FROM THE CHAIR
Keith A. Matthews

I am pleased to mark the initial edition of the Pesticides, Chemical Regulation, and Right-to-Know (PCRRTK) Committee Newsletter for the American Bar Association (ABA) Year 2017–2018. The committee has already hosted interesting and informative Friday Forums with distinguished guest speakers, including John Cruden, President, American College of Environmental Lawyers (ACOEL), former Assistant Attorney General, Environment Division, U.S. Department of Justice (DOJ), and Jim Jones, Executive Vice President, Consumer Specialty Products Association (CSPA), former Assistant Administrator, Office of Chemical Safety and Pollution Prevention (OCSPP), U.S. Environmental Protection Agency (EPA). Our Programming vice chairs have a number of events planned for 2017–2018 that will delve into issues of significant interest in chemicals regulation law and policy. Many of our members attended the Section of Environment, Energy, and Resources (SEER) Fall Conference in Baltimore, Maryland, and those responsible for planning the conference deserve credit and appreciation for the time spent in organizing a meeting that brimmed with numerous topical, insightful, and thought-provoking sessions.

This year we have embarked on a new leadership structure with co-chairs of PCRRTK. It has been an absolute pleasure for me to work collaboratively with Larry Culleen and to share with him the responsibilities of co-chairing the committee. We have decided to do so also with the “From the Chair” column for our newsletter. Larry will pen the “From the Chair” for the next issue, and we will co-author the column for the Summer 2018 issue.

It is amazing how time flies—the holidays are over and winter is here in a big way. I look forward to all of the events, programming, and member initiatives that the committee will put on in 2018.

PCRRTK strives to bring information and informed discussion to our members and guests in a myriad of ways to help facilitate reasonable and effective regulation of chemical products. Please do not hesitate to contact Larry, me, or any of our vice chairs with any suggestions on how we can continue to do so.

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Any opinions expressed are those of the contributors and shall not be construed to represent the policies of the American Bar Association or the Section of Environment, Energy, and Resources.
The U.S. Environmental Protection Agency (EPA) is facing legal challenges to three of the Toxic Substances Control Act (TSCA) framework rules that the agency issued in final during the summer of 2017. Environmental groups and other interested nongovernmental, nonprofit organizations have filed multiple lawsuits challenging EPA’s Risk Prioritization Rule, Risk Evaluation Rule, and Inventory Notification Active/Inactive Designation Rule (Inventory Reset Rule). Although these lawsuits remain pending, EPA is preparing to implement the rules facing legal challenges.

The June 2016 amendments to TSCA (Lautenberg Amendments) required EPA to issue final Risk Evaluation, Risk Prioritization, and Inventory Reset rules within a year of enactment, or by June 22, 2017. EPA timely made public final versions of the Risk Evaluation and Risk Prioritization Rules in June 2017 and promulgated the final editions in the Federal Register in July 2017. The final Inventory Reset rule was issued in August 2017. These “framework” rules are intended to provide guidance about how EPA will implement the requirements of the Lautenberg Amendments. The Risk Prioritization Rule creates a process by which EPA will identify and designate chemical substances as either “high-priority” or “low-priority.” The Lautenberg Amendments require high-priority chemicals to undergo risk evaluations pursuant to statutory deadlines. The Risk Evaluation Rule establishes EPA’s procedures for analyzing whether the conditions of use (or uses) of a high-priority chemical substance present an unreasonable risk to human health or the environment. The Inventory Reset Rule implements requirements in the Lautenberg Amendments that manufacturers and processors report to EPA which chemical substances are “active” in U.S. commerce. This includes any chemical substance manufactured or processed in the United States during the ten-year period prior to enactment of the Lautenberg Amendments. This rule is intended to help EPA identify which chemical substances are active in U.S. commerce and to allow EPA to prioritize active chemical substances for risk evaluations.

