideration in the risk evaluation under TSCA.[108] This is contrary to the statutory text, which requires that EPA determine whether there is an unreasonable risk *before* deciding to regulate under TSCA or another environmental law.[109] And even if exposure to a chemical is partially controlled through statutes like the Clean Air Act or Clean Water Act, EPA should not ignore the ancillary benefits that would come from further reductions in these exposure pathways.

For instance, in EPA's final risk evaluation for methylene chloride, the agency acknowledged that "exposures to the general population [of methylene chloride] may occur from the conditions of use due to releases to air, water or land," but it declined to consider risks to the general population from these exposure pathways because they fall under the jurisdiction of other federal statutes, such as the Clean Air Act, the Clean Water Act, and the Resource Conservation and Recovery Act.[110] EPA made no attempt to analyze whether the risks from such pathways were adequately controlled by these other laws or whether residual risk from the pathways could be addressed through TSCA.[111]

EPA has also declined to consider risks that explicitly fall outside the scope of TSCA. For example, in EPA's final risk evaluation for TCE, the agency chose not to evaluate risks posed from use of TCE in lace wigs and hair extensions.[112] Because these products are considered "cosmetics" under the Federal Food, Drug, and Cosmetic Act, and because such cosmetics are expressly excluded from the definition of "chemical substance" under TSCA, EPA did not evaluate whether the use of TCE in lace wigs and hair extensions poses an unreasonable risk.[113] It also did not consider the contribution of such uses to background exposures to TCE, which may contribute to the overall risk the chemical poses to the general population or vulnerable subpopulations.

The Biden administration has recently indicated that, in revising several risk evaluations, it may partially address some of these problems by conducting studies of air and water exposures to communities near industrial facilities.[114] But whether or not the pathways noted above were properly excluded at the risk evaluation stage, if a regulatory option would have the ancillary benefit of reducing risks under excluded exposure pathways, those ancillary benefits should be included in EPA's cost-benefit analysis. Going forward, EPA should ensure that these harms are examined in risk evaluations regardless of their potential regulation under other statutes, both because TSCA legally requires it and because it would facilitate better data and information on the health and environmental benefits from additional reductions in chemicals regulated under TSCA.

As noted above, TSCA mandates assessment of all risks from a chemical's conditions of use and contains broad language instructing EPA to consider all health and environmental benefits from regulating a chemical at the risk management stage.[115] Relevant executive orders and guidance documents also require consideration of all ascertainable benefits from regulation, even when achieving a particular kind of benefit is not the statutory purpose of the rule at issue.[116] The Office of Management and Budget (OMB) Circular A-4, a longstanding guidance document on cost-benefit analysis, expressly instructs agencies to consider important "ancillary benefits," which it defines as "favorable impact[s] . . . unrelated or secondary to the statutory purpose of the rulemaking."[117] It further counsels that "[t]he same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks."[118] EPA's Guidelines for Preparing Economic Analyses similarly instruct the agency to assess "ancillary [indirect] benefits and costs."[119] Including both direct and indirect effects is therefore necessary to allow meaningful comparisons between policy alternatives.[120]

In addition, courts have repeatedly required agencies to consider the ancillary effects of regulations. For example, the U.S. Court of Appeals for the D.C. Circuit required EPA to consider potential countervailing health risks when setting ambient air quality standards for ground-level ozone.[121] The same court struck down a National Highway Traffic Safety Administration fuel-efficiency rule for failing to consider indirect costs in the form of vehicle safety risk.[122] Although these precedents focus on the consideration of ancillary costs, there is no logical reason why agencies would not be similarly required to consider ancillary benefits.[123] Indirect benefits and indirect costs "are simply mirror images" of one another,[124] and the labels do not warrant different analytic treatment.[125]

Consequently, even if a chemical substance poses risks based in part on uses that are outside the scope of TSCA or exposures that could be regulated by other environmental laws, reductions in such risks are still regulatory benefits that should be considered in cost-benefit analysis. Ignoring these benefits would be arbitrary and capricious under the Administrative Procedure Act.[126]

## C. EPA Should Consider the Increased Susceptibility or Exposure of Certain Subpopulations in Estimating the Benefits of Risk Reductions

In assessing the health benefits of risk management strategies, EPA should account for the differential harms experienced by vulnerable subpopulations. These groups may experience additional benefits from risk reductions that should be reflected in the agency's cost-benefit analysis.

TSCA, as noted previously, requires EPA to evaluate whether a chemical substance poses an unreasonable risk not only to the average person but to those who may be especially vulnerable to the adverse effects of a chemical because of their greater susceptibility or exposure.[127] Factors that may cause a person to be more affected by a chemical's harms include their life stage,[128] genetics,[129] employment in certain jobs,[130] geographic location,[131] or exposure to other pollutants that may exacerbate the effects of the chemical in question.[132]

In the risk evaluations completed to date, EPA has identified a number of especially vulnerable subgroups that are likely to benefit even more than an average person from reductions in toxic chemicals.[133] For example, in its risk evaluation for methylene chloride, EPA found that smokers, those with existing cardiovascular disease, and fetuses and infants are more likely to be susceptible to methylene chloride.[134] Within these groups, fetuses and infants are especially vulnerable to significant neurotoxic and cardiovascular effects.[135] Therefore, a commensurate decrease in exposure will generate greater benefits for these subpopulations than for the overall population.

**In assessing the health benefits of risk management strategies, EPA should account for the differential harms experienced by vulnerable subpopulations.**

Similarly, in the risk evaluation for TCE, EPA found that the chemical is particularly dangerous for breastfeeding infants, who "could receive more than 80% of the daily lifetime advisory limit for adults" if nursing from a mother who receives the current occupational exposure limit of the chemical.[136] Such early exposures during a sensitive period of development can make these infants especially vulnerable to harmful health effects, including "speech and hearing impairments, liver problems, skin rashes, diabetes, kidney disease, urinary tract, and blood disorders" as well as cancer.[137] EPA should incorporate the particular benefits to these infants when assessing the costs and benefits of a more stringent regulatory option, as they will be considerably greater than those of an average adult.

## D. EPA Should Consider Unquantified Benefits When Selecting Among Risk Management Options

Quantification of harms from toxic substances can be challenging because of insufficient data to establish dose-response relationships, which show how a given quantity of a chemical produces a discrete harm.[138] In light of these informational challenges for many chemicals on the market, EPA should consider unquantifiable benefits when determining the appropriate stringency of a risk management rule. The need to consider unquantifiable benefits is well-established by the 2016 Lautenberg Act's legislative history, executive orders, judicial decisions, scholarship on cost-benefit analysis, and common sense.

