FROM THE CHAIR

Martha Marrapese

2013 was a banner year for the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee. In October, the Section of Environment, Energy, and Resources (SEER) selected our committee for three very noteworthy awards—Best Environmental Committee, Best Newsletter, and Best Programming. That kind of recognition at the 21st Fall Conference is even more notable considering our modest size of only 219 members. I was extremely honored to be able to receive these awards on all members’ behalf from SEER Chair Bill Penny (member, Stites & Harbison PLLC). You may wish to view our photo at http://www.americanbar.org/groups/environment_energy_resources/committees/comm_awards.html. Immediately following, Lynn L. Bergeson (member and Managing Partner, Bergeson & Campbell, P.C.) gave a keynote address at the packed plenary session, which was very well received. Thank you, Lynn, for all the ways in which you make PCRRTK shine, even on a very rainy morning in Baltimore.

Congratulations to PCRRTK’s 2013–2014 PCRRTK Young Lawyers Membership Vice-Chair Shailesh Sahay (associate, Arnold & Porter LLP). Shai successfully completed the ABA SEER Leadership Development Program Objective in 2013. During his participation in this program, Shai helped to design and lead a SEER-sponsored project to better understand why nonprofit organization attorneys (including nongovernmental organization (NGO), government, and academic attorneys) are underrepresented in SEER. Through a survey sent to attorneys in all 50 states, this group found the cost of membership and programming to be the primary deterrents. The 2012–2013 Leadership Development participants offered several recommendations for SEER leadership to consider in the future. At the present time, PCRRTK frequently offers free “brown bag” webinar programs and the Friday Forum sessions that Special Projects Vice-Chair Joanne Thelmo (general counsel, American Cleaning Institute) organizes are offered on a complimentary basis. We do not want cost to prevent practitioners from taking part in these highly informative sessions! Please do not hesitate to share other ideas with us on approaches to address the concerns over cost and programming.

What was your New Year’s resolution? Mine is to become more proficient with the professional opportunities that social media offers. You do not need a crystal ball to predict that lawyers will learn how to use social networking effectively for business. Dennis Kennedy and Allison Shields point out in their very useful American Bar Association (ABA) publications, *Facebook® in One Hour for Lawyers* and *LinkedIn® in One Hour for Lawyers*, that lawyers entering the profession today will be highly adept at using social media for business development. For the rest of us, this means...
Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter
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Lynn L. Bergeson, Editor

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Any opinions expressed are those of the contributors and shall not be construed to represent the policies of the American Bar Association or the Section of Environment, Energy, and Resources.

CALENDAR OF SECTION EVENTS

February 5-11, 2014
ABA Midyear Meeting
Chicago, IL

February 10, 2014
Regulating Executive Compensation: The Federal TARP Statute and the Role of the Pay Czar
Webinar
Free CLE!

February 19, 2014
Real Environmental Concerns in Real Property and Business Transactions
Webinar/Teleconference
Primary Sponsor: Business Law Section

February 19, 2014
So You’re Not In The Top 10% Of Your Class, That’s Not A Prerequisite For Success!
Non-CLE Webinar

February 20, 2014
Meet the ABA SEER—Social/Network Event
New York, NY

February 27, 2014
CERCLA Case Studies and Lessons Learned: Novel Approaches to and Noteworthy Outcomes for Superfund Sites
Webinar

March 20-22, 2014
43rd Spring Conference
The Grand America Hotel
Salt Lake City, UT

For full details, please visit www.ambar.org/EnvironCalendar
taking the plunge or risking missed opportunities. The ABA SEER LinkedIn page, for example, has 4264 members—are you one of them? Have you started a discussion or contributed a comment? I encourage you to contact PCRRTK Vice-Chair for Social Media Kirk Tracy (Kirk recently completed an internship with the American Water Works Association) for assistance in taking the social media plunge. Several of us can be followed for announcements on Twitter (e.g., Bill Penny is @tnenvlawyer, Kirk Tracy is @kirktracy, yours truly is @marrapesekhlaw; SEER is @ABAEnvLaw). And remember—whomever you follow, whatever you tweet, use the committee hashtag, #PCRRTK, to get the information shared.

Monthly PCRRTK Committee calls resume in 2014 on every last Monday of the month at 11:00 a.m. (EST/EDT). The calls typically run only 45 minutes, and are a quick way to stay abreast of the committee’s activities and participate. Dial in!

My very best wishes to all of you in the new year.

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

APPEAL BEING TAKEN TO ALJ DECISION IN TSCA SECTION 8(E) CASE
Lawrence E. Culleen

A company that was assessed a $2.5 million penalty will be seeking an appeal to the U.S. Environmental Protection Agency’s (EPA) Environmental Appeals Board of the initial decision that was handed down in November by the chief administrative law judge for the agency. The November decision, if upheld, would impose a $2.5 million penalty against the only U.S. producer of basic hexavalent chromium chemicals, Elementis Chromium Inc. (Elementis), because it did not submit a 2002 report of an epidemiological study in accordance with section 8(e) of the Toxic Substances Control Act (TSCA). In the Matter of Elementis Chromium Inc., EPA Docket No. TSCA-HQ-2010-5022 (Initial Decision Nov. 12, 2013).

Background

TSCA section 8(e) requires that when a person who manufactures, processes, or distributes a chemical substance or mixture obtains information that reasonably supports the conclusion that the substance or mixture presents a substantial risk of injury to health or the environment, the person must inform the agency immediately, unless they know the agency has already been informed. EPA’s most recent interpretive guidance on section 8(e) was issued in 2003 (68 Fed. Reg. 33,129 (June 3, 2003)).

