Environmental Quality Management

WASHINGTON WATCH

EPA's New, Final Work Plan Risk Assessments and What They Mean to You

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The United States Environmental Protection Agency (EPA) released on June 25, 2014, and on August 28, 2014, final risk assessments for targeted uses of four Toxic Substances Control Act (TSCA) Work Plan chemicals. The June assessment consists of certain uses of trichloroethylene (TCE), and the assessments released in August are for uses of methylene chloride or dichloromethane (DCM), antimony trioxide (ATO), and 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8,-hexamethylcyclopenta-[γ]-2-benzopyran (HHCB). The much anticipated release of these assessments marks a real milestone for EPA's Office of Chemical Safety and Pollution Prevention (OCSPP), and EPA is to be commended for its significant efforts in completing these assessments relatively quickly.

EPA states that its risk assessment on targeted uses of TCE identified health risks to consumers using spray aerosol degreasers and spray fixatives and to workers when TCE is used as a degreaser in small commercial shops and as a stain removing agent in dry cleaning. EPA's risk assessment on DCM, which is widely used in paint stripping products, indicates health risks to both workers and consumers who use these products and to bystanders in workplaces and residences where DCM is used. The risk assessments for ATO, which is used as a synergist in halogenated flame retardants, and

HHCB, which is used as a fragrance ingredient in commercial and consumer products, did not reveal concerns. Why these assessments are important, and what they mean to environmental professionals, are issues explained below.

Work Plan Chemicals Program: A Primer

The Work Plan Chemicals Program approach to prioritizing chemical substances for risk assessment purposes has been an OCSPP priority for several years now. It was rolled out in August 2011, when EPA invited stakeholders to provide feedback on its new approach for identifying priority chemicals and targeted uses of these chemicals for review and assessment under TSCA. EPA specifically invited public input on its "*Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment*" (Discussion Guide) (EPA, 2011). EPA also scheduled a webinar to review and consider the Discussion Guide and to ensure that public input was optimized.

The Discussion Guide is an important document because it outlines in considerable detail EPA's goal of chemical prioritization and its planned process for identifying priority chemicals for review, including prioritization factors and data sources. Furthermore, it describes how EPA will select certain chemicals from the priority list for assessment. EPA stated that it would use a two-step process to identify priority chemical substances for review and assessment under TSCA. Its goal is "to identify priority chemicals for near-term evaluation, not to screen and prioritize the entire TSCA Inventory of approximately 84,000 chemicals" (EPA, 2012a), which is an approximation of the chemical substances listed on the TSCA Inventory.

In Step 1, EPA identifies an initial group of priority chemicals for review by using a specific set of data sources to identify chemicals that meet one or more of certain priority factors. In Step 2, EPA refines that group by using a broader range of data sources to analyze further and select specific chemicals from the initial group for further assessment. As EPA works through the initial set of priority chemicals, it may repeat the two-step process "to select subsequent chemicals for review and assessment" (EPA, 2011, p. 2.)

EPA committed to use its existing information collection and testing authorities under TSCA Sections 4 (chemical testing) and 8 (recordkeeping and reporting) to develop needed information. EPA also lists its TSCA Section 11(c) subpoena authority as a tool to collect additional information if a priority chemical has a less robust hazard or exposure database. While EPA's authority under TSCA Section 11(c) is broad, EPA has seldom resorted to widespread use of this authority. EPA's specific notation of its authority is interpreted by some as an indication that EPA will deploy its subpoena authority more robustly going forward.

Prioritization Factors

The Discussion Guide lists the following factors for identifying candidate chemicals for review:

- Potentially of concern for children's health (*e.g.*, chemicals with reproductive or developmental effects);

- Persistent, bioaccumulative, and toxic (PBT);

- Probable or known carcinogens;
- Used in children's products;
- Used in consumer products; and
- Detected in biomonitoring programs.

EPA has indicated that chemicals meeting one or more of these factors would become part of the initial group for review. This approach generated a large initial list of chemicals. Unfortunately, the Discussion Guide offered no context regarding the relevance of exposure or other factors that would help to diminish the number of potential candidate chemicals.