**EPA should consider unquantifiable benefits when determining the appropriate stringency of a risk management rule. The need to consider unquantifiable benefits is well-established by the 2016 Lautenberg Act's legislative history, executive orders, judicial decisions, scholarship on cost-benefit analysis, and common sense.**

Congressional representatives have been troubled by the difficulty in quantifying and monetizing toxic chemicals' health harms since *Corrosion Proof Fittings*, in which the Fifth Circuit vacated EPA's asbestos ban partly because the agency did not quantify many health benefits of the rule. In that decision, the court suggested unquantifiable benefits could tip the scale towards a regulatory option in close cases but could not be used as a "trump card allowing EPA to justify any cost calculus, no matter how high."[139] This aspect of the opinion was pivotal in convincing Congress to strike the least burdensome language from the original law and to separate cost-benefit analysis, undertaken at the risk management stage, from the risk assessment.[140]

The original Senate bill to amend TSCA simply instructed EPA to consider both "quantifiable and non-quantifiable" factors in any cost-benefit analysis for a rule restricting a chemical's use.[141] This compromise

language reflected the desire for cost-benefit analysis to continue to play a role in risk management decisions, while acknowledging the difficulties in quantifying benefits.[142] The House bill sought to accomplish the same goal of decreasing the emphasis on monetizing benefits by detailing a list of factors for EPA to consider when selecting a risk management rule.[143] When reconciling the two bills, Congress opted to maintain the House's list of factors while inserting language that EPA's consideration of the health and environmental effects, as well as any costs and economic consequences, need only use "reasonably available information."[144] When Congress enacted the 2016 amendments, the lead Senate Democrat negotiators on the bill made clear that Congress did not want EPA to have to quantitatively determine that benefits outweigh costs, even while retaining costs and benefits as appropriate considerations when weighing risk management options.[145]

Furthermore, considering any significant, unquantified benefits when selecting among regulatory options is consistent with executive orders and related guidance on regulatory analysis.[146] Executive Order 12,866, for instance, instructs agencies to "assess all costs and benefits" when "deciding whether and how to regulate" and notes that "[c]osts and benefits shall be understood to include . . . costs and benefits that are difficult to quantify."[147] Executive Order 13,563 reaffirms these directives, while also enumerating some of the qualitative values relevant to agency decisions, such as "equity, human dignity, fairness, and distributive impacts."[148] President Biden's recent Memorandum on Modernizing Regulatory Review also emphasizes the importance of "fully account[ing] for regulatory benefits that are difficult or impossible to quantify."[149] Similarly to Executive Order 13,563, the memorandum lists some relevant values, including "social welfare, racial justice, environmental stewardship, human dignity, equity, and the interests of future generations."[150]

Judicial precedent also underscores the importance of considering unquantified benefits in cost-benefit analyses. The D.C. Circuit has held that uncertainty or insufficient data does not excuse agencies from qualitatively assessing regulatory effects.[151] Similarly, the Ninth Circuit has held that agencies cannot claim benefits are "too uncertain … [for] valuation and inclusion" when their own scientific studies show effects, as that impermissibly assigns these harms no value.[152] In most cases, while there may be a "range of values" for the unquantifiable benefits, that value "is certainly not zero."[153]

Finally, considering unquantified benefits is supported by decades of consistent regulatory practice, under presidents of both parties. The George H.W. Bush EPA "reject[ed] the position that only quantified information can be considered" in regulatory impact analyses.[154] Similarly, the Clinton EPA considered "unquantifiable benefits" when formulating emission standards.[155] And the George W. Bush EPA, in evaluating a rule restricting emissions from non-road diesel engines, based its decision on "consideration of all benefits and costs expected to result from the new standards, not just those benefits and costs which could be expressed here in dollar terms."[156] It also incorporated extensive non-monetized benefits to water quality when regulating power plants that harm aquatic organisms under the Clean Water Act.[157] The Obama EPA likewise relied on unquantified benefits to support numerous rulemakings, such as those for vehicle and power plant emissions standards.[158]

In keeping with these precedents, EPA has incorporated unquantified benefits into its cost-benefit analyses of recent toxics regulation. For instance, in 2016 the agency proposed a rule concerning TCE's use in dry-cleaning and aerosol degreasing that included unquantified benefits to human health and the environment.[159] Similarly, in 2017 EPA conducted a cost-benefit analysis for a methylene chloride regulation that included harms the agency did not have sufficient information to quantify.[160] EPA's analysis of the methylene chloride regulation also included a "break-even analysis" for effects on birth weight and pregnancy loss, a technique that allowed the agency to assess the benefits of reducing these harms even though dose-response relationships were unavailable.[161] Breakeven analysis can be used when the agency is missing either risk data or valuation data; it calculates how many incidences of harm would need to be avoided to "break-even"

when risk data is missing, or conversely, how much someone would need to be willing to pay to avoid the expected harm when valuation data is missing.[162] EPA should continue to incorporate such methods for considering unquantified benefits as they move toward risk management rulemakings.

## E. EPA Should Consider Potential Substitution Effects When Selecting Among Risk Management Options

EPA's restrictions on certain chemicals may lead companies to substitute other chemicals in the regulated chemicals' place. The agency should therefore assess whether these substitute products may pose their own health or environmental risks as well as additional costs to industry, in order to encourage the use of safer alternatives and select the regulatory option that maximizes net benefits. However, uncertainty about substitution effects should not preclude EPA from moving forward with a risk management rule, as TSCA provides that EPA need only "consider, to the extent practicable" the availability of substitutes based on reasonably available information.

When deciding whether to "prohibit or restrict" a chemical "in a manner that substantially prevents a specific condition of use," TSCA instructs EPA to consider "to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute."[163] This language, added as part of the 2016 Lautenberg Act, amended a briefer mention of substitutes in the 1976 statutory text; previously, the statute simply directed the agency to assess "the availability of substitutes" when restricting uses of a chemical.[164] While providing more detail about EPA's obligation to consider substitution effects, however, Congress did not want to require EPA to identify suitable alternatives before regulating or banning a substance. Proposals to impose such a mandate were rejected in drafting the 2016 amendments.[165] Instead, the 2016 amendments allow EPA to grant exemptions from risk management regulations for essential chemical uses where "no technically and economically feasible safer alternative is available."[166]

Furthermore, the requirement that EPA consider substitution effects is also limited to that which is practicable based on reasonably available information prepared as part of the chemical's risk assessment.[167] As discussed in Part I, Congress wanted to reduce the significant analytic and evidentiary requirements of the original statute through the 2016 amendments, particularly for rules in which EPA seeks to phase out use of a chemical.[168] Thus, while containing more detailed language on considering the economic feasibility and potential health effects of substitutes than the earlier version of the law, the 2016 Lautenberg Act cabined this requirement to ensure EPA can timely regulate toxic chemicals.[169] For instance, EPA should have discretion to consider the costs and benefits of substitutes qualitatively should they prove difficult to quantify, as EPA is required to base its assessment only on reasonably available information.

