FROM THE CHAIR—THE YEAR AHEAD
Joanne Thelmo

Welcome back to another great year with the PCRRTK Committee!

2015 was a wonderful year for the PCRRTK Committee and marked most memorably with the Senate’s passage of legislation to amend TSCA on December 17, 2015.

2015—looking back
- January 16: Ya-Wei Li, Director, Endangered Species Program, and Jason Rylander, Senior Staff Attorney, Defenders of Wildlife: Mitigation & Litigation Endangered Species Act
- February 5: Financing TSCA2.0 Roundtable Event
- April 28: Removing Roadblocks to TSCA Reform Legislation
- May 15: Mark Garvey, Senior Attorney, Office of Civil Enforcement, U.S. EPA: TSCA & FIFRA Compliance
- June 26: Nichelle Harriott, Science and Regulatory Director, Beyond Pesticides: Honey Bees & Neonicotinoid Pesticides
- July 9: Meet the ABA
- October 2: Gerald Couri II, Senior Environmental Policy Advisor, House Energy and Commerce Committee, U.S. Congress: Toxic Substances Control Act
- October 14: Hot Topics in Pesticide Law
- October 28–31: SEER 23rd Fall Conference

Surely this can only mean that 2016 will be even better with endless possibilities!

2016—looking forward
- January: Year-in-Review
- March: PCRRTK Newsletter
- March 4: Stacey Mitchell, Deputy General Counsel, Office of General Counsel, U.S. EPA
- April 29: Alexandra Dunn, Executive Director and General Counsel, Environmental Council of the States
- May: PCRRTK Newsletter
- Summer: Meet the ABA SEER
- October 5–8: SEER 24th Fall Conference

Your PCRRTK Committee’s primary commitment is to provide committee members with opportunities for personal scholarship, information exchange, and networking opportunities within the field.

Your PCRRTK Committee also strives to make it interesting every year but values your input.

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PCRRTK needs and seeks your involvement to keep our committee fresh and valuable for all.

This is your committee and it can only move forward with your help and input, which you are always welcome to share with me or a committee vice chair.

As we move forward into 2016 with renewed energy, I wish to extend a warm welcome to our new members, and a big thank-you to our long-standing members. Thank you for your continued participation and support of our committee.

Most especially, I wish each of you the very best this coming year!

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

PESTICIDES AND NPDES: INCREASED ENVIRONMENTAL PROTECTION OR JUST MORE PAPERWORK?
Susan M. Kirsch

On January 26, 2016, the U.S. Environmental Protection Agency (EPA) published a draft National Pollutant Discharge Elimination System (NPDES) pesticide general permit (PGP) for public comment. The publication marks the first reissuance of the PGP since its inception in 2011. The Sixth Circuit’s decision in National Cotton Council v. EPA, F.3d 927 (6th Cir. 2009), which vacated EPA’s 2007 rule exempting pesticides from NPDES permitting, required EPA to issue the PGP. In October 2011, EPA published a five-year PGP, which expires on October 31, 2016. Additionally, all states with delegated NPDES program authority developed and issued state versions of the PGP.

Since the Cotton Council litigation began, regulators, industry, and agriculture groups have voiced strong opposition to Clean Water Act (CWA) regulation of pesticide applications. Opponents contend that pesticides are adequately regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and dual regulation under the CWA does not bolster the water quality benefits already achieved with FIFRA compliance. In February 2011 congressional testimony, the then president of the Association of State and Interstate Water Pollution Control Administrators n/k/a Association of Clean Water Administrators (ACWA), Dr. Andrew Fisk, testified that implementation of NPDES pesticide permitting goes beyond a “paper exercise” for state programs, carrying with it additional resource burdens for compliance and technical assistance, stakeholder outreach, and enforcement. Fisk testified that inclusion of pesticide permitting expands the NPDES program nationally by 365,000 permittees, a 60 percent increase. State water quality program officials also expressed that they did not anticipate any meaningful water quality improvement would result from this new class of permits. Fisk also
cited statements from a 1971 House Committee Report on FIFRA as evidence that Congress intended for FIFRA to play a role in preventing water pollution.

