

Pesticides, Chemical Regulation, and Right-to-Know Committee Newsletter

Vol. 17, No. 1

November 2015

FROM THE CHAIR

Joanne Thelmo

On behalf of the Pesticides, Chemical Regulation, and Right-to-Know Committee (PCRRTK) leadership, I am excited to welcome you to our committee and our website!

Since 1999, our committee has offered a unique venue in addressing pesticides, chemical regulation, and information disclosure issues. I am pleased to play a part in this creative space and serve as chair of the committee. See more at <http://apps.americanbar.org/dch/committee.cfm?com=NR351500>

As I start my second year as chair, I wish to express my sincere gratitude to our vice chairs, both past and present, and to all our former chairs, listed below, for all their hard work and commitment to our committee.

Martha Marrapese (2012–2014)
Charles Franklin (2010–2012)
Mark Duvall (2008–2010)
Lynn Bergeson (2006–2008)
Larry Cullen (2004–2006)
Kipp Coddington (2002–2004)
Stanley Abramson (1999–2002)

Their contributions and leadership have enabled our committee to continue to flourish with an esprit de corps that makes it a privilege and honor to serve as your chair.

One of our committee's primary goals is to provide opportunities for professional discourse, substantive information exchange, and legal scholarship within the diverse bar of attorneys and related professionals interested or involved in pesticide, chemical, and information disclosure law, policy, and regulation.

We address these goals by encouraging broad participation in our programs, publications, and policy dialogues, and by developing programs and materials of value to law students and private, nonprofit, and government practitioners.

So here is a glimpse of what the PCRRTK world will look like in 2015–2016:

- Quarterly Newsletter (November, January, April, June) provides insightful analysis on recent issues and trends in the PCRRTK space as well as publishing opportunities.
- Complimentary Friday Forums provide monthly networking opportunities with colleagues; meet thought/government leaders and learn about critical issues.
- Monthly PCRRTK Conference Call, typically held on the third Thursday at 12:00 p.m. (ET).
- Opportunities to present, network, and collaborate with other organizations.
- Programming to be developed: committee program calls/brown bags/webinars.

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Lynn L. Bergeson, Editor

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**AMERICAN BAR ASSOCIATION
SECTION OF ENVIRONMENT,
ENERGY, AND RESOURCES**

CALENDAR OF SECTION EVENTS

December 3, 2015

**Joint Liability at CERCLA Mega-Sites:
Technical and Legal Strategies for Addressing
the New Paradigm**
CLE Webinar

December 11, 2015

**The Keystone Pipeline Decision – U.S. and
Canadian Perspectives**
Non-CLE Webinar

December 17, 2015

**Beyond Carbon: EPA's New Methane and
VOC New Source Performance Standards
and Draft Control Techniques Guidelines for
the Oil and Gas Industry**
CLE Webinar Series

January 12, 2016

**Outcomes from Paris Conference of the
Parties of the United Nations Conference on
Climate Change: Where Do We Go From
Here?**
CLE Webinar Series

January 26, 2016

**Look But Don't Touch: How Water Quality
Regulation Affects Water Availability**
CLE Webinar

February 10, 2016

Clean Power Plan Litigation Update
CLE Webinar Series

October 5-8, 2016

24th Fall Conference
Denver

**For full details, please visit
www.ambar.org/EnvironCalendar**

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I urge you to browse our website to learn more about our committee.

I plan to tweet and will continue to post on our website and look forward to many more opportunities to continue our conversation. I also encourage you to contact me or any vice chair with your ideas to expand our offerings or resources, or questions.

Now, it is with great pleasure that I introduce you to our vice chairs for 2015–2016. Please know that their information can also be found on the website's committee leadership link at <http://apps.americanbar.org/dch/comadd.cfm?com=NR351500&pg=1>.

Committee Newsletter

- Lynn Bergeson

Electronic Communications

- Freedom Smith
- Allison In

Membership

- Steven M. Christenson, Corporate In-house
- Eric Gotting, Law Firm
- Caleb Pearson, Students and Young Lawyers
- Stacy Tatman, Trade Associations and Young Lawyers
- Sara Beth Watson, Law Firm

Programs

- Larry Culleen
- Charles Franklin
- Irene Hantman
- Keith Matthews

Social Media

- Allison In
- Tayyaba Waqar

Special Projects

- Scott Schang
- Rachel Lattimore

The Year in Review

- Claudia O'Brien
- Alicia Edwards

At-Large

- Mark Duvall
- Herb Estreicher
- Charles Franklin, Government Affairs Special Committee Liaison
- Warren Lehrenbaum
- Martha Marrapese

I look forward to working with you to make this our very best year.

Joanne Thelmo is chair of the ABA SEER Pesticides, Chemical Regulation, and Right-to-Know Committee.



