

# Practitioner Insights

## Chemicals

### Practitioner Insights: Enhancing TSCA Reform Implementation

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The Frank R. Lautenberg Chemical Safety for the 21st Century Act significantly amended the Toxic Substances Control Act. The act, which has been in force for just over a year, made substantive changes to multiple sections of TSCA that are proving to be even more consequential than anticipated (new TSCA is identified as Pub. L. No. 114-182 and old TSCA was identified as Pub. L. No. 94-469).

Because the new act was effective immediately upon President Barack Obama signing it on June 22, 2016, it presented the U.S. Environmental Protection Agency and interested parties with the need to address and respond to new requirements and short statutory deadlines in key areas during the first year. EPA made significant progress in addressing these implementation challenges as seen by the:

- issuance of final procedural rule for prioritization, 82 Fed. Reg. 33753 (July 20, 2017), risk evaluation, 82 Fed. Reg. 33726 (July 20, 2017), and the reporting rule for TSCA Inventory active-inactive notification (not yet published);
- issuance of scoping documents for the set of 10 chemicals for which risk evaluations are underway, 82 Fed. Reg. 31592 (July 7, 2017);
- establishment of the Science Advisory Committee on Chemicals (SACC);
- issuance of final guidance to stakeholders in developing draft risk assessments under TSCA, as required under TSCA Section 26(l), 82 Fed. Reg. 33765; and
- progress toward completing the fees rule, which is expected in summer 2017, among other developments. While EPA is to be congratulated on the timely completion of—and progress made toward—these actions, other parts of new TSCA either have not fared as well during the first year (the new chemicals program under Section 5, which has seen significant delays in completing work) or seen no discernible progress (use of new testing authority under Section 4).

This paper, authored principally by former EPA officials and a practicing TSCA lawyer, all with long experience under old TSCA, provides suggestions for new approaches or “fixes” that could assist the agency and interested groups in moving toward smoother implementation of the new law, achieving policy goals, and ensuring greater transparency. These suggestions are presented in no particular order and in the spirit of urging other stakeholders to also think of creative ways to

ensure that new TSCA fulfills Congress's mandate to develop an effective domestic chemical management program.

**Establish FACA Committee for TSCA** The National Pollution Prevention and Toxics Advisory Committee, established under the Federal Advisory Committee Act (FACA), dissolved in 2007 after several members from the nongovernmental organization community elected to withdraw from membership in late 2006. We regretted this occurrence and have advocated to EPA the benefits that would come from forming a FACA committee focused on TSCA regulatory, policy, and program implementation issues.

We renew our call to form such a committee, recognizing that it would operate parallel to, and complement, the Science Advisory Committee on Chemicals. The committee could provide a forum to discuss policy issues such as use of the new Section 4 testing authorities as part of a strategic testing effort to inform new and existing chemical assessments and approaches, and whether local effects, such as skin and eye irritation, should be considered in assessing and regulating unreasonable risk.

The EPA's Pesticide Program Dialogue Committee (PPDC) was established in 1995. According to its charter, the committee is "to provide policy advice, information and recommendations to EPA" on matters related to the Federal Insecticide, Fungicide, and Rodenticide Act, and to "provide a public forum to discuss a wide variety of pesticide regulatory development and reform initiatives." The PPDC has been an enormously successful mechanism to identify, discuss, and resolve issues of concern to the pesticide community.

There is every reason to believe a comparable federal advisory committee created to address TSCA issues would be as effective, especially in light of the significant changes occasioned by Lautenberg's enactment. While we appreciate EPA's and stakeholders' investment of time in public hearings, they seldom provide the venue needed for thoughtful, reflective discourse on complicated regulatory and policy issues. The committee, for example, maintains a variety of subcommittees, whose members work on an ongoing basis to identify, discuss, and resolve issues. A FACA committee for TSCA-related issues would provide a predictable venue and ensure continuity of consideration on an ongoing basis by a well-informed membership as new questions arise. The open and public discussions also would ensure greater transparency.

**Open Docket for Submission of 'Fixes'** Many stakeholders are thinking hard about creative solutions to TSCA implementation challenges. To ensure that stakeholders know that EPA is solicitous of suggestions and proposed solutions, it may be helpful for the agency to open a docket to house these suggestions.

A docket, the opening of which would be noted in the Federal Register and listed on EPA's website, would provide an accessible, convenient, and transparent means for allowing stakeholders to review and consider suggestions, build upon them, and jump-start the development of other solutions based on submissions. This docket also could provide topics for further discussion by a new TSCA federal advisory committee.

