FROM THE CHAIR—SPRINGING FORWARD!
Joanne Thelmo

Dear Colleagues,

I wish to take this opportunity to share with you a brief snapshot of where the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee has been and where we’re headed. As you will see, the committee has been extremely busy.

2014

September 26: Friday Forum with the Honorable James J. Jones, Assistant Administrator for the Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency (EPA), at Sidley Austin

October 24: Friday Forum with House Committee on Energy and Commerce: David McCarthy, Chief Counsel, and John Stone, Counsel, at Arent Fox

November 12: All Day Discussion on Critical Issues with CropLife America at Steptoe & Johnson

November 14: Friday Forum with Dr. Richard A. Denison, Environmental Defense Fund, at Beveridge & Diamond


2015

January 16: Friday Forum with Defenders of Wildlife, Ya-Wei (Jake) Li, Director of Endangered Species Conservation, and Jason Rylander, Senior Staff Attorney, at Environmental Law Institute

February 5: A Policy Roundtable Lunch Discussion: The Price of Reform: Models for Financing a Toxic Substances Control Act 2.0 at Akin Gump


April 28: Removing Roadblocks to TSCA Reform Legislation at Arnold & Porter

May 15: Friday Forum with Mark Garvey, Toxics and Pesticides Enforcement Division, Office of Enforcement and Compliance Assurance, EPA, at Alliance of Automobile Manufacturers

June 23: Essentials of TSCA and REACH at Bergeson & Campbell

As you can see, our committee is off to a tremendous start and is busy. But, these programs and activities could not have happened without

Continued on page 3.
In this issue:

From the Chair—Springing Forward!
Joanne Thelmo .........................................1

White House Releases National Strategy to Protect Pollinator Health
Keith A. Matthews .....................................4

FIFRA: EPA Registers Second Nanoscale Pesticide After Prolonged Review
James G. Votaw .......................................5

Environmental Appeals Board Vacates $2.5 Million TSCA Section 8(e) Penalty
Lawrence E. Culleen ...................................8

Chemical Control Reform Efforts Under TSCA Should Include Federal “Voluntary” Programs
Charles L. Franklin .....................................11

TSCA: EPA Proposes Reporting and Record-keeping Requirements for Nanoscale Materials
Lynn L. Bergeson ......................................13

Is the Self-Audit Policy Getting a Major Face-Lift?
Lawrence E. Culleen ..................................16
your participation. Heartfelt thanks and kudos to all our former chairs, vice chairs, and members who organized and participated in these events.

In my prior message, I shared with you that I especially encourage each of us to grow, not just as individuals, but also to share our knowledge and experiences with each other. So please, if you have an idea or interest in writing or presenting, planning, or participating in our PCRRTK Committee, reach out to me or a vice chair. Here is our contact information:

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We welcome your involvement and hope that you will share your perspective with us.

**Joanne Thelmo** is chair of the ABA SEER, Pesticides, Chemical Regulation, and Right-to-Know Committee.
On May 19, 2015, Dr. John Holdren, director of the Office of Science and Technology Policy (OSTP), announced the release of the National Strategy to Promote the Health of Honey Bees and Other Pollinators. The National Strategy to protect pollinators was developed by the Pollinator Health Task Force, an interagency task force led by the U.S. Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA). Member agencies of the task force included the Departments of Defense, Education, Energy, Housing and Urban Development, and Transportation, along with the Council on Environmental Quality (CEQ), the National Science Foundation, OSTP, and the Smithsonian Institution. The National Strategy aims to address and mitigate environmental and ecological stressors to pollinators with the goals of (1) reducing losses of managed honey bee colonies to “economically sustainable” levels; (2) increasing monarch butterfly numbers; and (3) restoring or enhancing habitat available to pollinators.

Adverse effects to honey bee populations and other pollinators have been well documented. In its 2007 report, The Status of Pollinators in North America, the National Research Council noted that “[l]ong-term population trends for the honey bee, the most important managed pollinator, are demonstrably downward.” In 2014, USDA documented that the number of managed honey bee colonies declined from over 4 million in 1970 to approximately 2.7 million in 2015. USDA recently released preliminary data from the annual survey conducted by USDA, the Bee Informed Partnership, and the Apiary Inspectors of America that indicate that winter losses of bee colonies for 2014–2015 were 23.1 percent and that in 2014, for the first time, summer losses exceeded winter losses (27.4 percent), so that total losses of managed bee colonies from April 2014 to April 2015 were 42.1 percent, which is the second highest annual reported loss of managed honey bee colonies. Similarly, populations of monarch butterflies have been steadily decreasing, with overwintering monarchs covering a mere 1.13 hectare of overwintering habitat in Mexico in 2014–2015 (which is the second lowest recorded value, up slightly from 2013 to 2014’s 0.67 hectare (by comparison, in 1996–1997, the area of overwintering monarchs was 19.2 hectares)).

In response to these developments, the National Strategy to Promote the Health of Honey Bees and Other Pollinators seeks to reduce managed honey bee colony winter mortality to no more than 15 percent within 10 years, to increase the eastern population of the monarch butterfly to 225 million individuals covering 6 hectares of overwintering habitat in Mexico, and over the next five years, to restore or enhance 2.8 million hectares of U.S. land area suitable for arthropod pollinator foraging.

