FROM THE CHAIR
Keith A. Matthews

With the Thanksgiving holiday now past, and the end-of-the-year holidays fast approaching, the Pesticides, Chemical Regulation, and Right-to-Know Committee (PCRRTK) is close to marking the end of a significant year for chemicals regulation law. In the area of substantive law, 2016 will forever be remarkable for the long-overdue updating of the 40-year-old Toxic Substances Control Act (TSCA). H.R. 2576, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, signed into law by President Obama on June 22, 2016, effected numerous significant changes to TSCA—the full scope and breadth of which will not be completely apparent until the U.S. Environmental Protection Agency (EPA) has completed necessary implementing regulations. EPA has moved swiftly to take certain actions under the new law, including, for example, identifying particular persistent, bioaccumulative, and toxic (PBT) chemicals for assessment. On November 29, 2016, pursuant to section 6(b)(2) of amended TSCA, EPA announced the first ten chemicals for which risk evaluations will be conducted (asbestos, 1-bromopropane, carbon tetrachloride, cyclic aliphatic bromide cluster, 1,4-dioxane, methylene chloride, N-methylpyrrolidone, pigment violet 29, tetrachloroethylene, and trichloroethylene).

In addition, a new “bioengineered food” disclosure law was enacted in July. This law mandates that the U.S. Department of Agriculture (USDA) develop implementing regulations for the disclosure of components of genetic engineering in certain “bioengineered” foods. On October 19 and 20, EPA marked the 30th anniversary of the Toxics Release Inventory (TRI) reporting requirement at the annual TRI National Training Conference, and on November 15 and 16, EPA convened the second annual Safer Choice Partner and Stakeholder Summit to highlight the continued expansion of the Safer Choice chemicals labeling program.

In committee news, Joanne Thelmo ended a highly successful two-year tenure as committee chair in July. As Caleb Pearson, one of our vice chairs for Membership reported during a recent PCRRTK teleconference, during Joanne’s time as chair, membership in the committee increased significantly. We hope to build upon these successes with continued outreach to law students, newer lawyers, and government attorneys.

PCRRTK is very fortunate in that it continues to benefit from an extremely strong and capable cast of vice chairs. Our vice chairs for 2016–2017 are Lynn L. Bergeson, Newsletter; Steven Christenson, Eric Gotting, Caleb Pearson, and Stacy Tatman, Membership; Lawrence E. Culleen, Charles L. Franklin, and Irene A. Hantman, Programs; Mark N. Duvall, At Large; Herb Estreicher, At Large; Allison In and Tayyaba Waqar, Social Media; Rachel G. Lattimore and Sara Beth Watson, Special

Continued on page 3.
In this issue:

From the Chair
Keith A. Matthews ..................................1

EPA’s Formaldehyde Emission Standards for Composite Wood Products Set Sail for TSCA Title VI Regulation
Mark N. Duvall and Shengzhi Wang ....4

The New Testing to “Bee” Implemented: Basic Guidance for Pesticide Professionals
Andrew Yamanaka Belter ....................6

S. 764 Mandates Limited Disclosure of Genetically Engineered Foods Components
Keith A. Matthews ..........................9

Framework for Risk Evaluation Under New TSCA
Charles M. Auer and
Oscar Hernandez, Ph.D. ..........11

Big Changes on the Regulatory Horizon for Nanoscale Materials?
Lawrence E. Culleen and
Camille Heyboer ..............................14

Litigating the Obligation to Report Substantial Risk Information and Pay Penalties Under TSCA Section 8(e)
Irene Hantman ..............................16
Continued from page 1.

Projects; Warren U. Lehrenbaum, At Large; Martha E. Marrapese, At Large; Freedom Smith, Electronic Communications; Joanne Thelmo, Friday Forum; and James Votaw, The Year in Review.

PCRRTK has become well-known for its strong programming and this year will be no different. Irene, Larry, and Charles are developing interesting and informative events; Rachel and Sarah Beth are organizing the annual joint CropLife America/PCRRTK symposium on pesticides issues (to be held in Spring 2017); Joanne is lining up an interesting series of guest speakers for the Friday Forum; and we will be producing numerous podcasts, other informative electronic communications, as well as Allison and Tabby maintaining our presence on LinkedIn and Twitter.

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Global Chemical Control Handbook: A Guide to Chemical Management Programs

Lynn L. Bergeson

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(c) 2014, paperback

Global Chemical Control Handbook keeps practitioners abreast of these important developments—what they are, on what segment of the global supply chain they apply, and when and how these measures impact the business of chemicals. Providing a broad overview of key chemical management programs in the United States, Europe, Asia, and Central and South America, this book describes the key laws and their regulatory implementation in these jurisdictions. The authors provide a basic understanding of each law and help practitioners identify key business issues of concern.
EPA’S FORMALDEHYDE EMISSION STANDARDS FOR COMPOSITE WOOD PRODUCTS SET SAIL FOR TSCA TITLE VI REGULATION
Mark N. Duvall and Shengzhi Wang

Besides the much anticipated amendments to title I of the Toxic Substances Control Act (TSCA), the summer of 2016 also witnessed another new policy in the TSCA world: on July 27, the U.S. Environmental Protection Agency (EPA) issued in final the Formaldehyde Emission Standards for Composite Wood Products (standards) to implement title VI of TSCA. Building upon formaldehyde emission limits, the standards provide a range of obligations for the composite wood product industry, including compliance, certification, testing, labeling, record-keeping, and reporting.