Since 2011, there have been attempts to enact legislation that would prevent NPDES pesticide permitting. In the House, the Reducing Regulatory Burdens Act of 2011 (H.R. 872) would have amended FIFRA and the CWA to clarify congressional intent and eliminate NPDES permitting for pesticides approved for use under FIFRA. The House passed H.R. 872, but it ultimately stalled in the Senate. In 2015, Senator Crapo (R-ID) sponsored the Sensible Environmental Protection Act of 2015 (S. 1500), which attempts a similar legislative fix. Senator Gibbs (R-OH) revived the 2011 House bill and introduced the Reducing Regulatory Burdens Act of 2015 (H.R. 897). S. 1500 was sent to the Senate Environment and Public Works Committee in October 2015 where it awaits further action, and H.R. 897 similarly awaits committee action.

Irrespective of the debate over which statute should regulate pesticide applications, there are questions as to what impact pesticide applications covered by the PGP really have on water quality. In the fact sheet for the draft PGP, EPA discusses a 2006 U.S. Geological Survey (USGS) report on ten-year assessment of pesticides in U.S. streams and groundwater tested from 1992 to 2001. The USGS report stated that “for the pesticides sampled, surface and ground water are generally not being adversely affected by pesticide applications for irrigation, drinking water, and home/recreational uses.” USGS noted that the pesticide concentrations in agricultural streams most often originate from runoff from land applications and that its assessment focused mostly on nonpoint sources, which are exempted from CWA permitting. Unlike other traditional end-of-pipe point sources, it can be difficult to attribute the presence of pesticide residue in a particular stream to a particular point source pesticide application, such as aerial spraying, or whether it originated from nonpoint source runoff. Also, pesticide applications covered by PGP include those for aquatic weed control, so it may be difficult to determine if a pesticide detected is still serving its intended purpose (i.e., eradicating weeds) and is thus not considered a pollutant.

The PGP has both resource and legal ramifications for pesticide applicators. Under both the current and draft PGP, decision makers, which are the entities with control over the decision to perform pesticide applications that could discharge to water, must submit a notice of intent (NOI) seeking permit coverage, file annual reports, maintain records, and larger entities must develop pesticide discharge management plans. This also creates the need for coordination with two separate agencies (i.e., water quality control and pesticide control authorities). Operators, which are decision makers and any entity that performs the pesticide application, must meet technology-based effluent limitations (e.g., calibration, maintenance, and proper use of equipment), report adverse incidents, perform corrective actions, perform routine visual inspections of treatment area, and apply pesticides in accordance with FIFRA labeling requirements. Other than the corrective actions, most of the PGP requirements are rooted in FIFRA compliance and pesticide applicators that are fully complying with FIFRA would meet most of the CWA requirements. In many ways, the PGP merely represents a rebranding of the FIFRA requirements as CWA requirements.

In addition to increased paperwork, the PGP increases legal vulnerabilities for pesticide applicators. In the draft PGP fact sheet, EPA states that “[pesticide] applications in violation of certain FIFRA requirements could also be a violation of the permit and thus a violation of the CWA (e.g., exceeding label application rates).” Thus, the dual regulation under FIFRA and the CWA could result in an added layer of fines and enforcement for the same action or inaction that in the past would have just resulted in a FIFRA violation. The CWA includes citizen suit provisions that are not found in FIFRA. With EPA’s new NPDES electronic reporting requirements, PGP NOI submissions and
annual reports will be made immediately available to the public online. This online record access could invite further public scrutiny of pesticide applicator activities and provide data for potential CWA citizen suit challenges.

After five years of dual regulation of pesticide applications under the CWA and FIFRA, it remains unclear whether any water quality benefits have resulted beyond what FIFRA compliance achieved on its own. This expansion of the NPDES universe continues to add to the workload for state and federal permitting and compliance authorities, and has created additional regulatory compliance requirements and legal vulnerabilities for pesticide applicators. Studies have shown that pesticides in rivers and streams are not at levels that adversely impact water used for drinking water, irrigation, or recreation. It is difficult, if not impossible, to trace the presence of a particular pesticide to its specific source and whether it is the result of misuse or illegal discharge, or whether it is from nonpoint sources that are exempted from CWA regulation. Therefore, while CWA regulation of pesticides has brought on additional paperwork and resource demands for both regulators and permittees, there may not be any substantial improvement to water quality. There remains the possibility that Congress will enact legislation that ends CWA permitting for pesticides, but absent an act of Congress, we can expect EPA to continue to reissue the permit every five years. The comment period for the draft 2016 PGP will close on March 11, 2016.

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Call for NOMINATIONS

The Section is currently seeking nominations for awards recognizing and honoring individuals and organizations that have made significant accomplishments or demonstrated recognized leadership in the environmental, energy, and natural resources legal areas.

