FROM THE CHAIR
Martha Marrapese

By the time the next committee newsletter is published, you will have a new Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) chair. Simply put, I have found my involvement in PCRRTK and the Section of Environment, Energy, and Resources (SEER) to be a fantastic professional experience. Meeting and getting to know many of you better have been the best part of my time as chair. Our time is our most valued commodity as lawyers. Where we choose to place our time says a lot about what we think of the organization. In that respect, I cannot speak highly enough of the organization and the people who make up SEER and PCRRTK. There are so many of you who have contributed your time and expertise to PCRRTK and SEER and we have all benefitted from your commitment. I plan to continue to stay active—there is plenty to do. Thank you to everyone for your input, support, and participation in the committee during my time as chair.

On my personal list of unfinished business there are two very important items—committee membership and committee service projects. The position of committee vice chair for public service projects was eliminated across-the-board by SEER just as I took on the leadership of PCRRTK. In my opinion, this significantly undermined the leadership presence that is needed to guarantee results. Certainly the absence of the vice chair role does not mean that we as a committee cannot or should not engage in public service activities, but it makes it much more challenging. My hope is to see a PCRRTK member with a strong desire and/or record of public service step forward in the coming months and help our very active, talented, and fortunate committee give back to the community.

On the recruitment side, we are a strong and regular 200-plus-member committee, despite low enrollment by law students, government, and nongovernment organization members. To be a member of PCRRTK is free once you sign up to become a member of the American Bar Association (ABA) and SEER. My vision of our future is a 300-plus-member PCRRTK. We have made some progress in this area by simply analyzing our committee demographic. We have a great group of committee vice chairs who can build with that information, now that our understanding of who we are as a committee has improved.

We still have plenty going on in the next few months in the programming area—stay tuned for announcements about brown bag sessions on how to implement the new hazard communication rules, and the latest developments in pesticides and endangered species and minimum risk pesticide regulation. Our monthly PCRRTK teleconferences will continue on the last Monday of each month at 11:00 a.m. (Eastern). Don’t forget to tweet your announcements of upcoming events or exciting new developments and contribute on our content on the SEER LinkedIn page. And, we have those marvelous breakfast briefings hosted by Joanne Thelmo, general counsel at the American Cleaning Institute and our incoming PCRRTK chair, to keep looking forward to as well.

Martha E. Marrapese is a partner with Keller and Heckman LLP in Washington, D.C.
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Lynn L. Bergeson, Editor

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Republicans in the U.S. House of Representatives have waded into the unpredictable currents of federal legislative efforts to reform one of the nation’s least appreciated environmental laws. In late February and again in April 2014, Representative John Shimkus (R-IL), chair of the House Energy and Commerce Subcommittee on Environment and the Economy, released an initial and subsequently revised “Discussion Draft” of a bill to amend the nearly 38-year-old Toxic Substances Control Act (TSCA). The House Discussion Draft provides an opportunity for legislators to address in a new piece of legislation various concerns raised by critics of the bipartisan Senate bill (S. 1009—the “Chemical Safety Improvement Act”) introduced in the Senate in 2013 by Senators David Vitter (R-LA) and Frank Lautenberg (D-NJ). Senator Tom Udall (D-NM) has taken over as the leading Democratic cosponsor of CSIA in the wake of Senator Lautenberg’s death last year.

The first and second House Discussion Drafts were the subject of subcommittee hearings March 12 and April 29, respectively, each designed to generate bipartisan support and eventually produce a bill that can be introduced, make it out of committee, win support on the floor of the House, and be reckoned with in the Senate.

**Top Line Review.** The Discussion Draft requires the U.S. Environmental Protection Agency (EPA) to prioritize chemicals in commerce (active chemicals) into “high priority” and “low priority” categories for review and action by EPA; specifies only a few deadlines not included in the initial draft by which EPA must take regulatory actions; and provides the agency with the authority to take actions through administrative orders, consent agreements, or rulemakings. The latest draft attempts to steer clear of the controversy that arose over language in the Senate bill, which appeared to hinder private litigation alleging “toxic torts” and limit the states’ regulatory authority.

