An engagement guide for
The Frank R. Lautenberg Chemical Safety for the 21st Century Act
September 2016

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act was signed in to law. This is the first major overhaul of the law governing most chemicals used in everyday products in our homes, stores, and workplaces.[1] Now that the law has passed, the Environmental Protection Agency (EPA) has begun to implement it. Now and going forward, there are numerous opportunities for organizations and states to help shape or weigh in on the decisions being made by EPA. These decisions will be key to the success of the new law. The following is an overview of some of the key provisions in the Lautenberg Act and associated opportunities for engagement.

Safety Standard and Vulnerable Subpopulations

The old TSCA's safety standard included paralyzing cost-related regulatory burdens that prevented EPA from regulating even the worst chemicals. Under the Lautenberg Act,

[1] The Lautenberg Act amends the Toxic Substances Control Act, or TSCA. Certain chemicals used in consumer products fall outside of TSCA's jurisdiction; excluded are: 1) chemicals used in personal care products and cosmetics, food and food packaging, and drugs (all of which are regulated by FDA under different laws), and 2) pesticides (regulated by EPA but under a different law).

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decisions on whether a chemical presents an unreasonable risk to human health and the environment and should be regulated are to be based solely on those risks presented to human health and the environment and not on any other factors such as cost.

Importantly, for the first time, potential risks to vulnerable subpopulations are required to be considered in these health-based decisions for both new and existing chemicals, and restrictions imposed on chemicals must be sufficient to protect these subpopulations. A vulnerable subpopulation is defined as one that is "potentially exposed or susceptible" because of "either greater susceptibility or greater exposure" to risk and includes infants, children, pregnant women, workers, or the elderly, among others.

Consideration of vulnerable subpopulations will be required both in EPA's prioritization of chemicals and in its conduct of risk evaluations for those found to be high-priority. EPA is to develop rules governing each of these processes, which are discussed further below and offer engagement opportunities for those stakeholders with interests and expertise on particular subpopulations; see **Prioritization** and **Risk Evaluation** sections below. In addition, EPA is to establish an advisory committee with particular expertise on risk to vulnerable populations; see more on this committee immediately below.

Science Advisory Committee on Chemicals

Under the Lautenberg Act, within one year of enactment, EPA is directed to create a new advisory panel, known as the Science Advisory Committee on Chemicals (SACC) to provide EPA with expert input on the scientific and technical aspects of implementation of the law.

According to the Act, the committee is to include stakeholder representatives, "including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations."

Engagement Opportunities

EPA has published in the August 26 *Federal Register* a notice calling for nominations for five new board members to "provide advice and recommendations on the scientific basis for risk assessments, methodologies, and pollution prevention measures or approaches." Nominations will be accepted until October 11, 2016.

Prioritizing Chemicals in Use

There are approximately 85,000 chemicals on the TSCA inventory. The number of chemicals actually in active commerce is likely far smaller, and this number will become clear as the "reset" of the inventory called for under the new law takes place over the next few years.

EPA now has a mandate, under the new law, to review the risks posed by chemicals on the inventory that are in active commerce. Over time, EPA will be required to establish the priority (high or low) of all of these chemicals.

High-priority chemicals are those EPA determines may present an unreasonable risk, and they will undergo full risk evaluations against a health-based safety standard.

Low-priority chemicals are those EPA concludes have sufficient information (which EPA must identify) to establish that they are not high-priority substances.

Engagement opportunities:

Prioritization Process Rule: In December (6 months after enactment), EPA plans to propose a rule establishing a risk-based prioritization process, including criteria for designating chemical substances as high-priority substances or low-priority substances.

EPA held stakeholder meetings and solicited written comments during August. The next formal opportunity for stakeholders to engage with EPA will come when the rule is proposed for public comment (expected in December). The rule is expected to be finalized in June 2017.

Specific chemical prioritization decisions: Once EPA finalizes its prioritization process rule and begins prioritizing specific chemicals, the public will have several opportunities to weigh in.

First, EPA is to identify chemicals to undergo the prioritization process and provide 90 days for persons with relevant information to submit it to EPA. Second, once EPA proposes designating a chemical as a high or low priority, there will also be a 90-day comment period on the proposed designation.

Low-priority designations are judicially challengeable through civil action brought within 60 days of the designation. This might be pursued where an individual or group has a concern that a chemical should not have been designated low-priority and should undergo a full risk evaluation. Finally, a low-priority designation can be changed where new information about a chemical is brought to EPA's attention, which can be provided by any person or group.

