FROM THE CHAIR

Charles L. Franklin

The first half of 2011 was a particularly productive time for the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee and the pesticide/chemical regulatory bar in general, with both chemical and pesticide policy continuing to hold a prominent place in the public dialogue. If regulators and courts act on even half of the policy priorities that are lined up for this summer and fall, expect the brisk pace to continue.

First, a brief recap of some committee highlights. In late February, the ABA’s House of Delegates voted to approve House Resolution No. 118, urging Congress to take action on Toxic Substances Control Act (TSCA) reform. This resolution was developed and spearheaded by members of the committee with support and input from the section as a whole. In preparing it, we took care to recognize the wide diversity of perspectives within the PCRRTK committee membership. The language is provided below and the supporting report and text are available through the committee Web site under the TSCA Reform link or through the recently updated “TSCA Reform Practitioner’s Resource.” Let us know your thoughts on whether this reflects your perspective.

The committee continued to provide thoughtful, provocative, and inclusive programming in 2011, sponsoring four excellent brown-bag/webinar

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programs since the New Year. In early March, the committee sponsored a 90-minute panel presentation and webinar entitled Right to Know Versus Right to Intellectual Property: EPA’s Evolving Approach to Confidential Business Information. That same month, we cosponsored a two-hour program on TSCA reform with the D.C. Bar Association, entitled New Directions in Chemical Regulation.

In late April, EPA hosted the committee at its offices for a successful 90-minute lunchtime panel discussion and webinar entitled The NPDES Pesticide General Permit: Perspectives from the Hill, EPA, the Regulated Community, and Environmental Advocates. In May, the committee sponsored a half-day program and webinar entitled Nano Governance: The Current State of Federal, State, and International Regulation. Program speakers included federal, nongovernmental organization (NGO), and private sector representatives from the United States and Europe. Even Australia’s National Industrial Chemicals Notification and Assessment Scheme provided a PowerPoint presentation, but could not participate further due to the time difference.

These programs, while covering a diverse range of topics, had several important things in common. First, the organizers structured the events to maximize the potential for participation by committee members outside the D.C. area (and even the country in the case of the May nano program). The topics selected reflected some of the leading cutting-edge issues facing PCRRTK practitioners today. Finally, recognizing that many of the issues of greatest importance to our members are just as relevant to those outside the committee, program planners reached out to other SEER committees and ABA sections to obtain cosponsors and widen our reach.

The committee is also continuing its commitment to legal scholarship. The PCRRTK Newsletter offers insights from leading practitioners in the field, and the recently released ABA Year in Review offers an insightful section looking at developments in pesticide and chemical law during 2010. We also added a new Practitioner’s Resource to the committee Web site addressing confidential business information policy, and prepared updates to several other resource documents.

We are using these and other efforts to bring value to PCRRTK Committee members and to raise awareness of the importance and centrality of the issues covered by our members.

Which brings us to the second half of 2011 . . .

All indications are that pesticide and chemical regulatory policy will continue its rapid pace of change into 2012, and the PCRRTK committee gives its members an opportunity to monitor, if not participate in, the public policy dialogue—starting with many of the same issues we highlighted earlier this year but including many, many others. We invite you to get involved with the committee in a way that meets your needs. You have already made a great start by reading the newsletter. Maybe you want to plan or attend a future program. Write an article. Contribute to one of our current or planned Practitioner’s E-Reference documents or prepare other web content. Reach out to one of the other committee members to network. However you choose to participate in the committee, we hope membership will continue to be a valuable tool in your professional practice.

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EPA IS STEADILY INCREASING ITS ENFORCEMENT OF THE TSCA REGULATIONS: REQUIRING DISCLOSURE OF RESIDENTIAL LEAD-BASED PAINT AND ASSOCIATED HAZARDS

Philip A. Moffat and Stacey-Ann M. Taylor

On May 9, 2011, the U.S. Environmental Protection Agency’s (EPA) New England office (Region 1) announced that a property management company and four owners of rental properties in and around Holyoke, Massachusetts, were facing 27 violations of the federal lead-based paint disclosure rules enacted under section 1018 of the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. § 4852d). According to the press release, EPA discovered the violations through an inspection and subsequent information request. For each violation, EPA is authorized to impose an administrative penalty of up to $16,000 under section 409 of the Toxic Substances Control Act (TSCA), 15 U.S.C. § 2689. See 74 Fed. Reg. 626 (Jan. 7, 2009) (updating EPA’s “Civil Monetary Penalty Inflation Adjustment Rule”). The administrative penalties may, however, be only a portion of the defendants’ problem—section 1018 also provides a private cause of action for treble damages and allows a court to award attorney fees and costs to a prevailing plaintiff. 42 U.S.C. § 4852d(b)(3)–(4).

EPA’s latest announcement is part of an enforcement trend that began quietly in 2001. Since then, EPA has steadily increased enforcement of the rules, which are officially titled “Lead: Requirements for Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards in Housing,” but are frequently referred to simply as the “lead-based paint disclosure rule.” Region 1 alone has initiated at least 44 enforcement actions seeking over $1 million in penalties and $7.4 million in supplemental environmental projects. See David J. Monz & Eileen P. Conneely, Multi-Housing News Online, EPA Lead-based Paint Disclosure Rule Violations (Mar. 11, 2010), available at http://www.multihousingnews.com. The evolution of EPA’s enforcement policy with respect to this disclosure rule is also particularly important in light of new notification and training/certification requirements for contractors and other stakeholders subject to the separate renovation, repair, and painting (RRP) rule established under TSCA section 402(c)(3) and implemented at the federal and state levels.

To help minimize the risk of EPA enforcement or private lawsuits, counsel for property owners, property managers, real estate agents, or other stakeholders should remind their clients to review the lead-based paint disclosure rule’s requirements and take the steps necessary to ensure compliance. Set out below is a short history of the rule, a summary of its requirements, and an overview of the enforcement provisions.