**Notes on Specific Sections**

**Section 4—Testing of Chemical Substances and Mixtures.** The Discussion Draft would update EPA’s current authority to require testing of chemical substances, not only through test rules but also by administrative orders and negotiated consent agreements requiring manufacturers or processors to gather data on substances and mixtures. EPA could seek new data when needed to perform safety determinations, to enforce a rule or order, to review substances intended for export, or to implement another federal law. If currently available information is insufficient, screening level data must be sought first, followed by more elaborate testing if necessary. EPA must justify the use of an administrative order rather than a rulemaking.

**Section 5—New Chemicals and Significant New Uses.** The House Discussion Draft keeps in place the key features of the framework of EPA’s current new chemicals program including the 90-day premanufacture notification requirement for new chemicals and for notification when manufacturing or processing a substance subject to a significant new use.

Section 5(c) requires that EPA reach a determination regarding each new chemical or new use for which the agency receives notification. In doing so, EPA would be permitted to develop a “profile” of each substance reviewed, could request additional information and extend the review period to do so, and seek to limit (or prohibit) activities involving the new chemical substance if the substance “may present an unreasonable risk of harm to human health or the environment.” EPA would be authorized to take action by rule or order, or by reaching a consent agreement with the notice submitter. Existing exemptions from the notification requirements for R&D and test marketing activities and for non-isolated intermediate substances also are preserved.

**Section 6—Prioritizing and Safety Designations for Existing Chemicals.** One year following enactment, EPA must develop a “risk-based” process for prioritizing chemical substances in commerce as
either high or low priority. Substances for which there is the potential for high hazard and high exposure under the intended conditions of use must be identified as high priority chemicals. Those with high hazard or high exposure may be identified as high priority. The absence of health and safety data on a chemical substance would be considered a factor in such designations as would the potential for exposures to vulnerable subpopulations. Low priority chemicals are generally not subject to further review. Within four years of its ranking, EPA must complete a risk assessment of a high priority chemical substance to determine whether the substance “presents or will present” in the absence of regulation “a significant risk of harm to human health or the environment” under the “intended conditions of use.” EPA also may determine that additional information is needed before it completes a risk assessment, and it may delay further action to require the information be gathered and submitted pursuant to a rule, order, or consent agreement. Risk assessments may not consider costs or benefits and must consider “potentially exposed subpopulations.” EPA is instructed in the Discussion Draft not to take into consideration the costs and benefits of a substance or use of that substance. EPA would be required to publish its determinations and the analysis supporting the determination.

If EPA determines that a substance presents or will present a significant risk of harm to human health or the environment under its intended conditions of use, the Discussion Draft would require that within three years of completing the risk assessment, EPA issue a regulation that can restrict the chemical substance, mixtures which contain it, and even finished products (articles) containing the substance. EPA can establish requirements ranging from warning labels to complete prohibitions on the substance. EPA must consider whether feasible alternatives that reduce risk to health or the environment are available and likely to be used as a substitute by the time a restrictive rule would go into effect. The Discussion Draft includes a new provision requiring EPA to issue guidance regarding how it will take aggregate exposures into account in the regulatory context.

Section 8—Information Collection and Reporting. The Discussion Draft would require EPA to develop guidance (but not specifically regulations) concerning the types and level of detail for information that manufacturers and processors must report on use and exposures to chemicals in commerce. The draft bill would permit EPA to choose not to have its section 8 requirement apply to “chemicals extracted by reaction or otherwise from another substance for purposes of recycling or reclamation.” Addressing other concerns of the regulated community, specific chemical nomenclature conventions currently used in the industry would be preserved in the statute if amended as proposed. The Discussion Draft would distinguish between chemicals that are “active” in commerce and those that are not—while permitting sponsors of inactive chemicals to move them into “active” by giving notice to EPA. Existing requirements concerning recordkeeping for allegations of chemical harms and submitting of new data about chemical risks would be largely unaffected.

