



EPA's Problem Formulation Documents Illustrate Agency's Views on Risk Assessment Under TSCA

US EPA, TSCA, RISK ASSESSMENT

By ROGER PEARSON, June 13, 2018

U.S EPA has announced ten "problem formulation documents," which lay out how the agency plans on doing risk assessments on the initial ten chemicals it has chosen for **review under the 2016 TSCA amendments**¹⁾. The new set of documents reiterate the agency's position that risk assessments on these 10 chemicals and future assessments will look only at those "conditions of use" for a specific chemical that present the highest likelihood of causing future adverse impacts.

The 2016 TSCA amendments (known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act) require EPA to review chemicals currently in use in the United States to determine whether their continued use poses an "unreasonable risk" of injury to public health and the environment. If the answer is yes the agency must adopt a regulatory response that eliminates that unreasonable risk. In August of 2017 the agency published two "framework" rules—the Prioritization Rule and the Risk Evaluation Rule—that lay out the process the agency will use in determining which of the chemicals in its database will be subjected to a risk assessment and how that risk assessment will proceed.

The new Act also required EPA to select the first 10 chemicals that will go through the risk assessment process thereby skipping the Prioritization Rule. It published the list of those ten chemicals, as required, in December 2016. In June 2017, again as required, it published the initial "scope" of the risk assessments for each of the 10 chemicals laying out the uses for the chemical that EPA would evaluate in performing the assessment, as well as the procedures it will use in the evaluation [**EPA Releases Risk Evaluation Scope Documents for First Ten Chemicals under New TSCA Law**²⁾, July 12, 2017].

At the time EPA announced that these initial scoping documents were produced under a short deadline and that the agency would publish more detailed "problem formulation documents" based in part on comments received on the initial documents. It is these documents that the agency has just released.

Along with the formulation documents for each of the ten chemicals, **EPA has also issued a 15 page "preliminary" response**³⁾ addressing "cross cutting public comments" applicable to issues impacting all ten chemicals. Among the subjects discussed are comments regarding the "conditions of use" under which the chemicals will be evaluated. In its response EPA notes that it will not necessarily evaluate all of the activities involving the presence of the chemical. Instead, notes the agency, it will "focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to

be occurring, or reasonably foreseen to occur (i.e., is prospective or ongoing), and consequently does not generally intend to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal."

EPA's position on this issue is not new. The agency applied this same limitation in adopting its **Prioritization and Risk Evaluation Rules**⁴⁾ last August. Those two rules are currently the subject of a Ninth Circuit appeal brought by a coalition of environmental groups, who argue that 2016 Act requires EPA to undertake a "holistic" assessment of each chemical that includes such areas as the continuing impact of legacy uses.

What is new is that the dispute over what is required in a risk assessment has caught the attention of the New York Times. In a front page story on **June 8 the Times discussed**⁵⁾ the release of the "1500 pages of documents" that presumably refers to the EPA's problem formulation documents. The Times article quotes environmental groups and Senators who worked on the 2016 legislation as complaining that EPA is ignoring the law's intent to require the agency to do a "comprehensive" analysis of risk.

The Product Formulation Document for each of the ten chemicals can be found at the following links:

- **Asbestos**⁶⁾
- **1-Bromopropane**⁷⁾
- **Carbon Tetrachloride**⁸⁾
- **1, 4 Dioxane**⁹⁾
- **Cyclic Aliphatic Bromide Cluster (HBCD)**¹⁰⁾
- **Methylene Chloride**¹¹⁾
- **N-Methylpyrrolidone**¹²⁾
- **Perchloroethylene**¹³⁾
- **Pigment Violet 29**¹⁴⁾
- **Trichloroethylene**¹⁵⁾

Interested parties will have an opportunity to provide comments on each of the documents within 45 days after their publication in the Federal Register.

Asbestos¹⁶⁾ SNUR

In addition to the product formulation documents themselves EPA is proposing a significant new use rule (SNUR) that will **prevent new uses of asbestos**¹⁷⁾. The agency notes that this is the first such action on asbestos ever proposed. The inability of EPA under the previous version of TSCA to act against asbestos, despite its known risk, was one of the reasons cited for the 2016 amendments.

Resources for this article

1. review under the 2016 TSCA amendments

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten>

2. EPA Releases Risk Evaluation Scope Documents for First Ten Chemicals under New TSCA Law

<https://prop65clearinghouse.com/articles/13121>

3. EPA has also issued a 15 page "preliminary" response

<https://prop65clearinghouse.com/documents/26788>

4. Prioritization and Risk Evaluation Rules

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/prioritizing-existing-chemicals-risk-evaluation>

5. June 8 the Times discussed

<https://www.nytimes.com/2018/06/07/us/politics/epa-toxic-chemicals.html?rref=collection%2Fissuecollection%2Ftoday-s-new-york-times&action=click&contentCollection=todayspaper®ion=rank&module=package&version=highlights&contentPlacement=1&pgtype=collection>

6. Asbestos

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-asbestos-0>

7. 1-Bromopropane

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-1-bromopropane-1-bp>

8. Carbon Tetrachloride

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-carbon-tetrachloride>

9. 1, 4 Dioxane

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-14-dioxane>

10. Cyclic Aliphatic Bromide Cluster (HBCD)

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-cyclic-aliphatic-bromide-cluster-hbcd>

11. Methylene Chloride

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-methylene-chloride-0>

12. N-Methylpyrrolidone

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-n-methylpyrrolidone-nmp-0>

13. Perchloroethylene

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-perchloroethylene>

14. Pigment Violet 29

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-pigment-violet-29-anthra219-def6510>

15. Trichloroethylene

<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluation-trichloroethylene-tce-0>

16. prevent new uses of asbestos

<https://www.epa.gov/newsreleases/epa-takes-three-important-steps-ensure-chemical-safety-under-lautenberg-act-proposes>