Risk Evaluations of Existing Chemicals Deemed High-Priority

Under the Lautenberg Act, the main review of a chemical for safety is the risk evaluation. As noted above, high-priority chemicals will undergo full risk evaluations against a health-based safety standard. Within 6 months of prioritizing a chemical as high, EPA is to publish the scope of the risk evaluation to be conducted, identifying the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations the Administrator expects to consider. EPA then has three years, with a possible extension of six months, to finish the risk evaluation and make a final determination as to whether the chemical is safe

or the chemical is not and needs to be regulated. For any chemical found to present an unreasonable risk, EPA must either ban or phase it out, or impose restrictions sufficient for the chemical to no longer present such risk.

In each risk evaluation, EPA is expressly directed to identify and assess risks to vulnerable subpopulations. The Administrator will first determine which vulnerable subpopulations may be at risk from potential exposures to a specific chemical.

Engagement opportunities:

Risk Evaluation Process Rule: In December (6 months after enactment), EPA plans to propose a rule establishing the process it will use to conduct risk evaluations, including the criteria and process it will use to identify and assess risks to vulnerable subpopulations.

EPA held stakeholder meetings and solicited written comments during August on its risk evaluation process rule. The next formal opportunity for stakeholders to engage with EPA will come when the rule is proposed for public comment (expected in December). The rule is expected to be finalized in June 2017.

Specific chemical risk evaluations: Once EPA finalizes its risk evaluation rule and begins conducting risk evaluations on specific chemicals, the public will have several opportunities to weigh in.

While not specifically required by the law, we and other stakeholders are urging that EPA solicit public comments on the scope of each risk evaluation it conducts. Comments provided on each individual chemical will be important to ensure that EPA fully evaluates the potential risks of that chemical.

In addition, drafts of EPA risk evaluations are to be made available and provide at least 30 days for public comment, and those comments are to be considered by EPA in finalizing the risk evaluation.

As noted above, where a risk evaluation finds a chemical presents an unreasonable risk, EPA must either ban or phase it out, or impose restrictions sufficient for the chemical to no longer present such risk. In contrast, a final determination that a chemical does not present an unreasonable risk does not require any further action by EPA. However, such no-unreasonable-risk determinations are judicially challengeable. This might be pursued where an individual or group has a concern that EPA should not have determined that a chemical does not present an unreasonable risk.

First Chemicals to be Reviewed

Within six months of enactment, EPA must identify and be conducting risk evaluations for 10 chemicals drawn from its Work Plan. These chemicals do not need to be formally prioritized and the risk evaluations can proceed even before the risk evaluation process rule is finished.

Engagement opportunities:
EPA will look to its existing Work Plan chemicals in order to choose the first 10 chemicals to undergo full risk evaluations. Which of the Work Plan chemicals are chosen, will depend, at least in part, on informal input EPA receives from interested parties. Although there is no formal comment process, stakeholders can weigh in now with the agency to make their preferences known as to which chemicals should be named first, which EPA is expected to announce by December.

Restrictions on Chemicals that Present an Unreasonable Risk

Under the Lautenberg Act, whenever EPA makes a final determination that a chemical presents an unreasonable risk, EPA must develop a rule to either ban or phase out the chemical, or to impose restrictions sufficient for the chemical to no longer present such risk, including any identified risk to a vulnerable population.

EPA is to propose a risk management rule within 1 year of publishing a final risk evaluation that finds a chemical presents an unreasonable risk, and is to finalize that rule generally within another year. Extensions of up to two additional years are provided for where justified.

Engagement opportunities:
EPA must publish each proposed risk management rule for public comment. Once a rule is finalized, the rule and the underlying risk evaluation are judicially challengeable. This might be pursued where an individual or group has a concern that EPA's risk management rule is not sufficient to address the identified risks of a chemical, either to the general public or to particular subpopulations.

New Chemicals Entering the Market

Approximately 700 new chemicals come on the market ever year. Unlike the old law, under the Lautenberg Act, chemicals must receive a safety finding from EPA before they can enter the market. Specifically, before a new chemical can be made and sold, EPA must determine that the chemical is "not likely to present an unreasonable risk," i.e., that it would likely be found safe in a full risk assessment. If a new chemical: 1) does not meet the safety bar, 2) lacks information sufficient for EPA to determine that it does so, or 3) will be produced in large amounts and lead to large releases or exposures, it will not be allowed on the market unless EPA imposes restrictions on the chemical to the extent necessary to ensure that it is not likely to present an unreasonable risk.

Engagement opportunities: EPA is publishing its decisions on each new chemical and summaries of the basis for them. Stakeholders can now readily access this information. Information about new chemicals will be available to the public unless it is claimed and determined to qualify as confidential business information (CBI). There are new limitations

on CBI claims, however, (see **Transparency** section below) that mean more information will be publicly available.

Even where information on new chemicals is CBI, state officials will be able to access it. There is no longer any preemption of state activity based on EPA decisions on new chemicals, so states can use this information to decide whether any actions by the state are warranted; such actions could range from reporting, assessment or monitoring requirements to direct restrictions.

