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CHEMICALS

TSCA

Leveraging science and weight-of-evidence approaches is critical to sound chemical management under EPA's amended toxics law, according to the American Chemistry Council's Mike Walls. Ensuring EPA has the resources it needs to protect public health and the environment, encourage innovation and protect confidential information should be a long-term priority.

BNA Insights: Increased Scientific Rigor for Chemical Management

BY MICHAEL P. WALLS

Section 26 of the Toxic Substances Control Act (TSCA, 15 U.S.C. § 2624) has played an important, if overlooked, role in supporting the federal chemical management system. With the amendments to the section made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Public Law No. 114-182, hereafter ''the Lautenberg Act'' or ''the Act''), however, section 26 now has a prominent role in ensuring that the Act achieves the fundamental objectives of improving public confidence in the federal regulatory system, promoting transparency and protecting innovation and competitiveness.

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Section 26 Prior to Amendment by the Act Prior to amendment by the Lautenberg Act, the most important provisions of section 26 allowed EPA to assess fees for the submission of information under sections 4 and 5 and to extend any of its TSCA authorities applicable to chemical substances or mixtures to entire categories of substances or mixtures.

In 1986, when EPA first considered establishing fees pursuant to its section 26 authority, the Agency opted not to assess fees for the submission of information under section 4 and elected only to require fees for the submission of section 5 notices. The statute limited section 5 fees to $2,500, or $100 in the case of small business submitters. Prior to amendment by the Act, section 5 fees raised approximately $1.1 million a year, the vast majority of which was paid by larger entities.

EPA has exercised its authority over categories of substances and mixtures many times since TSCA was first enacted. For example, EPA has often used a cat-

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egory approach in reviewing new chemical substances under section 5. A category approach creates important efficiencies in EPA's decision-making, particularly because section 26(c) allows EPA to create categories based on similar molecular structures; physical, chemical or biological properties; or exposure pathways into the human body. Because the Lautenberg Act made no changes in section 26(c), EPA retains the ability to group chemical substances and mixtures into appropriate categories for the purposes of TSCA reporting, prioritization, evaluation and regulation.

Importantly, when it was first enacted, TSCA contained no provisions related to the quality and reliability of the scientific information EPA was to rely on.

As detailed in earlier BNA Insight articles, the Act makes substantial amendments to the primary operative provisions of sections 4, 5, 6, 8 and 14 of TSCA. To support those changes, section 26 requires rigorous standards for the science supporting EPA's decisions, expands EPA's fee authority and creates a dedicated TSCA fund for fee revenue. These modifications make section 26 critical to the successful implementation of the Act.

Modifications to Section 26 Promote High Quality Science, Provide EPA Additional Resources The amendments to section 26 made by the Lautenberg Act include some of the most significant changes to TSCA since its enactment in 1976. EPA now has a mandate to apply high quality, reliable scientific information and will have access to a significant source of additional funding to support the Act's testing, new chemicals, prioritization and evaluation provisions.

A. Section 26 Science Requirements. TSCA as first enacted contained no provisions directly related to the quality and reliability of scientific information on which EPA would base its decisions. Some scientific standard was implied, of course, in TSCA's requirement that EPA assess whether risks were ''unreasonable'' under section 6 and in the section 19 requirement that certain EPA decisions must be based on substantial evidence.

Best Available Science Section 26(h) of the Act requires EPA to use scientific information, technical procedures and models in a manner consistent with the best available science. Similar provisions have appeared before in other federal environmental laws, such as section 1412(b)(3) of the Safe Drinking Water Act. Under these provisions, federal agencies are responsible for ensuring that the highest-quality, most relevant scientific data are used to inform regulatory decisions and promote objective and reliable rulemaking. The Act helps provide context for the term, which must be interpreted in conjunction with the Act's requirement that EPA apply a ''weight-of-the-scientific-evidence'' approach in decision-making.

Under the Act, EPA is to apply the best available science in carrying out sections 4, 5, and 6. It must ensure that scientific information is reasonable for, and consistent with, the intended use of the information. It also requires that the information is relevant to decisions being made and that it comports with requirements for clarity and completeness, characterizes variability and uncertainty and has had independent verification or peer review. All told, this represents a significant advance in the effort to define and apply the best available science in the context of TSCA decisions.

Weight-of-the-Scientific-Evidence Section 26(i) of the Act requires EPA to make decisions based on the weight-of-the-scientific-evidence approach. A statement of additional views reflected in the record of the Senate debate on the Act, on June 7, 2016, noted that the ''term 'weight of the evidence' refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently and consistently, identify and evaluate each stream of evidence, including strengths, limitations and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations and relevance.'' This is more than a simple ''strength-of-the-evidence'' test; it requires EPA to fully describe the scientific evidence and how it assessed the weight of that information in reaching a decision. EPA is not unfamiliar with the weight-of-the-scientific evidence, but to date the approach has only been detailed in guidance (e.g., EPA's Guidance for Risk Assessments).