In August 2017, Earthjustice and 11 other organizations filed suit in the Ninth Circuit challenging the Risk Evaluation and Risk Prioritization Rules and alleging that the agency had violated the Administrative Procedure Act. Shortly thereafter, the Alliance of Nurses for Healthy Environments, Cape Fear River Watch, and the Natural Resources Defense Council and the Environmental Defense Fund (EDF) filed lawsuits in the Fourth and Second Circuits, respectively, also challenging the Risk Evaluation and Risk Prioritization Rules. The challenges to the Risk Evaluation Rule were consolidated in the Fourth Circuit, and the challenges to the Risk Prioritization Rule were consolidated in the Ninth Circuit. The petitioners filed a motion to consolidate the challenges in the Ninth Circuit, and the agency filed a motion to consolidate these challenges in the Fourth Circuit. The Fourth Circuit deferred ruling on EPA’s motion to consolidate pending a ruling by the Ninth Circuit on the petitioners’ motion to consolidate the cases in the Ninth Circuit. On December 11, 2017, following the Ninth Circuit’s denial of EPA’s motion to consolidate, the Fourth Circuit deferred ruling on the petitioners’ motion to consolidate the cases in the Fourth Circuit, the challenges to the Risk Evaluation and Risk Prioritization Rules were consolidated in the Ninth Circuit.

Trade associations representing chemical manufacturers and processors, and other trade groups, have shown significant interest in the challenges to the Risk Evaluation and Risk Prioritization Rules. In mid-September, the American Chemistry Council (ACC) and 16 other organizations moved to intervene in the challenges to these rules. In their motion to intervene, ACC and its co-movants argued with respect to the Risk Evaluation Rule that the rule ultimately will affect “what chemicals their members may manufacture, process, transport and use, and under what circumstances,” and expressed concern about the
uncertainty that could be created if the petitioners’ challenge to the Risk Evaluation Rule is successful. The Fourth Circuit has granted the motion to intervene in the challenge to the Risk Evaluation Rule. In their motion to intervene in the challenge to the Risk Prioritization Rule, ACC and its co-movants also focused on the need for certainty, noting that “[t]he outcome of the process under the Prioritization Rule will . . . provide Movants with greater certainty planning future operations.” Following the consolidation of the challenges in the Ninth Circuit, the Ninth Circuit also granted ACC and its co-movants permission to intervene.

EDF is also pursuing litigation in the D.C. Circuit challenging EPA’s Inventory Reset Rule. EDF’s statement of issues, filed in the D.C. Circuit on November 9, 2017, alleges, among others, the following defects with the final rule:

- The final rule will allow companies to assert Confidential Business Information (CBI) claims without complying with all of the requirements of the amended TSCA sections 8 and 14;
- The final rule will exempt chemicals produced solely for export from its requirements, even though TSCA does not provide for such an exemption; and
- The final rule will not require reporting to be completed until 420 days following the publication of the final rule, while TSCA states that the rule must require manufacturers and processors to complete reporting within 180 days after the publication of the rule.

With respect to the final issue raised by EDF, the final Inventory Update Rule does require manufacturers to report to EPA within 180 days after the publication of the final rule, but allows processors 420 days to complete reporting. EPA noted in the final rule that TSCA does not require EPA to impose retrospective reporting requirements on processors, and took the position that the agency’s authority to establish a mandatory 180-day reporting period for manufacturers also creates “implicit” authority for it to establish a retrospective reporting program for processors that allows for reporting beyond 180 days after the publication of the final Inventory Reset Rule.

Similar to the lawsuits challenging the Risk Evaluation and Risk Prioritization Rules, ACC and other trade groups have expressed interest in being involved in the litigation surrounding EDF’s challenge to the Inventory Reset Rule. Thus, ACC and its co-movants filed a motion to intervene in this action, arguing that the Inventory Reset Rule will affect their members because it will create an inventory of chemicals that may be used in the United States, it will assist EPA in identifying candidate chemical substances for risk evaluations, and the final rule will impact the processes that their members must follow to maintain the confidentiality of their chemical substances. The D.C. Circuit has granted the motion to intervene.

Although these challenges to three of EPA’s framework rules remain unresolved, and the nature of the objections to these rules remains largely unknown, no stays of the final regulations have been issued. Thus, EPA has begun implementing the final rules. Manufacturers of chemical substances that were manufactured in the United States during the ten-year period prior to June 22, 2016, must comply with the requirements of the Inventory Reset Rule not later than February 7, 2018. Processors choosing to report will have until October 5, 2018, to complete reporting. Additionally, during the first weeks of 2018, EPA intends to issue “problem formulation” statements that could affect previously issued documents setting forth the scope of the risk evaluations being conducted on the first ten chemicals to be evaluated under the new procedures. The potential impact of the ongoing litigation on implementation of the framework rules remains unknown. Stakeholders are urged to monitor the litigation and be mindful that potential changes could occur if the petitioners are successful in their challenges to these rules.

