wiley

NEWSLETTER

Public Comment Deadlines Near for EPA TSCA Framework Proposed Rules

March 2017

Product Stewardship and Sustainability Report

Last year, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg), which made substantial changes to the Toxic Substances Control Act (TSCA). These changes require the U.S. Environmental Protection Agency (EPA) to make substantive changes in the way that it regulates chemical substances in commerce. One major impact of Lautenberg is that it will substantially expand the agency's review of existing chemicals and bring more attention to their uses in consumer products.

Among the first actions required by the updated law by this June, EPA must promulgate a number of implementation rules that will establish new processes for the regulated community going forward. EPA recently proposed the three core "Framework" rules, which are now open for public comment:

- The first proposed rule is the "TSCA Inventory Notification (Active-Inactive) Requirements" rule, published on January 13, 2017. The public comment deadline is March 14, 2017. This rule would establish procedures to reset the TSCA Inventory of chemical substances used in commerce to identify those that are actually in use today (termed "active") to lay a foundation for EPA to identify chemicals for a more in-depth review for prioritization and risk evaluation. The technical aspects of this rule are discussed on page six of this Newsletter, but in summary: EPA proposes to require manufacturers and importers to notify EPA of any chemical substance manufactured or imported by that manufacturer or importer in the ten years prior to June 21, 2016. EPA would provide

Authors

Tracy Heinzman
Partner
202.719.7106
theinzman@wiley.law

Martha E. Marrapese
Partner
202.719.7156
mmarrapese@wiley.law

Practice Areas

Environment & Product Regulation

processors with a subsequent opportunity to voluntarily report active substances in U.S. commerce. EPA's proposal also includes instructions on re-activating an inactive TSCA Inventory chemical. Companies who need to report will need to be mindful of reporting the proper name for the chemical, documenting that the reported name is in fact on the Inventory, and providing up-front substantiation if they claim the substance name as confidential. Areas in which we recommend submitting comments by the 14th include:

- Requesting guidance on reporting considerations unique to importers of mixtures. These companies will need to work out the mechanics of reporting compliant ingredients whose identities are claimed as confidential by their upstream suppliers.
- Asking for guidance on when companies need to report byproducts as active substances.
- Supporting EPA's proposed exemptions for chemicals imported as part of an article, naturally occurring chemicals, impurities, and noncommercial byproducts.
- Confidential business information protection is complex in connection with health and safety information. It would be useful to have more guidance when making these submissions.

- The second proposed rule sets forth procedures and criteria that EPA proposes to use in prioritizing chemicals as high or low priority for subsequent risk evaluation. The public comment deadline is March 20, 2017. EPA designation of a chemical as high or low priority for risk evaluation will be extremely important. Chemicals designated as high priority will essentially be "shortlisted" for risk evaluation, whereas designation as low priority essentially constitutes a finding that risk evaluation is not necessary. We think the following considerations are important to consider and comment on:
    - Will EPA prioritize uses, or determine that a chemical meets the safety standard for a given use(s) during the prioritization stage?
    - In ultimately selecting a chemical substance on which to initiate prioritization, should EPA use criteria beyond those provided by Congress?
    - Should similar uses or similar chemistry be used to prioritize categories of chemical substances?
    - Should EPA place a lower priority on substances that have undergone new chemical reviews compared to chemicals grandfathered onto the Inventory that have never been reviewed?

Areas in which the Agency is seeking comments include:

- Should EPA define best available science, weight-of-the-evidence and sufficiency of information? Is it problematic not to define these terms?
- How should EPA structure and seek public input during pre-prioritization?
- Can and should EPA consider substitutes in the prioritization process?

- The third proposed rule is the "Procedures for Chemical Risk Evaluation Under the Amended TSCA." The public comment deadline also is March 20, 2017. The risk evaluation rule will establish the procedures that EPA will use for establishing the scope of a risk evaluation, conducting hazard and exposure assessments, and characterizing risks. EPA, for example, is proposing that any issues and concerns not

raised during a public comment period cannot be raised later. What happens if information is newly discovered or becomes available later during the three and half year period these risk evaluations are underway?

Some of the areas in which EPA is asking for comments include:

- The need for regulatory text requiring the use of specific elements of a systematic review approach for hazard identification.
- How can the proposed rule provide additional transparency, public accountability and opportunities for public participation?
- Should the agency define or provide guidance on the circumstances that give rise to a finding of unreasonable risk to improve certainty and predictability in the process?
- To what extent should existing EPA risk assessment guidance be updated or codified?
- How should EPA gather information to support manufacturer requests?
- Do all risk evaluations warrant peer review?
- How should interagency cooperation be managed?

Once promulgated, these rules will govern how the regulated community must interact with EPA in the context of chemical reviews for many years to come. The opportunity for public comment is a critical time to foster inquiry and engagement, in order to establish a reasonable and common understanding of what to expect, what is expected from industry, and establish government accountability. These rules will benefit by being informed by the realities and needs facing manufacturers, importers, processors and end users of TSCA-regulated substances. The way that EPA conducts these procedures will be extremely important to the ultimate determination and communication of the risks associated with a particular chemical.