Comments of Natural Resources Defense Council on Proposed Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act.

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The Natural Resources Defense Council ("NRDC") is a national, non-profit environmental organization of lawyers, scientists, and other professionals. NRDC presents these comments on behalf of our 2.8 million members and online activists. NRDC does not have any financial interest in the topic of these comments.

The Toxic Substances Control Act (TSCA), as amended by the Lautenberg Chemical Safety for the 21st Century Act, requires EPA to promulgate rules to establish "a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluation or low-priority substances for which risk evaluations are not warranted at this time."[1] This prioritization of chemicals is the starting point for risk evaluation, and given the tight timelines and the front-loaded process appropriately laid out by EPA, the proposed prioritization rule addresses issues of vital import for the risk evaluation that forms the heart of the new TSCA process. We appreciate EPA's thoughtful engagement with the issues presented in the prioritization process and submit these comments on key aspects of prioritization.

We summarize the substance of these comments before discussing each issue in greater detail.

- NRDC agrees with EPA that the statute establishes a default to high-priority designations for chemical substances because any single hazard or route of exposure may lead to a high-priority designation and only sufficient evidence to establish the lack of unreasonable risk may lead to a low-priority designation. The explicit language of the statute is bolstered by the purpose of the designation as the precursor to further analysis and not as a final decision on a chemical substance.
- NRDC also agrees with EPA that in keeping with the statutory default to high-priority designation and the statutory requirement to consider the full spectrum of conditions of use in the risk evaluation, EPA must consider all known, intended, or reasonably foreseeable activities related to a chemical substance in prioritizing a chemical substance.

[1] 15 U.S.C. § 2605(b)(1)(A).

- In evaluating a chemical for prioritization, EPA must also consider all "reasonably available" information, and given EPA's appropriate focus on ensuring that sufficient information is available for a risk evaluation, NRDC agrees with EPA's approach to defining "reasonably available" information as both existing information in EPA's possession as well as information that it can reasonably obtain. We provide suggestions for ensuring a thorough accounting of available information and filling information gaps during the screening process for prioritization.
- When it comes to the selection of candidate chemicals for prioritization, these comments also address the consideration of potential candidate chemicals' substitutes during the candidate selection (such consideration is premature), and the consideration of international obligations as part of candidate selection (they must be taken into account).
- In addition, we respond to EPA's request for comment on defining terms in the regulations. NRDC supports EPA's proposal not to define these terms because they evolve with the science and codification would unnecessarily constrain the consideration of the latest scientific understanding of the terms. Less rigid approaches to explicating these terms, such as guidance, are the better course to follow.
- Finally, we address the administrative law context for these rules and the applicability of Executive Order 13771.

The Statute Requires a Default to a High-Priority Designation for Chemical Substances

At the outset, we agree with EPA that the statute establishes a default of a high-priority designation.[2] The statute explicitly states that a chemical may be designated low priority only "based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance."[3] A high-priority substance is one that "may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation."[4] Thus, a chemical substance may not be designated low priority if there is not sufficient information to *establish* that the substance does not pose an unreasonable risk, i.e. that no potential hazard from or no potential route of exposure to the chemical poses a risk—since a hazard or a potential route of exposure under the conditions of use may present an unreasonable risk under the terms of the statute.[5] If there is not sufficient evidence to absolve the chemical ("establish" that it does not pose unreasonable risk), then the chemical must be designated high-priority; uncertainty favors a high-priority designation.

[2] *See* Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control, 82 Fed. Reg. 4825, 4827, 4832 (January 17, 2017). EPA seems to suggest in the Federal Register Notice that is has the option to establish a default designation to low-priority. 82 Fed. Reg. 4832. However, as we indicate in the discussion that follows, the high-priority default is statutorily compelled; EPA does not have the discretion to establish a low-priority default.

[3] 15 U.S.C. § 2605(b)(1)(B).

[4] *Id.*

[5] *See also* 82 Fed. Reg. 4830.

As EPA notes, a high-priority designation leads to further analysis while a low-priority designation is a final decision. This comports with a default to high-priority designation because such designation does not preclude further consideration of the chemical at this initial, screening stage before a full risk evaluation has been conducted.

Scope of Designation: In Keeping with the Default to High-Priority Designation, EPA Must Consider Risks Associated With All Known, Intended, and Reasonably Foreseeable Activities Related to a Chemical Substance

Consistent with the statutory default to a high-priority designation, EPA interprets the revised TSCA as requiring the Agency to consider all uses encompassed within conditions of use during risk evaluation, and accordingly structures the risk prioritization and scoping processes to obtain and assess information based on this "comprehensive approach" to chemical management.[6] This reading also conforms to EPA's proposed risk evaluation rule, where EPA outlines its interpretation that the amended TSCA requires EPA to evaluate all uses of a chemical that constitute the conditions of use, as the best way to meet its statutory obligations and the purpose underlying the revisions of the law.[7] EPA has already formalized this interpretation in denying a citizen petition under TSCA.[8]

This interpretation is correct, and we believe compelled by the plain reading of the law.[9] A contrary interpretation providing the Agency discretion to ignore any condition of use would violate the statutory directive concerning the designation of low-priority substances under Section 6(b)(1)(B)(ii) of TSCA. As discussed above, by definition, low-priority substances are chemicals found by EPA not to present an unreasonable risk to health and the environment, including to a potentially exposed or susceptible subpopulation, "because of a potential hazard and a potential route of exposure under the conditions of use." (Emphasis added). A single hazard or exposure under the conditions of use, broadly defined in the statute, is sufficient to compel a high-priority designation.[10] Where EPA lacks sufficient information regarding a substance, the default designation is "high priority", under Section 6(b)(1)(C)(iii) of TSCA. This default mechanism demonstrates the statutory obligation to perform a comprehensive chemical evaluation. EPA discretion to ignore some conditions of use would undermine the very purpose of the default mechanism – to confine low priority designations to chemicals which do not present an unreasonable risk under any conditions of use.[11]

A reading of the law requiring consideration of all known, intended, or reasonably foreseeable activities related to a chemical substance is also compelled by further statutory construction and legislative history. Specifically, the statute directs EPA to determine whether a chemical presents an unreasonable