Chemical substitutes have historically posed a serious challenge for EPA, as companies have repeatedly replaced one type of hazardous substance with an equally or even more hazardous compound.[170] The 2016 Lautenberg Act does not address this issue directly, but EPA's requirement to consider the effects of substitutes when deciding among risk management options could provide an opportunity for the agency to design risk management rules in ways that encourage the use of safer alternatives.

EPA should therefore evaluate any health and environmental effects associated with known substitute products and identify, to the extent practicable, alternatives that pose a lesser risk to health and the environment given available information. Including such an assessment may also encourage regulated industries to invest in safer alternatives if they are on notice that the agency may subsequently regulate potential substitutes that pose equal or greater hazards. EPA should also consider reasonably foreseeable non-health costs associated with a switch to substitute products in order to demonstrate that any such losses are outweighed by the health and environmental benefits from restricting the chemical's use.

## F. EPA Should Consider Distributional Consequences When Selecting Among Risk Management Options

In addition to assessing the various net benefits of available risk management options, EPA should also consider the differing distributional consequences of those options. These distributional effects may result from differing levels of exposure across subpopulations or from differing levels of susceptibility to health effects in certain subpopulations. A distributional analysis would examine whether the costs or benefits of a regulatory option are disproportionately borne by particular subpopulations, either through greater exposure or susceptibility.

Weighing risk management options in light of potential distributional effects is consistent with EPA's statutory requirements under TSCA as well as relevant executive orders and guidance documents. As discussed earlier, TSCA explicitly mandates that EPA assess how some populations may be more greatly harmed by certain toxic chemicals because of increased susceptibility or exposure. A distributional analysis is therefore consistent with Congress' intent to ensure toxics regulation is not just net beneficial, but also protects the most vulnerable. EPA's Guidelines for Preparing Economic Analyses also highlight the importance of looking at vulnerable subpopulations, noting that cost-benefit analysis should "consider how a policy affects the distribution of relevant health and environmental outcomes."[171]

In addition to fulfilling the agency's statutory obligations under TSCA, conducting distributional analyses is consistent with President Biden's emphasis on accounting for such impacts in his Memorandum on Modernizing Regulatory Review. The memorandum instructs agencies to "propose procedures that take into account the distributional consequences

of regulations, including as part of any quantitative or qualitative analysis of the costs and benefits of regulations, to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities."[172] President Biden's Memorandum builds off prior attention to these issues in Executive Orders 12,866 and 13,563. For example, Executive Order 12,866 recognized that "distributive impacts[] and equity" are relevant to assessing net benefits.[173] Executive Order 13,563 further specifies that "[w]here appropriate and permitted by law, each agency may consider (and discuss qualitatively) values that are difficult or impossible to quantify, including equity, human dignity, fairness, and distributive impacts."[174]

## G. EPA Should Rely on Cost-effectiveness Analysis Only When Deciding Between Two Options with Similar Net Benefits

TSCA requires EPA to examine the "cost-effectiveness" of risk management options in addition to their total costs and benefits.[175] However, this section of the law does not instruct the agency as to which one of these two measures should predominately inform its risk management decisions. Given this ambiguity, EPA has discretion over how much to rely on cost-effectiveness assessments when selecting among regulatory options, and relevant guidance documents suggest that EPA should rely on cost-effectiveness metrics only when choosing among regulatory options that have similar outcomes.[176]

A cost-effectiveness approach to evaluating regulatory options looks for the least costly means of "achieving a given regulatory end."[177] Guidelines from OMB and EPA thus specify that the approach is best suited to comparing different means of achieving the "same primary outcome."[178] When the regulatory options under consideration offer *different* levels of benefits, however, cost-effectiveness metrics are less useful, because "cost-effectiveness does not encompass an evaluation of whether that goal has been set appropriately to maximize social welfare."[179] In other words, it can aid an agency in determining the cheapest means of reducing a given increment of risk but not in determining how much risk to reduce. If regulatory option B imposes higher costs per unit of exposure reduction than option A but also reduces exposure by a far greater degree, it will be less cost-effective than option A but may still provide greater net benefits.[180]

As discussed earlier, while EPA must eliminate unreasonable risks, the statute does not limit EPA from regulating below this level. Thus, it will not always be the case that all available regulatory options yield the same level of benefits. When the options under consideration offer differing levels of health and environmental protection, a cost-benefit analysis, rather than a cost-effectiveness analysis, will be most useful to the agency in selecting a risk management approach.

# IV. Conclusion

To satisfy EPA's obligations under TSCA as well as relevant executive orders and guidance documents, the agency must consider the costs and benefits of its risk management rules. Any such analysis should include consideration of 1) benefits of regulating below the "unreasonable" risk level, 2) benefits from risk reductions of exposures that may fall under the jurisdiction of other statutes, 3) benefits from reducing harms to vulnerable subpopulations, 4) unquantified benefits, 5) substitution effects, and 6) distributional consequences. Additionally, EPA should rely on cost-effectiveness metrics only when choosing between risk management options that offer similar net benefits. Adhering to these best practices will help EPA select and support risk management rules that will be most welfare-enhancing for society as a whole.

# Endnotes

1 *See* 15 U.S.C. § 2601 *et seq*. The statute exempts certain classes of chemicals from TSCA regulation. *See* 15 U.S.C. § 2602(2)(B)(i)–(vi) (exempting mixtures, pesticides, tobacco products, nuclear material, firearms, food, drugs, and cosmetics from the definition of "chemical substance" under the Act).