The epidemiological study that was the subject of the proceeding was undertaken by an industry coalition that intended to generate data for purposes of influencing the Occupational Safety and Health Administration (OSHA) in its deliberations about modifications to a permissible exposure limit for hexavalent chromium by better characterizing mortality rates and effects associated with exposures in more modern manufacturing operations than were reflected in older studies. The 2002 epidemiological study examined mortality data for employees of four “modern” chromium chemical production facilities in the United States and Germany.
In the weeks preceding delivery of the 2002 report to the company, OSHA published in the Federal Register a request for information pertinent to occupational exposure to hexavalent chromium, including epidemiological information. The period for submitting data to OSHA remained open following the date on which the 2002 report was delivered to key recipients in the company. The company did not provide the 2002 report to OSHA, nor to EPA. EPA finally received the report in response to a subpoena issued to Elementis during 2008. Nearly two years thereafter, EPA filed its complaint against Elementis. The complaint alleged in a single count that the company violated TSCA sections 8(e) and 15(3)(B) by failing immediately to submit to EPA the information Elementis obtained in the form of the 2002 report of the epidemiological study. The complaint did not propose a specific penalty.

Elementis asserted multiple defenses, including its assertion that the 2002 epidemiological study did not need to be submitted to EPA because at the time the 2002 report was completed, EPA was adequately informed of the information in the study (i.e., workers in chromium processing facilities experience an increased risk of cancer). Elementis also asserted that EPA’s complaint was barred by the applicable statute of limitations.

The November 2013 Initial Decision

In the March 2011 preliminary ruling, the administrative law judge dismissed Elementis’s statute of limitations defense, ruling that violations of TSCA section 8(e) are continuing in nature, and thus not time barred until five years following submission of the 2002 report. The hearing eventually commenced after the issues to be adjudicated were narrowed and was concluded in 2012.

More than a year after the hearing record closed, in a detailed initial decision more than 90 pages long, Chief Administrative Judge Biro determined that Elementis was obliged to submit the 2002 report of the epidemiological study because there were “multiple and significant distinctions” in the report when compared with predecessor studies about which the EPA administrator already had been informed. The judge’s opinion described the various distinctions she concluded made the 2002 report sufficiently different and that it was not merely “corroborative” of earlier data. Judge Biro called attention in particular to the more modern nature of the conditions in the plants at which the workers studied had been employed; the inclusion of “short-term” workers in the data analyzed; reporting of data with respect to the presence of certain chemicals in the urine of the workers; and efforts taken in the 2002 study to control for the effects of smoking on the observations of lung effects in the workers studied.

The Penalty

Although EPA’s representatives calculated a $2.3 million penalty for the one count violation that continued to accumulate for six years, Judge Biro increased the penalty by an additional ten percent to more than $2.5 million based on the company’s “attitude”—a factor EPA is permitted to consider under its TSCA penalty policy. The $2.5 million penalty is large by any measure for a TSCA section 8(e) violation, especially given the single count upon which it is based. Nearly a decade earlier, however, DuPont agreed to pay a $10.5 million penalty and perform supplemental enforcement projects at a cost totaling an additional $6 million to resolve a multicount complaint alleging TSCA section 8(e) violations for the failure to submit certain biomonitoring data. News Release, EPA, EPA Settles PFOA Case Against DuPont for Largest Environmental Administrative Penalty in Agency History (Dec. 14, 2005), available at http://yosemite.epa.gov/opa/admpress.nsf/68b5f2d54f3eefd28525701500517fbi/fdeb2f665c66bb852570d7005d66651OpenDocument.

Status of the Appeal

Documents regarding the request for the appeal have not yet been posted to the publicly available portions of the docket for the Elementis case, so it
remains unclear when the Environmental Appeals Board will take up the case and whether oral arguments will be heard for the appeal.

**Importance of the Initial Decision**

Notwithstanding the appeal, Judge Biro’s initial decision in *Elementis* is nevertheless important to entities that devote resources to monitoring workplace exposures and tracking employee health records. When such data are compiled and analyzed to note trends and assess the nature of potential adverse health effects, the *Elementis* decision suggests that any finding of adverse health effects among employees could be reportable pursuant to TSCA section 8(e), even if the employees’ health effects are consistent with “known effects” of exposures to the same substance when there is a basis to conclude that there were differences in the exposures experienced by the employees studied. In light of the considerable variability in production facilities and manufacturing methods, and possibility that those differences could affect worker exposures, the decision in *Elementis* could have influence not only on future data-gathering efforts, but also raise doubts about decisions previously reached about studies not submitted historically based on a pre-*Elementis* good faith interpretation of the TSCA section 8(e) requirements.

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**A FLURRY OF ACTIVITY CHALLENGING EU PESTICIDE REGULATIONS**

**Peter L. Gray and Amy Wolfsheimer**

Earlier this year, the European Commission (EC) banned virtually all uses of four pesticides that it previously accepted as safe, based on the EC’s concerns that these substances are linked to bee colony collapse. Since then, the companies that developed these pesticides have filed groundbreaking legal challenges, seeking reversal of the virtual bans on clothianidin, thiamethixam, imidaclorpid, and fipronil.

Syngenta Crop Protection AG (Syngenta) and Bayer CropScience (Bayer), producers of clothianidin, thiamethixam, and imidaclorpid, filed legal challenges to Regulation 485/2013 (which the EC adopted on May 24, 2013). This regulation severely curtails the seed treatment uses of these neonicotinoid pesticides because of their alleged role in bee colony collapse. BASF Agro (BASF) has filed a legal challenge seeking reversal of the EC’s recently adopted ban on most uses of fipronil under Regulation 781/2013.