Background

In the pantheon of successful environmental programs, those that protect children from lead poisoning stand among the proudest. Despite the well-publicized statement of a former secretary of Health and Human Services (HHS) claiming that lead exposure is the number one environmental health threat to U.S. children, there are reasons for optimism. See, e.g., 61 Fed. Reg. 9064, 9065 (Mar. 6, 1996). Over the past three decades, the average blood lead level in U.S. children has declined by approximately 75 percent. This reduction is due in large part to a combination of industry efforts, as well as federal, state, and local regulations, such as those banning lead in gasoline and residential paint.

Residential use of lead-based paint stopped in 1978. EPA estimates that old lead-based paint is the most significant source of lead exposure today, however. See EPA, An Introduction to Indoor Air Quality, available at http://www.epa.gov/iaq/lead.html. According to EPA, infants and young children are especially vulnerable to lead exposure, which may cause developmental impairment, reading and learning disabilities, impaired hearing, reduced attention span, hyperactivity, and behavioral problems. Minority and low-income children are disproportionately affected by the presence of lead-based paint in and around the home.

In 1992, Congress sought to establish the infrastructure and standards necessary to reduce lead-based paint hazards in residential housing. It passed the Residential Lead-Based Paint Hazard Reduction Act of 1992,
which is also known as title X of the Housing and Community Development Act of 1992. Pub. L. No. 102-550. Title X amended TSCA, 15 U.S.C. §§ 2601–2692, to add title IV, Lead Exposure Reduction. EPA has utilized this authority to promulgate a suite of regulations, several of which it jointly adopted with other federal agencies.

The lead-based paint disclosure rule is one of the regulations that EPA adopted. (The RRP rule is another one.) Among other things, the lead-based paint disclosure rule requires property owners and their agents—i.e., property managers, real estate agents, etc.—to disclose the presence of known lead-based paint hazards to prospective purchasers or lessees. EPA and the Department of Housing and Urban Development (HUD) adopted the rule in 1996. 61 Fed. Reg. 9064 (Mar. 6, 1996).

**Disclosure Requirements**

The lead-based paint disclosure rule is codified in 40 C.F.R. part 745, subpart F, titled “Lead-Based Paint Poisoning Prevention in Certain Residential Structures.” It applies to so-called target housing, which is housing constructed prior to 1978 unless specifically exempted. 40 C.F.R. § 745.103. Although the rule’s requirements are relatively straightforward, their application frequently is not. To assist the real estate community, HUD and EPA have published several guidance documents in the form of “frequently asked questions.” See, e.g., EPA and HUD, Guidance on the Lead-Based Paint Disclosure Rule, Parts 1, 2, and 3 (Part 3 published Aug. 2, 2000), available at http://portal.hud.gov/hudportal/HUD?src= /program_offices/healthy_homes/enforcement/ disclosure.

The following list describes the major activities that must be completed before the purchaser or lessee is obligated under any contract.

- The seller or lessor, based on their actual knowledge, must disclose to their agent, as well as the purchaser or lessee, the presence of any lead-based paint or lead-based paint hazard in the target housing. 40 C.F.R. § 745.107(a)(2)–(3). “Lead-based paint” is defined as “paint or other surface coatings that contain lead equal to or in excess of 1.0 milligram per square centimeter or 0.5 percent by weight.” 40 C.F.R. § 745.103. A “lead-based paint hazard” is a “condition that causes exposure to lead from lead-contaminated dust, lead-contaminated soil, or lead-contaminated paint that is deteriorated or present in accessible surfaces, friction surfaces, or impact surfaces that would result in adverse human health effects. . . .” Id. EPA has established numerical standards to facilitate identification of such hazards. 40 C.F.R. § 745.65.
- The seller or lessor must provide the purchaser or lessee with available records or reports “pertaining to” lead-based paint or lead-based paint hazards in the target housing. 40 C.F.R. § 745.107(a)(4). EPA interprets this requirement as extending to records concerning lead present below hazard levels. See 66 Fed. Reg. 1206, 1210 (Jan. 5, 2001).
- The seller must provide a purchaser with a 10-day opportunity in which to conduct a risk assessment or inspection to identify lead-based paint or lead-based paint hazards. 40 C.F.R. § 745.110. This requirement does not apply to rental transactions. In addition, a purchaser may waive this opportunity. Id.
- Finally, the sale or lease contract must include an attachment containing prescribed informational elements. 40 C.F.R. § 745.113. The seller or lessor, their agent, and the purchaser or lessee, must sign the attachment to acknowledge their obligations and certify compliance. Id. The acknowledgement and certification are subject to a three-year record retention requirement. Id.

Although the above requirements are fairly comprehensive, they are not the only ones potentially applicable to real estate transactions under 40 C.F.R. § 745.119. Many states and local governments have
enacted their own lead-based paint disclosure regulations. Such requirements are separately enforceable by the responsible state or local authority.

**Enforcement**

A range of penalties and other relief may be imposed on violators of the federal requirements. Those available to the agencies are summarized in the following list, which is followed by a short discussion of the remedies available to private parties.

HUD and EPA can pursue the following sanctions:

- HUD may impose penalties of up to $11,000 per violation for knowing violations, and it may pursue injunctive relief in a federal district court. 42 U.S.C. § 3545; 24 C.F.R. pt. 30.
- EPA may impose civil penalties up to $16,000 per violation. See 42 U.S.C. § 4852d(b)(5); 15 U.S.C. § 2689; see also EPA, Section 1018—Disclosure Rule Enforcement Response and Penalty Policy (Dec. 2007) (Section 1018–ERP).
- In addition to, or in lieu of, civil enforcement, EPA is authorized under TSCA section 16, 15 U.S.C. § 2615, to seek criminal sanctions for knowing or willful violations. Upon conviction, a violator may be subject to a fine of not more than $25,000 for each day of violation or to imprisonment for not more than one year, or both. 15 U.S.C. § 2615(b); Section 1018–ERP at 9. The conviction is a misdemeanor.
- To compel compliance, EPA may also request that the Department of Justice make an application for injunctive relief in U.S. district court under TSCA section 17(a), 15 U.S.C. § 2616(a). See Section 1018–ERP at 9.