There was a four-month delay between when the EPA administrator signed the final rule on July 27 and when the final rule appeared in the Federal Register. The final rule appears at 81 Fed. Reg. 89,674 (Dec. 12, 2016).

Background and Estimated Impacts

Historically, California has been the pioneer in regulating formaldehyde emissions in composite wood products with its Airborne Toxic Control Measure (ATCM). In 2010, Congress enacted TSCA title VI to direct EPA to adopt federal standards. After missing a 2013 deadline, EPA eventually promulgated the standards in 2016. The standards are codified in 40 C.F.R. part 770.

The standards will affect the entire composite wood product supply chain, including panel producers, fabricators, distributors, retailers, and importers. EPA estimates that some 990,000 entities, including 922,000 small entities, will be affected. At the core, the standards set up emission limits for four categories of composite wood product panels: (1) hardwood plywood, (2) medium-density fiberboard, (3) thin medium-density fiberboard, and (4) particleboard. The limits apply to panels, component parts, and finished goods alike.

Key Obligations Under the Standards

All composite wood products, regardless of their form, must be certified, tested, and labeled unless exempt. The standards exclude certain products from the regulation. For the covered products, the standards provide a de minimis exemption from labeling, but not from other obligations. In addition, products with no-added formaldehyde-based or ultra-low-emitting formaldehyde resins may follow relaxed certification and testing rules.

Beginning December 12, 2017, only certified or exempt composite wood products may be sold in the United States. EPA will operate a title VI certification program, in which accreditation bodies will accredit third-party certifiers, and third-party certifiers will certify products for title VI compliance. Certification will be based on the product’s compliance with the applicable emissions standard, the correlation or equivalence between the testing method and the method for the development of the emission limits, and the product’s compliance with quality control requirements. For smooth transition, EPA will recognize valid certification under the California ATCM, and products so certified have a two-year window to transit into title VI certification.

Products are subject to further quarterly tests after certification. Failure in these tests requires that the noncomplying lots be separated from other certified products, prevented from entering into commerce, and then either disposed of or retested. Entities along the supply chain share obligations to withhold noncomplying lots that enter into market and to inform downstream users of the noncompliance.

Products must be labeled unless the de minimis exemption applies. The labeling requirements vary depending on the resin used—regular, no-added formaldehyde-based, or ultra-low-emitting formaldehyde resin—and the labeling party’s
intended action on the products, for general use or to be used for testing only. Labels for regular products to be supplied or sold should include information regarding producers, third-party certifiers, lots, and compliance certification. The standards, however, prohibit labeling as title VI compliant of a product manufactured (domestic) or imported (abroad) before the regulatory “manufactured-by” date, which is December 12, 2017.

Because the standards will not be immediately effective, EPA generally prohibits “stockpiling.” The term is defined as the manufacture or purchase of composite wood products between July 7, 2010, and June 12, 2017, at an average rate at least 20 percent greater than, for the purpose of evading the standards, the average rate of manufacture or purchase during 2009. Stockpiled inventory must be sold by December 12, 2017. The 2009 baseline may be unusually low because of the then economic recession. Affected companies may need to convince EPA that their current production rates are higher for reasons other than attempted evasion of the standards, such as an immediate increase in customer demand or sales or a planned business expansion.

**Differentiated Responsibilities Along the Supply Chain**

Under the standards, producers will be responsible for compliance with emission limits, certification, testing, and, presumably, labeling of most products (other than for finished goods). Fabricators, distributors, and retailers are required to take “reasonable precautions” to ensure that the composite wood products passing through them are title VI compliant. On this point, the standards only require that these parties obtain and maintain invoices, bills of lading, or other comparable documents from the supplier that contain a statement that the product is compliant or not subject to the standards (unlike the California ATCM, under which fabricators, distributors, and retailers have to make their own statements of compliance). Fabricators, distributors, and retailers also have labeling-related obligations. Fabricators themselves must label finished goods (or box or bundle of finished goods), whereas distributors and retailers must leave labels intact (where a label exists) or keep a system capable of tracking compliance and producer information upon customer request (where a label does not exist). In light of the labeling requirement, the standards depart from California’s ATCM in that the burden to assure compliance is now primarily on panel producers.

Importers have three general obligations under the standards. First, they have similar “reasonable precaution” record-keeping requirements, including getting compliance assurance from their suppliers and making available the record for EPA inspection. Importers, however, also have to identify panel producers and production date. This apparently presents a challenge to importers, in light of the extended international supply chain and the confidentiality concern that make it difficult for importers to identify the panel producer for relevant information. EPA thus allows an entity in the foreign supply chain to submit this information directly to EPA. Second, importers must ensure that the imported products are properly labeled and leave the label intact or maintain tracking information upon customer request. Finally, the standards require import certification for articles with composite wood products, which triggers TSCA’s general import certification regulation. This requirement will come into effect December 12, 2018, after which importers, presumably, will have to file positive certifications with the Customs and Border Protection.

**Laminated Products**

Special rules apply to laminated product producers. Like in the ATCM, laminated product producers are treated as regular fabricators under the standards. As such, they are bound by fabricator obligations beginning December 12, 2017. Unlike in the ATCM, however, laminated products will be classified as hardwood plywood under the standards beginning December 12, 2023. Thus by then, laminated product producers will also be
subject to all requirements for regular producers. Certain laminated products are exempt from hardwood plywood, but producers must maintain records establishing their eligibility for the exemption.