[6] *See* 82 Fed. Reg. 4829.
[7] *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562, 7565-6 (January 19, 2017).
[8] Fluoride Chemicals in Drinking Water; TSCA Section 21 Petition; Reasons for Agency Response, 82 Fed. Reg. 11878, 11880 (February 27, 2017).
[9] Therefore, we do not believe different readings of the law are possible, as suggested by the Agency at 82 Fed. Reg. 7565.
[10] *See* 82 Fed. Reg. 4830.
[11] *See* 82 Fed. Reg. 4830. NRDC supports proposed 702.11(d) as a codification of this statutory text and intent.

risk of injury to health or the environment under "the conditions of use" and to establish a risk evaluation process to conduct this inquiry.[12] In provision after provision, EPA is directed to evaluate the chemical under "the conditions of use."[13]

"Conditions of use" is expressly and broadly defined to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[14] Under this statutory definition, and in the various applications of the term in the law, including but not limited to the risk evaluation determination, there are no exceptions embedded in either the definition or in the application of the term when it is used. This absence of discretion to ignore uses for risk evaluation purposes is consistent with the legislative history supporting the comprehensive evaluation of a chemical and with the statutory requirements for priority designation.[15]

Furthermore, as EPA notes at 82 Fed. Reg. 4829, EPA is required to evaluate the "chemical substance"[16] as a whole,[17] not particular uses of the chemical in question. If the statute were interpreted to allow EPA to evaluate only a subset of uses of a chemical substance, the chemical substance could be determined to not pose an unreasonable risk based on the consideration of minor uses of the chemical even when other more significant uses were known or foreseen. This would not facilitate a consideration of the chemical substance as a whole, and would thereby undermine the statutory scheme.

This plain language reading is reinforced by the statutory directive to consider aggregate exposures, where relevant, because aggregate exposure assessments cannot be effectively conducted if all uses contributing to aggregate exposures are not considered. Evaluating the total exposure to a chemical is essential for assessing unreasonable risk to potentially exposed or susceptible populations, as directed by the statute.[18] As EPA notes, Section 6(b)(4)(F)(i) of TSCA requires that, in conducting a risk assessment, the Administrator "shall . . . integrate and assess available information on hazards and exposures . . . including information that is relevant to specific risks of injury to health and information on potentially exposed or susceptible subpopulations." (Emphasis added). A "potentially exposed or

[12] 15 U.S.C. § 2605(b)(4)(A), (B).
[13] *See, e.g.,* 15 U.S.C. § 2605(b)(1)(B), (b)(4)(F).
[14] 15 U.S.C. § 2602(4).
[15] *See* Senate Floor Debate, 162 Cong. Rec. S.3511-01, S3516 (Jun. 7, 2016) (Analysis and Views of Democratic Members (Boxer, Markey, Udall, Merkley), in regards to the "conditions of use" definition: "In fact, a new definition added to TSCA explicitly provides such authority [to consider reasonably anticipated uses in evaluating risk] and a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur.") (Emphasis added). If EPA had the discretion to ignore certain uses, there could be no mandate to consider future uses because the discretionary exception would swallow the rule.
[16] NRDC supports EPA's proposal to make clear that any reference to chemical substances in the regulations encompasses categories of chemical substances as defined in the statute, including groups of chemical substances or mixtures which share similar properties. As EPA notes, the statute explicitly states that "[a]ny action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures." 15 U.S.C. § 2625(c).
[17] 15 U.S.C. § 2605(b)(4)(A).
[18] *Id*.

susceptible subpopulation" is defined as "a group of individuals within the general population . . . who, due to either greater susceptibility or greater exposure, may be at greater risk" of adverse effects.[19] As the definition makes clear, risks to potentially exposed or susceptible subpopulations are premised on greater exposure or susceptibility. For such a subpopulation, a failure to consider the sum of all known or reasonably foreseeable additive exposures would constitute a failure to meet both the Section 6(b)(4)(F)(i) obligation to assess information relevant to susceptible populations, and the fundamental Section 6 obligation to protect potentially exposed or susceptible populations from unreasonable risk.

For example, when evaluating lead, EPA must identify the populations at risk (i.e., young children) receiving the "greater exposures," which requires consideration of aggregate exposures from the various relevant sources, including drinking water, emissions from industrial sources, consumer products, and lead paint in the home, since the risk to children from lead arises from their total exposure. The lead risk evaluation results would be based upon the impacts of the aggregate exposures to the children with the "greater exposures".

Indeed, in assessing exposures, the statute imposes an explicit "requirement" that EPA "take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance,"[20] and repeatedly refers to the EPA's consideration of whether a "combination of activities" involving the chemical presents a risk to health or the environment.[21] To consider the aggregate exposure from the frequency and number of exposures considered or the "combination of activities," EPA must look across the full spectrum of a chemical's use and disposal. [22]

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[19] 15 U.S.C. § 2602(12) (emphasis added).

[20] 15 U.S.C. § 2605(b)(4)(F)(iv) (emphasis added). NRDC agrees with EPA's proposal to include this language in the regulations concerning "exposure assessment," 82 Fed. Reg. 7579, in the Proposed Rule concerning risk evaluation; this appropriately incorporates the statutory requirement to consider aggregate exposures where relevant. Similarly, we agree with EPA's proposal to include the statutory requirement to "describe whether aggregate or sentinel exposures . . . were considered, and the basis for the consideration," 15 U.S.C. § 2605(b)(4)(F)(ii), in the regulatory sections concerning "risk characterization and peer review procedures." *See* 82 Fed. Reg. 7579. Unlike the substantive requirement to consider the frequency and number of exposures, this procedural provision simply imposes a descriptive requirement: to "describe" the nature and basis of the analysis. It does not modify the requirements of the exposure assessment to consider the duration, intensity, frequency, and number of exposures" and thus the obligation to perform aggregate exposures, where relevant.

[21] *See, e.g.,* 15 U.S.C. § 2605(a) (stating that "If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment . . .") (emphasis added); § 2605(d)(3)(A) (referring to the Administrator's consideration of the effects of "the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities") (emphasis added); § 2604(b)(2)(B) (requiring manufacturers or processors of new chemicals or of significant new uses of a chemical to submit information showing that "the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment") (emphasis added).

