JULY 2016

COMMENTARY

Key Changes in TSCA Reform Legislation

After years of efforts aimed at updating the Toxic Substances Control Act[1] ("TSCA"), the Frank R. Lautenberg Chemical Safety for the 21st Century Act[2] ("Act") was signed into law on June 22, 2016. Chemical manufacturers and processors should begin to plan what internal policy changes will be required in order to conform to the Act and anticipated amended regulations. This *Commentary* flags several key changes to TSCA set forth in the Act.

Newly Defined Terms

Two important defined terms were added, which the U.S. Environmental Protection Agency ("EPA" or "Agency") will use throughout the risk evaluation process of new and existing chemicals:

- "Conditions of use" are "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."[3]
- A "potentially exposed or susceptible subpopulation" is a "group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly."[4]

The risk evaluation process is discussed further below.

Broader EPA Authority to Require Information, Address Risks, and Limit Vertebrate Testing

The Act revises § 4 of TSCA to grant additional, flexible authority to EPA that allows the Agency to require the development of new information relating to a chemical substance, including information needed to prioritize chemicals and to perform risk evaluations. When utilizing this new authority, EPA must explain its reasoning behind the request for new information.

Additionally, the Act expands the scope of TSCA § 4(f), which requires EPA to take swift action when information becomes available that indicates that a chemical presents a significant risk of serious or widespread harm to humans. Previously, this provision was limited only to significant risks involving cancer, gene mutations, and birth defects, but this limitation has been removed. The Act also clarifies that EPA may not consider cost or other non-risk factors in determining that a risk is not unreasonable.

The Act also adds a new TSCA section, 4(h), which directs EPA to focus on reducing and replacing vertebrate animal testing. Within two years, EPA must develop a strategic plan to promote the development of alternative testing methods.

Strengthened Approach to Evaluating New Chemicals and Uses

The Act strengthens the general approach of TSCA § 5. It explicitly requires manufacturers and processers to submit premanufacture notices to EPA 90 days before beginning to manufacture or process the chemical substance. EPA must then review all new chemicals and significant new uses ("SNU"), make a determination, and take required action during that 90-day window. During the review process, EPA is required to consider "potentially exposed or susceptible populations" and "conditions of use." EPA may not consider cost or other non-risk factors.

There are three alternative determinations EPA may make under the Act:

1. **Unreasonable risk of injury to health or the environment**: If this is the case, EPA is required to take action pursuant to § (5)(f) and must also promulgate a Significant New Use Rule ("SNUR").
2. **Absence of sufficient information or production in substantial quantities resulting in substantial exposure to humans or the environment**: EPA is required to issue an order under § 5(e) and promulgate a SNUR if: (i) EPA has insufficient information to permit a reasoned evaluation of the chemical; or (ii) in the absence of sufficient information, the substance may present an unreasonable risk; or (iii) the substance is or will be produced in substantial quantities, and it enters or is anticipated to enter the environment in substantial quantities or there is or may be significant human exposure.
3. **Not likely to present an unreasonable risk**: If this is the case, manufacture or processing of the chemical may commence. Also, EPA is required to publish a statement regarding its finding in the *Federal Register*.

If EPA fails to make a determination by the end of the applicable review period, the Agency is required to refund all fees to the submitter. Notably, the Act resets the 90-day review period for premanufacture notices submitted before the Act was signed into law.

Evaluation of Existing Chemicals

The Act significantly revises TSCA § 6 by adding prioritization and risk evaluation steps for existing chemicals, deleting the "least burdensome requirement" language, and including timelines for completion of the key steps in the process.

Prioritization. Within one year, EPA must create a risk-based screening process for designating chemicals as either high or low priority that includes considerations such as hazard and exposure potential, "conditions of use," and storage near significant sources of drinking water. High-priority chemicals are those that "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 a potentially exposed or susceptible subpopulation."[5] Low-priority chemicals are those that do not meet the standard for a high-priority designation.

Risk Evaluation. Designating a chemical as a high-priority substance triggers the risk evaluation process. The Act requires EPA to have 10 ongoing risk evaluations within 180 days and 20 ongoing risk evaluations within three-and-a-half years.

Within six months after initiating the risk evaluation process, EPA must publish the scope of its intended risk evaluation. The purpose of the risk evaluation is to determine whether a chemical presents an unreasonable risk, without considering cost or other non-risk factors, under the conditions of use. If EPA concludes it does present an unreasonable risk, the chemical will be moved into the risk management process.