Data Sources for Identification of Priority Chemicals

EPA listed potential data sources it would consider in identifying chemical substances for prioritization. Key among them are the following lists: California's Proposition 65 (Prop 65) chemicals are listed as a data source for both carcinogen and reproductive chemicals (EPA, 2011, p. 4), "Potential Children's Health Concern" is identified as a factor, defined as chemicals with "some concern" under the National Toxicology Program (NTP) Center for the Evaluation of Risks to Human Reproduction (CERHR) program (EPA, 2011, p. 4). The "some concern" designation means a chemical is scored under the CERHR program in the middle of five levels. The Washington State Children's Safe Product Act list is identified as a source of data for children's products (EPA, 2011, p. 4.). As the Washington State list was not intended to prejudge a determination that a chemical has been used in children's

products, its inclusion as a data source was criticized by some as a basis to select Work Plan chemicals.

Identification of 83 Priority Chemicals

EPA refined the selection criteria based on public comment and on March 1, 2012, EPA's Office of Pollution Prevention and Toxics (OPPT) identified 83 chemicals for further review under the TSCA Work Plan and an initial schedule for review. EPA identified seven chemicals for risk assessment in 2012. EPA also stated that it intended to identify specific chemicals for risk assessment in 2013 and 2014. The announcement also briefly discussed OPPT's efforts to "build the pipeline of future assessment" and its continuing efforts to increase public access to chemical data and information (EPA, 2012b, p.1).

The seven chemicals selected for assessment included:

- Antimony and Antimony Compounds;
- HHCB;
- Long-Chain Chlorinated Paraffins;
- Medium-Chain Chlorinated Paraffins;
- Methylene Chloride;

- N-Methylpyrrolidone (NMP); and

- TCE.

EPA made adjustments to the second stage of the process described above 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.

EPA also clarified that in identifying a smaller set of chemicals for work in any given year, it would consider 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 Step 1 (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 risk assessments are targeted and scoped appropriately, and therefore would best be addressed in an out year;
- Whether certain chemicals, or groups of chemicals, have previously been assessed and addressed by EPA, so that risk assessment in later years may be more appropriate than in the earlier years of the Work Plan; and

- EPA work load considerations, including the scope and timing of work needed on specific chemicals and existing commitments for assessment.

In conducting risk assessments for targeted chemical uses, EPA stated that it would use information available through the data sources cited in its *TSCA Work Plan Chemicals: Methods Document* (EPA, 2012c). According to EPA, it expected to release draft risk assessments for public review and comment as each one is completed. If an assessment indicates significant risk associated with a particular use of a Work Plan chemical, EPA stated that it would evaluate and pursue appropriate risk reduction actions, as warranted. If an assessment indicates no significant risk, EPA will conclude its current work on that chemical.

On June 1, 2012, exactly three months after OPPT announced its TSCA Work Plan chemicals, EPA announced an additional 18 chemicals scheduled for assessment during calendar years 2013 and 2014. EPA stated that it selected the chemicals for a variety of reasons similar to those it used to identify the seven Work Plan chemicals it planned to assess in 2012. The chemicals include chemicals associated with specific hazards, such as potential carcinogenicity or reproductive or developmental toxicity; chemicals presenting PBT potential; and chemicals found in biomonitoring or reported in consumer products. EPA noted that some of the 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.

The 18 chemicals are:

- 1-Bromopropane
- Five Chlorinated Hydrocarbons:
  - 1,1-Dichloroethane
  - 1,2-Dichloropropane
  - 1,2-Dichloroethane
  - trans-1-2-Dichloroethylene
  - 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)
  - 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)-
  - 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)
- Octamethylcyclotetrasiloxane (D4).

