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FROM THE CHAIR: SCIENCE UNDER SCRUTINY AND IN TRANSITION

Charles L. Franklin

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.

In late December, after a testy and partisan end-of-the-year legislative battle over budget and appropriations, Senate Democrats agreed in conference to include certain House riders addressing IRIS in an Omnibus Appropriations bill. The bill requires EPA to implement certain recommendations from the NAS formaldehyde critique, requires EPA to provide a progress report to Congress on implementation of the NAS recommendations by March 2012, and requires EPA to submit up to three additional risk assessments for NAS review. The bill also requires NTP to submit its formaldehyde and styrene reports to NAS for peer review. Notably, Democrats fought off a number of other more extensive requirements.

Since the compromise, federal policymakers have debated whether the IRIS and NTP rider debate was a

win for administration foes or supporters. Regardless of one's perspective on that question, the bill ensures that these programs will continue to receive political, as well as scientific, scrutiny.

Transition to 21st-Century Toxicological Methodologies

While stakeholders continue to debate the merits of current hazard assessment tools and criteria, a separate effort is under way to revolutionize the way regulators assess chemical hazards. Some members may recall that in September 2010, the PCRRTK Committee hosted a program to discuss the federal government's "Tox21 Program," a partnership between EPA, the Food and Drug Administration (FDA), and the National Institute of Environmental Health Sciences to improve chemical screening efforts and reduce the reliance on extensive, time-consuming, and controversial animal testing. During the program, a blue ribbon panel of speakers spoke of the real and growing need for better, more efficient methods for developing health and safety data on chemicals approved for commerce in the United States—a challenge that is critical given the public push to modernize the Toxic Substances Control Act (TSCA) and improve data on the 80,000+ substances on the current TSCA inventory.

This program continues to make progress. In September 2011, EPA released a work plan for its Endocrine Disruptor Screening Program for the 21st Century, a program intended to replace all animal tests currently used to screen substances for endocrine disrupting effects with an alternative battery of laboratory (in vitro) and computer-based (*in silico*) testing over the next five years. In December 2011, EPA, the National Institutes of Health, and FDA initiated a joint effort under the Tox21 program to use robotic testing equipment and in vitro testing techniques to screen 10,000 compounds for potential toxicity.

If used correctly, these programs have the potential to increase the pace and efficiency of chemical prioritization efforts and, in the long term, chemical safety reviews. The lower cost and quicker results provided by these new methods could also reduce the inherent market barriers that traditional data call-in requirements have posed to industry, especially smaller business. Indeed, these new techniques could even pave the way for future agreement on a path forward on TSCA reform.

But here is where the science policy dilemma arises. . .

Putting Hazard Data in Context

These new Tox21 tests address hazard, not risk, and even then only at an initial screening level. Similarly, the much disputed IRIS and NTP reports speak only to the potential "hazard" or toxicity of the substances, not the likelihood of exposure or the resulting risk from any given use. Increasingly, however, some policymakers and stakeholders treat "hazard" or toxicity indicators as synonymous with "risk," such that the mere listing of a substance on one of a myriad of "chemicals of concern" lists constitutes a commercial death sentence for a substance or product. The state of California's Proposition 65, for example, imposes labeling requirements on any consumer product that contains even trace quantities of a substance it deems to be a carcinogen or reproductive toxicant, with no consideration of the relative risk of that substance over an unlisted alternative. California's recently released draft of its Green Chemistry Initiative consumer product regulation identifies over 3000 "chemicals of concern," cobbled together as a "list of lists" maintained by international, federal, and state officials.

But in a policy environment where the theoretical hazard of a substance is enough to create a de facto ban in the marketplace, how do policymakers ensure that new 21st-century screening tools will not be used to blacklist promising substances and materials based on some initial robotic tests? If reasonable people can disagree about the implications of extensively peer-reviewed epidemiological studies and animal data, is there any doubt that here will be disagreement on screening level assays?

The year 2012 will be one of continued scrutiny for EPA's 20th-century hazard assessment techniques and those proposed for the 21st century. In both cases, however, policymakers need to remember that a

substance's toxicological qualities only speak to one part of a risk analysis. If there is one maxim 21st-century toxicologists should retain from the 16th century, it is the classic maxim, coined by Paracelsus, and often quoted on EPA's own Web site: "the dose makes the poison."

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