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

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FROM THE CHAIR: SCIENCE UNDER SCRUTINY AND IN TRANSITION

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The substantive scope of the Pesticides, Chemical Regulation, and Right-to-Know Committee (PCRRTK) is broad, covering legislative, regulatory, and judicial developments relating to the regulation and use of chemicals and pesticides in myriad industrial, commercial, and consumer products. If there is any one common element to these practice areas, it is the importance of sound science policy as a foundation for risk assessment, risk characterization, and risk management. If regulatory policy is about managing the competing health, environmental, and societal risks of modern life, science policy is about the process of identifying and measuring those risks in a world of incomplete information. This is not an easy task, and reasonable people can disagree with any given policy approach.

With that in mind, consider two science policy stories from 2011 that will continue to unfold in the new year.

Scrutiny of federal hazard assessment methodologies: The U.S. Environmental Protection Agency's (EPA) Integrated Risk Information System (IRIS) program, managed by EPA's Office of Research and Development, has been a lightning rod for criticism for years, drawing both substantive and procedural critiques from stakeholders on all sides. Concern about the current IRIS process came to a head, however, in 2011, after the National Academy of Sciences (NAS) released a report criticizing aspects of EPA's draft formaldehyde hazard assessment, concluding, inter alia, that the draft report was "not prepared in a consistent fashion," "lacks clear links to an underlying conceptual framework," and contained "[in]sufficient documentation on methods and criteria for identifying evidence from epidemiologic and experimental studies, for critically evaluating individual studies, for assessing the weight of evidence, etc."

The NAS report reinforced concerns among industry stakeholders that EPA's hazard assessment process, revamped and streamlined in 2009, might be cutting corners, if not rendering biased conclusions. These concerns increased in June 2011, when the Department of Human and Health Services' National Toxicology Program (NTP) issued its 12th Report on Carcinogens, a report that raised the cancer classifications for both formaldehyde and another common chemical, styrene. Citing faults in the NTP's styrene analysis, and pointing to the earlier NAS critique of EPA's IRIS formaldehyde assessment, industry groups and congressional Republicans declared the administration's risk assessment process fundamentally flawed and called for delays in future action pending corrections. EPA and environmental advocates countered that while NAS had identified areas for improvement in the draft formaldehyde study, it had upheld most of the basic conclusions of the study, and had not rejected the entire report. EPA's announcement in September 2011 that it would make editorial changes to future IRIS reports, but would retain the same process, did little to reduce industry concerns.

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EPA HOLDS FIFRA SAP MEETING TO CONSIDER DRAFT NOTICE OF INTENT TO CANCEL RODENTICIDE REGISTRATIONS

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From November 1 to December 29, 2011, the U.S. Environmental Protection Agency (EPA) convened a meeting of its Federal, Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP). The FIFRA SAP is a standing panel of experts that advises EPA on scientific issues concerning FIFRA matters. The late 2011 SAP meeting was convened to review EPA's Draft Notice of Intent to Cancel and Notice of Denial of Registrations for Certain Rodenticide Bait Products (Draft NOIC). FIFRA section 25(d) requires that EPA must submit such documents to the SAP "for comment as to the impact on health and the environment of the action proposed." FIFRA does not, however, bind EPA to follow the advice of the SAP even with respect to purely scientific issues.

The Draft NOIC in this matter would cancel pesticide registrations for 20 rodenticide products. EPA is seeking to cancel these registrations because the products do not conform to its 2008 Risk Mitigation Decision (RMD) for Ten Rodenticides, which was the culmination of a lengthy reregistration analysis begun by EPA in the 1990s. During 2011, a federal district court held that EPA could not exercise its enforcement authority and treat products as "misbranded" because they failed to conform to the RMD requirements in lieu of following the formal cancellation procedures embodied in FIFRA if EPA wishes to remove such rodenticide products from the market. *Reckitt Benckiser v. Jackson*, 762 F. Supp. 2d 34 (D.D.C. 2011). According to the Draft NOIC, the products in question are not compliant with the RMD because they are sold for residential use and either (1) are in the form of loose baits (such as pellets or grains) or are sold as bait blocks without tamper-resistant bait stations; or (2) contain the "second-generation" anticoagulant active ingredients brodifacoum or difethialone. In the Draft NOIC, EPA contends that the products in question present risks to children, pets, and wildlife. In addition to seeking to cancel these 20 registrations, the Draft NOIC also would deny registration applications for four rodenticide products for similar reasons.

It is EPA's practice to issue "charge questions" to the FIFRA SAP. These questions are intended to focus the SAP's deliberations on issues identified as important by EPA. Importantly, the statute does not require EPA to provide such questions, and the SAP's statutory obligation is not specifically limited to addressing only questions posed by EPA.

The rodenticide SAP meeting began with a series of presentations by EPA on the scientific analyses it performed to support the Draft NOIC. Reckitt Benckiser, the registrant of twelve of the products potentially subject to cancellation and two of the products subject to denial, followed with its own presentations regarding the validity of EPA's analyses. The Louisville Apartment Association and Bell Laboratories also made short presentations.

On December 29, 2011, the SAP issued "meeting minutes," which contain the panel's responses to EPA's charge questions as well as other analyses relevant to the Draft NOIC. The minutes identified several shortcomings in EPA's analysis, particularly with respect to its assessment of consumer use rodenticide products' risks to humans and pets and regarding EPA's assessment concerning wildlife risks.

Following receipt of the SAP's report, EPA also is expected to receive comments on the Draft NOIC from the U.S. Department of Agriculture and the Department of Health and Human Services. If EPA chooses to proceed with a final NOIC, the subject registrants will receive notice and have the opportunity to request a cancellation hearing before an EPA administrative law judge.

FIFRA cancellations proceedings have been very infrequent. This proceeding is being monitored carefully by practitioners and other interested parties as it may become a model for proceedings in the future years.

Documents relating to the SAP meeting, including the minutes, can be found at http://www.epa.gov/scipoly/sap/meetings/2011/112911meeting.html.

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