To achieve these goals, the National Strategy includes the following elements: (1) a Pollinator Research Action Plan, which sets forth specific research objectives to better understand pollinator stressors and means to address them; (2) public education and outreach to “engage the U.S. public and the broader global community in the health of pollinating species”; (3) public-private partnerships to synergistically leverage federal investments and the significant private stakeholder interest in pollinator health; and (4) increasing and improving pollinator habitat by managing federal lands with an eye toward actions beneficial to pollinators, and encouraging similar actions on state, local, and private landholdings.

In addition to the actions above, the National Strategy calls for EPA to take certain steps regarding pesticides. In June 2014, EPA, Health Canada, and the California Department of Pesticide Regulation issued a harmonized guidance for assessing risks to honey bees posed by pesticides. EPA is to release new toxicity study guidelines to implement the harmonized honey bee risk assessment guidance. EPA is also to complete registration review of neonicotinoid pesticides; assess other pesticides for impacts on pollinators;
restrict the use of pesticides deemed to be most acutely toxic to bees; and expedite review of new Varroa mite pesticides.

The development and implementation of the National Strategy are not occurring in a vacuum. For example, DEFRA, the United Kingdom’s Department for Environment, Food & Rural Affairs, announced in November 2014 the National Pollinator Strategy. The DEFRA strategy is based on supporting pollinators on farmland; supporting pollinators across towns, cities, and the countryside; enhancing the response to pest and disease risk; raising awareness of what pollinators need to survive and thrive; and improving evidence on the status of pollinators and the service they provide. DEFRA’s goal is over a 10-year period to see improved pollinator habitat, improved pollinator health, no further extinctions of endangered pollinator species, enhanced public awareness of “the essential needs” of pollinators, and “evidence of action taken to support pollinators.”

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Leadership Development Program
Application Deadline: Friday, August 7, 2015

The Section is accepting applications for its Leadership Development Program (LDP). Now in its sixth year, the LDP is designed to support Section members interested in expanding a current leadership role or growing their knowledge of the Section so that they can assume a leadership role in the future. The Section is seeking to identify and enroll up to 12 Section members who exhibit an interest in increased Section involvement or leadership responsibility and who can commit to the LDP over one year (September 2015- August 2016). We anticipate that these individuals will reflect diversity and help the Section support ABA Goal III.

For more information, please visit www.ambar.org/EnvironLDP

FIFRA: EPA Registers Second Nanoscale Pesticide after Prolonged Review
James G. Votaw

On May 15, 2015, the U.S. Environmental Protection Agency (EPA) registered only the second nanoscale pesticide product registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). “NSPW-L30SS,” or “NanoSilva,” is an antimicrobial that protects plastics and textiles from stain and odors caused by bacteria, mold, and fungi. It is distributed as a liquid suspension containing silica-sulfur-nanosilver particulates designed to be incorporated into polymer master batches used to form threads and articles. It is not applied to existing surfaces. While a proportion of the silver is in the nanoscale range (3–12 nanometers (nm)), the manufacturing use silica-sulfur-silver composite particles average 320 nm. Docket No. EPA-HQ-OPP-2012-0594.

EPA first knowingly approved a nanoscale pesticide in 2011 when it conditionally registered HeiQ AGS-20, another textile materials preservative containing nanoscale silver. See Docket No. EPA–HQ–OPP–2009–0936. The agency uses the “knowingly” qualifier in this context because it previously registered a number of other silver pesticide products that it now suspects contain nanoscale silver. The agency established a single Pesticide Chemical Code to categorize and review all products containing nanoscale silver. See Docket No. EPA–HQ–OPP–2009–0936. The agency established a single Pesticide Chemical Code to categorize and review all products containing nanoscale silver and initiated the first nanosilver registration review in 2012 as a means to call in additional relevant data for such products. Docket No. EPA-HQ-OPP-2011-0370.

The NanoSilva new active ingredient was conditionally registered under FIFRA section 3(c)(7)(C), which, in limited circumstances, allows a new active ingredient to enter commerce before all required toxicity and other data have been submitted. This path is available only if the applicant has not had sufficient time to meet a new or non-standard data requirement imposed by the agency, and should last only long enough for the applicant to complete the missing work. In addition, EPA must also find, based on the data that are available, that the product will not present...
an unreasonable risk, and that allowing market entry before all data are in is in the public interest. For NanoSilva, EPA did not finally determine the full data requirements for registration until the final decision was issued. Key to its favorable risk determination was the finding that there were no detectable releases of nanosilver from the products in use, greatly minimizing any potential exposures. EPA found the registration to be in the public interest because use of the product would result in lower silver loading into the environment compared to other silver, silver zeolite, or silver salt antimicrobials. NanoSilva will have four years to meet the new-tiered data requirements. Extensive tier 2 testing may be avoided if tier 1 testing confirms that the product has no detectable releases of nanosilver particles.

