FROM THE CHAIR
Keith A. Matthews

As I write this introduction to our committee newsletter, we are about to enter the second half of the last month of the first quarter of calendar year 2017. It has been an eventful first three months of the year. I would like to reference the words of our Section chair, Seth Davis, in his “Views from the Chair” piece in the January/February issue of Trends. While noting the changed and charged political climate of this era, he described how the body of environmental laws that arose during the 1970s and 1980s were creations of bipartisan compromise from a time that seems long, long ago. Notwithstanding, however, the all-too-evident partisanship (often it seems that the only thing in Washington, D.C., that is bipartisan is partisanship—a headline in this morning’s New York Times is Look Who’s Threatening a Government Shutdown Now) that characterizes this political era, we in our world celebrated last year two noteworthy and remarkable bipartisan legislative achievements, the Frank R. Lautenberg Chemical Safety for the 21st Century Act and the Bioengineered Foods Disclosure Act, both signed by President Obama last summer.

These two acts are now in their implementation phase, where the federal agencies responsible for implementing the legislative mandates are promulgating the rules and developing the guidance that will effectuate the legislative intent. For these statutes, and for the myriad proposals now being floated on clean water, clean air, endangered species, and related laws, our committee continues, in the words of Seth (who was speaking of the Section as a whole), “to serve as the premier forum for discussions—at the highest level—of issues impacting [chemicals regulation] law. . . . We strive to have open discussions of key issues—open to all parties and points of view. Our discussions will be even more significant with the transition now taking place in Washington.”

I quote Seth’s words because they reflect one of the roles that our committee excels at—providing a forum for discussion. In January, we hosted Wendy Cleland-Hamnett, who was kind enough to join us for a Friday Forum at Ballard Spahr; and in February, Larry Culleen organized an outstanding forum on Lautenberg implementation in which several committee vice chairs participated and many of you attended. Upcoming, we have a forum on the Endangered Species Act that is being organized by Irene Hantman and Steve Richardson that will explore possible ways to reconcile the ongoing train wreck that exists at the intersection of the Federal Insecticide, Fungicide, and Rodenticide Act and the Endangered Species Act. Lynn Bergeson will moderate a Toxic Substances Control Act session at the Section’s 46th Spring Conference in Los Angeles in late March. We are pleased once again to join with CropLife America for a joint forum on topical issues in pesticides...
Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter
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Lynn L. Bergeson, Editor

In this issue:

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

Multiple TSCA Section 6 Rules Progressing Despite Government-Wide Regulatory Slowdown
Lawrence E. Culleen and Camille Heyboer.................................4

EPA Issues First Regulation of Nanomaterials as a Class
James G. Votaw ...................................7

White House Releases Final Update to the Coordinated Framework for the Regulation of Biotechnology
Lynn L. Bergeson..................................10

New Committee Leadership in Congress—More Gridlock or a New Era of Environmental Lawmaking?
Bart J. Kempf ......................................16

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AMERICAN BAR ASSOCIATION
SECTION OF ENVIRONMENT, ENERGY, AND RESOURCES

CALENDAR OF SECTION EVENTS

April 12, 2017
What Happens Now at EPA: Assessing the Executive Orders and Upcoming Regulatory Reform
Teleconference

April 13, 2017
Breaking Ground at Standing Rock: The Dakota Access Pipeline and Environmental Justice
Teleconference
Primary Sponsor: ABA Section of Civil Rights and Social Justice

April 13, 2017
Understanding the Trump Administration’s 2-for-1 Regulatory Policy
Washington, DC
Primary Sponsor: DC Bar

April 13, 2017
Environmental Justice: Initiatives and Strategies
Washington, DC
Primary Sponsor: Howard Law School & Environmental Law Institute

April 18, 2017
Negotiating the Environmental Provisions in a Real Estate Contract
CLE Webinar

April 20, 2017
A New Era of Environmental Law: Foundations and Principles Colloquium
The Elisabeth Haub School of Law at Pace University
White Plains, NY

For full details, please visit www.ambar.org/EnvirCalender
law—Sara Beth Watson and Rachel Lattimore are working to put together an informative and engaging program that is currently scheduled for a date in April. Our Programming vice chairs are working with Section members on brown bag sessions on specific developments in chemicals regulation law. Finally, and looking a bit to the future, we, of course, will again host our annual summer reception for law students.

In addition to the wonderful programming that we offer, the work of our dedicated vice chairs continues: I am truly grateful to James Votaw for stepping in to coordinate another outstanding *Year in Review* volume; Allison and Tabby maintain our significant presence in social media; Lynn continues to lead the production of the committee’s newsletter—which is second to none in informative and thoughtful content; and Freedom Smith has worked with the American Bar Association web team to ensure that our committee website is up-to-date and a key source of information on topics relevant to chemicals regulation.

The committee 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 me or one of our vice chairs with any suggestions on how we can continue to do so.

