CENTER FOR
ENVIRONMENTAL
ACCOUNTABILITY

Petition for Rulemaking

to Amend the U.S. Environmental Protection Agency's Regulations Regarding Chemical Risk Management Under the Toxic Substance Control Act (TSCA), 40 CFR Part 751, Subpart A

July 6, 2025

Lee Zeldin, Administrator
Environmental Protection Agency
Office of the Administrator, 1101A
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Petition for Rulemaking to Amend the U.S. Environmental Protection Agency's Regulations Regarding Chemical Risk Management Under the Toxic Substance Control Act (TSCA), 40 CFR Part 751, Subpart A

Dear Administrator Zeldin:

Pursuant to 5 U.S.C. §553(e) and 15 U.S.C. §2620(a), the Center for Environmental Accountability (CEA) respectfully requests that the U.S. Environmental Protection Agency (EPA) initiate notice-and-comment rulemaking to amend certain provisions in 40 C.F.R. Part 751, Subpart A, regarding EPA's procedures for risk management under Section 6 of the Toxic Substances Control Act (TSCA).

EPA's regulations currently do not prescribe procedural requirements for the TSCA Section 6 risk management rulemaking process. As a result, the risk management rulemaking process is largely hidden from the general public and the industry stakeholders whose livelihoods may be upended by the requirements imposed under a given chemical risk management regulation. The lack of clear guidance in EPA's regulations has created profound inconsistencies among the proposed and final rulemakings for chemical substances, further exacerbating the unpredictability of the process, and has allowed EPA to sidestep a meaningful explanation of its decision-making process during risk management.

This petition seeks to remedy these issues by amending 40 C.F.R. Part 751, Subpart A, in the following ways:

- Mandate that EPA promulgate risk management rules that are feasible, flexible, performance-based, and effective in fully mitigating unreasonable risk;
- Require EPA to avoid imposing unnecessary, burdensome, duplicative, or prescriptive requirements on regulated entities, especially small businesses;
- Define key terms, including "unreasonable risk," "to the extent necessary," and "ECEL" or Existing Chemical Exposure Limit;
- Ensure that each rulemaking notice includes a credible, objective, and realistic regulatory analysis of specified factors that is based on reasonably available information and consistent with applicable OMB guidance documents (*e.g.*, Circular A-4) and Executive Orders;

- Restrain EPA's ability to impose a prohibition or restriction on any condition of use until after EPA has determined that other requirements under this subsection will not eliminate the unreasonable risk;

- Require EPA to incorporate, as appropriate, a *de minimis* value by weight of the chemical substance in formulations as the threshold for the applicability of any risk management requirement;

- Require each proposed rule to be peer-reviewed by the Science Advisory Committee on Chemicals, which is composed of members with appropriate experience and expertise to review such rule;

- Anticipate that EPA will issue an Advanced Notice of Proposed Rulemaking (ANPRM) to solicit more timely and meaningful input from a diverse group of stakeholders, including potentially impacted facilities and small businesses, on information EPA considers critical to identifying and selecting requirements it may incorporate into a subsequent rule;

- Mandate that EPA coordinate with appropriate federal agencies including, but not limited to, OSHA and NIOSH for the purpose of minimizing any potential burdens of duplicative or conflicting requirements. In each rule, EPA will describe the results and outcomes of this coordination and will include in the docket associated with the rule, to the extent appropriate, written input from other federal agencies;

- Require EPA to refer to other federal agencies for actions to prevent unreasonable risk or reduce the unreasonable risk to a sufficient extent for certain conditions of use; and

- Require EPA to coordinate rulemaking actions with actions taken under other Federal laws administered in whole or in part by EPA, including the Office of Air and Radiation, Office of Water, and Office of Land and Emergency Management.

CEA respectfully submits that the amendments requested in this letter and its enclosures will empower EPA to efficiently, transparently, and lawfully meet its obligations under TSCA.

