



Portfolio Media, Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Targeting Priority Chemicals Under TSCA

Law360, New York (September 2, 2011) -- Embracing new social media tools, the U.S. Environmental Protection Agency on Aug. 18, 2011, invited stakeholders to provide feedback on its new approach for identifying priority chemicals for review and assessment under the Toxic Substances Control Act (TSCA). Noting that the EPA's online discussion forum will remain open until Sept. 14, 2011, the EPA invited public input on its "Discussion Guide: Background and Discussion Questions for Identifying Priority Chemicals for Review and Assessment" (available at <http://www.epa.gov/opptintr/existingchemicals/pubs/chempridiscguide.html>). The EPA has also scheduled a webinar on Sept. 7, 2011, to review and consider the Discussion Guide.

Background

The Discussion Guide outlines the EPA's goals of chemical prioritization, its planned process for determining priority chemicals for review, including prioritization factors and data sources, and an overview of how certain chemicals will be selected from the priority list for assessment. The EPA will use a two-step process to identify priority chemical substances for review and assessment under TSCA. According to EPA, 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."

In Step 1, the EPA plans to identify 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 the Action Plan priority factors. The EPA is seeking public input on two related aspects of Step 1: prioritization factors and data sources for prioritization factors.

In Step 2, the EPA intends to refine that group by using a broader range of data sources to analyze further and select specific chemicals from the initial group for further assessment. The EPA is seeking input on the data sources for further analysis to be used in Step 2. According to the EPA, as it "works through" the initial set of priority chemicals, it may repeat the two-step process "to select subsequent chemicals for review and assessment."

Importantly, in the Discussion Guide, the EPA clarifies that "Identification of a chemical as a priority chemical for review would not itself constitute a finding by the Agency that the chemical presents a risk to human health or the environment. Rather, identification of a chemical as a priority chemical would indicate only that the Agency intends to review it on a priority basis."

At the same time, careful review of the statement indicates that it applies to chemicals identified in Step 1 — assurances seem not be provided for those Step 1 chemicals selected for assessment pursuant to Step 2. While this may be the EPA's intent, the point is not clear in the document.

Further, and despite the EPA's disclaimer, there will almost certainly be important commercial and market implications for chemical substances that are listed as priority

chemicals for review or assessment, particularly in light of the potential for large lists evolving from Step 1 and the absence of a clear pathway on how Step 1 chemicals may be the subject of refinement to become Step 2 chemicals. Indeed, the development of a long list of chemicals under Step 1 may yield a de facto chemicals of concern list, complete with the attendant adverse implications so much has already been written about. For this reason, careful and deliberate consideration must be given to the factors that the EPA intends to use in its prioritization approach.

The EPA to Use Existing TSCA Authorities to Collect Needed Information

The EPA states that it will use its existing information collection and testing authorities under TSCA Sections 4 and 8 to develop needed information. The EPA also lists its TSCA Section 11(c) subpoena authority as a tool to collect additional information if a priority chemical has less robust hazard or exposure database. While the EPA's authority under Section 11(c) is broad, the EPA has not resorted to widespread use of this authority in years past. The Discussion Guide may be telegraphing the EPA's view that this is about to change.

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

The EPA has indicated that chemicals meeting one or more of these factors would become part of the initial group for review. As noted, this approach is likely to generate a very large initial list of chemicals. Unfortunately, the Discussion Guide offers no context regarding the relevance of exposure or other factors that may help to diminish the number of potential candidate chemicals. Seemingly there would be value in tiering or applying multiple factors to develop a workable starting point, and this is one area where public input may help refine the assessment process.

Industry stakeholders are likely to disagree strongly with the inclusion of "detected in biomonitoring" as an initial prioritization factor, whereas other stakeholders can be expected to support such a broad approach. In describing this factor, the EPA discusses "biomonitoring programs," whereas in Table 1 on data sources, the EPA limits the sources to "human biomonitoring." It is unclear if the EPA intended this phrase to narrow the scope of data to be considered.