Title X also provides a private cause of action under 42 U.S.C. § 4852d(b)(3). Persons who knowingly violate the rule’s requirements are jointly and severally liable to the purchaser or lessee in an amount equal to three times the damages incurred by such individual. *Id.* Moreover, the court may award a prevailing plaintiff court costs, reasonable attorney fees, and any expert witness fees. Although violations of the disclosure rule do not affect the validity or enforceability of any sale or lease contract or create a defect in title, 42 U.S.C. § 4852d(c), plaintiffs may have separate claims under state law where such remedies might be available.

**Conclusion**

Few would question the importance of protecting children’s health from harmful exposures to lead or other chemicals. The significant progress in reducing lead exposure to children that has been made to date is well documented by the U.S. Centers for Disease Control (CDC). At the same time, however, CDC continues to advocate for continued efforts on the part of all stakeholders to eliminate childhood lead poisoning. The lead-based paint disclosure rule is one initiative in pursuit of that laudable goal, and increasingly important in light of efforts at the federal and state levels to provide disclosure information under the separate RRP rule prior to activities that may contribute to the development of such hazards. EPA’s increasing enforcement of the lead-based paint disclosure rule’s requirements clearly signals the agency’s commitment to protecting public health by zealously guarding the public’s right to know about and understand the potential hazards of residential lead-based paint and associated hazards.

The views expressed above are those solely of the authors.

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ARE ANY CHEMICALS ENDOCRINE DISRUPTORS? THE EPA ENDOCRINE DISRUPTOR SCREENING PROGRAM HAS FAILED TO MEET DEADLINES

Irene Hantman

That the U.S. Environmental Protection Agency (EPA) has yet to determine whether any chemical is a potential endocrine disruptor, has lead the EPA inspector general (IG) to some harsh conclusions about EPA’s Endocrine Disruptor Screening Program (EDSP) in a recently issued report, which is available at http://www.epa.gov/oigearth/reports/2011/20110503-11-P-0215.pdf. The report, entitled EPA’s Endocrine Disruptor Screening Program Should Establish Management Controls to Ensure More Timely Results, is critical of EPA’s failure to meet the timeline for identification of chemicals of concern, validation of screening tools, and hazard assessment. EPA’s failure to establish management controls to support timely program implementation is also the subject of criticism.

In 1996, Congress passed the Food Quality Protection Act (FQPA) and amendments to the Safe Drinking Water Act to address public concerns about the presence of endocrine disruptors in food and water. The FQPA requires EPA to determine whether pesticides and other chemicals cause estrogenic or other endocrine effects in humans. The EDSP was established in 1998. The Natural Resources Defense Council sued EPA in 1999 for failing to meet statutory deadlines for program implementation. The 2001 settlement agreement required EPA to publish and solicit public comments on a preliminary list of chemicals to be screened by December 2002 and to begin hazard assessment by December 2005. The initial screening list was not published until June 2007. EPA has not yet begun hazard assessment.

EPA has been overwhelmed by the scope of the EDSP, and is struggling to establish the criteria for identifying chemicals that should be screened for potential endocrine effects, to develop screening methodologies, and to establish hazard assessment protocols. Of the 87,000 chemicals in the marketplace, EPA estimates that 40,000 have the potential to cause endocrine effects, yet the EDSP was unable to explain the basis for this estimate, and the IG has expressed concern that EPA has yet to define clearly the basis for determining which substances will be screened. The IG is also concerned that EPA does not plan to define the universe of chemicals for screening and testing. “[T]o effectively sort and prioritize potential endocrine disruptors for screening,” the IG emphasizes the need for a well-defined universe. Doing so would also allow EPA to estimate when screening and testing will be completed.

The IG recommends that EPA prioritize chemical screening efforts based on the strategy proposed by the Endocrine Disruptor Screening and Testing Advisory Committee. That strategy would “prioritize chemicals based on their potential for adverse effects, widespread exposure to humans and the environment, and statutory criteria.” The FQPA requires screening of all pesticides. In addition, the IG stresses the need for transparency in efforts to prioritize chemicals for screening.

EPA has proposed criteria for evaluating initial screening data. The criteria were published in the Federal Register on November 17, 2010. Draft Weight of Evidence Guidance Document: Evaluating Results of EDSP Tier 1 Screening to Identify Candidate Chemicals for Tier 2 Testing, 75 Fed. Reg. 67,963. EPA plans to issue the criteria in final by September 2011. A database has been posted on the EDSP Web site to catalog the status of EDSP test orders. To date, EPA has ordered testing of 67 chemicals to assess affects on hypothalamic-pituitary-thyroid axis, androgen receptors, aromatase activity, estrogen receptors, hypothalamic-pituitary-gonadal, and steroid synthesis. The first chemicals to be screened include pesticide active ingredients and high production volume chemicals used as pesticide inert ingredients. Sample test orders can be found at http://www.epa.gov/endo/pubs/regaspects/testorders.htm. An additional 134 chemicals were proposed for screening on November 17, 2010. See Endocrine Disruptor Screening Program; Second List of Chemicals for Tier 1 Screening, 75 Fed. Reg. 70,248.
EPA is likely to receive industry screening data before promulgating the criteria to evaluate screening results. The IG expressed concern that EPA may be accused of bias if criteria are not published before data are received.