Sincerely,

Marc Marie
President
Center for Environmental Accountability
marc@environmentalaccountability.org

Enclosures: Petition for Rulemaking
Attachment 1 – Proposed Model Rule

cc: David Fotouhi, Deputy Administrator
Travis Voyles, Assistant Deputy Administrator
Nancy Beck, Principal Deputy Administrator
Lynn Dekleva, Deputy Assistant Administrator

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Proposed TSCA Risk Management Procedural Regulations

40 CFR Part 751 Subpart A

The Center for Environmental Accountability (CEA) hereby petitions the U.S. Environmental Protection Agency (EPA), pursuant to 5 U.S.C. § 553(e) and 15 U.S.C. § 2620(a), to promulgate a TSCA 6(a) risk management procedural rule and amend Part 751 – Regulation of Certain Chemical Substances and Mixtures Under Section 6 of the Toxic Substance control Act, Subpart A – General Provisions.[1]

I. Background

Under the Toxic Substances Control Act (TSCA), upon a determination pursuant to a risk evaluation "that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities presents unreasonable risk," EPA must initiate a risk management rulemaking to eliminate the unreasonable risk. 15 U.S.C. 2605(a). In doing so, EPA must apply certain specified risk mitigation requirements,[2] but only "to the extent necessary" and only after considering other factors, including the costs and benefits of the proposed risk management rule.

One important risk management option that industry stakeholders can potentially pursue is to request an exemption under Section 6(g) of TSCA, in which EPA may exempt specific conditions of use from otherwise applicable risk management provisions that apply to other conditions of use. The submitter, however, must meet at least one of three criteria specified in 6(g) subsections (1)(A), (B), and (C). In granting a TSCA Section 6(g) exemption, EPA may impose conditions, but only if "necessary to protect health and the environment while achieving the purposes of the exemption." The purpose of these conditions is to "protect health and the environment to the extent feasible, recognizing that, by its nature, an exemption will allow for activities that present some degree of unreasonable risk."[3] Thus, under Section 6(g), EPA must engage in a balancing exercise to ensure that any conditions imposed do not inadvertently impede the submitter's ability to engage in the condition of use that is the subject of the exemption.

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[1] The current Subpart A - General Provisions was finalized by EPA as part of the final methylene chloride risk management rule (84 Fed. Reg. 11420 (March 27, 2019)). As noted in that final rule, "this action finalizes the general provisions related to definitions, exports and imports requirements, and enforcement and inspections." 84 Fed. Reg. at 11425. This petition would significantly amend Subpart A by including numerous other procedural provisions.

[2] TSCA Section 6(a) (1) – (7) delineates the risk mitigation measures that EPA may apply to the chemical substance in a Section 6(a) rulemaking. These include, among other measures, restrictions, prohibitions, and labelling.

[3] 162 Cong. Rec. S3511-01, at *3517.

EPA has never proposed a risk management procedural rule as a means of informing the public as to EPA's approach to eliminating unreasonable risk[4] or evaluating a Section 6(g) exemption request. This stands in stark contrast to the prioritization and risk evaluation procedural regulations promulgated by EPA within 18 months of the 2016 amendments to TSCA. It is certainly true that Section 6 of TSCA provides explicit language mandating these two procedural rules but is silent as to a similar rule for risk management. This does not mean, however, EPA lacks authority to promulgate a risk management procedural rule. Indeed, in amending TSCA, Congress added Section 26(k) giving EPA the authority to "develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments of this Act […]." We believe this petition fits squarely within the authorizing language of Section 26(k).

Promulgating a risk management procedural rule is not only necessary but long overdue. Without any procedural guideposts, each proposed and finalized chemical risk management rule under Section 6 of TSCA serves as a kind of proving ground for the thousands of industry stakeholders who struggle to decipher how and why they will be impacted by EPA's risk management measures. A risk management procedural rule is sorely needed to provide regulatory predictability and reliability, and to limit EPA's opportunities for arbitrary action.[5]

II. Summary of the Risk Management Procedural Rule

The risk management procedures[6] set forth in this petition fill the void that has left frustrated stakeholders guessing for years.

Among its many new provisions, the proposed risk management procedures would:

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[4] In 2020, several trade associations jointly submitted a petition for a risk management procedural rule, in which they sought "a rulemaking to establish […] procedural consistency, guidance, and transparency for EPA's risk management process." *See* https://www.epa.gov/petitions/petition-issue-procedural-risk-management-rule-under-tsca-section-6. EPA acknowledged receipt of the petition under the Administrative Procedure Act, not under TSCA section 21 as the petition was initially filed. EPA concluded that "Section 21 does not provide a means for petitioning EPA to initiate a procedural rule." *See* https://www.epa.gov/sites/default/files/2020-07/documents/acknowledgement_letter_nam.07282020.pdf. Nonetheless, EPA took no further action on the petition.