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The standard by which the U.S. Environmental Protection Agency’s (EPA) regulatory actions under the Toxic Substances Control Act (TSCA) are to be evaluated by the courts has never been abundantly clear. Under TSCA section 19(c)(1)(B), section 706 of the Administrative Procedure Act (APA), 5 U.S.C. § 706, applies for judicial review of TSCA rules and orders. 15 U.S.C. § 2618(c)(1)(B). For review of, inter alia, TSCA section 6(a) risk management rules and section 6(i)(1) “no unreasonable risk” orders, however, “the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such [rule/order] if the court finds that the [rule/order] is not supported by the substantial evidence in the rulemaking record taken as a whole.” Id. § 2618(c)(1)(B)(i). Given the newly amended TSCA risk evaluation standards, it is important to examine the “substantial evidence” standard as used in TSCA section 19(c).

Application of the Substantial Evidence Standard to TSCA Actions

Courts have differed over the years as to how to treat agency actions that are subject to substantial evidence review under APA and under TSCA. As an example, in Envtl. Def. Fund, Inc. v. EPA, the D.C. Circuit stated that the substantial evidence standard, as mandated by TSCA section 19(c), is more rigorous than the arbitrary and capricious review typically applied to informal rulemaking, though it noted that the difference may be largely semantic. 636 F.2d 1267, 1277-78 (D.C. Cir. 1980). The court did not appear to make any distinction between the APA substantial evidence review and the substantial evidence standard in TSCA section 19(c). Id. The court went on to state that in reviewing rulemaking records for substantial evidence, courts are to “ensure public accountability ‘by requiring the agency to identify relevant factual evidence, to explain the logic and the policies underlying any legislative choice, to state candidly any assumptions on which it relies, and to present its reasons for rejecting significant contrary evidence and argument.’” Id.

It may be the case, however, that review on “substantial evidence in the rulemaking record . . . taken as a whole,” as required by TSCA section 19(c), is not the same as review on “substantial evidence” as described in APA section 706(2)(E). In Chem. Mfrs. Ass’n v. EPA, the D.C. Circuit upheld an EPA rule issued under TSCA section 4 that required toxicological testing to determine the health effects of 2-ethylhexanoic acid (EHA), stating that EPA’s finding that EHA presented an “unreasonable risk of harm” was supported by substantial evidence. 859 F.2d 977, 992 (D.C. Cir. 1988). The court found that EPA had properly considered and discredited evidence introduced into the rulemaking record by the plaintiffs, and that EPA had shown, through a number of studies, that there is a “more-than-theoretical probability” that workers would be exposed to EHA, and that EHA is toxic enough that exposure may present “an unreasonable risk of injury to health.” Id.

In finding that EPA had acted based on substantial evidence, the D.C. Circuit stated “[t]his case, therefore, does not turn on an interpretation of the term ‘substantial evidence’ as it appears in the APA . . . but on an interpretation of the term ‘substantial evidence in the rulemaking record taken as a whole’ as it appears in TSCA.” Id. at 991. The court continued, “[d]espite the similarity in wording, Congress apparently contemplated that the TSCA standard should be viewed as a distinct standard; otherwise there would have been no need to specifically rule out the APA review standard.” Id.

The D.C. Circuit based this ruling in part on a review of the legislative history of TSCA. The 1976 House Report on TSCA stated that “[t]he Committee has chosen to adopt the ‘substantial evidence test,’ for the Committee intends that the reviewing court engage in a searching review of the Administrator’s reasons and explanations for the
Administrator’s conclusions.” See H.R. Rep. No. 94-1341 at 56 (1976). Similarly, the Conference Report on TSCA stated:

The conferees recognize that in rulemaking proceedings such as those contained in this bill, which are essentially informal and which involve both determinable facts and policy judgments derived therefrom, the traditional standard for review is that of “arbitrary and capricious.” However, the conferees have adopted the “substantial evidence” test because they intend that the reviewing court focus on the rulemaking record to see if the Administrator’s action is supported by that record. See H.R. Rep. No. 94-1679 at 96 (1976) (Conf. Rep.).

