Day 90 Report: Changes in Review of New Chemicals under the Frank R. Lautenberg Chemical Safety for the 21st Century Act

The passage of the Frank R. Lautenberg Chemical Safety for the 21st Century Act amending the Toxic Substances Control Act (TSCA) resulted in changes to EPA's New Chemicals Review program. This fact sheet provides an overview of the new requirements and a progress report on EPA's implementation efforts following the first 90 days of the law.

Background

The Frank R. Lautenberg Chemical Safety for the 21st Century Act went into effect immediately upon signature by the President on June 22, 2016. The New Chemicals program was the most immediately affected part of the EPA's TSCA program. There were several hundred chemicals at different stages of the review process as new submissions come in every day, totaling about 1000 per year. The EPA's goals were to implement the new provisions in Section 5, the part of the law covering new chemicals, consistent with the law, and to make decisions in a time frame that comes as close as possible to that experienced prior to the new law.

Because the new law, unlike the law it amended, requires an affirmative finding by EPA for every new chemical, EPA determined that new chemical submissions received prior to June 22, 2016, were not submitted under section 5 of the new law. EPA decided to consider new chemical notices that were in process at that time to be resubmitted, rather than require that companies physically resubmit, thus restarting the 90 day clock for EPA's review of those chemicals. The EPA then faced a number of challenges, including:

- Doubling up on review processes to reconsider pre-enactment decisions in light of the new standard for "resubmitted" PMNs, while keeping pace with new submissions.
- Developing and implementing a process for implementing the "not likely to present an unreasonable risk" finding, including new documentation and publication requirements.
- Implementing the provision of the new law which requires that EPA make an affirmative determination for both intended and reasonably foreseen uses of new chemicals.
- Implementing the new finding of "insufficient information to make a reasoned evaluation".

With the 90-day clock running on several hundred submissions, it took the EPA several weeks to put these components into place, including adding staff to review new chemicals, scheduling additional reviews and meetings, developing affirmative finding documents which meet legal requirements and provide useful information on EPA's reviews, and reaching the conclusion that making an affirmative finding for "reasonably foreseen" uses may require a section 5(e)

order where it might not have been necessary in the past. EPA then launched into full implementation, aiming to make a decision on every chemical within the 90 day period.

- **How is the EPA Doing?**

  EPA has reached interim or final determinations for most of the new chemical submissions that were within the 90-day review period when the new law was enacted. All submitters with interim determinations have requested, and EPA has granted, a suspension of the 90-day review period.

  - On June 22, 2016, there were about 200 chemicals in the process for which EPA had previously made decisions to develop orders or to seek additional information from submitters, based on a finding that each chemical "may present an unreasonable risk". The review period for these chemicals had been voluntarily suspended by the submitters. EPA quickly decided that the decisions on these chemicals would remain the same under the new law. Submitters have agreed to re-suspend the review period while orders are being developed or negotiated.

  - That left about 115 valid submissions within the 90 day review period on June 22nd. EPA re-reviewed these chemicals in light of the new requirements and made decisions prior to Day 90.

  - New chemical submissions received after June 22nd are being reviewed and will receive final or interim determinations within the 90 day review period.

- **How did the new chemicals review program change as a result of the Lautenberg Act's amendments to the Toxic Substances Control Act (TSCA)?**

  The statute changed the fundamental nature of EPA's review. One of the major changes is that EPA is now required to make an affirmative determination on the safety of new chemical substances or significant new uses of existing chemicals (identified by EPA in rulemaking) submitted under section 5(a) of TSCA before the chemicals can proceed to the marketplace, and the Agency must issue a determination for each chemical. Another significant change is that EPA now must determine whether the information on the chemical substance is sufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance. If EPA makes a determination of insufficient information, it can act on this basis *alone* under TSCA section 5(e). Another major difference with the new law is that EPA must consider the new chemical's potential uses (i.e., "reasonably foreseen" uses) when making its determination. Previously, EPA typically considered only known or intended uses of the new chemical substance when evaluating the potential for unreasonable risk. In addition, EPA must also now consider when making a determination any risks to groups of individuals who, due to either greater susceptibility or greater exposure, may be at greater risks of adverse effects than the general population.

- **Did the Lautenberg Act's amendments to TSCA result in a change in EPA's review of PMNs?**

  Yes. Given the differences in the statute, EPA is re-engineering its review process to address the changes in analysis and decision-making required by the new statutory provisions. For example, EPA is conducting a more thorough analysis early in the review process to identify potential uses of submitted new chemical substances to comply with the statute's requirement to make determinations, in part, on "reasonably foreseen" uses. Because the statute now requires that an affirmative determination be made by EPA on each pre-manufacture notice, EPA has revised its review process and documentation procedures to incorporate the two new types of determinations under the Act: 1) that there is insufficient information to make a determination and 2) that the chemicals substance is unlikely to present an unreasonable risk, and that such determinations be made available to the public. Also EPA has modified the structure, formatting and level of technical detail in its internal assessment documents to enable production of non-CBI determination documents for the public. Such public documents are now being made available on EPA's website for all TSCA section 5(a)(3)(C) determinations (i.e., "not likely to present unreasonable risk" determinations).

