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Late June 7, the Senate passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (H.R. 2576), which amends the Toxic Substances Control Act. Now, all eyes are on the EPA and what implementation will mean for products, regulatory processes and public health. Mark Duvall and his team at Beveridge & Diamond explore the early deadlines and requirements that will shape chemical evaluation and management in a world with an updated TSCA framework.

Now That TSCA Reform Is Here—What's Next?




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BY MARK N. DUVALL, RYAN J. CARRA, SARAH A. KETTENMANN, TIMOTHY J. SERIE, BEVERIDGE & DIAMOND PC

Waiting for TSCA reform has been like waiting for Godot—it never comes. Except that it has (almost) come—finally. The House of Representatives passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act on May 24, and the Senate passed it on June 7. President Obama is certain to sign the bill once it reaches his desk. Now attention turns to what comes next. The Environmental Protection Agency has many new obligations, some with time deadlines coming this year. Given the expected pace of implementation activity, manufacturers and processors should begin to assess their obligations and opportunities. This article reviews what to expect over the next two years.

1. EPA Implementation Obligations

In light of Congressional concerns that EPA would spend years getting ready to start implementing a reformed TSCA, the legislation establishes a series of deadlines. (The following assumes that President Barack Obama signs the bill in June 2016.)

a. By September 2016. The earliest deadline is 90 days after enactment, by which time EPA must publish in the Federal Register a list of mercury compounds that are prohibited from export.

b. By December 2016. Within six months of enactment, EPA must ensure that it is conducting risk evaluations on ten chemicals identified in the 2014 update to its TSCA Work Plan list of chemicals.[1] It has already completed draft risk assessments (probably to be renamed ''risk evaluations,'' the term used in the legislation) on 1-bromopropane, medium-chain chlorinated paraffins, and long-chain chlorinated paraffins. EPA may count these toward its quota of ten. EPA also has begun a risk assessment on octamethyltetracyclosiloxane (D4). That leaves six more chemicals.

Fortunately for EPA, under the TSCA Work Plan, it already has completed problem formulations for four clusters of flame retardants, covering a total of ten chemicals. It is ready to begin risk evaluations on them, if it has not done so already. It has also completed a ''problem formulation'' step for 1,4-dioxane. EPA should thus have no problem meeting its December quota of ten ongoing risk evaluations. Those problem formulations will probably serve as the scope of the risk evaluations to be conducted—and are becoming more routine after several National Academy of Sciences' reports urged the agency to consider the scope of risk reviews more deliberately through problem formulation.

EPA also has six months from enactment to decide whether to revise its standards for what qualifies as a small business, but first it must consult with the Small Business Administration and provide public notice and opportunity for comment.[2] Those standards have not been revised since 1988. If EPA does decide to revise those standards, it must do so through rulemaking, but there is no statutory deadline for such a rulemaking.

c. By April 2017. By April 1, 2017, EPA must publish in the Federal Register an inventory of mercury supply, use and trade in the United States.

d. By June 2017. Within one year of enactment, EPA must establish a risk-based screening process and criteria for designating chemicals as high- or low-priority substances. It must also establish the process by which it will conduct risk evaluations for high-priority substances. The TSCA Work Plan is likely to serve as the initial basis for these processes,[3] although EPA will need to adapt the TSCA Work Plan Chemicals Methods Document[4] to include the prioritization criteria and the process details included in the legislation.

By the same date, EPA must develop guidance to help manufacturers conduct and submit draft risk evaluations for the Agency's consideration. Again, the TSCA Work Plan is likely to be EPA's starting point.

EPA must also promulgate a final rule within the first year after enactment setting the procedures for the Inventory reset process. This is likely to be challenging for EPA, since it is probably starting from scratch. To some extent the original Inventory reporting period, with its Candidate list, may serve as a model. Once EPA adopts a final rule, it must then administer the Inventory Reset rule.

Also within one year of enactment, EPA must establish a Science Advisory Committee on Chemicals. Its membership will consist of ''representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise.'' In contrast, EPA's Chemical Safety Advisory Committee, established in 2015, consists of regular or special government employees ''who have demonstrated high levels of competence, knowledge, and expertise in scientific/technical fields relevant to chemical risk assessment and pollution prevention.'' Thus, EPA must establish a new advisory committee, similar to what it did when the pesticide-focused Food Quality Protection Act passed in 1996.

e. By June 2018. Within two years of enactment, EPA must develop any policies, procedures, and guidance that it determines are necessary to carry out the legislation. This will not involve rulemaking. EPA is likely to consider its current policies, procedures, and guidance as sufficient except to the extent that the legislation mandates changes. For example, in 2007 it issued guidance on risk assessments for metals and metal compounds. The legislation directs EPA to use that guidance or a successor document.

