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Practice Groups:

Environment, Land and Natural Resources

Global Government Solutions

Environmental Law Update: Comment Period for Three Proposed Toxic Substances Rules to Close in March

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Background

In June 2016, then-President Barack Obama signed into law the first major revisions to the 1976 Toxic Substances Control Act ("TSCA") in decades. The newly enacted Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act" or the "Act") overhauled the regulatory framework that governs chemical substances in the United States.[1]

This alert provides an overview of three proposed rules under the Lautenberg Act: the **Inventory Reset Rule**, **Chemical Prioritization Rule**, and **Risk Evaluation Rule** (each a "Rule"). The Environmental Protection Agency ("EPA") has submitted these three rules to the public for notice and comment. Comments regarding the Inventory Reset Rule must be received on or before March 14, 2017. Comments regarding the Chemical Prioritization Rule and Risk Evaluation Rule must be received on or before March 20, 2017.

While these three rules do not appear to be affected by the Trump administration's freeze on new regulations, the notice-and-comment schedule could be subject to change. Please check back for any future updates.

The Proposed Regulations

Inventory Reset Rule

Following the enactment of the original TSCA, EPA compiled and kept a list of chemical substances used in commerce since 1975. This list is known as the TSCA Chemical Substance Inventory, or simply the "TSCA Inventory." The Lautenberg Act requires that EPA designate chemical substances on the TSCA Inventory as either "active" or "inactive" in U.S. commerce. The proposed Inventory Reset Rule would fulfill the Lautenberg Act's mandate to update the TSCA Inventory and would have both retrospective and forward-looking application. The Inventory Reset Rule is especially relevant to manufacturers and importers of chemical substances that were listed on the TSCA Inventory between 2006 and 2016, as well as firms that are considering manufacturing, importing, or processing chemical substances presently listed as inactive. EPA estimates that, during the Rule's June 2017–

[1] For a more complete overview of the Lautenberg Act, please see our previous client alerts of June 28, 2016 [link: http://www.klgateshub.com/details/?pub=New-Toxic-Substances-Law-Will-Have-Far-Reaching-Impacts-on-American-Business-06-28-2016]; July 13, 2016 [link: http://www.klgateshub.com/details/?pub=Federal-Government-Rewrites-the-Rules-on-Getting-and-Using-Chemicals-in-the-Marketplace-07-13-2016]; July 28, 2016 [link: http://www.klgateshub.com/details/?pub=The-Most-Contentious-Issue--Federal-Preemption-in-the-Amended-Toxic-Substances-Control-Act-07-28-2016]; and August 29, 2016 [link: http://klgates.com/changes-to-confidential-business-information-disclosure-under-the-reformed-toxic-substances-control-act-08-29-2016/].

June 2018 "start-up" period, the average subject firm would see costs around $1,346 per submission (with an estimated seven chemicals per submission). Additionally, firms not currently registered in EPA's Central Data Exchange ("CDX") would see a cost of $40.22 per CDX registration.[2] EPA does not foresee significant costs of reporting under the Rule beyond the "start-up" period.

Under the **retrospective** component of the Rule, manufacturers would be required to notify EPA

> of each chemical substance on the TSCA Inventory that was manufactured for [a] nonexempt commercial purpose during the 10-year period ending on June 21, 2016. If EPA receives a valid notice for a chemical substance on the TSCA Inventory, EPA must designate that chemical substance as an active substance. If EPA receives no valid notice for a chemical substance on the TSCA Inventory (and that is subject to designation), EPA must designate that chemical substance as an inactive substance.[3]

Processors would not be required to report during the retrospective reporting period.

Under the **prospective** component of the Rule, anyone intending to manufacture or process a presently inactive substance for a nonexempt commercial purpose would be required to notify EPA beforehand. EPA would then change that substance's designation from inactive to active.

In this notice-and-comment period,

> EPA is proposing the procedures regarding the manner in which such retrospective and forward-looking activity notifications must be submitted, the details of the notification requirements, exemptions from such requirements, and procedures for handling claims of confidentiality.[4]

For further information on how to submit comments, see this link. [link to: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0426-0001] Comments must be received on or before March 14, 2017.

Chemical Prioritization Rule

Under the original TSCA, EPA was charged with administering a health-and-safety-review process for new chemicals before they entered the market.

> However, tens of thousands of chemical substances in existence at that time were "grandfathered in" with no requirement for EPA to ever evaluate their risks to health or the environment. The absence of a review requirement or deadlines for action, coupled with a burdensome statutory standard for taking risk management action on existing chemical substances, resulted in very few chemical substances ever being assessed for safety by EPA, and even fewer subject to restrictions to address identified risks.[5]

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[2] 82 Fed. Reg. at 4257.

[3] TSCA Inventory Notification (Active-Inactive) Requirements, 82 Fed. Reg. 4255-01, 4257 (proposed Jan. 13, 2017).