Keith A. Matthews is counsel with Wiley Rein LLP.
MULTIPLE TSCA SECTION 6 RULES PROGRESSING DESPITE GOVERNMENT-WIDE REGULATORY SLOWDOWN
Lawrence E. Culleen and Camille Heyboer

In the months immediately following enactment of the 2016 amendments to the Toxic Substances Control Act (TSCA), the U.S. Environmental Protection Agency (EPA or agency) has taken a remarkable number of actions to regulate chemical substances using its expanded section 6 authority. Among the highlights of the amendments are new statutory requirements directing EPA to (1) “prioritize” chemical substances for “risk evaluation,” and (following a risk evaluation) (2) take regulatory action sufficient to mitigate those risks to human health or the environment deemed “unreasonable” on the basis of the agency’s risk evaluation. Although a number of EPA rulemakings have been delayed by recent executive orders, the so-called TSCA framework rulemakings and EPA’s initial section 6 actions have thus far remained on schedule, setting up a busy few months ahead for those likely to be affected by any final rules that are promulgated.

EPA Section 6 Actions to Regulate Existing Chemical Substances

PBTs
The newly added section 6(h) requires EPA to take “expedited action” to mitigate risks from exposures to certain Work Plan chemical substances that EPA has a reasonable basis to conclude are toxic and has determined to be persistent and bioaccumulative (also known as PBTs). In September, EPA identified a list of seven PBTs that it considers to be subject to action under section 6(h). EPA narrowed this list to five substances in October after receiving a request under TSCA section 6(b) (4)(C)(ii) to remove two substances from the expedited PBT process. EPA will now conduct a full risk evaluation for these two substances: ethanone, 1-(1,2,3,4,5,6,7,8-octahydro-2,3,8,8-tetramethyl-2-naphthalenyl)—with the manufacturer(s) requesting the full risk evaluation covering 50 percent of the costs. The risk evaluations will presumably follow the process to be established in the framework rule for risk evaluations, which is still in the proposal and public comment phase.

The five substances that remain subject to the expedited PBT process are (1) decabromodiphenyl ethers (DecaBDE); (2) hexachlorobutadiene (HCBD); (3) pentachlorothio-phenol (PCTP); (4) tris (4-isopropylphenyl) phosphate; and (5) 2,4,6-tris(tert-butyl) phenol. To allow for expedited action, EPA is not required to complete a risk evaluation in accordance with the process still being established. Rather, the amended law requires EPA to complete an exposure and use assessment, prior to issuing a proposed section 6(a) rule to restrict exposure to these substances “to the extent practicable.” The proposal must be issued not later than mid-June 2019, with the final rule codified 18 months thereafter. EPA has signaled that it will begin to undertake further use and exposure assessments, though the agency has not yet offered additional information about the potential scope of these assessments.

First Ten Chemicals
On November 29, 2016, EPA published its initial list of ten “high priority” chemical substances from its 2014 Update to the Work Plan for Chemical Assessments (Work Plan Substances) that will undergo risk evaluations in accordance with deadlines established by the amended TSCA. The ten Work Plan Substances are:

- 1, 4 Dioxane
- 1-Bromopropane
- Asbestos
- Carbon Tetrachloride
- Cyclic Aliphatic Bromide Cluster
- Methylene Chloride
- N-methylpyrrolidone (NMP)
- Pigment Violet 29
- Tetrachloroethylene or perchloroethylene
- Trichloroethylene (TCE)
EPA’s designation of these ten chemical substances constitutes the initiation of the TSCA risk evaluation process for each of these substances. The agency is required to issue scoping documents for the risk evaluation of each of these substances by June 19, 2017.

On February 14, 2017, EPA held a public meeting to ascertain better the uses of the substances in anticipation of drafting and publishing the scope of the risk evaluations for the ten Work Plan Substances. EPA was particularly interested in receiving input from stakeholders about the uses of each substance as the agency has concluded that its risk evaluations must consider not only ongoing uses but also all reasonably foreseen uses. EPA also indicated at this meeting that it would not be issuing draft-scoping documents for comment prior to undertaking the risk evaluations of the Work Plan Substances. The agency has opened separate dockets, however, for each of these substances where interested parties may submit information and comments for EPA’s review during the scoping process. Interested parties were asked to submit their comments not later than March 15, 2017.

**Section 6(a) Rulemakings**

EPA successfully published several proposed section 6(a) rules that it was not compelled to issue under the amended law, but the rules were enabled by provision in the amendments that permitted EPA to issue proposals on the basis of risk assessments that were completed by EPA prior to June 2016. Details follow.

**TCE:** In early 2017, EPA proposed two rules on TCE pursuant to its authority under TSCA section 6(a)—one concerning use of TCE in vapor degreasing and another addressing use of TCE in aerosol degreasing and spot cleaning. In the preambles to the proposals, EPA stated that it had identified “significant risks” associated with the use of TCE for these purposes, and proposed to prohibit manufacture, import, processing, and distribution of TCE for these purposes. EPA is soliciting comments on both of its proposed TCE rules. Following a recent 30-day extension of the comment period for these two proposals, the deadline to submit comments for the rulemaking on the usage of TCE in vapor degreasing is April 19, 2017, and the deadline for the rulemaking related to aerosol degreasing and spot cleaning was March 16, 2017.

