FROM THE CHAIR—THE YEAR AHEAD
Joanne Thelmo

I wanted to take this opportunity to wish you all a Happy New Year and a productive and prosperous 2015!

This past year, our Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee was a tremendous success. At the 22nd Fall SEER Conference in Miami, our PCRRTK Committee earned two awards: Best Committee, Environmental (second consecutive year), and Best Newsletter (third consecutive year). A special note of thanks and appreciation to Martha Marrapese, our most recent chair (Partner, Keller & Heckman), and Lynn L. Bergeson, former Section chair, committee chair, and vice chair and editor of our newsletter (Member and Managing Partner, Bergeson & Campbell, P.C.).

Looking back over the last few months of 2014, our PCRRTK Committee continued to broaden its activities by collaborating with diverse organizations such as CropLife America (CLA), the Society of Environmental Toxicology and Chemistry (SETAC), and the Environmental Law Institute (ELI). These and other collaborations will continue in 2015. Thank you, Sara Beth Watson, at-large vice chair (of Counsel, Steptoe & Johnson), for making our day-long discussion on critical issues with CLA possible.

The New Year is a time of hope and aspirations for the future. So as this New Year unfolds, I would encourage each of us to make a resolution to grow. I especially encourage each of us to grow professionally, not just as individuals but also to share our knowledge and experiences with each other.

Our PCRRTK Committee is a great way to invest in our profession, expand our networks, and learn new areas of law. Whether you are a law student, young attorney, or seasoned professional looking to become more active, PCRRTK needs and seeks your involvement to keep our committee fresh and valuable for all.

A few ways to participate:

- Our monthly committee calls, which are the third Thursday of each month at 2:30 p.m. (ET), are an easy way to keep up with our committee’s activities;
- Our PCRRTK Friday breakfast forums are complimentary hour-long monthly events beginning at 8:30 a.m. (ET), where informal discussions with thought leaders and networking take place; and
- Our committee program calls/webinars are currently under development. On February 5, 2015, our committee hosted a complimentary in-person and teleconference program to discuss the funding challenges with the new Congress’s efforts to reform the Toxic Substances Control Act.

Thank you for your continued participation and support of our committee. Most especially, I wish each of you the very best this coming year!

Joanne Thelmo is chair of the ABA SEER, Pesticides, Chemical Regulation, and Right-to-Know Committee.
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As I begin my fourth full year as assistant administrator for chemical safety, my highest priority is to continue building on the progress that we have made in the last few years. When I started in this job, it was clear, despite the widely acknowledged shortcomings of the Toxic Substances Control Act (TSCA), that we needed to stand up a credible existing chemicals program. “Existing chemicals” are those that were already in commerce when TSCA was enacted in the 1970s, and were allowed to remain in commerce without further evaluation, except in unusual cases.

We have already taken a number of actions to address existing chemicals. One key initiative that has been building momentum the past few years is the TSCA Workplan for Chemical Assessments. In 2014, the U.S. Environmental Protection Agency (EPA) released final assessments on certain uses of four chemicals in the TSCA Workplan. The assessments for several uses of trichloroethylene (TCE) and methylene chloride (DCM) showed risk to consumers and workers. In 2015, EPA will begin taking risk reduction efforts to mitigate these risks. EPA will first try to negotiate voluntary risk reduction measures with the manufacturers of these chemicals. If these negotiations are unsuccessful, EPA will move forward with regulatory risk management under TSCA section 6, something that the agency has not done in more than 28 years.

In addition to risk reduction for chemicals for which assessments have been completed, we will continue working on assessments for other chemicals in the TSCA Workplan. For 2015, these include:

- N-Methylpyrrolidone (NMP) in paint stripper products;
- Three clusters of related chemicals used as flame retardants;
- Several uses of 1-Bromopropane (1-BP), including occupational uses of 1-BP in dry-cleaning and foam-gluing operations, and consumer uses in aerosol solvent cleaners and spray adhesives;
- 1,4-Dioxane;
- Long- and medium-chained chlorinated paraffins used as metal working and compounding agents and their effects on ecological receptors.

We have also increased the number of significant new use rules (SNUR) being issued for existing chemicals. A SNUR is a regulatory action that requires anyone who wishes to place a particular chemical into commerce, for a new use or former use that has been phased out, to submit a notification to EPA at least 90 days before beginning the activity. SNURs serve as a backstop to prevent manufacturing or importing of chemicals for uses that have been phased out, either voluntarily or through negotiations with EPA, from being reinitiated by other companies. SNURs provide the agency with an opportunity to evaluate the new use and, if necessary, take action to prohibit or limit the activity. EPA will continue to use SNURs to make sure that chemicals taken off the market for particularly risky uses remain off the market.

One of the most exciting things happening in 2015 is that EPA will be revealing a newly redesigned logo for the Design for the Environment (DfE) safer product labeling program. The DfE safer product labeling program helps consumers, businesses, and institutional buyers identify cleaning and other products that perform well and are safer for human health and the environment. In order to carry the label, every ingredient in a product must meet stringent human health, environmental, and performance criteria. In the past few years, it has become clear that the current DfE logo does not resonate with consumers and purchasers. In 2014, we conducted a rigorous outreach and information-gathering effort, reaching out to current DfE partner companies, numerous groups of stakeholders, and the general public. The selection of the redesigned logo will make use of the feedback gathered from all of these sources.
as well as drawing on market research. The goals of this effort are to convey better the program’s mission of promoting safer products; increase consumer recognition of the program; and to communicate to consumers the human health and environmental benefits of choosing safer products. We expect to reveal the redesigned logo to the public in the next month or so and hope to have the new logo displayed on products on store shelves in the second half of 2015.