A NEW FRONTIER OF SELF-DISCLOSURE? EPA ANNOUNCES EDISCLOSURE PORTAL

Lawrence E. Cullen and
Thomas A. Glazer

In June, the U.S. Environmental Protection Agency (EPA) previewed its new web-based eDisclosure portal that, if launched as planned in late 2015, will give companies a new way to self-report environmental violations. EPA is hoping that this new tool will be a win-win by making it easier for companies to disclose violations and by reducing the resources EPA must devote to oversight.

The eDisclosure portal will implement EPA's policy statement, "Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations," which is more commonly known as the "Audit Policy." EPA adopted the Audit Policy in 1995 and revised it in 2000. Under the Policy, when an entity can fulfill specific criteria demonstrating it has promptly and voluntarily disclosed and corrected certain violations of federal environmental laws and regulations, EPA will agree to reduce penalties, decline to recommend criminal prosecution, and refrain from submitting information requests for a company's internal audit reports.

Over the life of the Audit Policy, thousands of companies have submitted self-disclosure letters to reduce successfully and, in some cases, eliminate their civil penalties. But in recent years, EPA has signaled a waning interest in the Audit Policy. In its National Program Manager Guidance for FY 2013, EPA explained that "most violations disclosed under the Policy are not in the highest priority enforcement areas for protecting human health and the environment" and announced that it was considering modifications to the Audit Policy program. Many observers took this as a sign that EPA was considering doing away with the Audit Policy entirely, a prospect that invited considerable debate.

The launch of the eDisclosure system is a sign that EPA remains committed to the Audit Policy, provided EPA can administer the program with as few

resources as possible. It also represents an attempt by EPA to integrate the Audit Policy into its Next Generation Compliance initiative, whereby EPA is planning a greater reliance on technology across the board, including data analytics, electronic reporting, and advanced monitoring. This new focus comes as EPA is deemphasizing some of its traditional enforcement techniques. For example, EPA's most recent five-year strategic plan projects a decrease in the number of boots-on-the-ground inspections agency-wide.

As for the eDisclosure portal itself, for the purposes of administering the system, EPA has divided violations into two tiers. Tier 1 violations are routine violations of the Emergency Planning and Community Right-to-Know Act (EPCRA), which, according to EPA, comprise "about half" of the disclosures reported to the agency. When a company submits a Tier 1 violation through the portal, along with a certification of compliance within 60 days of discovering the violation, the system will automatically generate an electronic notice of determination with no assessment of civil penalties.

In contrast, Tier 2 violations are more serious and include EPCRA violations with "significant economic benefit" and all non-EPCRA violations. When a Tier 2 violation is submitted through the portal, EPA will make a case-by-case determination about whether an enforcement action is warranted and, if so, whether the reporting entity qualifies for a penalty reduction under the Audit Policy. Companies will also have 60 days to certify that they have come into compliance, with 30-day extensions routinely available and longer extensions available with a written justification.

The eDisclosure system will be a success if companies choose to use it. Whether companies in fact will use the system will ultimately depend on whether EPA can effectively and fairly manage the portal. If eDisclosure works well, it could be a useful tool for the regulated community to identify and report many types of violations. Concerns have been raised in certain circles that the portal could provide access to the general public of sensitive

information that businesses might prefer to keep out of the public domain, and which they have been able to do during the disclosure and negotiations process that is currently in place. If it turns out that these concerns are well founded, the operations of the system itself are found too difficult to use, or the promised benefits do not materialize, EPA may find itself once again considering changes to the Audit Policy.

Lawrence E. Culleen and **Thomas A. Glazer** work in the Washington, D.C. offices of Arnold & Porter and are active in chemical-regulatory matters.



Emerging Air and Climate Issues Series

Learn about emerging air and climate issues. Attendees may register for each webinar individually or for all four

webinars. Attendees who register for all four webinars will receive 25% off their total registration.

On November 18, 2015, the panelists will review several key questions the states will need to answer in order to craft compliance plans that satisfy the EPA's final Clean Power Plan.

On December 17, 2015, the panelists will discuss the EPA's proposed suite of requirements to reduce methane and VOC emissions from the oil and gas sector.

On January 12, 2016, the panelists will discuss the outcomes from the Paris Conference of the Parties of the United Nations Conference on Climate Change held December 2015.

On February 10, 2016, the panelists will provide an update on the status of litigation challenging the Clean Power Plan following the initiation of the litigation and resolution of preliminary and scheduling motions.

