

EPA “Whole Chemical” Approach to TSCA Risk Evaluations

Background

The 2016 amendments to the Toxic Substances Control Act (TSCA) were designed for EPA to identify and make “risk determinations” for conditions of use of a chemical that present “unreasonable risk” *as well as* those that “do not present unreasonable risk.” Both the inherent toxicity of a chemical *and* the likely exposures under its conditions of use must be evaluated to determine whether a chemical poses unreasonable risks to humans or the environment. Under TSCA, EPA is *required* to take risk management action on *specific* activities (i.e., uses) that may present an unreasonable risk of injury to health or the environment.

TSCA chemicals are important building block chemicals for industrial, commercial, and consumer uses. Therefore, EPA’s consideration of the specific conditions of use of these chemicals is important.

Until recently, EPA made multiple risk determinations of a single TSCA chemical substance under its multiple conditions of use. The risk determinations were clear because each was specific to a chemical substance’s condition of use.

EPA has now made a policy change to what it is calling a “whole chemical” approach. Under this approach, if a “majority” of the conditions of use the Agency includes in its risk evaluation are found to present an unreasonable risk, the Agency could, without stated criteria, make only one risk determination: determining that the whole chemical presents unreasonable risk—even when there are other conditions of use for that chemical that the Agency has found do not present unreasonable risk.

Problem

- A single “unreasonable risk” determination for a chemical will likely be interpreted by the public and the marketplace that the substance is unsafe in all circumstances, causing unnecessary public fear, confusion, market deselection, and could have profound impacts on the supply chain, even when EPA agrees that there are safe uses.
- EPA has not clearly explained why it is implementing a whole chemical approach or why it has not provided principles or criteria by which it will determine when to take a whole chemical approach in TSCA risk determinations.
- A single whole chemical unreasonable risk determination, when there are conditions of use that EPA has determined do not present an unreasonable risk, ignores the possibility of “no unreasonable risk” determinations for a chemical substance under its conditions of use.
- The whole chemical approach is not science- or risk-based. EPA appears to be only evaluating hazard, ignoring TSCA’s requirements to 1) consider, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use and 2) describe the weight of scientific evidence supporting the exposure description for the conditions of use.
- TSCA Section 26 requires that risk determinations be consistent with best available science and based on the weight of the scientific evidence. EPA has not satisfied these requirements in its whole chemical risk determination approach and has failed to engage the public or seek comment from stakeholders before it applied this approach.

Solution

EPA should discontinue the whole chemical approach and make safety determinations based on each individual uses at the end of the risk evaluation. For uses that receive a safety determination (i.e., “does not present unreasonable risk”) the process is then completed, and no further risk management measures are needed. Uses that are determined to “present unreasonable risk” should proceed to risk management.