On the regulatory front, we will finalize a rule regulating formaldehyde emissions in composite wood products. This rule will make national the requirements currently in place in California. We will also make a determination as to whether renovations in commercial and public buildings create a hazard from lead-based paint. If so, we will propose a regulatory approach, as required by statute. Finally, we intend to propose to modify existing use authorizations for polychlorinated biphenyls (PCB) in several contexts in late 2015 or early 2016. These authorizations were created over 30 years ago when there were no cost-effective alternatives to PCBs. Today, there are many alternatives and the useful life of the products containing PCBs is nearing an end.

I also expect that 2015 will be a turning point for our green chemistry program, as we work to identify barriers to adoption of greener chemistries, as well as a means to incentivize the adoption of these powerful technologies.

Another area where we have made progress over the past few years is in making health and safety data, and information on chemicals that the agency has collected under TSCA, more accessible to interested parties and the general public. In 2013, we launched ChemView, a powerful, web-based tool that allows easy access to thousands of documents, including hazard characterizations, alternative assessments, test data submitted to EPA, and TSCA regulatory actions. Since ChemView’s release, the agency has continued to add more information to the database, in addition to refining and enhancing the application’s functionality. This work on adding more information and creating a more robust and useful system will continue in 2015.

Also in 2015, we will be conducting a pilot program for the purpose of further refining the Draft Guidelines for Environmental Performance Standards and Ecolabels that were released in 2013. The goal of the draft guidelines is to establish a process for recognizing nongovernmental environmental standards for use in federal procurement. Under the pilot, EPA will contract with an organization(s) to convene several groups, including a governance committee and stakeholder panels. The groups will develop and pilot test an approach to implement the draft guidelines in a few sectors, including building paints/coatings/removers, building flooring, and furniture.

If you are interested in more details about these efforts, please visit our website at http://www.epa.gov/oppt/.

The Honorable James J. Jones is the assistant administrator of EPA’s Office of Chemical Safety and Pollution Prevention (OCSPP). Previously Jim served as acting assistant administrator of OCSPP from 2011 to 2013, and from 2007 to 2011 Jim was deputy assistant administrator for OCSPP. A substantially similar version of this article was published by ChemicalWatch.
CONFLICT MINERALS AND INFORMATION DISCLOSURE REQUIREMENTS: WHEN DOES COMPELLED COMMERCIAL SPEECH OVERREACH AND IMPLICATE THE FIRST AMENDMENT?
Eric P. Gotting, Martha Mraapeze, and Kelly V. Friend

The D.C. Circuit is in the midst of a spirited First Amendment debate as to what extent the First Amendment limits government efforts to require industry to disclose information publicly about products and supply chains. While the subject matter is narrow, focusing on a recently imposed duty on manufacturers to tell the government whether they use “conflict minerals” obtained from war-torn areas in Central Africa to make their products, the outcome could more widely impact the chemical industry. Although the government’s authority to require public disclosures is often not in doubt, particularly with regard to traditional labeling and warning requirements, the conflict minerals case asks what level of constitutional scrutiny courts should apply to broader “right-to-know” disclosure laws, which often address more than environmental or health concerns, and at what point such requirements reach beyond simply requesting factual information and, instead, force industry to adopt a message or opinion of the government or a third party, thus raising more serious First Amendment issues.

Commercial Speech and the First Amendment


When the government compels an individual or company to speak, the First Amendment, depending on the type of speech, can provide the speaker with varying levels of protection. At one end of the spectrum, courts diligently guard the speaker’s rights by subjecting the government to a strict level of scrutiny, at least when political, nationalistic, or religious speech is involved. Varnette, 319 U.S. at 642. But at the other end, when only commercial speech is at stake, the First Amendment often discounts the speaker’s interests in favor of giving the public access to information. In those circumstances, courts apply lower levels of scrutiny, and this distinction defines how courts often treat labeling and other disclosure requirements under the First Amendment.

It was not until 1976 that the Supreme Court held, in Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976), that the First Amendment applies to “commercial speech.” When discussing the importance of promoting the “free flow” of commercial information, the Court observed that in a free enterprise economy it is “a matter of public interest that [private economic] decisions, in the aggregate, be intelligent and well informed.” Id. at 765. The Court was careful to note, however, that while “commercial speech enjoys First Amendment protection, . . . a different degree of protection is necessary to insure that the flow of truthful and legitimate commercial information is unimpaired.” It then identified circumstances where the government could legitimately regulate such speech to protect the consumer rather than the speaker. These circumstances include time, place, and manner restrictions, forbidding false or misleading speech, and circumstances of interest to companies that are subject to environmental or health and safety regulations, requiring warnings and disclaimers “necessary to prevent [commercial speech] from being deceptive.” Id. at 770–73, 771 n.24.