[5] *See generally Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 212, 136 S. Ct. 2117, 2120, 195 L. Ed. 2d 382 (2016) (discussing the importance of stakeholder reliance interests in determining whether an agency rulemaking is arbitrary and capricious under the Administrative Procedure Act).

[6] Proposed revisions to the regulations are highlighted in red. Added language is displayed in regular typeface, while a strikethrough is used to indicate text that was removed. Existing language not subject to proposed revisions is displayed in black.

- Mandate that EPA promulgate risk management rules that are feasible, flexible, performance-based, and effective in fully mitigating unreasonable risk;
- Require EPA to avoid imposing unnecessary, burdensome, duplicative, or prescriptive requirements on regulated entities, especially small businesses;
- Define key terms, including "unreasonable risk," "to the extent necessary," and "ECEL" or Existing Chemical Exposure Limit;
- Ensure that each rulemaking notice includes a credible, objective, and realistic regulatory analysis of specified factors that is based on reasonably available information and consistent with applicable OMB guidance documents (*e.g.*, Circular A-4) and executive orders;
- Restrain EPA's ability to impose a prohibition or restriction on any condition of use until after EPA has determined that other requirements under this subsection will not eliminate the unreasonable risk;
- Require EPA to incorporate, as appropriate, a *de minimis* value by weight of the chemical substance in formulations as the threshold for the applicability of any risk management requirement;
- Require each proposed rule to be peer-reviewed by the Science Advisory Committee on Chemicals, which is composed of members with appropriate experience and expertise to review such rule;
- Anticipate that EPA will issue an Advanced Notice of Proposed Rulemaking (ANPRM) to solicit more timely and meaningful input from a diverse group of stakeholders, including potentially impacted facilities and small businesses, on information EPA considers critical to identifying and selecting requirements it may incorporate into a subsequent rule;
- Mandate that EPA coordinate with appropriate federal agencies including, but not limited to, OSHA and NIOSH for the purpose of minimizing any potential burdens of duplicative or conflicting requirements. In each rule, EPA will describe the results and outcomes of this coordination and will include in the docket associated with the rule, to the extent appropriate, written input from other federal agencies;
- Require EPA to refer to other federal agencies for actions to prevent unreasonable risk or reduce the unreasonable risk to a sufficient extent for certain conditions of use; and
- Require EPA to coordinate rulemaking actions with actions taken under other Federal laws administered in whole or in part by EPA, including the Office of Air and Radiation, Office of Water, and Office of Land and Emergency Management.

A risk management procedural rule would offer a window into how EPA will construct its prospective risk management rules and Section 6(g) exemptions. Through this window, stakeholders will be able to anticipate the contours of a forthcoming risk management rule and provide timely input into the development of the rule. The procedural rule aims to curtail EPA's

tendency, so evident in recent years, to create risk management policies on the fly, with truncated opportunities to provide public input.

III. Proposed Amendments

This section describes the rationale in support of the proposed amendments to 40 C.F.R. Part 751 – Regulation of Certain Chemical Substances and Mixtures Under Section 6 of the Toxic Substance control Act, Subpart A – General Provisions, as detailed in Attachment 1. Importantly, the proposed amendments conform EPA's approach to risk management with that of the proposed revisions to Risk Evaluation, by for example, shifting away from the Biden administration's "whole chemical approach" and toward a more targeted approach aligned with TSCA's language and sound policy.

A. Referring Risk Management to Other EPA Program Offices or Federal Agencies

The ultimate objective of each risk evaluation under TSCA Section 6 is "to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment […] under the conditions of use."[7] EPA must then engage in risk management to address the unreasonable risk. TSCA Section 9 makes clear that such risk management may be implemented by various offices within EPA or by other federal agencies. EPA, however, has made emphatically clear in every risk management rule finalized to date that no other agency or statute other than TSCA, implemented by the Office of Chemical Safety and Pollution Prevention, can address unreasonable risk.[8] EPA has, in effect, read TSCA Section 9 out of the law.[9]

As amended, Subpart A – General Provisions anticipates EPA requesting other federal agencies, such as the Consumer Products Safety Commission (CPSC) and the Occupational Safety and Health Administration (OSHA), to take risk management action to address unreasonable risk. If another federal agency declines to take action, then EPA would take the necessary action, subject to the provisions of this Subpart A. EPA also would implement risk management measures to address conditions of use that are not subject to other federal laws. For example, OSHA does not cover self-employed workers. But even in these instances, under the amended Subpart A and consistent with TSCA Section 9, EPA may determine that other laws implemented by other EPA offices (*e.g.*, Office of Water, Office of Air and Radiation) could

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[7] 15 U.S.C. § 2605(b)(4)(A).