Manufacturers may specifically request a risk evaluation for a particular chemical substance. If the chemical substance is on the 2014 update to the TSCA Work Plan for Chemical Assessments, then the manufacturer will be required to pay a fee sufficient to cover 50 percent of the cost of the risk evaluation. If not, then the manufacturer must pay 100 percent of the cost of the risk evaluation.

Risk Management. If EPA determines that a chemical substance presents an unreasonable risk, it must propose a rule

under TSCA § 6(a) within one year and publish a final rule within two years. When promulgating a rule under § 6(a), EPA is required to consider and publish a statement based on available information concerning:

- Effects and magnitude of exposure;
- Benefits of the chemical;
- Reasonably ascertainable economic consequences of the rule; and
- Availability of technically and economically feasible alternatives.

The Act provides for certain limitations and exemptions from § 6(a) rules, including:

- An exemption for replacement parts for complex durable and consumer goods;
- Restrictions on chemical substances contained in articles must be implemented only to the extent necessary so that the substance no longer presents an unreasonable risk; and
- Exemptions granted by EPA by rule when it is found that: (i) the use is critical or essential with no technically and economically feasible alternative; (ii) compliance would significantly disrupt the national economy; or (iii) the specific condition of use provides a substantial benefit to health, the environment, or public safety when compared to reasonably available alternatives.

Throughout the process, EPA decisions based on science must use information, technical procedures, and methodologies employed in a manner consistent with the best available science.

Limits on Protections for Confidential Business Information

The Act completely revises and amends TSCA § 14 regarding confidential business information. Non-protected information includes the following:

- General information describing manufacturing volumes (expressed in either aggregated volumes or ranges);
- General descriptions of the process used to manufacture or process a chemical substance or the industrial, consumer, or commercial functions of a chemical substance, mixture, or article containing a chemical substance or mixture; and
- Previously protected information regarding a chemical substance or mixture that is later banned.

With respect to information about later-banned chemicals, manufacturers and processors can protect themselves against disclosure by submitting to EPA, within 30 days of receiving notice of the chemical's ban, a request that explains why some or all of the information should not be disclosed or its disclosure should be delayed.

When making a confidentiality claim for information that may be protected under the Act, the applicant must submit a statement that asserts: (i) the person has taken reasonable steps to protect the information; (ii) the information is not required to be disclosed under federal law; (iii) the information's disclosure will cause substantial harm to the applicant's competitive standing; and (iv) the information is not readily discoverable through reverse engineering. The applicant must also have a generic name for the chemical substance that can be disclosed to the public and be able to describe the chemical's structure without disclosing any claimed confidential information or harming any competitive standing. If a manufacturer's or processor's request for confidentiality is denied, the company or individual can appeal the decision in the U.S. District Court for the District of Columbia or a U.S. district court where the company or individual resides or has its principal place of business.

In general, if EPA approves a claim of confidentiality, the information will be protected from disclosure for 10 years unless: (i) the manufacturer or processor notifies EPA that it is withdrawing the confidentiality claim; or (ii) EPA becomes aware that the information does not qualify for protection from disclosure.

EPA must notify the person who made the confidentiality claim at least 60 days before the expiration of the 10-year protection period. If the person wants to maintain the confidentiality of the information, he or she must resubstantiate the claim at least 30 days before the expiration date. EPA may require reassertion/resubstantiation of a confidentiality claim sooner than the standard 10 years if: (i) the chemical substance is designated high priority under TSCA § 6; (ii) a

chemical is moving from EPA's inactive substance list under the Act to its active substance list; or (iii) the protected information is important to assist EPA in conducting risk evaluations or promulgating rules under TSCA § 6.

The following types of information, however, are not generally subject to the substantiation requirements: (i) specific information on the manufacturing or processing of a chemical substance; (ii) marketing or sales information; (iii) information that identifies the customer or supplier; (iv) the specific composition of a chemical mixture; (v) the function of a chemical substance in a process, mixture, or article; (vi) the production or import volumes of a manufacturer or processor; and (vii) the specific chemical identity of the chemical substance prior to the date on which it is first offered for commercial distribution.

Even if EPA agrees with a particular confidentiality claim, the Act adds more individuals and organizations to the list of who can be privy to confidential information that is otherwise protected from disclosure, including: (i) a state or tribal government that seeks the information to enforce the law; (ii) a health or environmental professional employed by a federal or state agency if there is a written statement of need; and (iii) in the event of an emergency, a treating or responding physician, nurse, or other public health official. Any individual who can be privy to confidential information under the Act is subject to a $5,000 fine or up to one year's imprisonment, or both, for wrongful disclosure of protected information to individuals not entitled to it.