- Distinguished Achievement in Environmental Law and Policy
- Environment, Energy, and Resources Dedication to Diversity and Justice Award
- Environment, Energy, and Resources Government Attorney of the Year Award
- State or Local Bar Environment, Energy, and Resources Program of the Year Award
- Law Student Environment, Energy, and Resources Program of the Year Award
- ABA Award for Excellence in Environmental, Energy, and Resources Stewardship

Awards to be presented at the 2016 ABA Annual Meeting in San Francisco. Nomination deadline is May 9, 2016.

- ABA Award for Excellence in Environmental, Energy, and Resources Stewardship

Award to be presented at the 24th Fall Conference in Denver. Nomination deadline is July 8, 2016.

www.ambar.org/EnvironAwards
EPA Launches Its New Self-Audit Policy EDisclosure Portal
Lawrence E. Culleen and Thomas A. Glazer

On December 9, 2015, the U.S. Environmental Protection Agency (EPA) announced the launch of its new web-based eDisclosure portal. The portal gives companies a new way to self-report environmental violations with the goal of streamlining the process for both EPA and members of the regulated community. It appears EPA intends self-reported violations will come to EPA’s attention through this mechanism even if the disclosing party is not engaged in a voluntary self-audit.

The eDisclosure portal implements EPA’s policy statement on “Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations,” which is more commonly known as the “Audit Policy.” Since 1995, the Audit Policy “has provided an incentive for regulated entities to detect, promptly disclose, expeditiously correct and prevent violations of federal environmental requirements.” 80 Fed. Reg. 76,476, 76,476 (Dec. 9, 2015). According to EPA, the Audit Policy has led to the expansion of “environmental auditing and environmental management practices as key components of sound business practices.” Id. EPA has received disclosures of violations from “[t]housands of entities” and continues to receive “hundreds of new disclosures every year.” Id.

According to EPA, “[t]he large number of violations self-disclosed to EPA has taxed the Agency’s ability to promptly resolve all pending disclosures.” 80 Fed. Reg. at 76,477. In recent years, EPA had signaled waning interest in the Audit Policy. Most significantly, 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.

During June 2015, EPA resolved doubts about the agency’s commitment to the Self-Audit Policy when it foreshadowed the coming eDisclosure portal and hosted two webinars to explain the new eDisclosure system and receive stakeholder input on it. The webinars announced EPA’s intention to streamline the implementation of the Audit Policy “for more routine disclosures to make the process faster, more efficient, and to save time and resources for regulated entities and EPA.” 80 Fed. Reg. at 76,476. The launch of the eDisclosure system is the clearest sign in years that EPA remains committed to the Audit Policy, provided it can administer the program efficiently. The recent announcement underscored that the agency “continues to believe strongly in the benefits of its self-disclosure policies.” Id. The portal also is consistent with EPA’s “Next Generation Compliance” initiative, whereby EPA is shifting toward greater reliance on technology across the board, including data analytics, electronic reporting, and advanced monitoring.

Not all violations self-reported will qualify for reporting through the electronic portal. For the purposes of administering the eDisclosure portal, EPA has divided violations into two categories depending on their complexity. While EPA initially referred to these categories as “tiers,” it has since changed its terminology to avoid “possible confusion with Tier II Reports under the Emergency Planning and Community Right-to-Know Act [‘EPCRA’].” 80 Fed. Reg. at 76,477. Category 1 violations are routine EPCRA violations that comply with all of the Audit Policy conditions, which, according to EPA, comprise “about half” of the disclosures disclosed. When a company self-discloses a Category 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. EPA’s Federal
Register notice concerning the eDisclosure process explains that the portal deliberately streamlines the process for resolving these types of violations because the agency has significant experience with resolving such violations, compliance is easy to confirm, and the regulated community requested it. EPA promises to later evaluate whether other types of violations might be appropriate for Category 1 treatment.

In contrast, Category 2 violations are considered by EPA to be more serious and include all non-EPCRA violations and any EPCRA violations that were not discovered through a systematic self-audit program. When a Category 2 violation is submitted through the portal, EPA will make a case-by-case determination whether enforcement action is warranted and, if so, whether the reporting entity qualifies for a penalty reduction under the Audit Policy. Companies also will 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.