The IG also criticized EPA’s failure to publish criteria for hazard and risk assessment and for evaluating those data. Protocols for hazard and risk assessments may be completed by December 2012. The IG noted that EPA has a long history of conducting such assessments, which may accelerate this component of the screening process.

In response to the IG report, EPA agreed to develop a comprehensive management plan for the EDSP. The report is to cover efforts at least five years into the future. The EDSP plans to complete the report by June 2012.

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LAUTENBERG REINTRODUCES TSCA REFORM LEGISLATION

Lynn L. Bergeson

On April 14, 2011, Senator Frank R. Lautenberg (D-NJ) introduced the Safe Chemicals Act of 2011, which is intended to modernize the Toxic Substances Control Act (TSCA) to require chemical companies to demonstrate the safety of industrial chemicals and the U.S. Environmental Protection Agency (EPA) to evaluate safety based on the best available science. The bill is cosponsored by Senators Amy Klobuchar (D-MN), Charles Schumer (D-NY), and Barbara Boxer (D-CA). Lautenberg previously introduced TSCA reform legislation in the 111th Congress, the Safe Chemicals Act of 2010 (S. 3209). In response to feedback from chemical industry leaders, public officials, scientists, doctors, academics, and nonprofit organizations, Lautenberg states that he has made several changes to improve the bill. For example, according to Lautenberg, the updated bill establishes risk-based prioritization categories so that EPA can focus its resources on the highest-risk chemicals. The bill also requires chemical companies to submit initially basic hazard and exposure data to determine quickly any risk, and to assess the need for further testing or restrictions. Below is a summary of key differences between Lautenberg’s current bill and S. 3209, as well as significant provisions that have been retained. Detailed analysis of S. 3209 is available from Bergeson & Campbell, P.C., in memoranda of April 27, 2010 (http://www.lawbc.com/news/2010/04/summary-and-comparison-of-the-tsca-reform-legislation/) and July 28, 2010 (http://www.lawbc.com/news/2010/07/house-introduces-tsca-reform-legislation-summary-and-comparison-of-house-and-senate-bills-and-house-discussion-draft/). The current Lautenberg bill is 182 pages (S. 3209 was 169 pages).

Section 3. Findings, Policy, and Goal—While the changes to section 2 of TSCA largely track with S. 3209, key changes from that bill are as follows:

- All references to “mixtures” have been deleted from this section of the bill. Although this appears to be an important change, it is largely undone by new section 26(c)(3) that states “any action authorized or required to be taken by the Administrator or any other person under any provision of this Act is likewise also authorized or required with respect to a mixture, if the Administrator determines that such extension is reasonable and efficient” (emphasis added). The net effect of the new language at section 26(c)(3) is to give EPA authority to extend all authorities and requirements under the act to mixtures (this would include, for example, the following statutory requirements and EPA authorities: Section 4 Minimum Data Set; Section 5 new chemical notifications; Section 6 prioritization and safety standard determinations; Section 8 declarations; etc.) after making a determination that such an extension is “reasonable and efficient”—terms not clearly defined in the bill.

- In section 2(c) on “Goal,” the new bill retains S. 3209 language with an important change as shown:

1. reviewing all chemical substances for safety and identifying the highest priority chemical substances for expedited review;
2. determining whether all chemical substances in commerce meet the safety standard under this title.

The effect is to specify that while the goal includes reviewing all chemical substances, it does not include determining whether all chemicals meet the safety standard.

Section 4. Definitions—Section 3 of TSCA has been revised as follows (numbers in parentheses identify the placement of the definitions discussed):

- The definition for “adverse effect” that appeared in S. 3209 has been dropped although the term is still used, including in several definitions.

- “Aggregate exposure” (2) is defined to include all sources of exposure, including exposures derivative of non-TSCA uses (uses subject to the Federal Food, Drug, and Cosmetic Act, for example), notwithstanding that regulating
cosmetic chemical exposures using TSCA has not been discussed over the years.

The term “bioaccumulative” (3) would be defined as “the chemical substance or mixture, as determined by the Administrator, can significantly accumulate in biota, as indicated through monitoring data, or is highly likely to accumulate in biota, as indicated by other evidence.” This is a change from S. 3209, which cross-referenced EPA’s policy statement on “Persistent, Bioaccumulative and Toxic” (PBT) chemicals, and the new requirement that the term include a chemical-specific determination (as opposed to meeting specific criteria as appeared in EPA’s policy statement), and seems to both expand the possible meaning and to be tied to the way that PBT chemicals are treated under section 6 in the draft bill.

- The definition for “chemical identity” (4) no longer includes provisions concerning mixtures, but see below where new section 26(c)(3) grants EPA authority to extend authorities and requirements to mixtures if the administrator determines that “such extension is reasonable and efficient.”

- The definition for “chemical substance” (5) deletes the reference to “articles” that appeared in S. 3209 but retains the provision allowing the administrator to determine, notwithstanding molecular identity, that a variant of a chemical substance is a new chemical substance (of key significance to the nano community).

- The term “cumulative exposure” (7) is defined to refer to aggregate exposures from multiple chemicals that “are known or suspected to contribute appreciably to the same or similar adverse effect” (the italicized text is an addition to the S. 3209 definition and has the effect of broadening the meaning, especially as “similar” adverse effects are not explicitly defined).

- Consistent with S. 3209, the definitions for terms “distribute in commerce” (8) and “distribution in commerce” would be expanded to include the export or offer for export of the substance, mixture, or article.

- Consistent with S. 3209, “environment” (10) would be defined to include “ambient and indoor air.”

- Consistent with S. 3209, a “new chemical substance” (15) would be defined as one “for which the manufacturer or processor of the chemical substance has not submitted a declaration” (the use of “the” has the effect of extending this requirement to each manufacturer or processor of the new chemical).

