What Product Manufacturers Need to Know About TSCA Reform

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WHAT EVERY MANUFACTURER SHOULD KNOW ABOUT TSCA REFORM

Recent amendments to the federal law governing toxic chemicals will bring significant changes that could impact a broad array of manufacturers. Manufacturers need to monitor the implementation of this new law to assess carefully and, when necessary, attempt to mitigate the chances of Environmental Protection Agency ("EPA") prohibitions or restrictions on the use of chemicals that are necessary to make your products.

Federal designation and regulation of "toxic chemicals" have long been of primary concern to chemical manufacturers and importers (while the companies that simply use these substances have generally been less impacted). That all changed with the passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act ("TSCA Amendments"). The new requirements impose significant responsibilities on the myriad of manufacturing companies that use existing "toxic chemicals."[1] As a result, prospects are significantly higher that EPA, on an expedited timetable, may find that chemicals that are commonly used in manufactured products present an "unreasonable risk" (as newly redefined in the Amendments) and impose labeling requirements, usage restrictions, or even outright bans on their use.

1. Existing Products May Be In Peril

The TSCA Amendments have confirmed and expanded EPA's legal authority to regulate existing "toxic" substances (*i.e.*, chemicals, mineral and manmade fibers, and particles) in products. The new provisions require EPA to designate at least ten existing chemicals as high-

[1] TSCA as amended is available at https://www.law.cornell.edu/uscode/text/15/chapter-53/subchapter-I. "Existing chemicals" are those chemicals on the EPA's official list or inventory. The changes also affect new chemicals (those not on the existing chemicals inventory), but these and other provisions are not discussed in this article.

priority substances by late December 2016, and at least 20 more by the end of 2019, with further designations to follow at a pace consistent with EPA's ability to perform the work.[2]

EPA must assess the human health and environmental risks to workers and consumers from these high-priority substances in manufactured and recycled products. In terms of timing, EPA generally has just a three and a half year post-designation deadline to complete each assessment. This is fast forward mode for EPA.[3]

The TSCA Amendments instituted an innovative two stage process. If the human health or environmental risk from exposure to the priority hazardous substance exceeds an EPA-derived unreasonable risk exposure level (the so called unreasonable risk level), EPA must issue a binding regulation within two years, selecting one or more of the potential restrictions listed in the Amendments (ranging from bans, warning labels, record keeping, and notification and/or recalls). The restriction will be based on consideration of human health or environmental risk, benefits of the uses, and the reasonably ascertainable economic consequences of the rule (including costs and cost effectiveness).[4] However, EPA is no longer required to choose the least burdensome restriction, increasing the likelihood that more stringent measures will become the norm.

Consideration of risk reduction options is triggered if the exposure presents an "unreasonable risk of injury to health or the environment," but unlike the pre-June 2016 TSCA

[2] 15 U.S. Code § 2605(b). EPA, First Year Implementation Plan, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-2 ("EPA TSCA Implementation Plan"). The TSCA Amendments also require EPA to propose regulations governing how EPA evaluates risk and selects the high-priority substances by December 31, 2016. *Id.*

[3] There are fifteen 2012 TSCA work plan chemical substances with risk assessments either completed, currently under peer review, being formulated or where a chemical assessment is underway.

[4] 15 U.S. Code § 2605 (c)(2)(A).

definition of "unreasonable risk," EPA now explicitly cannot consider costs or other non-risk factors in determining the meaning of the term "unreasonable risk" and must protect "potentially exposed or susceptible subpopulation[s]," such as children, the elderly, among other groups.[5] EPA must integrate and analyze available information on, among other things, toxicity, the potentially exposed or susceptible subpopulations, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance, the best available science, the extent of independent verification or peer review of the information or methods, and the weight of the scientific evidence, among other factors.[6] If EPA considers "aggregate or sentinel exposures to a chemical substance under the conditions of use,"[7] it must provide an explanation of this decision.[8]

How to apply these new "unreasonable risk" criteria and select a specific risk reduction requirement are not explicitly defined in the statute and are different from the approach historically taken by EPA. As a result, EPA is likely to have the broader flexibility to impose more stringent risk reduction requirements more expeditiously.[9] EPA staff have indicated that this

[5] 15 U.S.C. § 2605(b)(4)(D).