All told, the Act reflects the first time in federal law that a best available science and weight-of-the-scientific-evidence requirement appear in a statutory requirement applicable to agency decision-making. Subsequent implementation and interpretation of these provisions in chemical-specific decisions will no doubt be the subject of considerable future debate. Importantly, these provisions require EPA to be more robust in identifying high quality, reliable and relevant information in its TSCA decisions. Over time, that process should help move the focus from the scientific information to the policy implications of that information.

Adhering to Science Provisions The American Chemistry Council (ACC) believes it is critical for EPA to apply the Act's science provisions in new rulemakings for the prioritization and risk evaluation processes.

Under the Act, EPA must promulgate rules for a risk-based prioritization screening process and the risk evaluation process under section 6(b). Both rules should incorporate the best available science and weight-of-the-scientific-evidence requirements of section 26. The section 26 provisions are, in fact, legal requirements that EPA must meet in implementing both the Act and the rules. Notably, Congress elected to include the science provisions as stand-alone requirements in section 26; they are not included in broad requirements that EPA establish policies, procedures and guidance (section 26(l)). This is not to say that appropriate guidance on what constitutes high quality, reliable and relevant information should not be provided when appropriate, however. ACC's position is that the statutory mandate is clear and should be reflected in the process rules.

As science is the core of the risk evaluation process and will influence risk management decisions, the section 26 mandate is substantive and must be described in adequate detail in the regulation. EPA's risk evaluation process rule will contain provisions relating to how the Agency will define the conditions of use for a substance under review and how it will identify potentially exposed subpopulations. This information is critical to enable public understanding of how EPA will apply these terms to ensure consistency and uniformity in the risk evaluation process. EPA should also ensure consistency and uniformity by making clear how it will judge the quality, reliability and relevance of scientific information.

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Applying Scientific Standards Several examples may illustrate the point. In the prioritization and risk evaluation rules, EPA should state a preference for actual, rather than modeled, data, if it is available. Modeled information should conform to realistic exposure scenarios. EPA should provide clear rationales for the use of any default assumptions in the evaluation process. EPA also must define the uncertainties apparent in the scientific information and evaluate the impact of those uncertainties in decisions. The agency should explain it will judge the adequacy of peer-reviewed information. Importantly, to the extent that the Act's new Science Advisory Committee on Chemicals (SACC) itself conducts a peer review of risk evaluations, EPA's risk evaluation process rule should detail how the SACC reviews will be integrated. Each of these examples is relevant to how EPA will identify the best available science and decide the weight of the evidence.

One of the key objectives of the Act was to promote a process where more information about chemical hazards and exposures is brought forward to inform prioritization and risk evaluation decisions. As more data and information become available (including data generated from emerging high-throughput assessment tools), evaluations will become more difficult, particularly the complex considerations of dose and human relevance that EPA will have to make. These evaluations will directly affect the likely choice of appropriate risk management actions, and thus it is critical that the scientific information relied on by the Agency—and the process of identifying its quality, relevance and reproducibility—be transparent. Section 26(j) furthers this objective by requiring EPA to provide a list of all studies considered and their results, as well as a nontechnical summary to help inform the public.

Periodic Updates Notably, the Act does not assume that science will remain static. Section 26(l)(2) requires EPA to reflect new scientific developments and understandings in its policies, procedures and guidance at least every five years after the date of enactment. The update process should allow EPA to rapidly incorporate developing tools and test methods, such as high throughput screening approaches into both the prioritization and risk evaluation process. This requirement is an important contrast to TSCA before it was amended by the Act and should help ensure that EPA continues to apply the best available science in its processes.

B. New Resources for EPA. Section 26(b) of the Lautenberg Act provides the Agency important new authority to develop a fee system that generates sufficient revenue for the program, while meeting the objective of a simple, transparent system. The provision also establishes a new, dedicated TSCA Service Fee Fund.

Under the Act, EPA can assess fees for the submission of information under sections 4 and 5 and for the substances subject to risk evaluations under section 6(b). Fee revenue must be not more than reasonably necessary to defray up to $25 million, or 25 percent of EPA's administrative costs, whichever is lower. Although fees can attach to relevant section 4, 5 and 6 actions, EPA can use the fee revenue to defray the costs of administering sections 4, 5, 6 and reviews of section 14 claims to protect confidential business information (CBI). Notably, EPA cannot assess a fee directly for CBI claims. By its terms, the Act prevents EPA from assessing fees for activity under any other section of TSCA, including section 8. As under prior law, EPA must consider small business interests in establishing fee levels.

In a policy decision aimed at increasing the overall throughput in the process, the Act permits manufacturers to request that EPA conduct a risk evaluation, subject to an agreement that manufacturers pay 100 percent of the costs associated with the evaluation (or in the case of certain chemicals on EPA's Work Plan, 50 percent of the costs). The Act further limits the number of manufacturer-requested evaluations to between 25 percent and 50 percent of the total number of evaluations underway. Payment for manufacturer-requested risk evaluations is not counted toward the $25 million/25 percent cap.