The NanoSilva registration decision comes nearly six years after the application was filed and nearly two years after EPA published its proposed approval of the registration for public comment. This is far longer than the 18-month period EPA normally is given to act on such registrations under the Pesticide Registration Improvement Act (and extensions). The delay in this case was associated in large part with deciding what particular data would be needed to assess the nanosilver active ingredient. EPA convened a meeting of its FIFRA Scientific Advisory Panel (SAP) to examine this question in 2009 for all nanoscale metals. The SAP did not give specific data recommendations, but generally advised EPA that it should not rely on hazard and exposure data developed for larger scale products to evaluate nanoscale chemical risks, and should take great care in bridging even among chemically identical nanoscale products of different sizes or with different coatings. While prolonged premarket regulatory reviews may be extremely damaging to smaller companies, effectively locking them out of markets for innovative products, the registrant in this case may have benefited from the delay and steady progress of science while its application was pending. Most if not all of the public literature toxicity studies on which EPA relied in granting the registration were completed after the application was filed.

Potential Litigation Challenges

EPA’s analysis and rationale in support of its favorable registration decision reflect lessons learned from its experience with HeiQ AGS-20. That 2011 registration decision was promptly challenged by the Natural Resources Defense Council (NRDC). The challengers argued that EPA’s risk analysis was flawed both because it had not considered the most vulnerable exposed consumer population (infants), and because the analysis did not include an assessment of aggregate exposure from all potential sources of nanoscale silver. A divided Ninth Circuit panel ultimately rejected both of these arguments, but along the way the agency had difficulty at times pointing to a basis for some of its risk modeling practices and assumptions in the administrative record, complicating the defense. Natural Res. Def. Council v. U.S. EPA, 735 F.3d 873 (9th Cir. 2013). (The court vacated and remanded a narrow part of the registration based on some ambiguous decision language from the agency that was addressed before the mandate issued.) No doubt anticipating possible challenges in this case, EPA’s oral toxicity analysis of the NanoSilva product was premised on assumed exposure to 1 to 2-year-olds, but EPA also bracketed that analysis with parallel reviews assuming exposure to both younger (infants) and older children, for “transparency.” Similarly, the decision details the reasons that a risk assessment based on aggregate exposures to nanosilver from all potential sources is neither legally required nor physically possible at this time, but nevertheless describes the results of a risk assessment premised on aggregate exposures to NanoSilva and HeiQ AGS-20. This additional analysis was supplemented by more complete references to the agency’s internal modeling and decisional guidance, better articulation of its decision process, and extended consideration of all comments on the proposed decision.

Key adverse comments on the proposed decision included failure to include a risk assessment for aggregate exposures, failure to support public interest claims, and disagreements with certain study selections. Apparently in response to comments, EPA ultimately trimmed its explicit
public interest justifications for the decision to omit specific reference to consumer benefits from longer lasting antimicrobials, and support of innovative chemistries that may lead to more lower-risk pesticides. EPA rejected arguments from current silver pesticide product registrants that it was improper for EPA to distinguish between chemically identical silver substances with the same mode of action (silver ion) on the basis of particle size, and on that basis treat the nanoscale substances as new active ingredients (not similar to any previously registered silver). Among other things, this classification triggers extensive new data requirements for which there likely is no existing database. While acknowledging that discriminating on the basis of particle size is a new approach for defining new actives, EPA asserts that the statute leaves it considerable, perhaps unreviewable, discretion in this area. See, e.g., Syngenta Crop Protection, Inc. v. EPA, 439 F. Supp. 2d 458 (M.D.N.C. 2006). But particle size may not be the only consideration. Elsewhere, the agency suggests that until the different nanosilver characteristics that affect behavior and toxicity are well defined, EPA may need to assess applications for all new nanosilver products “as EPA would assess a new active ingredient.” This is consistent with the agency’s proposed policy for classification of applications for products containing nanoscale ingredients.

**Implications for FIFRA Registrants**

The NanoSilva decision provides some useful insight for those planning or currently producing or distributing a pesticide with a significant nanoscale fraction and not previously evaluated by EPA on that basis. It appears EPA will continue to classify or, regardless of classification, at least assess, all applications for new nanoscale pesticide products as it would for a new active ingredient absent convincing data bridging to a larger scale or previously registered nanoscale product. Final registration data requirements will continue to be decided on a case-by-case basis. Because these are fully decided at the end of the review process, future nanoscale product registrations will continue to be made on a conditional basis with extensive pending data development obligations.

Conditional registration for new active ingredients depends on advancement of the public interest. It will be critical for applicants to identify the public interest benefits of their products and to support those benefit claims with data. EPA has demonstrated with the discretion exercised in these cases that it will support innovations in pesticide chemistry where there are public benefits. Nevertheless, regulatory review times and interim and final decision making will continue to be protracted. In the absence of a large body of relevant size-specific toxicology data, assessment will be characterized by heavy reliance on large uncertainty factors and convincing, application-specific product exposure data, including close characterization of the physical and chemical form or transformation products of the chemical at the time of exposure.