2 *See* 947 F.2d 1201, 1219 (5th Cir. 1991); Kevin McLean, *Three Years After—Where Does Implementation of the Lautenberg Act Stand?*, Harv. L. Sch. Env't & Energy L. Program 10–14 (Feb. 26, 2020), http://eelp.law.harvard.edu/wp-content/uploads/McLean-TSCA.pdf ("After the Corrosion Proof decision invalidated the results of a decade of effort to deal with a chemical of great concern, EPA stepped back from regulating existing chemicals due to the perceived very high burdens of meeting TSCA's cost-benefit balancing requirement and showing that it was promulgating the 'least burdensome' regulatory requirements needed to address any identified unreasonable risk.").

3 *See* S. Rep. No. 114-67, at 2 (2015) ("In the years since TSCA was first enacted, it has become clear that effective implementation of TSCA by the Environmental Protection Agency (EPA) has been challenged by shortcomings in the statute itself, and by several key decisions of Federal Courts and the Agency's interpretation of those decisions. S. 697 [the Lautenberg Act] . . . is intended to enhance confidence in the federal chemical regulatory system, provide EPA the authority necessary for efficient and effective regulation of chemical risks, and foster safety and innovation in commercial chemistry."); H. Rep. No. 114-176, at 17 (2015) (explaining that Congress amended TSCA with "the aim of strengthening the Environmental Protection Agency's (EPA's) ability to evaluate and regulate potentially hazardous chemicals").

4 For an explanation of these steps, see *How EPA Evaluates the Safety of Existing Chemicals*, Env't Prot. Agency, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals (last visited July 25, 2021). Note that if a manufacturer requests a risk evaluation, the agency may skip the prioritization step. *See id.*

5 These steps were mandated by the 2016 amendments to TSCA, commonly called the Lautenberg Act. Compare the pre-Lautenberg version of 15 U.S.C. § 2605 with the modern version.

6 *See* 15 U.S.C. § 2605(b)(1).

7 *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753 (July 20, 2017).

8 *See* 15 U.S.C. § 2605(b)(1)(B)(i).

9 *See* 15 U.S.C. § 2605(b)(3)(B).

10 15 U.S.C. § 2605(b)(1)(A).

11 *See Prioritizing Existing Chemicals for Risk Evaluation*, Env't Prot. Agency, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation (last visited July 25, 2021).

12 *See* 15 U.S.C. § 2605(b)(1)(B).

13 *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. at 33,754.

14 *See id.* at 33,755.

15 *See* 15 U.S.C. § 2625(c).

16 *See* Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 Fed. Reg. 91,927, 91,928 (Dec. 19, 2016).

17 15 U.S.C. § 2605(b)(2)(D).

18 *See* 15 U.S.C. § 2605(b)(3)(A).

19 *See* 15 U.S.C. § 2605(b)(4).

20 *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017).

21 15 U.S.C. § 2605(b)(4)(A).

22 15 U.S.C. § 2602(12) (defining "potentially exposed or susceptible subpopulation"); *id.* § 2605(b)(4)(F) ("In conducting a risk evaluation under this subsection, the Administrator shall . . . integrate and assess available . . . information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator.").

23 15 U.S.C. § 2602(4).

24 15 U.S.C. § 2605(b)(4)(F)(iii).

25 *See* 15 U.S.C. § 2605(b)(4)(A).

26 Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,741 (July 20, 2017).

27 *Id.*

28 *Id.*

29 *See id.* Note that this comment period for the scope is not required by statute.

30 *See id.* at 33,726.

31 *Id.* at 33,742.

32 *Id.* at 33,741.

33 *See id.* at 33,752.

[34] *Id.*

[35] *Id.* at 33,731–32 (describing the factors EPA will consider in determining what constitutes the best available science); *see also* 15 U.S.C. § 2625(h) and (i) (listing several factors EPA should consider when deciding what constitutes the best available science and the weight of scientific evidence).

[36] *See* 15 U.S.C. § 2605(b)(4)(G).

[37] *See* Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 Fed. Reg. 91,927 (Dec. 19, 2016).

[38] *See Chemicals Undergoing Risk Evaluation under TSCA*, Env't Prot. Agency, https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca (last visited July 25, 2021).

[39] *See, e.g.,* Nat'l Acad. of Sci., The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations 5–7 (2021) (critiquing EPA's risk evaluation methodology as lacking in objectivity, transparency, and comprehensiveness).

[40] 15 U.S.C. § 2605(b)(4)(A).

[41] 15 U.S.C. § 2602(4).

[42] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,728, 33,742 (July 20, 2017).

[43] *Id.* at 33,729.

[44] *Id.*

[45] *See* Safer Chemicals, Healthy Families v. EPA, 943 F.3d 397, 418–19 (9th Cir. 2019).

[46] *See id.* at 419 (explaining that "conditions of use that the Administrator 'expects to consider' does not grant EPA discretion to exclude conditions of use").

[47] *See* Comments of Safer Chemicals Healthy Families, Earthjustice, Environmental Health Strategy Center and Natural Resources Defense Council on Draft Scoping Documents for Seven High-Priority Substances Under the Toxic Substances Control Act (TSCA) 6 (June 8, 2020), https://saferchemicals.org/wp-content/uploads/2020/06/schf_comments_on_epa_scopes06082020.pdf ("In its initial 10 evaluations, EPA excluded undisputed conditions of use based on the claim that it had discretion under TSCA to pick and choose the conditions it would evaluate and that its risk evaluation framework rule authorized it to exercise such discretion. However, the Ninth Circuit's decision in Safer Chemicals v. United States EPA, 943 F.3d 397 (9th Cir. 2019) holds that EPA's risk evaluation framework rule does not grant the agency discretion to exclude conditions of use from the scope of risk evaluations.").

[48] *See* Safer Chemicals, Healthy Families, 943 F.3d at 421 ("[W]e hold that EPA's exclusion of legacy uses and associated disposals contradicts TSCA's plain language.").

[49] *See* Robert Sussman, Notice of Intent to File Suit to Compel EPA to Perform Non-Discretionary Act under Section 6(b) of TSCA (Jan. 26, 2021), https://www.epa.gov/sites/production/files/2021-02/documents/2021-01-26_asbestos_tsca_noi_redacted.pdf (filing suit against EPA following the Safer Chemicals decision, arguing that EPA violated TSCA by excluding legacy uses of asbestos from the chemical's risk evaluation). *See also* Diana DiGangi, *ADAO Seeks Broad EPA Asbestos Regulation Despite Split Evaluations*, Inside TSCA (June 2, 2021)

[50] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,729, 33,742 (July 20, 2017) (asserting that the agency could exclude exposure pathways from risk evaluations that were "adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks").