EPA considered alternatives to prohibiting both uses of TCE, but ultimately determined that these alternatives would not provide sufficient protection to consumers from these products. In coming to the conclusion that the risks presented by the use of TCE in vapor degreasing would be best addressed through a prohibition on the use, EPA also considered the possibility of mitigating these risks by allowing the use of TCE in “closed-loop” vapor degreasing systems and requiring workers operating these systems to wear protective equipment. EPA rejected this option because it determined that there were commercially available alternatives to TCE for vapor degreasing and because the use of these alternatives was determined to be less expensive than requiring companies to use closed-loop systems and provide protective equipment. EPA considered a similar alternative option for the use of TCE in aerosol degreasing and spot cleaning. The agency considered requiring the use of personal protective equipment and/or engineering controls in commercial degreasing operations, but also determined that, due to costs, companies were more likely to use alternatives to TCE than to implement respiratory protection programs.

**NMP and Methylene Chloride:** On January 19, 2017, EPA published its proposed rule on NMP and methylene chloride (MeCl2). In addition to requirements specific to each substance, EPA proposed separate but similar prohibitions on consumer uses for paint and coating removal products containing methylene chloride and NMP, as well as package size and “down-stream” notification and record-keeping requirements for manufacturers, processors, and distributors of methylene chloride and NMP. EPA is soliciting comments on this rulemaking, and interested parties may submit comments by April 19, 2017.
The MeCl2 provisions, if promulgated, will prohibit the manufacture, import, processing, and distribution of methylene chloride for all consumer and most commercial paint and coating removal uses, with a ten-year exemption for critical national security purposes. This proposed rule does not apply to commercial furniture refinishing. EPA indicated that it plans to issue a separate rulemaking for methylene chloride in commercial furniture refinishing, although the status of that rulemaking is unclear in light of recent guidance from the executive branch with respect to new regulations.

EPA’s rulemaking proposes two alternatives for reducing what it considers to be unreasonable health risks posed by exposure to NMP. First, EPA is proposing a prohibition on the manufacture, import, processing, and distribution of NMP for all consumer and most commercial paint and coating removal uses, with a ten-year exemption for critical national security purposes. Alternatively, EPA is proposing a multifaceted approach to reducing potential risks of exposure to NMP during paint and coating removal, including the reformulation of paint and coating removal products containing NMP to not exceed 35 percent NMP by weight and a requirement that the packaging of paint and coating removal products containing NMP include additional warnings about potential health effects and recommending personal protective equipment for NMP product users.

Conclusion

Despite the recent actions from the Trump administration to delay and reduce regulations, EPA appears to be committed to moving forward with the regulations, and (other than an extension in the TCE rules comment periods) thus far the substance of the proposals has remained untouched and on schedule. Though additional actions from the executive branch could derail any or all of these regulations, at this phase stakeholders should do all that they can to submit timely and effective comments, and be prepared for the impact of these rulemakings in the event that the TSCA rulemaking process continues unchanged.

Lawrence E. Culleen is a partner and Camille Heyboer is a legal resource assistant with Arnold & Porter Kaye Scholer LLP.

2017 Call for Nominations

The 2017 Call for Nominations

**Award for Distinguished Achievement in Environmental Law and Policy** will be given in recognition of individuals or organizations who have distinguished themselves in environmental law and policy, contributing significant leadership in improving the substance, process or understanding of environmental protection and sustainable development. Eligible individuals must be lawyers and may include academics, policymakers, legislators, and practitioners, members of the judiciary or journalists.

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

**Environment, Energy, and Resources Government Attorney of the Year Award** will recognize exceptional achievement by federal, state, tribal, or local government attorneys who have worked or are working in the field of environment, energy, or natural resources law and are esteemed by their peers and viewed as having consistently achieved distinction in an exemplary way. The award will be for sustained career achievement, not simply individual projects or recent accomplishments. Nominees are likely to be currently serving, or recently retired, career attorneys for federal, state, tribal, or local governmental entities.

**Law Student Environment, Energy, and Resources Program of the Year Award** will be given in recognition of the best student-organized educational program or public service project of the year addressing issues in the field of environmental, energy, or natural resources law. The program or project must have occurred during the 2016 calendar year [consideration may be given to allowing projects that occurred in the 2015-2016 or 2016-2017 academic years]. Nominees are likely to be law student societies, groups, or committees focused on environmental, energy, and natural resources issues.

**State or Local Bar Environment, Energy, and Resources Program of the Year Award** will be given in recognition of the best continuing legal education program or public service project of the year focused on issues in the field of environmental, energy, or natural resources law. The program or project must have occurred during the 2016 calendar year. Nominees are likely to be state or local bar sections or committees focused on environmental, energy, and natural resources issues.

Nomination deadline: May 12, 2017. These awards will be presented at the ABA Annual Meeting in New York in August 2017.
Before now, the U.S. Environmental Protection Agency (EPA) has evaluated and regulated the potential risks of particular nanoscale materials only on a case-by-case basis, either in the context of the Toxic Substances Control Act (TSCA) new chemical premanufacture notifications (PMN), low release and exposure (LoREX) exemptions, section 5(e) orders and significant new use rules (SNUR), or individual Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) pesticide registrations. On January 12, 2017, EPA issued its first rule directed at nanomaterials as a class. Chemical Substances When Manufactured or Processed as Nanoscale Materials; TSCA Reporting and Recordkeeping Requirements; Final Rule, 82 Fed. Reg. 3,641 (Jan. 12, 2017). This TSCA section 8 reporting rule will require all persons who propose to commence manufacturing (including importing) or processing certain nanoscale materials, or who have done so in the past three years, to prepare and submit a PMN-like report for each material, detailing its identity, properties, uses, production volumes, workplace and environmental exposures, and human health and environmental hazards, to the extent known or reasonably ascertainable. EPA estimates an average of 164 hours per report. Additional reports must be submitted for the same material if production changes are made that intentionally change the shape, size, or certain physicochemical properties of the material (referred to as a “discrete form”). Those manufacturing or processing reportable nanoscale materials prior to the May 12, 2017, effective date will have one year to submit reports for those materials. For other persons and materials, the reporting obligation begins on the effective date.