**Conclusion**

Industry should prepare now for compliance with the standards. Entities doing business in California will have a significant advantage in doing so, given the standards’ similarity to the California ATCM. But all interested parties may wish to monitor any guidance from EPA for a better understanding of the standards.

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**THE NEW TESTING TO “BEE” IMPLEMENTED: BASIC GUIDANCE FOR PESTICIDE PROFESSIONALS**

Andrew Yamanaka Belter

Bee population decline necessitated that pesticide registrations include new tests, and pesticide professionals must understand these new tests to advise their clients properly. This article explains why.

**A Look at the Old Testing**

The U.S. Environmental Protection Agency (EPA) is updating its three-tiered pesticide registration system to better evaluate pesticide effects believed to impact honeybees. Attorneys and other pesticide professionals must understand the new system to advise their clients. For the experienced pest professional, the new pesticide testing retains the previous three-tiered system, a description of which may be helpful to newcomers to the process.

Tier 1 includes a screening tool that previously applied laboratory screening to test for honeybee adult acute contact toxicity and honeybee adult toxicity of residues on foliage.

Tier 2 moves to a “semi-field study” that characterizes risk at the colony level and previously included a field feeding study. This study is described as a field-level test where bee colonies are located in an open field setting, but exposure is delivered at predetermined concentrations in either sucrose solution or a pollen supplement to provide information on long-term effects.

Tier 3 is a “full-field study” intended to resolve uncertainties to address specific long-term questions regarding the potential effects of the pesticide compound at the colony level where the compound is applied in accordance with label conditions. This includes field-testing studies that typically take into account the broad dynamics of a whole colony in a free-foraging scenario and consider long-term effects on the colony, such as over-wintering success.
The New Testing

Despite previous laboratory and field-testing standards, bee populations have declined. Reacting to this decline and in accordance with the Obama administration’s mandate to mitigate risks to bees, “Presidential Memorandum—Creating a Federal Strategy to Promote the Health of Honey Bees and Other Pollinators,” available at https://www.whitehouse.gov/the-press-office/2014/06/20/presidential-memorandum-creating-federal-strategy-promote-health-honey-b, EPA crafted a rule to codify new data requirements for pesticide registrations to ensure that substances do not pose unreasonable risks to bees. The rule seeks to codify six new tests: testing for honeybee adult acute oral toxicity, testing for honeybee larvae acute oral toxicity, testing for honeybee adult chronic oral toxicity, testing for honeybee larvae chronic oral toxicity, semi-field testing for pollinators, and measuring residues in pollen and nectar. Attorneys and other professionals must understand these critical changes to advise their clients effectively.

The additions affecting laboratory testing are:

- Testing for honeybee adult acute oral toxicity to identify the oral median lethal dose (LD50) for adult bees. LD50 is the dose at which half of the individual bees tested die.
- Testing for honeybee larvae acute oral toxicity to identify the oral LD50 dose for bee larvae.
- Testing for honeybee adult chronic oral toxicity to identify effects following repeat exposures (e.g., ten-day) to the test compound for adult bees.
- Testing for honeybee larvae chronic oral toxicity to identify effects following repeat exposures (e.g., ten-day) to the test compound for bee larvae.

The additions affecting field testing include semi-field testing for pollinators to determine exposure to bee colonies within enclosures and to provide information on exposure as well as the effects on a whole colony; and measure of residues in pollen and nectar testing to provide exposure information (from the pollen and nectar) following product application at label rates. A closer look at these requirements follows.

Tier One

EPA provides, and reviewing courts agree, that Tier 1 assessment includes EPA reviewing studies to determine the pesticide’s “acute median lethal dose for both contact doses (i.e., bees sprayed directly with the chemical) [and] oral doses (bees consuming nectar or pollen contaminated with the chemical).” Pollinator Stewardship Council v. U.S. E.P.A., 806 F.3d 520, 524 (9th Cir. 2015). EPA then determines the concentration of the pesticide that can be expected in the environment by analyzing the pesticide’s characteristics and the proposed application rate. Id. at 524. After determining the acute median lethal doses and the expected environmental concentrations, EPA divides the expected environmental concentrations with the acute median lethal doses to determine the “risk quotient.” Id. at 525. For bees, the “risk quotient” cut-off number that necessitates further study is 0.4. Id. Additionally, to refine the risk analysis for oral exposure, EPA determines risk quotients for various types of bees (e.g., adult and larvae, and different castes within adult bees such as worker, drone, and queen) by reviewing more studies to determine how much pesticide manifests itself in the pollen and nectar of sprayed crops and accounting for the type of bees’ specific consumption patterns. Id. Finally, EPA compares those refined risk quotients to the 0.4 cutoff that reflects whether the pesticide should undergo Tier 2 testing. Id. If those risk quotients are above 0.4, EPA mandates Tier 2 testing.

Tier Two

If Tier 2 testing is necessary, EPA reviews studies where bees were forced to feed on pesticide-treated crops. Id. These “semi-field” studies represent a better reflection of “the effect that a pesticide would have on the functioning of the entire colony.” Id. The studies may not, however, accurately reflect a true colony because the bees are stressed from being put into a tunnel and, therefore, “die
at much higher rates than in their normal environment.” *Id.* Additionally, the studied bees feed on only treated crop, so the studies do not reflect that bees in the environment feed on a variety of crops. *Id.* Beyond the inability to reflect lethality accurately, the studies cannot determine sub-lethal effects because the studies cannot last more than ten days due to the stress the bees endure from being put into a tunnel. *Id.* at 525–26. Based on Tier 2 testing, EPA determines whether additional data and studies are needed. *Id.* at 526.

