ANALYSIS OF SIGNIFICANT CHANGES TO THE TOXIC SUBSTANCES CONTROL ACT (TSCA)

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On June 22, 2016, President Obama signed into law the Frank R. Launtenberg Chemical Safety for the 21st Century Act, the first significant changes to the primary chemical control law in the U.S. since it was enacted in 1976.
The Frank R. Launtenberg Chemical Safety Act for the 21st Century is the first substantive amendment to the Toxic Substances Control Act (TSCA) since the statute’s enactment in 1976. The bi-partisan legislation makes fundamental changes in the Environmental Protection Agency’s (EPA or Agency) approach to chemical management by amending provisions of TSCA, including definitions, testing, review and regulation of new and existing chemicals, information reporting, confidential business information, state preemption, and fees. EPA also is provided with a number of new authorities and mandates.

EPA will face numerous challenges in implementing the new TSCA program, including meeting statutorily-set deadlines, needing congressional appropriations and drafting new regulations, policies, and procedures. While the new law was the result of bi-partisan efforts and compromise over an extended period of time, it remains to be seen how long a honeymoon period EPA will be given by Congress, states, industry, public health advocates and other stakeholders.

Because of the vastly changed TSCA landscape and because ILMA members manufacture, use, process, import, export, or sell products containing chemicals, we have prepared this analysis so that ILMA members can become familiar with the new regulatory regime. Please contact us (jleiter@bmalaw.net; dbryant@bmalaw.net) if you have any questions.

I. EXECUTIVE SUMMARY

Stripped to the “bare bones,” the new law makes six key changes to EPA’s TSCA program:

1. **TSCA Inventory Reset**: Within the first year after enactment, EPA must develop a rule for resetting the TSCA Inventory. The intent is for EPA, using industry-supplied data, to maintain a real-time inventory of all chemicals in active commerce in the U.S.

2. **Screening and Prioritization Process**: All chemicals on the updated, active TSCA Inventory will undergo a risk prioritization process and EPA will designate chemicals as “high priority” or “low priority.”

3. **Risk Evaluation and Risk Management**: “High priority” chemicals will be subject to risk evaluations. EPA will establish the scope of uses and exposures to consider, and the Agency can order testing or the generation of new information. Based on the risk evaluation, EPA can ban a chemical or implement other risk management measures, such as restrictions or specific labeling. EPA also can perform risk evaluations on chemicals nominated by manufacturers and funded by industry.

4. **Order Authority**: EPA will now be able to compel testing or submission of information on a chemical through an order or consent agreement, rather than by a rule, under a legal standard that has been significantly lowered.

5. **Confidential Business Information**: Confidential business information (CBI) claims for information submitted to EPA will have to be asserted and substantiated up front, as well as reasserted and re-substantiated on a periodic basis.

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1 President Obama signed the legislation into law on June 22, 2016. The implementation dates discussed in this alert all will be timed from this June 22 enactment date.
(6) Preemption of New State and Local Laws/Regulations: State and local laws and regulations that were in effect as of August 31, 2003, or actions taken or started on a specific chemical before April 22, 2016, will not be preempted by subsequent actions by EPA; however, other laws and regulations will be preempted under certain circumstances.

Despite the difficulty in predicting how EPA will implement the new TSCA program, there are certain steps we recommend ILMA members take to prepare for the changes that are coming:

1. Ascertain those products that contain chemical components that are likely to become “high priority” targets for EPA-required risk evaluations. Consider whether there are alternatives if customers begin deselecting products if they learn that EPA is commencing a risk evaluation for that chemical component.

2. Confirm the chemical nomenclature for the chemical components used in the products. Because EPA will reset the TSCA Inventory for those chemicals in active commerce, there will be increased scrutiny of Chemical Abstract Service (CAS) numbers and names.

3. Because certain states do not want to see their ability to regulate certain chemicals diminished, it remains important to monitor state-level developments.

4. Review any existing CBI claims, as EPA will require them to be asserted and substantiated up front and then those claims must be reasserted and re-substantiated.

The following are key deadline dates for EPA actions set forth in the new law:

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<th>Key Provision</th>
<th>Deadline</th>
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<td>EPA must undertake risk evaluations on ten TSCA Work Plan Chemicals.</td>
<td>December 2016</td>
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<td>EPA must publish its inventory reset rule.</td>
<td>June 2017</td>
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<td>EPA must establish its risk-based screening process for high and low-priority chemicals.</td>
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<td>EPA must develop guidance for manufacturers to conduct and submit risk evaluations.</td>
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<td>EPA must establish a Science Advisory Committee on chemicals.</td>
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<td>EPA must develop its policies and procedures for implementation of the law.</td>
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<td>EPA must decide whether to revise its standards for “small businesses.”</td>
<td>December 2018</td>
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The following section analyzes key provisions in the new law of importance to ILMA members. The discussion follows the order of TSCA.