Four years later, in Central Hudson Gas & Electric Corp. v. Public Service Commission of New York, 447 U.S. 557 (1980), the Supreme Court revisited commercial speech and the First Amendment in a case involving a ban on promotional advertising by electric utilities. At issue was whether the
government could limit speech even when there was no risk of consumer deception. The Court held that it could, provided the government met a three-part test that has become known as “intermediate scrutiny.” Under this approach, the state must: (1) assert a “substantial” interest; (2) demonstrate that the regulation directly advances the governmental interest; and (3) show that the restriction is not more extensive than is necessary to serve that interest. \textit{Id.} at 564–66. The Court held that the order violated the First Amendment because it was not “narrowly tailored” to achieve the state’s goal of energy conservation. Because the ban applied to all promotional advertising, not just speech related to energy consumption, the commission had failed to consider less intrusive alternatives, such as establishing a system whereby the commission would review proposed advertisements to ensure that advertising unrelated to conservation issues was permitted. \textit{Id.} at 568–71.

Left unanswered in \textit{Central Hudson}, however, was whether intermediate scrutiny or some other test would apply to compelled disclosures involving commercial speech. That question was finally addressed by the Supreme Court in \textit{Zauderer v. Office of Disciplinary Counsel}, 471 U.S. 626 (1985), in which it applied a more lenient “reasonable relation” test to “purely factual and uncontroversial” disclosures. The case involved an Ohio regulation that required attorneys advertising contingent-fee arrangements to disclose that clients would have to pay costs even where the case was unsuccessful and there was no recovery. The Court reasoned that “because disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech, warning[s] or disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception.” \textit{Id.} Accordingly, it held that an “advertiser’s rights are adequately protected as long as disclosure requirements are reasonably related to the State’s interest in preventing deception of consumers.” \textit{Id.} In applying the “reasonable relation” test to the Ohio regulation, and ultimately finding that it “easily passe[d] muster” under the standard, the Court made clear that, in cases of compelled disclosures, the government will often be subject to a low First Amendment bar. For example, the \textit{Zauderer} decision flatly rejected the notion that the state was required to show that the attorney disclosure requirement was “narrowly tailored” to preventing deception in advertising. \textit{Id.} at 651 n.14. The Court, moreover, spent little time debating whether the government’s interest was sufficient; the “possibility of deception [was] self-evident” and that was “reasonable enough” to support the requirement. \textit{Id.} at 652–53.

Subsequently, the courts have assessed whether lower level scrutiny should be applied to all compelled disclosures or only those aimed at preventing consumer deception. Indeed, the \textit{Zauderer} case could be read narrowly, as it dealt with a state regulation geared toward eliminating misleading statements in attorney advertising and even couched the “reasonable relation” test in those terms (i.e., the state must have an “interest in preventing deception of consumers”). \textit{Id.} at 651. But the Court also spoke from a broader perspective when it harkened back to \textit{Virginia Board} in noting that “First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides” and, as a consequence, a speaker’s interest in not providing information is “minimal.” \textit{Id.} How courts have interpreted the scope of \textit{Zauderer} is no small matter. At stake is the level of scrutiny to be applied, which in turn can mean the difference between finding a First Amendment violation or not.

**Conflict Minerals and Other Key Disclosure Cases**

The majority of U.S. federal circuit courts apply \textit{Zauderer} broadly. Until recently, however, the D.C. Circuit generally adopted the more narrow approach that the “reasonable relation” test does not apply to commercial speech unless the underlying goal of the government’s compelled disclosure is to guard against consumer deception. See \textit{R.J. Reynolds Tobacco Co. v. FDA}, 696 F.3d
As a result, it has been relatively difficult in that circuit for the federal government to justify certain disclosures. The recent D.C. Circuit decision involving conflict minerals is illustrative.

In *National Ass’n of Manufacturers v. SEC*, 748 F.3d 359 (D.C. Cir. 2014) (*NAM*), the D.C. Circuit considered an industry challenge to a Securities and Exchange Commission’s (SEC) rule that confronts the ongoing armed conflict and humanitarian crisis in the Democratic Republic of the Congo and surrounding areas (DRC). Under the SEC’s regulation, a publicly traded manufacturer is required to disclose in a report filed with the SEC, as well as on its website, whether its products contain a “conflict mineral” (e.g., gold) that was mined in the DRC and, therefore, helped finance armed conflict in the region. *See Conflict Minerals*, 77 Fed. Reg. 56,274 (Sept. 12, 2012). Because the SEC rule was not designed to protect against consumer deception, the D.C. Circuit applied *Central Hudson’s* intermediate scrutiny test. The court found that the SEC rule violated the First Amendment because it was not “narrowly tailored” to achieve the regulation’s goals. The SEC had, according to the court, failed to present any evidence that it had considered “less restrictive means” to the compelled disclosures. *NAM*, 748 F.3d at 371–73.