**Covered Nanoscale Materials**

In preparing this rule, EPA has stated repeatedly that it has not concluded that all nanoscale materials present special risks. There is no particular risk associated with nanoscale particle size alone. But some materials do present different properties when produced at the nanoscale, and those properties themselves may present special risks (e.g., inert gold becoming highly reactive when produced at the nanoscale), or may be benign from an environmental, health, and safety (EHS) perspective (e.g., changing color or fluorescence) but, EPA suggests, may have other, accompanying unique properties that do present special risks. In the rule, EPA’s aim is to cast a broad (fishing) net and collect information on all materials that present with any special size-related properties at the nanoscale and then assess whether those properties or materials may present special risks that warrant further investigation or risk management. As a result, other than the exemptions, the actual reporting criteria are largely uncorrelated with potential hazard or risk. They are instead focused on identifying materials that may present “unique or novel” properties at the nanoscale, without regard to whether those properties suggest increased hazard.

Reports are required only for nanoscale materials that (1) are solids at ambient temperatures; (2) have a particle size as handled less than or equal to 100 nanometers (nm) in one or more dimensions; (3) have “unique and novel” size-dependent properties; and (4) must have been made or processed in the nanoscale form with the specific intent to obtain the “unique and novel” size-dependent property, the apparent theory being that one would not bother making the material in the nanoscale form if the resulting property was not “unique and novel.” The important limiting term “unique and novel” was not defined in the proposed rule, but in the final rule, without prior proposal or public comment, EPA defined unique and novel properties as “those that vary from [properties] associated with other forms or sizes of the same substance.” Instead of limiting the scope of coverage, this definition appears to have the effect of enlarging the scope to cover materials with very common and predictable properties associated with smaller-sized particles. All nanoscale materials will have more surface area than the same mass of the material made in larger
particle size formats. The definition also arguably has the unintended effect of exempting from reporting relatively exotic nanoscale materials, such as carbon nanotubes and fullerenes, that exist only in the nanoscale size range and therefore do not have properties that “vary” from those of a larger form of the same substance because there is no larger form of the same substance. 73 Fed. Reg. 64,946 (Oct. 31, 2008). In addition, like the many exempt nanoscale biological materials, the special properties of carbon nanotubes and fullerenes are less dependent on size and more dependent on chemical structure and shape.

**Excluded Nanoscale Materials**

There are a number of reporting exclusions for nanoscale materials that, by their nature, have been deemed to have a low potential for size-dependent properties that will present special risks. Reporting is not required for materials that are aggregates and agglomerates greater than 100 nm in three dimensions as made or used, even if comprised of primary particles that are less than 100 nm. This also excludes larger scale materials with nanoscale surface features. Reporting generally is not required for unintentionally present nanoscale fractions of larger-sized materials, or where the nanoscale fraction is 1 percent or less by weight. Nor is reporting required for a wide range of biological materials (e.g., DNA, proteins, and enzymes, among others), substances that form in films to be less than 100 nm, and substances that dissociate completely in water to form ions less than 100 nm. Substances that release ions but do not completely dissociate are not exempt. Many nanoscale substances are incorporated into formulated products or matrices. The preamble to the final rule clarifies that otherwise covered nanomaterials are not reportable by processors after they have been incorporated into a formulated product, a polymer matrix, or an article, but processors that prepare these mixtures are not exempt. In a significant break from the proposal, the final rule omits an express exemption for nanoclays and nanoscale zinc oxide materials. These materials are reportable in particular cases if they otherwise meet the size and “unique and novel” applicability criteria. The rule does not apply to “new chemicals” that are not yet on the TSCA Inventory. Nor does it apply to materials subject to the TSCA research and development (R&D) exemption, and materials not subject to TSCA, such as pesticides, foods, drugs, and cosmetics.

**Exempt Persons**

Small business entities with total sales (together with those of their parent companies) of less than $11 million are exempt. Also exempt are companies that submitted a PMN or other TSCA section 5 notice for the particular nanoscale substance after 2004. This exemption applies only to the section 5 notice submitter and not to others making or processing the same substance. There is some uncertainty about how the rule applies to a person that first makes or processes a material (or a discrete form of a material) after the effective date where the same material (or discrete form) was made or processed by others before the effective date and reported by one or more of those other persons within the original one-year window. As written, the rule does not appear to require reporting from such persons. This construction may make it possible for current reportable material manufacturers and importers to shield their future new downstream customers from reporting obligations by submitting their own reports as early as possible. Otherwise exempt small businesses may also conclude that such protection for future customers would be worth the investment.