[6] 15 U.S. Code § 2605 (b)(4) (F).

[7] Sentinel exposure is a "plausible upper-bound individual human … within a broad [use] category. … If the estimated exposure for the sentinel product … results in an acceptable risk assessment outcome …, then there is no need to continue estimating the exposure for the different subcategories." ACC, Comments (August 24, 2016), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0028. Aggregate exposure is exposure from all uses and pathways, including background exposures. Biomonitoring data measures aggregate exposures. Environmental groups support the use aggregate exposures (i.e., the sum of exposures from all pathways and sources, including background levels of chemicals unrelated to the product uses), but argue against the use of sentinel exposure approach. Comments of a Coalition of Environmental Groups (August 24, 2016), available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0400-0058.

[8] 15 U.S. Code § 2625 (h).

[9] The seminal judicial opinion concerning EPA's pre-TSCA Amendments authority overturned EPA's rule banning all uses of asbestos in products because "spending $200-300 million to save approximately seven lives (approximately $30-40 million per life) over thirteen years" was not reasonable. *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1217, 1220, 1223-29 (5th Cir. 1991) How

new "unreasonable risk" and risk reduction determinations will be performed on a substance-by-substance and use-by-use basis, and the relevant analyses will include exposures throughout the lifecycle of the product.[10] The Amendments also allow EPA to issue worker protection requirements if the Occupational Safety and Health Administration ("OSHA") fails to issue a regulation or order to reduce the risk after being notified by EPA.[11] With this provision and others that allow EPA to impose costs of testing priority chemicals on manufacturers, even if a substance is not subject to an outright ban, companies could be incurring additional costs throughout the life of the product.

Historically, EPA has been criticized for its slow pace under TSCA. With the new requirements, EPA will now move full speed ahead to regulate existing chemicals in products.[12]

2. Substances That May Be Classified As "High-priority" (As Early As This Year)

EPA will continue to address identified risks from trichloroethylene (TCE), methylene chloride (MC) and N-methylpyrrolidone (NMP), chemicals for which EPA has already performed or begun a risk evaluation, with deadlines ranging from October to December 2017.[13] The

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the TSCA Amendments (with its two stage process and changed definition of unreasonable risk) might change this result no doubt will be litigated.

[10] For example, historically, EPA tended to take action when the cancer risk was above a one-in-ten thousand lifetime risk level, and not take action when the risk was less than a one-in-one million risk level, with case-by-case balancing when the cancer risks were between these risk levels. Many environmental stakeholders and some regulators advocate abandoning this framework.

[11] 15 U.S.C. § 2608. OSHA has already requested EPA to take the lead on worker exposure limits for existing chemicals. OSHA Letter from David Michaels, Assistant Secretary for Occupational Safety and Health, Depart of Labor to James Jones, Assistant Administrator, Office of Chemical Safety and Pollution Prevention, EPA (June 8, 2016).

[12] EPA currently has 15 TSCA work plan chemical substances with risk assessments either completed, under peer review, being formulated or otherwise underway.

[13] EPA TSCA Implementation Plan, note 2, above.

other initial "high-priority" substances must be selected before the end of this year. The most likely candidates are:

- asbestos and asbestos-like fibers (which may be broadly defined to include, talc, other fibers, and even mineral fragments),
- metals (such as arsenic, lead, hexavalent chromium, and cadmium),
- phthalates,
- bisphenol-A (BPA),
- tetrabromobisphenol A,
- flame retardants (chlorinated and brominated),
- 1-bromopropane,
- p-dichlorobenzene,
- perchloroethylene,
- bis(2-ethylhexyl) adipate,
- vinyl chloride,
- bromoform,
- styrene,
- ethylbenzene, and
- 1,4-dioxane.[14]

These chemicals are widely used in a variety of manufacturing industries. Any company that uses these substances at any point in its process should actively monitor EPA's forthcoming high-priority substance lists (in December 2016 or subsequently) and become involved in EPA's follow-on actions.