II. Key Provisions of the Bill

A. Section 4 — Testing

The new law gives EPA additional authority to require testing of chemicals and mixtures through orders and consent agreements if the Agency determines that additional information is needed in a particular situation (e.g., to review a pre-manufacture notice (PMN) submitted for a new chemical under Section 5).\(^2\) EPA previously had to go through a formal notice-and-comment rulemaking — a test rule — to require additional testing by companies. EPA, however, does retain the flexibility under the new law to issue test rules.

EPA must explain the basis for its action in using orders and consent agreements. The testing requirement implores EPA to reduce, to the extent it is able to, the use of vertebrate animals and to implement alternatives for chemical testing. Additionally, EPA is instructed to develop a plan to implement alternative test methods within two years of enactment. Further, EPA must submit a “progress report” to Congress every five years that outlines the various steps the Agency has taken and will take to further implement alternative test methods.

As a result of EPA’s new ability to require testing via administrative orders, ILMA members should anticipate the Agency requiring new test data for human health and environmental effects for both “new” chemicals submitted under Section 5 and “existing” chemicals under Section 6.

B. Section 5 — New Chemicals

While the new law maintains the requirement that a PMN be submitted for a “new chemical” at least 90 days before commencement of manufacture or processing, the revised Section 5 now requires EPA to make a determination that the chemical presents or will present an unreasonable risk of injury to human health or the environment, that the Agency has insufficient information to make such a determination, or that the chemical is not likely to present an unreasonable risk.

If EPA determines that a new chemical poses an unreasonable risk of injury to human health or the environment, the new law instructs that the Agency “shall consider” whether to regulate that chemical by proposing a Significant New Use Rule (SNUR). If EPA elects not to proceed with a SNUR, the Agency is required to publish a statement that articulates the reasons why it declined to do so.

If EPA concludes that a new chemical is not likely to present an unreasonable risk to human health or the environment, the Agency must publish its findings/conclusions in the Federal Register as soon as possible once that final determination is made.

Unlike the prior law, EPA must make an affirmative decision on a chemical substance and cannot simply allow the 90-day review period to expire without making one of the three above-outlined determinations.\(^3\) Importantly, the new law does not allow the consideration of cost or other non-risk factors by EPA when the Agency makes its threshold risk determination for a new chemical.

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\(^2\) The new law also expands EPA’s ability to take expedited action when new information about a chemical suggests a significant risk to humans.

\(^3\) If EPA does not meet the timeline to make a determination, the Agency must refund the fees (unless the Agency certifies that the PMN submitter did not provide adequate information or it unduly delayed the process) paid by the PMN submitter and still make a determination.
It is important to note that the new chemicals process under Section 5 will present a higher threshold, as EPA is instructed by the new law to consider additional factors previously not required. For example, the Agency must examine how a new chemical, under intended or foreseeable conditions of use, may impact susceptible subpopulations (e.g., infants, children, pregnant women, workers and the elderly). Further, because the new law now requires EPA to make a specific determination regarding the PMN substance, it is possible that the Agency will require additional information and test data to assist in its decision. Finally, given the additional requirements, it is also likely that the PMN process will slow and the time to get a PMN approved will be longer, as the new chemicals office at EPA already is stretched thin.

C. Section 6 — Existing Chemicals and Mixtures

Congress made significant changes to TSCA Section 6, which covers “existing chemicals.” The revised Section 6 adds risk prioritization, risk evaluation, and risk management steps, essentially requiring EPA to make three separate decisions regarding an existing chemical. Each portion of this process is outlined in more detail below.

i. Prioritization

The new law adds a prioritization process requiring EPA to establish a risk-based screening process to review chemicals currently in commerce within one year after enactment that takes into account factors such as hazard and exposure potential, persistence, bioaccumulation, and the volume of use. The Agency must designate substances as either “high priority” or “low priority” without consideration of cost or other non-risk factors. EPA is to designate a chemical as a high-priority substance if the Agency concludes, without consideration of non-risk factors, that the chemical may present an unreasonable risk. The Agency is instructed to designate a chemical as low-priority if a determination is made that the chemical is unlikely to pose an unreasonable risk.

EPA must review at least 10 chemicals from its existing 2014 TSCA Work Plan and commence risk evaluations of those substances within 180 days of the new law’s enactment.4

Also, within three and a half years after enactment, at least 20 chemicals must be designated “high priority” and subject to risk evaluations and 20 chemicals must be designated as “low priority.” EPA is to give preference to chemicals that are on the 2014 TSCA Work Plan5 that scored high for persistence and bioaccumulation.

