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Energy/Environmental

How has TSCA reform legislation changed the approach to evaluating new chemicals?

As you may know, after years of efforts aimed at updating the Toxic Substances Control Act, the Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed into law on June 22, 2016. One of the many changes under the Act is that it strengthens the general approach to the evaluation of new chemicals and uses. The evaluation process still begins with manufacturers and processors submitting pre-manufacture notices to the U.S. Environmental Protection Agency 90 days before beginning to manufacture or process the chemical substance. EPA must then review all new chemicals and significant new uses, make a determination and take required action during that 90 day window.

During the review process, EPA is now required to consider “potentially exposed or susceptible populations” and “conditions of use.” These are new terms that have been added to TSCA through the Act:

- “Conditions of use” are “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.”
- A “potentially exposed or susceptible subpopulation” is a “group of individuals

within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers or the elderly.”

While EPA *must* consider “potentially exposed or susceptible populations” and “conditions of use,” the Act states that EPA *may not* consider cost or other non-risk factors.

There are three alternative determinations EPA may make under the Act:

1. **Unreasonable risk of injury to health or the environment:** If this is the case, EPA is required to take action pursuant to TSCA § (5)(f) and must also promulgate a Significant New Use Rule.
2. **Absence of sufficient information or production in substantial quantities resulting in substantial exposure to humans or the environment:** EPA is required to issue an order under § 5(e) and promulgate a SNUR if: (1) EPA has insufficient information to permit a reasoned evaluation of the chemical; (2) in the absence of sufficient information, the substance may present an unreasonable risk; or (3) the substance is or will be produced in substantial quantities, and it enters or is anticipated to enter the



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environment in substantial quantities, or there is or may be significant human exposure.

3. **Not likely to present an unreasonable risk:** If this is the case, manufacture or processing of the chemical may commence. Also, EPA is required to publish a statement regarding its finding in the Federal Register.

If EPA fails to make a determination by the end of the applicable review period, it must refund all fees to the submitter. Notably, the Act resets the 90 day review period for pre-manufacture notices submitted before the Act was signed into law. ■

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