The tiered testing programs for the HeiQ and NanoSilva products are similar, with differences in part reflecting differences in composition, use, and what was known about nanosilver release and hazard characteristics at the time of registration. They may serve as useful benchmarks for future and currently pending nanoscale pesticide applicants. Both the testing tiers and risk analysis confirm that products with limited release potential are likely to fare better on review, and careful consideration should be given toward developing acceptable release data.

EPA will continue to solicit public involvement. The agency is only required to publish notice and solicit and accept public comments at the time the application is filed and required data are submitted. FIFRA § 3(c)(4), 7 U.S.C. § 136a(c)(4). In both the NanoSilva and HeiQ AGS-20 cases, EPA voluntarily initiated a second public comment period at the time a proposed decision was ready. These comments have doubtlessly led to a more rigorous and transparent decision-making process and a higher degree of confidence in the outcome, but they also appear to add 18 months to two years to the registration decision-making process.

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ENVIRONMENTAL APPEALS BOARD VACATES $2.5 MILLION TSCA SECTION 8(E) PENALTY
Lawrence E. Culleen

In an unexpected ruling, the U.S. Environmental Protection Agency’s (EPA) Environmental Appeals Board (EAB) reversed a key aspect of the agency’s Chief Administrative Law Judge’s (ALJ) determination in a Toxic Substances Control Act (TSCA) enforcement case and in so doing set aside the landmark penalty that had been handed down by the ALJ. The EAB nevertheless upheld the ALJ’s finding that violations of TSCA section 8(e), 15 U.S.C. § 2607(e), are continuing in nature for each day an entity fails to fulfill the statutory requirement to submit immediately to EPA information that “reasonably supports the conclusion” that a chemical substance presents a “substantial risk of injury” to health or the environment.


In spite of the EAB’s determination that no penalty should be awarded, vacating the multi-million dollar penalty does not provide comfort regarding the scope of this reporting requirement to parties subject to section 8(e). In fact, the EAB “flatly reject[ed]” Elementis’s contention that the study as a whole did not constitute reportable information under section 8(e). The EAB also rejected Elementis’s argument that the enforcement action was untimely because the civil enforcement action was not commenced within five years of the time when Elementis obtained the study. (The precedent that the general federal statute of limitations applies in TSCA civil enforcement cases was established by the D.C. Circuit in a case in which Arnold & Porter represented the plaintiff, 3M Co. v. Browner, 17 F.3d 1453, 1457–58 (D.C. Cir. 1994).) Instead, for the basis of its reversal of the ALJ’s decision, the EAB looked to long-standing EPA guidance that interprets TSCA section 8(e)’s reporting obligation to include an exemption from reporting for “corroborative” information. The EAB made a point of reiterating that it would have affirmed the ALJ’s decision in its entirety if it were solely guided by the text of TSCA section 8(e), but said that EPA’s own guidance documents had constrained the statute’s “broad reach.” This leaves open the possibility that the agency could revise its historical guidance and readily expand the section 8(e) reporting obligation in the future.

Background

The focus of the Elementis enforcement proceeding was a workplace epidemiological study commissioned in 1998 by a trade group of which Elementis—the only U.S. producer of basic hexavalent chromium chemicals—was a member. The trade group and its members were interested in generating data that could undermine or refute data upon which the Occupational Safety and Health Administration (OSHA) would rely when considering modifications to the permissible exposure limit (PEL) for hexavalent chromium. The trade group hoped that its epidemiological study would better characterize mortality rates and effects associated with exposures in more contemporary manufacturing conditions than were reflected in previous studies.

A final copy of the study was submitted to an
Elementis official in October 2002. The report showed that workplace inhalation exposure to hexavalent chromium was associated with an increased incidence of lung cancer. An Elementis official determined that Elementis was not required to submit the study to EPA (though he admitted that he did not review TSCA or any EPA guidance documents to make this determination). Two years earlier, an EPA employee had completed a similar study on behalf of the agency. The EPA study also had found a positive association between cumulative hexavalent chromium exposure and lung cancer. Importantly, the lowest dose level associated with a statistically significant lung cancer effect in the EPA study was lower than the exposure level at which such an effect was observed in the trade group’s study.

Around the same time the Elementis official received the final report on the trade group’s study, a public request was issued by OSHA seeking data on hexavalent chromium. Although the company participated in OSHA’s rulemaking proceedings on hexavalent chromium PELs between 2002 and 2006, Elementis did not submit the report. In 2006, EPA learned of the existence of the study and issued a subpoena that resulted in EPA finally receiving the final report from Elementis in 2008. It took two more years for EPA to file its administrative complaint against Elementis, alleging that the company violated TSCA section 8(e) by not immediately submitting the final report of the epidemiological study when it obtained it in October 2002.

**ALJ’s Decision**

In a prehearing determination made in March 2011, the agency’s chief ALJ denied Elementis’s motion to dismiss the enforcement action as untimely. In re Elementis Chromium, Inc., EPA Docket No. TSCA-HQ-2010-0522 (Order on Respondent’s Motion for Judgment on the Pleadings Mar. 28, 2011), http://yosemite.epa.gov/OA/RHC/EPAAdmin.nsf/Filing s/93139538CA24554E85257A63001B7A45/$File/tscahq20105022_001.pdf. The denial was grounded in the judge’s determination upholding EPA’s longstanding interpretation that violations of TSCA section 8(e) are continuing in nature. In 2013, after a three-day evidentiary hearing, the judge held that the trade group study was the type of information required to be submitted under section 8(e) and that the study was not information that was “corroborative of well-established adverse effects,” which EPA guidance would have interpreted as being exempt from the reporting requirement. The ALJ said that the study did not concern a “well-established adverse effect” and that there were “multiple and significant distinctions” between the trade association study and the earlier EPA study.