Also within the first two years after enactment, EPA must develop a strategic plan to promote the development and implementation of alternative test methods to

[1] The list is available at https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.

[2] The current standards appear in 40 C.F.R. § 700.43.

[3] For an analysis of how the TSCA Work Plan has served as a pilot project for implementation of TSCA reform, see Mark N. Duvall, *Implementing TSCA Legislation: Insights From EPA's TSCA Work Plan*, Bloomberg BNA Chemical Regulation Reporter (2015); 187 DEN B-1, 9/28/15.

[4] Available at https://www.epa.gov/sites/production/files/2014-03/documents/work_plan_methods_document_web_final.pdf.

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reduce, refine or replace vertebrate animal testing and provide information of equivalent or better quality and relevance.

f. Other Early Obligations. EPA must consult with parties potentially subject to fee payments intended to cover a portion of the cost of implementing TSCA reform. It has no statutory deadline for doing so, but it cannot set fees and start collecting them until it has completed this obligation. The legislation calls for EPA to set fees rather than having Congress set fees, as is the case with user fees for pesticides, drugs, and medical devices under other statutes. However, the statutory fees for those products generally ratify what the agency and affected parties have agreed. Thus, the process should be generally similar with EPA's TSCA fees. The legislation retains the portion of current section 26(b)(1), which requires EPA to set fees ''by rule,'' meaning that EPA must go through notice-and-comment rulemaking in addition to consulting and meeting with affected parties.

In addition to preparing to implement TSCA reform, EPA must also set priorities, conduct risk evaluations, and, if appropriate, establish restrictions by rulemaking. Each of those steps has statutory deadlines. Under the TSCA Work Plan, EPA has completed risk assessments for the solvents n-methylpyrrolidone (NMP), methylene chloride, and trichloroethylene (TCE). It plans to issue proposed risk management rules for those chemicals in September and October 2016. Since these risk assessments were completed before enactment of TSCA reform, EPA may not regard them as subject to the new deadlines of one year from completion of the risk evaluation for publication of a proposed rule and two years for completion of a final rule, subject to a maximum of a two-year extension. If it does, EPA will have to get cracking on those rulemakings. It is already behind the statutory schedule, since EPA completed the risk assessments for methylene chloride and TCE in 2014 and the risk assessment for NMP in March 2015.

Under amended section 5, EPA must begin making affirmative findings based on its review of premanufacture notices (PMNs) and significant new use notices (SNUNs). EPA must decide whether the new chemical or significant new use presents an unreasonable risk; may present an unreasonable risk; will be produced in substantial quantities and is anticipated to enter the environment in substantial quantities or there may be significant or substantial human exposure; or is not likely to present an unreasonable risk. This requirement may apply to PMNs and SNUNs for which the review period did not expire prior to enactment and will apply to those submitted after enactment.

The new language on articles in Section 5 may apply to current proposed significant new use rules (SNURs) and will apply to post-enactment SNURs for which EPA proposes to waive the standard exemption for the SNUR chemical in articles. That language requires EPA to make an affirmative finding in the SNUR that the reasonable potential for exposure to the SNUR chemical through the article justifies notification. EPA currently has proposed SNURs which would waive the articles exemption for polybrominated diphenyl ethers (applicable to PBDEs in all articles); long-chain perfluoroalkyl carboxylates (applicable to their presence in all articles); perfluoroalkyl sulfonates (applicable to those compounds in carpets); and 2,4-toluene diisocyanate, 2,6-tolune diisocyanate, and unspecified toluene diisocyanate isomers (applicable to the chemical in all articles).

2. Opportunities and Challenges for Industry

As EPA proceeds with rulemaking or providing other opportunities for comment, industry members should take advantage of those opportunities and provide their perspectives on TSCA implementation. The decisions that EPA makes following those opportunities for comment are likely to affect how EPA implements TSCA in the decades to come. The rulemaking on fees will have a direct financial impact on affected manufacturers and processors, so they should participate in the rulemaking process.