Section 9—Relationship to Other Federal Laws. Consistent with themes expressed elsewhere in the Discussion Draft, the amendments proposed to TSCA section 9 would require EPA to determine whether taking regulatory action under TSCA is more cost-effective than acting under another federal law.

Sections 12 and 13—Exports and Imports. In recent years, EPA has exhibited a willingness to take regulatory actions that would affect certain articles on the basis of chemicals that are used in their manufacture. In response to concerns raised about EPA’s efforts in this regard, the Discussion Draft would disable EPA’s ability to regulate exported and imported articles other than through rulemakings under the amended section 6.

Section 14—Confidential Information. The Discussion Draft makes clear that the amendments proposed to replace the current section 14(a) would require that trade secrets meeting the Freedom of Information Act criteria (5 U.S.C. § 552(b)(4)) “shall not be disclosed.” The Discussion Draft’s section 14 also shields other commercially sensitive information from disclosure, such as manufacturing and processing
Section 16—Penalties. The Discussion Draft would increase the civil penalties for violations of TSCA to US$37,500 per day for each violation, and would increase criminal penalties to US$50,000 per day. The Discussion Draft also adds a provision creating a new category of violation when a person knowingly places others in imminent danger of “death or serious bodily harm.” The fine in such circumstances could be as much as $250,000 and/or imprisonment.

Section 17—Preemption. Lately, the most closely monitored issue in the TSCA reform debate has been the provisions related to preemption. The Discussion Draft would amend TSCA section 18 such that TSCA would preempt state or local laws and regulations that require development or submission of information that EPA has called for under sections 4, 5, or 6 and state or local regulations and laws that restrict a substance, mixture, or article for its intended conditions of use after:

- The agency has determined that a substance does not warrant regulation under section 5(c) or section 6(b);
- EPA has issued a regulation or order restricting the chemical;
- The review period ends for a new chemical or new use subject to notification under section 5; or
- The agency has determined a substance to be “low priority.”

The Discussion Draft does not preempt state or local laws undertaken pursuant to any other federal law. Perhaps to the great relief of trial lawyers who also have voiced concerns about S. 1009, the Discussion Draft would have no effect on claims for monetary damages or equitable relief brought under state laws alleging personal injury, death, or property damage arising from exposures to a substance or mixture.

Section 27—Preservation of Authority. Unlike the Senate bill, the House Discussion Draft professes that it does not amend or alter EPA’s authority under TSCA, or the “continued application or validity of any EPA action under TSCA” prior to enactment of the amendments. This implies that all current TSCA regulations, consent orders, testing agreements, reporting rules, and Inventory listings would remain unchanged and in effect unless modified by EPA.

Conclusion

While the House Discussion Draft may yet garner enthusiasm for the introduction of a bill and a floor vote, it must do so soon if bipartisan progress is to be made before the election season arrives in earnest, dimming hope for further progress.

Lawrence E. Culleen is a partner with Arnold & Porter LLP in Washington, D.C.
The U.S. Environmental Protection Agency (EPA) published a notice on April 4, 2014, announcing that it issued a testing order that incorporates an enforceable consent agreement (ECA) for octamethylcyclotetrasiloxane (D4), a chemical intermediate and component of personal care products. 79 Fed. Reg. 18,822. There are two big take away messages here. First, that EPA issued a testing order at all under Toxic Substances Control Act (TSCA) section 4 is big news as none has been issued in a while. Second, this is not your standard section 4 order for the reasons discussed below. The ECA may well serve as a template for other similar ECAs, and stakeholders may wish to read on to understand what is new and different about this ECA.