[51] *See* 15 U.S.C. § 2602(2)(B)(i)–(vi) (exempting mixtures, pesticides, tobacco products, nuclear material, firearms, food, drugs, and cosmetics from the definition of "chemical" under the Act).

[52] *See, e.g.,* EPA, Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) 60–63 (June 2020), https://www.epa.gov/sites/production/files/2020-06/documents/1_mecl_risk_evaluation_final.pdf [hereinafter "Risk Evaluation for Methylene Chloride"] (exempting numerous exposure pathways from methylene chloride's risk evaluation because the chemical is also subject to regulation under the Clean Air Act, Clean Water Act, CERCLA, and Safe Drinking Water Act.)

[53] 15 U.S.C. § 2608(a)(1).

[54] 15 U.S.C. § 2608(b)(1).

[55] *See* Opening Brief for Petitioners State of New York et al. at 27, Neighbors for Env't Just. v. EPA, No. 20-72091 (9th Cir. Jan. 25, 2021) ("EPA cannot know whether unreasonable risk can be 'eliminated or reduced to a sufficient extent' under other laws until it completes a lawful, comprehensive section 6 risk evaluation that identifies all unreasonable risk posed by a chemical.").

[56] *See id.*

[57] Labor unions and state attorneys general, in addition to numerous environmental and health groups, have filed petitions for review of EPA's 1,4-dioxane risk evaluation. *See, e.g.,* Petition for Review, International Union et. al v. EPA, No. 21-1057 (D.C. Cir. Feb. 10, 2021); Petition for Review, New York et al v. EPA, No. 21-70684 (9th Cir. Mar. 22, 2021).

[58] *See* Petition for Review, Asbestos Disease Awareness Org. v. EPA, No. 21-70160 (9th Cir. Jan. 26, 2021), https://www.epa.gov/sites/production/files/2021-02/docu-

ments/2021-01-26_petition_for_review_21-70160.pdf.

[59] *See* Petition for Review, Cal. Professional Firefighters v. EPA, No. 20-73578 (9th Cir. Dec. 8, 2020); *see also* Petition for Review, Int'l Union, United v. EPA, No. 20-01482 (D.C. Cir. Dec. 3, 2020), https://www.epa.gov/sites/production/files/2020-12/documents/hbcd_re_uaw_petition_1.pdf.

[60] *See* Opening Brief for Petitioners State of New York et al., *Neighbors for Env't Just.*, *supra* note 55, at 16.

[61] *See id.*

[62] *See EPA Announces Path Forward for TSCA Chemical Risk Evaluations*, Env't Prot. Agency, https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations (last visited July 25, 2021); *see also* David LaRoss, *EPA Sets Timeline for Revisiting Trump-Era TSCA Chemical Evaluations*, Inside TSCA (June 30, 2021).

[63] *See id.*

[64] *See id.*

[65] 15 U.S.C. § 2605(a).

[66] Toxic Substances Control Act of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. §§ 2601-2629 (1976)), § 2605(a) (requiring the administrator to regulate chemical substances "to the extent necessary to protect adequately against such risk using the least burdensome requirements").

[67] 947 F.2d 1201 (5th Cir. 1991).

[68] *Id.* at 1216–17 (finding that EPA violated TSCA by only comparing the benefits of a total ban on certain asbestos uses against its continued unregulated use, rather than "calculating how many lives a less burdensome regulation would save, and at what cost. . . [i]n order to impose a regulation at the top of the hierarchy -- a total ban of asbestos -- the EPA must show not only that its proposed action reduces the risk of the product to an adequate level, but also that the actions Congress identified as less burdensome also would not do the job"). On concerns about the least burdensome requirement in amending the law, *see* S. Rep. No. 114-67, at 4 (2015).

[69] *See* 15 U.S.C. § 2605(a)(1)–(7).

[70] *See* 15 U.S.C. § 2605(a) (stipulating that EPA must regulate chemicals found to pose an unreasonable risk "to the extent necessary so that the chemical substance or mixture no longer presents such risk").

[71] S. Rep. No. 114-67, at 4 (2015) (discussing the need to eliminate the least burdensome requirement because the clause "has been viewed as a requirement that EPA assess the costs and burdens of all possible regulatory and chemical options" following the *Corrosion Proof Fittings* decision).

[72] *See* Nat'l Research Council, Science and Decisions: Advancing Risk Assessment 8, 177 (2009) (discussing the scientific evidence that there is no safe threshold for carcinogenic and noncarcinogenic compounds, and recommending that EPA should model the benefits of pollution reductions accordingly).

[73] *See* Maria Hegstad, *EPA Seeks Remand to Reconsider Scope of TSCA 1,4-Dioxane Evaluation*, Inside TSCA (June 11, 2021).

[74] *See EPA Announces Path Forward for TSCA Chemical Risk Evaluations*, *supra* note 62.

[75] *See id.*

[76] The statutory requirements for evaluating the risks of new chemicals were also amended in the 2016 Lautenberg Act, but they are not the focus of this report. Under the statute, EPA must make an express determination of a new chemical's safety before it can be introduced or used in a significantly new way. *See* 15 U.S.C. § 2604(a)(3).

[77] *See* 162 Cong. Rec. S3513 (daily ed. June 7, 2016) (statement of Sen. Udall) (explaining that while the old law required EPA to "consider the costs and benefits of regulation when studying the safety of chemicals," EPA must now "consider only the health and environmental impacts of a chemical. If they demonstrate a risk, EPA will have to regulate").

[78] *See id.*

[79] *See* 15 U.S.C. § 2605(c)(2)(B).

[80] *See id.* § 2605(c)(2)(A)(i)–(iv).

[81] *See id.* § 2605(c)(2)(A)(iv)(I)–(III).

[82] *See id.* § 2605(c)(2)(A).

[83] *Id.* § 2605(c)(2)(A)(iv)(II). Note that EPA is required to consider at least one regulatory alternative in addition to its final selection.

[84] *See* Office of Mgmt. & Budget, Circular A-4: Regulatory Analysis 18-31, 37 (2003), https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf (hereinafter "Circular A-4") (discussing the use of cost-benefit analysis for evaluating the health and environmental effects of regulations as well as private sector compliance costs and savings).

[85] *See* Exec. Order No. 12,866 § 6(a)(3)(C), 58 Fed. Reg. 51,735 (Oct. 4, 1993) (requiring agencies, to the extent feasible, to conduct cost-benefit analyses for significant rules, which includes those that have an annual effect on the economy of $100 million or more, as well as those that may present inconsistences with actions taken by other agencies, materially alter the budgetary impact of entitlements, or raise novel legal or policy issues).

