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VIA ELECTRONIC FILING

Dr. Jeffery Morris
Acting Director, Office of Pollution Prevention and Toxics (7407M)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460-0001

RE: Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 Fed. Reg. 7,562) (January 19, 2017); Docket Nos. EPA-HQ-OPPT-2016-0654; FRL-9957-75; RIN: 2070-AK20

Dear Dr. Morris:

The U.S. Chamber of Commerce ("Chamber"), the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and dedicated to promoting, protecting, and defending America's free enterprise system, offers these comments to the U.S. Environmental Protection Agency ("EPA") on EPA's proposed "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" ("the proposed rule").[1] The Chamber provides these comments to assist EPA in its development of a new chemical evaluation and management program that is effective and based on high-quality and sound science.

I. Background

The Chamber has long supported a high-quality and science-based chemical management and evaluation program. After close to a decade of reform efforts, President Obama signed the Frank R. Lautenberg Chemical Safety for the 21st Century Act[2] ("LCSA") into law on June 22, 2016, amending the Toxic Substances Control Act[3] ("TSCA") for the first time since it was enacted in 1976.

[1] 82 Fed. Reg. 7,562 (Jan. 19, 2017).
[2] Pub. L. No. 114-182, 130 Stat. 448 (June 22, 2016).
[3] 15 U.S.C. § 2601 et seq. (1976). Hereinafter, all references to TSCA include the LCSA amendments.

Risk evaluation is the second step in the new process for reviewing and managing existing chemical substances. At the core of TSCA reform is this improved process for conducting risk evaluations in order to determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including the unreasonable risk to a potentially exposed or susceptible subpopulation . . . under the conditions of use."[4] As such, EPA's development of high quality risk evaluations is a key measure of success for the statute.

On January 19, 2017, EPA published the proposed rule in the *Federal Register*.[5] The proposed rule provides for five steps in the new risk evaluation process: 1) scoping; 2) a hazard assessment; 3) an exposure assessment; 4) a risk characterization; and 5) a risk determination.[6] It also suggests that this process be used on the first ten chemicals to be evaluated, those chemicals receiving a "high priority" designation during the prioritization process, and any chemical substances for which EPA has initiated a risk evaluation based on a manufacturer's request.[7]

Specifically, EPA must include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider within the scope of each risk evaluation.[8] Moreover, each risk evaluation must:

> 1) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator; 2) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration; 3) not consider costs or other nonrisk factors; 4) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and 5) describe the weight of the scientific evidence for the identified hazard and exposure.[9]

The Chamber offers these comments as a means to help EPA develop a risk evaluation process that is both transparent and grounded in high-quality scientific standards. The Chamber has two general comments on the proposed rule:

1. EPA should use a more flexible approach in determining the "conditions of use" for a chemical substance; and

[4] 15 U.S.C. at § 2605(b)(4)(A); 82 Fed. Reg. at 7,563.
[5] *See generally supra* note 1.
[6] *Id.*
[7] 82 Fed. Reg. at 7,569.
[8] 15 U.S.C. § 2605(b)(4)(D); 82 Fed. Reg. at 7,563.
[9] 15 U.S.C. § 2605(b)(4)(F); 82 Fed. Reg. at 7,563.

2. EPA should explain how it will apply the "best available science" and "weight of evidence" standards, found in section 26 of TSCA, to both scientific substance and process.

The following comments expand upon these issues and offer additional suggestions for developing a simple, sound, and well-tailored risk evaluation process.

II. EPA Should Adopt a More Flexible Approach to Conditions of Use for the Risk Evaluation Process

TSCA requires that EPA begin the risk evaluations for 10 chemical substances drawn from the 2014 update to the TSCA Work Plan for Chemical Assessments no later than 180 days after LCSA was signed into law.[10] Moreover, EPA is required to have 20 risk evaluations for high priority substances underway, subject to the limitation "that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments," as well as 20 low-priority designations, no later than three and one half years after the law was signed.[11]

EPA must complete a risk evaluation for a chemical substance within three years of initiation, although that may be extended six months.[12] In order to meet these deadlines while ensuring that all risk evaluations are thorough and complete, it is imperative that EPA develop a flexible standard for scoping risk evaluations under TSCA.