To register for one program or the series, please visit:

<http://shop.americanbar.org/eBus/Store/ProductDetails.aspx?productId=226121678>

NRDC SUES EPA FOR A FAILURE TO ISSUE HAZARDOUS SUBSTANCE REGULATIONS: THE END OF A DECADES-LONG PUBLIC RISK IN SIGHT

Jack Morgan

Currently there are no federal regulations that prevent hazardous substance spills at onshore facilities, such as tank farms, or in communities where a spill of those chemicals could threaten water supplies. The U.S. Environmental Protection Agency (EPA) has the authority to issue spill prevention regulations for onshore facilities that hold hazardous substances in aboveground storage tanks (ASTs); in fact, EPA has been required to issue spill prevention regulations for such facilities since 1972. ASTs that contain hazardous substances can pose threats to millions of Americans because there is no universal measure to assess the tanks' integrity or ensure they will not leak. Years of exposure to weather deteriorate the tanks, and heighten the tanks' potential to release hazardous substances into water supplies.

On July 21, 2015, the Natural Resources Defense Council (NRDC) filed a complaint on behalf of the Environmental Justice Health Alliance for Chemical Policy Reform (EJHA) and People Concerned About Chemical Safety (PCCS) against EPA and EPA Administrator Gina McCarthy in her official capacity as administrator, in the U.S. District Court for the Southern District of New York. The case has been assigned to Judge Shira A. Sheindlin. The complaint alleges EPA is in violation of section 311(j)(1)(C) of the Clean Water Act (CWA), which gives EPA a non-discretionary duty to issue regulations to prevent spills and releases of hazardous substances from non-transportation-related onshore facilities. In addition, the complaint alleges EPA is in violation of two subsequent executive orders implementing that provision of the CWA. The plaintiffs seek a declaratory judgment that EPA is in violation of the CWA and an order compelling EPA immediately to begin a rulemaking and issue the required spill prevention regulations.

Some believe the complaint has a good chance of succeeding because the CWA mandates EPA to issue spill prevention regulations for onshore facilities with hazardous substances, and for equipment at onshore facilities that hold hazardous substances, such as ASTs, yet EPA has not done so. Although some argue EPA has ignored two executive orders enforcing section 311(j)(1)(C) of the CWA for years, it may be required to issue the regulations at the end of its battle with NRDC.

Section 311(j)(1)(C) of the CWA directs EPA “as soon as practicable” to issue regulations under the National Contingency Plan (NCP) to establish “procedures, methods, and equipment and other requirements for equipment to prevent discharges of oil and hazardous substances from [. . .] onshore facilities [. . .], and to contain such discharges.” The prescribed regulations must establish procedures and methods to prevent *and* contain discharges of hazardous substances and oil from onshore facilities. They also must provide requirements for equipment at onshore facilities, such as ASTs.

Soon after Congress passed the bill in 1972, EPA issued regulations under the NCP to prevent oil spills that defined “non-transportation-related onshore and offshore facilities” for purposes of oil and included safety standards for ASTs containing oil. EPA passed regulations under the NCP in 1994 to contain oil and hazardous substance spills. While the 1994 regulations outline response procedures and cleanup measures and designate the U.S. Coast Guard as the first responder after a spill occurs, they do not prevent spills of either oil or hazardous substances. Although there are preemptive regulations under the NCP that set requirements for ASTs and other standards to prevent oil spills at onshore facilities, today there are no similar preemptive regulations for equipment holding hazardous substances or standards that prevent hazardous substance spills.

EPA likely focused on spill prevention regulations for oil in the 1970s because oil production in the United States peaked at 3.5 billion barrels per

year in 1970. Between February 1970 and January 1971, four major oil spills occurred in the United States, and one in Canada. The total amount of oil spilled was 12.7 million gallons, and the total cleanup costs exceeded \$15 million. These spills were not all from onshore facilities but they fueled the public’s concern. The oil boom and resulting onshore pollution concerns overshadowed the congressional mandate to regulate onshore storage of chemicals.

Hazardous substance spills were far fewer in number than oil spills and drew much less public attention. In addition, data on the effects of hazardous substance spills were sparse, and the cleanup costs did not come close to those of oil spills. For example, in 1971 a storage pond on the Peace River in Florida released two billion gallons of sludge from phosphate mining operations that contaminated the Charlotte Harbor area for nearly 60 miles. Sludge remained at the bottom of the river through 1974, was continuously flushed by heavy rains, and repetitively contaminated the water. Also, in 1974, an herbicide manufacturing plant in Alliance, Ohio, caught fire, allowing hydrogen chloride and other toxic gases to escape and reach residential neighborhoods. EPA had to evacuate a hospital of 500 patients when the wind changed direction. The public saw hazardous substance releases as opportunities to react, and likely overlooked preventative measures for such incidents because oil spills continued to grow in number, followed by high cleanup costs and lost oil revenues.

Political obstacles also played a role in stymieing EPA’s ability to issue spill prevention regulations. President Nixon oversaw the creation of EPA, signed the CWA, and supported EPA’s issuance of spill prevention regulations for oil and hazardous substances. EPA proposed spill prevention regulations for oil in 1972 and for hazardous substances in 1973. Thereafter, the oil regulations were promulgated in 1976 under the Ford administration. The hazardous substance regulations were subsequently issued in 1978 under the Carter administration, yet the Manufacturing

Chemists Association successfully overturned the rule in the U.S. District Court for the Western District of Louisiana. Since then, EPA has not issued spill prevention regulations for hazardous substances.