Several months later, in July 2014, the D.C. Circuit issued an en banc opinion, *American Meat Institute v. USDA*, 760 F.3d 18 (D.C. Cir. 2014), that took a different tack. With this opinion, the court joined other federal circuits in adopting a lower bar for the government to overcome First Amendment challenges to compelled disclosures, regardless of whether a risk of consumer deception is involved. *See, e.g.*, *Nat’l Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001) (lower level scrutiny applied to uphold law compelling manufacturers to inform consumers that their products contain mercury). The court applied the “reasonable relation” test established in *Zauderer* for “purely factual and uncontroversial” disclosures. The court upheld a rule adopted by the Department of Agriculture requiring meat packaging to indicate country of origin (e.g., “born in the United States”) and, in doing so, did not subject the regulation to more exacting requirements seen under intermediate scrutiny (e.g., “narrowly tailored”). As a result, the court overruled *NAM* to the extent that the decision limited the “reasonable relation” test to instances of consumer deception. *American Meat Inst.*, 760 F.3d at 22–23. While noting that *Zauderer* is not entirely clear as to its proper scope, the court ultimately found that the language used by the Supreme Court to justify applying lower level scrutiny to factual and uncontroversial disclosures “sweeps far more broadly than the interest in remedying deception.” The court cited to *Zauderer*’s distinction between disclosure requirements and prohibitions on commercial speech, with First Amendment protections for speakers much weaker when the former is involved. While reiterating the First Amendment’s role in improving the flow of information to consumers, the court stated that “[a]ll told, *Zauderer*’s characterization of the speaker’s interest in opposing forced disclosure of such information as ‘minimal’ seems inherently applicable beyond the problem of deception, as other circuits have found.” *Id.* at 22.

After finding that the country of origin’s labeling requirements were justified by the government’s interest in allowing consumers to make an informed choice regarding the characteristics (e.g., processing safety) associated with meat products, the court rejected arguments that the U.S. Department of Agriculture was required to offer evidence that the disclosures would, in fact, effectively meet this goal or make an affirmative showing that they are “narrowly tailored” to their underlying purpose. The court stated the government showed that the labeling advances the informational goal and represents a reasonable fit “between . . . means and ends” simply by crafting a “purely factual and uncontroversial” disclosure requirement. *Id.* at 23–26. The en banc panel concluded that the “self-evident tendency of a disclosure mandate to assure that recipients get the mandated information may in part explain why, where that is the goal, many such mandates have persisted for decades without anyone questioning their constitutionality.” *Id.* at 26 (citing labeling
requirements regarding fiber content, care instructions for clothing, and listing of ingredients).

**What Does the Future Hold?**

Even though the *NAM* decision was vacated in part, the battle involving the First Amendment and the conflict minerals rule is not over. As noted above, *Zauderer* only applies to “purely factual and uncontroversial” disclosures. The *NAM* court did not address this issue in its holding, relying solely on its application of the consumer deception limitation. But in the wake of the *American Meat* decision, the D.C. Circuit has granted a panel rehearing in the conflict minerals case to decide whether the SEC rule requires something beyond a factual or uncontroversial disclosure and, if so, should a higher level of constitutional scrutiny apply. And for those trying to predict the outcome of this reconsideration, it should be noted that the majority in the original *NAM* decision stated in dicta that “it was far from clear that the description at issue—whether a product is ‘conflict free’—is factual and non-ideological.” *NAM*, 748 F.3d at 371.

- While, as a general matter, *American Meat* might make it increasingly difficult for industry to challenge information disclosure requirements in the area of chemical control, there are some takeaways in the conflict minerals litigation and other First Amendment decisions that practitioners should keep in mind. The fast pace with which compelled disclosure rules, and in particular right-to-know requirements, are being enacted heightens the need carefully to evaluate disclosure requirements related to the manufacture and use of chemicals to determine whether they raise First Amendment concerns. Consider the following:

  - Disclosure requirements that promote nothing more than “consumer curiosity” raise questions about when consumer interest, standing alone, may be insufficient to compel manufacturers to speak against their will;
  - Look for instances where the connection between the information to be disclosed and the purported interests of the government in the compelled speech is specious or highly speculative;
  - A compelled disclosure cannot be so unjustified or unduly burdensome so as to chill protected speech. In the labeling context, courts have “found that this condition exists where the required disclosure is so lengthy that it ‘effectively rules out’ advertising by the desired means.” *Dwyer v. Cappell*, 762 F.3d 275, 283 (3d Cir. 2014) (quotations in original); and
  - Ask whether a federal or state agency has authority to require a certain disclosure. If the agency is not so authorized, then as a matter of law the government does not have a legitimate interest in requiring the disclosure.

In closing, federal and state governments undoubtedly have significant leeway to require disclosures of chemical-related information. But, the First Amendment is not boundless. Even with commercial speech, practitioners should always remain cognizant of the constitutional limitations placed on compelled disclosures.

**Eric P. Gotting, Martha Marrapese, and Kelly V. Friend**, Keller and Heckman, are members of the ABA SEER Pesticide, Chemical Regulation and Right-to-Know Committee and developed this article as a joint publication with SEER’s Environmental Disclosure Committee to ensure broad circulation to SEER practitioners.
AGRICULTURAL BIOTECHNOLOGY DEVELOPMENTS
Keith A. Matthews

The past quarter has been very eventful with respect to matters concerning agricultural biotechnology. There was significant litigation activity, electoral results, domestic regulatory developments, and a foreign regulatory development that had important impacts regarding international trade. Some of the more important developments are briefly summarized below.