Certain defects may result in an EPA decision to not unconditionally register a pesticide. Pesticides may be regulated to “the extent necessary to prevent unreasonable adverse effects on the environment. . . .” 7 U.S.C. § 136a. To achieve that protection, EPA’s regulations require EPA to “[r]eview[] all relevant data in [its] possession” and to “determine[] that no additional data are necessary” to assure that the pesticide usage would result in no unreasonable adverse effects. 40 C.F.R. § 152.112(b)-(c). In *Pollinator Stewardship Council*, EPA noted several deficiencies in the studies, including that (1) the majority of the studies used lower than proposed application rates; (2) no study was conducted according to “OECD 75 guidance,” which matters because even though the regulations do not mandate Organization for Economic Cooperation and Development (OECD) compliance, the regulations are clear that studies done in accordance with OECD protocol will suffice to meet EPA’s data requirements; and (3) no study provided information about longer-term effects on colony strength. *See Pollinator Stewardship Council*, 806 F.3d at 526–37. To assure that your client completes its application and registration correctly (or to challenge another’s application), review risk quotients, review that the test studies used the proposed dosage, review whether the client/registrant submitted at least one study that is performed according to OECD 75 guidance, and review whether the client/registrant drew conclusions about long-term effects on colony strength.

**Tier Three**

Finally, after Tier 2 assessments are completed if EPA requires more information, examine the available field-level studies. Attorneys and other professionals should advise their clients that Tier 3 assessments are necessary “[i]f refined exposure and/or effect data or risk mitigation options at the Tier [2] level do not indicate acceptable risk or substantial uncertainties remain, then EPA may require a Tier [3] evaluation to resolve uncertainties.” “How We Assess Risks to Pollinators,” available at https://www.epa.gov/pollinator-protection/how-we-assess-risks-pollinators. Thus, EPA retains discretion to require Tier 3 evaluation if Tier 2 data are insufficient. If field-level studies are necessary, but no studies are available, the registrant should produce a field-level study.

Lawyers and other pesticide professionals must maintain a thorough understanding of the new tests and related criteria that EPA will apply when deciding registration applications. Only a complete understanding of the law and science of pesticides will ensure the best possible outcome for registration applications or, failing that, ensure the best possible record is created for attorneys attempting to challenge an adverse registration decision. For further information, see “How We Assess Risks to Pollinators,” *supra*.


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On July 29, 2016, President Obama signed into law S. 764, mandating the establishment of a federal disclosure scheme applicable to so-called bioengineered foods. With the enactment of S. 764, it appears that the United States is on a path to establish a coherent disclosure regime for a limited subset of foods that have been genetically engineered (GE), or that contain ingredients derived through genetic engineering.

S. 764 derived from bills passed in both the House and Senate. In 2015, the House of Representatives passed H.R. 1599, the Safe and Accurate Food Labeling Act of 2015. H.R. 1599, in pertinent part, (1) mandated that the U.S. Food and Drug Administration (FDA) continue its voluntary consultation process for GE foods; (2) explicitly stated that the fact that a food is GE is not material to a determination as to whether there is a difference in safety between a GE food and a conventional counterpart; (3) allowed FDA to require labeling of GE food if there is a material difference in the functional, nutritional, or compositional characteristics of the GE food and if the disclosure of such differences is necessary to protect public health and safety; (4) made it unlawful to sell in interstate commerce a food derived from a GE plant unless FDA has determined that the food is safe for humans or animals; (5) required the U.S. Department of Agriculture (USDA) to publish on its website a registry of GE plants that have been evaluated by USDA and FDA; (6) required that within one year of enactment USDA issue “interim final regulations” to carry out the procedures required under the act; and (7) preempted, as of the date of enactment, state and local requirements applicable to GE foods that are not identical to the actions of USDA and FDA. H.R. 1599 also required USDA to establish a national GE food certification program and national standards for the voluntary labeling of GE and non-GE foods.

S. 764 mandates that any bioengineered food that completes the federal pre-market review not be treated as less safe or safer than a non-bioengineered conventional counterpart. This is consistent with the long-standing position of the U.S. Environmental Protection Agency (EPA), FDA, and USDA that GE foods present no unique risks when compared to conventional counterparts.

Efforts in the Senate to pass companion legislation were unsuccessful. Notwithstanding the failure to pass a voluntary GE foods labeling bill, Senators Pat Roberts and Debbie Stabenow, chair and ranking member of the Senate Committee on Agriculture, Nutrition, & Forestry, continued to work on a compromise approach, which they announced on June 23. The compromise bill, S. 764, passed the Senate on July 7, and the House of Representatives on July 14.

S. 764 mandates a compromise labeling approach that requires “disclosure” of information regarding certain GE foods and food components, but does not require covered entities to utilize a particular form of disclosure. Within two years, USDA must promulgate regulations establishing a mandatory disclosure standard for “bioengineered food.” Once promulgated, the USDA disclosure scheme will be mandatory for covered entities. The USDA regulations must require that disclosure be either in the form of text, symbol, or an electronic or digital link. Use of any of these methods will be sufficient to meet the disclosure requirement. The regulations must prohibit food from animals consuming GE feed from being considered to be bioengineered, and must exclude food served in restaurants and produced by “very small food manufacturers.”