**Controversial Reporting Deadlines**

Persons engaged in manufacturing (including importing) reportable nanoscale substances (and any discrete form) at any time during the three years prior to the effective date of the rule have until **May 12, 2018**, to submit a separate, one-time report for each reportable material. More controversial is the additional requirement for each subsequent manufacturer, importer, or processor, in the future of the same material (or new material),
to submit its own PMN-like report to EPA, and to report it 135 days before commencement of the new activity. This proposal drew strong criticism during the comment period because, among other things, some argued that it effectively created a SNUR for all covered nanomaterials without meeting the risk criteria established by the statute applicable to SNURs. Without prior proposal or public comment, the final rule addressed this concern to some degree by including an alternative reporting window. Where the intended start of manufacturing or processing was less than 135 days away, companies could instead report within 30 days after forming the intent to commence the activity. Although EPA correctly states in the preamble to the final rule that the 135-day reporting obligation does not expressly prohibit the start of manufacture or processing until the end of that period, the inhibitory effect is the same if a company can be penalized for “late” reports submitted less than 135 days before commencement. The newly added 30-day reporting option provides additional flexibility, but may be impractical given uncertainty about exactly when a company forms a specific manufacturing intent, and because the period is much too short. Based on EPA’s estimate of the average time needed to complete a submission, it would require an individual to work on the report nearly six hours/day every day in the 30-day reporting period to meet the regulatory deadline.

**Extent of Respondents’ Duty to Investigate Facts**

Respondents need only supply information that is “known or reasonably ascertainable.” This standard requires reporting companies to conduct careful investigation and review of available facts, including, according to EPA, asking material suppliers and customers for information to fill gaps in knowledge. But it does not include the obligation to conduct any testing on a material to determine whether it triggers any of the applicability criteria, or which methods to use. This may be particularly significant in respect of determining whether a process change has produced a reportable “discrete form,” which may turn on whether there is an intentional change in size, zeta potential, surface area, dispersion stability or surface reactivity that is greater than seven times the standard deviation of the measured value. New testing is not required to make these judgments and, in the absence of data, new reporting may not be required unless the person reasonably knows that the criteria have been met even without specific test data. EPA has committed to provide further guidance concerning which information it believes is “reasonably ascertainable.”

**Minimizing Impact on Product Supply and Distribution Chains**

Companies potentially subject to reporting should start now to assess how reporting may affect their product development process and supply and product distribution chains. Reporting for static products may represent only a one-time inconvenience for nanomaterial manufacturers and importers. But as a commercial matter, manufacturers should start to plan now for means to limit the potential burden on their current and future direct and indirect customers, who may have their own reporting obligations. This might include providing clear guidance on the extent of the customer’s reporting obligations with, for example, prepackaged product information, product stewardship guidance to ensure safer handling, and potentially regulatory form assembly and submission services. Manufacturers that continually modify or improve their nanoscale material products will need to build checks into their own systems to know when they have made a new “discrete material” triggering new reporting obligations.

**Special Compliance Risks**

Companies also need to prepare for two other possible contingencies. First, as part of inventorying a company’s nanomaterial handling activities that must be reported, it may discover potential violations of TSCA, such as past failure to recognize and provide EPA with PMNs of new chemicals being made or imported, failure to provide required TSCA import certifications, noncompliance with
applicable SNURs for certain nanoscale materials, or previously undisclosed studies subject to disclosure under TSCA section 8(e). To prepare for these risks, companies may decide to couple the nanomaterial product inquiry with a TSCA compliance audit. This would give the company the opportunity to disclose and correct promptly any violations discovered without incurring gravity-based penalties using EPA’s audit policy.

The second concern is the potential discovery of previously unknown hazard information and/or inadequate material handling practices that may result in, for example, unnecessary chemical exposures to workers, or adverse environmental impacts. The long lead time allowed for current manufacturers and processors to assemble and submit their initial reports provides an ideal opportunity for companies to audit and improve these systems before reporting, where warranted, so that the final report submitted to EPA effectively demonstrates that no further regulation or testing is warranted for the particular nanomaterial under the circumstances of use.

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On January 4, 2017, the White House announced the release of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology. The 2017 Update provides a comprehensive summary of the roles and responsibilities of the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) with respect to regulating biotechnology products. Together with the National Strategy for Modernizing the Regulatory System for Biotechnology Products, published in September 2016, the 2017 Update offers a “complete picture of a robust and flexible regulatory structure that provides appropriate oversight for all products of modern biotechnology.” Within that regulatory structure, the federal agencies “maintain high standards that, based on the best available science, protect health and the environment, while also establishing transparent, coordinated, predictable and efficient regulatory practices.” More information is available in the White House blog item, Increasing the Transparency, Coordination, and Predictability of the Biotechnology Regulatory System.

Background

On July 2, 2015, the White House Office of Science and Technology Policy (OSTP), the Office of Management and Budget (OMB), the U.S. Trade Representative, and the Council on Environmental Quality issued a memorandum directing EPA, FDA, and USDA to update the Coordinated Framework for the Regulation of Biotechnology. The Obama administration asked EPA, FDA, and USDA to accomplish three tasks: clarify the current roles and responsibilities of EPA, FDA, and USDA in the regulatory process; develop a long-term strategy to ensure that the federal regulatory system is equipped to assess efficiently the risks,
On October 6, 2015, OSTP issued a request for information (RFI) to solicit relevant data and information, including case studies that may assist in the development of the proposed update to the Coordinated Framework. The RFI was intended to assist OSTP in clarifying the current roles and responsibilities of EPA, FDA, and USDA, and the development of a long-term strategy consistent with the objectives described in the July 2, 2015, memorandum. Three public meetings were held to solicit comment on the current federal roles and responsibilities regarding biotechnology products.