[22] Accordingly, NRDC fully expects the Analysis Plan in the scoping documents, as proposed in 40 CFR 702.39(c)(5), to expressly identify the aggregate exposure scenarios EPA intends to include in a chemical's risk evaluation. The pre-prioritization process and the draft scoping document comment period would enable the public to identify the

In sum, in light of the plain language of the statute requiring consideration of "the conditions of use," without exception; the requirement to evaluate chemical substances, not particular uses; and of the requirement to consider aggregate exposures, where relevant, TSCA as revised compels EPA to evaluate all known, intended, and reasonably foreseeable activities associated with a chemical, as embodied in "the conditions of use."

Intended, known, or reasonably foreseeable circumstances

We now turn to what are considered "intended, known, or reasonably foreseeable" circumstances under the law. These are three separate and independent descriptors of the circumstances constituting conditions of use, and therefore EPA must give meaning to each of the descriptors when identifying conditions of use for a particular chemical.

Some have suggested these descriptors preclude EPA's consideration of conditions of use which violate federal environmental or workplace regulations, exposures inconsistent with labels, and/or uses inconsistent with the manufacturer's intended use of a chemical or product.[23] However, as explained below, such limitations would violate the statute since they fail to give independent meaning to each of the descriptors. Moreover, EPA's mandate to protect "potentially exposed or susceptible populations," as the term is defined in the law, precludes EPA from summarily dismissing such conditions of use without considering whether existing regulations adequately protect such populations.

For example, the manufacturer's intended use of a chemical or product is only one descriptor applying to the conditions of use. Where the manufacturer knows the chemical or product is actually used in other ways, the public knows of other uses, and/or the Administrator can reasonably foresee other uses (based upon the chemical or product's properties and functionality), the statute compels EPA to identify such conditions of use. The reality is chemicals and products are often used in multiple ways, particularly if there are no legal constraints against such uses, and these conditions of use cannot be rejected simply because the manufacturer alleges it never intended those uses (while profiting from the sales).[24]

The same legal analysis holds true for chemical or product labels, which may largely reflect manufacturer intent. Moreover, in the case of labels for consumer products particularly, adherence to label use instructions cannot be assumed as a factual matter, particularly where the public and EPA "knows," or EPA can reasonable foresee, exposure scenarios inconsistent with labels. Indeed, EPA

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conditions of use and aggregate exposure scenarios warranting evaluation, in anticipation of the final scoping document.

[23] *See*, *e.g.*, "ACC Comments to Inform EPA's Rulemaking on the Conduct of Risk Evaluations under the Lautenberg Chemical Safety Act," at 10, August 24, 2016, in EPA docket "Meetings: Processes for Risk Evaluation and Chemical Prioritization for Risk Evaluation under the Amended Toxic Substances Control Act," comment ID: EPA-HQ-OPPT-2016-0400-0028.

[24] Indeed, one potential outcome of the Section 6 regulatory process is a risk management rule prohibiting the very uses the manufacturer claims it does not intend.

recently identified 48 relevant studies or meta-analyses concluding consumers and professionals do not follow the advice on the label for a variety of reasons.[25]

Even in the case where federal environmental or workplace standards apply, the relevant considerations are what is known to the Agency or the public, or what EPA can reasonably foresee, regarding uses and exposures related to the chemical. This will be a fact-based, chemical-specific inquiry, which may lead EPA to conclude exposures can exceed the relevant standards, or that the regulations themselves were not set (or adequately complied with) to protect the susceptible populations EPA is charged to protect under Section 6 of TSCA. The reality is some standards are either outdated or intended to protect the general population, not the vulnerable populations specially targeted for protection under the revised TSCA.

The presence of a chemical in a product or waste stream as an impurity or byproduct does not affect the conditions of use definition or scope. Its existence will generally be "known" or "reasonably foreseen" by the manufacturer or EPA. The uses and exposures associated with impurities or byproducts can be significant and their contribution to overall exposure and risk must be accounted for in EPA's risk evaluations. For example, as noted in a report by the European Centre for Ecotoxicology and Toxicology of Chemicals on the toxicity of possible impurities and by-products in fluorocarbon products, the presence of a highly toxic impurity (e.g., 0.1% of dichloroacetylene in a sample of dichlorodifluoromethane) could heavily influence the toxicity of the parent compound.[26] Additionally, recent research on impurities found in pesticides (e.g., in formulated glyphosate[27] and bromofenviphos[28]) demonstrated that known impurities in pesticide formulations could damage certain types of human cells more than parent compounds alone.

EPA must also consider uses and potential routes of exposure that are not under EPA's regulatory jurisdiction under TSCA, including in food processing and packaging, and via use in such items as personal care products and cosmetics. The risk evaluations conducted by EPA cannot accurately assess whether a chemical poses an unreasonable risk if all such uses and potential sources of exposure are not accounted for. Whether and how to address uses and potential sources of exposure that are found to contribute to an unreasonable risk is a matter for the risk management stage of the process, including potential exercise of the Agency's authority under Section 9 of TSCA.

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[25] Trichloroethylene; Regulation of Certain Uses Under TSCA § 6(a), 81 Fed. Reg. 91592, 91601 (December 16, 2016).

[26] European Centre for Ecotoxicology and Toxicology of Chemicals. (2008). TR 103 - Toxicity of Possible Impurities and By-products in Fluorocarbon Products. Brussels, Belgium. Available at: http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-103.pdf. Accessed 3/19/2017

[27] Kwiatkowska M, Jarosiewicz P, Michałowicz J, Koter-Michalak M, Huras B, Bukowska B (2016) The Impact of Glyphosate, Its Metabolites and Impurities on Viability, ATP Level and Morphological changes in Human Peripheral Blood Mononuclear Cells. PLoS ONE 11(6): e0156946. doi:10.1371/journal.pone.0156946. Available at: http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0156946. Accessed 3/19/2017.

[28] Sosnowska B, Huras B, Bukowska, B (2015) Oxidative stress in human erythrocytes treated with bromfenvinphos and its impurities. Pesticide Biochemistry and Physiology 118. doi: 10.1016/j.pestbp.2014.11.009. Available at: http://www.sciencedirect.com/science/article/pii/S0048357514002223. Accessed 3/19/2017.

