US EPA Releases Draft TSCA Chemical Risk Assessments: What Can We Infer?

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The United States Environmental Protection Agency (US EPA) released its first draft risk assessments developed under the Toxic Substances Control Act (TSCA) "Work Plan Program" on January 4, 2013.

The draft risk assessments cover particular uses of five chemicals found in household products: methylene chloride or dichloromethane (DCM) and N-methylpyrrolidone (NMP) in paint stripper products; trichloroethylene (TCE) as a degreaser and a spray-on protective coating; antimony trioxide (ATO) as a synergist in halogenated flame retardants; and 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta-[γ]-2-benzopyran (HHCB) as a fragrance ingredient in commercial and consumer products.

While the chemicals covered in these first draft assessments may or may not be of interest to *Environmental Quality Management* readers, the draft assessments can give us a sense of how the Agency is approaching this very important process.

Background on TSCA "Work Plan Program" Approach to Risk Assessment

US EPA's Office of Pollution Prevention and Toxics (OPPT) has struggled for years to identify priority chemicals, assess their potential risk, and propose risk management measures under TSCA. The process has not been easy. The Chemical Assessment and Management Program (ChAMP), which was rolled out in 2009, was essentially soon replaced with "Chemical Action Plans (CAP)." The CAP approach met with significant pushback from industry stakeholders, and in March 2012, US EPA announced its "Work Plan Program" as part of its comprehensive approach to enhance the existing chemicals management program.

Under the Work Plan Program, US EPA identified a Work Plan schedule of 83 chemicals that it believes require further review under TSCA. The Agency then identified seven chemicals for risk assessment in 2012. It also announced plans to complete some of these assessments in the near term and to initiate additional assessments from the Work Plan in the coming years.

The first seven chemicals slated for assessment were: antimony and antimony compounds; HHCB (1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta[g]-2-benzopyran); long-chain chlorinated paraffins; medium-chain chlorinated paraffins; methylene chloride; N-methylpyrrolidone; and trichloroethylene.

To conduct the risk assessments, US EPA announced that would use information available through the data sources cited in its *TSCA Work Plan Chemicals Methods Document* and other sources. Further, the Agency stated that it "would welcome the submission of additional relevant information on these chemicals, such as unpublished studies not already available through the existing literature."

In mid-2012, OPPT announced that it had identified an additional 18 chemicals[1] for assessment during 2013 and 2014. US EPA stated that it selected these chemicals for reasons similar to those it used to identify the original seven Work Plan Program chemicals.

The 18 additional chemicals span the range of the Work Plan screening criteria and include chemicals associated with specific hazards, such as potential carcinogenicity or reproductive or developmental toxicity; chemicals presenting persistent, bioaccumulative, and toxic (PBT) potential; and chemicals found in biomonitoring or reported in consumer products. The Agency noted that some of these chemicals, such as the five chlorinated hydrocarbons, the three flame retardants, and the four fragrance chemicals, may present an effective opportunity to assess groups of related chemicals together.

Ranking System is added to Process

US EPA has also made adjustments to the second stage of its Work Plan process and developed a hazard, exposure, and persistence/bioaccumulation ranking system to score and screen the chemicals into four priority bins: high, moderate, low, or chemicals that could not be scored, but may be candidates for information gathering. When EPA rolled out its approach for identifying priority chemicals in September 2011, it envisioned a two-step process. The first stage focused on identifying chemicals meeting one or more stated criteria. The second stage consisted of applying a ranking system to score and screen chemicals into four priority bins. The adjustments EPA made to this second stage fine-tuned the methodology to refine the screening process.

Using this process, US EPA identified the full set of 83 chemicals as candidates for risk assessment over the next several years. Each of the 83 chemicals scored high under this screening process based on their combined hazard, exposure, and persistence and bioaccumulation characteristics.

In regard to identifying a smaller set of chemicals for work in any given year, US EPA states that it considers a number of factors, including:

- Whether the chemical was identified as a "High" ranking chemical;
- Whether the chemical reflects more than one of the factors identified in the first phase (for example, chemicals that were identified as a potential concern for children's health and also were PBT) and whether each of the factors was covered by the set of chemicals;
- Whether certain chemicals, or groups of chemicals, would benefit from some preliminary work to assure that the risk assessments are targeted and scoped appropriately, and therefore, would best be addressed in at a later year;
- Whether certain chemicals or groups of chemicals have been assessed previously and addressed by US EPA, so that risk assessments need not be conducted in the first few years of the Work Plan and can wait until later; and
- US EPA's own workload considerations, including the scope and timing of work needed on specific chemicals and existing commitments for assessment.

US EPA Releases Draft Risk Assessments

Given the critical importance of the Work Plan Program in identifying and assessing the risk posed by candidate chemicals under TSCA, many stakeholders understandably have questioned how exactly US EPA would conduct the assessment. Thus, US EPA's recent release of the first risk assessments was a much-anticipated event.