Once EPA promulgates its rule for the prioritization process, it is likely that new or additional procedures and processes will be added to those statutory requirements outlined in the new law.

ii. Risk Evaluation

Subsequent to the prioritization process, the Agency is instructed to conduct risk evaluations on those chemicals deemed “high priority.” EPA is to develop procedures for risk evaluations within one year after enactment. The new law removes the requirement from Section 6 that EPA utilize the “least burdensome requirements” when conducting risk assessments. That language has previously proven fatal to many of EPA’s actions when attempting to regulate existing substances, such as asbestos.

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4 The new law sets forth the standard for risk evaluations — that is, whether the chemical presents an unreasonable risk to human health or the environment without consideration of cost or other non-risk factors, but includes unreasonable risk to potentially exposed or susceptible subpopulations.

5 Both medium- and long-chain chlorinated paraffins are on the 2014 TSCA Work Plan. EPA already completed its draft risk assessments on both substances and could count these assessments toward its statutory quota.
EPA must publish within six months after commencing a risk evaluation the scope of the work to be done (e.g., hazards, exposures and conditions of use.) Risk evaluations must be completed within three years; however, the Agency may extend the deadline for an additional six months. The process also calls for a formal notice-and-comment mechanism for 30 days to allow for stakeholders to review and comment on the draft risk evaluation before it becomes final.

Industry also has the ability to request that EPA conduct a risk evaluation/risk assessment on chemical substances. These requests eventually may account for 25-50 percent of the risk evaluations; however, industry is financially responsible for any specifically requested risk evaluations.

iii. Risk Management
If the determination is made from the risk evaluation that the chemical substance presents an unreasonable risk to the environment or human health, EPA must propose a risk management rule in the Federal Register within one year and publish a final rule within two years (although extensions may be granted for up to an additional two years under limited circumstances).

EPA must publish a notice of proposed rulemaking that outlines with specificity the reasons for the proposed rule. Stakeholders then have an opportunity to comment on the proposed rule and submit data and other relevant information. EPA must consider that information “in the rulemaking record” when crafting and subsequently publishing its final rule. The law also instructs the Agency to outline the effective date of the rule, the specific ban or phase out date, compliance dates, the full implementation deadline, and provide for a reasonable period to transition.

The final rule published in the Federal Register must outline the overall issues and effects of the chemical on human health and the environment, the benefits of the chemical, the economic consequences of the rule, and the costs and benefits. Additionally, the Agency must outline one or more alternative regulatory courses of action and consideration must be given to the availability of replacements and alternatives.

The revised Section 6 makes it easier for EPA to regulate existing chemicals. For years, EPA has viewed Section 6 as an ineffective tool to regulate chemicals currently in commerce because of the requirement that the Agency utilize the “least burdensome” means to assess and regulate a substance. While, the new law explicitly removes the consideration of cost and other non-risk factors during the risk prioritization and risk evaluation steps, EPA must consider costs and non-risk factors during risk management.

The new law mandates a fairly aggressive pace for EPA to review chemicals within the first year and then evaluate them. It remains to be seen if EPA will be able to comply with Congress’ tight timeline.

An interesting feature of Section 6, coupled with the potential preemptive effective, is the ability for industry to request that EPA conduct a risk evaluation on a particular substance. For instance, if a company possesses favorable health, safety and environmental data on a chemical, it could request that the Agency conduct a risk evaluation. If EPA determines that it does not present an unreasonable risk, the preemption provisions (outlined below) then preclude states from reaching an alternative conclusion. This could be an invaluable tool for industry going forward.

D. Chlorinated Paraffins Impact — Nomenclature
The new law allows for continued use of TSCA nomenclature (e.g., how chemicals are named and referenced) that was in use on the date the legislation was signed into law, and it maintains the use of the Soap and Detergent Association nomenclature system from 1978. Unfortunately for ILMMA members, particularly those who manufacture metalworking fluids and have been dealing with the on-going regulatory situation with medium-chain chlorinated paraffins and
long-chain chlorinated paraffins (MCCPs and LCCPs), it appears that the new law will not prevent EPA from continuing to pursue its current course of action of treating MCCPs and LCCPs as new chemicals under Section 5. Specifically, the language in the new law, “Nothing in subparagraph (B), nor any action of the Administrator pursuant to subparagraph (B), shall be construed as a basis to conclude that any chemical substance is not a new chemical substance,” gives EPA the authority to maintain its current regulatory path.

