



Environmental Groups File Opening Brief in Ninth Circuit Challenging TSCA Framework Rules

TSCA, LITIGATION, US EPA

By ROGER PEARSON, May 14, 2018

Fifteen organizations—including environmental groups, unions, public health groups, and local advocates—have joined together to file an opening brief with the Ninth Circuit challenging U.S. EPA's major "framework rules" implementing the 2016 amendments to the Toxic Substances Control Act (TSCA). The groups include the Environmental Defense Fund, the Natural Resources Defense Council, and the Sierra Club.

The 2016 TSCA amendments (known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act) require EPA to promulgate two "Framework" rules.

The first of these sets forth the procedures the agency applies to "prioritize" the selection of chemicals for risk assessment under the Act [the Prioritization Rule] [see **EPA Releases Ideas for Identifying Candidates for TSCA Prioritization**¹⁾, November 21, 2017].

The second, **the Risk Evaluation Rule**²⁾ establishes the procedures the agency must follow in undertaking risk assessments of chemicals designated for review under the Prioritization Rule.

The final version of both of these rules were published on July 20, 2017 and issued for purposes of judicial review on August 3, 2017. Six petitions were filed by various groups challenging both rules in three federal Circuit courts, and consolidated for review in the Ninth Circuit. **Safer Chemicals, Healthy Families et al v. US EPA, Opening brief, 17-17-72260**³⁾ (9th Circuit of Appeal, April 16, 2018).

The various petitioners have coalesced together **to file a single brief**⁴⁾ setting forth their arguments. The gist of their challenge is that EPA's final Framework Rules impermissibly narrow the "conditions of use" that the agency looks at in applying the two rules to a specific chemical.

According to the Petitioners' brief the Act 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." The Petitioners argue that this definition encompasses the chemical's entire lifecycle from manufacturing and processing to use and disposal. The agency is then required to make a "holistic determination" of whether the chemical presents an unreasonable risk of injury to human health or the environment, including to potentially exposed susceptible subpopulations.

EPA published its proposed Framework Rules in January of 2017 as one of its last actions under the Obama Administration. The Petitioners, in laying out the history of the two rules, note that the proposed rules "complied with TSCA's mandate to take a comprehensive approach to chemical risk evaluation." The proposed Prioritization Rule committed EPA to "designate the priority of a 'chemical substance' as a whole," rather than looking only at specific use or subsets of uses. In the proposed Risk Evaluation Rule EPA construed TSCA to require it to conduct risk assessments on "the chemical substance" not on individual "conditions of use."

The Petitioners note that at least until April 12, 2017 there was no indication that the final rules would deviate from this holistic approach. However, in April 2017, the Trump Administration appointed Dr. Nancy Beck as Deputy Assistant Administrator for EPA's Office of Chemical Safety and Pollution Prevention, which oversees the TSCA program. Before her appointment Dr. Beck was the director for regulatory science policy at the American Chemistry Council (ACC), which has intervened in this appeal on EPA's side. In that position Dr. Beck presented ACC's recommendations for the Framework Rules at an EPA public meeting in August of 2016 and signed ACC's comments outlining its desired approach for the rules. Those comments and subsequent proposals suggested that instead of looking at all possible "conditions of use" for a chemical under the two rules, the agency should instead focus on those uses that presented the highest likelihood of potential concern.

After her arrival at EPA Dr. Beck was advised that she could not participate in any meetings or decisions that relate to any individual ACC comment. Nevertheless, note the Petitioners, when the final Framework Rules were published the agency had abruptly reversed course and generally followed ACC's suggested approach by allowing the Administrator the discretion to ignore some potential conditions of use.

The Petitioners brief outlines the following questions that it wants the Ninth Circuit to answer in resolving this appeal:

- Does TSCA grant EPA authority to pick and choose which conditions of use it will consider in prioritizing chemicals and conducting risk evaluations?
- Does TSCA permit EPA to conclude a risk evaluation without determining whether the chemical substance "as a whole" presents an "unreasonable risk?"
- Has EPA unlawfully rewritten the definition of "conditions of use" by excluding a chemical's ongoing and future use and disposal, if the chemical's manufacture, processing, and distribution for that specific use have been discontinued?
- Does EPA violate TSCA's directive that it consider all "reasonably available information" when making priority designations and conducting risk assessments in the following provisions of the Framework Rules:
 - Penalizing incomplete submissions by public commenters;
 - Creating thresholds for considering scientific information;
 - Allowing manufacturers to withhold relevant information about a chemical when requesting risk evaluations; and
 - Failing to require EPA to consider during prioritization whether it has adequate information to

conduct a risk evaluation?

EPA's response brief is due to the Court on July 5.

Resources for this article

1. EPA Releases Ideas for Identifying Candidates for TSCA Prioritization

<https://prop65clearinghouse.com/articles/13249>

2. the Risk Evaluation Rule

<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0327-0001>

3. Safer Chemicals, Healthy Families et al v. US EPA, Opening brief, 17-17-72260

<https://prop65clearinghouse.com/documents/26727>

4. to file a single brief

<http://blogs.edf.org/health/2018/04/17/edf-joins-opening-brief-in-legal-challenge-to-epas-prioritization-and-risk-evaluation-rules/>