Available Information Extends Beyond Existing Information

As the emphasis on intended, known, or reasonably foreseeable uses indicates, in both prioritization and risk evaluation, the availability of information for chemical assessments is critical for the timely completion of each task. In the proposed rule on risk evaluation,[29] the Agency has defined "reasonably available" information as "existing information that EPA possesses, or can reasonable obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation." This definition of "reasonably available" is appropriate within the front-loaded prioritization and risk evaluation framework proposed by EPA and by extension to the prioritization process.

This front-loaded process requires that EPA compile available information before prioritization to ensure an efficient prioritization and risk evaluation process, particularly to identify and fill data gaps using its data collection authority, including those under TSCA sections 4, 8, and 11(c). As EPA has stated, "EPA generally expects to pursue a significant amount of data gathering before initiating prioritization."[30] In this context, EPA's proposal for information accumulation in this proposed rule should be improved. EPA has proposed a rule which states that if, after the screening review, EPA does not "believe" that it has sufficient information for a priority designation, it is "likely" to use its information gathering authorities to generate the necessary information before pursuing prioritization.[31] Instead of leaving things so open-ended, NRDC recommends that EPA reflect the preamble intent in the regulatory language by replacing the relevant language with the phrase "EPA shall use its information gathering authorities under the Act as needed to meet the Agency's risk evaluation obligations under the Act."

To guarantee that ample information is collected and data gaps are appropriately identified, the Agency should develop a process for identifying the information necessary for completing a risk evaluation in the pre-prioritization phase of chemical assessments. Potential sources of information should be outlined for each condition of use for each chemical or class of chemicals related to, but not limited to: chemical properties (e.g., physical and chemical characteristics, related chemistries, metabolic potential, etc.), sources of hazard and dose response information (e.g., animal, non-animal, epidemiologic, mechanistic studies, etc.), sources of aggregate and cumulative exposure information (e.g., sources of near- and far-field exposure including environmental release information, production volume, presence in consumer and household products, dietary intake, occupational exposure, modeling tools with mechanisms for quantifying uncertainty and variability, etc.), and sensitive and/or vulnerable subpopulations.

When outlining the information necessary for the successful completion of the prioritization, scoping, and risk evaluation steps of a chemical assessment, the Agency has several internal processes that could be adapted for this purpose. For example, for hazard assessment, the Safer Choice Master Criteria for Safer Chemical Ingredients provides a useful matrix for organizing and collecting information across

[29] 82 Fed. Reg. 7568.
[30] 82 Fed. Reg. 4828, col. 3.
[31] Proposed Rule § 702.7(f), 82 Fed. Reg. 4836.

multiple attributes of concern (e.g., acute mammalian toxicity, carcinogenicity, genetic toxicity, etc.) for chemicals and chemical classes.[32]

In addition to the Safer Choice Master Criteria, another resource that the Agency could utilize and build upon for organizing exposure-based information is the Draft Guidelines for Human Exposure Assessment developed by the Risk Assessment Forum.[33] Though the document is still in draft form, it provides an organizational frame for gathering information necessary to complete a comprehensive exposure assessment.

Once essential information and sources have been identified, the Agency should also seek to organize initial findings in a way that is easily accessible and transparent. For example, the existing framework for generating scoping documents during the pesticide registration review process provides a systematic method for walking through data sources and data gaps. These scoping documents provide clearly delineated sections for information collected across risk assessment domains (e.g, hazard and exposure), sources of information, highlight gaps in knowledge, and give rationale for particular decision points.

The examples listed above are not meant to be completely inclusive and are not intended to provide procedures that should be codified within the final rule, but seek to illustrate ways in which the Agency can facilitate the efficient data gathering exercises and help identify specific mechanisms to acquire missing/needed information in the pre-prioritization, prioritization, scoping, and risk evaluation processes via internal processes and guidance documents as appropriate.

As a structural device for organizing and managing the flow of information to the Agency, NRDC recommends the development of a chemical-specific roadmap during the screening stage of the process. The roadmap would start with identifying the types and categories of information the Agency needs to complete the scoping document for the chemical, as discussed above and as proposed in the risk evaluation notice at 40 CFR 702.39(c).[34] The roadmap would then indicate the information EPA possesses at the time, the data gaps remaining, the tools EPA has or intends to utilize to obtain the needed data, and the timetable for receipt of the information. EPA would make the roadmap available for public review and comment no later than when it publishes the Federal Register notice initiating the prioritization process for the chemical.[35] Ideally, EPA would be reaching out to stakeholders during the screening process to solicit information on conditions of use, hazards, exposures, and use of information gathering authorities, including a working draft roadmap.

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[32] U.S. Environmental Protection Agency. *Safer Choice Master Criteria for Safer Chemical Ingredients* Available at: https://www.epa.gov/saferchoice/safer-choice-master-criteria-safer-chemical-ingredients. Accessed 2/24/2017

[33] Risk Assessment Forum. U.S. Environmental Protection Agency. (2016). Guidelines for Human Exposure Assessment: Peer Review Draft. Washington, D.C.

[34] 82 Fed. Reg. 7577.

[35] The Agency should be well positioned to specify the information gaps and tools it will use to fill the gaps by the time the prioritization process is initiated, since under proposed 40 CFR 702.7(f), EPA is "likely" to use its TSCA authorities to fill data gaps before initiating prioritization. *See* 82 Fed. Reg. 4836.

Other Screening Considerations: Consideration of Potential Candidate's Substitutes During Candidate Selection

While NRDC shares EPA's concern over the regrettable substitution of toxic chemicals, consideration of a potential candidate's substitute chemicals during the prioritization process is premature, unnecessary, and may be counterproductive in some cases. Therefore, we urge EPA to delete this consideration from proposed 40 CFR 702.7(b).

We believe the consideration is premature because EPA will lack sufficient information at this juncture to fully understand and evaluate all the conditions of use for a chemical, all the relevant alternatives, and which uses and exposures will ultimately drive the unreasonable risk determination for the chemical. Accordingly, EPA would be making priority decisions based upon partial information, and as a result, inviting inappropriate decisions based upon uses or exposures of lesser importance.

Moreover, the TSCA Section 6 risk evaluation and risk management processes could require a decade or more before fully engaging with the safety of substitute chemicals, and thus the substitutes EPA may identify as alternatives at the prioritization stage may be very different from the alternatives utilized and available when the Section 6 action is fully implemented. In short, at the prioritization stage, EPA lacks sufficient evidence about the safety of alternatives many years into the future, at the time EPA's risk management decisions would be made.

