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Chemicals

Practitioner Insights: Protecting Stakeholders Under the New TSCA

The recent amendments to section 6 of the Toxic Substances Control Act (TSCA) mean that the Environmental Protection Agency (EPA) can regulate, is regulating, and will regulate chemical substances as never before. The amendments present challenges to stakeholders, but also opportunities to influence potential EPA decisions that may determine the future commercial viability of those substances.

This paper explores those challenges and opportunities. It suggests answers to the following stakeholder questions:

- Why should I care if EPA reviews my chemical substance?
- When will EPA take actions for additional chemical substances?
- How does EPA decide which chemical substances to address?
- How can I influence whether EPA designates my chemical substance as a low-priority substance?
- How can I influence whether EPA conducts a risk evaluation for my chemical substance?
- How can I influence EPA's risk evaluation for my chemical substance?
- How can I influence EPA's risk management rulemaking for my chemical?

1. The New Section 6 Section 6 now directs EPA to take three key steps while meeting deadlines for completing action. The first step is for EPA to designate chemical substances as high or low priorities for risk evaluation.

The second step is for EPA to conduct risk evaluations. Through the risk evaluation, EPA must: ''determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.''

The third step is for EPA to regulate any chemical substance that it determines presents an unreasonable risk. It must adopt a rule to ban, restrict, or otherwise regulate the substance to ensure it no longer presents such risk.

EPA has published procedural rules for implementing the prioritization and risk evaluation steps: the prioritization rule, 40 C.F.R. Part 702, Subpart A, and the risk evaluation rule, 40 C.F.R. Part 702, Subpart B.

2. Why Should I Care if EPA Reviews My Chemical Substance? If EPA decides to take action under section 6 with respect to a chemical substance, that decision will significantly impact the manufacturers, processors, and end users of that substance, as well as other stakeholders. The decision could add costs; hurt or help commercial and public acceptance of the substance; support or hinder related tort litigation; and ultimately determine whether the substance may continue on the market and, if so, under what restrictions. The impacts could come throughout the section 6 process:

- EPA may require testing of the chemical substance to close data gaps before making a prioritization decision. EPA now may order manufacturers and processors of a substance to develop ''new information for the purposes of prioritizing a chemical substance under section 6(b).'' Such testing could cost millions of dollars.
- EPA may designate a chemical substance as one which ''may present an unreasonable risk.'' That is the standard for qualifying as a high-priority substance. The marketplace may react negatively to a substance so designated, since EPA has placed it on the track toward possible regulation. Under section 5, EPA has extensively relied on a ''may present'' finding to restrict chemical substances.
- EPA may designate the chemical substance as a low-priority substance. To do so, it must find that the substance does not meet the ''may present'' standard. Having a low-priority designation may help in the marketplace and with tort suits for manufacturers, processors, and end users of the substance.

■ EPA may determine that a chemical substance ''presents an unreasonable risk.'' That determination may be commercially devastating, at least for the conditions of use determined by EPA to present the unreasonable risk. In addition, plaintiffs' lawyers may argue that the determination is evidence of negligence by those who manufacture, process, or use that substance, at least for the conditions of use for which EPA makes that determination.

■ EPA may determine that the chemical substance does not present an unreasonable risk, either under any of the conditions of use within the scope of the risk evaluation, or under the conditions of use of importance to a stakeholder. That determination may be important both commercially and for its significance in tort suits.

■ EPA may ban or restrict future manufacturing, processing, distribution, use, and disposal of a chemical substance. Once it has made a determination that a chemical substance presents an unreasonable risk, EPA must regulate it ''to the extent necessary so that the chemical substance or mixture no longer presents such a risk.''

■ EPA may adopt a reasonable risk management rule that preempts state regulatory requirements for the chemical substance. Compliance with the restrictions may be evidence that a manufacturer, processor, or end user of the substance acted reasonably for purposes of tort litigation.

In short, there may be compelling reasons why a stakeholder may want, or not want, EPA to take action under section 6 with respect to a particular substance.

3. When Will EPA Take Actions for Additional Chemical Substances? EPA has begun section 6 actions for multiple chemical substances: ten chemical substances or categories slated to receive risk evaluations; five chemical substances or categories designated as persistent, bioaccumulative, and toxic; and two substances for which a manufacturer requested EPA to conduct risk evaluations.

EPA is probably already at work identifying candidates for prioritization. During this pre-prioritization step, EPA expects to consider the quality, objectivity, utility, and integrity of the available information. It may also determine whether or not information can be developed and collected, reviewed, and incorporated into analyses and decisions in a timely manner; if so, it may order testing.

EPA must begin the official prioritization process no later than March 22, 2019, by announcing candidates for prioritization. Nine months later, by Dec. 22, 2019, EPA must have designated at least 20 high-priority substances and at least 20 low-priority substances. Of course, EPA may begin the process earlier.

4. How Does EPA Decide Which Chemical Substances to Address? Stakeholders should check whether or not their chemical substances of interest are included in the 2014 update to the TSCA Work Plan list. At least 10 of the initial 20 high-priority substances must come from this list. It includes 90 chemical substances or categories. The 17 substances or categories which EPA has already set for action under section 6 came from this list. That leaves 73 remaining to be designated for risk evaluations.