Vermont Labeling Statute Litigation

On May 8, 2014, Vermont Governor Peter Shumlin signed into law Act 120, which establishes mandatory labeling requirements for food products sold for human consumption that contain ingredients produced through genetic engineering. Act 120 requires all covered food to have labeling indicating that it is either entirely or partially produced with genetic engineering. Relevant raw agricultural commodities must be labeled as “produced with genetic engineering.” Covered processed foods must be labeled “partially produced with genetic engineering,” “may be produced with genetic engineering,” or “produced with genetic engineering.”

On June 12, 2014, the Grocery Manufacturers Association, the Snack Food Association, the International Dairy Foods Association, and the National Association of Manufacturers filed a complaint in the U.S. District Court for the District of Vermont seeking declaratory and injunctive relief, and asserting five counts variously alleging violations of the First, Fifth, and Fourteenth Amendments, the Commerce Clause and Supremacy Clause, and the doctrine of preemption.

On August 8, 2014, the defendants, the Attorney General of Vermont, the Governor of Vermont, and the Commissioners of the Department of Health and the Department of Finance and Management, moved to dismiss plaintiffs’ complaint. On September 11, 2014, plaintiffs moved for a preliminary injunction enjoining the defendants from implementing Act 120, and moved for leave to amend their complaint. After briefing on these matters, oral argument was held on January 7, 2015.

2,4-D and Glyphosate Resistant Corn and Soybeans

On October 15, 2014, the U.S. Environmental Protection Agency (EPA) granted a time-limited registration to Dow AgroSciences for the herbicide Enlist Duo, which is a combination of specially formulated 2,4-D and glyphosate. Enlist Duo is intended to be used on corn and soybean genetically engineered to be resistant to 2,4-D and glyphosate. The October registration was for use in Illinois, Indiana, Iowa, Ohio, South Dakota, and Wisconsin. EPA imposed extraordinary conditions on the registration regarding spray drift and weed resistance management. EPA took comments until November 14, 2014, on whether to extend the registration to ten additional states.

Previously, the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service had granted three separate petitions that requested determinations of non-regulated status under the Plant Protection Act (PPA) for cultivars of corn and soybeans genetically engineered to be resistant to 2,4-D, glyphosate, glufosinate, or “fop” herbicides such as quizalofop.

On October 22, 2014, the Center for Food Safety and other environmental activist organization petitioners filed a petition for review of EPA’s registration of Enlist Duo with the U.S. Court of Appeals for the Ninth Circuit. The petitioners request that the court review and set aside EPA’s registration of Enlist Duo and find that EPA violated the Endangered Species Act by not consulting with the Fish and Wildlife Service (FWS) and the National Marine Fisheries Service (NMFS) (the Services).
**Syngenta Seeds, Inc. v. County of Kauai**


As enacted, Ordinance 960 would have subjected specified agricultural entities to pesticide use disclosure requirements, and would have required all commercial agricultural entities that “intentionally or knowingly possess any genetically modified organism” to disclose specific information about such crops in annual reports to the County of Kauai Office of Economic Development and to the Hawaii State Department of Agriculture. In addition to the mandatory reporting and disclosure requirements, Ordinance 960 also would have imposed pesticide use restrictions in the form of large mandatory buffer zones. Ordinance 960 also mandated an environmental and public health impact study, and imposed civil penalties for noncompliance.

Plaintiffs challenged the county’s authority to enact and enforce Ordinance 960 on the basis that (1) the ordinance is preempted under both federal and state law; (2) the ordinance’s applicability to a narrowly delineated class violates equal protection provisions of both the United States and Hawaii Constitutions; (3) the ordinance violates due process provisions of both the United States and Hawaii Constitutions; (4) the ordinance would effect a taking of property without just compensation in violation of the Hawaii Constitution; (5) the ordinance constitutes a violation of the Dormant Commerce Clause; (6) the ordinance constitutes unconstitutional interference with the conduct of foreign affairs; and (7) the ordinance violates the Hawaii Uniform Trade Secrets Act, article XI of the Hawaii Constitution, the Kauai County Charter, and Hawaii state law regarding civil fines, and is a violation of the Hawaii Open Meetings Act.

The court found in favor of the plaintiffs on their claims of preemption under Hawaii state law finding that, under a “comprehensive statutory scheme test,” the pesticide use restrictions of Ordinance 960 are preempted on the basis that the state’s statutory “scheme and associated administrative rules cover the same subject matter as Ordinance 960.” The court also ruled that the requirements for annual genetically modified organism reporting requirements are impliedly preempted under the state’s comprehensive regulatory scheme. The court declined to rule on the other claims, ruling that its finding that the ordinance is preempted under Hawaii state law rendered the remaining claims moot.

Interestingly, however, the court ruled that the notification requirements related to genetically engineered crops are not preempted by federal law. Unlike the broad ruling that local regulation of pesticide use, as contemplated in Ordinance 960, is preempted by the state’s comprehensive pesticides regulatory scheme, the ruling that Ordinance 960’s requirements are not preempted by federal law is narrowly cast. The court addressed Ordinance 960 in relation to both the Plant Protection Act (PPA and the Federal Insecticide, Fungicide, and Rodenticide Act. The court found that Ordinance 960 is not expressly preempted by the PPA because the PPA’s preemption provision applies specifically to the “movement in interstate commerce” of subject organisms (e.g., plants, plant pests, noxious weeds, plant products, or biological control organisms) where USDA has issued a regulation or order to prevent dissemination of the subject...
organism within the United States (i.e., where such organisms are “regulated articles” under the PPA). Given that Ordinance 960 would not have regulated the movement of any subject organism, “nor permit anything that federal law has proscribed,” the court found that it is not preempted by the PPA. The court’s order enjoined the County of Kauai from “implementing or enforcing Ordinance 960.”