- The term “persistent” (16) would be defined as “the chemical substance or mixture, as determined by the Administrator, significantly persists in 1 or more environmental media, as indicated by monitoring data or other evidence.” This is a change from S. 3209, which cross-referenced EPA’s policy statement on PBT chemicals, and the new requirement that the term include a chemical-specific determination (as opposed to meeting specific criteria as appeared in EPA’s policy statement), and seems to both expand the possible meaning and to be tied to the way that PBT chemicals are treated under section 6 in the draft bill.

- The definition of “reasonable certainty of no harm” from S. 3209 is no longer included, although the term (slightly modified to “reasonable certainty that no harm will result”) is still used in the section 6 safety standard. The S. 3209 definition had included the concept of “negligible risk of any adverse effect” in the definition, which seemingly clarified the meaning of “no harm.”

- The definition for “special substance characteristic” has been retained, including considerations for size or size distribution; shape and surface structure; reactivity; and any other properties that may significantly affect the risks posed (again, of key significance to the nano community).

- While generally consistent with S. 3209, the definition of “vulnerable human population” is clarified to make clear that only “human populations” are included. The term includes
explicit subcategories similar to S. 3209 such as “workers that work with chemical substances and mixtures” and “members of any other appropriate population identified by the Administrator.”

**Section 5. Minimum Data Sets and Testing of Chemical Substances**—Section 4 of TSCA would be revised as follows:

- The Minimum Data Set requirements at section 4(a)(1) have been substantially revised compared to the approach in S. 3209 and the bill would require a rule to be promulgated by EPA that would:
  - Require Minimum Data Sets (changed from “set”) to include the minimum amount of information necessary for the administrator to conduct a “screening-level risk assessment of the chemical substance or category of chemical substances, including information on the characteristics, toxicological properties, exposure, and use of a chemical substance” (S. 3209 had tied the Minimum Data Sets requirement to a data set that “will be useful in conducting safety standard determinations” under section 6—thus the revised bill would significantly reduce the purpose that must be met by the Minimum Data Sets). In addition, the revised bill makes clear that “varied or tiered data” requirements can be used and that EPA “shall identify the particular minimum data set that applies” to a chemical substance or category of chemical substances. The net result is to provide substantially greater flexibility to EPA in developing the Minimum Data Set requirements; and
  - “[E]ncourage and facilitate the use of alternative testing methods and testing strategies to generate information quickly, at low cost, and without the use of animal-based testing, including toxicity pathway-based risk assessment, in vitro studies, systems biology, computational toxicology, bioinformatics, and high-throughput screening.”

- In an important change, section 4(a)(2) would require “each manufacturer and processor” to submit the Minimum Data Set for the chemical—S. 3209 had required “the manufacturers and processors” to submit the Minimum Data Set. The effect of the change is seemingly to impose an individual requirement for submitting the Minimum Data Set on each manufacturer and processor, whereas S. 3209 could be read to impose a collective requirement on all manufacturers and processors. The change is likely to increase the implementation complexity of meeting the Minimum Data Set requirement and the need for “each manufacturer” and “each processor” to meet the requirement has an effect similar to a registration requirement (until a person has submitted the Minimum Data Set for a particular chemical substance, any manufacture or processing of the chemical substance by that person would be in violation of this requirement). This is a significant change and seems to have an effect of substantially increasing the scope and effect of the requirement to submit a Minimum Data Set and could be viewed as counterbalancing the flexibility otherwise seen in the section 4(a)(1) changes. It is also likely to increase significantly the burdens on EPA in dealing with requests for exemptions from the Minimum Data Set as well as reimbursements for Minimum Data Set testing.

- Consistent with S. 3209, the Minimum Data Set on existing chemicals would be due within the earlier of 18 months after the date on which the substance is assigned to a section 6 priority class, or five years after the date of enactment, whereas the Minimum Data Set would be required at the time of filing notifications for new chemicals (which continues the bias that was identified against new chemicals seen in S. 3209).
• The text in the remaining parts of this section largely tracks the approach found in S. 3209, including giving EPA authority to require, by rule or order, testing “as necessary for making any determination or carrying out any provision of this Act”; and submission of samples. In determining these testing requirements and the period for submission, EPA is required to consider relative costs and the availability of facilities and personnel to do the required testing.

Section 6. Manufacturing and Processing Notices—Section 5 of TSCA would be revised as follows:

• Whereas S. 3209 had extended the new chemical notification requirements to mixtures, the revised bill has deleted mixtures from the requirements under section 5. At the same time, as noted above, new section 26(c)(3) gives EPA authority to extend such requirements to mixtures, a change that largely undermines the significance of the change made regarding mixtures under this section of the bill.

• Consistent with S. 3209, under section 5(a)(1) a new chemical notification would be required of any person manufacturing or processing a new chemical. Also under this section and consistent with S. 3209, EPA can approve a new chemical if it finds that the substance meets the section 6 safety standard or that the substance does not meet a series of terms regarding production volume, release, toxicity, etc.

• The text in the remaining parts of this section largely tracks with that appearing in S. 3209, including deletion of the section 5(h)(4) exemption authority that was found in TSCA.

• While Lautenberg’s previous bill would have required EPA to develop and publish a priority list of not less than 300 chemical substances for which safety determinations would first be made, the current bill would amend TSCA section 6 to require EPA to develop and publish a list that (1) contains the names of the chemical substances or categories of chemical substances that the administrator determines warrant placement within one of three “priority classes”; and (2) identifies the priority class to which each listed chemical substance or category of chemical substances has been assigned by the administrator. Under S. 3209, prioritization for safety determinations was based on production volume, use, hazard, exposure information, etc. The chart on the next page provides more information on the different priority classes that would be created under the bill (emphasis added).