Transparency and Information Access

The Lautenberg Act requires EPA to review most claims of Confidential Business Information (CBI) and approve or deny those claims. Most CBI claims are required to be substantiated and expire after 10 years unless re-substantiated. The Act lays out certain information that is presumed CBI and other information, such as chemical identity in a health and safety study, that is presumed to be or must be made public.

For the first time, CBI is to be shared with state, local and tribal governments, health and environmental professionals and first responders, subject to confidentiality agreements and, in the latter cases, statements of need.

<u>Engagement opportunities</u>
EPA is to develop guidance delineating the nature of the statements of need and confidentiality agreements required for CBI disclosures. That guidance is to be subject to public comment, so there is an opportunity for interested groups to provide input to EPA to help shape that guidance and comment on it once a draft is issued.

A new requirement of the Lautenberg Act is for EPA, in consultation with the Centers for Disease Control and Prevention, to "develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed" for government health and environmental professionals or treating physicians or nurses and first responders. The manner and form in which information is shared, and the speed with which this system is put in place, could have significant implications for the availability of needed information. This is not one of the actions that EPA has put on its first-year implementation calendar, but groups affected by this provision can urge EPA to move quickly to develop it and provide input on how the system should work.

For groups working with states, CBI can be an important source of information on chemicals within a state's borders. In addition, the limiting of unsubstantiated CBI claims and the expiration of CBI claims not renewed will mean significantly more information should become available to researchers and the public about existing chemicals. Working with EPA to ensure and facilitate access to such information, as provided under the new law, is an important near-term engagement opportunity.

Legal Recourses

There are a number of deadlines contained in the new law intended to make sure that chemicals are being prioritized, evaluated and regulated at an appropriate pace. For instance, EPA must be conducting risk evaluations on at least 20 high-priority chemicals, and must have named at least 20 low-priority chemicals, within 3.5 years of enactment of the law. Deadlines, discussed above, govern each step of the prioritization, risk evaluation and risk management process.

As noted earlier, many EPA decisions under the law are considered final agency actions that are judicially challengeable.

Engagement opportunities:
The deadlines laid out in the law are judicially enforceable. EPA is required to meet them and can be sued if it doesn't.

As previously noted, persons or groups disagreeing with final EPA actions can sue EPA to seek judicial remedy.

Finally, citizens can bring civil actions to compel EPA to undertake any action that is mandatory under the law, should EPA have failed to do so.

(See also the discussion of waivers under **Preemption** below.)

Preemption of State Authority

Under the Lautenberg Act, if a chemical is undergoing a risk evaluation or has been found to be either safe or has been regulated, there is some preemption of new or existing state restrictions on that specific chemical – but only for uses and risks included in the scope of EPA's consideration of the chemical. For instance, if EPA acts on a chemical but doesn't look at a particular use, that use can be restricted by a state. State actions taken prior to April 22, 2016, are grandfathered in, as are both past and future actions taken under California's Proposition 65 and Massachusetts' Toxics Use Reduction Act.

While there can be preemption of new state restrictions during a risk evaluation, that preemption lifts if EPA misses its deadline to complete the risk evaluation or, if EPA finds a chemical presents an unreasonable risk, until the mandated regulations are put in place.

For more information on what is and is not preempted under the Lautenberg Act, see this summary.

Engagement Opportunities:
There are a number of ways that states can continue to act under the Lautenberg Act even while EPA is conducting a risk evaluation or once it has made a final determination on a chemical's safety and has regulated that chemical as necessary. Only direct restrictions on chemical production and use are potentially preempted, and not state requirements

imposing reporting, monitoring, or other information-related obligations. Decisions EPA makes on chemicals reviewed under the New Chemicals program are not preemptive, so states can act on those chemicals coming on to the market until and unless EPA takes them up and undertakes risk evaluations of them as existing chemicals. In addition, states can act on any chemical EPA has not taken up for review or has designated low-priority.

States can readily get a waiver to act during the risk evaluation (the period during which so-called "pause preemption" applies). In addition, administrative actions to restrict a chemical initiated by a state prior to EPA's initiation of the risk evaluation can be completed pursuant to a waiver. If EPA doesn't decide on a state waiver application before the applicable deadline, the waiver is automatically approved.

After EPA takes its final action on a chemical, either declaring it safe or restricting it, it is harder for a state to get a waiver. But, there are conditions laid out for obtaining one, and there is a mandate and deadline for EPA to decide on any waiver request. A state or any other person can challenge EPA in court for failure to decide on any waiver request, or challenge its decision to grant or deny a waiver; hence, a state or another person can sue to force a decision on a waiver or seek reversal of a waiver denial.