Data Sources for Overall Identification of Priority Chemicals

The EPA lists in Table 1 potential data sources it would consider in identifying chemical substances for prioritization. As a threshold matter, the EPA should be encouraged to recognize the limited utility, if not the propriety, of including chemicals proposed for listing in the Convention on Long-range Transboundary Air Pollution (LRTAP) or Protocol on Persistent Organic Pollutants (POP). Other issues our initial review of the list reveals include:

- Proposition 65 chemicals are listed as a data source for both carcinogen and

reproductive chemicals. Rather than reference the Prop 65 lists, the data source list would be more defensible if it relied upon underlying studies/sources supporting the Prop 65 listing itself, including National Toxicology Program (NTP) studies, International Agency for Research on Cancer (IARC) determinations and related "primary source" determinations.

- "Potential Children's Health Concern" is identified as a factor, defined as chemicals with "some concern" under the NTP Center for the Evaluation of Risks to Human Reproduction (CERHR) program. The "some concern" designation means a chemical is scored under the CERHR program with the middle of five levels. Aside from the fact the program no longer exists, some can be expected to argue that the listing of chemicals with this equivocal a rating should not be included.
- The Washington State Children's Safe Product Act list is identified as a source of data for children's products. This is a list of chemicals for which manufacturers must report by August 2012. In that this reporting function is not intended to prejudice a determination that a chemical has been used in children's products, its inclusion as a data source would appear inappropriate.
- While Inventory Update Reporting (IUR)/Chemical Data Reporting (CDR) Rule information would appear a promising source of information on which the EPA could rely in prioritizing chemicals, more screening is needed to identify chemicals that warrant priority treatment. By this standard, IUR/CDR Rule information would appear too broad to be useful.

Discussion

The EPA document outlines in broad strokes how the EPA intends to identify priority chemicals for review and assessment. Critically important points and details in the approach are lacking and can only be surmised given the cursory treatment provided in the Discussion Guide. It is clear that Step 1 could generate a large and unwieldy list of chemicals that would need to be winnowed considerably to yield a manageable list of chemicals suitable for assessment. What happens after Step 1 to get to Step 2 is entirely unclear.

The EPA states that it would consider "risk-based prioritization factors" in Step 1. The data sources identified, however, are limited to exposure or hazard factors and, only through some ill-defined integration step would risk-based understandings emerge. While the EPA takes pains to state that it will focus only on TSCA chemicals and uses, it is not clear that the EPA will integrate the Step 1 data given that chemicals meeting "one or more factors" would go into the review step.

With respect to Step 2, the EPA only discusses the data sources proposed to be applied, and offers no indication of how the sources will be assessed and be integrated. The data sources listed are very broad and how some could actually be applied in practice is unclear (e.g., it is not clear how the Organization for Economic Co-operation and Development emission scenario documents could be applied given their general nature). Although the document is not clear on the point, presumably the assessment documents listed in Table 1 (Integrated Risk Information System, Screening Information Data Sets, etc.) would also be applied in Step 2.

While the dialogue the EPA hopes to elicit should provide a good opportunity for stakeholders to engage, the lack of meaningful discussion in the document regarding

whether or how information will be integrated, the EPA's approach to assessment, and the near total focus in the Discussion Guide on data sources and additional prioritization factors may limit its value.

The EPA's invitation to discuss those factors that should "receive greater consideration than others" may remedy this deficit, but only partially. Given the many and widely different data sources the EPA identifies, careful review of the list and a thoughtful evaluation of how the different data sources might be used by the EPA would be valuable points for industry to consider and on which to elaborate in written comments to the EPA.

--By Lynn L. Bergeson, Bergeson & Campbell PC

Lynn Bergeson is managing director of Bergeson & Campbell, P.C., a Washington, D.C., law firm focusing on conventional and engineered nanoscale chemical, pesticide, and other specialty chemical product approval and regulation, environmental health and safety law, chemical product litigation, and associated business issues, and president of The Acta Group LLC and The Acta Group EU Ltd., with offices in Washington, D.C., and Manchester, U.K.

The opinions expressed are those of the author and do not necessarily reflect the views of the firm, its clients, or Portfolio Media, publisher of Law360. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

All Content © 2003-2010, Portfolio Media, Inc.