[8] *See*, *e.g.*, 89 Fed. Reg. 102568, 102616 (Dec. 17, 2024) (claiming in its final risk management rulemaking for trichloroethylene (TCE) that "TSCA is the only regulatory authority able to prevent or reduce unreasonable risk of TCE to a sufficient extent across the range of conditions of use, exposures, and populations of concern").

[9] *See Great-W. Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 217–18, 122 S. Ct. 708, 717, 151 L. Ed. 2d 635 (2002) (reasoning that it is the duty of the courts "to avoid rendering what Congress has plainly done devoid of reason and effect").

eliminate or reduce to a sufficient extent the unreasonable risk attributed to the relevant conditions of use.

B. TSCA Section 6 Risk Management Rulemaking

The risk management rules for 8 of the initial 10 chemicals subject to TSCA Section 6 risk evaluations – all of which were proposed and some finalized under the prior administration[10] – were plagued by truncated opportunities for public comment. As a result, industry stakeholders had little time to review, comprehend, and respond to proposed risk mitigation measures premised on conservative unreasonable risk determinations and faulty assumptions of conditions of use. Clearly, stakeholders need more opportunities to provide EPA with requisite information to construct rational risk management rules. The proposed amendments aim to fundamentally alter how and when EPA engages in risk management rulemaking.

1. Advanced Notice of Proposed Rulemaking

Before issuing a risk management rule under this Subpart, EPA may issue an ANPRM to solicit more timely and meaningful input from a diverse group of stakeholders, including potentially impacted facilities and small businesses, on information EPA considers critical to identifying and selecting requirements it may incorporate into a subsequent rule.

2. The Notice of Proposed Rulemaking

The risk management rules issued by the previous administration were plagued by an inadequate regulatory analysis.[11] The proposed amendments aim to address this issue by including an ANPRM provision as noted above and also by requiring that each regulatory analysis undergirding a risk management rule is consistent with OMB guidance and executive orders. The new requirements for the Agency's regulatory analysis aim to bring EPA's risk management rulemakings in line with the overall policy goal of TSCA, namely that:

> [A]uthority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation while fulfilling the primary purpose of this chapter to assure that such innovation and commerce in such chemical substances and

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[10] Final Rule for Asbestos (Part 1) (March 2024); Final Rule for Methylene Chloride (April 2024); Proposed Rule for N-Methylpyrrolidone (NMP) (June 2024); Proposed Rule for 1-Bromopropane (1-BP) (July 2024); Final rule for Carbon Tetrachloride (CTC) (December 2024); Proposed Rule for C.I. Pigment Violet 29 (PV29) (December 2024); Final Rule for Perchloroethylene (PCE) (December 2024); Final Rule for Trichloroethylene (TCE (December 2024). *See* https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/ongoing-and-completed-chemical-risk-evaluations-under.

[11] *See, e.g.*, Final Risk Management Rulemaking for TCE, 89 Fed. Reg. 102568, 102573 (Dec. 17, 2024) (conceding that "EPA was unable to quantify all incremental costs of this rule.")

mixtures do not present an unreasonable risk of injury to health or the environment.[12]

Subpart A amendments also include the language of TSCA Section 6(c)(2)(A) Statement of Effects, but importantly add the term "conditions of use" to clarify that the effects and benefits of the chemical substance pertain only to those conditions of use determined to present unreasonable risk and thus requiring a risk management rule. Under the recent *Loper Bright* decision, focusing the risk management rule on specific conditions of use that present unreasonable risk rather than the whole chemical reflects the "best reading" of TSCA.[13]

In deciding whether to impose prohibitions or restrictions on a chemical in a risk management rule, TSCA Section 6 requires 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 when the proposed prohibition or other restriction takes effect."[14] In addition to including this statutory requirement, amended Subpart A also requires EPA to include in its analysis any negative impacts of potential alternatives and engage with its New Chemicals Division (within the Office of Chemical Safety and Pollution Prevention) and other federal agencies on the availability of potential alternatives.