• Consistent with S. 3209, the bill would prohibit judicial review of the assignment of a particular chemical substance; a determination by the administrator of whether a particular assignment is warranted; a response to a petition to include a particular chemical substance on the list; and the issuance of a recommendation to list a chemical substance.

• Under the act (emphasis added), the administrator “shall base the determination of whether the safety standard has been met solely on considerations of human health and the environment, including the health of vulnerable human populations.” In making a safety standard determination, the administrator shall (1) to the extent practicable, review and incorporate any available scientific information relating to the effect of cumulative exposure to that chemical substance on human health and the environment; and (2) find that a chemical substance meets the safety standard only if there is a reasonable certainty that no harm will result to human health or the environment from aggregate exposure to the chemical substance. The proposed standard is similar to the one contained in the House bill
<table>
<thead>
<tr>
<th>Definition</th>
<th>Priority Class 1</th>
<th>Priority Class 2</th>
<th>Priority Class 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>Chemical substances that the administrator determines require immediate risk management</td>
<td>Chemical substances that the administrator determines require safety standard determinations</td>
<td>Chemical substances that the administrator determines require no immediate action</td>
</tr>
</tbody>
</table>
| **Assignment** | The administrator must determine that the chemical substance is, or is degraded and metabolized into, a persistent, bioaccumulative, and toxic substance with the potential for widespread exposure to humans or other organisms. | (1) *In General*—If the administrator determines, based on any more-than-theoretical concern, that there is uncertainty as to whether a chemical substance would satisfy the safety standard in a determination, the administrator shall assign that chemical substance priority class 2.  
(2) *Condition*—The administrator shall assign chemical substances to priority class 2 subject to the following conditions:  
(I) The rate at which chemical substances are added to priority class 2 shall be expeditious, but shall not exceed the rate at which the administrator reasonably anticipates completing safety standard determinations; and  
(II) The administrator shall first assign to priority class 2 those chemical substances that present the greater risks to human health or the environment, as determined by the administrator. | The administrator shall assign a chemical substance to priority class 3 if the chemical substance has intrinsic properties such that the chemical substance, as determined by the administrator, does not and would not, at any stage of the life cycle, pose any risk of adverse effects to human health or the environment under existing, proposed, or anticipated levels of exposure to, or production or patterns of use of, that chemical substance. |
<table>
<thead>
<tr>
<th>Priority Class 1</th>
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<th>Priority Class 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial Assignment</strong></td>
<td>Not later than one year after the date of enactment, the administrator shall assign not less than 20, but not more than 30, chemical substances to the initial priority class 1.</td>
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<td><strong>Risk Management</strong></td>
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<tr>
<td><strong>Expedited Exposure Reduction</strong></td>
<td>As soon as practicable, but not later than 18 months after the date on which a chemical substance is assigned to priority class 1, the administrator shall impose conditions on the manufacturing, processing, use, distribution in commerce, and disposal of a chemical substance assigned to priority class 1 that the administrator determines necessary to achieve the greatest practicable reductions in human or environmental exposure to the chemical substance.</td>
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<tr>
<td><strong>Residual Risk Assessment</strong></td>
<td>Not later than one year after the effective date of any conditions established above, the administrator shall (1) determine whether the chemical substance meets the applicable safety standard for the chemical substance, taking into account the residual risk posed by continued exposure to the chemical substance; and</td>
<td></td>
</tr>
</tbody>
</table>
(H.R. 5820) from the last Congress. Relative to that bill, the proposal would delete the need to consider the life cycle of the chemical but is otherwise generally similar. The revised bill makes explicit that the standard is based "solely" on health and the environment and that the standard is met "only" if there is a reasonable certainty that no harm will result from aggregate exposure (as noted above in the Definitions section, the current bill does not include a definition for this term, whereas S. 3209 had defined "reasonable certainty of no harm").

- Not later than five years after the date of enactment, and not less frequently than once every five years thereafter, the administrator shall review the methodology and may revise it to reflect new scientific developments or understandings. A determination by the administrator that a manufacturer or processor has not established that the chemical substance meets the applicable safety standard would not be subject to judicial review.

- The revised bill provides considerable latitude in determining that a chemical falls into priority class 2—this comes from the "any more-than-theoretical concern that there is uncertainty" as to whether the chemical would satisfy the safety standard. Within 30 months after a chemical substance is assigned to priority class 2, manufacturers and processors must update the Minimum Data Set, if the data set was submitted prior to the assignment of the chemical substance to priority class 2; submit
any additional information the administrator may require to make a safety standard determination, including any information the administrator determines is necessary to be developed by testing; and indicate whether the chemical substance, including specified uses to be evaluated and any proposed conditions on the specified uses, meets the safety standard.

The administrator would have one year after the earlier of the date of receipt of a complete submission or the applicable submission deadline, or after initiating a redetermination, to determine, or redetermine, as appropriate, whether the manufacturers and processors have established that the chemical substance meets the safety standard.

As for the burden of proof, and consistent with S. 3209, it “shall be the duty of . . . the manufacturers and processors of a chemical substance to provide sufficient information for the Administrator to determine whether the chemical substance meets the applicable safety standard.” In what seems to be a subtle but important change compared to S. 3209, the current bill would not require that EPA assess whether industry has met its burden of proof; rather it would require that EPA determine whether the applicable safety standard has been met.

Interestingly, the safety determination shall be “supported by an assessment of risk conducted by an employee of the Environmental Protection Agency” and the “determination of whether the safety standard has been met . . . [shall be based] solely on considerations of human health and the environment, including the health of vulnerable human populations.”

EPA is to base safety determinations on the “best available science” and the administrator “shall base the determination on the recommendation of the National Academy of Sciences in the report ‘Science and Decisions.’” It is not clear how any conflict over this language would be resolved if the academy or other authoritative body were to change its recommended approach over time.