The broad ruling on preemption of Ordinance 960, on the basis that the state of Hawaii has exercised legislative authority to enact and implement a broadly comprehensive pesticides regulatory scheme, will doubtless have ramifications on attempts by other counties in Hawaii to impose local restrictions on cultivation of genetically engineered crops.

**Hawaii Floriculture and Nursery Ass’n v. County of Hawaii**

On November 26, 2014, the U.S. District Court for the District of Hawaii granted summary judgment in favor of plaintiffs in *Hawaii Floriculture and Nursery Ass’n v. County of Hawaii*, Civ. No. 14-00267 BMK (Haw. Cir. Nov. 26, 2014). *Hawaii Floriculture* was a challenge to Hawaii County Ordinance 13-121 (codified as Hawaii County Code §§ 14-128, et seq.), which generally prohibited open air cultivation, propagation, development, or testing of genetically engineered plants. While the ordinance did provide for specific exemptions, including cultivation of genetically engineered papaya under specified conditions, and continued cultivation of GE crops in “specific locations where genetically engineered crops or plants have been customarily open air cultivated, propagated, or developed” prior to the effective date of the ordinance, if such locations were registered in accordance with requirements of the ordinance, it nonetheless constituted a significant burden on individuals and entities who desired to utilize agricultural biotechnology techniques.

Plaintiffs challenged Ordinance 13-121 on the basis that it was (1) preempted under federal law; (2) preempted under Hawaii state law; (3) violative of the Commerce Clause of the United States Constitution; and (4) effected a regulatory taking in violation of the Hawaii State Constitution. Before the court was plaintiffs’ motion for summary judgment on counts 1 and 2. In addressing the claim that Ordinance 13-121 was preempted under Hawaii state law, the court noted that “[t]hese are the same arguments for state preemption that this Court faced in *Syngenta Seeds, Inc. v. County of Kauai.*” The court determined that “its analysis in Syngenta applies with equal force to Ordinance 13-121,” and concluded that “Hawaii state law impliedly preempts and invalidates Ordinance 13-121.” With respect to federal preemption, the court ruled that Ordinance 13-121 is preempted by the express preemption clause of the PPA to the extent that the ordinance prohibited field testing of plants permitted by USDA as “regulated articles” that are “plant pests” or “noxious weeds” under the PPA. The court ruled that Ordinance 13-121 is not impliedly preempted by federal law.

**Agrisure Viptera**

On December 22, 2014, Syngenta announced that China has granted the safety certificate for Syngenta’s Agrisure Viptera, genetically engineered corn containing event MIR 162 (efficacious against lepidopteran pests). The safety certificate allows import of genetically engineered corn containing event MIR 162 for food and feed use in China. China’s previous refusal to allow imports of corn shipments that may have contained MIR 162 corn constituted a significant trade issue.

**Ag Biotech Electoral Initiatives**

Electoral initiatives that would have required labeling of foods containing genetically engineered ingredients lost in Oregon and Colorado, 50.03 percent to 49.97 percent, and 65.5 percent to 34.5 percent, respectively. In Maui County, Hawaii, voters passed an initiative, 50.2 percent to 47.9 percent, that would temporarily “prohibit cultivation or reproduction of genetically engineered organisms within the County” pending an “Environmental Public Health Impact Statement” to be reviewed by the Maui County Council.
U.S. House of Representatives Energy and Commerce Subcommittee on Health Hearing

On December 10, 2014, the Subcommittee on Health of the House Energy and Commerce Committee held a hearing on the U.S. Food and Drug Administration’s role in the regulation of genetically modified food ingredients. Appearing before the subcommittee were the director of the Center for Food Safety and Applied Nutrition and a panel of stakeholders with interest and/or expertise in the risk assessment of genetically engineered foods. A focal point of discussion was the bill introduced by Representatives Mike Pompeo (R-KS) and G. K. Butterfield (D-NC), the Safe and Accurate Food Labeling Act of 2014 (H.R. 4432), intended to address the phenomenon of proliferating state efforts to require labeling of genetically engineered foods.

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WHAT WILL BECOME OF TSCA REFORM IN THE NEW CONGRESS?
Lawrence E. Culleen

With 2015 upon us and with the members of the new 114th Congress just getting situated, manufacturers, processors, and distributors of chemical-based products are wondering whether the nearly 40-year-old Toxic Substances Control Act (TSCA) will finally be revamped in the next legislative session.

When Congress passed TSCA in 1976, it was believed the legislation’s cross media coverage and “cradle-to-grave” scope provided the U.S. Environmental Protection Agency (EPA) everything it could ever need to fill the gaps left by other media-specific environmental laws of the early 1970s. Nevertheless, the common wisdom now is that the agency’s current authority under TSCA to compel chemical producers and processors to generate health and environmental effects data and, on the basis of such information, to take action to mitigate risks presented by chemical substances has been inadequate. That TSCA reform legislation has not been enacted is surprising given that the desire for a legislative update to TSCA is uniformly accepted by key players at each end of the political spectrum.