The EC’s decision to ban most uses of these pesticides was based on a scientific review conducted by the European Food Safety Authority (EFSA). In their legal challenges, Syngenta and Bayer assert that there are numerous flaws in EFSA’s scientific review, including the following: EFSA ignored relevant science; used a new, disputed methodology for its risk assessment; and failed to find risk to bee colony survival. Syngenta and Bayer also argue that EFSA’s scientific review and the EC’s adoption of severe regulatory restrictions of the subject pesticides were rushed, compromising scientific review and stakeholder opportunities for input. Additionally, they argue that Regulation 485/2013 violates the precautionary principle and the principle of proportionality, requirements for all European Union (EU) acts. Because of the above-listed concerns, Syngenta and Bayer conclude that Regulation 485/2013 violates the principle of good administration and the duty of
All three companies face an uphill battle to vacate (or “annul”) these regulations. The Treaty on the Functioning of the European Union, as amended by the Lisbon Treaty, states that if an action for annulment of a regulation “is well founded, the Court of Justice of the European Union shall declare the act concerned to be void.” (See Article 264 of the Treaty.) Preparing a “well founded” legal challenge to a regulation may not seem like a particularly daunting standard, but based on prior case law, it appears to mirror the Chevron deference under United States case law.

In a case for annulment under the predecessor to the EC’s current pesticide regulation, the reviewing court upheld a directive that curtailed a substance’s use notwithstanding that the rapporteur Member State that evaluated the studies and risks determined that the substance did not pose unacceptable risks and should be approved without such restrictions. *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute*, Case C-77/09 (22 Dec. 2010). In upholding the restrictions, the reviewing court stated that “the Commission must be allowed a wide discretion” because it must make complex scientific assessments.

Much like under the Chevron analysis, however, the EC is still bound by procedural duties and cannot render arbitrary decisions. The reviewing court in *Gowan* noted that “courts of the European Union must verify whether the relevant procedural rules have been complied with, whether the facts admitted by the Commission have been accurately stated and whether there has been a manifest error of appraisal or a misuse of powers.” As a result, where parties assert that the EC has “committed a manifest error of appraisal,” the courts must decide whether the EC impartially examined all the relevant facts, whether the decision “lacks a scientific basis,” or whether the EC did not adhere to required procedure.

Based on the foregoing, we can expect the courts considering the Bayer, Syngenta, and BASF legal challenges to accord some deference to the EC regulations the companies are challenging. That said, if the courts find that the regulations lack scientific foundation or that they were enacted in violation of required procedures, they may annul the regulations. The lack of on point precedent makes it perilous to predict outcomes at this point.

Peter L. Gray is a partner and Amy Wolfsheimer is an associate in the Washington, D.C., office of McKenna Long & Aldridge LLP. Mr. Gray and Ms. Wolfsheimer focus their practice on chemical regulation and litigation.
TOXIC SUBSTANCES AT OUR BORDERS
Chelsea O’Sullivan

Section 13 of the Toxic Substances Control Act (TSCA) requires chemical substances, mixtures, or articles containing a chemical substance or mixture not TSCA compliant to be denied entry into the United States. The statute on its face appears to be the basis for robust enforcement of TSCA requirements pertinent to imported chemicals. In practice, however, there is surprisingly little regulation of imported chemicals because the U.S. Environmental Protection Agency (EPA) lacks sufficient information to target noncompliant imports. This article explores why this is so, and proposes methods to begin closing the information gap.

Current TSCA Regulatory Scheme

Under the current TSCA regulatory scheme, importers of mixtures or chemical substances in bulk are required to sign and file with the director of the port of entry a statement certifying the shipment is either in compliance with, or not subject to, TSCA. 19 C.F.R. § 12.121(a). A signed certification statement asserts that the shipment complies with all applicable requirements of TSCA, namely sections 5, 6, 7, and TSCA title IV. EPA, Section 13 Import Certification, available at http://www.epa.gov/opptintr/import-export/pubs/sec13.html. EPA and the Customs and Border Protection (CBP) share enforcement authority. Due to the structure of the current regulatory regime, and the legal standards utilized by each agency, the burden falls on EPA to enforce TSCA section 13. Customs Regulations Amendments Relating to Specific Classes of Merchandise, 17 Cust. B. & Dec. 353, 359 (1983).

Customs’ enforcement role is limited to the time the shipment is undergoing entry procedures. Id. at 359 (“as a practical matter, EPA—rather than Customs—will ultimately determine whether an import complies”). As part of its general enforcement efforts, Customs examines all goods as they enter the United States to determine the value of the goods, whether the goods must be marked with their country of origin or require special marking or labeling, whether the shipment contains prohibited items or narcotics, whether the goods are properly invoiced, and whether the actual quantity correlates with the quantity listed on the invoice. CBP, Pub. No. 0000-0504, Importing into the United States: A Guide for Commercial Importers at 20 (Nov. 2006) (Guide for Commercial Importers), available at http://www.cbp.gov/linkhandler/cgov/newsroom/publications/trade/iius.ctt/iius.pdf. In the context of TSCA section 13 certification, Customs also confirms the import certification is present. Customs does not verify the import certification statement during a regular examination of imports.

