Before the United States Environmental Protection Agency

n-Methylpyrrolidone (NMP); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment; 87 Fed. Reg. 39511 (July 1, 2022); Dockets EPA-HQ-OPPT-2016-0743/FRL-9943-01-OCSPP

Comments of the Chemical Users Coalition

Introduction

Chemical Users Coalition ("CUC") appreciates the opportunity to provide these comments in response to the U.S. Environmental Protection Agency's ("EPA's" and "the Agency's") recent notice announcing the availability of and requesting public comment on a draft revision to the risk determination for the n-methylpyrrolidone ("NMP") risk evaluation issued under the Toxic Substances Control Act ("TSCA"). In the notice, EPA stated that the Agency intended to implement two changes to the approach taken in the risk determination in its December 2020 risk evaluation for NMP: (1) the Agency would apply a "whole chemical" approach to the risk determination instead of a condition-of-use-specific approach, and (2) the Agency would remove the assumption of use of personal protective equipment ("PPE").

CUC is an association of companies from diverse industries that typically acquire and use, rather than manufacture or import, chemical substances.[1] To thrive in a competitive global economy, our Members depend on the availability of certain existing substances for which there are not technically feasible substitutes as well as a reliable pipeline for innovative new chemistries. Consequently, our Members encourage EPA to develop regulatory approaches that encourage innovation and permit sustainability. Thus, CUC supports measures that protect health and the environment in a manner that enables the regulated community to pursue technological innovation simultaneously with economic development in the United States. This is critical in the area of chemical regulatory policy, which necessarily addresses emerging information about health and environmental risk.

CUC is concerned that the revised approach EPA intends to take to the risk determinations in its TSCA Section 6 risk evaluations fails to provide an accurate picture of the risks presented by a chemical substance under the substance's actual conditions of use. CUC urges EPA to continue to include reasonable assumptions regarding the use of PPE when making risk determinations and to make condition-of-use-specific risk determinations for NMP and other chemical substances. Such an approach is grounded in the statute and regulations, and supported by sound science.

EPA Should Consider Compliance with Applicable Personal Protective Equipment Requirements in Its Risk Determinations

EPA has proposed that "that the risk determination should be explicit that it does not rely on assumptions regarding the use of [PPE] in making the unreasonable risk determination under

[1] CUC's Members include Airbus S.A.S., The Boeing Company, Carrier Corporation, HP Incorporated, IBM Company, Intel Corporation, Lockheed Martin Corporation, National Electrical Manufacturers Association, Raytheon Technologies Corporation, Sony Electronics, Inc., and TDK U.S.A. Corporation.

TSCA Section 6 … ; rather, the use of PPE would be considered during risk management as appropriate."[2] This decision to relegate consideration of PPE use to the risk management stage is not consistent with the statute and implementing regulations, which require EPA to determine whether a chemical substance presents an unreasonable risk "under the conditions of use."[3]

TSCA defines "conditions of use" as "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."[4] The structure of the definition makes clear that "circumstances" includes more than the fact that a substance is manufactured, imported, processed, etc. Therefore, "circumstances" logically includes aspects of the context in which a chemical substance is manufactured, imported, processed, etc., including whether workers wear PPE. EPA's elimination of the PPE assumption also effectively eliminates "circumstances" from the definition of "conditions of use." Use of PPE is a circumstance that "is intended, known, or reasonably foreseen." PPE use therefore belongs as a component of the conditions of use that the TSCA Section 6 risk evaluations must consider.

Moreover, by failing to accurately assess exposures during the practical conditions of use of chemical substances, the Agency's new approach to risk determinations makes the risk evaluations merely hazard assessments, since "risk" is a function of the intersection of hazard and exposure. TSCA has a clear focus on both of these elements in its framework for evaluating and managing chemical substances, from the prioritization process (which requires that designation of high-priority substances be based on both a "potential hazard" and a "potential route of exposure under the conditions of use")[5] to the risk evaluation requirements (which require integration and assessment of information "available on hazards and exposures for the conditions of use of the chemical substance").[6]

Furthermore, Section 26(k) of TSCA specifically requires the Agency to take into consideration *all information* which is reasonably available to the Agency concerning both hazard *and exposure* information. Nevertheless, in the draft revised risk determination, EPA states that there may be potentially exposed or susceptible subpopulations of workers not covered by Occupational Safety and Health Administration ("OSHA") PPE requirements and other OSHA standards, such as self-employed individuals and public sector workers not covered by a State Plan or workers whose employer is out of compliance with the OSHA standards. However, rather than locating and further assessing in a transparent manner the information and data which might support such assumptions, the revised risk determination does not supply any basis in the record for reaching such a conclusion.