Specifically, EPA's initiation of the prioritization process triggers a 12 month evaluation period. Once the priority chemical designation is made, this is followed by a 3-3.5 year risk evaluation process, and then a 2-4 year rulemaking to set risk management standards. The effective date of the risk management standards may extend up to five years from the date of promulgation, and EPA is expressly authorized under Sections 6 (c) and (d) of TSCA to consider the availability of safer alternatives when setting the effective date of the risk management rules. Accordingly, industry will have more than ten years to develop safer substitutes for the chemical in question. EPA should not be making decisions about alternatives in year 1 of an 11-13.5 year process, given the technical capacity of the industry to change quickly when properly motivated.

Moreover, even in the unlikely event that the availability of a safer substitute remains at issue after this time has expired, EPA also retains the authority under Section 6(g) of TSCA to issue an exemption for essential uses where no safer alternative is available. This exemption can be extended until a safer alternative is available. The Section 6(g) authority vitiates the need to address the safety of alternatives during the prioritization process.

EPA's proposal may also be counterproductive in some cases. If EPA chose not to designate a chemical "high priority" because of a lack of available substitutes, EPA would merely perpetuate the status quo indefinitely, leaving both the toxic chemical and the toxic substitutes on the market. Such a result is not consistent with EPA's mandate under the revised TSCA. The better choice would be to designate the chemical "high priority" and use the subsequent risk evaluation and risk management processes to

leverage change in product formulations.[36] The Agency would then be in a position to use its effective date and exemption authorities to secure industry commitments on alternatives development and deployment.

Lastly, EPA is required to conduct risk evaluations and reach determinations "without consideration of costs or other non-risk factors," under Section 6(b)(4)(A) of TSCA. Since the risk determination is rendered for the particular chemical under evaluation, consideration of chemicals not covered within the chemical or category designation is a non-risk factor for the chemical in question, and thus prohibited under the revised statute.

In summary, EPA has ample authorities to address the problem of availability of alternatives, if and when it arises, in the risk management decision-making process. The issue is best addressed at that stage, when the "unreasonable risk" conditions of use and associated exposures are known, the alternatives information is current, and the Agency can leverage its available authorities to effect changes in product formulation.

Other Screening Considerations: Consideration of International Obligations in Candidate Selection

When selecting chemicals for prioritization, EPA must consider its international obligations under relevant Conventions and treaties. Compliance with these obligations can often require action under Section 6 of TSCA, and thus the need to prioritize chemicals covered by these obligations. Accordingly, we urge EPA to clarify in the preamble that under proposed 40 CFR 702.7(b), in determining the chemical substances with the greatest hazard and exposure potential, EPA will take into account relevant international agreements and the USA obligations flowing from such agreements.

The Minamata Convention on Mercury exemplifies this need. The United States will become a Party to this Convention when it comes into force later this year. Under the Convention, the United States government has an obligation to reduce to *de minimis* levels the use of mercury in the products listed in Annex A of the Convention, pursuant to Article 4.2.[37] Since almost 19.5 tons of mercury was used to produce mercury-added switches and relays sold in the USA in 2010,[38] the last year for which data are available, substantial mercury reductions in switches and relays will likely be required soon to meet Convention obligations.

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[36] EPA could include both the candidate chemical and the toxic substitutes as a category designation, based upon similarities in use, under Section 26(c) of TSCA. This approach would be particularly useful where there are both safe and unsafe alternatives, and EPA seeks to promote the use of the safe alternatives.

[37] *See* United States of America, Notification Under Article 4, Paragraph 2, of Information on Domestic Measures and Strategies Implemented to Address Mercury-Added Products, Including those in Part I of Annex A to the Minamata Convention on Mercury, http://www.mercuryconvention.org/Portals/11/documents/submissions/USA%20declaration_Art%204%20para%202.pdf.

[38] *See* Interstate Mercury Education and Reduction Clearinghouse, Fact Sheet Mercury Use in Switches & Relays, http://www.newmoa.org/prevention/mercury/imerc/factsheets/switches_relays_2014.pdf.

Similarly, under Article 5 of the Convention, the United States has an obligation to take measures to reduce mercury use in polyurethane production, aimed at phasing out the use over 10 years.[39] New mandated mercury inventory and reporting requirements under the revised TSCA will generate the data regarding use that are needed to support this effort.

Mercury is not listed on the 2014 TSCA Work Plan, and thus cannot be drawn from that list for prioritization purposes. Ironically, mercury was listed on the 2012 Work Plan, but was removed in the 2014 update because the Agency believed the well-known hazards of mercury do not need additional study, and further efforts to address this "priority" chemical would be undertaken pursuant to the Minamata Convention.[40] Assuming arguendo this rationale had validity in 2014, it no longer applies under the revised TSCA, where Section 6 action now hinges on the priority designation. Accordingly, US international obligations must be considered and reflected in the new TSCA prioritization process.

To Allow Them to Evolve With the Science, EPA Should Not Codify Scientific Terms

In the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Proposed Rule[41] ("Proposed Prioritization Rule") and the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act[42] ("Proposed Risk Evaluation Rule"), EPA requests comments on whether to include a definition or codification of scientific terms in the rules. Specifically, EPA seeks comments on defining terms such as "best available science," "weight-of-the-evidence," and "sufficiency of information" within the final rules.[43]

As EPA stated in the preamble of both rules:

> Defining these and other scientific terms in the proposed rule is unnecessary and ultimately problematic. These terms have and will continue to evolve with changing scientific methods and innovation. Codifying specific definitions for these phrases may inhibit the flexibility of the Agency to quickly adapt and implement changing science.[44]

Rather than codifying terms in the Final Rule, the Agency proposes to use "existing guidance definitions" and updates to the guidance documents as necessary. NRDC supports this approach as consistent with both the science and the construct of the law.

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[39] *See* Minamata Convention on Mercury, Oct. 2013, Annex B, Part II. The Convention text can be found at http://www.mercuryconvention.org/Portals/11/documents/Booklets/Minamata%20Convention%20on%20Mercury_booklet_English.pdf.

[40] *See* EPA, TSCA Work Plan for Chemical Assessments: 2014 Update, at 7 (Oct. 2014), https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

[41] 82 Fed. Reg. 4825.

[42] 82 Fed. Reg. 7562.