The decision not to verify each import certification is consistent with Customs policy of informed compliance and prior disclosure. Informed compliance is “a shared responsibility between CBP and the import community wherein CBP effectively communicates its requirements” and the regulated community “exercise[s] reasonable care” to “conduct their regulated activities in accordance with U.S. law and regulations.” Guide for Commercial Importers at 26. As part of its informed compliance policy, Customs encourages companies to take responsibility for their own compliance and take advantage of Customs prior disclosure policy. According to Customs, prior disclosure is the “complete disclosure of [ ] a violation, before or without knowledge of a formal Custom[s] investigation of the violation.” CBP, ABC’s of Prior Disclosure at 8 (Apr. 2004), available at http://www.cbp.gov/linkhandler/cgov/trade/legal/informed_compliance_pubs/icp028r2.ctt/icp028r2.pdf. If a company chooses to disclose a potential violation prior to any formal investigation, penalties can be drastically reduced. The penalty can be reduced to zero if the shipment is an unliquidated entry and no fraud is involved. The goal of this program is to create a culture of compliance, encourage businesses to self-assess their activities periodically, and thus lower administrative costs.
In contrast to Customs presence at the border and the “reasonable care” standard, EPA enforcement efforts are concentrated on the post-entry phase, and operate under a strict liability rule. Since EPA is not present at the border, EPA often discovers TSCA section 13 violations through enforcement of other TSCA requirements. For example, in 3M Company, 3 E.A.D. 816 (E.A.B. 1992), the respondent imported two chemical substances in violation of TSCA section 5 premanufacture notification (PMN) requirements. The respondent erroneously believed the substances were listed on the TSCA Inventory and did not require a section 5 notification prior to entry into the United States. Acting on that erroneous belief, the respondent certified, under TSCA section 13, that the shipments were TSCA compliant. The section 13 violation only came to light as a result of the investigation into the section 5 PMN requirements.

EPA is required by statute to impose strict liability for violations of TSCA section 13. Section 16 of TSCA demands that “[a]ny person who violates [TSCA] shall be liable to the United States for a civil penalty.” Accordingly, EPA seeks penalties (though they may be reduced or remitted) even when a company voluntarily discloses a potential violation. Memorandum from Director Jessie Baskerville to Regional Division Directors, Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12 and 13 at 15 (1999). Whereas Customs provides an opportunity essentially to erase a violation with prior disclosure, at a minimum, EPA imposes a penalty sufficient to counteract the economic benefit gained by noncompliance. For instance, the Dow Corning Corporation voluntarily disclosed violations of TSCA sections 5 and 13 prior to any formal EPA investigation. Dow Corning Corp., 1993 WL 302442, at *2 (EPA A.L.J. 1993). The penalty was substantially reduced from $172,500 to $46,000 to reflect the voluntary disclosure, but the respondent was still held strictly liable for the violation. Id. at *2–3.

Under the current regulatory scheme, there are two different legal standards applied to imported chemicals. Customs, which is in the position to stop noncompliant imports from entering the United States, is operating on a reasonable care standard and does not have the technical expertise to verify a certification statement. EPA is operating under a strict liability regime and has the technical expertise but lacks the presence at the border to prevent entry of noncompliant chemicals. The result is most regulation of imported chemicals is administered by EPA and occurs after the chemical has entered the United States.

**Reconsidering Roles at the Border**

Congress determined it appropriate for EPA to take the lead on enforcing TSCA section 13 while retaining Customs as the border inspection agency. The problem with this bifurcated approach is that it results in a border patrol without expertise and an expert agency lacking information. Customs is in the best physical position to stop noncompliant chemical substances from entering the United States, but has declined to verify import certification forms because it lacks expertise. Customs Regulations Amendments Relating to Specific Classes of Merchandise, supra. EPA has the mandate and the expertise to take enforcement action, but lacks the necessary information on chemical shipments to make informed regulatory decisions and effectively target noncompliant imports after they enter the United States.

The current regulatory structure creates an information gap because entry documents and the section 13 import certification statement do not provide EPA with information relevant to a regulatory program. At the time of entry, Customs classifies a shipment based on the Harmonized Tariff Schedule, which utilizes broad categories to identify the appropriate import duty. International Trade Commission, HTS Online Reference Tool, available at http://hts.usitc.gov/. These categories are sufficient for tax purposes but do not distinguish among particular chemical identities with enough specificity to assist EPA in preventing unreasonable

The import certification statement, though a specific requirement for chemical imports, is a generalized affirmation of compliance or inapplicability that does not provide information about what portion of TSCA a shipment is subject to, or what exemption is claimed. 19 C.F.R. § 12.121(a)(1) (Positive Certification: “I certify that all chemical substances in this shipment comply with all applicable rules or orders under TSCA and that I am not offering a chemical substance for entry in violation of TSCA or any applicable rule or order under TSCA.” Negative Certification: “I certify that all chemicals in this shipment are not subject to TSCA”). The import scheme under TSCA would benefit from reforms to address these issues to equip EPA better to discharge its TSCA enforcement responsibility.

Designing a Better System

In an ideal world, EPA would have access to real-time information on chemical shipments and work with Customs to prevent noncompliant chemicals from entering the United States. Current efforts to reform the International Trade Data System (ITDS), though still in the early stages of development and implementation, envision such a world. CBP, Report to Congress on the International Trade Data System at 3 (CBP Report to Congress) (Dec. 2012), available at http://www.itds.gov/linkhandler/itds/toolbox/library/resource_documents/2011_itds_report_final.ctt/2011_itds_report_final.pdf. Since the early 1990s, Customs has been working on an extensive reform of the ITDS. The goal of the reform is to create an “electronic single window for reporting imports and exports to the government.” The current plan for the ITDS, if implemented, has the potential to increase drastically the information available to EPA. For example, Customs is currently testing and implementing the “Participating Message Set” that will “provide the capability to collect data elements required by other agencies.” Under this model, Customs would collect requested information about chemical shipments on behalf of EPA, send that information to EPA upon arrival of a shipment subject to TSCA section 13, and provide EPA an opportunity to review the admissibility of the shipment. CBP, Customs and Border Protection International Trade Data System Concept of Operations, Public Version 1.3 at 27 (Sept. 2010), http://www.itds.gov/linkhandler/itds/news/con_op.ctt/con_op.pdf. Under this type of system, EPA could potentially receive real-time data on chemicals entering the United States. The “single window system” envisioned by Customs has great potential, but it is still far from being fully implemented. In its latest report to Congress on the ITDS, Customs reported that budget constraints, a loss of contract support, and consequential loss of expertise could adversely affect its ability to continue with timely implementation of ITDS reform. CBP Report to Congress at iii.