The Inventory Reset rule, due by June 2017, will trigger the need for prompt industry action. Manufacturers must, and processors may, report to EPA within six months of promulgation of the final rule (i.e., potentially by December 2017) all chemicals that they have manufactured (or processed) within the preceding 10 years prior to enactment. In doing so, they must also notify EPA if they continue to claim as confidential the chemical identities of any chemicals that they manufactured (or processed) during that period that appear on the Confidential Inventory. Later, they will have to substantiate those confidentiality claims to EPA. Failure to notify and substantiate may result in those chemical identities being added to the Public Inventory. Companies may want to get started early to prepare to meet these requirements.

Persons who submit PMNs and SNUNs should be aware of EPA's obligation to make an affirmative finding about risk and the potential for increased EPA scrutiny resulting from that obligation. They may want to consider developing additional information that will allow EPA to find that their chemical or significant new use is not likely to present an unreasonable risk.

A manufacturer will be able to request that EPA designate a chemical that it manufactures as a high-priority substance. Between a quarter and a half of all high-priority substances must be requested by manufacturers (assuming a sufficient supply for appropriate requests), so there is a good chance that EPA will grant appropriate requests. Manufacturers or their trade associations may want to consider making such requests. Processors, who are not authorized to make requests, may approach their suppliers and ask them to submit requests. Keep in mind, however, that EPA will charge requestors the full cost of evaluating requested chemicals that are not TSCA Work Plan chemicals and 50 percent of that cost for chemicals that are TSCA Work Plan chemicals.

Companies should review the TSCA Work Plan chemicals list for chemicals of importance to them, and plan accordingly. They should particularly consider the TSCA Work Plan chemicals for which EPA must promulgate risk management rules within three years without a requirement to conduct a risk evaluation. The following may be those chemicals:

- Butanamide, 2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)biz(azo)bis[N-(4-chloro-2, 5-dimethoxyphenyl)-3-oxo- (Pigment Yellow 83), CAS No. 5567-15-7.

- Decabromodiphenyl ethers (DecaBDE), CAS No. 1163-19-5.
- Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,5,5-tetramethyl-2-naphthalenyl)-, CAS No. 54464-59-4.
- Ethanone, 1-(1,2,3,4,5,6,7,8-octahydro- 2,3,8,8-tetramethyl-2-naphthalenyl)-, CAS No. 55464-57-2.
- Hexachlorobutadiene, CAS No. 87-68-3.
- 4-tert-Octylphenol (4-(1,1,3,3- Tetramethylbutyl-phenol), CAS No. 140-66-9.
- Pentachlorothio-phenol, CAS No. 133-49-3.
- Phenol, isopropylated, phosphate (3:1) (iPTPP), CAS No. 68937-41-7.
- 2,4,6-Tris (-tert-butyl) phenol, CAS No. 732-26-3.

Finally, as EPA prioritizes, conducts a risk evaluation for, and possibly regulates an individual chemical, affected companies or their trade associations should consider participating at each stage in the process to have a voice in the ultimate outcome.

Mark Duvall is a former in-house counsel at a global chemical company, and leads Beveridge & Diamond's TSCA practice group. He advises on enforcement actions, counseling, rulemaking, advocacy, and legislative actions. He chairs the TSCA Dialogue Group, a group of companies that manufacture, import, distribute or sell chemicals, and related trade associations, that addresses TSCA implementation. He also works with foreign counterparts to TSCA, including REACH and the Canadian Environmental Protection Act. Ryan Carra uses his extensive technical background to counsel clients in the electronics, chemicals, and energy sectors on environmental regulatory issues relating to extended producer responsibility, waste classification, chemical hazard classification, chemical notification requirements, and product materials restrictions both domestically and abroad. Tim Serie focuses his practice on chemical, product, and environmental regulatory matters and litigation. Prior to joining Beveridge & Diamond, Tim worked as counsel at the American Coatings Association. Sarah Kettenmann maintains a diverse environmental practice including chemical regulatory counseling, CERCLA litigation, and regulatory matters involving waste facility permits under the Resource Conservation and Recovery Act. Before joining Beveridge & Diamond, Sarah clerked for the Hon. Chase T. Rogers, Chief Justice of the Connecticut Supreme Court.

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