OPPT Releases Draft Chemical Risk Assessments

EPA announced on January 4, 2013, the availability of the first draft risk assessments developed under the TSCA Work Plan Program. The draft risk assessments are for particular uses of five chemicals found in household products: methylene chloride or DCM and NMP in paint stripper products; TCE as a degreaser and a spray-on protective coating; ATO as a synergist in halogenated flame retardants; and HHCB as a fragrance ingredient in commercial and consumer products. EPA provided a 60-day comment period and requested nominations for expert peer reviewers.

EPA stated that the draft assessments focused either on human health or ecological hazards for specific uses that are subject to TSCA regulation. Three of the draft risk assessments -- DCM, NMP, and TCE -- indicated a potential concern for human health under specific exposure scenarios for particular uses. The draft assessments for ATO and HHCB indicate a low concern for ecological risks. EPA stated that the draft risk assessments on the two remaining chemicals from the initial group of seven work plan chemicals scheduled to begin assessment in 2012—the long- and medium-chain chlorinated paraffins—are on a different schedule for completion.

EPA's draft assessments were clearly and carefully presented, albeit quite conservative in the approaches applied and the conclusions obtained. Because of the detail provided, the bases for EPA's health risk conclusions are clearly set forth. EPA did a good job of identifying and discussing the uncertainties in its assessments, but consistently opted for conservative, worst-case assumptions and approaches.

OPPT Releases Final Risk Assessments for Certain Work Plan Chemicals

TCE

On June 25, 2014, EPA released its final risk assessment for TCE (EPA, 2014a). TCE is a volatile organic compound (VOC) classified as a carcinogen that has been widely used as a solvent and degreaser in large-scale industrial processes, small commercial shops, and in some products used by individual consumers. The assessment identified health risks from TCE exposures to consumers using spray aerosol degreasers and spray fixatives. It also identified health risks to workers when TCE is used as a degreaser in small commercial shops and as a stain removing agent in dry cleaning. EPA convened a workshop in July 2014 to discuss potential TCE degreaser alternatives and risk reduction approaches and pledged to conduct other activities to address TCE uses as a stain removing agent in dry cleaning and as a clear protective spray fixative. EPA recommended that people take precautions to reduce exposures, such as using the product outside or in an extremely well-ventilated area and wearing protective equipment to reduce exposure.

On August 28, 2014, EPA announced the release of three final additional risk assessments for DCM, ATO, and HHCB. EPA noted that it is also currently evaluating risks of another chemical in paint strippers, NMP. EPA has released a draft risk assessment for NMP that identifies risks associated with use of NMP-containing paint strippers. EPA states that it "does not expect the final risk assessment to significantly change this conclusion, and therefore recommends that those using NMP-containing paint strippers also take measures to minimize exposure" (EPA, 2014b). As to the three

assessments EPA issued in final in August, only DCM identified applications found to pose concern. EPA did not identify concerns with ATO or HHCB, as discussed below.

DCM

In the final risk assessment, EPA describes DCM as:

…a volatile organic compound (VOC) that is used as a solvent in a wide range of industrial, commercial and consumer use applications, such as adhesives, paint stripping, pharmaceuticals, metal cleaning, chemical processing, and aerosols. It is the primary ingredient in many paint stripping products (EPA, 2014c. p. 19).

OPPT also:
…identified DCM for further evaluation based on its likely carcinogenic properties in humans, high potential for human exposure as it is widely used in consumer products, and reported releases to the environment. For instance, DCM has been detected in drinking water, indoor environments, ambient air, groundwater and soil (EPA, 2014c. p. 19).

The risk assessment identifies cancer risk concerns and short-term and long-term non-cancer risks for workers and "occupational bystanders" (other workers within the facility who are indirectly exposed) from the use of DCM-containing paint strippers. The final risk assessment also identifies short-term non-cancer risks for consumers and residential bystanders from the use of DCM-containing paint strippers.

According to EPA, it is considering a range of possible voluntary and regulatory actions to address concerns. Options include transitioning to safer chemicals and greener processes/technologies, promoting best practices, and phasing out uses. EPA anticipates conducting a workshop in late 2014 on potential alternatives and risk reduction approaches. In the meantime, EPA recommends that consumers check the label to determine if the product contains DCM or methylene chloride. If so, EPA recommends taking precautions that can reduce exposures.