TSCA Service Fund The TSCA Service Fee Fund is a self-executing provision of the Act and requires no regulatory implementation. Therefore, as of June 22, 2016, all existing TSCA fees should be deposited in the Fund. Because the Act requires Congress to appropriate all such revenues for use in defraying costs, and Congress has not yet acted as of the date this article was written, current deposits into the Fund cannot be used by EPA. Ongoing negotiations toward a concurrent budget resolution may address this issue.

Tracking Actions and Costs It should be clear that EPA's current and anticipated costs in administering sections 4, 5, 6 and 14 are relevant to decisions about the new fee system. Clearly EPA's costs to administer TSCA will increase compared to current costs. Unfortunately, current TSCA costs are not subject to a comprehensive tracking mechanism, and it is difficult to understand the relationship of current appropriations to the TSCA program. The President's budget recognizes approximately $56 million in appropriations to the TSCA program. However, this amount does not appear to cover fully-loaded overhead costs or the increased costs associated with implementation of the Act three years after enactment, when the Agency must have at least 20 chemicals under review.

The Act will remedy this situation through requirements for biennial reports to Congress on the fee program and EPA's costs. Specifically, the Act requires EPA to report on the fees collected and amounts disbursed from the Fund, the reasonableness of the fees compared to EPA's projected costs and the results of an annual audit of the Fund. These provisions will ensure that appropriations and fee revenue to EPA for the purposes of implementing the Act are more clearly understood by the public and the regulated community that will pay the fees. The reports to Congress and the annual audits will provide important data to inform the fee adjustment process, whereby EPA will review fees every three years and adjust them to reflect inflation and the costs of administration.

Fee Program Precedents The Act's fee program has some precedent in the fee systems established under the Pesticide Registration Improvement Act (PRIA), the Prescription Drug User Fee Act (PDUFA) and the Medical Device User Fee and Modernization Act (MDUFMA). Those programs provide important lessons for the broader TSCA fee program but are far more complicated than the fee program expected under TSCA. The regulatory objective under these precedents is to register or license products to individual manufacturers—a far different regulatory outcome than

TSCA. Like PRIA, PDUFA and MDUFMA, however, the Act requires Congress to reauthorize the TSCA fee system on a periodic basis (in this case, in 10 years after enactment).

Key Issues in Establishing Fees The Act creates discretionary authority for EPA to assess the fees through a specific rulemaking. EPA has indicated that it intends to propose a fee rule by mid-December 2016, with the goal of making the rule final within one year of enactment. EPA held a broad public consultation on the fee system on August 13, 2016. The Act also requires EPA to consult industry representatives on the fee system.

Key questions will arise around the level of fees established for section 4 and 5 submissions and those for risk evaluations under section 6(b). Under prior law, section 5 fees were capped at $2,500 ($100 for small businesses). One possibility is that EPA could simply adjust the old statutory fee limits for inflation.

For section 6(b) risk evaluations, however, the only benchmark that exists is EPA's risk evaluation process under the TSCA Work Plan Chemicals Program. In a statement made at the March 18, 2015, hearing of the Senate Environment and Public Works Committee, Senator Tom Udall indicated that, on the basis of information provided by EPA, the cost of ''evaluating and regulating from the start to the finish is at least $2.5 million'' per chemical. EPA Assistant Administrator Jim Jones confirmed that estimate in response to a question posed at the April 14, 2015, hearing of the House Subcommittee on Environment and the Economy, in which he attributed 60 percent of those costs to the regulatory phase, for which fees cannot be assessed under LCSA. On that basis, it appears fair to estimate an average risk evaluation cost of approximately $1 million (40 percent of $2.5 million). However, it is not clear that the $1 million estimate includes overhead costs.

ACC supports EPA's expanded fee authority. ACC and its members recognize that LCSA imposes on EPA an obligation to screen all chemicals in commerce, evaluate risks of high priority substances and regulate certain conditions of use, when necessary. The Act also requires EPA to review all claims to protect chemical identity from public disclosure and a significant representative portion of all other confidentiality claims. While these activities have typically been funded through general revenues, Congress provided EPA expanded fee authority to offset some of the Agency's increased costs associated with implementing the Act. The fees will hopefully provide additional resources to ensure that EPA can make efficient and effective decisions.

In ACC's view, EPA's proposed fee rule should establish a fee system that is as simple as possible, that is fair and equitable with respect to defraying the cost of EPA's administrative actions and that is based on the level of effort required for the Agency's action.

Conclusion The science and science policy provisions of section 26 play a crucial role in assuring that EPA's TSCA decisions are grounded in high-quality, reliable and relevant scientific information. The fee provisions of section 26 also have an important role in assuring that EPA has appropriate resources to support work under the Lautenberg Chemical Safety Act and an appropriate level of accountability in how fee revenue is applied. Taken together, the amendments elevate the relative importance of section 26 in a more robust federal chemical regulatory program.

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