NAS report: strengthen agbio regs and relations

On April 5, the US National Research Council (NRC), the operating arm of the National Academy of Sciences (NAS; Washington, DC), released a report by its Committee on Genetically Modified Pest-Protected Plants. Although protesters demanded peremptory rejection of the report's conclusions, they might have revised their demands if they had read it first—perhaps the clearest message is the need for stronger, better coordinated and defined federal regulation, and improved communication with the public.

Unlike many NRC studies, this one had no outside sponsors, in part reflecting NRC's efforts to avoid any appearance of nonobjectivity. Before NRC released its report, however, protesters parading outside NAS headquarters claimed that the report was "corrupt and industry-tainted" because of conflicts of interest affecting several committee members. For instance, Fred Gould, an entomologist at North Carolina State University, was criticized for receiving research support from industry parties, including Monsanto and Dow Agrosciences, and activists recalled Michael Phillips, who was employed by NRC and was running the committee until he left to become an industry advocate at BIO.

Gould countered accusations of bias by pointing out that he also receives funding from the US Department of Agriculture (USDA; Washington, DC) and the Union of Concerned Scientists. Meanwhile, Henry Miller, a former US Food and Drug Administration (FDA; Rockville, MD) official, argues that the panel that produced the report was actually dominated by proregulatory forces, including Stanley Abramson, Fred Betz, and Morris Levin, who are all former Environmental Protection Agency (EPA; Washington, DC) staffers who helped craft and defend the policy.

Indeed, the report recommends strengthening the current federal regulatory regime overseeing agricultural biotechnology. Specifically, it calls on the EPA, USDA, and the FDA to better coordinate their overlapping efforts and to provide better guidance to their respective clients on "regulatory issues that are the purview of each respective agency."

NRC panel chair Perry Adkisson, who is chancellor emeritus of Texas A&M University (College Station, TX), says that the report does conclude that genetically modified (GM) foods are safe to eat: "The committee is not aware of any evidence suggesting that foods on the market today are unsafe to eat as a result of genetic modification," he says. But he points out that "public acceptance of these foods ultimately depends on the credibility of the testing and regulatory process, which must be as rigorous as possible and based on the soundest of science. . .," adding that "the federal agencies responsible for regulating them must take steps to better coordinate their work and to expand public access to the regulatory process."

Since the mid 1980s, federal agencies have worked under the guidance of a "Coordinated Framework," adapting existing statutes to the task of evaluating and regulating biotech products, according to Adkisson. "We believe that today the scope of each agency's oversight needs to be clarified, especially when a new product is to be reviewed by more than one agency."

When the NRC panel began its review early in 1999, an important initial focus was on proposed rules from EPA, under authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), that describe how agency officials plan to oversee field tests of certain "pesticides" produced by genetically engineered plants. Although the FIFRA proposals have served biotechnology companies since 1994 as a working guide for overseeing the commercialization of genetically engineered crops, the proposals drew sharp criticisms from a group of academic scientists, who complained to Congress about them and urged the NRC panel to reexamine these issues (*Nature Biotechnology* **17**, 415, 1999).

"That EPA regulation has never been made final," says NRC panel member Rebecca Goldburg, a senior scientist with Environmental Defense (New York). "A principal recommendation [of the NRC report] is that EPA complete the process of developing and implementing this guidance."

Panel member Stanley Abramson, an attorney with Arent Fox Kintner Plotkin & Kahn (Washington, DC), says the panel recommends that agency officials take steps to correct the "erroneous perception" that it regulates plants as pesticides.

In another important gesture to criticisms of the regulatory system, the report recommends that federal agencies "aggressively seek to reduce regulatory costs for small biotechnology start-ups, small to medium size seed companies, and public sector breeders by providing flexibility with respect to data requirements, considering fee waivers wherever possible, and helping these parties navigate their regulatory system."

Health-related and ecological research is also a priority of the report. For instance, it recommends developing "improved methods for identifying potential allergens in pest-protected plants, specifically, the development of tests with human immune-system endpoints and of more reliable animal models." It also calls for federal agencies to establish a "database for natural plant compounds of potential dietary or other toxicological concern." In addition, the report notes that "the use of pest-protected crops could lead to greater biodiversity in agroecosystems where they replace the use of those insecticides." It also calls for "rigorous field evaluations" of the impact of transgenic plants on "nontarget organisms," and recommends evaluating "gene flow" from transgenic plants into weedy relatives as well as developing methods to decrease the potential for that flow.

Jeffrey L. Fox

USDA biotech advisory panel plots uncertain course

About one week before the NRC report was released, Secretary of Agriculture Dan Glickman also sought new ways to quell some of the unrest that currently surrounds agricultural biotechnology. He personally welcomed the 38 members of a newly formed USDA advisory committee—the Advisory Committee on Agricultural Biotechnology (ACAB)—to the committee's inaugural meeting. Almost immediately, however, it appeared that ACAB is being torn in several directions at once—an inevitable outcome of the diverse opinions held among its members about several key issues, such as the safe use of GM organisms to make food and fiber, and the labeling of products that derive from such organisms. Members range from Linda Fisher of Monsanto and C.S. Prakash of Tuskegee University, who favor agricultural biotechnology, to Rebecca Goldburg of Environmental Defense and Michael Hansen of the Consumers Union. These contradictions did not seem to faze Secretary Glickman. "I am a strong believer in the potential for agricultural biotechnology," he says. "Your thoughts and guidance on our role as a public research body and how we can be more inclusive and responsive to public needs will be of great value," he added, urging committee members to engage in "civil and thoughtful discussion" about a wide range of mainly nontechnical issues, rather than "shrill debate." Glickman also noted that USDA has arranged with NAS to establish a "Standing Committee on Biotechnology, Food and Fiber Production, and the Environment," whose main purpose will be to subject the department's regulatory process to "rigorous, independent, and credible scientific review." This new NAS committee, which is being co-chaired by biologist Barbara Schaal of Washington University (St. Louis, MO) and former National Institutes of Health (Bethesda, MD) Director Harold Varmus of Memorial Sloan-Kettering Cancer Center (New York), plans to hold its first meeting early in May. *JLF*