One reason explaining why EPA has been slow to issue spill prevention regulations for hazardous substances is that today more than 90 percent of ASTs at onshore facilities hold petroleum products; the remaining 10 percent of ASTs with hazardous substances are mostly clustered in industrial areas. This statistic has led to the mistaken belief that the number of people that would be affected by a discharge of hazardous substances from ASTs is relatively small. Although data show hazardous substance spills are likely to occur in industrial areas, spills travel fast and can go unnoticed; containment alone has proven to be an inadequate safety measure.

In 2014, when 10,000 gallons of 4-methylcyclohexanemethanol (MCHM) spilled into the Elk River in West Virginia, the harm associated with hazardous substance spills gained national attention. The Elk River spill occurred 1.5 miles from a drinking water intake that serves 300,000 West Virginians. Governor Earl Tomblin declared a state of emergency in nine counties, and banned those residents from using their tap water for drinking, cooking, washing, or bathing. The ban lasted for five days, and lasted up to ten days or longer for pregnant women and a small percentage of the residents. Although only 369 West Virginians sought medical treatment for symptoms such as nausea and itching, and 13 of those were hospitalized, the fear for the potential risks associated with hazardous substance spills still resonates with the population.

The absence of federal regulation has shifted the responsibility to regulate ASTs containing hazardous substances on the states. While some states had AST inspection regulations prior to the Elk River spill, West Virginia confronted its inadequate regulatory scheme head-on in 2014. Many states followed West Virginia, and

successfully passed legislation that requires inspections of existing ASTs. Inconsistent state regulations create disarray for interstate industries, however, which can increase dangers to the public.

State-by-state regulations are not efficient as industrial standards because industries could be in compliance in one state, yet out of compliance in another. Industries are tasked with organizing each state's standards and staying in compliance. The increased potential for industry to be out of compliance increases the danger to the public. In light of this, some believe a single federal standard would be more efficient and effective in providing adequate protection for the public. Further, a federal standard would avoid federal/state redundancy because it would preempt state regulations.

The foregoing summary suggests that NRDC's request, if implemented, would allow EPA to maintain regulatory efficiency. Most importantly, a federal standard would fill the current void in federal regulations: while EPA passed regulations to contain oil and hazardous substance spills, and to prevent oil spills, it has not implemented regulations to prevent hazardous substance spills.

NRDC is winding up and will take the first crack in decades to ensure EPA implements the directive, preempts threats to water supplies, and protects the public from hazardous substance spills at onshore facilities.

Jack Morgan is a University of Richmond School of Law, J.D. Candidate 2016.

SYNTHETIC BIOLOGY'S CHALLENGE TO U.S. REGULATORY SYSTEMS

Lynn L. Bergeson

On October 15, 2015, the Woodrow Wilson International Center for Scholars' (Wilson Center) Synthetic Biology Project released a report, *THE DNA OF THE U.S. REGULATORY SYSTEM: ARE WE GETTING IT RIGHT FOR SYNTHETIC BIOLOGY?*, authored by the lawyers, experts, scientists, and policy specialists of Bergeson & Campbell, P.C. (B&C) on how synthetic biology applications would be regulated by the U.S. Coordinated Framework for Regulation of Biotechnology, how this would affect the market pathway of these applications, and whether the existing framework will protect human health and the environment. According to the report, the U.S. regulatory oversight of synthetic biology across the board needs to be modernized to reflect better promising technologies routinely entering the market. From a statutory perspective, the pertinent enabling laws appear sufficiently broad to empower federal agencies to address potential risks and promote the benefits of synthetic biology. The regulatory infrastructure, however, is often ill-suited to address nimbly, comprehensively, and—in some cases—at all the regulatory implications of new products derivative of synthetic biology. As highlighted in the report's illustrative case studies, competing and sometimes conflicting jurisdictional issues confound prompt and effective government oversight. The novelty of some technologies challenges even government staff in sorting out which agency has primary jurisdiction over a particular product or new technology, or which office within an agency should be exercising regulatory oversight.

The Oxitec case study in the report highlights the threshold regulatory issues that can arise within a single agency, the U.S. Food and Drug Administration (FDA), in the synthetic biology context. Oxitec has developed a genetically engineered mosquito that is highly effective in decreasing the population of disease-carrying *A. aegypti* mosquitos through breeding after the

engineered mosquito is released into the wild. The Oxitec mosquito does not fit cleanly into any FDA regulatory category; eventually it was determined to assess it as an animal drug by one office of FDA rather than by another FDA office as a human drug, though its ultimate goal is to reduce yellow fever and allied diseases in human beings—and hence to act as a human drug. Uncertainty is expensive. Without a reliably defined regulatory assessment pathway, innovation is discouraged. For Oxitec, a threshold question even had arisen whether the U.S. Department of Agriculture (USDA) rather than FDA should be in charge, if its engineered mosquito could be described as a pest control technology.