The judge’s opinion detailed five distinctions she concluded made the trade group study sufficiently different from its predecessors, including the EPA study, such that it was not merely “corroborative” of earlier data. In particular, the judge called attention to (1) the more modern conditions in the plants at which the workers studied had been employed; (2) the inclusion of “short-term” workers in the data analyzed; (3) reporting of data with respect to the presence of certain chemicals in the urine of the workers; (4) the level of detail provided about the “job exposure matrix” used in the study; and (5) efforts taken to control for the effects of smoking on the observations of lung effects in the workers studied.

**The Environmental Appeals Board’s Decision**

In reversing the ALJ’s decision, the EAB addressed three main issues: the statute of limitations, interpretation of section 8(e), and the impact of EPA guidance on the interpretation of section 8(e). On the first two issues, the EAB squarely affirmed the judge’s conclusions, but ruled in favor of Elementis on the decisive third issue.

1. **The enforcement action was timely because failures to comply with section 8(e) are continuing violations.** The EAB concluded that EPA’s enforcement action was not time-barred because failure to comply with section 8(e)’s reporting requirement was a continuing violation. The
EAB said this characterization was “not only the most natural reading” of TSCA but also “the interpretation that furthers Congress’ purpose in enacting TSCA.” Since it ultimately did not find Elementis liable, the EAB did not take up the question of whether EPA could recover daily penalties for the entire period of violation (from 2002 to 2008) or whether the agency was limited to recovering penalties only for the days in which Elementis was in violation during the five-year limitations period preceding commencement of the enforcement action.

2. **Considering only section 8(e) itself, the trade group’s study was presumptively reportable information.** The EAB was not at all persuaded by Elementis’s “cramped reading” of section 8(e), which would have limited the scope of information required to be reported. Elementis argued that the only reportable information in the trade group study would have added nothing to what EPA already knew from its own study. Therefore, Elementis contended, it was proper not to submit the trade group study because EPA was adequately informed of the information. The EAB instead concluded that the trade group’s study, “in its entirety,” was information that reasonably supported a conclusion of substantial risk of injury and that (in the absence of EPA guidance) would have been required to be submitted to EPA. The EAB noted that it is not merely the bare conclusion of a study that is reportable under section 8(e), but the underlying data, assumptions, methodology, and analyses.

3. **Long-standing EPA guidance exempted the study from reporting because it was corroborative of a well-established adverse effect.** After ruling against Elementis on the first two points, the EAB turned to EPA guidance dating back to 1978 that interprets section 8(e) to include exemptions for otherwise reportable information, including an exemption for information that is “corroborative of well-established adverse effects in the scientific literature.” 43 Fed. Reg. 11,110 (Mar. 16, 1978); see also EPA, TSCA SECTION 8(E) REPORTING GUIDE (June 1991), http://www.epa.gov/opptintr/tsca8e/pubs/1991guidance.pdf; 58 Fed. Reg. 37,735 (July 13, 1993); 68 Fed. Reg. 33,129 (June 3, 2003); EPA, Frequent Questions: September 2006, http://www.epa.gov/oppt/ tsca8e/pubs/frequentlyaskedquestionsfaqs. html#2006 (last visited Mar. 18, 2015). The EAB said that a “consistent theme” of the guidance on this exemption is that information is non-corroborative only when it shows that the effects of a chemical substance or mixture are “of a more serious degree or a different kind” than previously known. In this case’s context, “more serious” would require either that a study show adverse effects occurring at lower dose levels or in a shorter time frame. Unlike the ALJ, the EAB found that, based on EPA guidance, the trade group study did address a well-established adverse effect—lung cancer—resulting from inhalation exposures. The EAB said that EPA and the ALJ had “strayed far” from the meaning of the term “adverse effect” when they treated new information about lung cancer risk and the dose-response relationship between hexavalent chromium and lung cancer as new information about adverse effects. The EAB then proceeded to find that the trade group’s study was corroborative of hexavalent chromium’s lung cancer effect. The EAB said that none of the five distinctions that the ALJ identified between the trade group study and the EPA study showed that hexavalent chromium causes lung cancer at lower doses or within a shorter time to the onset of cancer in the prior study already in the agency’s possession. Therefore, even if the trade group study provided new, valuable, or different information, it could not be non-corroborative under these circumstances.
Significance of the Decision

The EAB’s decision highlights the complexities of applying agency guidance on the exemption for “corroborative” information in the context of human epidemiological studies, especially where there are factual differences concerning the ways in which exposures occurred and the periods of time being evaluated. Not surprisingly, the EAB suggested that the agency consider explicitly excluding epidemiological studies from the exemption from reporting for corroborative information. Alternatively, the EAB suggested that because cancer studies “can be particularly complex and controversial,” it might be simpler for both the regulated community and EPA to remove cancer studies from the exemption’s scope.