On September 16, 2016, the White House released a proposed Update to the Coordinated Framework, as well as the National Strategy. In the National Strategy, the federal agencies demonstrate their sustained commitment to ensuring the safety of future biotechnology products, increasing public confidence in the regulatory system, and preventing unnecessary barriers to future innovation and competitiveness.

2017 Update to the Coordinated Framework

The 2017 Update is intended to clarify the current roles and responsibilities of the primary agencies involved in the regulation of biotechnology products. The accompanying National Strategy, published in September 2016, identifies future steps intended to ensure the regulatory system addresses novel types of products developed through advances in science and technology appropriately.

Principles for the Regulation of the Products of Biotechnology

The Update to the Coordinated Framework lists principles drawn from the 1986 Coordinated Framework, the 1992 Update to the Coordinated Framework, Executive Orders 13563 and 13610, the 2011 Principles for Regulation and Oversight of Emerging Technologies memorandum, and the 2015 memorandum. According to the Update to the Coordinated Framework, certain principles “continue to serve as guidance for the primary regulatory agencies that help ensure the safety of biotechnology products”: federal statutes and implementing regulations regulate products based on specific uses; the intended introduction of biotechnology products into the environment can be subject to federal oversight under federal statute(s) related to such products and their intended application; each agency uses its existing statutory authorities and regulations to ensure the safety of the biotechnology products for their intended applications; and underlying statutes define the boundaries of the scope of oversight afforded to each regulatory agency.

Roles and Responsibilities of the Primary Agencies That Regulate the Products of Biotechnology

To clarify which biotechnology product areas are within the authority and responsibility of each agency, the 2017 Update describes the types of biotechnology product areas regulated by the various components within each primary regulatory agency (i.e., EPA, FDA, or USDA), organized by agency. The 2017 Update provides an overview of the statutory authorities used by each agency and the health and environmental protection goals each agency derives from those authorities (organized by agency); identifies the product areas that fall within the statutory authorities and responsibilities of each agency (organized by agency); and summarizes the role each agency plays in the regulation of biotechnology products (organized by product category). The 2017 Update notes that the specific regulatory path (and relevant procedures) applicable to any product, including a biotechnology product, are dependent on the nature and characteristics of the product and its application. The 2017 Update includes Table 1 that summarizes the statutes and protection goals related to EPA, FDA, and USDA for the regulation of biotechnology products:
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<th>Agency</th>
<th>Statute</th>
<th>Protection Goal</th>
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| EPA | Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) | Prevent and eliminate unreasonable adverse effects on the environment.  
- For environmental and occupational risks, this involves comparing economic, social, and environmental risks to human health and the environment and benefits associated with the pesticide use.  
- For dietary or residential human health effects, the sole standard is the “safety” of all the combined exposures to the pesticide and related compounds. |
| Federal Food, Drug, and Cosmetic (FD&C) Act | Ensure that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. |
| Toxic Substances Control Act (TSCA) | Prevent the manufacture, processing, distribution in commerce, use, or disposal of chemical substances, or any combination of such activities with such substances, from presenting an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible population, without consideration of costs or other nonrisk factors. |
| FDA | FD&C Act | Ensure human and animal food is safe, sanitary, and properly labeled.  
Ensure human and animal drugs are safe and effective.  
Ensure the reasonable assurance of the safety and effectiveness of devices intended for human use.  
Ensure cosmetics are safe and properly labeled. |
| Public Health Service (PHS) Act | Ensure the safety, purity, and potency of biological products. |
| USDA | Animal Health Protection Act (AHPA) | Protect livestock from animal pest and disease risks. |
| Plant Protection Act (PPA) | Protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks. |
| Federal Meat Inspection Act (FMIA) | Ensure that the U.S.’s commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled. |
| Poultry Products Inspection Act (PPIA) | Ensure that the U.S.’s commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled. |
| Egg Products Inspection Act (EPIA) | Ensure that the U.S.’s commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled. |
| Virus-Serum-Toxin Act (VSTA) | Ensure that veterinary biologics are pure, safe, potent, and effective. |
The 2017 Update to the Coordinated Framework clarifies the roles each agency plays for different product areas, particularly for those products that fall within the scope of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment by providing a table of responsibilities, organized by biotechnology product area. Table 2 of the 2017 Update (pages 28-35) describes the offices within each agency or agencies that may have regulatory responsibility for a given biotechnology product area, as well as relevant coordination across the agencies.

**Interagency Communication and Coordination**

The 2017 Update clarifies the mechanisms currently in place that enable communication and sharing of information, as appropriate and necessary, among EPA, FDA, and USDA. According to the 2017 Update, these mechanisms are “particularly helpful with respect to regulation of products that fall under the purview of more than one agency or may necessitate close coordination prior to decision making.” The mechanisms reviewed include formal and ad hoc interagency working groups and memoranda of understanding.