These reports suggest, as the D.C. Circuit ruled in Chem. Mfrs. Ass’n, that in enacting TSCA, Congress meant to subject actions by EPA under TSCA to a stricter level of scrutiny than under APA arbitrary and capricious review or indeed under APA substantial evidence review. As such, it seems possible that TSCA substantial evidence review is differentiated from APA substantial evidence. See Chem. Mfrs. Ass’n, 859 F.2d at 991; see also Consumers Union of U.S., Inc. v. FTC, 801 F.2d 417, 422 (D.C. Cir. 1986) (stating that in the context of the APA, the substantial evidence test and the arbitrary and capricious test are “one and the same,” but that the APA standard of review may be altered if “Congress’ intent to make a substantive change is clear on the statute’s face”). Other courts of appeal do not appear to have taken this stance, however, and the D.C. Circuit has not explained exactly how the two standards differ as a practical matter. Indeed, the vast majority of courts do not make any distinction between the substantial evidence standards under TSCA and APA, and simply apply the judicial rulings on the APA standard to TSCA actions. See, e.g., Envtl. Def. Fund, 636 at 1277. Thus, while the courts’ application of the substantial evidence standard in cases such as Envtl. Def. Fund seems consistent with previous courts’ application of the substantial evidence standard under APA, Chem. Mfrs. Ass’n seems to draw an unclear distinction between the substantial evidence standards under APA and under TSCA.

The Substantial Evidence Standard in TSCA Restricts EPA’s Reliance on Materials Outside an “Official Record”

It is possible that Congress included substantial evidence review in TSCA, not because it intended to raise the standard of review for TSCA actions, but because it intended to restrict the bases for EPA’s actions under TSCA. In Ass’n of Data Processing Serv. Orgs., then-Judge Scalia explained, while ruling on a Federal Reserve order issued under the Bank Holding Company Act of 1956, that with regard to factual support under the two standards, the choice between arbitrary and capricious and substantial evidence was more or less semantic because “it is impossible to conceive of a nonarbitrary factual judgment supported only by evidence that is not substantial in the APA sense.” See 745 F.2d at 683–84. Judge Scalia stated emphatically that “[i]n their application to the requirements of factual support the substantial evidence test and the arbitrary and capricious test are the same.” Id.

Judge Scalia did not, however, believe the substantial evidence standard was pointless; he argued that the function of the substantial evidence standard was “to emphasize that in the case of formal proceedings the factual support for the decision must be found in the closed record as opposed to elsewhere.” Id. at 683. By contrast, the arbitrary and capricious standard, as applied to informal agency actions, permits the agency to review all information before it, not simply the information in the formal record. Id. at 684. This opinion may lend a certain amount of insight into Congress’s statement in the Conference Report for TSCA that it intended the reviewing court to focus on the record to see if the administrator’s action is supported by that record; if the substantial evidence standard is intended to restrict agencies to acting solely based on the evidence in the formal record, then Congress may have originally included the
substantial evidence standard in TSCA section 19(c) with the intent of restricting the information and evidence upon which EPA could rely in acting under TSCA, though if this is the case, it is unclear why Congress did not simply refer directly to the substantial evidence standard in APA.

It is also important to note that before the Lautenberg Amendments, TSCA section 6(a) rules were issued after a formal hearing with an opportunity for cross-examination; this may suggest that Congress included the substantial evidence test, traditionally only applied to formal proceedings, in TSCA only because some TSCA actions subject to TSCA section 19(c)(1)(B)(i), while not technically “formal” rulemakings, were originally subject to formal requirements that went beyond the processes applicable to traditional informal rulemakings. If this is the case, even though TSCA section 6(a) actions are no longer based on a “formal record,” and not all TSCA actions subject to TSCA section 19(c)(1)(B)(i) were required to be based on a formal record, Congress may have retained the substantial evidence standard in TSCA as a way to restrict the bases for EPA action, as suggested above.