A controversial aspect of S. 764 is the scope of foods that are subject to the disclosure requirements. S. 764 mandates disclosures related to “bioengineered foods,” which is defined by the statute as a food “that contains genetic material that has been modified through in vitro recombinant deoxyribonucleic acid (DNA) techniques” and “for which the modification could not otherwise be obtained through conventional
breeding or found in nature.” Taken literally, this may constitute a very limited scope for bioengineered foods. By restricting the definition to food that “contains genetic material” and that has been modified in ways that “could not otherwise be obtained through conventional breeding or found in nature,” S. 764 essentially limits the regulatory scope to foods that have not been processed to the extent that genetic material has been removed; and for which the genetic modification could not be accomplished with sexually compatible organisms. Examples of the latter are the GE plants that express pesticidal proteins derived from the bacteria Bacillus thuringiensis (B.t). It is possible, however, that many gene modifications produced by gene-editing techniques such as CRISPR, TALENs, zinc finger nucleases, and RNAi could conceivably be found in nature and could be developed through conventional breeding. Thus, the scope of gene-edited plants that do not fall under the definition of bioengineering could be large.

USDA’s Office of General Counsel, in a letter to Senator Stabenow, opined that “Section 291(1) of the Senate bill provides authority to include food in the national disclosure program, including products of certain gene editing techniques. This would include novel gene editing techniques such as CRISPR ‘when they are used to produce plants or seeds with traits that could not be created with conventional breeding techniques.’” It remains to be seen how USDA describes the scope of covered foods in the implementing regulations, but the plain language of the statute appears to leave a potentially large universe of gene-edited constructs outside of its scope. Current gene-editing techniques such as CRISPR, TALENs, zinc finger nucleases, and RNAi can be used to produce gene-edited foods with alterations that could be found in nature, and that also could conceivably be created through conventional breeding. In “technical comments” submitted to the Senate Agriculture, Nutrition, & Forestry Committee, FDA noted “[i]t may be difficult to demonstrate that a particular modification could not be obtained through conventional breeding.” S. 764 also imposes broad preemption of state and local government GE labeling requirements. S. 764 contains two express preemption provisions. The first provision, section 293(e) of the statute, prohibits states or localities from establishing or continuing in effect any requirement relating to the labeling or disclosure of whether a food is bioengineered or was developed or produced using bioengineering for food products that are subject to the federal standard, unless the requirement is identical to the federal “mandatory disclosure requirement.” This provision is likely best read as not being effective prior to the promulgation of USDA’s implementing regulations. The second preemption provision, section 295, is much broader. Section 295 prohibits a state or local government from establishing or continuing in effect “as to any food or seed in interstate commerce” any requirement relating to whether a food or seed is “genetically engineered” or “was developed or produced using genetic engineering.” This prohibition is not conditioned on consistency with federal regulations or any other limitation. Rather, it unequivocally prohibits a state or local government from establishing or continuing in effect a labeling or disclosure requirement applicable to GE food. Thus, upon the enactment of S. 764, the Vermont GE foods labeling law that went into effect as of July 1 (Act 120) was immediately preempted.

The debate over the utility of GE food disclosure will now move to the rulemaking process where many of the actual details of the national standards will be established by USDA. There likely will be substantial public interest in this rulemaking.

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FRAMEWORK FOR RISK EVALUATION UNDER NEW TSCA
Charles M. Auer and Oscar Hernandez, Ph.D.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act significantly amends and strengthens the Toxic Substances Control Act (Pub. L. No. 94-469, “old TSCA”). “New” TSCA (Pub. L. No. 114-182) includes specific new requirements for the development of section 6(b) risk evaluations (RE) and also applies section 26 science requirements to this process.

Background

Under old TSCA, an unreasonable risk finding was required to support a risk management action under section 6(a). The process and conduct of the risk assessment necessary to support the unreasonable risk finding were not outlined in old TSCA. New TSCA explicitly separates section 6(b) RE from section 6(a) risk management. Costs or other non-risk factors are, however, included in the section 6(c) requirements for promulgation of section 6(a) rules.

New TSCA section 6(b) requires the U.S. Environmental Protection Agency (EPA), within one year after enactment, to establish by rule a staged scientific evaluation procedure, beginning with prioritization and followed as necessary by RE. These stages precede and serve to assess scientifically and tee up chemicals for regulatory action if certain hazard and exposure determinations regarding “unreasonable risk” can be met. Section 6(b)(4)(A) requires that EPA conduct REs “to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an reasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by [EPA], under the conditions of use.”

Two terms directly relevant to the conduct of REs were introduced and defined in new TSCA. First, conditions of use (COU) is defined in new TSCA section 3(4) as “...the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” This term encompasses all phases of the commercial life of a TSCA chemical and is a critical parameter that defines the context for determining the exposure/exposure potential of a chemical. EPA is granted discretion to determine the COU components that will become the focus of the RE. Second, the term “potentially exposed or susceptible subpopulation” (PESS) is defined in section 3(12) as “...a group of individuals within the general population identified by [EPA] who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” PESS involves a discretionary EPA determination of sensitive subpopulations that are relevant under the COU. EPA is not required to address all possible subpopulations but must identify the scientific basis for the relevant PESS.