EPA is also looking to address “TSCA compliance problems that may negatively impact chemical safety . . . through enhancements to the Automated Commercial Environment/International Trade Data System.” As part of that effort, EPA is shifting toward electronic-based regulatory systems and implementing shared data services rather than continuing to rely on the paper-based regulatory programs and disconnected information systems currently in place. Particularly relevant to the ITDS reform and import regulation, the Office of Enforcement and Compliance Assurance (OECA) is shifting toward electronic reporting by regulated entities to ensure more accurate, complete, and timely information. Transitioning EPA’s databases
and regulatory programs to centralized electronic systems will enable EPA to utilize more efficiently the information gained through Customs’ Participating Message Set program.

**Improving the Import Process**

There are reforms that can greatly improve EPA’s ability to regulate imported chemicals prior to the implementation of the Customs ITDS reforms. EPA urgently needs more information on the identity of the chemical substances being imported and what TSCA requirements those chemicals are subject to. EPA could more effectively regulate chemical imports if, as part of the entry and section 13 certification process, importers were required to list the Chemical Abstracts Service (CAS) numbers (or other regulatory identification numbers) of the shipment, the regulatory requirements a shipment is subject to, and/or any exemptions claimed. Including such information in the import process would generate data on shipments of imported chemicals that EPA could then use to target enforcement efforts.

EPA’s TSCA Section 13 Import Compliance Checklist provides a good example of the type of information needed to determine compliance with TSCA. EPA, TSCA Section 13 Import Compliance Checklist, Pub. No. 740-B-08-001 (Import Checklist) (2008), available at http://www.epa.gov/oppt/import-export/pubs/checklist.pdf. The guidance directs importers to identify the chemical substances in a shipment by CAS number or other applicable regulatory identification number, such as a PMN number or a low-volume exemption number. *Id.* at 4. The guidance also directs importers to answer several yes/no questions to determine whether negative certification, positive certification, or no certification is required. *Id.* at 4–13. The questions reflect the reasons a chemical is covered by a different statute, exempt from TSCA, or subject to particular TSCA requirements. Once all the questions on the import checklist are answered, the importer has gathered information on the specific chemical identity of the shipment and all of the relevant regulatory requirements. For instance, after following the import checklist, the importer would have established the CAS number, PMN number, Significant New Use Notice case number, Low Volume Exemption number, Low Release and Exposure Exemption number, and/or Test Market Exemption number. Alternatively, the importer would know which exemption it was claiming, such as research and development, or a polymer exemption.

The information gathered by following EPA’s import checklist could be incorporated into the import process through inclusion in the entry documents or reformulation of the TSCA section 13 certification. The entry documents already request a description of a shipment’s contents. CBP, *What Every Member of the Trade Community Should Know About: Entry* at 10 (2004), available at http://www.nelsonint.com/wp-content/uploads/2013/05/Entry.pdf. All importers required to complete a section 13 certification could be required to specify the applicable TSCA regulatory requirements and corresponding identification numbers or applicable exemption in the entry document description. Alternatively, that information could be incorporated into the section 13 certification statement itself. For instance, the importer would state in addition to the positive or negative certification the CAS number or other identification number, and all the TSCA requirements that the chemical is subject to (with corresponding identification numbers), or the exemption being claimed. Import Checklist at 4–13. Increasing the information provided by the import certification statement enables EPA to better target potential violations after entry.

The current regulatory program is designed to accommodate the limitations of a paper-based regulatory program. 19 C.F.R. § 12.121 (“The appropriate certification . . . must appear as a typed or stamped statement[.] . . . A blanket certification must be filed . . . on the letterhead of the certifying firm[.] . . . [and] certification statements . . . may be signed by means of an authorized facsimile signature”). Under a paper-based program, information requirements are burdensome because it
is difficult to update and keep track of paper documents. As Customs and EPA move toward electronic-based regulatory programs, the burden of gathering and maintaining information will be drastically reduced. In the context of section 13 certification, the burden of adding information to entry documents will be nominal.

The information suggested by EPA’s Import Checklist is information a company should already have available if it is operating with requisite due diligence. The importer and the broker already transfer information between each other about the contents of the shipment for current entry requirements. Chematar Inc., 1987 WL 109690, *2 (EPA A.L.J 1987); CBP, What Every Member of the Trade Community Should Know About: Customs Brokers at 29 (Jan. 2005). The more detailed certification requirement just specifies what information they are required to provide. The additional information suggested by the Import Checklist is easily incorporated into the current entry documents, especially as those documents are becoming progressively more electronic. 77 Fed. Reg. 19,030 (Mar. 29, 2012); 74 Fed. Reg. 69,015 (Dec. 30, 2009); 68 Fed. Reg. 68,140 (Dec. 5, 2003). The role of Customs would also not substantially change. Customs would simply confirm that the certification was present and that there was a reason stated for the particular type of certification. EPA would still be responsible for enforcing the accuracy of the information given. The difference would be in the amount of information available to EPA.

This change also paves the way for the ITDS reform that Customs is currently developing. As the ITDS reforms are implemented, the more detailed certification process described here will provide a basis for EPA’s Participating Message Set, thereby streamlining development and implementation of a real-time verification system. CBP Report to Congress at ii. Additionally, the reform is somewhat self-enforcing because companies will have to provide the identification numbers that prove their compliance. If an importer does not have the appropriate identification number, the importer will be alerted that their product has a problem, and have an opportunity to address that problem before completing the import process.

**Conclusion**

It is apparent that the current system could be improved to facilitate better regulation of chemicals at our borders. Though complete denial of entry for noncompliant chemical shipments is still far from being achieved, substantial improvements in regulatory and enforcement efforts can be attained by reworking the current system to provide more information to EPA. Gathering information on the specific TSCA regulatory requirements and exemptions claimed by importers of chemicals enables EPA to make more informed regulatory and enforcement decisions and paves the way for an integrated real-time system of import regulation.