EPA has thus far relied heavily on prohibitions or restrictions as the tools of choice in proposing and finalizing risk management rules. In some instances, EPA simply assumed that regulated entities were not able to address unreasonable risk through other risk mitigation means.[15] Amended Subpart A addresses EPA's draconian approach in a number of ways. The term "to the extent necessary" in TSCA Section 6 would be defined to make clear that prohibitions or restrictions cannot be imposed if other (less draconian) measures can eliminate the unreasonable risk. These procedural requirements guard against the adoption of unnecessary restrictions for chemical risk management that may be considered arbitrary and capricious.[16]

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[12] 15 U.S.C. § 2601(b)(3); *see Stand Up for California! v. United States Dep't of the Interior*, 994 F.3d 616, 627 (D.C. Cir. 2021) (using introductory "findings" section in statutory interpretation).

[13] *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 373, 144 S. Ct. 2244, 2247, 219 L. Ed. 2d 832 (2024).

[14] 15 U.S.C. § 2605(c)(2)(C).

[15] *See, e.g.*, 89 Fed. Reg. at 102579 ("[P]rohibition of all conditions of use ultimately is necessary to address the unreasonable risk").

[16] *See* 5 U.S.C. § 706 (requiring courts to hold unlawful any agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; contrary to constitutional right, power, privilege, or immunity; or in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" among other provisions); *see also Loper Bright* at 391, 144 S. Ct. at 2261 (holding that the Administrative Procedure Act was originally

Moreover, under the Subpart A amendments, EPA must provide a regulated entity an opportunity to demonstrate that other measures are ineffective at eliminating the unreasonable risk before EPA imposes a prohibition or restriction on a condition of use.[17] These other measures could include a workplace chemical protection program (WCPP), which EPA has relied on in recent risk management rules. Although EPA repeatedly has stated that the WCCP is "performance based," in reality the WCCP is layered with unnecessary requirements.[18] To address this incongruity, amended Subpart A underscores that to the extent EPA proposes a WCPP, it must be performance based.

As noted in Section III.B above, EPA has issued a total of eight proposed or final risk management rules, some of which include an existing chemical exposure limit (ECEL) that if met would fully address the unreasonable risk. The regulatory challenge, however, is that some of the ECELs proposed and finalized by EPA are unattainably low.[19] To the extent EPA proposes an ECEL in future risk management rulemakings, amendments to Subpart A specify that any ECEL must be technically and economically feasible to achieve with existing technology and methods. Similarly, a definition for a STEL or short-term exposure limit also has been added to Subpart A, which would require any STEL also to be technically and economically feasible.

a) Control Banding Approach

Control banding is a promising approach to address occupational risks, consistent with a performance-based approach to eliminating unreasonable risk, but heretofore EPA has neither mentioned, let alone proposed this approach in any risk management rule. As described in

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enacted by Congress in 1946 "as a check upon administrators whose zeal might otherwise have carried them to excesses not contemplated in legislation creating their offices.") (internal citations omitted).

[17] In the past, EPA would routinely propose prohibitions or restrictions as the primary regulatory proposal under the assumption that industry stakeholders could not address unreasonable risk in any other manner. But then, ironically, EPA's alternative regulatory proposal would not include such prohibitions or restrictions for certain conditions of use. *See, e.g.*, Proposed Rule for NMP, 89 Fed. Reg. at 51162-64 (recommending prohibition as the proposed regulatory action for many conditions of use and recommending a workplace chemical protection plan (WCPP) as the primary alternative action for those same conditions of use).

[18] *See* 89 Fed. Reg. at 102607 (describing the WCPP as "non-prescriptive" and allowing "regulated entities [to] have flexibility to select controls in accordance with the hierarchy of controls"); *compare id.* at 102627-28 (listing numerous prescriptive requirements for exposure monitoring, demarcation of regulated areas, respirator use and availability, and other prohibited activities).