[4] *Id.* at 4255. For further information on how the Lautenberg Act changes the procedures regarding claims of confidential business information, please see our alert of August 29, 2016 [link: http://klgates.com/changes-to-confidential-business-information-disclosure-under-the-reformed-toxic-substances-control-act-08-29-2016/].

[5] Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 4825-01, 4826 (proposed Jan. 17, 2017).

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The Lautenberg Act requires EPA to develop a risk-based screening process and to designate chemical substances as either High-Priority Substances or Low-Priority Substances. The Act further specifies the process and criteria for designation, "including preferences for certain chemical substances that EPA must apply, the procedural steps, definitions of High-Priority Substances and Low-Priority Substances, and screening criteria that EPA must consider."

The Lautenberg Act defines a "High-Priority Substance" as one that,

> *without consideration of costs or other non-risk factors*, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by the [EPA] Administrator . . . .[6]

By contrast, a "Low-Priority Substance," as defined in the Act, is one that, "based on information sufficient to establish, *without consideration of costs or other non-risk factors*, does not meet the standard for designating a chemical substance a High-Priority Substance."[7]

The Chemical Prioritization Rule would create a four-phase process for designating a chemical substance as either High Priority or Low Priority:

1. Pre-Prioritization: EPA would apply the preferences enumerated in the Act, along with other criteria, "to narrow the pool of potential candidates, and identify a single chemical substance (or category of chemical substances) to screen against the statutory criteria."
2. Initiation: EPA would "announce a candidate chemical substance and give the public a 90-day comment period to submit relevant information."
3. Proposed Designation: EPA would "propose to designate a chemical substance as either a High-Priority Substance or a Low-Priority Substance, publish the proposed designation and the information, analysis, and basis used to make the designation, and take public comment a second time for 90 days."
4. Final Designation: EPA would then "either finalize a High-Priority Substance designation and initiate a risk evaluation, or finalize a Low-Priority Substance designation." In the event of a Low-Priority designation, EPA would not conduct a risk evaluation on the chemical substance unless and until information gave EPA reason to revisit that priority designation.[8]

For further information on how to submit comments, see this link. [link to: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0636-0001] Comments must be received on or before March 20, 2017.

Risk Evaluation Rule

The Lautenberg Act also requires EPA to establish a process for conducting risk evaluations of certain chemicals. These evaluations must "determine whether a chemical substance

[6] *Id.* (citing 15 U.S.C. § 2605(b)(1)(B)(i)) (emphasis added).
[7] *Id.* (citing 15 U.S.C. § 2605(b)(1)(B)(ii)) (emphasis added).
[8] *Id.*

presents an unreasonable risk of injury to health or the environment, *without consideration of costs or other non-risk factors*, including an unreasonable risk to a potentially exposed or susceptible subpopulation . . . ."[9]

The chemical substances subject to the risk evaluation process are:

1. Ten chemical substances identified from the 2014 update to the TSCA Work Plan;
2. High-Priority Substances;
3. Requested chemicals submitted by manufacturers for a risk evaluation.[10]

The proposed Risk Evaluation Rule would identify the steps of the risk evaluation process, including:

1. Scope: EPA would "identify the conditions of use, hazards, exposures, and any potentially exposed or susceptible subpopulations that the EPA expects to consider."[11]
2. Hazard Assessment: EPA would identify "the types of adverse health or environmental effects that can be caused by exposure to some agent in question, and to characterize the quality and weight of evidence supporting this identification."[12]
3. Exposure Assessment: EPA would "take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure assessment."[13]
4. Risk Characterization: This "conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made." It would take place "for both human health risk assessments and ecological risk assessments."[14]
5. Risk Determination: Finally, EPA would determine whether a substance presents an unreasonable risk of injury to health or the environment. If EPA finds that the substance "does not present an unreasonable risk of injury to health or the environment under the conditions of use[,]" this determination "will be issued by order, published in the Federal Register, and considered to be a final EPA action. Alternatively, the EPA may determine that the substance does present an unreasonable risk under one or more conditions of use, in which case EPA must . . . impose requirements to the extent necessary so that the substance no longer presents such risk."[15]

[9] Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 7562-01, 7563 (proposed Jan. 19, 2017) (citing 15 U.S.C. § 2605(b)(4)(A)) (emphasis added).
[10] *Id.*
[11] *Id.* at 7570.
[12] *Id.*
[13] *Id.* at 7571.
[14] *Id.*
[15] *Id.* at 7572.

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For further information on how to submit comments, see this link. [link to: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0654-0001] Comments must be received on or before March 20, 2017.

Conclusion

With its proposed Inventory Reset Rule, Chemical Prioritization Rule, and Risk Evaluation Rule, EPA is taking key steps in implementing the first major changes to TSCA in decades. The regulated community now has an opportunity to weigh in on these important proposed changes ahead of the coming March deadlines.

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