Although environmental legislation is not the first topic that many would predict to be on the minds of Republican leaders now that they control both chambers, it is plausible that TSCA reform legislation may be the one area where legislators in the Senate and House are likely to agree that bipartisan progress can be made. This may be due in large measure to the groundwork laid by the late Senator Frank Lautenberg (D-NJ) and Louisiana’s Senator David Vitter (R-LA), who in 2013 introduced compromise TSCA reform legislation (the Chemical Safety Improvement Act (CSIA), https://www.govtrack.us/congress/bills/113/s1009/text (which has been considerably furthered by Senators Tom Udall (D-NM) and Vitter following Senator Lautenberg’s death), and

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During the 18 months since the CSIA was introduced in the Senate, there was considerable behind-the-scenes discussions concerning that bill, which both informed and later responded to the Shimkus discussion drafts that were floated in the House. The results of those discussions were reflected in several draft versions of bills marking up the CSIA that were produced collaboratively by Senators Udall and Vitter. Nevertheless, their efforts did not produce a version of the CSIA that was sufficiently modified to garner the support of then-Senate Environment and Public Works (EPW) Chair Senator Barbara Boxer (D-CA). The Udall-Vitter discussion draft, however, was ultimately leaked by Senator Boxer in the context of her simultaneous release of her own markup of the Udall-Vitter discussion draft (http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=55202dfb-9a1c-45b5-8eb2-dff2ee414606; http://www.epw.senate.gov/public/index.cfm?FuseAction=Files.View&FileStore_id=3865eedd-aa32-47da-9d6a-17fd277a1d7bz). Doing so has allowed negotiators to be able finally to share with others the positions from the left with which future sponsors and co-sponsors of a TSCA reform bill will need to contend if a new bill is to emerge in 2015 and face debate in the committee and eventually on the Senate floor.

It is not entirely clear, however, whether the Senate or the House will be more likely to move first in the 2015 legislative session. While new EPW Chair Senator Inhofe (R-OK) has voiced his support for TSCA reform, many observers are waiting for the incoming chair to make more specific statements about TSCA before articulating publicly their own positions on some of the subtle and not-so-subtle differences between the draft versions of the marked-up CSIA that emerged in the fall of 2014. In fact, in light of the shift of power in the Senate, it is arguable that Senator Boxer’s 2014 markup of the Udall-Vitter draft of the CSIA may lack relevance when considering a starting point for TSCA reform legislation in the new session. It is possible that if the incoming chair decides he wants to move TSCA reform legislation, he may wish to roll back the clock to the original CSIA as a starting point for discussions.

That Representative Shimkus is expected to return as chair of the Environment and the Economy Subcommittee in the House bodes well for TSCA reform enthusiasts, given the willingness he showed throughout 2014 to hold hearings and dive into the nuances of TSCA in a way largely unseen in the House in decades. This may have familiarized committee members on both sides of the aisle, many of who will return to their seats for the 114th Congress. Moreover, the departure of Representative Henry Waxman (D-CA) from the House may make it difficult for Democrats in the House to find another member who understands the law well enough forcefully and credibly to articulate Democrats’ differences with the chairperson if a TSCA reform bill is to be introduced in that chamber. If anything, Waxman’s departure may require Representative Shimkus to work even harder at being a moderating force if Republicans sense the void left by Waxman and seek to exploit it by advancing a bill that is farther to the right than the most recent drafts shared by the chair in the previous session.

To many observers, the foregoing conditions have set the stage for what heretofore has eluded proponents of TSCA reform legislation by demonstrating the necessity for all parties to find the middle ground. The 18 months since the CSIA emerged have clarified that there is widespread agreement on the need for EPA to be tasked with setting priorities for performing chemical risk assessments, and must be challenged further to take regulatory actions within deadlines that should not be left entirely to the agency. Arguably, there is much word-smithing yet to be done to articulate
those positions agreeably in a revised bill, but success on those points is a possibility. Where more significant struggles are likely to emerge, and if the middle ground is to be found, the areas in which compromise (or concessions) will most likely be needed include:

- **Federal preemption of state chemical regulatory actions:** Not surprisingly, Senator Boxer and Representative Waxman, both of California, have wanted to protect the activist state’s ability to regulate chemicals in commerce and in products. Meanwhile, the producers and users of chemical substances want a uniform national standard.

- **What is “safe”?** Because the various bills to amend introduced in recent Congresses would require EPA to perform some form of “safety assessment” on certain chemical substances, it is unlikely advocates will walk away from this concept in the near term. Moreover, there is a fixation with the “unreasonable risk” standard in TSCA because critics incorrectly seek to blame EPA inactivity on the statutory threshold for action. Thus, some change in this phrasing likely will be necessary for such critics to be convinced that “reform” has been achieved. In doing so, inevitably a Pandora’s box must be opened and successfully vetted concerning what exposures are to be taken into consideration (including to the young and aged), and whether a safety determination should also address aggregate exposures through multiple pathways from the same and analogous substance.