Establishment of New Fund and Fee Structure

The Act amends § 26 of TSCA to establish a TSCA Service Fee Fund and directs EPA to promulgate a rule to collect fees of up to $25,000,000 annually to cover the costs of EPA's work under TSCA, such as reviewing premanufacture notices and performing risk evaluations. EPA's goal is to establish a final rule setting out the TSCA fee structure by June 2017.

Increased Penalties

The Act increases penalties for violations of TSCA §§ 15 and 409. Civil penalties are now $37,500 per violation per day, instead of $25,000. Criminal violations are now subject to a fine of $50,000 per violation per day, instead of $25,000. Additionally, the Act adds a section on imminent danger of death or serious bodily injury. A person who knowingly or willfully violates § 15 or 409 and knows that the violation will put another individual in imminent danger of death or serious bodily injury can be subject to fines up to $250,000, a prison sentence of no more than 15 years, or both. In the event that an organization commits such a knowing violation, it can be fined up to $1 million per violation.

Limited Preemption of State Laws

Section 13 of the Act (revising TSCA § 18) limits states' power to establish laws or regulations that:

- Address development of information about a chemical substance already regulated by EPA;
- Restrict the development of a chemical substance that EPA has determined does not pose an unreasonable risk;
- Impose new use notification requirements for chemical substances already subject to federal notification requirements; or
- Impose penalties more stringent than the penalties imposed under TSCA for identical requirements.

States continue to have the authority to:

- Enforce state laws and regulations enacted before April 22, 2016;
- Continue with actions taken pursuant to state laws in effect on August 31, 2003;
- Implement reporting, monitoring, or information obligations not otherwise required under federal law;
- Enact state laws and regulations related to water quality, air quality, or waste treatment or disposal, as long as they do not impose restrictions covered by TSCA; and
- Co-enforce laws or regulations identical to federal laws or regulations.

In addition, a state may apply for an exemption to preemption.

Discretionary Exemptions. EPA may grant an exemption if: (i) compelling conditions warrant granting the exemption in order to protect health or the environment; (ii) the state requirement would not unduly burden interstate commerce;

(iii) compliance with the state requirement would not violate any applicable federal law; and (iv) the state requirement is designed to address a risk identified consistent with the best available science, using supporting studies conducted using sound scientific practices and based on the weight of the scientific evidence.

EPA must make a determination on discretionary exemption requests within 180 days of when the application for exemption is submitted.

Mandatory Exemptions. EPA must grant an exemption if the state requirement: (i) would not be unduly burdensome to interstate commerce; would not be in violation of any federal law, rule, or order; and addresses a concern based on peer-reviewed science; or (ii) was enacted to prohibit or restrict the manufacture, processing, distribution, or use of a chemical substance within 18 months of the date EPA initiated the prioritization process for the chemical substance or published the scope of the risk evaluation, whichever is sooner.

EPA must make determinations on mandatory exemption applications within 110 days after the application is filed.

Mercury Inventory and Amended Ban on Mercury Exports

Section 8 of the Act requires EPA to publish an inventory of mercury supply, use, and trade in the United States no later than April 1, 2017, and every three years thereafter. To assist in the preparation of this inventory, every person who manufactures mercury or mercury-added products or uses mercury in a manufacturing process will be required to make periodic reports to EPA. EPA has two years to promulgate a rule setting forth the requirements for these periodic reports.

Section 10 of the Act outlines the types of elemental mercury that have been added to the list of prohibited mercury exports. Beginning January 1, 2020, no U.S.-based individual or business can export any of the following mercury compounds: mercury chloride or calomel, mercury oxide, mercury sulfate, mercury nitrate, cinnabar or mercury sulphide, and any other mercury compound that EPA subsequently adds to the list. Within 90 days after the Act takes effect, EPA must publish in the *Federal Register* a list of the mercury types prohibited from export and can subsequently update the list.

The one exception to the mercury ban rule will be individuals or companies that export mercury compounds to countries that are members of the Organization for Economic Co-operation and Development for environmentally sound disposal, as long as the mercury or mercury compound will not later be recovered, recycled, or reclaimed for use or direct reuse.

Within five years of the Act's enactment, EPA must draft a report to submit to Congress on all mercury or mercury compounds that are exported for disposal that makes a recommendation on whether Congress should limit or prohibit the mercury's export for disposal.

New Regulations Forthcoming

As can be seen from the above, EPA will be promulgating a host of new regulations to comply with the Act. Companies should monitor these developments and comment on proposed regulations as necessary.

Lawyer Contacts

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com/contactus/.

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Endnotes

1 15 U.S.C. § 2601 *et seq.*

2 H.R. 2576, 114th Cong.

3 *Id.* § 3(2).

4 *Id.* § 3(4)

5 *Id.* § 6(3).