It is still too early to predict whether EPA will make any effort to revise its section 8(e) policies, although it can likely do so in this context without the benefit of notice and comment rulemaking. If the agency does not offer amended, published guidance, given the financial stakes in TSCA section 8(e) penalties cases, it is likely that unwelcomed future “guidance” could be handed down in the form of decisions reached in adjudicated enforcement cases.

Lawrence E. Culleen is a partner with Arnold & Porter LLP in Washington, D.C.

CHEMICAL CONTROL REFORM EFFORTS UNDER TSCA SHOULD INCLUDE FEDERAL “VOLUNTARY” PROGRAMS

Charles L. Franklin

As lawmakers and stakeholders debate whether and how to reform the 40-year old Toxic Substances Control Act (TSCA), 15 U.S.C. § 2601 et seq., it is important to recognize that traditional regulatory development and enforcement are not the only tools federal regulators use to shape and influence chemical research, development, commercialization, and selection. Increasingly, the U.S. Environmental Protection Agency (EPA) and other federal agencies are using the Internet, social media, and health and environmental marketing techniques to promote market adoption and deselection of substances and products that would be difficult, if not impossible, to accomplish using regulatory authority alone. If the goal of TSCA reform is to reestablish the federal government’s credibility in setting risk-based, data-driven health and environmental safety standards for chemicals used in commerce, any new bill should recalibrate EPA’s voluntary program authority as well.

The line between regulatory authority and market influence has blurred over the past two decades. Following the 1991 Corrosion Proof Fittings decision that overturned EPA's comprehensive ban on asbestos, EPA largely abandoned its TSCA section 6 risk management authority, opting instead for public-private partnerships and market-based incentive programs like the Design for the Environment (DfE) program, the “Environmentally Pre-ferable Products” website, and related efforts. See www.epa.gov/saferchoice and www.gov/epp. These programs steer consumers, retailers, and their supply chains toward products and product inputs that EPA has deemed to be “safer” or preferable based on simple hazard screens that equate a product’s safety and environmental impact to the theoretical toxicity of its individual ingredients.

While popular with many stakeholders and expedient from a resource management perspective,
hazard-based ingredient standards say little about the ultimate safety, let alone the broader sustainability, of the end-use product. See, e.g., Charles L. Franklin, *Chasing Hazards: Toxicity, Sustainability, and the Hazard Paradox*, American Bar Association, Natural Resources & Environment, volume 29, number 4 (Spring 2015). Indeed, in October 2014, the National Research Council (NRC) issued a report evaluating EPA’s DfE program, along with several other state and third-party alternative analysis regimes, recommending “increased focus on comparative exposure assessment” and greater consideration of “other metrics, including environmental impact, cost, performance and social impact” in assessing potential trade-offs. National Academies of Science (NAS), NRC, *A Framework to Guide Selection of Chemical Alternatives*, ISBN 978-0-309-31013-0 (2014), 1–7, available at http://www.nap.edu/catalog/18872/a-framework-to-guide-selection-of-chemical-alternatives. Notwithstanding the recommendations of the 2014 NAS report, the Obama administration essentially doubled down on its hazard-only paradigm five months later when, in March 2015, it rebranded its DfE labeling program as the “Safer Choice” labeling program while making negligible changes to the evaluation criteria used to assess the relative safety of selected products.

To date, there has been little, if any, public debate about the merits of aligning EPA’s voluntary program activities with EPA’s regulatory activities under a reformed TSCA statute. With three very different legislative proposals still in play, however, it is not too late. Section 24 of the bipartisan Frank R. Launtenberg Chemical Safety for the 21st Century Act (introduced March 10, 2015) would amend section 27 of TSCA, governing “Development and Evaluation of Test Methods,” and direct EPA to establish an interagency “Sustainable Chemistry Program” to promote and coordinate federal sustainable chemistry research, development, demonstration, technology transfer, commercialization, education, and training activities. See https://www.govtrack.us/congress/bills/114/s697. As introduced, the bill would grant the administrator complete discretion in defining the scope, meaning, and criteria underpinning such sustainable chemistry efforts, raising concerns that EPA might disregard calls for consideration of exposure and life-cycle considerations as it did with its Safer Choice program. One way to prevent this without imposing undue constraints on EPA reasonable discretion would be to insert a clarifying sentence in the bill requiring EPA to consider and follow the recommendations of the non-partisan 2014 NAS report when developing a framework for its Sustainable Chemistry Program:

“The activities of [EPA’s Sustainable Chemistry Program] shall be designed to—

(1) Incorporate the recommendations of the National Academies of Science (NAS) in their 2014 Report, *A Framework to Guide Selection of Chemical Alternatives*, ISBN 978-0-309-31013-0 (2014), including, but not limited to placing a greater emphasis on comparative exposure assessment and lifecycle thinking;”

Neither the TSCA Modernization Act of 2015 discussion draft released by Congressman Shimkus in April 2015 nor the Alan Reinstein and Trevor Schaefer Toxic Chemical Protection Act, S. 725, as introduced by Senator Boxer and Senator Markey in March 2015, includes any reference to EPA’s voluntary program authorities. Still, nothing would prevent including such a provision in future drafts or consensus documents in the course of future negotiations.