ATO

The final risk assessment addresses effects on ecological receptors from the use of ATO as a synergist in halogenated flame retardants. The final risk assessment states that EPA's OPPT identified key sources of uncertainty related to limitations in the available hazard and exposure information, and conservative assumptions incorporated in the Exposure and Fate Assessment Screening Tool, version 2, (E-FAST2) model estimates of antimony surface water concentrations. According to the assessment, although these uncertainties may limit data interpretation, "EPA/OPPT has high confidence in its minimal risk finding based on the following considerations:" (EPA, 2014d. p. 19) the use of release data for antimony compounds and conservative assumptions incorporated in the EFAST-2 model estimates likely overestimate ATO exposure potential; and environmental monitoring data obtained during the last three years show no exceedances of the hazard benchmarks identified to be protective of sensitive ecological species (EPA, 2014d. p. 19).

HHCB

According to the final risk assessment:
HHCB is one of the most widely used polycyclic musk fragrance ingredients in a range of consumer products including perfumes, cosmetics, shampoos, lotions, detergents, fabric softeners, and household cleaners (EPA, 2014e. p. 12).

Although HHCB is not produced in the United States, it is imported and compounded into fragrance oils, which are blended into end-use products and sold for both commercial and consumer use. Problem formulation resulted in the assessment focusing on environmental risk to the aquatic environments from the use of HHCB as a fragrance ingredient in consumer and commercial products. The final risk assessment states that, under the exposure scenarios assessed, "current environmental exposure concentrations are one to two orders of magnitude below hazard concentrations (risk quotients (RQs) < 1) of concern for aquatic or sediment-dwelling organisms" (EPA, 2014e. p. 13). The final risk assessment notes that "[t]he inability to assess potential risks to terrestrial invertebrates and plants is a major uncertainty associated with this assessment" (EPA, 2014e. p. 13).

Discussion

So why does this matter, and what does it mean to environmental professionals? First, it means OCSPP is very much committed to its TSCA revitalization initiative first announced in 2009 by then-EPA Administrator Lisa Jackson. The efforts of OCSPP leadership, especially as articulated by OCSPP Assistant Administrator Jim Jones, are fairly substantial here given

the rollout of the program in 2011 and the completion of final risk assessments in mid-2014. That is no small feat for a division of EPA that has not historically been in the business of developing risk assessments.

Second, the release of these assessments reflects OCSPP's sustained commitment to use its existing TSCA authority to the maximum extent possible. While EPA supports TSCA legislative modernization, it is clear that it is not about to rely upon the vagaries of the legislative process to ensure chemical substances targeted for priority review are assessed, alternatives are identified, and risk mitigation measures are identified and communicated.

Third, that these assessments have been completed within a reasonable period of time and through a deliberative process that invites significant stakeholder engagement, demonstrates that OPPT has the political will and horsepower to pull this off. OPPT has tried previously and failed. That the Work Plan approach is, in fact, working and has final risk assessments to show for its efforts goes a long way in addressing a skeptical public's lack of faith in EPA's ability to utilize TSCA to manage risks from chemical substances.

Fourth, the assessments demonstrate that TSCA as it exists now is capable of being implemented successfully to diminish the use of chemicals believed to pose harm and identify alternatives to those applications -- all without TSCA reform. As legislative measures to reform TSCA have stalled yet again, it is reassuring to many that the current law has vitality and that EPA can use it now to get things done.

Finally, the release of these assessments offers yet another reminder to chemical producers, downstream users, and product formulators to be mindful of the opportunities presented for new chemical alternatives believed to be safer than those for which EPA has identified clear risks to targeted users, as in the case of DCM. The pressures on product manufacturers to select the safest and most efficacious chemical ingredients for their products can only be expected to increase.

This is a program to watch. Stay tuned as EPA OCSPP will continue to issue risk assessments for target uses of Work Plan chemicals. What these assessments conclude will have a significant impact on downstream customers and their uses of these chemicals.

References

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