Where the synthetic biology product is a cosmetic ingredient, uncertainties going forward are magnified because cosmetics in most cases are not subject to pre-market review by FDA, which typically relies on enforcement authorities it can deploy against improperly labeled cosmetics already on the market. Accuracy in labeling is a slippery slope when it comes to synthetic biology, as described in the case study on squalene, which is used as an emollient in lotions. The best source of natural squalene is shark oil, but with some shark species deemed endangered and plant sources often uneconomical, the biotechnology firm Amyris has developed and is marketing synthetic squalene through the engineering of proprietary yeast strains, for cosmetic use. This poses the question whether synthetically derived squalene is the same for regulatory/labeling purposes as squalene from fish oil or plant oil sources. Consumers are entitled to accuracy in labeling, but neither consumers nor product developers are well served if the regulatory agency in charge has not addressed and clarified the issue ahead of the launch of the cosmetic product in the commercial market.

The fundamental issue of which regulatory statute applies to a synthetic biology product can be unexpectedly complex, as depicted by another case study in the report on PBAN. PBAN is a naturally occurring substance that encourages female insects to produce pheromones to attract males for mating;

researchers have developed a genetically modified strain of *E. coli* that yields a synthetic PBAN used in an innovative process for moth control. Mixed with a sugar solution, the synthetic PBAN is placed in a trap as food for female moths, inducing them to produce pheromones, which in turn attracts male moths into the trap. The use of a biopesticide in a trap for purposes of mitigating a pest typically requires registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), despite a FIFRA exemption for pheromones; synthetic PBAN, while inducing pheromone production, is not itself a pheromone. Thus, PBAN is subject to FIFRA although it is a more benign approach to pest control than is a conventional pesticide. As the case study notes, if synthetic PBAN had obtained the benefit of the FIFRA exemption, it still might be subject to the Toxic Substances Control Act (TSCA) or other authorities. Depending on its use, and on whether other substances would be placed in the trap along with it, other regulatory scenarios could be triggered. The process of deciding whether and how to regulate a synthetic biology product may well require as much effort as the regulatory process itself.

Aside from challenges presented by the underlying legislation and regulatory oversight as depicted in the case studies, the problem is exacerbated at the implementing agency level. Given the significant and growing shortages in government staff and funding throughout the federal agencies, including those whose regulatory reach extends to synthetic biology, technological literacy remains a critical problem. Government personnel with institutional know-how and expertise retiring from the workforce are not in all cases being replaced, and those who are added are not always being provided with opportunities to be made aware of and understand new synthetic biology technologies entering the commercial space. Better, more systematic, and routine communication and coordination between and among federal agencies are also needed, along with more routine briefings of government staff by the private sector. Deeply embedded stove piping often confounds communication and coordination within and among

government offices, and blunts opportunities for more efficient, informed reviews of new products.

The report recommends improvements that are needed, including increased funding to federal agencies; “embedded” new technology stewards in each office of all relevant federal agencies to monitor and coordinate topics of emerging technologies and share information with other agency offices; dedicated centers of technological excellence in pertinent federal offices to stay abreast of new developments; regular routine intervention by industry and academic innovators to brief government agencies on trends, developments, and challenges; the implementation of an ongoing process to demystify synthetic biology and its products so that they are more clearly and accurately understood by federal decision makers and the public; and the creation of a long-range, government-wide strategy to assure that, going forward, the regulation of synthetic biology encourages innovation while timely identifying and addressing risks through a science-based, transparent process that encourages public confidence.

Some of these recommendations are reflected in a July 2, 2015, memorandum issued by key executive branch offices that directs the U.S. Environmental Protection Agency (EPA), FDA, and USDA to update the 1986 Coordinated Framework for Regulation of Biotechnology (coordinated framework or CF), under which these agencies have proceeded for nearly three decades. The directive to revise the coordinated framework, discussed below, is long overdue. Comments from the public on how best to modernize the coordinated framework were solicited by the White House Office of Science and Technology Policy (OSTP) on October 6, 2015. Specifically, OSTP seeks answers to these questions:

1. What additional clarification could be provided regarding what biotechnology product areas are within the statutory authority and responsibility of each agency?
2. What additional clarification could be

provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?

3. How can federal agencies improve their communication to consumers, industry, and other stakeholders regarding the authorities, practices, and bases for decision making used to ensure the safety of the products of biotechnology?
4. Are there relevant data and information, including case studies that can inform the update to the CF or the development of the long-term strategy regarding how to improve the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?
5. Are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

Comments were due by November 13, 2015.