If anything is clear from this analysis, it is that the precise requirements of the TSCA substantial evidence standard are entirely unclear. Even the D.C. Circuit seems unable to articulate precisely what the standard requires EPA to prove in its rulemaking record. Given the range of opinions and interpretations of the section 19(c) standard, the time seems ripe for the courts to decide exactly what is required of EPA in crafting rulemaking records under TSCA.

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EPA SEEKS COMMENT ON MERCURY INVENTORY RULE
Lawrence E. Culleen

In late October, the U.S. Environmental Protection Agency (EPA) proposed a rule that will impose reporting requirements on manufacturers and importers of mercury or mercury-added products, and others who intentionally use mercury in a manufacturing process. The proposed rule, titled “Mercury; Reporting Requirements for the TSCA Mercury Inventory” (Mercury Inventory Rule), was promulgated to satisfy requirements in the June 2016 Lautenberg Amendments to the Toxic Substances Control Act (TSCA).

Pursuant to TSCA’s amended section 8(b)(10)(D), EPA is required to publish an inventory of mercury “supply, use, and trade in the United States.” EPA published the first Mercury Inventory in March 2017. The TSCA amendments also require the agency to publish a final reporting rule by June 22, 2018, the second anniversary of the TSCA amendments. The timing of the final rule is intended to permit EPA to gather information and publish the next Mercury Inventory by April 1, 2020, and on a triennial basis thereafter. The proposed rule sets forth reporting requirements for manufacturers and importers of mercury and mercury-added products, and others who intentionally use mercury in a manufacturing process. EPA sought comments on the proposed Mercury Inventory Rule until January 11, 2018.

The proposed Mercury Inventory Rule describes the type of entities that will be required to submit reports to EPA, and provides information about the information that these entities will be required to submit. The statute requires EPA to publish an “inventory of mercury supply, use, and trade in the United States.” The proposed rule discusses the agency’s interpretation that the term “supply” covers the manufacture and storage of mercury, the term “use” includes intentionally using mercury in a manufacturing process and the manufacture of a mercury-added product, and the term “trade” covers importing, exporting, and distributing in commerce mercury or mercury-added products. Entities engaged in those activities will be required to report; in contrast, entities involved in the handling, generation, or management of wastes containing mercury are specifically exempted from the requirements of the proposed rule unless they recover mercury from the wastes and store it for sale or use.

Under the proposed rule, reporting entities will be required to provide information, including (1) the amount of mercury used in the covered activities each year; (2) the quantity of mercury and mercury containing compounds manufactured, imported, or intentionally used in manufacturing processes; (3) the mercury-added products being manufactured or imported; (4) the manufacturing processes in which mercury was used and how the mercury was used in these manufacturing processes; (5) the country from which importers received mercury or mercury-added products; (6) the countries to which covered entities shipped mercury or mercury-added products; and (7) the industries purchasing mercury or mercury-added products from covered entities.

Notably, the proposed rule does not set a volume threshold beneath which reporting would not be required. EPA’s decision not to establish such a threshold was based on language in TSCA section 8(b)(10)(D)(i), which requires EPA to issue a regulation direct “any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process” to report. EPA interprets this provision to mean that the reporting requirements of this rule should cover all manufacturers and importers of mercury and mercury-added products, and all entities that intentionally use mercury in a manufacturing process, regardless of the quantity involved. EPA sought public comment on whether a reporting threshold should be included in the final rule.

The proposed rule also provides guidance concerning when a company is considered to have intentionally used mercury in a manufacturing
process. EPA noted that it considers the intentional use of mercury in a manufacturing process to be similar to “processing” as defined under TSCA section 3(13) or to be tied to the expectation of a commercial benefit for doing so. EPA attempts to distinguish manufacturing of mercury and mercury-added products from the intentional use of mercury in a manufacturing process by stating that, during the former category, mercury would be added intentionally to and would remain in the final product for a specific commercial purpose. In contrast, during activities that fall into the latter category, mercury would be used during the manufacturing process, but would not be expected to remain present in the final product. Thus, if mercury remains present in a product following the use of mercury in a manufacturing process, but the mercury does not serve a functional purpose, the proposed rule considers the mercury to be a reportable “impurity.” The requirement to report mercury as an impurity in a finished product in which it is unintentionally present is a departure from other TSCA regulations, such as most TSCA section 5 regulations and the section 8 Chemical Data Reporting (CDR) regulation.