[86] *See id.*

[87] *See id.*

[88] 15 U.S.C. § 2605(a).

[89] *Id.*

[90] *Id.* § 2605(c)(2)(A)(i)–(iv).

[91] *See, e.g.,* Circular A-4, *supra* note 84, at 26 (instructing agencies to consider indirect benefits, which include any "favorable impact . . . secondary to the statutory purpose of the rulemaking"); EPA, Guidelines for Preparing Economic Analyses 11-2 (2010), https://www.epa.gov/sites/production/files/2017-09/documents/ee-0568-11.pdf (hereinafter "Guidelines for Preparing Economic Analyses") (instructing EPA to assess "all identifiable costs and benefits," including direct effects "as well as ancillary [indirect] benefits and costs").

[92] Guidelines for Preparing Economic Analyses, *supra* note 91, at 11-2 (emphasis added).

[93] Exec. Order No. 12,866, § 1(a), 58 Fed. Reg. 51,735 (1993) (emphasis added).

[94] Exec. Order No. 13,563, § 1(b)–(c), 76 Fed. Reg. 3821 (2011).

[95] *See, e.g.,* EPA, Risk Evaluation for Methylene Chloride, *supra* note 52, at 454–55 ("Generally, EPA considers 1x10-6 to 1x10-4 as the appropriate benchmark for the general population.").

[96] *See id.*; *see also* EPA, Risk Evaluation for Trichloroethylene 409 (Nov. 2020), https://www.epa.gov/sites/production/files/2020-11/documents/1._risk_evaluation_for_trichloroethylene_tce_casrn_79-01-6.pdf. (hereinafter "Risk Evaluation for Trichloroethylene").

[97] *See* EPA, Risk Evaluation for 1,4-Dioxane 273 (Dec. 2020), https://www.epa.gov/sites/production/files/2020-12/documents/1._risk_evaluation_for_14-dioxane_casrn_123-91-1.pdf.

[98] *See* Nat'l Research Council, *supra* note 72, at 8, 177; Kimberly M. Castle & Richard L. Revesz, *Environmental Standards, Thresholds, and the Next Battleground of Climate Change Regulations*, 103 Minn. L. Rev. 1349, 1372 (2019); Al McGartland et al., *Estimating the Health Benefits of Environmental Regulations*, 357 Sci. 457 (2017) (agreeing with the National Academy of Sciences conclusion that "the default assumption of a population threshold built into the RfD [reference dose] is questionable for most environmental contaminants").

[99] *See id.*

[100] *See* Risk Evaluation for Trichloroethylene, *supra* note 96, at 459.

[101] *Id.* at 102, 459.

[102] *See* Env't Def. Fund, Comments for Toxic Substances Control Act (TSCA) Science Advisory Committee on Chemicals Review of the Draft Risk Evaluation of Trichloroethylene 80–89 (Mar. 18, 2020), http://blogs.edf.org/health/files/2020/03/EDF_TCE_Comment_SACC-3-18-20-FINAL.pdf.

[103] EPA, Economic Analysis of Proposed TSCA Section 6 Action on Trichloroethylene in Dry Cleaning Spot Removers and Aerosol Degreasers ES-7 (Nov. 15, 2016), https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0163-0003.

[104] EPA has recently indicated that, in revising seven chemical risk evaluations completed during the Trump administration, the agency will conduct at least limited sampling of air and water exposures near "fenceline" communities. However, it is not clear if EPA will undertake a more extensive review of such exposures. *See EPA Announces Path Forward for TSCA Chemical Risk Evaluations*, EPA Press Office, https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations (last visited July 25, 2021).

[105] *See* 15 U.S.C. § 2608(a)(1).

[106] *See id.* § 2608(a)(2)–(4).

[107] *See id.*

[108] *See* EPA, Summary of Public Comments Received on the Draft Scopes of the Risk Evaluations for Twenty Chemical Substances Under the Toxic Substances Control Act (TSCA) 10–11 (Aug. 2020), https://www.epa.gov/sites/production/files/2020-09/documents/rtc_on_draft_scopes_20_hps.pdf (asserting that "identified exposure pathways, including exposure to the general population and certain potentially exposed susceptible subpopulations, covered under the jurisdiction of other EPA-administered statutes and regulatory programs are not within the scope of the risk evaluation").

[109] *See supra* Part I of this report.

[110] *Id.*

[111] *See id.*

[112] *See* Risk Evaluation for Trichloroethylene, *supra* note 96, at 52.

[113] *See* 15 U.S.C. § 2602(2)(B)(iv).

[114] *See EPA Announces Path Forward for TSCA Chemical Risk Evaluations*, *supra* note 104.

[115] *See* 15 U.S.C. § 2605(b)(1)(A); § 2605(c)(2)(A).

[116] *See* Exec. Order No. 12,866, § 1(a), 58 Fed. Reg. 51,735 (1993); Exec. Order No. 13,563, § 1(b)–(c), 76 Fed. Reg. 3821 (2011).

[117] Circular A-4, *supra* note 84, at 26.

[118] *Id.*

[119] Guidelines for Preparing Economic Analyses, *supra* note 91, at 11-2.

[120] *See id.* at 7-1.

[121] Am. Trucking Ass'ns, Inc. v. EPA, 175 F.3d 1027, 1051–52 (D.C. Cir. 1999) *rev'd on other grounds sub nom.* Whitman v. Am. Trucking Ass'ns, Inc., 531 U.S. 457 (2001).

[122] Competitive Enter. Inst. v. Nat'l Highway Traffic Safety Admin., 856 F.2d 321, 326–27 (D.C. Cir. 1992); *see also* U.S. Telecom Ass'n v. FCC, 290 F.3d 415, 424–25 (D.C. Cir. 2002) (remanding a rule for failure to consider indirect costs).

[123] Recent EPA rulemakings on vehicle emissions standards reflect this interchangeability, accounting for the indirect, positive benefits of consumer fuel savings in their cost-benefit assessments. *See* EPA, Draft Regulatory Impact Analysis: Proposed Rulemaking to Establish Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards x (2009).

[124] *See* Samuel J. Rascoff & Richard L. Revesz, *The Biases of Risk Tradeoff Analysis: Towards Parity in Environmental and Health-and-Safety Regulation*, 69 U. Chi. L. Rev. 1763, 1793 (2002)

[125] *See* Christopher C. DeMuth & Douglas H. Ginsburg, *Rationalism in Regulation*, 108 Mich. L. Rev. 877, 888 (2010) (stating that there are "no legal, political, or intellectual . . . impediments to treating ancillary benefits and countervailing risks equally in cost-benefit analysis").

