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US EPA Releases Problem Formulation Documents for "First Ten" TSCA Risk Evaluations

Written by Steve Owens 6/19/18

The United States Environmental Protection Agency (US EPA) has formally released "problem formulation" documents for the risk evaluations it is conducting on the "first ten" chemical substances under the amended Toxic Substances Control Act (TSCA). Formal notice of the problem formulation documents was published in the Federal Register on June 11, 2018. Comments on the problem formulations must be submitted to US EPA by July 26, 2018.

US EPA has stated that goal of the problem formulation effort is to produce a "conceptual model and an analysis plan" for each risk evaluation. The conceptual model "describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation." The analysis plan "is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs."

The problem formulation documents are intended to "refine" the scoping documents that US EPA issued in June 2017 for the risk evaluations. The "refinements" apply to the conditions of use, hazards, exposures and the potentially exposed and susceptible

subpopulations that will be considered in the risk evaluations. Moreover, while each problem formulation is tailored to issues relating to the specific chemical substance covered by the relevant risk evaluation, the problem formulations generally narrow the "conditions of use" that will be covered by the risk evaluations.

In particular, US EPA is removing from the risk evaluations "any activities and exposure pathways that EPA has concluded do not warrant inclusion in the risk evaluation," such as activities for which the agency has insufficient information to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Additionally, US EPA is generally excluding from the risk evaluations exposure pathways addressed under other US EPA-administered environmental statutes, including specifically the Clean Air Act, the Safe Drinking Water Act, the Clean Water Act, and the Resource Conservation and Recovery Act. The problem formulation documents explain that US EPA is exercising its discretion under TSCA "to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA."

The problem formulations also identify any conditions of use, hazards, or exposure pathways identified in the scope documents that will be included in the risk evaluations but which US EPA "does not expect to further analyze in the risk evaluation." The problem formulations state that US EPA "expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis" and that "[e]ach risk evaluation will be 'fit-for-purpose,' meaning not all conditions of use will warrant the same level of

evaluation," including reaching some conclusions "without comprehensive or quantitative risk evaluations."

US EPA has stated that the problem formulation documents are an "interim step" to refine the scope documents prior to publication of the draft risk evaluations. Although US EPA is taking comments on the problem formulation documents, the Agency does not intend to revise them. Instead, US EPA will consider any comments submitted on the documents when developing the draft risk evaluations.

The problem formulation documents can be found on the US EPA website here and in the dockets for the first ten risk evaluations on the www.regulations.gov website as follows:

1,4-Dioxane – EPA-HQ-OPPT-2016-0723

1-Bromopropane – EPA-HQ-OPPT-2016-0741

Asbestos – EPA-HQ-OPPT-2016-0736

Carbon Tetrachloride – EPA-HQ-OPPT-2016-0733

Cyclic Aliphatic Bromide Cluster (HBCD) – EPA-HQ-OPPT-2016-0735

Methylene Chloride – EPA-HQ-OPPT-2016-0742

N-Methylpyrrolidone (NMP) – EPA-HQ-OPPT-2016-0743

Pigment Violet 29 – EPA-HQ-OPPT-2016-0725

Trichloroethylene (TCE) – EPA-HQ-OPPT-2016-0737

Tetrachloroethylene (aka perchloroethylene) – EPA-HQ-OPPT-2016-0732