[14] This list reflects the author's judgment, based on the selection criteria, stakeholders' proposed priority substances, the amount of preliminary evaluation work already performed on these substances, EPA's current view of the exposure to these chemicals, and the tight time limits for decisions. The TSCA Amendments priority substance selection process will likely be similar to EPA's current TSCA chemical prioritization work plan process. See, Comments of EPA TSCA staff at the August 9-10th stakeholder public comment meetings on the EPA risk evaluation and prioritization rules (Metals Framework at 4-5 to 4-7 (2007), *available at* https://www.epa.gov/sites/production/files/2013-09/documents/metals-risk-assessment-final.pdf). One modification to prior practice is that, under the TSCA Amendments, EPA must follow the EPA Metals Framework in assessing risk from metals.

3. Many Critical Issues Remain Unanswered

A number of critical issues were not explicitly resolved in the Amendments and, therefore, will be decided in EPA risk evaluation and other regulations or in guidance. While it is difficult to predict precisely what EPA will do, EPA is likely to default to its existing practices, unless the statute mandates a different course or parties convince EPA that another approach is more appropriate. At a minimum, EPA will have to grapple with the issues described below.

In the last few years, although the trend at EPA has been toward a more precautionary approach, EPA has been criticized for basing its toxicity determinations on limited and/or flawed data from worst-case studies rather than using the weight of the evidence from the best scientific studies.[15] In comments to date, industry has advocated use of the best science, with weight of the evidence approaches. Not surprisingly, many in the environmental community have urged EPA to adopt more precautionary assumptions and policies to ease, simplify, and speed up the risk reduction process.[16]

EPA staff has stated that determinations of the exposure levels that trigger the new "unreasonable risk" determination (*i.e.*, the human health or environmental risk that is unreasonable at a corresponding exposure level) may focus the nature of the population subject to the exposure (*e.g.*, perhaps setting "unreasonable risk" levels lower for susceptible subpopulations or even using risk management goals lower than the one-in-one million risk

[15] *E.g.*, Nat'l Research Council of the Nat'l Acads., Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde, at 112 (April 2011), *available at* http://www.nap.edu/catalog/13142.html.

[16] See oral comments at EPA's August 9th Comment meeting and compare written comments of the American Chemistry Council and the Coalition of environmental groups (see www.regulation.gov at *docket # EPA-HQ-OPPT-2016-0400*).

level).[17] EPA's wide discretion has prompted concern in the regulated community about the lack of certainty in this process.[18]

Importantly for manufacturers, EPA acknowledged that it often does not have data on uses and resulting exposures and lacks even generally accepted methods to measure many exposures; a clear warning flag for products subject to regulation. EPA is explicitly seeking input on how to gather use-specific exposure information, and how to define and apply concepts such as "sentinel," "aggregate," and "potential exposure." Some claim that EPA should obtain data on exposures, vulnerable populations, and other critical risk evaluation information primarily from public outreach. Industry and environmental groups appear to be at loggerheads over, among other things, when and how to consider aggregate exposure from all uses and pathways, as well as sentinel exposures.[19] Because of the absence of common meanings for many of these terms, many public comments are likely and EPA must establish new policies consistent with the Amendments.

Once EPA determines that an "unreasonable risk" exists, the Agency has broad discretion to determine the type of risk reduction action that should be taken. Recent EPA TSCA chemical risk assessments have proposed risk reduction requirements more frequently, and EPA has adopted more stringent requirements.

Given the significant business risks and uncertainties associated with these new requirements, early engagement is warranted to permit the development and submission of

[17] Id. (based on the author's understanding of the comments at EPA August 9th meeting and recent EPA risk management policy trends).