Redirecting EPA’s voluntary programs to consider exposure, risk, and other life-cycle impacts will not resolve the difficult issues remaining for lawmakers in the regulatory reform debate. It could, however, ensure that EPA’s own voluntary programmatic activities do not undermine or contradict the carefully crafted federal risk framework of a reformed chemical control statute.

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On April 6, 2015, the U.S. Environmental Protection Agency (EPA) issued a Toxic Substances Control Act (TSCA) section 8(a) proposed rule concerning reporting and record-keeping requirements for certain chemical substances when manufactured (including imported) or processed at the nanoscale. EPA proposes to require persons that manufacture or process these chemical substances to report electronically to EPA certain information, including the specific chemical identity, production volume, methods of manufacture and processing, exposure and release information, and existing data concerning environmental and health effects. EPA also proposes to require any persons who intend to manufacture or process chemical substances as discrete nanoscale materials after the effective date of the final rule to notify EPA of the same information at least 135 days before the intended date of commencement of manufacture or processing. Comments are due by July 6, 2015.

The proposed rule is long overdue and EPA’s perseverance is laudable. EPA has stated repeatedly that it needs the information requested to conclude confidently that nanoscale versions of existing chemical substances pose no unreasonable risk, and to reassure the public what the nano community has been stating for years. That said, the proposal will almost certainly elicit diverse comments from stakeholders along the value chain. The proposal also breaks new ground in requiring reporting under section 8(a) for processors (which are typically not subject to reporting under section 8(a) rules, for example, the Chemical Data Reporting (CDR) rule), perhaps in recognition that different discrete nanoscale forms might be produced via processing. The criteria set forth in the proposal for defining what is subject to reporting, what is exempt, and a requirement for future reporting by entities that intend to manufacture or process a discrete form of a reportable chemical substance at least 135 days before commencement of manufacture or processing will be the subject of much debate.

Chemical Substances That Would Be Reportable

The proposed rule would apply to chemical substances that are solids at 25°C and atmospheric pressure and that are manufactured or processed in a form where the primary particles, aggregates, or agglomerates are in the size range of 1–100 nanometers (nm) and exhibit unique and novel characteristics or properties because of their size. It would apply to chemical substances containing primary particles, aggregates, or agglomerates in the size range of 1–100 nm in at least one dimension, and would not apply to chemical substances that only have trace amounts of primary particles, aggregates, or agglomerates in the size range of 1–100 nm, such that the chemical substance does not exhibit the unique and novel characteristics or properties because of particle size. Importantly, EPA is proposing these parameters for purposes of identifying chemical substances that are subject to the rule, not to establish a definition of what is a nanoscale material.

Discrete Forms

Under the proposed rule, manufacturers and processors of multiple nanoscale forms of the same chemical substance would in some cases need to report separately for each discrete form of the reportable chemical substance. EPA proposes to distinguish the forms based on a combination of three factors: (1) a change in process to affect a change in size and/or a change in properties of the chemical substances manufactured at the nanoscale; (2) a change in mean particle size of 10 percent or greater; and (3) the measured change in at least one of the following properties, zeta potential, specific surface area, dispersion stability, or surface reactivity, is greater than seven times the standard deviation of the measured values.

Chemical Mixtures

The proposed rule would also apply to chemical
substances that are manufactured or processed in a nanoscale form “solely as a component of a mixture, encapsulated material, or composite.” Chemical substances at the nanoscale that are manufactured but are then incorporated into mixtures, encapsulated materials, or composites by that manufacturer would not require separate reporting for their incorporation. EPA states that the person reporting the chemical substance would have to report each step of its manufacture, processing, and use to the extent it is known or reasonably ascertainable, however.

**Exclusions**

EPA notes that a chemical substance, as defined under TSCA section 3(2), does not include any food, food additive, drug, cosmetic, medical device, pesticide, or other excluded materials. EPA states that such materials are not subject to this rule. EPA proposes to exclude certain biological materials (e.g., DNA, RNA, and proteins). EPA seeks comment to identify other specific biological materials that should be excluded from reporting and the reasons for excluding them, including microorganisms and viral-based products, lipids, carbohydrates, enzymes, and peptides. EPA proposes to exclude chemical substances that dissociate completely in water to form ions that are less than 1 nm. This exclusion would not apply to chemical substances manufactured at the nanoscale that release ions but do not dissociate in water to form those ions. EPA states that it believes that the chemical substances that would be excluded do not exhibit new properties when their size falls in the range of 1–100 nm and manufacturing or processing such substances at the nanoscale should therefore not be subject to the reporting requirements. EPA seeks comment to identify other water soluble compounds that should be excluded from reporting and the reasons for excluding them.