**Future Reviews of and Updates to the Coordinated Framework**

To clarify the mechanism and timeline for regularly reviewing and updating the Coordinated Framework, the 2017 Update discusses provisions for future review of the Coordinated Framework. For at least five years, beginning in 2017, the Biotechnology Working Group, which was created by the July 2015 memorandum, will produce an annual report on specific steps that agencies are taking to implement the National Strategy and any other steps that the agencies are taking to improve the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products. According to the 2017 Update, the annual report will be made available to the public. The 2017 Update states that at the end of this work the Biotechnology Working Group is expected to continue monitoring scientific and technical developments in biotechnology and its applications and to work with stakeholders to undertake future updates to the Coordinated Framework as warranted.

**Clarifying Roles and Responsibilities Through Case Studies**

The 2017 Update includes useful case studies that are intended to provide general information to developers who believe they have, or are uncertain as to whether they may have, a biotechnology product that is subject to regulation under one or more of the federal laws described in the Coordinated Framework. The 2017 Update uses case studies as a means of demonstrating how a developer might navigate the regulatory framework, starting from research activities in the laboratory, to full commercialization of the product. Certain products may also have post-market monitoring and reporting requirements. The case studies of hypothetical genetically engineered organisms include corn with pesticidal properties; a rose plant with increased pigment production in its petals; plant pest and non-plant pest microbial pesticides; a rabbit producing a recombinant insulin for treatment of humans; and algae for biofuel production. The individual regulatory path that a product takes is based on its characteristics and application, as one or both can affect the regulatory status and relevant requirements established in the various regulations that underlie the Coordinated Framework. Recognizing that intricacies exist in any regulatory system, the 2017 Update states that EPA, FDA, and USDA “welcome and encourage developers of biotechnology products to contact the agencies at the early stages of product discovery or development so any questions related to regulatory status, safety, and/or effectiveness can be identified and adequately addressed.” According to the 2017 Update, “[c]ontacting agencies at the early stages of product development may make the regulatory process more predictable for applicants.”

**NAS Report**

On March 9, 2017, the National Academies of Sciences, Engineering, and Medicine (NAS)
announced the prepublication version release of its new report, Preparing for Future Products of Biotechnology. As noted above, NAS was tasked with looking into the future and describing the possible future products of biotechnology that will arise over the next five-to-ten years, as well as providing some insights that can help shape the capabilities within the agencies as they move forward.

Via an ad hoc committee, the Committee on Future Biotechnology Products and Opportunities to Enhance Capabilities of the Biotechnology Regulatory System, NAS developed this report through several months of gathering and synthesizing information from several sources, including 74 speakers over the course of three in-person meetings and eight webinars, including one presented by the author of this article; responses to its request for information from a dozen federal agencies; statements solicited from members of the public at its in-person meetings; written comments through the duration of the study; and recent NAS studies related to future products of biotechnology.

The report presents conclusions concerning the future biotechnology products themselves, as well as the challenges that federal agencies will face in regulating them, which include:

- The bio-economy is growing rapidly and the U.S. regulatory system needs to provide a balanced approach for consideration of the many competing interests in the face of this expansion;
- The profusion of biotechnology products over the next five-to-ten years has the potential to overwhelm the U.S. regulatory system, which may be exacerbated by a disconnect between research in regulatory science and expected uses of future biotechnology products;
- Regulators will face difficult challenges as they grapple with a broad array of new types of biotechnology products—

for example, cosmetics, toys, pets, and office supplies—that go beyond contained industrial uses and traditional environmental release; and

- The safe use of new biotechnology products requires rigorous, predictable, and transparent risk analysis processes whose comprehensiveness, depth, and throughput mirror the scope, scale, complexity, and tempo of future biotechnology applications.

The report provides three recommendations for federal agencies in responding to these challenges, which it states should be taken to “enhance the ability of the biotechnology regulatory system to oversee the consumer safety and environmental protection required for future biotechnology products”:

1. EPA, FDA, USDA, and other agencies involved in the regulation of future biotechnology products should increase scientific capabilities, tools, expertise, and horizon scanning in key areas of expected growth of biotechnology, including natural, regulatory, and social sciences.
2. EPA, FDA, and USDA should increase their use of pilot projects to advance understanding and use of ecological risk assessments and benefit analyses for future biotechnology products that are unfamiliar and complex and to prototype new approaches for iterative risk analyses that incorporate external peer review and public participation.
3. The National Science Foundation, the Department of Defense, the Department of Energy, the National Institute of Standards and Technology, and other agencies that fund biotechnology research with the potential to lead to new biotechnology products should increase their investments in regulatory science and link research and education activities to regulatory-science activities.
Conclusion

The 2017 Update represents a thoughtful and very useful step in clarifying the roles participating federal agencies play in the commercialization of products of biotechnology. The Obama administration is to be commended for its swift and comprehensive updating of the Coordinated Framework. The final version of the framework helps clarify the often-daunting regulatory process that innovators and others in the area face when they create new biotech products and wish to commercialize them. The NAS report that was just released is an excellent companion document stakeholders should read. It reinforces many of the same messages, made all the more urgent given the budget-cutting nature of the current Trump administration.