**Background**

According to EPA, D4 is a high production volume chemical (100–500 million pounds per year), is highly persistent in sediment, exhibits high bioaccumulation potential, is a potential reproductive toxicant, exhibits aquatic toxicity, is present in biomonitoring (blood, breast milk, and aquatic species), and is used in consumer products, including soaps and detergents, adhesives and sealants, and polishes and sanitation products. EPA most recently expressed concern with D4 on June 1, 2012, when EPA added D4 and 17 other chemicals to the list of chemicals for assessment in 2013 and 2014 under EPA’s Work Plan Chemicals program (see http://www.lawbc.com/regulatory-developments/entry/epa-announces-work-plan-chemicals-for-assessment-during-2013-and-2014/). EPA’s interest in D4 goes way back, however, almost 30 years to November 1984 when EPA’s Interagency Testing Committee (ITC) recommended what was then referred to as octamethylcyclotetrasiloxane (OMCTS) be considered for chemical fate and environmental effects testing. In 1985, EPA issued a proposed TSCA test rule requiring OMCTS manufacturers to conduct certain chemical fate and environmental effects testing. 50 Fed. Reg. 45,123 (Oct. 30, 1985). A final rule announcing an ECA was issued four years later on January 10, 1989. 54 Fed. Reg. 818.

**Key Testing Parameters**

As reported in several trade press accounts, the negotiations relating to the new ECA were protracted and difficult. Under the ECA, EPA will require testing for D4’s presence in several environmental media. The testing program will be conducted over a one-year period. EPA will use the information obtained through the ECA in conjunction with other available data to assess exposures and risks due to environmental releases from D4. As a result of the ECA, exporters of D4, including persons who do not sign the ECA, are subject to TSCA export notification requirements.

According to the *Federal Register* notice, Dow Corning Corporation, Evonik Corporation, Momentive Performance Materials USA Inc., Shin-Etsu Silicones of America, Inc., and Wacker Chemical Corporation agreed to certain environmental testing that EPA will use to characterize sources and pathways of release of D4 to the environment and resulting exposures of aquatic and sediment dwelling organisms to D4. The ECA requires testing for the presence of D4 around specified wastewater treatment plants (WWTP) at the method detection limits specified in the ECA. The notice states that environmental testing will be conducted at direct discharge sites. Direct discharge sites are D4 manufacturing and/or processing sites that discharge process wastewater into the environment after on-site wastewater treatment. Environmental testing will be conducted at WWTPs serving indirect discharge sites. Indirect discharge sites are D4 processing sites, including product formulation sites that discharge process wastewater to off-site WWTPs. The notice states that primarily non-industrial WWTPs receive less than 15 percent of wastewater from industrial facilities and, preferably, no wastewater from D4 manufacturing or processing (including product formulation) sites. Environmental testing will be conducted at WWTPs serving primarily non-industrial wastewater treatment sites. Reportedly, the number of...
monitoring sites was a key stumbling block during the negotiations.

Following completion of the required environmental testing, the signatory companies must submit a final report to EPA. EPA states that it intends to release the final report to the public. EPA will use the test data to develop D4 environmental exposure and risk assessments. EPA notes that other federal agencies, including the Agency for Toxic Substances and Disease Registry (ATSDR), the Consumer Product Safety Commission (CPSC), and the U.S. Food and Drug Administration (FDA), could use the data in assessing chemical risks and in taking appropriate actions within their programs.

**Interesting Aspects of the ECA**

As of April 4, 2014, the effective date of the ECA and the order that incorporates the ECA under TSCA section 4, any of the signatory companies or any other person who exports or intends to export any D4 that is the subject of the ECA and order that incorporates the ECA, in any form, is subject to the export notification requirements of TSCA section 12(b). Section 12(b) requires any person who exports or intends to export to a foreign country a chemical substance or mixture for which the submission of data is required under TSCA section 4 to submit a notification of the export or intended export to EPA. Typically, EPA provides a 30-day period before export notification is required. Not so here.