EPA proposes to exclude from the reporting requirements nanoclays, zinc oxide, and chemical substances manufactured at the nanoscale as part of a film on a surface. EPA states that it believes that information collected on these materials “would be of limited value because either they have been well-characterized or they present little exposure potential.” EPA requests comment on these proposed exclusions and whether other chemical substances manufactured at the nanoscale should be excluded. Commenters should explain why they believe the chemical substances manufactured at the nanoscale should be excluded.

EPA notes that the general exemptions to TSCA section 8(a) reporting would be applicable. Persons that manufacture or process, or intend to manufacture or process, these chemical substances as part of articles, as impurities, or in small quantities solely for research and development would not be subject to this action.

EPA proposes an alternate to the existing exemption for small manufacturers. Under TSCA section 8(a) rules, a company qualifies as a small manufacturer by meeting either of the following two standards: (1) sales of the company are less than $40 million per year and the company does not manufacture more than 100,000 pounds annually of an individual substance at any individual site owned or controlled by the company; or (2) sales are less than $4 million regardless of the quantity manufactured. The proposed rule would define a small manufacturer or processor as any company with sales of less than $4 million, as the 100,000-pound threshold in the existing exemption “did not contemplate typical production volumes for chemical substances manufactured at the nanoscale.” EPA requests comment on the proposed small manufacturer or processor exemption.

The proposed rule would not require manufacturers or processors to report certain information already submitted to EPA. EPA states that a person who submitted a TSCA chemical notice under section 5 on or after January 1, 2005, would not be required to report regarding the same substance under this proposed TSCA section 8(a) rule except where the person manufactured or processed a new discrete form of the reportable chemical substance. In addition, any person who has already reported under the Nanoscale Materials Stewardship
Program (NMSP) part or all of the information that would be required under the proposed rule would not need to report that information again. EPA states that the purpose of these exemptions is to avoid duplicative reporting and, as an example, new chemical notices that have been reviewed as nanoscale materials would not be subject to reporting the same information under the proposed rule.

**Timeline for Reporting**

EPA proposes that persons who manufacture or process a discrete form of a reportable chemical substance at any time during the three years prior to the final effective date of the rule would report to EPA six months after the final effective date of the rule. EPA also proposes a continuing requirement that persons who intend to manufacture or process a discrete form of a reportable chemical substance on or after the effective date of the rule would report to EPA at least 135 days before commencement of manufacture or processing.

**Reportable Information**

EPA proposes one-time reporting of certain information, including specific chemical identity, production volume, methods of manufacture and processing, use, exposure and release information, and available health and safety data. For this proposed rule, EPA modified an information reporting form developed for the NMSP. Any person required to report under the proposed rule would supply the information identified in the form to the extent it is known to or reasonably ascertainable by them. Once EPA publishes the proposed rule, it will place a draft of the proposed reporting form in the docket for public review. EPA requests comment on whether any information proposed to be collected is duplicative of information collected under other federal statutes and should thus be excluded.

**Development of Additional Data**

EPA notes that a TSCA section 8(a) rule may not require persons to develop test data for submission to EPA. EPA encourages respondents to provide any relevant data on chemical substances manufactured at the nanoscale they decide to develop, however. EPA suggests that persons who intend to conduct testing consult with EPA before selecting a protocol for testing a chemical substance manufactured at the nanoscale. EPA also encourages persons that would be required to submit TSCA section 8(a) data under the proposed rule to provide information on the potential benefits regarding the reportable chemical substance.

EPA seeks public comment on all aspects of the proposed rule. In addition to specific requests noted above, EPA is interested in comments pertaining to a specific list of issues as described in the Federal Register.

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**NOMINATE**

**Call for Nominations due August 10, 2015**

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IS THE SELF-AUDIT POLICY GETTING A MAJOR FACELIFT?
Lawrence E. Culleen

In the 20 years following its initial adoption in 1995, the U.S. Environmental Protection Agency (EPA) has seen its enthusiasm for its “Self-Audit Policy” (Policy) wax and wane. The policy is referred to in Federal Register notices as “Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations.” The policy enables entities that identify, voluntarily self-disclose, and timely mitigate violations of environmental laws to benefit from as much as a complete reduction in the gravity-based portion of potential civil penalties.

In recent years during the Obama presidency, the focus seemed to be more on the proverbial stick than the carrot. In fact, the agency appeared at one time to be giving hints that it might abandon the policy all together. Now, EPA may be considering what could be significant modifications to the policy, and initially, in the manner in which self-disclosures are filed.

In late May, the agency announced that it would hold two webinars addressing EPA’s plans to “modernize” implementation of the policy and the related small business compliance policy. http://www2.epa.gov/compliance/small-business-compliance. EPA is moving toward a plan it has coined “eDisclosure,” which will be centered on a new centralized, web-based system by which EPA can receive and process reports of violations disclosed pursuant to the two policies. EPA intends to streamline the mechanisms for providing disclosures to the agency, which EPA expects will also enable quicker responses. Of potential concern to regulated entities that have taken advantage of the policy in the past is the degree to which the website will create greater awareness on the part of third parties of pending and historical compliance matters before the agency. It remains unclear whether the agency’s intention also is to provide a streamlined, data-driven service for third parties to bring allegations of violations to EPA’s attention.

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