Lynn L. Bergeson is managing partner of Bergeson & Campbell, P.C. (B&C®), a Washington, D.C. law firm focusing on conventional, nanoscale, and biobased industrial, agricultural, and specialty chemical product regulation and approval matters, and chemical product litigation. She is president of The Acta Group, L.L.C. and managing director of The Acta Group EU, Ltd with offices in Washington, D.C. and Manchester, UK.

SAFETY FOR FARM WORKERS: EPA ISSUES FINAL CHANGES TO THE AGRICULTURAL WORKER PROTECTION STANDARD

Jacqueline Morley

The U.S. Environmental Protection Agency (EPA) issued on November 2, 2015, final revisions to the 1992 Agricultural Worker Protection Standard (WPS). 80 Fed. Reg. 67,496. The new WPS regulations require agricultural employers to implement health and safety protections for farm workers and their families. The revisions to the WPS represent a concerted effort on the part of EPA and the U.S. Department of Labor (DOL) to prevent these incidents from occurring and have been written with the hope that the changes they portend will create safer and healthier working environments for farm workers across the country.

The rule outlines standards designed to prevent harmful exposure to the pesticides being applied to crops. EPA estimates that there are roughly two million farm workers in the United States employed on farms, forests, and nurseries around the country that use pesticides in any year. The WPS is designed specifically to protect workers that come in contact on a daily basis with pesticides, whether that be through direct application of the pesticides or through the handling of pesticide-treated crops.

The revisions are believed to be essential to protect public health. There are between 1800 and 3000 pesticide-related incidents reported daily. Due to endemic underreporting, however, it is believed these incidents occur with much greater frequency.

Although the overhaul of the regulations affects many WPS provisions, the biggest improvements involve safety and training. The new provisions prohibit agricultural employers from employing workers under 18 years of age to handle pesticides, with exemptions afforded to family members of farm owners. These exemptions are intended to avoid placing an undue burden on owners of small farms, many of who rely on family members for

labor. With this in mind, the new provisions also include an expansion of the term “immediate family” as it is defined within the statute to include a wider range of family members, such as aunts, uncles, and grandparents. Under the new WPS regulations, agricultural employers must ensure no workers enter into a treated area or the application exclusion zone, which is a 0-100 foot area around the application equipment during pesticide application on farms, forests, and nurseries.

The revisions also involve changes to training and information services; in the previous version of the WPS, farm workers were only required to attend training every five years. The updated WPS requires employers to train all workers and handlers annually and eliminates the five-day grace period, ensuring that workers are trained before they work in any area with pesticides. Additionally, agricultural employers must make safety information more readily available and visible to workers, and further instructions pertaining to medical assistance must be added.

The revisions also cover changes to personal protective equipment and decontamination supplies. Prior to the updates, there were no specific requirements for the amount of water made available to each worker; agricultural employers were required to provide workers with “enough” water for “routine washing” and “emergency eye-flushing.” Under the new provisions, these amounts are specified and are to be measured at the beginning of each work period. Agricultural employers are also required to give more extensive instructions on the prevention of take-home exposure, particularly the type of exposure that can occur from contaminated work clothing.

The WPS requires agricultural employers to maintain training records for two years following completion. These records should include (1) the worker’s name and signature; (2) the employer’s name; (3) the date of the training; (4) information about which EPA-approved training materials were used; and (5) the trainer’s name and qualifications. In addition, application records and safety data

sheets (SDS) must be maintained for a period of two years after the expiration of the restricted entry interval (REI). REIs are restrictions placed on workers by the WPS to attempt to limit the amount of exposure to pesticides immediately after application. These alterations are large improvements from the old provisions, which included no record-keeping requirements. REIs for specific pesticides are determined based upon the toxicity of that pesticide and tend to last from 12 to 17 hours. Areas that have been treated need to be marked by agricultural employers so that workers are not inadvertently exposed to newly applied pesticides. Certain workers may be cleared as early-entry workers; they are allowed to enter into REI areas before the warning period has ended. The WPS has always required that agricultural employers provide additional training to early-entry workers. Under the new rules, owners are required to more extensively warn and document early-entry workers of the particular hazards and application specifics pertaining to the pesticide being handled. These changes will only further ensure that workers are safe and protected from the hazardous pesticides that they handle on a daily basis.

Due to the amount of time needed to implement the updates, many of the provisions give farm owners from 14 months to two years to begin compliance with the new rules. The effective date is **January 1, 2016**. Agricultural employers will have 14 months to two years to be in full compliance.

What you need to know:

- The regulations become effective 14 months to two years following the publication of the new WPS in the *Federal Register*.
- Agricultural employers are required to provide annual training to workers and handlers.
- Agricultural employers are required to keep records of both worker training and pesticide application. These records must be kept on the establishment for two

years after the date of completion of the training or date of expiration of the REI, respectively.