The exemption provisions at section 6(e) are essentially the same as those in S. 3209.

Section 9. Reporting and Retention of Information—Section 8 of TSCA would be revised as follows:

The bill no longer includes a requirement that the administrator publish in the Federal Register a list of all chemical substances distributed in commerce that categorizes the chemical substances “into categories based on known health or environmental effects, exposure, insufficient data, or other category that the Administrator considers appropriate.”

The other provisions largely track those found in S. 3209.

Section 12. Exports

Whereas S. 3209 had deleted TSCA’s export notification requirements for actions taken under section 4 of TSCA, the current bill would add back the requirement for export notifications if a chemical is subject to data submission requirements. This seems to be a significant change that seemingly would require export notifications on all chemicals (this seems to be the case because all chemicals, both new and existing, would seemingly be subject to the section 4 Minimum Data Set, e.g., it is not clear that chemicals can be exempted from this requirement, although perhaps some flexibility can be found).

Section 13. Entry into Customs Territory of the United States

TSCA section 13 would be amended to include an important new provision regarding import as part of an article: “Chemical substances and mixtures imported as part of an
article shall be subject to the same requirements under this Act as if the substances and mixtures had been imported in bulk, except as the administrator may provide by rule under this Act, or as the Secretary of Homeland Security may provide by rule.” This requirement for substances and mixtures imported as part of an article would thus apply all statutory obligations to such substances in imported articles (including, e.g., submission of a Minimum Data Set, new chemical notification, section 8 declaration, etc.) unless and to the extent such requirements have been excluded by rule.

**Section 14. Disclosure of Data**

- Under the bill, no later than one year after the date of enactment, the EPA administrator would identify by rule those types of information for which the administrator shall not prospectively specify the term of confidentiality.

- The provision allowing manufacturers, processors, or distributors to designate data believed to be entitled to confidential treatment does not limit the authority of the administrator to determine that particular information, previously considered entitled to confidential treatment, is no longer entitled to such treatment.

- The bill would amend TSCA to allow that, if the EPA administrator determines that the release of confidential data is necessary to protect against an “imminent and substantial endangerment to health or the environment,” then no notice is required. TSCA section 14(c)(2)(B)(i) currently allows EPA to release confidential data if the administrator determines that the release is necessary to protect against an “imminent, unreasonable risk of injury to health or the environment,” using such means as the administrator determines will provide at least 24 hours’ notice before such release.

- The bill would clarify that confidential business information (CBI) may be shared with state governments if “1 or more applicable agreements ensure that the recipient government will take appropriate steps to maintain the confidentiality of the information.”

- The bill contains a catch-all provision that clarifies the administrator retains the authority to determine that certain information previously determined as eligible for CBI treatment is no longer subject to such protection

**Section 18. Preemption**

- While the previous bill included a preemption provision, the provision has been completely rewritten and seemingly narrowed compared to S. 3209:

  Nothing in this Act affects the right of a State or a political subdivision of a State to adopt or enforce any regulation, requirement, or standard of performance that is different from, or in addition to, a regulation, requirement, liability, or standard of performance established pursuant to this Act unless compliance with both this Act and the State or political subdivision of a State regulation, requirement, or standard of performance is impossible, in which case the applicable provisions of this Act shall control.

**Section 23. Administration of the Toxic Substances Control Act**

- As noted above, the bill would amend TSCA section 26(c) to add the following provision, which would greatly expand the scope of the bill and EPA’s jurisdiction:

  MIXTURES.—Any action authorized or required to be taken by the Administrator or any other person under any provision of this Act with respect to a chemical substance is likewise also
authorized or required with respect to a mixture, if the Administrator determines that such extension is reasonable and efficient.

- **Section 29. Expedited Action on Chemicals of Highest Concern**
  - The current bill does not include this provision.
  - The other sections in the revised bill largely track with the provisions that appeared in S. 3209.

**Observations and Comments**

The newly circulated language makes clear attempts to respond to industry’s criticism of last year’s proposal, and which was similarly levied against the companion House legislation. Examples include making clear in section 2 on “Goal” that a safety determination is not required on all chemicals, clarifying and limiting the purposes of the section 4 Minimum Data Set to “screening level information,” and separating out categories of section 6 priorities and actions in lieu of blanket and encompassing data generation, assessment, and safety standard determination requirements that S. 3209 applied to all chemicals. The explicit section 6 list of chemicals is removed and left to a process where EPA will evaluate data and take action. The proposed bill also attempts to strike a more workable balance in its approach to preemption. The treatment of mixtures is greatly facilitated conceptually, but as noted, it remains potentially open-ended depending on the EPA definition of “reasonable and efficient” (and any decisions by EPA in this regard would likely involve litigation over its scope by parties who believe it is either too broad or too narrow).

At the same time, it is also clear that the proposal introduces a number of significant new requirements and expansions in other requirements. One example is the treatment of “mixtures” as discussed above. Other examples include the requirements that each manufacturer or processor of a chemical must submit a Minimum Data Set; that seemingly all chemicals would be subject to export notification; and that substances in imported articles must meet all statutory requirements unless the requirements have been excluded by rule.

As is often noted, “the devil is in the details.” There are unclear elements about the proposal that will determine exactly what the scope, reach, and impact of these amendments would be. At the same time, it is another set of specific amendments, redrafted to respond to earlier criticisms, which should put more pressure on those in the chemical industry to respond with specific counterproposals or an altogether alternative set of amendments.