To address EPA’s obligation to avoid duplicative and burdensome reporting under TSCA, the preamble discusses the agency’s efforts to coordinate with the entity that implements the Interstate Mercury Education and Reduction Clearinghouse (IMERC) and to be considerate of the information and timing requirements of the CDR and Toxics Release Inventory (TRI) reporting obligations. Thus, EPA states its intent to design the electronic reporting system for the final Mercury Inventory Rule in such a way that entities already complying with IMERC reporting standards will be allowed to bypass certain reporting fields. Similarly, EPA also intends to allow entities that submit data pursuant to the CDR rule to bypass certain reporting fields in the agency’s electronic reporting system.

EPA is seeking public comment on a wide range of issues addressed in the rule. For example, taking into account that the amended TSCA expands the current ban on exports of elemental mercury to prohibit the export of certain mercury compounds by January 2020, EPA announced it believes that including one cycle of reporting information relating to these compounds will be beneficial to the agency notwithstanding the ban. Accordingly, the proposed rule would require entities that export these compounds to submit reports to EPA to provide a “baseline” for export activities between April 1, 2017, and January 1, 2020. EPA has requested comment regarding the value of collecting information about the export of mercury compounds that will soon be restricted from export. Additionally, EPA sought comment on the agency’s proposal to exempt entities that only use, but do not themselves manufacture or import, mercury-added products. The exemption is intended to avoid double-counting certain mercury uses, and to reduce the reporting burden on downstream entities.

EPA is required to issue a final Mercury Inventory Rule by June 2018. The agency will likely be pressed to review timely and respond to public comments and issue a final rule by the statutory deadline. Interested parties should remain apprised of developments, and should be ready to engage EPA well in advance of the deadline for issuing the final rule.

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FDA ISSUES GUIDANCE ON JURISDICTIONAL DIVIDE WITH EPA ON MOSQUITO-RELATED PRODUCTS
Lynn L. Bergeson and Timothy D. Backstrom

On October 4, 2017, the U.S. Food and Drug Administration (FDA) announced the availability of final guidance that clarifies FDA and U.S. Environmental Protection Agency (EPA) jurisdiction over the regulation of mosquito-related products intended to function as pesticides, including those produced through the use of biotechnology. 82 Fed. Reg. 46,500. Guidance for Industry #236, “Clarification of FDA and EPA Jurisdiction over Mosquito-Related Products” (Guidance), provides information for stakeholders regarding the regulatory oversight of articles, including substances, for use in or on mosquitoes (mosquito-related products). FDA states that it is providing the Guidance to clarify circumstances under which such products are regulated by FDA as new animal drugs under the Federal Food, Drug, and Cosmetic Act (FFDCA) and other circumstances under which such products are regulated by EPA as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Scope of Guidance

FDA notes that the Guidance is important in light of the public health urgency of countering the spread of mosquito-borne disease such as that caused by the Zika virus. While novel mosquito control technologies have gained greater attention, there has been confusion regarding FDA and EPA jurisdiction over such products. FDA, working collaboratively with EPA, is providing the Guidance to clarify the regulatory oversight of mosquito-related products. This includes, but is not limited to, those produced through biotechnology.

FDA and EPA Jurisdiction over Mosquito-Related Products

In the Guidance, FDA clarifies that the phrase “articles (other than food) intended to affect the structure or any function of the body of man or other animals” in the FFDCA’s drug definition does not include articles intended to function as pesticides by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes. FDA states that it believes that this interpretation is consistent with congressional intent and provides a rational approach for dividing responsibilities between FDA and EPA in regulating mosquito-related products.

The Guidance includes the following examples of new animal drugs regulated by FDA:

- Products intended to reduce the virus/pathogen load within a mosquito, including reduction in virus/pathogen replication and spread within the mosquito and/or reduction in virus/pathogen transmissibility from mosquitoes to humans; and
- Products intended to prevent mosquito-borne disease in humans or animals.

Examples of pesticide products regulated by EPA are “[p]roducts intended to reduce the population of mosquitoes (for example, by killing them at some point in their life cycle, or by interfering with their reproduction or development).”