In contrast, EPA's approach in the December 2020 risk evaluation reflected a more reasonable approach in that it was generally based on available information which was cited in the record. While CUC members do not concede that the various exposure assumptions and conclusions EPA reached in the December 2020 document are entirely accurate and would not

[2] 87 Fed. Reg. at 39513.
[3] 15 U.S.C. § 2605(b)(4)(A); *see also* 40 C.F.R. § 702.41.
[4] 15 U.S.C. § 2602(4).
[5] 15 U.S.C. § 2605(b)(1)(B)(i).
[6] 15 U.S.C. § 2605(b)(4)(F).

benefit from considerable refinements, at least under the Agency's approach at that time, EPA based its decisions on unreasonable risk to workers and made explicit that EPA's "high-end exposure estimates" took into account certain "uncertainties related to whether or not workers are using PPE."[7] EPA stated that it believed this was "a reasonable and appropriate approach that reflects workplace practices, accounts for reasonably available information related to worker protection practices, and addresses uncertainties regarding available [sic] and use of PPE."[8] Moreover, differing exposure estimates were provided reflecting the use of PPE under certain conditions of use evaluated. EPA should continue to adhere to what it learned about worker protection practices from "reasonably available" information instead of speculating regarding what other types of conditions of use of NMP (or another chemical substance) might exist.

The Whole Chemical Approach Is Not Consistent with TSCA and Will Result in Skewed Understandings of the Risks of Chemical Substances

The condition-of-use-specific determinations of unreasonable risk in the December 2020 risk evaluation provided a clear picture of EPA's decision-making regarding the risks presented and not presented by NMP. The whole chemical approach in the revised risk determination fails to provide this clarity. Furthermore, the whole chemical approach is not grounded either in TSCA's statutory requirements or the implementing regulations.

First, the whole chemical approach is at odds with the structure Congress created in the 2016 amendments for prioritizing, evaluating, and managing the risks of existing chemical substances. The statute presumes that at the conclusion of a risk evaluation, EPA will issue either a determination that a chemical substance presents an unreasonable risk or a determination that it does not present an unreasonable risk.[9] However, the practical effect of the whole chemical approach is that there are unlikely to be any determinations of no unreasonable risk if a whole chemical approach is used. Because substances undergoing a risk evaluation are drawn from pools of substances for which available information already indicates a risk, it is extraordinarily likely that the Agency's risk evaluation will identify an unreasonable risk under at least one condition of use. Congress limited the pool of chemicals for which the first 10 risk evaluations could be conducted to substances already included on the 2014 update of the TSCA Work Plan for Chemical Assessments, which included chemicals previously selected based on their hazard and potential exposure, as well as other considerations such as persistence and bioaccumulation.[10] Moreover, future risk evaluations will be conducted for chemical substances that EPA has already determined "may present" an unreasonable risk through the prioritization process. The inclusion of the provisions for a finding of no unreasonable risk are evidence that Congress did not intend that there would always be a determination of unreasonable risk for every substance being evaluated, and that Congress must have intended for specific conditions of use to be evaluated by the Agency and risk determinations made for each of those uses.[11] If a whole chemical approach is used, the

[7] EPA, EPA Doc. No. 740-R1-8009, Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP), at 28 (Dec. 2020).
[8] *Id.*
[9] *See* 15 U.S.C. § 2605(i).
[10] 15 U.S.C. § 2605(b)(2)(A).
[11] 15 U.S.C. § 2605(b)(1)(B)(i).

distinction between the "may present" standard for prioritization and "presents" standard for triggering risk management regulations could be lost.

Second, the whole chemical approach is inconsistent with the regulations establishing the process for conducting risk evaluations. Although TSCA itself sets forth basic requirements and principles for the scope and conduct of risk evaluations, the statute directs the EPA Administrator to promulgate regulations establishing the process for conducting risk evaluations and directs that risk evaluations be conducted and published "in accordance with" that rule.[12] The whole chemical approach of the revised risk determination is plainly not "in accordance with" the Risk Evaluation Framework Rule that EPA promulgated in 2017.[13]

Most significantly, the whole chemical approach is inconsistent with 40 C.F.R. § 702.47, which provides that "[a]s part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment *under each condition of uses* [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents" (emphasis added). The plain language of this regulation requires condition-of-use-specific risk determinations.[14] The preamble to the final framework rule reinforces that this provision provides that a separate risk determination will be made for each condition of use, stating: "EPA's determinations will specify whether each condition of use identified for a chemical substance does or does not present an unreasonable risk of injury to health or the environment."[15] The preamble goes on to note that any Section 6(a) risk management rule "would apply only to the condition(s) of use that present an unreasonable risk, and those that do not present an unreasonable risk will not be subject to risk management."[16] EPA said it would "clarify in the draft and final risk evaluation documents specifically which condition(s) of use warrant risk management and which do not."[17] Given the clear language in the regulatory provision that specifically addresses unreasonable risk determinations (40 C.F.R. § 702.47) and the accompanying discussion in the preamble to the final rule, EPA's arguments that the regulations do not call for use-by-use risk determinations are not persuasive.

In addition, whereas the Risk Prioritization Framework Rule explicitly states that priority designations are "for a chemical substance, not for a specific condition or conditions of uses of a chemical substance,"[18] there is no such provision in the Risk Evaluation Framework Rule. The absence of such language when EPA made clear provision for a whole chemical approach in another part of the Section 6 implementing regulations is further evidence foreclosing a whole chemical approach in this context.

