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EPA Issues New Draft Risk Evaluation Documents Under TSCA that Impact PET Manufacturing

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The Environmental Protection Agency (EPA) has issued a revised unreasonable risk determination that preliminarily concluded that polyethylene terephthalate (PET) manufacturing contributes to an overall unreasonable risk from 1,4-dioxane, with respect to occupational and drinking water exposures. Under Section 6 of the Toxic Substances Control Act (TSCA), EPA evaluates the risk of chemicals to determine whether uses present "unreasonable risk." A determination of unreasonable risk triggers mandatory risk management regulations to ensure that the chemical no longer presents unreasonable risk. These regulations can include outright bans or prohibitions, among other risk management actions.

On July 10, 2023, EPA announced the availability for public comment on a 2023 draft supplement to the 1,4-dioxane risk evaluation, which would greatly expand the scope of a December 2020 "Final Risk Evaluation for 1,4-Dioxane" (2020 RE). The Draft Supplement:

1. Adds and evaluates ten conditions of use (COUs) for which EPA believes there are exposures to 1,4-dioxane produced as a "byproduct;"
2. Assesses the environmental releases and concentrations of 1,4-dioxane in surface water, ground water, and air for all the COUs; and
3. Presents estimated human exposure and risk characterizations for occupational exposures to the ten additional COUs and estimated human exposure and risk characterizations for general population exposures to environmental (air and water) releases from all COUs.

With respect to PET manufacturing, EPA assessed 1,4-dioxane occupational, air, and water exposures from PET manufacturing, in which 1,4-dioxane is produced as a byproduct.

Then on July 26, 2023, EPA issued a draft revision of the risk determination for 1,4-dioxane, which was a revision of the 2020 RE (that was issued under the previous administration). Under the prior administration, unreasonable risk determinations were made on a condition of use basis, while the revised risk determination uses a "whole chemical" basis. Significantly, under the "whole chemical" approach, EPA no longer assumes that environmental exposures are adequately controlled under other EPA programs. This change resulted in EPA's preliminarily conclusion that PET manufacturing contributes to the overall unreasonable risk from 1,4-dioxane, with respect to drinking water exposures.

More recently, on August 8, 2023, EPA announced that it calculated an existing chemical exposure limit (ECEL) for 1,4-dioxane to be 0.055 ppm for inhalation exposures as an 8-hour time-weighted average (TWA) for use in workplace settings under TSCA. The ECEL is based on the inhalation unit risk for lifetime cancer risks. The announcement identifies sampling analytical methods as EPA will not propose an ECEL that is not analytically measurable. Of note, the Occupational Safety and Health Administration (OSHA) set a permissible exposure limit (PEL) for an 8-hour TWA for 1,4-dioxane of 100 ppm, 2000 times higher than the proposed ECEL.

The ECEL value is expected to be included in EPA's forthcoming proposed risk management rule for 1,4-dioxane. Importantly, manufacturers, processors, and users of 1,4-dioxane impacted by EPA's draft supplement, draft revised unreasonable risk determination, and ECEL should consider commenting on these drafts and should assess their ability to meet the ECEL.

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