- **The standard for taking regulatory actions:** Notwithstanding the so-called safety standard issue, one of the most difficult issues that remains is defining what role, if any, risk and benefit analysis should play in determining when to regulate and the nature of regulatory actions that may be taken under an amended TSCA.

- **Funding:** How to finance an invigorated EPA’s activities under a revised TSCA is perhaps the 800-pound gorilla that must be addressed. Short of converting TSCA to a chemicals and uses registration program, the current TSCA program and EPA’s requirements do not readily lend themselves to a fee structure such as the now familiar one implemented by EPA for pesticides.

If interested parties continue to make these challenges seem insurmountable, then legislators may decide not to invest the energy required to find a path forward for TSCA reform during 2015.

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TSCA: NEW SNURS SIGNAL NARROWING OF ARTICLE EXEMPTION
Lynn L. Bergeson

On December 29, 2014, the U.S. Environmental Protection Agency (EPA) published a final rule signaling renewed interest in asserting Toxic Substances Control Act (TSCA) jurisdiction over articles. The final rule adds nine benzidine-based chemical substances to the existing significant new use rule (SNUR) on benzidine-based chemical substances, and, with respect to both the newly added and the previously listed benzidine-based chemical substances, makes inapplicable the exemption relating to persons that import or process the substances as part of an article. EPA’s press release announcing the rule includes a quote from Jim Jones, assistant administrator for the Office of Chemical Safety and Pollution Prevention, who stated: “There must be a level playing field for U.S. businesses—which is why we’re targeting harmful chemicals no longer used in the U.S. that find their way into commerce, sometimes through imported products.” The final rule enables EPA to restrict or limit any new uses of these chemicals, including imported goods with these chemicals. The final rule also includes a SNUR for di-n-pentyl phthalate (DnPP) and a SNUR for chloroalkanes, C12-13. Under the rule, persons who intend to manufacture, import, or process these chemical substances for an activity that is designated as a significant new use must notify EPA at least 90 days before commencing such manufacture or processing.

Benzidine-Based Dyes

EPA states that the final SNUR “closes a loophole” to ensure that the nine benzidine-based dyes and products containing them, such as clothing, cannot be imported without EPA review and possible restriction. According to EPA, exposure to benzidine-based dyes is of concern to consumers, workers, and children because benzidine dyes can be converted in the body into a chemical that is known to cause cancer. EPA states that these dyes also have the potential to separate from textiles, such as clothing, that are in prolonged contact with human skin, increasing exposure risks. According to EPA, the nine benzidine substances covered under the SNUR are no longer in use. EPA states that it is amending the preexisting SNUR so that the notification requirement also applies to importers and processors of these chemical substances as part of articles, such as clothing.

DnPP

According to EPA, it is concerned about DnPP because it has been shown to cause developmental and/or reproductive effects in laboratory animals. EPA states that “[p]hthalates are used in many industrial and consumer products, many of which pose potentially high exposure risks to consumers, workers and children. Additionally, phthalates have been detected in food and humans.”

Chloroalkanes C12-13

EPA states that chloroalkanes, C12-13, are part of a group of chemicals known as short-chain chlorinated paraffins (SCCP), which are used in a variety of industrial applications, primarily as lubricants and coolants in metal cutting and metal forming operations. According to EPA, SCCPs are no longer in use. EPA states that SCCPs have been shown to be toxic to ecosystems and have been found in a variety of environmental sources, including air, sediment, surface waters, and wastewater. SCCPs have also been measured in a variety of aquatic animals, including freshwater aquatic species, marine mammals, and avian and terrestrial wildlife. EPA states that it “believes that any new uses of SCCPs could cause these chemicals to be released in to the environment and increase potential exposure. Such an increase should not occur without opportunity for EPA to review and control as appropriate.”

Discussion

EPA states in the final rule that, consistent with its past practice for issuing SNURs under TSCA
section 5(a)(2), its decision to issue a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Instead, EPA's final rule is based on its determination that if the use begins or resumes, the use may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. EPA notes that since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of EPA's limited resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

The final rule is notable for the way that it applies to imported articles containing any of the benzidine-based chemicals. EPA has been working in selected cases for a number of years to make inapplicable the 40 C.F.R. section 721.45(f) exemption for articles that otherwise applies to SNURs. TSCA defines “article” as “a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end-use function(s) depending in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition that have no commercial purpose separate from that of an article, and that results from a chemical reaction that occurs upon end use of other chemical substances, mixtures, or articles.” Fluids and particles are not considered articles, however, regardless of shape or design. Historically, articles that contain chemical substances subject to a SNUR that are not intended to be removed and have no separate commercial purpose are generally exempt from TSCA.

The first such recent final SNUR was issued in October 2013 for long-chain perfluoroalkyl carboxylate (LCPFAC) chemical substances that, among other provisions, designates import of LCPFAC chemical substances as part of carpets as a significant new use. The final rule on benzidine-based chemicals is broader in that it is not limited to certain articles and for this reason is precedent.

Stakeholders who have an interest in the legal and policy underpinnings of EPA’s thinking in this regard should review the relevant comments submitted in response to the proposed rule and EPA’s response to those comments in the final rule. Given EPA’s clear interest in more broadly applying SNURs to articles, in imported goods or otherwise, this is an important emerging TSCA issue to monitor. The rule is effective on February 27, 2015.

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