[43] As discussed below, since EPA did not propose any definitions of these terms, EPA cannot promulgate a final rule containing definitions of these terms without first proposing specific language for public comment.

[44] 82 Fed. Reg. 4828; 82 Fed. Reg. 7572.

The legal context for this issue is instructive. First, none of these terms are defined in statute, including "weight of evidence" on which Congress requires EPA to base its Section 6 decisions pursuant to Section 26(i) of TSCA. The lack of definitions indicates Congressional reluctance to restrict the Agency's flexibility in applying these terms to Section 6 actions.

Second, under Section 26(l)(1) of TSCA, EPA is required to issue new "policies, procedures, and guidance" as needed to implement Section 6 (and other aspects) of TSCA. The language expressly refers to policies and guidance, thereby acknowledging the continuing role these administrative mechanisms would retain in the revised law. Moreover, the statutory deadline for discharging this obligation, June 22, 2018, is after the statutory deadline for completing the prioritization and risk evaluation rules, and thus strong evidence of Congressional intent that the rules will be augmented by policies and guidance as needed to implement Section 6 of TSCA.

Third, Section 26(l)(2) of TSCA further provides for mandatory, ongoing five year reviews of the "policies, procedures and guidance" developed under paragraph (1), and requires EPA to revise these materials and mechanisms as needed "to reflect new scientific developments or understandings." Congress expressly accounted for the evolving nature of science, and required EPA to update the science underlying the policies and guidance. Congress did not include a comparable five year review mandate for the prioritization and risk evaluation rules, thereby indicating the Congressional preference for using policies and guidance as needed in this context.

Lastly, we note Congress established a Science Advisory Committee under Section 26(o) of TSCA, charged with providing "independent advice and expert consultation" on the "scientific and technical aspects" of issues arising under TSCA. Therefore, when developing and reviewing the scientific policies and guidance under Section 26(l) of TSCA, interpreting weight of evidence under Section 26(i), and making technical decisions and policies regarding "reasonably available information" under Section 26(k) of TSCA, EPA can and should access the Science Advisory Committee for advice on the latest science underlying these matters, and need not restrict them through regulations.

The Technical Problems with Stakeholder Suggestions to Codify Specific Scientific Definitions and Processes

In order to ensure and maintain an efficient risk evaluation process, the Agency must not create a system in which terms of scientific importance are unnecessarily restricted, but instead should allow the terms to evolve with shifts in scientific thinking and discovery. Indeed, the terms "best available science," "weight-of-the-evidence," and "sufficiency of information" can all be expected to change over time and context, with definitions most efficiently delineated in guidance documents rather than in a rule. The 21st century has been an explosive time for scientific discovery, particularly in the fields of hazard and exposure assessment, creating an environment in which shifts in the definitions of each of the terms highlighted in the preamble to the Proposed Prioritization Rule and Proposed Risk Evaluation Rule can be reasonably anticipated. The rapid advances seen in computational, biological, and chemical

approaches to risk assessment[45] supports the Agency position that the final prioritization and risk evaluation rules, should not "unduly [restrict] the specific science that will be used to conduct the evaluations."[46] To ultimately ensure the protection of human and environmental health in its TSCA evaluations in the future, the Agency must maintain the "flexibility to adapt and keep current with changing science."[47]

As we discuss more conceptually above, the desire from some stakeholder groups for explicit definitions of terms within the final rules[48] has the potential to substantially decrease the flexibility of the Agency to respond to change in the scientific landscape and thereby impede EPA's TSCA implementation. We address some specific examples here. For instance, the American Chemistry Council has recommended that EPA define the terms "best available science" (and other similar terms), "fit for purpose," "weight of evidence" (WOE), and "sufficiency of information," as well as explicitly define processes or mechanisms by which to evaluate hazard, exposure, or dose response assessments. Each of these suggestions raises concerns.

The term "best available science," while often used, is an amorphous, judgement-laden concept that can shift greatly over time. For example, the use of mechanistic information has changed significantly within EPA cancer assessments. While the 1986 USEPA Guidelines for Carcinogen Risk Asssessment[49] utilized mechanistic information in a more limited way – going so far as to state that "[a]t present, mechanisms of the carcinogenesis process are largely unknown and data are generally limited," mechanistic data became an important source of information in the 2006 Guidelines for Carcinogen Risk Assessment.[50] Had "best available science" been defined solely as the use of whole animal systems or epidemiologic studies, an important evidence stream could be missing from or unusable in current cancer assessments.

Congress itself found defining the term "best available science" to be a difficult proposition. The original legislation that was the starting point for what was eventually enacted into law included a definition of the term. That provision was abandoned in later versions of the legislation and was not included in the final law.[51] This decision was in keeping with a more general trend from the first introduced version of the legislation to the final enacted version of removing most of the heavily prescriptive science-policy

[45] National Academies of Sciences, Engineering, and Medicine. 2017. Using 21st Century Science to Improve Risk-Related Evaluations. Washington, DC: The National Academies Press. doi: https://doi.org/10.17226/24635.
[46] 82 Fed. Reg. 7567.
[47] *Id.*
[48] For example, see "ACC Comments to Inform EPA's Rulemaking on the Conduct of Risk Evaluations under the Lautenberg Chemical Safety Act", in EPA docket "Meetings: Processes for Risk Evaluation and Chemical Prioritization for Risk Evaluation under the Amended Toxic Substances Control Act," comment ID: EPA-HQ-OPPT-2016-0400-0028.
[49] U.S. EPA. Guidelines for Carcinogen Risk Assessment (1986). U.S. Environmental Protection Agency, Washington, DC, EPA/630/R-00/004, 1986.
[50] U.S. EPA. Guidelines for Carcinogen Risk Assessment (2005). U.S. Environmental Protection Agency, Washington, DC, EPA/630/P-03/001F, 2005.
[51] *See* Chemical Safety Improvement Act (CSIA) of 2013, S.1009, page 7, lines 14-23.

language, and ultimately providing the EPA with some general direction and a great deal of discretion, as is reflected in Section 26(h) of the final law.[52]