- **What are the possible outcomes of a PMN review?**

  The new law requires determinations for all pre-manufacture notices (PMNs), microbial commercial activity notices (MCANs) and significant new use notices (SNUNs). These determinations include:

  - the chemical presents an unreasonable risk, in which case EPA must act under TSCA section 5(f);
  - the information available is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical, in which case EPA must act under TSCA section 5(e);
  - in the absence of sufficient information to permit a reasoned evaluation of health and environmental effects, the chemical may present an unreasonable risk, in which case EPA must act under TSCA section 5(e);
  - the chemical will be produced in substantial quantities and may reasonably be anticipated to either enter the environment in substantial quantities or result in significant or substantial human exposure, in which case EPA must act under TSCA section 5(e); or
  - the chemical is not likely to present an unreasonable risk.

- **Why is EPA issuing more Orders under section 5(e)?**

EPA expects that a higher percentage of PMNs/SNUNs/MCANs will be regulated with Orders under TSCA section 5(e) than were so regulated under TSCA before the Lautenberg Act was enacted. This is because the statutory standard has changed such that EPA must now make an affirmative determination that a chemical substance or significant new use either presents an unreasonable risk, in the absence of sufficient information to permit a reasoned evaluation of effects may present an unreasonable risk, or is not likely to present unreasonable risk. The statute also directs the Agency to act under TSCA section 5(e) if it determines that the information available to EPA is insufficient to permit a reasoned evaluation of health and environmental effects" (a new determination under the Lautenberg Act). In the past, a chemical for which there is insufficient information alone would have been "dropped" from review.

- **Will EPA be issuing SNURs under the new law?**

EPA is now required to develop a SNUR with any TSCA section 5(e) Order. The SNUR will contain essentially the same provisions as the Order to ensure that all other manufacturers or processors of the PMN substance after the effective date of the rule will do so in a manner that is consistent with the Order or submit a notice to provide EPA an opportunity to review any significant new uses.

- **How will EPA notify submitters of its determination?**

For those chemicals that EPA determines are not likely to present an unreasonable risk of injury to health or the environment, EPA will notify the submitter of its decision under TSCA section 5(a)(3)(C) and publish its findings in a statement in the Federal Register pursuant to TSCA section 5(g). EPA will also post all other final determinations on its new chemicals web page and in ChemView.

- **Will EPA continue to issue so-called "non-section 5(e) SNURs"?**

The Agency's authority to issue SNURs derives from section 5(a)(2) – not section 5(e). Section 5(a)(2) was not changed under the recent amendments to TSCA. The Agency fully expects to continue to exercise its SNUR authority, as appropriate, in the context of both new and existing chemicals.

Prior to the Lautenberg Act amendments to TSCA, some PMNs were "dropped" from further review and a "non-section 5(e) SNUR" was issued because EPA had determined that potential uses, other than those intended by the PMN submitter, were significant new uses which might result in exposures of concern. Because EPA under the Lautenberg Act now must consider those reasonably foreseen uses when making a determination on the PMN submission, that subset of PMNs will now be subject to orders (typically consent orders) issued under TSCA section 5(e), limiting the submitter to the conditions of manufacture, distribution, use and disposal that were described in their PMN submission. EPA expects

that many of these consent orders will be agreed to without the need for negotiation and that manufacture can commence quickly once the consent orders are signed.

EPA also will continue to issue SNURs for significant new uses for existing chemicals. These are typically not associated with consent orders and thus could be characterized as "non-section 5(e) SNURs".

- **Did the new law require that EPA reassess any of the PMNs that were under review as of June 22, 2016?**

  Yes. EPA has to review, under the Lautenberg Act's standard, all of the PMN cases that were under review as of June 22, 2016.

- **How many PMNs, SNUNs and MCANs were under review at EPA when the new law went into effect?**

  When the new TSCA law was enacted on June 22, 2016, there were 315 PMNs, 8 SNUNs and 11 MCANs (total of 334) under review at EPA.

  Of these 334 cases, 115 were cases for which EPA had, prior to June 22, made a tentative determination of "may present an unreasonable risk" and the submitter had requested and EPA had agreed to a suspension of EPA's 90-day review of the notice in order to either work with EPA on developing a Consent Order pursuant to section 5(e) to address any potential risks associated with the PMN or to conduct testing necessary for EPA to determine that the chemical may not present an unreasonable risk.