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NEW COMMITTEE LEADERSHIP IN CONGRESS—MORE GRIDLOCK OR A NEW ERA OF ENVIRONMENTAL LAWMAKING?
Bart J. Kempf

During the Obama administration, in particular after the 2010 mid-term elections in which Democrats lost their majority in the U.S. House of Representatives, legislative gridlock became standard operating procedure in Washington. In many instances, important policymaking occurred in the context of negotiating appropriations continuing resolutions and increases in the debt ceiling rather than through regular order. To be sure, a handful of bipartisan achievements occurred, e.g., enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act, but most substantive lawmaking had effectively ground to a halt prior to the election of President Trump.

With Republicans in control of Washington, many have high hopes for a resurgence in legislative activity, while others are in a more defensive posture, seeking to block new initiatives. Key cogs in the federal policymaking apparatus are the chairmen and chairwomen, and ranking members, of Senate and House Committees with jurisdiction over environmental and natural resources issues. With respect to issues of importance to the Pesticides, Chemical Regulation, and Right-to-Know Committee, the key committees and associated chairs/ranking members for the 115th Congress are:

- Senate Environment and Public Works (EPW) (Chair: Barrasso, R-WY; Ranking: Carper, D-DE)
- Senate Agriculture, Nutrition, and Forestry (Chair: Roberts, R-KS; Ranking: Stabenow, D-MI)
- Senate Appropriations (Chair: Cochran, R-MS; Ranking: Leahy, D-VT)
- House Energy and Commerce (Chair: Walden, R-OR; Ranking: Pallone, D-NJ)
- House Natural Resources (Chair: Bishop, R-UT; Ranking: Grijalva, D-AZ)
- House Agriculture (Chair: Conaway, R-TX; Ranking: Peterson, D-MN)
- House Appropriations (Chair: Frelinghuysen, R-NJ; Ranking: Lowey, D-NY)

In the House, the only changes from the previous Congress are the rise of Walden to the chair of Energy and Commerce and Frelinghuysen to chair of Appropriations. In the Senate, the EPW chair and ranking member are new to their positions, and Leahy is taking the reins as the top Democrat on Appropriations from retired Maryland Senator Mikulski. Otherwise, the pertinent committee leadership in the Senate is unchanged.

What impact will these committee leaders have on environmental and natural resources issues? First and foremost, it is important to bear in mind a fundamental principle of federal lawmaking: the Senate is where bills go to die. The majority in the House can fairly easily push forward its agenda and its preferred legislation due to rules that provide the minority party with very limited power. In the Senate, however, a variety of rules, including the 60-vote threshold required to move forward most legislation, serve as a significant check on the majority’s ability to legislate. Accordingly, most bills sent to the Senate by the House have a difficult time surmounting the 60-vote threshold.

Against this backdrop, the general expectation is that the House, much like in the 114th Congress, will pass a large number of measures intended to reform or amend environmental and natural resources laws and regulations, while certain Democrats in the Senate will go to great measures to block the more aggressive aspects of President Trump’s and the Republicans’ agenda. With respect to committee governance relevant to environmental and natural resources issues, arguably the most momentous leadership change in a generation occurred with the rise of Chairman Barrasso and Ranking Member Carper on EPW. This follows an era of unprecedented stability in
leadership on EPW—beginning in 2003 and lasting approximately 15 years—during which the EPW chairmanship was held by either Senator Inhofe (R-OK) or recently retired Senator Boxer (D-CA).

Going forward, there is likely to be a measure of continuity between the positions and the agendas of Inhofe and Barrasso, in part due to the fact that both represent energy-producing states where federal statutes such as the Endangered Species Act have been criticized by a range of interests. It remains to be seen whether Carper will approach his EPW role, however, with the fierce devotion to conservation causes demonstrated by Boxer. Indeed, Boxer was a stalwart, fighting tooth-and-nail against efforts large and small that some perceived to threaten the environment and natural resources. For example, Boxer opposed a measure supported by Carper—the Sensible Environmental Protection Act (SEPA)—which would have clarified that Clean Water Act permits are not required for pesticide applications in or near water. See Carper, Coons Applaud Committee Approval of Bipartisan Measure to Ease Burden on Delaware Farmers, https://www.carper.senate.gov/public/index.cfm/pressreleases?ID=cc246331-1e7d-4ac7-8353-ed81344ebf1c. Some suspect that Carper’s past support for SEPA may indicate a greater willingness to come to the table on certain issues.

Also notable is Leahy’s decision to give up his long-standing position as the top Democrat on the Judiciary Committee to become Ranking Member on Appropriations. With earmarks no longer a part of the appropriations process, the position, in many ways, lacks the prominence that it once held. Several recent appropriations continuing resolutions, marked by brinksmanship, however, have included extensive and substantive horse trading on environmental and natural resources issues. Consequently, the leaders of the relevant committees, including Leahy, will have an important role to play in negotiating appropriations bills and associated policy riders.

After years of gridlock and with the GOP takeover of the legislative and executive branches, many perceive an opportunity to revisit federal environmental and natural resources laws that have been on the books and largely untouched for decades. The role of new committee chairs, in particular Carper on EPW, could result in opportunities to legislate, if only in minor ways. Washington observers will be scrutinizing Carper’s decisions to see how he chooses to step into his new role.

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