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**UPDATING THE INVENTORY UPDATE REPORTING RULE: EPA CALLS A TIME-OUT ON TSCA REPORTING**

**Lawrence E. Culleen and Peggy Otum**

When the U.S. Environmental Protection Agency (EPA) issued its proposal for modifying the Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) rule, the agency anticipated promulgating a final rule by the spring of 2011, in advance of the June 1, 2011–September 30, 2011, IUR submission period (2011 submission period). See 75 Fed. Reg. 49,656 (Aug. 13, 2010). On May 11, 2011, however, EPA announced in a Federal Register notice that it would not issue its modifications of the IUR rules in final form before the start of the 2011 submission period and suspended the 2011 submission period until further notice. See Fed. Reg. 27,271 (May 11, 2011). As a result, companies that are required to submit information under the IUR rules must wait for EPA to provide (1) revised dates for the next submission period, and (2) the terms of the final modifications to the IUR rules.
Since the agency published its proposed rule to modify the IUR rules on August 13, 2010, EPA has received numerous comments from industry reacting negatively to a long list of changes that EPA hopes will improve chemicals reporting. Among those changes is a new requirement to report certain chemical substances that are the subject of particular TSCA rules and/or orders, regardless of the production volume. EPA also proposes to increase the frequency of reporting from five years to four years and to expand the data that some companies would be required to collect and submit. The proposed rule has also drawn criticism in certain circles because it would require reporting of processing and use information for all chemical substances by eliminating the 300,000 lb production volume threshold that triggered such requirements in the previous reporting cycle, and diminishing the ability to claim as confidential as much information as the rule now allows.

EPA also emphasized comments that it received from environmental and public health groups advocating for more rigorous data collection for the purpose of future risk-based decision making.

Although it is uncertain whether and in what form EPA will release a final rule, it is clear that the existing IUR rule provides a baseline of reporting requirements upon which EPA is determined to expand (i.e., it is not likely that a final rule will repeal or soften the existing requirements). Regulated companies should therefore continue to be prepared to report, at a minimum, all of the information required for the 2006 reporting cycle and be prepared to have to submit potentially all of the information that would be required if the rule under consideration at OMB is promulgated by EPA as it was written.

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UPDATE ON NPDES PERMIT REQUIREMENT FOR PESTICIDE APPLICATIONS

Brandon W. Neuschafer

Those following the U.S. Environmental Protection Agency’s (EPA) efforts to implement a National Pollutant Discharge Elimination System (NPDES) permitting system for certain pesticide applications pursuant to its obligations under National Cotton Council v. EPA (6th Cir. 2009) know that the past months have seen a significant amount of regulatory, legislative, and judicial activity. This article provides a summary of these activities. Keep an eye out for the Section on Environment, Energy, and Resources’ upcoming issue of Natural Resources & Environment magazine for a detailed discussion of the substantive issues surrounding EPA’s implementation of the Sixth Circuit decision.
Background

On March 28, 2011, the Sixth Circuit Court of the U.S. Court of Appeals granted an EPA request for a six-month stay of the permitting program deadline to October 31, 2011, to allow EPA to complete its Endangered Species Act (ESA) consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service and to implement a new electronic system for tracking notices of intent to be bound by the general permit. In addition, the extension was needed to allow states time to prepare and implement their own NPDES permitting programs. Permit applications under the general permit are now due by October 31, 2011, but EPA and relevant states have yet to publish final general permits.

On March 31, 2011, the House passed H.R. 872, the Reducing Regulatory Burdens Act of 2011, which specifically exempts from Clean Water Act (CWA) jurisdiction any pesticide application that was conducted in accordance with Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requirements (or, in other words, any application that was consistent with the product’s label). This bill, introduced by Rep. Bob Gibbs (R-OK), passed 293 to 130 with substantial bipartisan support.

After House passage, the Reducing Regulatory Burdens Act was referred to the Senate Committee on Agriculture, Nutrition and Forestry. The Senate is also considering S. 718, which was introduced by Sen. Pat Roberts (R-KS), the committee’s ranking Senate member. As of early June, S. 718 has a number of Republican cosponsors but no Democratic cosponsors. Committee Chair Debbie Stabenow (D-MI) has indicated she is awaiting feedback sought from EPA.

In April, several state pesticide and water pollution control authorities authored a letter to Senate leadership urging the Senate to “take legislative action to avoid duplicative environmental permitting requirements for applications of pesticides.” The letter, which was signed by the presidents of the American Association of Pesticide Control Officials, the Association of States Interstate Water Pollution Control Administrators, the National Association of State Departments of Agriculture, and the National Association of State Foresters, referenced many of the critiques of the permitting program, notably the regulatory and cost burdens imposed on industry and state agencies.

More Current Events

Nonetheless, EPA is pressing forward with the obligations imposed by the Sixth Circuit. On April 1, 2011, EPA informally released a “prepublication version” of the draft final general permit. This prepublication version was not published in the Federal Register, but was released to assist state officials in preparing their counterpart permits in final form. The prepublication version differs from the draft permit published in 2010 in several respects, including the removal from the definition of “operator” of entities with control over financing of a pesticide application, although a financing entity may be classified as an operator for other reasons, including if it controls the decision to make the application.

The prepublication version also does not reflect the results of EPA’s ESA consultation. EPA has not indicated when the ESA consultation is expected to be completed, but has said it intends to publish the final general permit by July 30, 2011. Should the ESA consultation result in substantial or significant modifications to the draft general permit, however, an additional 30-day notice and comment period might be required, potentially pushing the timeline for publication of a final general permit beyond October 2011.

Time is tight, and the potential impacts of EPA’s permitting program are significant. By EPA’s calculations, the National Cotton Council decision will increase the total number of discharges subject to CWA jurisdiction by 65 percent each year, covering millions of pesticide applications previously considered exempt from the NPDES requirements of the CWA. EPA also calculates that over one million hours and $50 million will be spent on compliance with the permit obligations. Should the Senate refuse to act, EPA will issue the permit in final form and the issue will surely return to the courts as neither industry, state officials, nor environmental groups appear satisfied with the permit.

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