US EPA states generally that the draft assessments focus either on human health or on ecological hazards for specific uses that are subject to TSCA regulation. Three of the draft risk assessments— Methylene Chloride or Dichloromethane (DCM), N-Methylpyrrolidone (NMP), and Trichloroethylene (TCE)—indicate potential concern for human health under specific exposure scenarios for particular uses. The draft assessments for Antimony Trioxide (ATO) and 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8,-

hexamethylcyclopenta[g]-2-benzopyran (HHCB) indicate low concern for ecological risks.

If US EPA concludes in the final risk assessments that there is a potential for concern, it states that it will take appropriate action to address possible risks.

The *Federal Register* notice includes the following information on the draft risk assessments:

HHCB

HHCB is a synthetic polycyclic musk used as an ingredient in a wide range of consumer products, including perfumes, cosmetics, shampoos, lotions, detergents, fabric softeners, and cleaning agents. The draft assessment focuses on environmental risk due to release of HHCB to the aquatic and terrestrial environment from all combined uses. Human health risks have been evaluated previously and are summarized in the draft assessment.

For HHCB, US EPA is asking for nominations of peer reviewers who are experts in the following areas: aquatic ecotoxicology, terrestrial ecotoxicology, fate and biodegradation, fate and bioaccumulation, environmental risk assessment (aquatic and terrestrial), and analytical chemistry of organic wastewater contaminants.

TCE

The draft assessment focuses on uses of TCE as a degreaser and in consumer products used by individuals in the arts/crafts field. Given the range of endpoints (cancer; non-cancer, including potential effects on the developing fetus), the susceptible populations addressed are children and adults of all ages (including pregnant women). Thus, the draft assessment focuses on all human life stages.

For TCE, US EPA is asking for nominations of peer reviewers who are experts in the following areas: toxicology of TCE (developmental cardiotoxicity, immunotoxicology, reproductive toxicology, and cancer biology), expertise in physiologically based pharmaco-kinetics (PBPK) modeling for TCE, exposure of volatile organics, experts on use of volatiles as solvent degreasers and in the arts/crafts field, chemical/environmental

risk assessment experts, and experts familiar with environmental release data and associated modeling/interpretation.

ATO

The draft assessment focuses on the ecological hazards that may be associated with ATO use in flame retardants. Human health risks for the flame retardant use have been evaluated previously and are summarized in this draft assessment. Because ATO use in plastics was previously evaluated for human health and the environment, that use scenario is not evaluated.

For ATO, US EPA is asking for nominations of peer reviewers who are experts in the following areas: exposure modeling, aquatic ecotoxicology, terrestrial ecotoxicology, inorganic chemistry addressing water and sediment issues, and ground water.

DCM and NMP

The related draft assessments focus on the use of DCM and NMP in paint stripping and will be addressed by the same peer review panel.

The draft assessment for DCM focuses on inhalation exposure to consumers and workers, and addresses human health concerns for both cancer and non-cancer effects. The low concern for environmental effects of DCM is discussed in the draft assessment.

The draft assessment for NMP focuses on acute and chronic inhalation and dermal exposure to consumers and workers in the paint stripping use. The endpoint of concern is developmental toxicity. The low concern for environmental effects of NMP is discussed in the draft assessment.

For DCM and NMP, US EPA is asking for nominations of peer reviewers who are experts in the following areas: inhalation toxicology, toxicokinetics/PBPK modeling, dermal toxicology, neurotoxicology, immunotoxicology, developmental and reproductive toxicology, cancer biology, expertise in U.S. consumer modeling (inhalation and dermal), and expertise in occupational exposure assessment (inhalation and dermal), especially as related to volatile organic chemicals.

Status of Two Remaining Draft Risk Assessments

US EPA states that the draft risk assessments on the two remaining chemicals from the initial group of seven (the long- and medium-chain chlorinated paraffins), which were scheduled to begin assessment in 2012, are on a different schedule for completion than the other five. US EPA intends to make the draft risk assessments for these chemicals available for public comment through another *Federal Register* notice issued on a later date.

Next Steps in the Work Plan Program Process

In the *Federal Register* notice announcing the availability of the draft risk assessments, US EPA also stated that it intends to publish for public comment the list of candidate peer reviewers in a future *Federal Register.* These candidates will include those nominated by the public and those identified by a US EPA contractor. The contractor, informed by public comments, will then select the peer reviewers for the risk assessments.

The detailed Peer Review Plans for the draft assessments are accessible through the US EPA's Peer Review Agenda website at http://cfpub.US EPA.gov/si/si_public_pr_agenda.cfm.

US EPA will consider comments received from the public and the subsequent peer review during its preparation of the final individual chemical risk assessments. In addition, the Agency will provide a written report describing how it addressed public and reviewer comments in the final assessments. US EPA will issue another *Federal Register* notice to announce the availability of the final risk assessments.

Discussion

The first draft risk assessments are clearly and carefully presented. They are also quite conservative in regard to the approaches used and the conclusions they reach, however. This may not bode well for the chemicals that were assessed and could invite greater restrictions, particularly as they apply to consumer uses.