Moreover, EPA has not explained how the whole chemical approach to risk determinations is "employed in a manner consistent with the best available science" or a "weight of scientific evidence" approach. EPA should explain how this approach is compelled by the factors and

[12] 15 U.S.C. § 2605(b)(4)(B)–(C).
[13] 82 Fed. Reg. 33726 (July 20, 2017) (codified at 40 C.F.R. part 702, subpart B).
[14] CUC acknowledges that the Ninth Circuit found some ambiguity in the text of the regulation. *See* Safer Chems., Happy Families v. EPA, 943 F.3d 397, 413 (9th Cir. 2019).
[15] 82 Fed. Reg. at 33744.
[16] *Id.*
[17] *Id.*
[18] 40 C.F.R. § 702.1(b).

scientific and information standards articulated by Congress in the amendments to TSCA Section 26.

In addition, even if the Agency's arguments were persuasive, it is not clear how EPA intends to determine when it will use the whole chemical approach and when it will use a condition of use approach to risk determinations. Nor has EPA made clear how the switch to a whole chemical approach may affect risk management. As discussed further below, the new approach implies that the Agency would feel warranted, in risk-management rulemakings, to impose requirements or restrictions affecting conditions of use for which no specific finding has been made that the conditions of use present unreasonable risks. Such lack of clarity undermines the effectiveness and durability of TSCA decision-making. It also raises concerns about potentially arbitrary and capricious decision-making as well as about transparency, accountability, and predictability.[19]

EPA's Policy Changes for Risk Evaluations May Lead to Unwarranted Impacts on Importers of Articles Containing Chemical Substances Subject to Risk Evaluations

CUC is concerned that the policy changes implemented in the revised risk determinations may have unwarranted impacts on the import of manufactured articles containing a chemical substance for which EPA conducts a risk evaluation. For example, the December 2020 risk evaluation indicated that certain consumer uses of NMP, including in paint and coating removers, adhesive removers, and in cleaning and furniture care products, do not present an unreasonable risk.[20] By taking a whole chemical approach, however, EPA likely creates a public perception that these conditions of use present an unreasonable risk without any basis in the record.

The whole chemical approach also is likely to increase the likelihood that EPA will regulate the use of chemical substances in articles despite that use not being deemed to present an unreasonable risk. The revised risk determination suggests that this scenario is, in fact, very likely. Although the preamble to the final Risk Evaluation Framework Rule stated that any Section 6(a) risk management rule "would apply only to the condition(s) of use that present an unreasonable risk,"[21] the draft revised risk determination states EPA's view that Section 6(a) permits EPA to "regulate upstream activities (e.g., processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (e.g., consumer use) even if the upstream activities are not unreasonable risk drivers."[22] To CUC, this raises the question of whether import or

[19] It is worth noting that the lack of predictability may be particularly significant for manufacturer-requested risk evaluations, in which manufacturers identify conditions of use for evaluation in their requests, and EPA evaluates whether the requested conditions of use warrant inclusion within the scope of a risk evaluation and whether any additional conditions of use warrant inclusion. 40 C.F.R. § 702.37(e)(3). A whole chemical approach could make it less likely that manufacturers would submit requests because they would have less assurance that the conditions of use with which they are concerned would not be lumped with other conditions of use that potentially present higher levels of risk.

[20] EPA, EPA Doc. No. 740-R1-8009, Risk Evaluation for n-Methylpyrrolidone (2-Pyrrolidinone, 1-Methyl-) (NMP), at 30 (Dec. 2020).

[21] 82 Fed. Reg. 33726, 33744 (July 20, 2017).

[22] EPA, Unreasonable Risk Determination 2 (not dated), https://www.epa.gov/system/files/documents/2022-06/Risk%20Determination%20NMP.pdf.

distribution of articles might be unfairly regulated to address downstream conditions of use, such as the continued use, recycling, or disposal of such articles.

It would clearly not be consistent with the intent of TSCA to impose risk management requirements on articles *per se* to address risks presented by other conditions of use. Indeed, TSCA contains a specific provision that constrains the risk management actions EPA can take with respect to articles. That provision provides:

> In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).[23]

This provision makes clear that the extent to which articles should be regulated is dictated by what risks a risk evaluation identifies as stemming from exposure to a chemical substance in an article, and that articles should not be regulated to ameliorate risks presented by other conditions of use. The whole chemical approach will functionally disable this important provision of Section 6, and Congress's intent for including it.

Conclusion

As articulated above, CUC is concerned that EPA's policy changes regarding its approach to risk evaluations and risk determinations will warp the presentation and public interpretations of the Agency's conclusions about risk and have unwarranted impacts on future risk management decision-making, as well as unfairly impugn products and conditions of use which have not been critically and transparently assessed. CUC also believes that the policy changes are not properly grounded in the statute or consistent with TSCA's implementing regulations.

CUC Members would be pleased to meet with EPA personnel to discuss these comments and related issues as the Agency continues its efforts to review its first 10 risk evaluations and to conduct the next set of risk evaluations.

[23] 15 U.S.C. § 2605(b)(4)(E).