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When the Natural Resources Defense Council (NRDC) sought judicial review of the U.S. Environmental Protection Agency’s (EPA) decision to grant conditional registrations for HeiQ AGS-20 and AGS-20 U (collectively, AGS-20) pesticide products that EPA has determined contain nanoscale silver (nanosilver), many observers expected the court’s decision to have broad implications for EPA policy concerning nanoscale pesticides or for EPA’s use of conditional registrations for new active ingredients. Instead, on November 7, 2013, the U.S. Court of Appeals for the Ninth Circuit issued an exquisitely narrow decision that both vacated a part of the EPA decision to register AGS-20 and rejected each of the principal objections to the registrations made by NRDC. The decision is available at: http://cdn.ca9.uscourts.gov/datastore/opinions/2013/11/07/12-70268.pdf.

The court vacated EPA’s decision “insofar as it 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 AGS-20.” The opinion by a majority of the appellate panel based this holding solely on EPA’s failure to follow its own rule requiring risk mitigation after calculating a margin of exposure (MOE) for aggregate exposure to AGS-20 of exactly 1000. The court also stated that this holding has no effect on “any portion of EPA’s decision where the calculated MOE is greater than 1,000.” The majority opinion denied NRDC’s other objections to the registration decision, holding that substantial evidence supported EPA’s decision to use the characteristics of toddlers rather than infants in its risk assessment for AGS-20, as well as EPA’s decision not to consider other sources of exposure to nanosilver in its risk assessment. In a dissenting opinion, one member of the panel disagreed with the decision by the majority to deny these other objections.

After the court’s opinion was issued, both NRDC and HeiQ issued statements characterizing the decision as favorable, but the actual practical effects of the decision are more equivocal. Nothing in the court’s decision has any general or adverse implications for EPA policy concerning nanopesticides, but the decision could still have disrupted the registration and marketing of the affected HeiQ products. To preserve commercial continuity for the products subject to the remand, HeiQ requested that EPA amend the affected registrations to make certain changes responsive to the court’s decision. The requested amendments included a modest reduction of the maximum application rate, as well as a limitation to treatment of garments or textiles intended for use by adults.

Background

EPA announced in December 2011 that it was conditionally registering a pesticide product containing nanosilver as a new active ingredient. HeiQ AGS-20 is a silver-based antimicrobial product approved for use as a preservative for textiles. Issuance of the registration followed a lengthy review by EPA and its Scientific Advisory Panel. EPA’s December 1, 2011, announcement is available at: http://www.epa.gov/oppfead1/cb/csb_page/updates/2011/nanosilver.html.

Because EPA decided to treat the nanosilver in AGS-20 as a new active ingredient, EPA issued the conditional registration for AGS-20 under Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 3(c)(7)(C). As a condition of registration, EPA required HeiQ to develop and submit additional data to confirm EPA’s initial determination that AGS-20 would not cause unreasonable adverse effects on human health or the environment.

NRDC’s Lawsuit

On January 26, 2012, NRDC filed suit in the U.S. Court of Appeals for the Ninth Circuit challenging
the FIFRA registration of AGS-20, arguing that EPA should not have allowed use of AGS-20 in clothing, baby blankets, and other textiles “without the legally-required data about its suspected harmful effects on humans and wildlife.” NRDC challenged EPA's actions under FIFRA section 16(b), which allows “any person” who claims to be adversely affected by an EPA order issued after a “public hearing” to obtain judicial review “praying that the order be set aside in whole or in part.” Courts have construed a process in which EPA solicits public comment and compiles a record to constitute a public hearing within the meaning of this provision.

In its April 16, 2012, brief, NRDC argued that EPA's decision to conditionally register AGS-20 was not supported by substantial evidence. NRDC argued that EPA should have considered exposure by infants in its risk assessment, and that this “would have shown that AGS-20 poses unacceptable risks, and thus may have ‘unreasonable adverse effects.’” NRDC also argued that EPA should have considered the risk from aggregate exposure to AGS-20 along with other sources of nanosilver, and that such an assessment would have also shown that registering AGS-20 presented unacceptable risks.

On June 14, 2012, EPA filed a brief arguing that NRDC lacked standing to challenge EPA's decision to register AGS-20 because NRDC did not demonstrate that it or its members face an injury that is “actual or imminent,” rather than “conjectural or hypothetical.” EPA also argued that its decision was supported by substantial evidence. According to EPA, it “conservatively estimated potential consumer exposure to nanosilver from HeiQ AGS-20, assuming, among other things, that 35% of the silver contained in an AGS-20 treated textile that is chewed or worn could be ingested or absorbed as nanosilver, and that a three-year-old child could be exposed to a new textile daily for six months.” With respect to aggregate exposure to nanosilver from sources other than AGS-20, EPA argued that “FIFRA neither requires aggregation nor specifies when aggregation might be appropriate,” and that the decision not to address other sources of nanosilver was appropriate “because there was no data indicating that any other products contain nanosilver that is chemically similar to the nanosilver in AGS-20.”

On August 7, 2013, the court ordered supplemental briefs addressing EPA's determination that aggregate oral and dermal exposure when AGS-20 is used as a surface treatment does not present a risk concern even though EPA calculated an MOE for this exposure of exactly 1000. EPA’s August 21, 2013, supplemental brief argued that the precise aggregate MOE for this scenario prior to rounding was 1006, which is greater than the target MOE of 1000 or less. EPA also argued that the MOE was based on conservative assumptions that likely overestimate the amount of nanosilver exposure. NRDC argued in its August 29, 2013, supplemental brief that, given a calculated MOE of 1000, which is not greater than the target MOE of 1000, EPA’s decision criterion dictates a finding that the risk is of concern and mitigation is required. In its September 5, 2013, reply brief, EPA reiterated its view that its risk assessment is reasonable and adhered to the MOE framework guidelines in this case, regardless of whether the aggregate MOE is 1000 or 1006.