Similarly, we agree that the terms "fit for purpose" and "sufficiency of information" should not be defined within the final Prioritization or Risk Evaluation rules. "Sufficiency of information" and "fit for purpose" are both ill-defined concepts that have no clear scientific definition, nor is their use mandated by the statute. Since they are somewhat overlapping concepts, both dealing with the availability of information for specific decision types, we treat them similarly here. Information needs can vary significantly based upon the stage of an evaluation (e.g., prioritization versus risk assessment versus risk management), and an inflexible definition could limit the consideration of the appropriate science. For instance, as discussed in a recent report released by the National Academies of Sciences,[53] tools like chemical read-across (i.e., using data from well-studied, existing chemicals to predict the toxicity of chemicals with limited data based upon similar structure, biological activity, or metabolism) could be appropriately used for some purposes, but the report also indicated that "[r]ead-across can be problematic, and caution is needed before its conclusions are relied on heavily."[54] Read-across methods could be sufficient for and/or "fit for purpose" for upgrading the designation of a chemical (e.g., identifying a chemical as "high priority") or for chemical screening, such as narrowing the chemicals to undergo Tier 1 and Tier 2 screening in the Endocrine Disruptor Screening Program, but would not be sufficient or "fit for purpose" as the sole source of information to downgrade a chemical classification (e.g., identifying a chemical as "low priority").

Defining the concept of "weight of evidence" also raises concerns. The definition of WOE is triply troubling: it varies with context, it is vague, and there are numerous definitions in use. In its 2009 report, *Science and Decisions: Advancing Risk Assessment,* the National Research Council (NRC) described WOE as a phrase used to "describe the strength of the scientific inferences that can be drawn from a given body of evidence."[55] It noted that WOE evaluations "[vary] greatly among chemicals and other hazardous agents in type, quantity, and quality."

NRC consequently concluded that "it is not possible to describe the WOE evaluation in other than relatively general terms. It is thus not unexpected that WOE judgements in particular cases can vary among experts and that consensus is sometimes difficult to achieve."[56]Similarly, the National Research Council 2014 report on the *Review of EPA's Integrated Risk Information System (IRIS) Process* found that the phrase WOE had become "far too vague as used in practice and thus is of little scientific use."[57]

[52] *Compare*, for example, CSIA, p.14, line 1 to p.15, line 4 *with* the final Section 26(h).
[53] National Academies of Sciences, Engineering, and Medicine. 2017. Using 21st Century Science to Improve Risk-Related Evaluations. Washington, DC: The National Academies Press. doi:https://doi.org/10.17226/24635.
[54] *Id.* at 78.
[55] National Research Council. 2009. Science and Decisions: Advancing Risk Assessment. Washington, DC: The National Academies Press. doi:https://doi.org/10.17226/12209.
[56] *Id.*
[57] National Research Council. 2014. Review of EPA's Integrated Risk Information System (IRIS) Process. Washington, DC: The National Academies Press. doi:https://doi.org/10.17226/18764.

The 2014 committee also found various definitions in existence, including seemingly simplistic balancing equations with evidence supporting hazard on one side and evidence refuting hazard on the other, to more intricate "systematic review" processes with pre-established protocols and comprehensive inclusion of a variety of data sources. These definitions each proved unsatisfactory to the committee, with the committee ultimately recommending abandoning "weight of evidence" and instead employing the term "evidence integration" as a more appropriate and useful term for the data integration step involved in IRIS assessments.

In addition to the dangers of defining scientific terms, explicitly defining processes or mechanisms by which to evaluate hazard, exposure, or dose response assessments is overly restrictive.[58] While the overarching framework for risk assessment in federal regulatory decisions has remained largely unchanged since the 1983 publication of *Risk Assessment in the Federal Government: Managing the Process*[59] or "the Red Book," the tools used to generate information and the processes by which to interpret those data is an ever changing and on-going process. As highlighted extensively in the recent National Academies of Sciences report, "Using 21st Century Science to Improve Risk-Related Evaluations,"[60] the increased use of probabilistic statistical methods and computational tools, not yet discovered or used in wide practice when the Red Book was printed, have the potential to significantly alter the ways in which modern risk assessment is and will be conducted.

As these examples demonstrate, the codification of a WOE definition within a rule that requires a lengthy legal process before changes can be made can severely limit the ability of the Agency to use the most appropriate tools to evaluate the potential risks posed by chemicals in products and the environment.

While the definition of these scientific terms should not be fixed in the final Prioritization or Risk Evaluation rules, NRDC strongly supports transparency in the WOE narratives and determinations associated with the processes these terms reference. It is essential to public trust that the inclusion and exclusion criteria for specific studies and lines of evidence be presented in a transparent and accessible way.

Administrative Law Context for TSCA Prioritization/Risk Evaluation Rules and the Applicability of Executive Order 13771

Finally, EPA is under a statutory obligation to issue final prioritization and risk evaluation rules by June 22, 2017.[61] This Congressional directive to finalize the rules quickly is evidence of frustration after decades of Agency inaction on TSCA and the need for EPA to swiftly implement the newly strengthened

[58] See, for example, pages 15-17 and appendices B, C, and D of "ACC Comments to Inform EPA"s Rulemaking on the Conduct of Risk Evaluations under the Lautenberg Chemical Safety Act," in EPA docket "Meetings: Processes for Risk Evaluation and Chemical Prioritization for Risk Evaluation under the Amended Toxic Substances Control Act," comment ID: EPA-HQ-OPPT-2016-0400-0028.
[59] National Research Council. 1983. Risk Assessment in the Federal Government: Managing the Process. Washington, DC: The National Academies Press. doi:https://doi.org/10.17226/366.
[60] National Academies of Sciences, Engineering, and Medicine. 2017. Using 21st Century Science to Improve Risk-Related Evaluations. Washington, DC: The National Academies Press. doi:https://doi.org/10.17226/24635.
[61] 15 U.S.C. § 2605(b)(1)(A), (b)(4)(B).

TSCA risk evaluation process. The lack of mandatory deadlines was discussed repeatedly in testimony and other commentary about the original version of the legislation that ultimately resulted in the new law enacted in June 2016.[62] [63] The need for mandatory, enforceable deadlines was accepted fairly quickly by all stakeholders as an essential element of TSCA legislation and it became a key component of future drafts and versions of legislation in both the House and Senate.