[126] *See* 5 U.S.C. § 706(2)(A).

[127] *See* 15 U.S.C. § 2605(b)(4)(A). TSCA defines a vulnerable population as "a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." *See id.* § 2602(12).

[128] Infants or developing fetuses are a prime example of a sensitive life stage. *See generally* Deborah Bennett et al., *Project TENDR: Targeting Environmental Neuro-Developmental Risks, The TENDR Consensus Statement*, 124 Env't Health Persp. A118 (2016) (reviewing literature on toxic chemicals' potential to cause neurodevelopmental harms in children).

[129] *See generally* Patricia D. Koman et al., *Population Susceptibility: A Vital Consideration in Chemical Risk Evaluation Under the Lautenberg Toxic Substances Control Act*, 17 PLoS Biol 1 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6715167/.

[130] *See generally* Anh Hoang et al. *Assessment of Methylene Chloride–Related Fatalities in the United States*, 1980-2018, 181 JAMA Internal Med. 797 (June 2021), https://pubmed.ncbi.nlm.nih.gov/33871539/ (finding that workers are exposed to far higher levels of methylene chloride than consumers, contributing to numerous fatalities in occupational settings).

[131] *See generally* Michael Ash & James K. Boyce, *Racial Disparities in Pollution Exposure and Employment at US Industrial Facilities*, 115 PNAS 10636 (2018) (showing that minorities are disproportionately exposed to toxic pollutants because of their proximity to hazardous facilities, which are disproportionately sited near or within minority communities).

[132] *See generally* Ronald N. Kostoff et al., *Setting Safer Exposure Limits for Toxic Substance Combinations*, 140 Food & Chem. Toxicology 111346 (2020) (presenting approaches to modify regulatory exposure limits to address the synergistic effects of toxic pollutants).

[133] Some of these vulnerable groups are those highlighted by the statute, such as workers, pregnant women, infants, and the elderly, but others are unique to the chemical at issue. For example, in its risk evaluation for 1-Bromopropane, EPA identified certain prosthetic users as a susceptible population because the chemical "is an available cleaner for implantable prosthetic devices." *See* EPA, Risk Evaluation for 1-Bromopropane (n-Propyl Bromide) 176 (Aug. 2020), https://www.epa.gov/sites/production/files/2020-08/documents/risk_evaluation_for_1-bromopropane_n-propyl_bromide.pdf.

[134] *See* Risk Evaluation for Methylene Chloride, *supra* note 52, at 35.

[135] *See id.*

[136] *See* Risk Evaluation for Trichloroethylene, *supra* note 96, at 259.

[137] *See* Paloma I. Beamer et al., *Concentration of Trichloroethylene in Breast Milk and Household Water from Nogales, Arizona*, 46 Env't Sci. Tech. 9055, 9055 (2012).

[138] To appropriately quantify the value of a restriction, it is necessary to know the extent of damage avoided; this requires a dose-response relationship between the chemical and the harm, which is lacking for many toxic chemicals. *See* Bruce P. Lanphear, *The Impact of Toxins on the Developing Brain*, 36 Ann. Rev. Pub. Health 211, 216 (2015) (discussing the challenges of quantifying harms from toxic chemicals on neurodevelopmental outcomes and noting that "[t]he shape of the dose–response relationship is not well established for many toxins").

[139] Corrosion Proof Fittings v. EPA, 947 F.2d 1201, 1219 (5th Cir. 1991) ("Unquantified benefits can, at times, permissibly tip the balance in close cases. They cannot, however, be used to effect a wholesale shift on the balance beam. Such a use makes a mockery of the requirements of TSCA that the EPA weigh the costs of its actions before it chooses the least burdensome alternative.").

[140] *See* S. Rep. No. 114-67, at 4 (2015) ("The requirement that EPA choose the "least burdensome" regulatory control for a chemical substance has been viewed as a requirement that EPA assess the costs and burdens of all possible regulatory and chemical options"); *see also The TSCA Modernization Act of 2015, Hearing on H.R. 2576 Before the Subcomm.*

*on Environment and the Economy of the H. Comm. on Energy and Commerce*, 114th Cong. 26 (2015) (hereinafter *"The TSCA Modernization Act of 2015 Hearing"*) (describing the importance of improving the agency's discretion to consider non-quantifiable benefits in the final bill) (noting that "the risks that we are looking at are often not quantifiable but the costs almost always are, and what we got out of the Corrosion Proof case was a finding that the Agency had to numerically determine that those benefits literally numerically were larger than the costs, which creates—you end up with a cost-biased standard, which has been one of the problems that we have had. So being clear about whether the Congress is looking for a cost-benefit balancing or you want a standard that requires the consideration of costs, which may not sound like it is a lot different but actually in reality it is quite different, would be very useful").

141 *See* S. Rep. No. 114-67, at 4 (2015) ("In deciding which restrictions to impose under paragraph (3) as part of developing a rule under paragraph (1), the Administrator shall take into consideration, to the extent practicable based on reasonably available information, *the quantifiable and nonquantifiable costs and benefits* of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.") (emphasis added).

142 *See Frank R. Lautenberg Chemical Safety for the 21st Century Act: Hearing on S. 697 Before the S. Comm. on Environment and Public Works*, 114th Cong. 75 (2015) (dialogue between Hon. Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, EPA, and Senator John Barrasso) (Senator Barrasso questioned Jones about EPA's opinion on cost-benefit analysis in the final bill and whether the statute improved the 1976 law by including non-quantifiable benefits; Jones agreed that this was an improvement, noting "[t]he agency and the executive branch in general thinks cost benefit analysis is very important for regulation, which is why for the last 30 years the government, the executive branch has required of itself to do cost benefit analysis. The difficulty that we have had under TSCA is that most of the benefits that we are worried about . . . are not easily monetized. So we end up with a very cost-biased standard. Because it is easy to monetize the costs, but you can't monetize the benefits, which makes it very difficult to show that your benefits outweigh your costs").

143 *See* H. Rep. 114-76, at 4 (2015). The House was equally concerned with the challenges of monetizing benefits. *See The TSCA Modernization Act of 2015 Hearing*, *supra* note 140, at 26, 32, 39-40, 75.

144 *See* 15 U.S.C. § 2605(c)(2)(A).