**The Court’s Decision**

In the majority opinion by Circuit Judge Bybee, the court first determined that NRDC had demonstrated that its members have Article III standing to challenge the conditional registration of AGS-20, because there is “a ‘credible threat’ that a probabilistic harm will materialize” and the alleged risk of injury is not too speculative to confer standing. The court then addressed three potential objections to the EPA decision to conditionally register AGS-20. With respect to the two principal objections that were originally raised by NRDC, the court found that the EPA decision was supported by substantial evidence, but the court also found that EPA’s decision with respect to the specific issue addressed by the supplemental briefing was not supported by substantial evidence and vacated that part of the decision. Specifically, the court found that EPA did not follow its own “rule of decision,”
under which “there is a risk concern requiring mitigation when the short- or intermediate-term MOE is less than or equal to 1,000.” The court rejected EPA's argument that the MOE was actually 1006, which it found to be based on a methodology that did not properly apply conventional rules for rounding. The court also rejected EPA's argument that the calculated MOE of exactly 1000 was based on very conservative assumptions and that an MOE near 1000 is acceptable, stating that “[a]lthough EPA's point is well taken as a practical matter, it is irrelevant as a legal matter.” Noting that the rule of decision was created by EPA rather than the court, the court stated that it could not “revise EPA's assumptions, alter its rule of decision, or perform our own risk assessment.”

The majority opinion found that there was substantial evidence supporting EPA's decision to use three-year-olds rather than infants in its risk assessment. The court stated: “Infants are more vulnerable because they weigh less, but toddlers are more vulnerable because they can chew fabric aggressively.” The court acknowledged that there could be a “reasonable basis for disagreement” on this issue, but found there was substantial evidence supporting the choice as made by EPA.

The court also found that there was substantial evidence supporting EPA's decision not to include other sources of nanosilver exposure in its risk assessment for AGS-20. The court stated that “Congress expressly required aggregate risk assessment for food-use pesticides,” but did not impose a similar requirement for pesticides not resulting in residues in food. The court also noted that EPA has treated the nanosilver in AGS-20 as a “new active ingredient,” and that EPA could reasonably conclude based on the available information that “other types of nanosilver might not be chemically similar to AGS-20” or that consumers may not “be exposed to them in the same way in meaningful quantities.”

A dissenting opinion written by Judge Adelman, a district judge sitting on the panel by designation, argued that all members of the panel found one aspect of the EPA decision was flawed, so the court should have vacated the registrations issued in reliance on that decision rather than only purporting to vacate a part of the decision. The dissenting opinion argues that it was not appropriate for the court to partially deny and to partially grant the petition, that the court did not need to rule specifically on additional objections raised by NRDC, and that the court ruled incorrectly on the merits of these additional objections. The majority opinion responds to the dissent by construing FIFRA section 16(b) to require that the court resolve “all of the arguments presented by the party petitioning for review . . .”

**Product Amendments**

Under the applicable procedural rules, the mandate formally remanding the HeiQ registration decision to EPA was not scheduled to issue until the end of 2013. Rather than waiting for the remand to make revisions responsive to the court’s decision, HeiQ and EPA began discussing product amendments that could be adopted promptly.

On December 18, 2013, HeiQ issued a press release announcing that EPA had approved two amendments to the registrations for AGS-20. The HeiQ announcement stated that EPA approved amendments “reducing the maximum application rate for HeiQ AGS-20 by 1 ppm” (from 20 ppm to 19 ppm) and limiting use of AGS-20 “to garments and textiles intended for adults, excluding garments for infants and toddlers as well as other textiles that infants or toddlers might wear and chew.”

The mandate officially remanding the registration decision for the HeiQ nanosilver products to EPA was issued on January 2, 2014.

**Analysis**

The sole basis given by the court for its decision is extremely narrow. The court has essentially stated that EPA itself established binding rules for its decision and that EPA is obligated to follow its own rules. Nevertheless, we believe that scientists may
be frustrated by the implicit premise of this narrow ruling that an MOE of 1000 can be meaningfully distinguished from an MOE of 1001. The narrow basis for the court’s decision also suggested that EPA would be able to identify mitigation that would result in an MOE exceeding 1000.

Although the court only vacated a part of the EPA decision supporting conditional registration of AGS-20, that part of the decision was an essential constituent element in EPA’s rationale for granting the registrations. Accordingly, a reasonable construction of the court’s action is that the HeiQ registrations themselves would have been vacated, pending EPA actions on remand that address and resolve the specific problem identified by the court. By obtaining EPA approval of product amendments responsive to the court’s decision prior to the formal remand, HeiQ prevented a potential interruption in the commercial availability of its nanosilver products. The first amendment reducing the maximum application rate from 20 ppm to 19 ppm should be sufficient by itself to resolve the narrow problem identified by the court.

We note that the court specifically ruled against the two principal objections that were originally articulated by NRDC in its petition for review. It would likely have been difficult for NRDC to renew these objections following an EPA decision on remand, unless NRDC could argue that the record assembled during the remand provided new grounds for these objections. In this instance, the second amendment limiting use of AGS-20 to textiles intended for adults should preclude NRDC from making any renewed objection that is based on the purported risk to toddlers or to infants.

We expect EPA to prepare a new risk assessment for AGS-20 at some juncture, because HeiQ has recently submitted new data that are likely to alter the assumptions upon which the current risk assessment is predicated. In addition, EPA has stated that it intends to evaluate the characteristics of a variety of registered pesticide products that contain metallic silver or silver compounds in the forthcoming registration review process.