EPA will continue to accept and process outside the automated eDisclosure system any new owner self-disclosures and any potential criminal violations disclosed to the Voluntary Disclosure Board. Moreover, eDisclosure is not designed to receive or process any information claimed as confidential business information (CBI), so entities that use the portal as an initial interface with the agency must take care to submit only sanitized (non-CBI) information through the online system. Any follow-up CBI required to be submitted must be done manually according to the agency’s procedures.

There are certain administrative encumbrances that might make it impossible for law firms that historically have made disclosures on behalf of their clients to use the electronic portal. For example, to disclose a potential violation through the eDisclosure system, the reporting party must first register to file with the Centralized Web-Based Portal, which requires the reporting party to have registered with EPA’s Central Data Exchange (CDX) system.

Now that the eDisclosure system is live, it may take some time before it is clear that the portal is a reliable and helpful tool for the regulated community. If EPA succeeds in its goal “to make the process faster, more efficient, and to save time and resources for regulated entities and EPA, while still retaining the incentives to self-police environmental problems,” that should be a win-win for both government and the regulated community. If not, the regulated community may find itself once again speculating about the Audit Policy’s fate.

Lawrence E. Culleen is a Partner at the Washington, D.C. offices of Arnold & Porter LLP (A&P) and is active in chemical-regulatory matters. Tom Glazer is a former Associate of A&P.
Significant issues concerning the scope of the U.S. Environmental Protection Agency’s (EPA) authority to cancel summarily conditional registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are raised by recent events concerning flubendiamide products sold in the United States. In a January 29, 2016, letter to flubendiamide registrants, EPA stated that it had made a determination of unreasonable adverse effects on the environment posed by the products and that under the terms of EPA’s preliminary acceptance letter (PAL) for the registration, the registrants were required, without any further process, to submit a request for voluntary cancellation of all flubendiamide products within one week. Bayer responded to EPA’s letter on February 5 on behalf of Bayer and on behalf of Nichino American, Inc., stating strong disagreement both with EPA’s risk assessment conclusions and with EPA’s authority to require voluntary cancellation based on the PAL terms.

Conditional registrations for pesticides containing flubendiamide were first granted by EPA in 2008 under FIFRA section 3(c)(7). As one condition of registration, EPA required Bayer to conduct environmental fate studies that have since been submitted and reviewed. EPA also adopted an initial expiration date for all registrations of flubendiamide products of July 31, 2013, that EPA later agreed to extend several times to allow time for further review and discussion of the submitted data. In its January 29, 2016, letter, EPA describes the condition that it asserts Bayer accepted and must now meet. EPA states: “As a condition of registration as established in the preliminary acceptance letter (PAL) for flubendiamide, dated July 31, 2008, if the Agency were to make a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects to the environment, within (1) week of notification of this finding, BC/NAI will submit a request for the voluntary cancellation of the flubendiamide technical and all end-use products.” EPA further contends that the only hearing available to the registrants is pursuant to FIFRA section 6(e), which is intended to address whether a condition of registration has been met and existing stocks issues (e.g., the requirements that will be applicable to product already in the channels of trade at the time of cancellation).

Bayer’s February 5, 2016, letter characterizes the condition in question as “unlawful,” and states that EPA’s current “demand” for voluntary cancellation is invalid because “[i]n making this demand, EPA relies on an unlawful condition of registration that EPA devised in an effort to bypass required statutory cancellation proceedings, deny Bayer and Nichino due process rights in their registrations granted by Congress, and shield EPA’s future scientific and regulatory determinations from required interagency and scientific peer review.” Bayer’s letter further disputes EPA’s assertion that a FIFRA section 6(e) hearing is appropriate, stating: “Second, if EPA has now determined that further registration of flubendiamide will cause unreasonable adverse effects and wishes to cancel the registrations, EPA must initiate the normal cancellation process under FIFRA Section 6(b).”

In summary, because Bayer has not submitted the “voluntary” cancellation requests EPA demands, EPA has stated that it will initiate the FIFRA cancellation process for conditional registrations established under FIFRA section 6(e). Although this process affords Bayer an opportunity for an administrative hearing, the issues in a conditional registration hearing under FIFRA section 6(e) are limited to “whether the registrant has initiated and pursued appropriate action to comply with the condition,” and the EPA determination concerning disposition of existing stocks. Bayer argues that the condition as it was originally imposed by EPA was improper and denies statutory due process rights,
and that EPA must afford Bayer a full adjudicatory hearing under FIFRA section 6(b) rather than the limited hearing provided under FIFRA section 6(e).