How will EPA choose among these 73? Section 6 directs EPA to give preference to those on the list that have a Persistence and Bioaccumulation Score of 3 (as indicated on that list) and to those that are known human carcinogens and have high acute and chronic toxicity (as indicated on that list).

The entries on the list meeting those criteria not already designated for risk evaluations are the following:

■ Arsenic and arsenic compounds;
■ Cadmium and cadmium compounds;
■ Chromium and chromium compounds;
■ Cobalt and cobalt compounds;
■ Lead and lead compounds;
■ Long-chain chlorinated paraffins (C18-20);
■ Medium-chain chlorinated paraffins (C14-17);
■ Molybdenum and molybdenum compounds;
■ Nickel and nickel compound;
■ Octamethylcyclotetrasiloxane; and
■ Pigment Yellow 83

Another factor in EPA's decisions may be whether other federal agencies are regulating those substances. For example, eight of the phthalates on the list are being addressed by the Consumer Product Safety Commission, and the Food and Drug Administration regulates most uses of bisphenol A, also on the list.

EPA may select up to 10 of the initial 20 high-priority substances from those not on the TSCA Work Plan list. How will it select these? Its general objective is to select those substances with the greatest hazard and exposure potential first, considering reasonably available information on the relative hazard and exposure of potential candidates. It must also consider these factors:

■ The chemical substance's hazard and exposure potential;
■ The chemical substance's persistence and bioaccumulation;
■ Potentially exposed or susceptible subpopulations;
■ Storage of the chemical substance near significant sources of drinking water;
■ The chemical substance's conditions of use or significant changes in conditions of use;
■ The chemical substance's production volume or significant changes in production volume; and
■ Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

Another important factor is the availability of information on the chemical substance or category. Stakeholders may want to evaluate the extent of the information available on their chemicals of interest. An EPA request or requirement for additional information on a chemical substance may be an indication of EPA's interest in the substance during the current pre-prioritization activities.

5. How Can I Influence Whether EPA Designates My Chemical Substance as a Low-priority Substance? A low-priority substance is one for which ''the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard. . .for designating a chemical substance a high-priority substance.'' In other words, EPA must have sufficient information to conclude that the substance does not qualify for a ''may present an unreasonable risk'' finding.

EPA has advised that its Safer Chemicals Ingredients List ''will be a good starting point for identifying potential candidates for Low-Priority Substance designations.'' A stakeholder may advocate that a substance

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should be designated as low-priority by doing the following:

- Checking the Safer Chemicals Ingredients List to see if the substance is listed there;
- Reviewing the available hazard and exposure information to see if a ''may present'' finding is unlikely for any condition of use for the substance;
- Assessing the completeness of the information available to EPA on the substance;
- Supplementing that information with submissions to EPA if appropriate; and
- Advocating to EPA that it should select the chemical as a candidate for low-priority designation.

6. How Can I Influence Whether EPA Conducts a Risk Evaluation for My Chemical Substance? There are two routes to an EPA risk evaluation on a chemical substance: through a manufacturer request and through the prioritization process. Both provide opportunities for stakeholder advocacy which may influence EPA's decision.

a. Manufacturer requests

A manufacturer may request EPA to conduct a risk evaluation on its chemical substance. In most circumstances, a manufacturer would only make such a request if it expected EPA to conclude that the substance does not present an unreasonable risk, at least for the conditions of use of interest to the manufacturer.

There will probably be few manufacturer requests. The up-front information requirements for manufacturer requests are substantial. So is the associated fee. A requesting manufacturer must agree to pay 50 percent of EPA's cost of conducting the requested risk evaluation if the substance is on the TSCA Work Plan and 100 percent of the cost if it is not. EPA has estimated that cost at $3.7 million.

Manufacturer requests will be subject to at least a 45-day comment period. Stakeholders may want to supplement the information provided in the request or focus on different conditions of use.

b. Using the Prioritization Process

The most effective time for influencing whether EPA takes action on a chemical substance may be during the pre-prioritization step. Accordingly, stakeholders may want to submit information and advocacy about a substance to EPA proactively, prior to EPA formally identifying the substance as a candidate for prioritization. Developing that information may take months or years, so planning ahead can be critical. Planning often involves development of a coordinated strategy that identifies potential allies in the process, allocates sufficient budget, identifies information needs, and establishes a timetable for information development.

Exposure information is likely to be particularly important to EPA. For occupational exposure, information about engineering controls and personal protective equipment used to prevent or limit exposure may be helpful. Industrial hygiene monitoring results and measurements of concentrations in environmental media can provide real-world data on actual exposure conditions. In some cases, stakeholders may want to conduct exposure monitoring to develop the exposure data that EPA needs to make section 6 decisions.