Guidance for Sponsors/Manufacturers of Products Intended for Use on Mosquitoes

In the Guidance, FDA encourages sponsors of mosquito-related products, other than those that are “intended to prevent, destroy, repel, or mitigate mosquitoes by controlling a mosquito population,” to contact FDA early in the development process. FDA states that if a developer has a jurisdictional question, such as which agency or agencies would have oversight of a mosquito-related product that is expressly intended for both mosquito population control and human disease suppression, the developer may contact either or both agencies via the contacts listed. FDA and EPA will consult with each other on the jurisdictional question, “as is already common practice.” The agencies may suggest a joint meeting among EPA, FDA, and the sponsor to discuss appropriate pathways to market.
Discussion


The Guidance is a welcome addition to the growing body of work generated by federal agencies intended to assist stakeholders in sorting out the challenging jurisdictional issues that often arise in the context of procuring federal agency approval of products of biotechnology and synthetic biology. The legal and procedural issues that Oxitec, Ltd. (Oxitec), experienced in obtaining approval for a field trial of its genetically engineered Aedes aegypti mosquito designed to prevent reproduction is a perfect example of this jurisdictional quagmire, and undoubtedly the reason the new Guidance was prepared. An argument could be made that a technology designed to control a pest should be regulated under FIFRA. Yet, others have speculated that the Oxitec product is primarily intended to prevent or mitigate a human disease and thus should be regulated as a human drug rather than an animal drug. Because the modified mosquito was designed to limit the viability of offspring, FDA initially reviewed the mosquito as an animal drug for a minor species.

The new FDA Guidance states that products intended to prevent mosquito-borne disease in humans or animals are regulated as new animal drugs subject to FDA jurisdiction, but products intended to control mosquito populations would be regulated by EPA as pesticides. That FDA and EPA are attempting to clarify their respective jurisdictions is appreciated. Potential commenters may wish to consider whether the Guidance offers sufficient clarity for product development planning purposes. If “products intended to prevent mosquito-borne disease in humans or animals” are under FDA jurisdiction, the status of mosquito repellents currently registered by EPA that make claims about repelling mosquitoes that carry the Zika virus, the West Nile virus, or other viruses is unclear. Additionally, it would seem that the Oxitec mosquito is intended to reduce the mosquito population, among other goals. The Guidance is a good start, but further clarification likely will be needed to support emerging technologies.

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Join your colleagues at the beautiful Hilton Orlando Bonnet Creek Resort, April 18–20, 2018, to gain practical knowledge from the nation’s leading lawyers, top government officials, in-house counsel, and academics on a wide variety of timely topics.
On September 20, 2017, by a three-to-two majority, the U.S. Consumer Product Safety Commission (CPSC) granted a petition to start the process to ban the use of a large class of flame retardants in certain consumer products. This action was unusual because CPSC overrode its own staff’s recommendation to deny the petition because it failed to meet the statutory and scientific criteria laid out in the Federal Hazardous Substances Act (FHSA). At issue are non-polymeric organohalogen flame retardants (OFR), meaning flame retardants that contain halogens (including chlorine or bromine) and do not chemically bind to the polymer matrix to which they have been added. They are simply mixed in with the rest of the polymer. The specific categories of consumer products included in the petition are durable infant or toddler products; children’s toys; child-care articles or other children’s products (other than children’s car seats); upholstered furniture sold for use in residences; mattresses and mattress pads; and plastic casings surrounding electronics.

To implement an OFR ban, CPSC must first convene a Chronic Hazard Advisory Panel (CHAP). Once convened, the CHAP will review scientific data and provide CPSC a report addressing any OFR hazards. This will help CPSC formulate any future rule. In the interim, CPSC issued “guidance” in the Federal Register on September 28, 2017, recommending that manufacturers of products in the specified categories, and the supply chain generally, avoid OFRs. CPSC further recommended that consumers ask about the presence of OFRs in products they buy. CPSC cited “[s]cientific evidence to date [that] demonstrates that OFRs, when used in non-polymeric, additive form, migrate from consumer products, leading to widespread human exposure to mixtures of these chemicals.” CPSC’s decision responded to a 2015 petition filed by Earthjustice and other nongovernmental organizations (NGO) requesting a ban on OFRs. They argued warnings would not be adequate, and sought to avoid so-called regrettable substitution of non-banned but objectionable OFRs for banned, equally objectionable OFRs. The NGOs cite “a nexus” between “mere presence” of OFRs in products and “exposures that put consumers at risk of harm.”