An earlier Senate version of the legislation had stronger nomenclature language that likely would have resolved the chlorinated paraffins issues prospectively; however, the new law leaves sufficient room for EPA similarly to deem that a chemical is not properly described by its CAS number. Therefore, EPA's strategy to conclude that a chemical is insufficiently described on the TSCA Inventory and, therefore, is a “new chemical,” remains a tool in EPA's regulatory toolbox; however, the revised Section 6 provisions should encourage the Agency to follow the appropriate process for regulating chemicals that are existing substances.

E. **Section 8 — Inventory Reset**

When TSCA was originally enacted in 1976, all chemicals currently in commerce were presumed “safe” and were placed on the TSCA Inventory. As ILMA members are aware, a substance must be on the TSCA Inventory for a chemical company to manufacture or import that substance. The new law instructs EPA to determine which chemicals are still in active commerce. More specifically, it instructs EPA, within one year of enactment, to publish a rule that requires chemical manufacturers (and allows processors) to notify EPA of the status of the chemical within 180 days of rule's publication in the *Federal Register*. Subsequently, depending upon the information received, the Administrator then designates chemicals as either “active” or “inactive.” However, the reset will not involve removing chemicals from the TSCA Inventory.

“Inactive” chemicals can be changed to “active” status by notifying EPA.

F. **Section 14 — Confidential Business Information**

The new law completely replaces TSCA Section 14 dealing with confidential business information (CBI). Companies seeking to protect CBI must provide a written request to the Agency that outlines that previous measures have been taken to protect the information in question, that no federal law requires disclosure, a statement that there is reasonable basis that disclosure is likely to cause substantial harm to the company, and that there is a reasonable basis to believe that the information may not be obtainable through reverse engineering. The new law further instructs EPA to develop additional, specific rules for substantiation. CBI claims are valid for ten years, and a company must re-assert its CBI claims not later than 60 days before the expiration of the previous ten-year period.

Importantly, the new law also outlines that “mixed information” (e.g., information that contains both CBI and non-CBI) will remain protected from disclosure despite the fact that it contains some non-CBI. The new law does not protect against disclosure any information that is a part of any health and safety study.

Additionally, if the Agency promulgates a 6(a) rule to ban or phase out a chemical, all of the potential CBI claims are presumed inapplicable. Further, any “general information” pertaining to aggregated production volumes and information pertaining to the process used in manufacturing or processing of a chemical “that customarily would be shared with the general public or within an industry sector” is not generally protected from disclosure.
G. Section 18 — State Preemption

While prior iterations of the TSCA reform legislation had different “grandfathering” dates or dates from which state laws are preempted, the new law sets August 31, 2003 as the grandfathering date. As a result, any state law “on the books” (e.g., California’s Proposition 65) prior to that date will not be preempted. Additionally, any state action or requirement commenced or imposed prior to April 22, 2016 (Earth Day) that relates to a certain chemical substance will similarly not be preempted. However, states are preempted from enacting laws that are counter to EPA’s determination that a chemical does not present an unreasonable risk. States may not enact laws during the “high priority pause” or the period in which EPA designates and publishes the scope of the risk evaluation until the Agency completes its work on that chemical and makes an affirmative determination about the chemical. However, states may seek a waiver from the “high priority pause” to regulate the chemical while EPA is completing its risk evaluation. Importantly as well, the new law does allow for co-enforcement by states.

The new law gives EPA additional authority and power that it previously did not possess. The trade off, from industry’s vantage point, was supposed to be strong preemption language to prevent states from implementing a patchwork of laws that increasingly makes interstate commerce more difficult. Through months of negotiations the preemption language was softened. For example, prior versions of the bill would have prevented co-enforcement by states and would have implemented a “low-priority pause” that would have prevented states from regulating a chemical once it received that designation from EPA.

However, there still are several favorable preemption provisions for industry within the new law. For example, the high-priority pause gives industry certainty (unless a waiver is granted) that states will not regulate a substance while EPA is conducting its risk evaluation. Once EPA makes a determination that a chemical does present an unreasonable risk, states are effectively barred from reaching an alternative conclusion. So while the preemption language is not as bold as it was in previous legislation, there are still positive components within the new law that should provide much needed certainty and uniformity for ILMA members.

III. Conclusion

Waiting for TSCA reform has been like “Waiting for Godot” — that is nobody thought that the statutory overhaul would ever come to fruition. Full attention now turns to EPA and implementation. The full effect of the reformed TSCA likely will not be felt for several years as EPA works through the various deadlines set by Congress. However, as EPA proceeds with rulemakings and drafting new policies and procedures, there will be opportunities for ILMA and its members to provide information and perspectives. The TSCA Inventory reset rule, due in one year, will drive a lot of the immediate need for action up and down supply chains. Given resource issues, as well as the upcoming presidential election and Congressional temperament, EPA’s implementation of the new law certainly has a number of challenges.

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ILMA will keep members apprised of any new developments.