Section 6(b)(4)(F) specifies five requirements that EPA must meet in conducting REs. First, EPA is required to “integrate and assess available information on hazards and exposures for the conditions of use...including information that is relevant to specific risks...and information on [PESS] identified as relevant by [EPA].” The requirement to “integrate and assess available information” is consistent with the approach in old TSCA risk assessment. The exposure assessment, however, focuses on exposures for the COU, a scope aspect that is not found in a typical EPA risk assessment. This requirement adds emphasis on identification of PESS, a new aspect that comprises external (potentially exposed) and intrinsic (biological, relating to susceptibility) characteristics that influence the response of a subpopulation to chemical exposures. Examples of the former include geography or occupation (proximity to
a source of exposure), cultural habits, lifestyle, and diet while characteristics that contribute to susceptibility include age, life stage, gender, genetic differences, and preexisting health status.

The second and third requirements address the exposure component of the RE. One requires EPA to “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance.” The second requires that EPA include descriptions of the exposure component of the RE including “whether aggregate or sentinel exposures to a chemical substance under the COUs were considered, and the basis for that consideration.” The former are basic elements that inform about a potential exposure situation with differential (higher) exposure and apply to the relevant COU scenarios. Regarding the latter, there is no requirement to conduct aggregate or sentinel exposure assessments under the conditions of use in all cases, only to describe whether such assessments were conducted and, if so, the reasoning used. Aggregate exposure means the combined exposures to a single chemical across multiple routes and multiple pathways (EPA, Exposure Assessment Tools by Tiers and Types—Aggregate and Cumulative, available at https://www.epa.gov/expobox/exposure-assessment-tools-tiers-and-types-aggregate-and-cumulative). The term “sentinel exposure” is not defined in new TSCA, nor is it defined as such in EPA’s Guidelines for Human Exposure Assessment, available at https://www.epa.gov/osa/guidelines-human-exposure-assessment). A possible illustration is the use of categories of uses in consumer products where a sentinel product is one that produces the highest plausible exposure for an ingredient within a given category. If this exposure estimate does not engender risk, it obviates the need to consider additional subcategories. Health Canada used sentinel products to prioritize exposures to chemicals in consumer products during their categorization of the Domestic Substances List (DSL) (see http://www.tera.org/Peer/Exposure/4.%20Sentinel%20Product%20Construct%20-%20Chaisson.ppt). Aggregate and sentinel exposure could play a role is determining whether unreasonable risks are or are not presented and could potentially be useful in determining the relevance of certain exposure scenarios as part of the COU determination.

Under the fourth requirement, EPA must describe the weight of the scientific evidence (WOE) for the identified hazard and exposure information. The final requirement is not to consider cost or other non-risk factors in the determination of unreasonable risk.

Section 26 includes a number of new provisions relating to scientific standards and WOE. Section 26(h) concerns scientific standards and requires that EPA, in making science-based decisions under sections 4, 5, and 6, “shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable,” a series of scientific standards at section 26(h)(1)-(5). These standards provide the basis for and the scientific framework within which EPA will address questions such as the extent to which the information and methods, among others, are reasonable for and consistent with, and relevant for the intended use, the clarity and completeness of the documentation, the extent to which the variability and uncertainty in the information/methods are evaluated and characterized, and the extent of peer review. All contribute to an understanding of the quality and appropriateness of the hazard and exposure information relied on and the underlying scientific strength of the RE. These scientific standards are a faithful reflection of the EPA’s data quality considerations. (See EPA’s Human Health Assessment Framework, available at https://www.epa.gov/risk/framework-human-health-risk-assessment-information-decision-making, and Guidance for Exposure Assessment, available at https://www.epa.gov/osa/guidelines-human-exposure-assessment.)

Application of these data quality standards takes place within the regulatory context and information may be acceptable in one situation and
unacceptable in another. For example, information required to conduct a screening level risk assessment may be appropriate to support initial determinations on new chemicals or prioritization designations, but may not be sufficient for a RE.

Section 26(i) requires that science-based decisions be based on the WOE and applies to decisions on testing, new chemicals, and prioritizations and REs. WOE is generally regarded as a narrative that describes the strength, weaknesses, and relevance of the information considered in supporting hazard, exposure, and risk conclusions. WOE has elements of both a process and a framework. As a process, WOE relies on expert judgment for its evaluation of different lines of evidence. There is no consensus framework for WOE nor do all EPA program risk assessments incorporate the concept. When used, WOE has been largely confined to the hazard components. (See EPA, Guidelines for Carcinogen Risk Assessment (Mar. 2005), available at https://www.epa.gov/risk/guidelines-carcinogen-risk-assessment.) Section 6(b)(4)(F) explicitly requires that WOE be described for both hazard and exposure assessments. While EPA does not have formal guidance for WOE, it has developed analytical tools in the form of guidance for risk characterization (Risk Characterization Handbook (Dec. 2000), app. A, available at https://www.epa.gov/risk/risk-characterization-handbook), which states that a risk characterization should be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR). The TCCR principles offer a flexible set of criteria consistent with new TSCA requirements and scientific standards and may provide a starting point for developing guidance for incorporating WOE into REs as required by law.

Conclusions

The technical requirements summarized above for new TSCA are, for the most part, reflective of EPA’s risk assessment practices. Differences from a traditional risk assessment are apparent in aspects such as the following: the requirement to conduct the RE under the COU as determined by EPA; added emphasis on the identification and consideration of PESS; the explicit description of certain exposure assessment parameters, including consideration of aggregate and sentinel exposures; and the incorporation of WOE as an explicit analytical component. The framework as outlined by Congress defines standards and features that distinguish REs from a conventional EPA risk assessment.