  An additional 84 of these 334 cases had been preliminarily evaluated prior to June 22, but no interim determinations had been made for these cases. Rather, they were placed into "standard review" (a more in-depth evaluation of the potential risks associated with the new chemical substance or new use). These companies had requested and EPA had agreed to a suspension of the 90-day review period as well.

  EPA re-initiated review of the remaining 135 cases using the new statutory standard. As of September 19, 2016, EPA final determinations were made or the reviews had been completed for 43 cases as follows:

  - 8 cases have been withdrawn by the submitters
  - EPA has determined that 13 were incomplete or invalid submissions
  - EPA made final determinations of "not likely to present an unreasonable risk" for 22 new chemicals (13 PMNs and 9 MCANs).

  Of the remaining 92 of these 135 cases, as of September 19, 2016, EPA had made interim determinations of "may present an unreasonable risk" or "insufficient available information to evaluate effects" for 84 cases. EPA has not made interim or final determinations for the other 8 cases but has initiated a more detailed analysis known as "standard review" of these cases, which will also be reviewed in the context of the new statute.

The submitters of the 291 notices for which EPA has not made final determinations or for which the review has not been completed (i.e., 334 total cases less the 43 cases for which EPA has made final determinations or the reviews have been completed) have all been notified of the status of their submissions.

- **How many notices are currently in the agency's queue?**

  As of September 27, 2016, there are 220 TSCA section 5(a)(1) new chemical notices under review for which EPA has not yet made an interim or final determinations.

  For background, of these 220 cases, 88 cases were submitted prior to the enactment of the Lautenberg Act on June 22, 2016; all of these cases are in "standard review."

- **What is the breakdown of cases for which EPA intends to issue Orders under section 5(e)?**

  As of September 19, 2016, EPA had made interim determinations under section 5(e) for 199 cases in the pipeline as of June 22 as follows:
  - 12 Recommend section 5(e) regulation – Insufficient information
  - 144 Recommend section 5(e) regulation – May present unreasonable risk for intended and reasonably foreseen uses
  - 43 Recommend section 5(e) regulation – May present unreasonable risk for reasonably foreseen uses
  - 0 Recommend section 5(e) regulation – Exposure based only (Note: EPA has made this determination for several cases in conjunction with the "may present an unreasonable risk" determination)

- **Has the Agency made any determinations that PMN, MCANs or SNUNs will present unreasonable risks pursuant to TSCA section 5(f)?**

  No, the Agency has not yet made any section 5(f) determinations.

- **Submitters are asking for, and EPA is granting, suspensions of the law's 90 day review period. Does this mean that the Agency is unable to make determinations in a timely manner under the new law?**

  The statute became effective immediately upon signature and EPA is making great strides to meet its obligations for reviewing PMNs within the applicable review period. It is important to remember that approximately 199 of the PMNs that were under review at the time of the law's passage were cases where the submitter had requested, and EPA granted, a suspension of EPA's 90-day review of the notice in order to either work with EPA on developing a consent order pursuant to section 5(e) to address any potential risks associated with the PMN, or to conduct testing necessary for EPA to determine that the

chemical may not present an unreasonable risk, or to allow EPA to conduct a more in-depth evaluation of the potential risks associated with the new chemical substance or the new use before making a regulatory decision. In addition, since enactment, EPA has been reviewing new submissions as well as the 135 re-initiated reviews of cases that were "in the pipeline" at the time of the law's passage. The Agency fully expects to meet its obligations under the statute and expects the review workload to even out once this initial wave of decisions is complete.

- **What will happen for those cases where the agency fails to reach a decision on within the 90-day review period?**

  Section 5(a)(4) of the law provides that if EPA fails to render a determination on a notice by the end of the applicable review period, the Agency must refund to the submitter all fees charged for review of the notice and the Administrator is not relieved of the duty to make an affirmative determination on the chemical. However, submitters of the 291 cases for which EPA has not made final determinations yet under TSCA section 5(a)(3) have requested a suspension of the 90-day review period so that EPA has sufficient time to develop and negotiate Orders under TSCA section 5(e) or to evaluate new information provided by the submitters on their cases. EPA has granted those requests.

- **What types of information would it be helpful for the Agency to receive with the new chemical notice in order for reviews to proceed quickly?**

  TSCA does not require that any specific test information be submitted with a new chemical notice other than such information in the possession or control of the person submitting the notice. Because relatively few new chemical notices are submitted with robust test information, EPA must often rely on structure activity relationships, information on analogs, and expert judgement to estimate and evaluate physical/chemical properties, environmental transport and fate, environmental effects and human health effects. To the extent that submitters can generate additional information on physical/chemical properties, fate, toxicity and exposure on the substance, or provide such information on a suitable analog, it would facilitate EPA's review. It also expedites review when EPA receives this information at the time of the PMN submission, since subsequent and/or repeated submissions of information slow down EPA's review process.