145 *See* 162 Cong. Rec. S3517 (daily ed. June 7, 2016) (explaining that the list of factors for EPA to consider does not "require EPA to demonstrate benefits outweigh costs, to definitively determine or select the least-cost alternative, or to select an option that is demonstrably cost-effective or is the least burdensome adequately protective option. Rather, it requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified. The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in Corrosion Proof Fittings v. EPA 947 F.2d 1201 (5th Cir. 1991)").

146 *See* Cass R. Sunstein & Robert W. Hahn, *A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis*, 150 U. Pa. L. Rev. 1489, 1498 (2002) (noting that cost benefit analysis "requires a full accounting of the consequences of an action, in both quantitative and qualitative terms").

147 *See* Exec. Order No. 12,866 § 1(b)(6), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

148 Exec. Order No. 13,563 § 1(c), 76 Fed. Reg. 3821 (2011).

149 *See Modernizing Regulatory Review*, The White House Briefing Room, https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/modernizing-regulatory-review (last visited July 25, 2021).

150 *Id.*

151 Pub. Citizen v. FMCSA, 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.").

152 Center for Biological Diversity v. NHTSA, 538 F.3d 1172, 1192, 1200 (9th Cir. 2008).

153 *Id.* at 1200–01.

154 National Emission Standards for Hazardous Air Pollutants, 55 Fed. Reg. 8292, 8302 (Mar. 7, 1990).

155 NESHAPS: Final Standards for Hazardous Air Pollutants for Hazardous Waste Combustors, 64 Fed. Reg. 52,828, 53,023 (Sep. 30, 1999).

156 Control of Emissions of Air Pollution from Nonroad Diesel Engines and Fuel, 69 Fed. Reg. 38,958, 39,138 (June 29, 2004).

157 *See* National Pollutant Discharge Elimination System--Final Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 69 Fed. Reg. 41,576, 41,661–62 (July 9, 2004).

158 *See, e.g.,* Carbon Pollution Emission Guidelines for Existing Stationary Sources, 80 Fed. Reg. 64,662, 64,682 (Oct. 23, 2015); 2017 and Later Model Year Light-Duty Vehicle Greenhouse Gas Emissions and Corporate Average Fuel Economy Standards, 77 Fed. Reg. 62,624, 62,912 (Oct. 15, 2012).

[159] *See* EPA, Economic Analysis of Proposed TSCA Section 6 Action on Trichloroethylene in Dry Cleaning Spot Removers and Aerosol Degreasers ES-10 (Dec. 2016) (including unquantified benefits for human health and the environment in its cost-benefit assessment for regulating TCE under TSCA 6(a) for dry cleaning and aerosol degreasing).

[160] *See* EPA, Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal 5-97 (Jan. 2017) (explaining that EPA did not quantify the health impacts of certain tumors in men because of their rarity).

[161] *See id.* at 6-3–6-12 (Jan. 2017).

[162] *See* Guidelines for Preparing Economic Analyses, *supra* note 91, at 7-50.

[163] 15 U.S.C. § 2605(c)(2)(C).

[164] *See* Toxic Substances Control Act of 1976, Pub. L. No. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. §§ 2601-2629 (1976)), § 2605(c)(1)(C).

[165] *See, e.g., H.R._____ [Discussion Draft], Subcomm. on Environment and the Economy, H. Comm. Energy and Commerce*, 113th Cong. 44 (2014) (stating that EPA can only prohibit or substantially restrict specific uses of a chemical "when technically and economically feasible alternatives . . . are available").

[166] *See* 15 U.S.C. § 2605(g)(1) (allowing for exemptions in cases of critical or essential chemical uses where there are no alternatives).

[167] *See* 15 U.S.C. § 2605(c)(2)(C) (directing EPA to consider the availability of substitutes, their economic feasibility, and their benefits to the environment "based on the information published under subparagraph (A) [the risk management subparagraph]").

[168] *See* S. Rep. No. 114-67, at 18-19 (2015); H. Rep. No. 114-176, at 26 (2015) (explaining that Congress sought to ensure that "the universe of data from which the Administrator would be making a cost-effectiveness decision would be limited to only that information provided and considered as part of the rulemaking record").

[169] *See* 15 U.S.C. § 2601(b)(2) (stating that Congress' purpose in amending the law was to provide "adequate authority . . . to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment"). As noted, the law also provides strict deadlines to ensure EPA acts in a timely manner with risk management rules. EPA has only one year to propose a risk management rule after completion of a final risk evaluation and two years to finalize it, subject to certain extensions. *See* 15 U.S.C. § 2605(c)(1)(A)–(C).

[170] *See* Joseph Allen, *Stop Playing Whack-A-Mole with Hazardous Chemicals*, Wash. Post (Dec. 15, 2016), https://www.washingtonpost.com/opinions/stop-playing-whack-a-mole-with-hazardous-chemicals/2016/12/15/9a357090-bb36-11e6-91ee-1adddfe36cbe_story.html (discussing how DDT, bisphenol A (BPA), and flame retardant chemicals have all been replaced with chemicals that have similar or worse health effects).

[171] Guidelines for Preparing Economic Analyses, *supra* note 91, at 10-7.

[172] *See* Modernizing Regulatory Review, *supra* note 149.

[173] Exec. Order No. 12,866 § 1(a), 58 Fed. Reg. 51,735 (Oct. 4, 1993).

[174] Exec. Order No. 13,563 § 1(c), 76 Fed. Reg. 3821 (Jan. 18, 2011).

[175] *See* 15 U.S.C. § 2605(c)(2)(A)(iv)(III) (instructing EPA to consider "the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator").

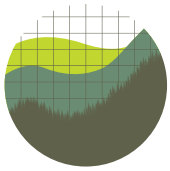
[176] *See* Circular A-4, *supra* note 84, at 11 (explaining that "cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome").

[177] Eric A Posner, *Transfer Regulations and Cost-Effectiveness Analysis*, 53 Duke L. J. 1067, 1069 (2003) ("Cost effectiveness analysis is a procedure for comparing the different means for achieving a given regulatory end; it identifies the least costly means as the most cost-effective.").

[178] *See* Circular A-4, *supra* note 84, at 11; *see also* Guidelines for Preparing Economic Analyses, *supra* note 91, at 1-5.

[179] Guidelines for Preparing Economic Analyses, *supra* note 91, at 4-2.

[180] *See id.* ("All efficient policies are cost-effective, but it is not necessarily true that all cost-effective policies are efficient.").



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