Perhaps more significant is that these elements are not considerations but are requirements for which the implementation and outputs need to be documented and discussed in the process rules for prioritization and RE and in more specific detail in the documentation that accompanies specific determinations. The fact that low-priority designations and final REs are all legally reviewable highlights the need for EPA carefully to consider and document the scientific issues and decisions made under new TSCA section 6(b).

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BIG CHANGES ON THE REGULATORY HORIZON FOR NANOSCALE MATERIALS?
Lawrence E. Culleen and Camille Heyboer

The U.S. Environmental Protection Agency’s (EPA) first federal environmental regulation imposing reporting requirements specifically for nanoscale materials may be on its way. The regulation is expected to create reporting and record-keeping requirements for both current and future manufacturers and processors of existing and new chemical substances produced at the nanoscale. The proposed rule was issued in April 2015, and in October 2016 EPA sent its version of the final rule to the Office of Management and Budget (OMB) for review. If OMB’s review of the rule is completed within the next few weeks, it is possible the final rule could be issued before the change in administration.

Scope of the Rulemaking

If promulgated as it was initially proposed, the final Toxic Substances Control Act (TSCA) section 8(a) reporting rule will require manufacturers (including importers) and processors of nanoscale materials to submit a one-time only report to EPA concerning their current production of nanoscale versions of substances already listed on the TSCA Inventory and require manufacturers and processors to provide notice prior to commencing manufacture of a new nanoscale substance (i.e., a substance not yet listed on the TSCA Inventory). Under the terms of the proposed rule, current manufacturers and processors of nanoscale materials would submit reports within six months after the final rule becomes effective. Manufacturers and processors of new nanoscale materials would be expected to notify EPA at least 135 days before beginning manufacture or processing. Small businesses and those who manufacture or process small quantities of nanomaterials solely for research and development purposes will be exempt.

Impact of the Recent TSCA Amendments

Comprehensive amendments to TSCA—signed into law by President Obama in June 2016—are already having an impact on companies that have submitted premanufacture notifications for substances that are manufactured in conventional ways on a scale that is not considered to be “nano.” EPA reviews of new chemical notifications often are taking a good deal longer than the standard 90-day review provided under section 5 of TSCA for new chemical substances. The 2016 amendments notably did not impact the provisions of TSCA section 8 pertinent to the nanoscale substances reporting rule. The TSCA amendments nevertheless create concerns for businesses that must report commercially sensitive information to EPA (particularly regarding cutting-edge technologies) that might be shared with the general public and state regulatory officials. It is not clear whether a state regulatory agency might seek to regulate a production facility or discourage manufacture within the state of nanoscale substances based on information that could come to light as a product of new section 8 reporting obligations. Perhaps less significant, TSCA section 14 creates new certification and substantiation requirements for manufacturers submitting materials to EPA as confidential business information.

Input from Stakeholders

EPA’s proposed nanoscale materials rule received broad support from environmental interest groups and a myriad of largely negative responses from commercial and research-oriented associations and interest groups around the world. Among the topics receiving the greatest attention were the definition EPA proposed for which substances would be “reportable” and the complexities that could arise in trying to determine what constitutes a “discrete form” of a nanoscale substance. Commenters also suggested that using TSCA section 8(a) to require reporting on “new” substances was inappropriate given the agency’s existing authority under section 5 of TSCA. The list of substances to be exempt from reporting was overly limited according to many commenters. The agency’s assessment of the potential economic impacts of the regulation drew
much criticism as did EPA’s proposal to redefine the threshold for small businesses that would be exempted from a final nano reporting rule.

**What Comes Next?**

The following assumes the final rule emerges before a change in administrations:

- **Enforcement Consequences:** EPA considers nanoscale forms of chemical substances not already listed in the TSCA Inventory to be new chemical substances subject to the reporting requirements of TSCA section 5. There is a potential risk that a business submitting a report required under the final TSCA section 8(a) rule for what it believes to be a substance already listed on the Inventory might learn that EPA considers the substance reported to be a “new” chemical substance rather than simply a nanoscale “form” of a substance listed on the TSCA Inventory. The consequences of TSCA section 5 violations can be significantly disruptive to business relationships and financially devastating for a company.

- **Use of Information Collected Pursuant to the Final Rule:** EPA has stated that it intends to use the information it gathers under this rulemaking to determine if any further regulatory action on nanoscale materials is required. It is worth noting that EPA has assessed nearly 200 “new” nanoscale substances under the section 5 program and, in a significant percentage of those instances, has imposed some level of regulatory restrictions on the nanoscale chemicals it has reviewed. The recent amendments to TSCA greatly increase the likelihood that a report received by EPA under a section 8(a) rule could trigger a TSCA section 4 administrative order compelling the production and submission of additional data. The recent amendments to section 14 of TSCA also enable EPA to share with state regulators certain confidential information that the agency receives under the statute, which individual states could use to impose restrictions independent of EPA action.

- **Further Action on Nanoscale Materials:** EPA’s TSCA section 8(a) rulemaking on nanoscale materials is one of several notable actions the agency has taken on nanoscale substances within the past few years. In March 2015, EPA reiterated its position that makers and marketers of products containing nanoscale silver are subject to Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) registration requirements if the products are sold with antimicrobial (pesticidal) claims. This action came after years of what environmental groups considered to be EPA inaction on nanoscale materials, and may be viewed as a sign of the agency’s renewed focus on regulating nanoscale substances under a variety of statutory authorities.