[18] *E.g. see* comments cited in n. 16 above.
[19] Id.

actual data for the risk evaluation as a better basis for evaluation than the default option of worst-case assumptions. Such information also must be in the record in case litigation becomes the only viable option.

4. Action Items For Manufacturers[20]

First, evaluate and monitor your business risks. Increasingly, environmental groups, the media, regulators, and the plaintiffs' bar allege that the mere presence of substances in products may cause personal injury (although most risk evaluations are based on exposure of test animals to high concentrations), and, therefore, should be removed from products. At a minimum, companies should confirm the inventory of chemicals used in their processes, identify the chemicals that EPA (or states in a few instances) is likely to regulate, and track EPA's implementation of the TSCA Amendments. Based upon that assessment, a determination can be made on whether, and to what degree, to get involved in the EPA implementation process.

Second, do not assume you can rely on chemical manufacturers. The interests of the chemical manufacturers and product manufacturers may be different. A product manufacturer that has cost-effective substitutes for high-priority substances in its products may prefer to avoid the considerable transaction costs of trying to convince EPA not to ban or restrict the use of a substance.

Also, many industry stakeholders argue correctly that if a risk evaluation is performed using hypothetical (*i.e.*, unrealistic) high end exposure and other assumptions, and this so called screening risk evaluation does not find an "unreasonable risk," then more detailed evaluations using lower (albeit more representative exposures) are not necessary. While this

[20] This article does not constitute legal advice. Consult an attorney for legal advice applicable to particular facts and circumstances.

kind of approach saves cost and should accelerate the risk evaluation process, it may have potential downsides. For example, some uses of "high-priority" substances in certain products may present a low-priority or *de minimis* risk. However, the federal preemption of duplicative state or local laws in the TSCA Amendments apply "only to …the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation."[21] The use of such a screening risk evaluation is unlikely to include the hazards, exposures, risks, and uses or conditions of use for these low risk uses. As a result, a product manufacturer may not be able to avail itself of the preemption protection intended by the TSCA Amendments.

On the other hand, if a screening risk evaluation exceeds the "unreasonable risk" exposure level, consumers, juries and even judges in litigation may misinterpret the meaning of the screening level and assume that EPA's regulatory designation as a "high-priority" substance means that the substance causes actual harm (in layman's terms) in any product. Either of these eventualities may adversely affect manufacturers that use even de minimis levels of these substances in their products.

Third, consider providing input on exposure issues. EPA's TSCA decisions will largely be a function of the worker, consumer, and postconsumer exposures related to the substances used in products. Generally, neither EPA, the chemical manufacturers, nor the public possess the quantum of exposure information necessary for a detailed risk evaluation of whether an "unreasonable risk" exists. Measurement protocols may not exist or existing

[21] 15 U.S.C. § 2617(c). The preemption provisions of the TSCA Amendments are some of the most complex provision in the statute. A detailed discussion of these provisions is beyond the scope of this article.

methods may be inappropriate for the product-specific risk assessment. It takes time and resources to develop the data necessary to enable EPA to calculate the regulatory risks. Given these difficulties, much of the critical exposure information may be more cost-effectively gathered voluntarily by manufacturers that use these substances in their products (as opposed to EPA).[22] Similarly, situated manufacturers also might consider sharing the costs of information gathering.

5. Conclusion

The TSCA Amendments enacted earlier this year have brought about significant changes, which may come as a surprise to manufacturers that were not involved in the legislative debates that took place over the course of several years. All manufacturers should examine the new requirements closely for business risks and prudent manufacturers also will seek potential new business opportunities.

[22] Manufacturers may wish to seek confidential business information (CBI) classification for information they submit to EPA, but should be aware that the Amendments have made CBI classifications more challenging. 15 U.S. Code § 2613(c)(2); and EPA, The Frank R. Lautenberg Chemical Safety for the 21st Century Act: Frequent Questions Q37 (last updated September 8, 2016), available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act-0#confidential.

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