[19] EPA even admitted that its proposed ECEL for TCE (0.0011 parts per million) was "significantly lower than the detection limits of available monitoring and analytical methods for TCE." *See* 89 Fed. Reg. at 102580.

amended Subpart A, control banding is a simplified, qualitative strategy for the assessment of occupational risks and selection of controls. When applying a control banding approach, occupational risks are grouped into control categories or "bands" based on a risk assessment. Control banding may be an especially useful tool for small businesses. Under amended Subpart A, control banding could be used in lieu of or in addition to ECELs as a tool to eliminate unreasonable risk in the workplace.

For some chemicals, EPA has proposed *de minimis* thresholds[20] below which risk management requirements would not apply to the chemical substance in formulations. But EPA has proposed such thresholds inconsistently and in at least one instance, inexplicably failed to propose a threshold at all.[21] To address these anomalies, under Subpart A, EPA would propose thresholds consistent with the requirements under the OSHA Hazard Communication standard at 29 CFR 1910.1200.

Subpart A, as amended, also includes language to reduce the compliance burden of regulated entities by allowing them to rely on current documented risk measures.

C. Peer Review

EPA has never subjected any risk management rule to peer review, but it should, particularly with regard to the regulatory analysis and alternatives analyses. Peer review would be conducted by the Science Advisory Committee on Chemicals, established in the 2016 TSCA amendment, populated with members who have the expertise to conduct such reviews.

D. Rulemaking Procedures

TSCA Section 6 specifies the procedures EPA must follow in promulgating risk management rules, including for example "publish[ing] a notice […] stating with particularity the reason for the proposed rule" and "specify[ing] the date on which [the rule] shall take effect, which date shall be as soon as practicable" among other procedures.[22] Additional procedures delineated in amended Subpart A would require EPA to provide a minimum of a 60 to 90-day comment period, with opportunities for extension as appropriate. This would correct EPA's all

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[20] EPA has also referred to de minimis thresholds as regulatory thresholds. *See* 89 Fed. Reg. at 102591 ("EPA is establishing a regulatory threshold of 0.1% for TCE, indicating that TCE at concentrations less than 0.1% by weight are not subject to the prohibitions and restrictions outlined in this rulemaking.")

[21] *See* 89 Fed. Reg. at 51166.

[22] 15 U.S.C. § 2605(d)(1)(A).

too frequent practice of truncating the public comment period and denying requests for extensions.[23]

Other provisions included in amended Subpart A would not only require EPA to coordinate with other federal agencies, but describe the results and outcomes of this coordination and include in each public docket associated with the rule, to the extent appropriate, written input from these federal agencies. In each risk management rule to date, EPA explicitly acknowledges that it coordinates with other agencies, but it is not always clear what resulted from this coordination.[24] This new language aims to address this omission.

E. Additional Rulemaking

EPA recognizes that regulated entities may become aware of information after the issuance of a final rule that indicates a prohibited or otherwise restricted condition of use can meet the exemption conditions of Subpart A or the requirements of the rule to allow the condition of use to continue.[25] In such instances, Subpart A explicitly recognizes EPA's authority to consider petitions for rulemaking submitted by such regulated entities after the final rule is issued, and either before or after the effective dates of such rule. If EPA finds a reasonable basis exists to conclude that such a request is warranted so as to enable the continuation of the conditions of use that are the subject of the petition for rulemaking, EPA can exercise its enforcement discretion by issuing an enforcement statement not to pursue enforcement action against the petitioner for up to two years or until EPA promulgates the amended rule, whichever is earlier.[26]

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[23] Requests for extension of comment periods were rejected, for example, during the TCE rulemaking (Document ID EPA-HQ-OPPT-2020-0642-0237), and during the methylene chloride rulemaking (Document ID EPA-HQ-OPPT-2020-0642-0717).

[24] *See* 89 Fed. Reg. at 102616 (mentioning inter-agency coordination and then blanketly dismissing potential mitigating impacts from OSHA's existing standards and CPSC's authorities).

[25] *See, e.g.*, Proposed Rulemaking for NMP, 89 Fed. Reg. at 51151 ("EPA recognizes that there may be instances where an ongoing use … is identified after the [] rule is finalized, but the final rule prohibits that use. For instances like that, EPA requests comments on an appropriate, predictable process that could expedite reconsideration for [these] uses.").

