Biotech Policy Draws Flood of Comments

Hardly anybody seems to be comfortable with the way the Environmental Protection Agency (EPA) plans to regulate genetically engineered products, but there is little agreement on how it should be done differently. This is apparent from dozens of letters submitted by university researchers, professional societies, industry, and environmental groups in response to a draft proposal to regulate biotechnology that was circulated by the federal government in January.

The proposal articulated the plans of several agencies that will be involved in regulating various aspects of biotechnology—namely the Environmental Protection Agency, the Food and Drug Administration, and the U.S. Department of Agriculture—and was coordinated by the White House Office of Science and Technology Policy. It was EPA's approach that elicited the most comment.

A persistent complaint is that EPA intends to subject genetic engineering methods and products to more elaborate review than similar products produced by conventional techniques. EPA, in fact, is already asking Monsanto and University of California researchers for more information before they can conduct field tests of genetically engineered microbial pesticides.

Many objected to EPA's premise that products produced by genetic manipulation may pose special risks. Commenters pointed out that the Department of Agriculture and the Food and Drug Administration have said that they plan to evaluate biotechnology products no differently from any others. The American Society for Microbiology remarked that EPA's plans to single out biotechnology products "is unfair, unnecessary and not in the public interest." EPA should evaluate the product on its own merits, regardless of its method of manufacture, it said.

The Natural Resources Defense Council took a different view, however. "The technology is new, and the risks therefore, though unknown and not easily characterized or quantifiable, may indeed be fundamentally different from the risks posed by chemical substances and other industrial products," it argued.

(The National Academy of Sciences proposed last year to address some of these issues in a $600,000 study. No government agency has signed up to fund the project, however. The study would evaluate the scientific basis for predicting possible adverse effects of genetically engineered organisms released into the environment. The American Society for Microbiology will hold a 4-day meeting on this topic beginning 10 June in Philadelphia.)

The scope of EPA's authority was also challenged. Under federal law, EPA can require a variety of information about a new chemical before it is manufactured. But what constitutes a "new" chemical and what is naturally occurring in the context of biotechnology have not yet been precisely defined by the agency. Whatever definition the agency chooses will influence the speed with which products are approved for manufacture. In its draft proposal, EPA suggested that a chemical is new if it is manufactured by recombinant DNA methods and also by other genetic techniques that do not rely on recombinant DNA, such as cell fusion, plasmid transfer, and transfection.

Several biotechnology companies and many researchers said that EPA should not define "new" so broadly because nonrecombinant DNA techniques mimic what already occurs in nature. The National Institutes of Health (NIH) advisory group on recombinant DNA—commonly known by its acronym RAC—also pointed out that cell fusion is already subject to federal standards governing basic laboratory research.

The biotechnology company Genex, of Rockville, Maryland, was virtually alone in supporting the idea of putting all these techniques under the heading of new chemicals. "Speculations about what could exist in nature seem likely to be wasteful of time and resources," company president J. Leslie Glick wrote. " . . . [T]echniques used to produce a microorganism are not necessarily related to the degree of risk that the microorganism may pose to either health or the environment." Rather, the risk is related to the microbe's genetic characteristics, its ability to survive and to transfer genetic information to other species, and the concentration in which it will be used. To distinguish between the different genetic techniques "would seem to suggest—and will probably so imply to the lay public that recombinant DNA techniques are more likely . . . to produce dangerous microorganisms" than other methods that are less precise in producing genetic changes.

In the January document, the White House science office floated the idea of creating a biotechnology science board, and this idea drew many questions. It proposed setting up committees similar to NIH's RAC at EPA, Agriculture, the Food and Drug Administration, and the National Science Foundation. The committees, which would be composed of scientists, would report to the science board. The science office recommended that the board be placed directly under the assistant secretary of health at the Department of Health and Human Services, but intentionally left the function of this new review mechanism vague and solicited comment.

Industrial Biotechnology Association, a trade group representing major companies involved in genetic engineering, echoed the comments of many by remarking that "it had reservations about how this [review mechanism] would work in reality." The association said it was worried that the board would introduce another layer of bureaucracy in the review process.

A working group of RAC had a host of questions about the board and the new committees, their authority and role, but did not offer any clear-cut plan of its own. "Whatever approach is adopted, it must retain public confidence and trust." Representatives of the public, it said, should be included in the membership of the committees and boards, and meetings should be open. The other point, the working group stressed, is that the NIH committee should continue to have oversight over all laboratory research in recombinant DNA, both academic and industrial.

All these comments are now being mulled over by the various agencies. According to EPA staff members, there were no big surprises among the responses. Nevertheless, the issues raised and their resolution will shape the course of U.S. research and development in biotechnology. The Administration plans to circulate the final policy document this fall.—**MARJORIE SUN**