Interestingly also, the *Federal Register* notes that as of the effective date of the order (April 4, 2014), “any of the Companies, as well as any other person, who exports or intends to export any D4 that is the subject of this ECA and Order that incorporates the ECA, in any form, are subject to the export notification requirements of TSCA section 12(b)” (emphasis added). While the meaning of “in any form” is less than clear in the *Federal Register* notice and the point is not explained in the ECA text, 40 C.F.R. § 707.60(b) states that “[n]o notice of export will be required for articles . . . unless” EPA “so requires in the context of individual section 5, 6, or 7 actions.” Thus, despite the lack of clarity, the export notification requirement, absent additional EPA action, does not extend to articles containing D4.

Substantively, the testing requirements under the ECA are unique. This ECA represents one of the few attempts to generate exposure test data pertinent to a substance. Another example is the ECA on refractory ceramic fibers (40 C.F.R. § 799.5000), which issued in 1993 and included exposure monitoring testing. As noted, testing is to be conducted on samples collected at four direct discharge locations and five indirect discharge locations that include D4 processors, including product formulators.

Finally, this is the first ECA to issue since EPA changed its approach in 2010 to developing ECAs to include discrete timelines for negotiation. For more information on the new section 4 process, see [http://www.lawbc.com/regulatory-developments/entry/epa-proposes-amendments-to-tsca-section-4-enforceable-consent-agreement-pro/](http://www.lawbc.com/regulatory-developments/entry/epa-proposes-amendments-to-tsca-section-4-enforceable-consent-agreement-pro/). The fact that the revised negotiation approach was successful and given the need for and difficulties in otherwise obtaining exposure test data, this approach with D4 could serve as a template for future ECAs intended to assess chemical exposures.


Lynn L. Bergeson is managing partner of Bergeson & Campbell, P.C. (B&C®), a Washington, D.C., law firm focusing on conventional, nanoscale, and biobased industrial, agricultural, and specialty chemical product regulation and approval matters, and chemical product litigation. She is president of The Acta Group, LLC., and managing director of The Acta Group EU, Ltd with offices in Washington, D.C., and Manchester, UK. Timothy D. Backstrom is Of Counsel with B&C®.
NANOSILVER IN CONSUMER PRODUCTS
Nadia Kaddour

Metallic silver (in a particulate or “colloidal” form) and silver salts have been used widely in consumer products for their antimicrobial activity. In recent years, it is the nanoscale form of silver that has received the attention of researchers and companies. If nanosilver, like other forms of silver, is incorporated in a pesticide formulation for its antimicrobial properties, it must be registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA defines a “pesticide” as any substance intended for preventing, destroying, repelling, or mitigating any pest (the term “pest” includes any fungus, bacterium, or other microorganism). The pesticidal intent is an important element in the definition of a pesticide.

Under FIFRA implementing regulations, a substance is considered to be intended for a pesticidal purpose if (a) the person who distributes or sells the substance claims, states, or implies (by labeling or otherwise) (1) that the substance can or should be used as a pesticide; or (2) that the substance consists of or contains an active ingredient and that it can be used to manufacture a pesticide; or (b) the substance consists of or contains one or more active ingredients and has no significant commercially valuable use as distributed or sold other than (1) use for a pesticidal purpose, (2) use for manufacture of a pesticide; or (c) the person who distributes or sells the substance has actual or constructive knowledge that the substance will be used, or is intended to be used, for a pesticidal purpose.

Under regulations implementing FIFRA, an exemption from FIFRA registration requirements exists for “treated articles.” A “treated article” refers to an article or product that is treated with a registered antimicrobial pesticide to protect the article or product itself (for example wood products treated to protect the wood against fungus infestation). Under this exemption, provided the pesticide is used to protect the article, the product containing the pesticide need not be registered under FIFRA if no pesticidal claim is made with regard to the treated article itself. Articles treated with a pesticide claimed to be effective in controlling microorganisms (e.g., E.coli) cannot benefit from the “treated articles” exemption and must be registered as a pesticide because such claim constitutes a pesticide claim that goes beyond the preservation of the “treated article” itself.