[26] EPA already has enforcement discretion to develop an enforcement statement and thus this new language in Subpart A is not necessary. The language was included, however, as an alternative to language granting EPA authority to enter into a consent order with the petition submitter to allow for the continuation of the conditions of use pending the outcome of EPA's review of the petition. TSCA section 6 does not explicitly authorize EPA to enter into consent orders (unlike section 5), and thus including consent order regulatory authority may be viewed as exceeding the bounds of EPA's statutory authority under TSCA and inconsistent with the "best reading" of the statute. *See Loper Bright* at 371, 144 S. Ct. at 2247.

F. Exemptions

Subpart A includes language consistent with TSCA section 6 and adds language to underscore that any condition associated with granting an exemption cannot impede the exemption itself and that an exemption for a condition of use by its very nature means that unreasonable risk may still persist.

IV. Impact of Proposed Regulations on Risk Management Procedures

For illustrative purposes, the following is a narrative describing how Subpart A proposed regulatory changes governing procedures for risk management would be applied in the context of a discrete risk management rule.

Following the risk evaluation, and to the extent EPA identifies information needs critical to selecting requirements to incorporate into a risk management rule, pursuant to Section 751.6, EPA would issue an ANPRM to solicit such information, providing stakeholders with a minimum of a 60-day comment period. For those *occupational* conditions of use (COUs) that present unreasonable risk, under Section 751.10, EPA would determine whether any such risk could be prevented or reduced to a sufficient extent by action taken under the Occupational Health and Safety Act. Assuming EPA makes an affirmative determination, EPA would develop a report describing the COUs that present unreasonable risk and promptly submit it to OSHA. If OSHA opts not to pursue risk mitigation action, then the occupational COUs would be addressed by EPA in a rulemaking. This rule also would address any COUs that do not fall under OSHA's jurisdiction. If any *consumer* COU presents unreasonable risk, EPA would engage in a similar exercise with the Consumer Products Safety Commission.

EPA would coordinate its rulemaking actions under this Subpart with other EPA offices (*e.g.,* Office of Air and Radiation, Office of Water, and Office of Land and Emergency Management). This intra-agency coordination is a continuation of the active engagement by EPA's offices throughout the processes set forth in 40 CFR part 702, Subpart A and Subpart B.

If, following these new procedural steps, EPA still needs to engage in TSCA rulemaking under amended Subpart A, EPA's notice of rulemaking would be informed by information received in response to the ANPRM described above, and under Section 751.3(a) the notice would contain a credible, objective, and realistic regulatory analysis of the factors enumerated in this Section consistent with applicable OMB guidance documents (*e.g.,* Circular A-4) and Executive Orders. Critically, EPA would describe *how* it considered these factors and *how* they influenced EPA's selection of requirements under this Subpart.

The notice of rulemaking also would include, to the extent necessary, one or more of the requirements in Section 751.6, so as to eliminate unreasonable risk with respect to the general population (*e.g.,* consumers) and any potentially exposed or susceptible subpopulation (*e.g.*, workers). If EPA anticipates proposing a prohibition or restriction under this Subpart on any condition of use, EPA must first determine that other requirements will not eliminate the unreasonable risk. In this regard, EPA would provide employers with an opportunity to demonstrate that such other requirements were ineffective at eliminating the unreasonable risk

before EPA imposes a prohibition or restriction of a condition of use. EPA will not assume a regulated entity is incapable of complying with any requirement under this subsection.

If EPA were to propose a prohibition or other restriction, then the notice would need to include an alternatives analysis, to the extent practicable, describing whether technically and economically feasible alternatives that benefit health or the environment, compared to the condition of use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect. This analysis would assess whether any alternative could undue or entirely negate in certain circumstances the requirements of any rule under this Subpart. EPA will coordinate with its New Chemicals Division and other federal agencies regarding the potential availability of alternatives.

As part of each notice, EPA would include, as appropriate, a *de minimis* value by weight of the chemical substance in formulations and mixtures as the threshold for the applicability of any requirement under this Subpart. To the extent practicable, the threshold will be consistent with the requirements under the OSHA Hazard Communication standard at 29 CFR 1910.1200 so as to lessen the regulatory burden on the regulated community, including small businesses, and to foster compliance and consistent risk communication.

Each proposed rule would be subject to peer review by the Science Advisory Committee on Chemicals, constituted by members with appropriate experience and expertise.