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TSCA Reform Legislation Creates New Opportunities to Demonstrate Chemical Safety

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Environmental

Imagine that you could get the federal government to determine that your substance is safe when used as directed, and that determination could assist in fending off state regulation, reduce product and environmental liability risk, and produce a potential competitive advantage.

This real-world possibility is a result of significant reforms signed into law by President Obama today, June 22, that are designed to strengthen the Toxic Substances Control Act (TSCA).[1] This rare bi-partisan legislative effort clarifies the Environmental Protection Agency's (EPA's) review authority for new and existing chemicals, contains clearer health and environmental-based standards for action, makes clearer the pace and prioritization of regulatory efforts, and clarifies the appropriate treatment of information, as well as the role of the state and federal governments in regulating chemicals.

In addition to these and other changes, the new law allows manufacturers to request that the EPA conduct a safety assessment on their substances, thereby providing a science-based process to vindicate safe substances in a public forum. This mechanism may prove especially important in industries that have been the targets of burdensome state-level regulation or unscientific attacks on the safety of their substances. Companies that market consumer products containing chemical substances may particularly benefit from these changes.

What is a Safety Assessment and How is it Done?

A safety assessment is a process whereby EPA evaluates the safety of a substance based on the available scientific information.[2] EPA has two years to develop, through rulemaking, the procedures it will use for assessments, including company-requested assessments.[3] After an assessment, EPA makes a determination about whether that substance meets the safety standard. A substance will meet that safety standard if it does not present an unreasonable risk of injury to the general population or any potentially exposed or susceptible population or to the

[1] Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576).

[2] *Id.* at § 3(14).

[3] *Id.* at § 3A(b).

environment, without accounting for costs or other non-risk factors.[4] If the substance does not meet the safety standard, EPA must issue a rule imposing restrictions necessary to ensure that the substance meets the safety standard.

Companies can request that EPA perform a safety assessment on a chemical substance. EPA does not have to accept such requests, but between 25% and 50% of risk evaluations must be manufacturer-initiated. Manufacturer-initiated evaluations for new chemicals do not count towards the 50% cap. EPA is required to initiate safety assessments for at least 20 high-priority substances within three and a half years of the bill's passage.[5] Thus, between five and ten high-priority substances will be reviewed based on manufacturer requests by 2020.

The Benefits of a Safety Assessment

Limited Preemption of State Regulation: A safety determination can aid compliance by putting substances under a single, unified regulatory regime. State laws are generally preempted with respect to a substance once either (1) EPA has found that the substance meets TSCA's safety standard or (2) EPA has found that a substance did not meet the safety standard and the rule it issued pursuant to that finding is in effect.[6] However, TSCA preemption is limited in several ways. For example, preemption only applies to conditions of use that are the subject of EPA's safety determination or new uses for which EPA has required notification.[7]

Decreased Risk of Civil Tort Liability: Safety determinations will not be dispositive in private litigation,[8] but they can be persuasive evidence in a private product or environmental liability suit. This protection is particularly strong with respect to punitive damages.[9]

Preference of Private Vendors: Many large retailers are hesitant to stock products containing substances that are not verifiable as safe. Public assessments like the ones EPA will be conducting under TSCA tend to be more thorough than private safety assessments,[10] and will likely carry great weight with large retailers. In addition, private safety assessments can be submitted to EPA to short-circuit the timing and facilitate a quicker review. Now that TSCA reform has launched a viable system for public safety assessments, large retailers may come to prefer products containing substances that have gone through a public safety assessment.

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[4] *Id.* at § 3(16).

[5] *Id.* at § 4A(a)(2)(C)(i).

[6] *Id.* at § 18(a)(1)(B).

[7] *Id.* at § 18(c)(1), (2).

[8] *Id*. at § 18(g)(2)(A).

[9] *See, e.g.*, E. Donald Elliott & Gail Charnley Elliott, *Private Product-Risk Assessment and the Role of Government*, 23 JOHN LINER REV., Summer 2009, 73.