**Develop Approaches for New Chemical Cases** EPA repeatedly committed to "clear the backlog" of new chemical reviews under TSCA Section 5 by the end of July 2017. According to media reports, the backlog peaked in December 2016 and has gone down since then. The agency has worked hard to diminish the backlog and its efforts are commendable. The problem, however, is complicated as there are two parts to the backlog problem: completion of EPA's determinations on new chemical notices, and completion of any needed actions, including negotiation and execution of final consent orders under Section 5(e). The progress made to date on the backlog has been focused exclusively on the former and essentially ignores the latter, thus distorting somewhat the true measure of success.

The consent order backlog involves EPA and the submitters working together to resolve issues and agreeing on a final consent order using a voluntary suspension procedure to extend the review period beyond the initial 90 days.

A compelling argument can be made that, as amended, Congress intended TSCA Section 5 to require EPA to apply a fixed review period and to use Section 5(c) if needed to extend that period for a maximum of 90 additional days to allow for issuance of needed orders under Section 5(e) (also see our paper "Is the Section 5 Review Period Fixed or Flexible in New TSCA?"). While we offer no objection to the use of the voluntary suspension procedure, there is concern that new chemical cases languish indefinitely rather than being resolved in a timely way.

We offer the following thought-starter approach as a way to broaden the thinking while also increasing EPA's and industry's accountability to act with dispatch. One way of staging the new chemical review period is to include both an informal voluntary suspension period and a formal regulatory period in cases where the issues remain unresolved. The elements of our suggestion are as follows:

- EPA's goal should be to decide pre-manufacture notification (PMN) cases by day 90 to the greatest extent possible. This deadline, or an earlier one, should be met as a matter of course for the overwhelming majority of "not likely" determinations made under TSCA Section 5(a)(3)(C).

- To ensure an informed understanding of any regulatory concerns, by day 45 or earlier, EPA provides the notifier with appropriately sanitized copies of relevant initial agency assessment reports and commits to providing updated reports as they become available.

- If a case cannot be resolved by day 90, an informal voluntary suspension can be used for a maximum of 90 additional days (180 days total).

- Establish the expectation of timely responses by industry and EPA during both the initial review and voluntary suspension periods. This could involve, for example, a 15-day response deadline for submission of comments or additional information, which, if met by the notifier, is subsequently to be met by EPA in its response to the new information. Recognizing that not all issues can be resolved in 15 days, if the submitter requires more time, EPA gets a corresponding extension to prepare its response. If EPA is not timely in responding to the notifier, however, the process continues but the Office Director and Assistant Administrator are informed of the missed deadline.

■ Before the end of the 180 total days, EPA will communicate a decision to drop the case (*i.e.*, make a “not likely” determination at TSCA Section 5(a)(3)(C) possibly with a non-Section 5(e) Significant New Use Rule (SNUR)), to issue in final the Section 5(e) consent order and provide the order for signature (during a short suspension period if needed), or to use an adversarial order under Section 5(e).

■ If EPA decides to take the last course of action, it will use TSCA Section 5(c) to extend the review period for an additional 90 days and the procedure at Section 5(e)(1)(B) will apply. We recommend that the process include a step at day 180 when EPA informs the submitter in writing “of the substance of the determination” (this is from Section 5(e)(1)(B)(ii)), which will underlie the adversarial order.

■ The order itself will be issued no later than 45 days and it will be effective in 45 days (270 total days)—an approach generally taken from Section 5(e)(1)(i). The notifier can withdraw the case from review, comply with it, or legally challenge the order.

We believe that by imposing deadlines for decisions, responses, and actions, stakeholders’ interests will be better served and more aligned with the spirit of the amended TSCA. This approach also will give submitters incentive to develop more thoughtful and complete notices that contain the requisite information for EPA to make its determinations. If such information is not included or cannot be developed in a timely manner, the notice may be withdrawn without penalty or prejudice other than the loss of the submission fee.

**Certain New Chemical Polymers** EPA’s Office of Pollution Prevention and Toxics published May 22 a notice under TSCA Section 5(a)(3)(C) concerning a pre-manufacture notification polymer that evidently was intended to be manufactured in a way that met the polymer exemption at 40 C.F.R. § 723.250. It was identified as PMN P-17-0227.