- Workers must be 18 years of age or older to handle pesticides.
- Information about pesticide application must be displayed at a “central display” location for at least 30 days after an REI application. This should be a place where workers are most likely to pass by through the course of their workday.
- Before reentering an REI area, the agricultural employer must ensure that workers and handlers are provided with the location of pesticide safety information, the location of pesticide application and hazard information, and the location of decontamination supplies.
- Farm families are eligible for a number of exceptions under the new rule.

The revised standards are seen as a welcome, long-overdue improvement; other workforces have had comparable safety provisions for some time now. The provisions seemed to be met with general support and relief from farm worker advocacy groups and United Farm Workers (UFW). The new provisions are believed to address many of the problems present in the old WPS. Although concerns have been raised about certain aspects of the new rules, specifically the claimed greater costs to growers and the lack of requirements for information to be provided in other languages, the changes are an important step forward in securing farm workers the protections they need.

Jacqueline Morley is a law clerk with the U.S. Environmental Protection Agency.

WHITE HOUSE DIRECTS AGENCIES TO MODERNIZE THE COORDINATED FRAMEWORK FOR THE REGULATION OF BIOTECHNOLOGY

Lynn L. Bergeson

With little fanfare, in July of this year the White House Office of Science and Technology Policy (OSTP), the Office of Management and Budget (OMB), the U.S. Trade Representative (USTR), and the Council on Environmental Quality (CEQ) issued a memorandum directing the U.S. Environmental Protection Agency (EPA), the U.S. Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to update the Coordinated Framework for the Regulation of Biotechnology (CF). Last updated in 1992 and first rolled out in 1986, the CF outlines a comprehensive federal regulatory policy for products of biotechnology. The memorandum directs the federal agencies to develop a long-term strategy to ensure that the regulatory system for biotechnology products is prepared for future products, and commissions an expert analysis of the future landscape of biotechnology products. A July 2, 2015, OSTP blog item entitled Improving Transparency and Ensuring Continued Safety in Biotechnology notes that the complexity of the array of regulations and guidance documents developed by EPA, FDA, and USDA “can make it difficult for the public to understand how the safety of biotechnology products is evaluated, and navigating the regulatory process for these products can be unduly challenging, especially for small companies.” The memorandum states that the objectives “are to ensure public confidence in the regulatory system and to prevent unnecessary barriers to future innovation and competitiveness by improving the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products while continuing to protect health and the environment.”

The CF describes the federal regulatory policy intended to ensure the safety of biotechnology products. The 1992 update to the CF “sets forth

a risk-based, scientifically sound basis for the oversight of activities that introduce biotechnology products into the environment.” According to the memorandum, the update affirmed that federal oversight should focus on the characteristics of the product and the environment into which it is being introduced, rather than the process by which the product is created.

The memorandum states that federal agencies regulating biotechnology products “should continually strive to improve predictability, increase efficiency, and reduce uncertainty in their regulatory processes and requirements.” Improvements must:

- Maintain high standards that are based on the best available science and that deliver appropriate health and environmental protection;
- Establish transparent, coordinated, predictable, and efficient regulatory practices across agencies with overlapping jurisdiction; and
- Promote public confidence in the oversight of the products of biotechnology through clear and transparent public engagement.

The memorandum initiates a process to help advance these aims, beginning with the following one-year objectives: (1) development of an updated CF to clarify the roles and responsibilities of the agencies that regulate the products of biotechnology; (2) formulation of a long-term strategy to ensure that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, promoting public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens; and (3) commissioning an external, independent analysis of the future landscape of biotechnology products. According to the memorandum, the following elements will support the process to achieve these objectives:

- *Biotechnology Working Group Under the Emerging Technologies Interagency Policy Coordination Committee:* The Biotechnology Working Group will include representatives from the Executive Office of the President, EPA, FDA, and USDA.
- *Mission and Function of the Biotechnology Working Group:* Within one year of the date of the memorandum, the Biotechnology Working Group shall take steps detailed below and others, as appropriate, to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology. The Working Group will:

1. Update the CF to clarify the current roles and responsibilities of the agencies that regulate the products of biotechnology, after input from the public; and
 2. Develop a long-term strategy to ensure that the federal regulatory system is equipped to assess efficiently the risks, if any, associated with future products of biotechnology while supporting innovation, protecting health and the environment, maintaining public confidence in the regulatory process, increasing transparency and predictability, and reducing unnecessary costs and burdens.
- *Independent Assessment:* EPA, FDA, and USDA shall commission an external, independent analysis of the future landscape of biotechnology products that will identify (1) potential new risks and frameworks for risk assessment, and (2) areas in which the risks or lack of risks relating to the products of biotechnology are well understood. The review will help inform future policymaking. Due to the rapid pace of change in this arena, an external analysis should be completed at least every five years.