Assuming a timely review and clearance by OMB, EPA currently plans to publish the final nanoscale chemicals reporting rule in the Federal Register in January 2017. A number of groups have already met with OMB to express concerns about a final section 8(a) rule concerning nanoscale substances. Stakeholders should pay attention to the status of this rulemaking and consider whether to provide their input to OMB before the final rule is published.

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LITIGATING THE OBLIGATION TO REPORT SUBSTANTIAL RISK INFORMATION AND PAY PENALTIES UNDER TSCA SECTION 8(E)
Irene Hantman

On December 9, 2016, four major chemical manufacturers filed a motion to dismiss the Toxic Substances Control Act (TSCA section 8(e) claims filed against them by a law firm (Kasowitz) under the False Claims Act (FCA). Under the qui tam provision of the FCA, individuals may pursue claims against any person who “knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.” (30 U.S.C. § 3730(b)(1); 30 U.S.C. 3729(a)(1)(G).) In this case, Kasowitz asserts that BASF, Bayer (now Convestro), Dow, and Huntsman failed to pay penalties allegedly owed under the U.S. Environmental Protection Agency’s (EPA) TSCA section 8(e) Compliance Audit Program (CAP).

The case was originally filed in the U.S. District Court, Northern District of California in May 2015. In November 2016 the case was transferred to U.S. District Court for the District of Columbia, and a status hearing was held December 1, 2016.

EPA’s Compliance Audit Program (CAP)

In the early 1990s, EPA used the CAP to encourage companies to come into compliance with TSCA section 8(e) requirements regarding the immediate reporting of “new information that reasonably supports a conclusion that a chemical substance or mixture presents a substantial risk of injury to health or the environment” (substantial risk information). In the Federal Register notice announcing the program, EPA explained that section 8(e) is very important to the agency’s ability to obtain information needed to set priorities and perform risk assessments. More than 100 companies participated in the program.

The CAP invited companies to enter into agreements with EPA to audit their past compliance with section 8(e). Companies entering into CAP agreements with the agency were assured that the agency would pursue only limited penalties and that it would forgo late and/or nonreporting TSCA section 8(e) civil penalties. This could represent substantial savings to companies; in its Enforcement Response Policy, EPA asserts that a section 8(e) violation is a continuing violation. That is, the violation continues from the date when the substantial risk information should have been disclosed through every day on which it has not been disclosed. There is no “statute of limitations” for continuing violations. Although the CAP provided significant protections to participants, EPA reserved its rights to take appropriate enforcement action if the agency later determined that a company was required to submit a study or report under the CAP but failed to do so.

Litigation

While pursuing personal injury litigation against the chemical manufacturers over exposure to certain isocyanate chemicals, Kasowitz identified information that led to filing this lawsuit. The isocyanates involved are methylene diphenyl diisocyanate (MDI), polymeric MDI (PMDI), and toluene diisocyanate (TDI). Isocyanates are used in the manufacture of polyurethane materials including liquid coatings, paints, and adhesives, flexible and rigid foam, and elastomers.

This complaint alleges that the defendants withheld substantial risk information regarding respiratory injury when inhaled at levels below applicable inhalation exposure limits and from de minimis dermal contact. According to Kasowitz, none of the substantial risk information at issue in the case was published in the scientific literature or otherwise available to EPA.

Arguing that the violations began as early as 1980 and continued up until the complaint was filed, Kasowitz claims that the defendants owe billions in penalties under section 8(e). In addition, penalties under the FCA can more than triple. The qui tam
provisions of the FCA grant up to 30 percent of any settlement to the private plaintiff.

Kasowitz has put forth a complex legal argument positing that, while BASF, Bayer, Dow, and Huntsman participated in the CAP, they had substantial risk information which section 8(e) obligated them to submit to EPA; were contractually obligated to submit all previously unreported substantial risk information through the CAP; knowingly concealed or knowingly and improperly avoided a contractual obligation to transmit civil penalties for their failure to comply with section 8(e) reporting requirements in violation of the FCA; and made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money to the U.S. government in violation of the FCA.

The complaint is voluminous, comprising nearly 400 pages plus exhibits. Its description of BASF, Bayer, Dow, and Huntsman’s behavior is very unfavorable. The allegations include assertions that the companies:

• Refused to report the substantial risk information to EPA, even as they continued to obtain and/or develop separate and additional substantial risk information that corroborated the previously obtained or developed substantial risk information

• Refused to report the substantial risk information to EPA, even as they reported the results of animal studies that they claimed showed a less certain causal relationship between isocyanate skin contact and respiratory response.


• Demonstrated their intention to conceal the substantial risk information when they issued health effect disclosures in their Material Safety Data Sheets (MSDS) and product labels.

None of these points is addressed by the defendants’ motion to dismiss. The defendants instead argue that Kasowitz has failed to meet the required elements of claim under the FCA. Specifically, they explain that penalties not assessed by EPA do not comprise an “obligation to pay” under the FCA. Kasowitz’s response to the motion is due on February 7, 2017.

Implications

The enrollment period for the CAP expired more than 20 years ago. Today, companies interested in addressing liability for failing timely to submit substantial risk information to EPA must seek the protection of the Audit Policy, using the agency’s new eDisclosure system.

If this case is successful, companies defending toxic tort litigation may see discovery expanded in search of similar substantial risk information.

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