Hazard data may also be important. For example, ecotoxicity studies can supplant modeling for ecotoxicity endpoints on which EPA might otherwise rely. Measured factors such as log KOW can replace a modeled environmental fate result with actual data. If a flawed study indicating a significant hazard is available to EPA, stakeholders may want to point out those flaws, since EPA must regulate on the basis of the best available science and the weight of the scientific evidence. Even better would be conducting a more reliable study on that endpoint and submitting it to EPA.

Stakeholders should plan to submit full studies wherever possible, because brief summaries are unlikely to be convincing to EPA.

Once EPA selects candidates for a high-priority designation, stakeholders will have opportunities for additional input. Publication of the list of candidates for high- or low-priority designation will trigger a 90-day comment period. After further review, EPA will publish a list of proposed designations of high- and low-priority substances, triggering a second 90-day comment period. Stakeholders should take advantage of these opportunities, if only to reiterate previous comments and to respond to comments by EPA and other stakeholders.

7. How Can I influence EPA's Risk Evaluation for My Chemical Substance? Once EPA designates a chemical substance or category as high priority, or accepts a manufacturer request, it will conduct a risk evaluation for that substance or category. The risk evaluation process offers opportunities for comment. EPA will publish a draft scope for the risk evaluation, with at least a 45-day comment period. EPA will publish a draft risk evaluation for comment, with at least a 60-day comment period.

Stakeholder comments on the proposed scope of a risk evaluation may be critical, since the scope determines which conditions of use (potentially, less than all) will be evaluated. Stakeholder comments on the draft risk evaluation may have less impact, since by then EPA will have completed virtually the entire risk evaluation process and may be up against a statutory deadline.

Stakeholder comments should react to EPA drafts, but also provide additional information not cited by EPA that may help provide a more balanced assessment. In addition, stakeholders may want to act proactively by submitting a risk evaluation of their own. EPA has published guidance for developing such risk evaluations. Preparation of a stakeholder risk evaluation will require a significant investment of time and resources.

Stakeholders may want to focus their comments on the conditions of use of importance to them. EPA will determine that a chemical substance presents an unreasonable risk if a single condition of use merits that determination, but it will also make determinations for the other conditions of use within the scope of the risk evaluation as well, and those may be of greater importance to the stakeholder.

8. How Can I Influence EPA's Risk Management Rulemaking for My Chemical? EPA must publish a proposed risk management rule banning or restricting a chemical substance that it determines presents an unreasonable risk. Stakeholders will have an opportunity to comment on the proposed rule. In addition, they may want to submit information and arguments before then in an effort to influence the proposed rule. Stakeholders will have a variety of important issues to address in their advocacy to EPA.

A critical issue may be which risk management measures EPA will impose. Its selection may determine whether or not the chemical substance will remain commercially viable. A risk management rule must ban, restrict, or otherwise regulate a chemical substance ''to the extent necessary so that the chemical substance or mixture no longer presents such risk.'' Stakeholders will want to comment on which restrictions are necessary and the impact of restrictions on conditions of use not determined to present an unreasonable risk.

In selecting risk management measures, EPA must consider some non-risk factors that were excluded from the prioritization and risk evaluation steps. These include the benefits of the chemical substance for various uses; the reasonably ascertainable economic consequences of the rule, such as the likely effect of the rule on the national economy, small business, and technological innovation; the costs and benefits of the rule and at least one alternative regulatory action; and the cost-effectiveness of the rule and at least one alternative. Stakeholders will want to present their views on these issues to EPA, since its selection of risk management measures must consider these factors to the extent practicable.

In addition, stakeholders may want to address other issues that EPA may have to consider, such as possible exemptions for replacement parts and articles containing the chemical substance being restricted. Also, if EPA plans to propose restrictions that would effectively preclude a condition of use, it must also consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted will be reasonably available as a substitute when the restrictions take effect. Stakeholder information and advocacy will be important.

Compliance dates may also be issues for comment. EPA must adopt compliance dates that are as soon as practicable and no more than five years after promulgation of the rule, but they may vary for different persons. The timing can be crucial to stakeholders.

Conclusion The 2016 amendments to section 6 of TSCA mean that EPA will be much more active than previously in identifying, evaluating, and regulating chemical substances. Its actions since enactment of the amendments demonstrate that new reality. Stakeholders have many opportunities to take part in the different steps of the section 6 process and even more incentives to be involved.

Stakeholder involvement will be more effective the earlier it occurs in the section 6 process. Stakeholders are encouraged to develop and implement far-sighted strategies concerning the chemical substances of importance to them, without waiting for EPA to make critical decisions that may influence the remainder of the process. Once EPA does initiate actions on those substances, stakeholders should plan to stay involved until the entire process is completed.

Mark Duvall is a principal at Beveridge & Diamond, where he heads the TSCA practice and advises clients on all aspects of TSCA. Ryan Carra is an associate who uses his extensive technical background to counsel clients in the chemicals and products sectors regarding environmental regulatory issues. Tim Serie is an associate at the firm where he focuses his practice on chemicals, product, and environmental regulatory matters, including TSCA reform implementation.

The opinions expressed here do not represent those of Bloomberg BNA, which welcomes other points of view.

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