Significantly, in November 2016, a bi-partisan group of Senators, led by Senators James Inhofe of Oklahoma and Tom Udall of New Mexico, wrote a letter to Vice President-Elect Pence urging prompt and effective implementation of TSCA by the new Administration, including stressing the importance of the new EPA Administrator "appreciating" the deadlines in the revised law.[64] The letter noted the new law "requires [EPA] to make many critical decisions in the first months and years of the program" and noted that the Agency "has a crucial role to play in ensuring that the promise of the new law is realized." The Senators stated their expectation that EPA would "vigorously implement the new law" including "moving expeditiously to identify and address chemicals with the greatest potential impact on public health, especially affecting vulnerable populations expressly required to be protected in the Act, including pregnant women, children, workers, and other at-risk communities." The letter concluded that "it is essential to maintain momentum during the Presidential transition and in the early months of the new Administration to ensure that this new law is successful."

There is no question that after 40-years of almost total inaction to address the threats posed by the thousands of grandfathered "existing" chemicals, Congress intended EPA to move forward steadily and on schedule to fulfill its obligations under the new law. It is troubling then that in a recent public meeting held by EPA to take public comment on the scoping process and the first 10 chemicals EPA has selected for risk evaluation, representatives of the chemical manufacturer's trade association suggested that EPA should not worry about the statutory deadlines and instead focus on "getting it right." EPA should ignore this poor advice and fulfill its mandatory duties under the law, including meeting its deadlines for completing rulemakings on risk evaluation, prioritization, and scoping. In the preamble to the proposed rule, EPA appropriately emphasizes meeting its statutory responsibilities, and there is no reason for the Agency to deviate from that course in the final rule.

For the same reasons, due to the statutory deadlines in TSCA, the prioritization and risk evaluation rules are not subject to Executive Order 13771, since the express language of the Order indicates it does not

[62] See, for example, separate testimony from Ansje Miller, Eastern States Director, Center for Environmental Health; Nancy Buermeyer, Senior Policy Strategist, Breast Cancer Fund; Daniel Rosenberg, Senior Attorney, NRDC from Senate Environment and Public Works Committee Hearing: "Strengthening Public Health Protections by Addressing Toxic Chemical Threats" (July 31, 2013); and blog from Safer Chemicals Healthy Families, "SCHF Issues Position on Chemical Safety Improvement Act" (June 11, 2013); and Safer Chemicals Healthy Families full-page ad in Congress Daily, "Make it Stronger" (July 31, 2013) (https://twitter.com/hashtag/MakeItStonger?src=hash&ref_src=twsrc%5Etfw).

[63] See, for example, "Testimony of Jim Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency, Before the Energy and Commerce Committee, Energy and Environment Subcommittee, United States Congress" (April 14, 2015).

[64] See attachment 1.

apply "where prohibited by law." EPA cannot comply with the Order *and* meet its TSCA obligations for finalization by June.[65] Nor do these rules come close to triggering the $100 million cost thresholds for applying the Executive Order, as specified in the accompanying guidance.[66]

When issuing the final rules, EPA also must bear in mind its obligations to provide adequate public notice and comment under the Administrative Procedures Act. EPA cannot reverse course from the proposed rules without limitation. The contents of the final rules must be a 'logical outgrowth' of the rule it originally proposed." *Northeast Maryland Waste Disposal Auth. v. E.P.A.*, 358 F.3d 936, 951-52 (D.C. Cir. 2004) (per curiam).

As part of the rulemaking process, agencies are required to "describe the range of alternatives being considered with reasonable specificity. Otherwise, interested parties will not know what to comment on, and notice will not lead to better-informed decision making." *Small Refiner Lead Phase-Down Task Force v. U.S. E.P.A.*, 705 F.2d 506, 549 (D.C. Cir. 1983). A provision in the final rule that had "no roots in the agency's proposal" cannot be a logical outgrowth because "[s]omething is not a logical outgrowth of nothing." *Envtl. Integrity Project v. E.P.A.*, 425 F.3d 992, 996 (D.C. Cir. 2005) (quoting *Kooritzky v. Reich*, 17 F.3d 1509, 1513 (D.C. Cir. 1994)).

For example, an unexpressed intention cannot convert a final rule into a logical outgrowth. *Shell Oil Co. v. E.P.A.*, 950 F.2d 741, 751 (D.C. Cir. 1991). The rationale behind requiring agencies to follow the notice-and-comment rulemaking procedure is to alert the public of new rules and regulations and to provide those interested parties with the opportunity to participate in the rulemaking process. *Int'l Union, United Mine Workers of Am. v. Mine Safety and Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005). In order for the notice-and-comment process to function as designed, "[i]nterested parties cannot be expected to divine [the agency's] unspoken thoughts." *Shell Oil Co.*, 950 F.2d at 751.

Agencies cannot rely solely on comments to show they complied with the APA's notice requirements. "As a general rule, [an agency] must itself provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment." *Small Refiner*, 705 F.2d at 549. Thus, EPA is limited in the degree to which it may diverge from what it has proposed without triggering the need for a re-proposal of its rule. And in any case, no such re-proposal is needed as the proposal is basically sound and consistent with the statute, requiring only clarification in a few places as discussed herein.

Conclusion

EPA's prioritization and risk evaluation rules are the linchpin of the reformed TSCA program. They will set the "groundrules" for how some of the most important elements of the TSCA program will operate

[65] NRDC has also challenged the constitutionality of the Executive Order, since it directs federal agencies to violate the laws that govern rulemaking – laws that neither require nor allow the kind of cost-only analysis and cost-based trading the Executive Order mandates.

[66] See https://www.whitehouse.gov/the-press-office/2017/02/02/interim-guidance-implementing-section-2-executive-order-january-30-2017. EPA estimated annual costs of $69,353 for the risk evaluation rule (82 Fed. Reg. 7574), and did not estimate any costs to the regulated community for the prioritization rule.

for years if not decades. Moreover, the content of these "groundrules" – and the decisions that EPA will make going forward with implementation -- will have profound implications for the health of millions of Americans. To break the cycle of failure that has burdened the TSCA program for so long, it is critical that the Agency finalize these rules within the statutorily mandated deadlines and in a manner that is fully consistent with the underlying law. EPA's proposed prioritization rule is fundamentally sound, and we support EPA's approach. NRDC appreciates the opportunity to comment on this important proposal and we look forward to working with EPA to ensure that implementation of the revised TSCA provides the protections for health and the environment the law requires.

Sincerely,

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