This dispute presents a variety of significant legal questions concerning conditional registrations. It has also sparked the interest of groups who have asserted that EPA should not grant conditional registrations. The stakes are large regarding EPA’s ability to utilize the conditional registration process to bypass the FIFRA procedures that typically afford a full hearing on the merits before cancellation, and the pesticide industry will be watching this matter with great interest.

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APHIS SEeks COMMENT ON POTENTIALLY SIGNIFICANT CHANGES TO REGULATIONS REGARDING GE ORGANISMS

Lynn L. Bergeson

In February, the U.S. Department of Agriculture’s (USDA) Animal and Plant Health Inspection Service (APHIS) announced its intent to “prepare a programmatic environmental impact statement (EIS)” regarding the importation, interstate movement, and environmental release of certain genetically engineered (GE) organisms. The notice identifies issues to be evaluated in the EIS and requests comment on four alternatives.

Background

Under the Plant Protection Act, APHIS regulates the introduction into the environment of GE organisms that may present a plant pest risk. APHIS’ regulation of certain GE organisms to protect plant health is aligned with the Coordinated Framework for the Regulation of Biotechnology (CF). While APHIS, the U.S. Environmental Protection Agency (EPA), and the U.S. Food and Drug Administration are working to modernize CF issues and activities, the notice states “that effort” is distinct from APHIS’ effort to revise its biotechnology regulations. The notice addresses only changes to APHIS’ regulations.

During the past 28 years of APHIS’ regulation of GE organisms, advances in biotechnology and stakeholder issues have emerged, and APHIS is considering amending the GE organisms regulations to address these advances. APHIS states that the changes would ensure that it “can continue to effectively regulate the products of biotechnology” that may pose plant pest or noxious weed risks.

Aspects of the human environment that may be affected by regulatory revisions that APHIS has preliminarily identified for evaluation in the EIS will include impacts on U.S. agriculture and forestry production (e.g., conventional,
biotechnology-based, and organic); current and future uses of products of biotechnology in agriculture and forestry; agronomic practices used in biotechnology crop production that may have environmental consequences or impacts; and other implications.

APHIS has identified new definitions to be used in its proposed biotechnology regulations for consideration in the EIS. These include biotechnology (laboratory-based techniques to create or modify a genome that result in a viable organism with intended altered phenotypes), product of biotechnology (an organism developed using biotechnology), and regulated organism (an organism developed using biotechnology that poses plant pest or noxious weed risks as documented in an APHIS risk analysis that APHIS has determined to regulate).

APHIS will use these proposed definitions in its four proposed alternatives in the EIS. The first alternative is to take no action. APHIS would make no changes to the regulations for GE organisms that pose a potential plant pest risk.

Under the second option, APHIS would revise its regulations to implement a two-step process that would ensure a thorough review of a product of biotechnology’s potential to pose plant health risks. Such a two-step process would enable it to consider and place risk-appropriate regulatory controls on the importation, movement, or “outdoor” use of those products that are determined to pose actual plant pest or noxious weed risks.

The third alternative is to provide for the regulation of “products of biotechnology” as either plant pests or noxious weeds using the existing plant pest “analysis trigger” or a noxious weed “analysis trigger” that might classify plants produced through biotechnology as potential plant pests or noxious weeds. Introductions of products of biotechnology that posed a plant pest or noxious weed risk would require a permit and conditions would be applied for import, interstate movement, or “outdoor” use.

Regulatory actions would enable it to become an “all-encompassing, wide-scale regulatory permitting authority,” but still comply with the CF and support the continued development of products of biotechnology.

The final alternative is to withdraw the current regulations and implement a voluntary consultative process for certain products of biotechnology whereby APHIS would document plant pest or noxious weed risks, if any, of certain products of biotechnology as defined above.

Discussion

As the public’s attention has been focused in recent days on the Zika virus and the role genetically modified mosquitoes may play in fighting the explosive spread of the virus, the notice is likely to generate significant comment. Whether other federal agencies might invite similar public consideration of regulatory options on the merits, the same level of review is unclear. Under the guise of reviewing the effectiveness of the current CF, some options for change to the EPA roles as they relate to USDA efforts might be part of what some stakeholders will want to comment. As some of the USDA decisions to deregulate traits then go to EPA for review under the Federal Insecticide, Fungicide, and Rodenticide Act, some observers may leverage the USDA review process as a means to prompt changes to the EPA process.

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