EPA proposed that it identify and consider *all* conditions of use for all risk evaluations that it conducts. Conditions of use are defined by TSCA as "the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[13] To that extent, the proposed rule provides that a risk evaluation "must encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance."[14]

The statute, however, does not require that EPA consider *all* conditions of use. A plain reading of the statute confirms this assertion, and at no point does it modify "conditions of use" with the term "all." Moreover, the statute provides that EPA should only contemplate those conditions of use that the [EPA] Administrator *expects to consider*.[15] The term "expects to consider" should be interpreted narrowly, in that EPA should not consider every condition of use, but rather only those that are reasonable under the circumstances.

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[10] 15 U.S.C. § 2605(b)(2)(A).
[11] 15 U.S.C. § 2605(b)(2)(B).
[12] 15 U.S.C. § 2605(b)(4)(G); 82 Fed. Reg. at 7,564.
[13] 15 U.S.C. § 2602(4).
[14] 82 Fed. Reg. at 7,565.
[15] *See supra* note 8.

EPA is merely using its discretion in the matter to make an unreasonable interpretation of the statute, and, in doing so, hindering its ability to meet the statute's goals and provide well-tailored risk evaluations. It should instead take a tiered approach to the terms "conditions of use." This would require EPA to only conduct risk evaluations for certain uses of chemicals, and disregard those that do not pose an unreasonable risk to a potentially exposed or susceptible subpopulation. EPA would be more likely to meet its deadlines and conserve and focus its resources on certain uses of chemical substances that truly pose a risk.

III. EPA Should Exclude Certain Chemicals and Conditions of Use from the Risk Evaluation Process

EPA does not need to include certain chemical substances in its risk evaluation process. Excluding these chemicals would allow EPA to meet its statutorily mandated deadlines and ensure that those chemicals that do undergo risk evaluations receive the proper treatment. TSCA provides that certain categories of chemicals should be excluded from what are considered "chemical substances" for the purposes of the statute.[16] EPA should clarify that these categories will remain outside the scope of EPA's risk evaluation process.

EPA should also exclude any conditions of use that are already regulated under another statute. TSCA previously excluded any conditions of use that were regulated by another statute from the scope of its risk evaluation process. These statutes include the Federal Insecticide, Fungicide, and Rodenticide Act[17] and the Federal Food, Drug, and Cosmetic Act,[18] among others. It is not necessary that EPA include these "non-TSCA" uses when a chemical enters the risk evaluation process, but in the event that it does, EPA should prepare a thorough justification for doing so.

Finally, EPA should not consider any low exposure conditions of use when considering chemical substances for risk evaluation. There are times when chemical substances are deemed to have a very low, if any, exposure level. These scenarios, such as closed system use, should be excluded from the scope of EPA's risk evaluation process.

[16] 15 U.S.C. § 2602(2)(B) (These categories are: 1) any mixture, 2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide, 3) tobacco or any tobacco product, 4) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.] and regulations issued under such Act), 5) any article the sale of which is subject to the tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. 4181] (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code) and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and 6) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 321]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.).

[17] 7 U.S.C. § 136 et seq. (1910).

[18] 21 U.S.C. § 301 et seq. (1938).

IV. EPA Should Explain How and When It Will Apply the Section 26 Scientific Standards to the Proposed Rule

Section 26 of TSCA sets forth certain scientific standards that EPA must apply when making scientific decisions regarding certain provisions of the statute, including section 6 risk evaluations.[19] EPA must also make any decision under those sections based on the "weight of the scientific evidence,"[20] and a risk evaluation must "describe the weight of the scientific evidence for the identified hazard and exposure."[21]

These requirements put the public on notice about the quality of information used by EPA, and EPA must provide an explanation as to how it plans to comply with them when making decisions regarding risk evaluations. It is imperative that EPA adhere to Congressional intent when conducting risk evaluations, and applying these safeguards is a necessary step in that direction.

V. Conclusion

The Chamber appreciates the opportunity to comment on this important matter. It is imperative that EPA develop an efficient, high-quality, and science-based chemical management and review program in accordance with the new TSCA, and ensure that the proposed rule is developed correctly and is a step in the right direction.

If you have questions regarding these comments, please contact me at wkovacs@uschamber.com or at (202) 463-5457.

Sincerely,

William L. Kovacs

[19] 15 U.S.C. § 2625(h) (Those standards are: 1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; 2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; 3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; 4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and 5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.).

[20] 15 U.S.C. § 2605(b)(4)(A).

[21] 15 U.S.C. § 2605(b)(4)(F)(v).