The first FIFRA registration application that the U.S. Environmental Protection Agency (EPA) expressly evaluated as a nanosilver product was filed in 2008 by HeiQ, AG. The pesticide product for which HeiQ sought registration is a nanosilver material intended to be applied to manufactured textiles to suppress the growth of microbes that cause odors and degradation.

In December 2011, EPA conditionally registered this pesticide product containing nanosilver as a “new” active ingredient. The conditional registration was challenged in federal court and in November 2013 the U.S. Court of Appeals for the Ninth Circuit partially vacated EPA’s decision. The court vacated the registration to the extent that EPA concluded that there was no risk concern requiring mitigation for short- and intermediate-term aggregate oral and dermal exposure to textiles that are surface coated with the nanosilver material. The court ruled that EPA did not properly apply its risk assessment rule, which was based on the calculation of a margin of exposure (MOE). After setting the target MOE at 1000, EPA calculated the actual MOE under a number of scenarios and came to the determination that there would be a risk concern requiring mitigation if the calculated MOE for inhalation, oral, or dermal exposure (short-term and intermediate-term) was less than or equal to 1000. EPA found that the aggregate MOE for a textile surface coated with the HeiQ silver nanomaterial was exactly 1000, and therefore should have concluded that there was a risk concern requiring mitigation. Following this decision, EPA approved an application by HeiQ to reduce the allowed application rate, thereby resulting in an MOE exceeding 1000.

In a Stop Sale, Use or Removal Order of March 2014, EPA ordered Pathway Investment Corp. (Pathway) not to sell any of its nanosilver-infused plastic food containers because EPA claimed they were unregistered pesticide products and their
distribution constituted an unlawful act under FIFRA. EPA’s order first referred to the claims made by Pathway on its Web site, labels, product’s description sheet, and benefit sheets distributed to its vendors. The claims stated the use of nanosilver technology in the manufacture of the food containers and the benefits of such technology (“nanosilver particles help reduce the growth of . . . bacteria,” “helped food stay fresh up to 3 times longer . . .”). EPA concluded that the use of the term “nanosilver” on the labeling, Web site, and marketing materials established that Pathway had actual or constructive knowledge that its customers would use the food containers as pesticides. Pursuant to FIFRA regulations, having actual or constructive knowledge that the substance will be used for a pesticidal purpose will cause the substance to be considered to be intended for a pesticidal purpose, and thus to be a pesticide requiring registration. EPA also reviewed Pathway’s vendors’ Web sites and found that pesticidal claims were made on those sites as well.

EPA next focused on the nanosilver substance infused in the plastic food containers and concluded that the presence of nanosilver in the plastic containers rendered these containers pesticide products requiring registration under FIFRA.

Claims, actual or constructive knowledge, and composition were the basis of EPA’s Order, which concluded that Pathway nanosilver infused plastic food containers were intended for a pesticidal purpose and thus were subject to registration in accordance with the provisions of FIFRA implementing regulations.

EPA brought similar claims to marketers in 2008 and 2009. EPA reviewed the public health and the pesticidal claims made by two companies (IOGEAR and Samsung) regarding nanosilver coating on computer peripherals and computer laptops and ordered fines exceeding $200,000 against them because EPA considered these products to be pesticide products requiring registration under FIFRA and the products were not in fact registered.

Following the issuance of the orders, these companies chose to stop distributing the products containing nanosilver materials rather than applying for a FIFRA registration. According to EPA, there are currently no consumer products containing nanosilver materials registered under FIFRA. Because the review of claims is usually the first step in EPA’s FIFRA investigation, companies should give close and careful attention to their product claims.

Nadia Kaddour is an associate with Kevin MacCarthy Associates, P.C. in New York City.
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