- *Budgeting for Efficiency:* EPA, FDA, and USDA shall work with OSTP and OMB, within the president's annual budget formulation process, to develop a plan for supporting the implementation of this memo in agency fiscal year (FY) **2017** budget requests and, as appropriate, in future budget submissions.
- *Annual Reporting:* For at least five years, starting one year after the release of the strategy described above, the Biotechnology Working Group will produce an annual report on specific steps that agencies are taking to implement that strategy and any other steps that the agencies are taking to improve the transparency, coordination, predictability, and efficiency of the regulation of biotechnology products. This report will be made available to the public by the Executive Office of the President.

The OSTP blog item states that the administration recognizes the importance of public engagement throughout this process. As part of this process, the administration will hold three public engagement sessions over the year in different regions of the country. The first listening session announced by FDA on October 15, 2015, Modernizing the Regulatory System for Biotechnology Products: First Public Meeting, occurred on October 30, 2015. According to the blog item, the update to the CF will undergo public notice and comment before it is issued in final. The blog item includes a link to sign up to be kept up-to-date on these activities.

On October 6, 2015, the White House 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 CF. The RFI will 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 jointly issued by OSTP, OMB, USTR, and CEQ directing EPA, FDA, and USDA to update the CF.

OSTP seeks answers to these questions:

1. What additional clarification could be provided regarding which biotechnology product areas are within the statutory authority and responsibility of each agency?
2. What additional clarification could be provided regarding the roles that each agency plays for different biotechnology product areas, particularly for those product areas that fall within the responsibility of multiple agencies, and how those roles relate to each other in the course of a regulatory assessment?
3. How can federal agencies improve their communication to consumers, industry, and other stakeholders regarding the authorities, practices, and bases for decision making used to ensure the safety of the products of biotechnology?
4. Are there relevant data and information, including case studies, which can inform the update to the CF or the development of the long-term strategy regarding how to improve the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?
5. Are there specific issues that should be addressed in the update of the CF or in the long-term strategy in order to increase the transparency, coordination, predictability, and efficiency of the regulatory system for the products of biotechnology?

On October 15, 2015, Bergeson & Campbell, P.C. (B&C[®]) and the Woodrow Wilson International Center for Scholars (Wilson Center) Synthetic Biology Project released *THE DNA OF THE U.S. REGULATORY SYSTEM: ARE WE GETTING IT RIGHT FOR SYNTHETIC BIOLOGY?*, a report authored by the legal experts, scientists, and policy specialists of B&C and released through the Wilson Center's Synthetic Biology Project. The report includes a survey of the current commercial applications of synthetic

biology, analysis of issues facing U.S. regulatory systems and agencies called into play by products of synthetic biology, case studies illustrative of how novel technologies challenge the regulatory infrastructure and can induce competing and sometimes conflicting jurisdictional oversight, and a review of recommendations for improvement, including those contained in the July 2, 2015, memorandum.

Discussion

That the CF needs a do over is clear. A number of recent reports have convincingly outlined the reasons why the CF can no longer nimbly, clearly, or comprehensively regulate products of biotechnology and call for exactly what the administration announced on July 2. Last year, the Venter Institute issued a landmark analysis of the domestic biotechnology regulatory system in which it highlighted the critical need for modernizing the CF. J. CRAIG VENTER INSTITUTE, *SYNTHETIC BIOLOGY AND THE U.S. BIOTECHNOLOGY REGULATORY SYSTEM: CHALLENGES AND OPTIONS* (May 2014), available at www.jcvi.org/cms/fileadmin/site/research/projects/synthetic-biology-and-the-us-regulatory-system/full-report.pdf. More recently, the National Research Council of the National Academies issued, on March 13, 2015, *INDUSTRIALIZATION OF BIOLOGY: A ROADMAP TO ACCELERATE THE ADVANCE MANUFACTURING OF CHEMICALS*. The report,

prepared by the Board on Chemical Sciences and Technology, Board on Life Sciences, Division on Earth and Life Studies, identified the challenges and opportunities posed by the current regulatory system relating to biotechnology and synthetic biology. See <http://www.nap.edu/catalog/19001/industrialization-of-biology-a-roadmap-to-accelerate-the-advanced-manufacturing>.

The administration's decision to modernize the CF is welcome news. Given the step-wise approach set forth in the memorandum, no changes can be expected for quite a while. If TSCA reform legislation is enacted, it will be important to ensure that the modernizing of TSCA and the modernizing of the CF are aligned. If TSCA reform legislation does not advance this year, it will be interesting to see how renewed efforts to reauthorize TSCA and the modernizing of the CF progress in tandem. In any event, biotech stakeholders should monitor and engage in this initiative as appropriate.

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