Given the narrow ground for the court’s decision, it appears unlikely to have broad significance for EPA’s regulation of nanomaterials, or for EPA’s issuance of conditional registrations under FIFRA. NRDC may nominally characterize the court’s decision as a victory, but the court’s narrow critique has no evident effect on the general methodology that EPA has adopted for evaluating and registering nanoscale pesticides. Moreover, since EPA has already approved incremental mitigation measures, the decision is unlikely to lead to any disruption in the commercial availability of the affected HeiQ products.

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2013 was a watershed year for advocates of Toxic Substances Control Act (TSCA) modernization. After years of debate over one-sided, single-party bills, the late Senator Frank Lautenberg (D-NJ), together with Republican Senator David Vitter (R-LA) and a very small, very disciplined group of policymakers, staff, and stakeholders, surprised most TSCA insiders with a compromise bill, the Consumer Safety Improvement Act (CSIA), S. 1009. And while CSIA received a mixed reception, to say the least, the simple fact is that it provided the first meaningful opportunity for Democrats and Republicans in both Houses to discuss some of the very tricky and technical challenges associated with chemical control in 2013—issues like mandatory testing, appropriate safety standards, confidential business information, vulnerable subpopulations, and state preemption. To date, however, one parochial but critical issue has remained unaddressed in the TSCA modernization debate—how to fund it and staff it.

Not that a few policymakers have not tried. During a recent House hearing on TSCA modernization, at least four different congressional members questioned Jim Jones, the U.S. Environmental Protection Agency’s (EPA) assistant administrator in charge of chemical and pesticide control policy, about the level of resources required to support an expanded TSCA program. Jones offered consistent, if understated, responses, indicating that absent additional resources, EPA’s rate of progress “would be meaningfully constrained.”

Translation: Creating and maintaining a first-class chemical control system is expensive—really expensive—in terms of money, time, and human resources. And the costs do not just fall on the private sector. Policymakers can shift the burden for planning, financing, and conducting environmental, health, and safety testing to industry participants and private labs, and they can even outsource large parts of the risk-assessment and characterization process to the private sector, but, ultimately, the job of validating industry risk findings and making tough risk management decisions across multiple substances, products, companies, and sectors must be done by regulators. Such government functions do not come cheap.

Take EPA’s pesticide program, a niche sector of the chemical industry regulated under separate statutory authority due to the unique hazard and exposure risks associated with the manufacture and use of such “economic poisons.” Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the 1996 Food Quality Protection Act (FQPA) and supplemented by key provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA regulates the import, manufacture, distribution, and use of pesticides and pesticide products using many of the enhanced regulatory tools being recommended for a modernized TSCA program: pre-submission data requirements and pre-market review requiring an affirmative safety determination for each use and a more stringent safety standard, among other tools.

The result is a “best-in-class” pesticide regulatory framework, to be sure, but also a much greater level of federal oversight, meaning larger commitments of budgetary and EPA staff resources on a chemical-per-chemical basis than currently exist for the much larger universe of industrial chemicals regulated under TSCA.

Consider this: In 2012, EPA’s Office of Pesticide Programs required approximately 828 staff and roughly $115 million in budgetary resources, including both Science and Technology (S&T) and Environmental Programs & Management (EPM) funds to register 118 new pesticidal active ingredients (across all divisions); update safety findings for 70 older pesticide active ingredients currently in commerce (out of a total universe of between 800 and 1200 registered active ingredients); and respond to roughly 1450 other registration and labeling-related requests or
amendments relating to existing active ingredients, products, and uses.

During the same period, EPA’s Office of Chemical Safety and Pollution Prevention had less than half the dedicated staff and budget to act on roughly 1000 new chemical submissions while trying to make headway in reviewing just a fraction of the 84,000 substances currently on the TSCA Inventory. In short, a modernized toxics program will have to manage ten times the number of new substances and complete retrospective safety determinations for between 50 and 100 times the number of substances handled by the better-funded FIFRA program. Moreover, this ramp-up comes at a time when Congress is pushing to reduce, not expand, EPA’s budget.

EPA itself has long recognized that funding is a key factor. As early as 2009, former Administrator Lisa Jackson emphasized in her “Essential Principles for [TSCA reform]” document that any new legislation should give EPA a sustained source of funding and that “manufacturers of chemicals should support the costs of Agency implementation, including the review of information provided by manufacturers.” Successful federal licensing programs like FIFRA and FFDCA have addressed this challenge by imposing application and user fees on industry participants.

But while chemical manufacturers likely would support reasonable application and review fees to ensure thorough and timely reviews, would they accept fees of up to $500,000 per substance and two-year review periods as established for new pesticide active ingredients? Would such costs, and the massive increase in the workforce required to support these reviews be politically feasible? Instituting a grand FIFRA/FFDCA-style regulatory framework on the massive pipeline of new and existing chemicals regulated under TSCA sounds wonderful in theory. In practice, it creates the risk that the United States will create another “paper tiger”—impressive in print but uneconomical, and hence, unsustainable, in practice.

The point of this analysis is not to discourage TSCA modernization efforts generally, or to undermine the current bipartisan efforts with CSIA in particular. But as stakeholders on both sides work together to find common ground on the arcane legal and technical details of a compromise bill, they need to ensure that the resulting framework is both politically and financially sustainable, so our colleagues will not be writing articles about yet another failed chemical program in 2050.

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The Environment, Energy, and Resources Dedication to Diversity and Justice Award will recognize people, entities, or organizations that have made significant accomplishments or demonstrated recognized leadership in the areas of environmental justice and/or a commitment to gender, racial, and ethnic diversity in the environment, energy, and natural resources legal area. Accomplishments in promoting access to environment/energy/resources rule of law and to justice can also be recognized via this award.

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