In concluding that the substance was not likely to present an unreasonable risk based on low human health and environmental hazards, EPA added a “polymer exemption flag” to the chemical name. The polymer exemption criteria lay out specific characteristics that describe a low-hazard polymer, *a priori*. EPA developed the criteria while reviewing many polymer PMNs in the 1980s and 1990s and found that a polymer meeting those criteria presents low hazard to health or the environment. EPA’s explanation of the flag is as follows: “The chemical must be manufactured such that it meets the polymer exemption criteria as described under 40 C.F.R. § 723.250(e)(1), in addition to meeting the definition of polymer at 40 C.F.R. § 723.250(b).”

We applaud the office’s flexibility and creative use of a flag to limit the forms of the polymer that could be made based on its determination. This approach avoided the use of more burdensome regulatory action, such as a consent order and/or SNUR, which otherwise may have been needed to achieve the same end. We urge EPA to develop guidance explaining the purpose of the flag and its effect. The new flag seems to be distinctly different from other Inventory flags that indicate some status (*e.g.*, XU = exempt from the Chemical Data Reporting rule; S = proposed or final SNUR), but do not otherwise restrict the identity of the substance or how such a substance is manufactured.

We believe there may be additional broader and more flexible approaches to resolving the issues that polymer cases can present. (We offer such a proposal, the details of which are available in “Bergeson & Campbell, P.C. Suggests New Approaches to EPA in Managing New Chemical Polymers.”) It uses the polymer name, perhaps with the addition of a definition, to limit the polymers that can be made based on a given name to a subcategory of the possible polymers that meets the polymer exemption criteria or satisfies criteria EPA developed.

The proposal is based on the agency’s polymer guidance, which states that “[a]n Inventory listing for each polymer describes a category of possible chemicals that would fit that substance name, instead of just representing a single molecular structure” and can vary within that listing in molecular weight and composition (*e.g.*, the ratios or the order of reaction of the starting monomers; *Toxics Substances Control Act Inventory Representation for Polymeric Substances* (1995)).

As EPA states, polymer listings on the Inventory are categories of substances and EPA can develop nomenclature methodology that permits dividing a particular category into subcategories. This approach can be used to distinguish broadly named polymers from a subcategory of those polymers that satisfy criteria signaling that they are considered low hazard by EPA.

We believe that a system based on use of the chemical identity to create subcategories that limit the forms of the polymer that can be manufactured under that name provides strong protection with minimal EPA resources, and neither a TSCA Section 5(e) order nor a Section 5(a)(2) SNUR is required. Our approach minimizes the delays in realizing the benefits of low-hazard polymers and thus gives expression to Congress’s goal of encouraging the innovation of greener chemicals. Arguably, EPA could make the “not likely” determination on such polymers early in the pre-manufacture notification review process, as was the case for “polymer drops” under old TSCA (see EPA, “Chemistry Assistance Manual for Pre-manufacture Notification Submitters” (1997)). Further, under new TSCA, manufacture can commence once the determination is made.

We recognize that the approaches discussed in our polymer paper could be used as an alternative or as a complement to EPA’s polymer exemption flag approach. In our view, the approaches and the reasoning discussed in the paper lay a foundation for a more comprehensive scheme that could provide EPA flexibility in meeting the legal and timing requirements under Section 5(a). The scheme potentially could be applied more broadly to substances with Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB). Such approaches also would speed commercial innovation via the introduction of low-hazard substances while at the same time avoiding the impacts of unnecessary regulatory impediments to the supply chain.

**New Chemical Category Documents** EPA recently made available copies of four revised lung toxicity category documents (available from the agency’s Office of Pollution Prevention and Toxics). These update earlier versions of the documents and explain the basis for concerns EPA has identified in connection with certain new chemicals falling into these categories. The documents also include discussion of EPA’s planned tiered-

testing strategy for each category. Because of the new and increased requirements for EPA review of and actions on new chemicals, other changes such as TSCA Section 4 tiered-testing and animal welfare considerations, and the sound science provisions in Section 26, these documents play a more central role in the agency's decision-making process than was the case under old TSCA.

Many of the category documents also are quite dated. While we welcome the recently updated versions, we encourage EPA to update and improve relevant new chemical category documents to reflect more specifically the role they play under new TSCA. Section 26(l)(1) also is relevant to this discussion in its requirement that EPA within two years after enactment de-

velop "policies, procedures, and guidance" to carry out the amendments to the law. Providing an opportunity for public review would enhance the utility of the category documents and foster transparency.

**Conclusion** To its credit, the new administration has been receptive to stakeholders' suggestions concerning the implementation of new TSCA. We offer these suggestions in the spirit of ensuring that the new legislation is implemented in a way that offers the best possible chance of success in fulfilling Congress's intent.

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