Why Is This Potential Ban So Unusual?

No legal or scientific precedent exists for grouping such a broad class of chemicals under a single regulation. The covered OFRs have varying chemical, physical, and toxicological properties. They could number in the hundreds. In fact, CPSC staff recommended denying the petition because staff concluded that OFRs are too distinct to be treated as a single class. CPSC staff’s view aligns with the U.S. Environmental Protection Agency’s (EPA) in the latter’s assessment of certain flame retardants under the Toxic Substances Control Act. There, EPA established “clusters” of three to seven structurally similar flame retardants. By requesting a ban on consumer products containing “any [OFR],” the NGOs seek bans on chemicals that do not yet exist, or that may not yet be publicly identified or scientifically studied. Moreover, the NGOs seek to ban categorically OFRs regardless of actual OFR levels in consumer products or associated exposures. Thus, the petition asked CPSC to assume that environmental and health data for known OFRs are universally applicable to all OFRs. The petition also assumed that the mere presence of OFRs in consumer products would produce adverse health effects. Previously, when data were unavailable, CPSC conducted exposure studies to assess human health risks from flame retardant usage in mattresses. EPA also used predictive models to address data gaps for its assessment of flame retardants, with chemical structures forming a starting point. Based on these analyses, CPSC staff concluded that existing data for OFRs cannot be used to assess all OFRs. To ban a chemical, CPSC must first classify it as a “hazardous substance” based on a risk analysis. To
ban the use of tris (2,3-dibromopropyl) phosphate in children’s clothing in 1977, for example, CPSC used a risk assessment based on CPSC and National Cancer Institute testing data. Here, CPSC staff said conducting a risk assessment was not possible due to a lack of toxicological and exposure data, particularly as to OFRs as a class.

What Steps Must CPSC Take Before It Can Adopt a Rule Banning OFRs?

While the commission majority overruled the staff recommendation in granting the petition, that is only the first legal step. CPSC faces strict requirements before imposing bans on chemical substances. The FHSA requires CPSC to find that “the degree or nature of the hazard involved in the presence or use of such substance in households is such that the objective of the protection of the public health and safety can be adequately served only by keeping such substance, when so intended or packaged, out of the channels of interstate commerce.” Thus, before banning a substance, CPSC must examine its use and packaging, and potential exposure from that use. It must also conclude that other appropriate measures (including warnings) will not protect public health and safety from the hazards posed by the substance. CPSC also must convene a CHAP before banning a substance (see Consumer Product Safety Act (CPSA) §§ 31 and 28). CPSC specifically directed that the CHAP consider consumer exposure “to mixtures of [OFRs]” and “may use any generally accepted scientific methodology to fill in the data gaps, as appropriate.” Recent CHAP activity suggests the process will take a long time. Despite a theoretical 120-day deadline to produce a report, CPSC’s phthalates CHAP issued conclusions six years after Congress directed its creation, and a final rule took another three years.

What Does This Mean for Consumers and Manufacturers?

CPSC faces significant legal hurdles in conducting a future rulemaking to ban OFRs. Grouping chemicals identified as diverse by a sister agency (EPA), and treated individually by other regulators, will pose a heavy burden on CPSC. The FHSA focuses on individual substances, not dissimilar groupings of substances. Furthermore, data gaps will need to be filled in. Without substantial new data, any ultimate ban on all OFRs likely will be vulnerable to a legal challenge. The petition grant is not a ban, and the guidance document has no legal effect, as the document itself recognizes. CPSC staff cited California upholstered furniture flammability standard changes, state flame retardant bans, and consumer preferences as reasons for reduced uses of OFRs already. CPSC’s actions, however, represent a marked shift for an agency whose traditional focus has been on reducing the risk of fire, to one that appears to prioritize eliminating chemicals from the marketplace. The CHAP process will likely take years, and will require a rigorous analysis of the available science. Many factors—including new scientific data, new fire retardant technologies, marketplace developments, and changes in the makeup of the commission—will influence the eventual outcome.

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