[10] Frank R. Lautenberg Chemical Safety for the 21st Century Act at § 77 - 78.

Factors to Consider

It is too early to say whether a safety assessment will be right for a given manufacturer, but there are certain situations where a safety assessment could be particularly beneficial. Here are a few of the many factors that will be important to consider when determining whether to initiate a safety assessment:

- **Is there scientific information supporting the safety of your substance?** What weight is EPA likely to give to that type of evidence?
- **Is your substance stigmatized on the basis of unscientific criticism?** The safety assessment provides a public forum to vindicate safe substances, which will likely provide a significant benefit for manufacturers of substances that have been stigmatized based on inaccurate information.
- **Is your substance heavily regulated at the state level?** The preemption provisions mentioned above will be especially valuable for substances that have been heavily regulated at the state level.
- **Is EPA likely to assess the safety of your substance even without a manufacturer request?** Manufacturers have to pay for the costs of for assessments that they initiate,[11] so it may be in a manufacturer's interest not to initiate an assessment where EPA is likely to initiate one on its own.

New Opportunities to Consider

Participate in Rulemakings That Will Shape EPA's Process for Prioritizing Reviews and Conducting Assessments

EPA has two years to develop, through rulemakings, the procedures it will use for assessments, including company-requested assessments.[12] Which particular EPA rulemaking is important will vary by industry, and may merit further analysis. For example, rulemakings will flesh out the types of evidence EPA will focus on when making determinations, and these decisions may affect the outcome of a safety assessment. Among the issues for consideration, for example, will be the extent to which EPA incorporates pathways-based toxicology. These newly developing toxicological assessment approaches can facilitate reviews through predictive modes of action.[13] In a similar vein, there are multiple opportunities within the statute for EPA to delay the implementation of the TSCA reform legislation.

Participating in these rulemakings may be important even for those companies not currently planning to request a safety assessment. EPA must initiate safety assessments for at least 20

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[11] *Id.* at § 26(b)(4)(D)(i). A manufacturer only pays half of the cost if the substance was already in EPA's 2014 work plan. *Id.* at § 26(b)(4)(D)(ii).

[12] *Id.* at § 3A(b).

[13] TSCA's restrictions on animal testing may indicate a statutory preference for a pathways-based approach, but EPA's preference remains unclear and participating in the relevant rulemaking remains important.

high-priority substances within three and a half years,[14] and no more than half of these assessments can be manufacturer-initiated.[15] Likewise, EPA will be fleshing out its procedures for evaluating new chemicals and significant new uses. If there is a realistic possibility EPA will decide to assess a substance that implicates a particular product or industry, it may be important to participate in the relevant rulemakings.

Pre-Submission Hearing

If you decide to initiate a safety assessment, it likely would be helpful to set up a pre-submission meeting with EPA. Attorneys with experience working with EPA can use this meeting to assess the likelihood of a safety determination and calibrate a petition to best address EPA's concerns.

Improve the Chances EPA Will Select a Particular Substance for Assessment

EPA's prioritization principles will be fleshed out in rulemakings taking place over the next two years, but the newly revised statute favors substances that meet certain criteria. For example, the statute places an emphasis on substances that come in contact with "potentially exposed or susceptible subpopulations," such as pregnant women, infants, or the elderly.[16] Preference is also given to petitions where EPA determines that, "restrictions imposed by 1 or more states have the potential to have a significant impact on interstate commerce."[17] A petition that focuses on these elements is more likely to be prioritized. Prioritization can have a large effect on the speed with which a petition is handled. Under TSCA as amended, assessments that are given a high priority must be completed within three years of designation,[18] while low-priority assessments have a much more lenient timeframe. Counsel can assist in crafting a petition to enhance its prospects for prioritization by EPA.

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[14] *Id.* at § 6(b)(2)(B).

[15] *Id.* at § 6(b)(4)(E)(i)(II).

[16] *Id.* at § 6(b)(1)(A).

[17] *Id.* at § 6(b)(4)(E)(iii).

[18] *Id.* at § 6(a)(4).