While such conservatism may be appropriate for preliminary or screening-level risk assessments, the assumptions used in these first draft assessments appear to overstate inappropriately the risk conclusions and their significance—especially since the assessments are intended to be followed by "appropriate risk reduction actions" if potential risks are determined to exist.

Another potential issue involves the level of detail provided by the assessments. The detail provides the bases for the US EPA to set forth its health risk conclusions; however, this level of detail may also be seen as providing multiple "hand-holds" for raising issues with—and contesting—the Agency's judgments regarding the construction of the assessment and the conclusions that were reached. Although US EPA has done a good job of identifying and discussing the uncertainties in its assessments, the Agency also appears to have opted consistently for conservative, worst-case assumptions and approaches.

The results of the peer reviews and peer review panels' reactions to US EPA's approach will no doubt provide important insights into the assessments themselves and whether a more refined and realistic approach is suggested for future Work Plan Program risk assessments.

Improvement to the Process?

Taking a step back, these assessments appear to be the next step in the continued "TSCA revitalization" effort of the current Office of Chemical Safety and Pollution Prevention leadership, especially as articulated by Jim Jones, Acting Assistant Administrator. The assessments, while conservative, will clearly indicate what OPPT believes to be the best risk assessment estimate given the knowledge that the Agency currently possesses regarding hazard and exposure. Should an interested party claim that the risk estimates are unreasonable overestimates, the burden shall rest on it to supplement the current record and allow OPPT to revise its assessments and perhaps reach a different conclusion.

This is intended, in part, to improve on past practices where incomplete or missing information was often identified, and then any follow-up was left to an uncertain fate.

Separately, it will remain to be seen whether any new approach can result in more meaningful generation of additional data or enhance regulatory conclusions made by the program.

"Influential" or "Highly Influential?"

Another issue concerns the adequacy of the peer review process that US EPA plans to conduct on what it has classified "influential" draft risk assessments. On December 21, 2012, Senator James Inhofe (R-OK),

Ranking Member of the Senate Environment and Public Works Committee, and Committee Members Senators Lamar Alexander (R-TN), Mike Crapo (R-ID), and David Vitter (R-LA) requested that US EPA classify the risk assessments prepared under the TSCA Work Plan as "highly influential."

Because US EPA chose to classify the assessment as merely "influential," the Senators noted that the studies would be subject to a less rigorous peer review than would be the case if they were classified as "highly influential." The Senators cite the Office of Management and Budget (OMB) *2004 Final Information Quality Bulletin for Peer Review* and US EPA's *Peer Review Handbook*, both of which state that "highly influential" scientific assessments are those that are "novel, controversial, or precedent-setting," or that have significant interagency interest.

Thus, the Senators recommended that to ensure a "robust body of reviewers," US EPA encourage the public to nominate peer review candidates. Further, to be consistent with the best practices of the National Academies and US EPA's Science Advisory Board, the Agency should allow the public to comment on the specific peer reviewers under consideration. The Senators also criticized US EPA's plan to conduct the peer reviews by teleconference and encouraged the Agency to respond to public comments in writing.

While US EPA will solicit nominations from the public for peer review candidates and allow comment on specific peer reviewers, it appears that US EPA does not intend to follow all of the Senators' recommendations.

Based on language in the draft risk assessments, it appears that the Agency has decided to continue to classify the risk assessments as "influential" scientific assessments and not to conduct any peer review sessions in person. Each draft risk assessment states: "A peer review panel is being arranged for this influential work plan assessment product based upon need and following Agency peer review guidance. The format will be a teleconference of an *ad hoc* panel meeting consisting of independent experts."

How this plays out will likely affect US EPA's future approach to Work Plan risk assessments.

Readers should stay tuned for further developments. As TSCA reform legislation continues to creep along at a glacial pace, the Work Plan Program appears to be at the center of US EPA's enhanced chemicals management

program. Thus, it is a critically important initiative. As noted, although the assessments are draft and on five specific chemical substances, the approach US EPA is taking on these assessments will likely be applied to other Work Plan Program chemicals.

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[1] The 18 chemicals are: 1-Bromopropane; Five Chlorinated Hydrocarbons: 1,1-Dichloroethane; 1,2-Dichloropropane; 1,2-Dichloroethane; trans-1-2-Dichloroethylene; and 1,1,2-Trichloroethane. 4-tert-Octylphenol. Three Flame Retardants: Bis(2-Ethylhexyl)-3,4,5,6-tetrabromophthalate (TBPH); 2-Ethylhexyl-2,3,4,5-tetrabromobenzoate (TBB); and Tris(2-chloroethyl)phosphate (TCEP) Four Fragrance Chemicals: Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-; Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,5,5-tetramethyl-2-naphthalenyl)-; Ethanone, 1-(1,2,3,5,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-; and Ethanone, 1-(1,2,3,4,6,7,8,8a-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-4-sec-Butyl-2,6-di-tert-butylphenol; 2,4,6-Tri-tert-butylphenol; P,p'-Oxybis(benzenesulfonyl hydrazide); and Octamethylcyclotetrasiloxane (D4).