White House to Release Biotechnology Guidelines

Federal agencies detail how they will review products of genetic engineering

AFTER a year and a half of development, federal guidelines to regulate biotechnology will soon be released. Under the plan, federal regulatory agencies, including the Environmental Protection Agency (EPA) and the U.S. Department of Agriculture (USDA), lay out in detail the procedures they intend to use in reviewing genetically engineered organisms for safety before they are tested in the environment or marketed.

The guidelines were approved by the White House Domestic Policy Council on 20 May and then sent to President Reagan for the final stamp of approval, which is expected. The guidelines have not yet been made public but will be published in the *Federal Register* shortly after the White House signs off on them.

The Administration, under the auspices of the White House Office of Science and Technology Policy, developed the guidelines in order to provide a coherent regulatory framework for the biotechnology industry. The release of the guidelines, which were first circulated for comment in December 1984, comes at a time of increasing public debate on Capitol Hill and in local communities about the adequacy of federal procedures to oversee field tests of genetically altered organisms.

According to drafts of the guidelines and interviews with sources at the agencies, the rules will result in the creation of several new government advisory panels concerned with biotechnology issues at EPA and USDA. Another new panel, a high-level Administration group, was formed last November and is called the Biotechnology Science Coordinating Committee. It comprises senior officials from the regulatory agencies, the National Science Foundation, and the National Institutes of Health.

The new federal plan does not change the recombinant DNA guidelines established in 1976 by the National Institutes of Health. It does, however, shift much of the responsibility for reviewing applications involving agricultural research and products away from NIH's recombinant DNA advisory group to EPA and USDA. The shift allows the NIH advisory group to return to its original purpose of reviewing biomedical research proposals involving recombinant DNA technology.

The guiding regulatory principle among the agencies as they developed the guidelines is that they should focus on the nature of the product itself, rather than the way it is made. It is based on the premise that biotechnology, which encompasses various techniques to manipulate genes, is not inherently dangerous. Any potential risks should be evaluated according to the characteristics of the products themselves.

Adoption of this principle led EPA, which has authority over pesticides and toxic substances, to make several changes in its policy. Originally, EPA proposed to subject all genetically engineered organisms to the same review procedures. Now, it sets up two different levels of review, one less stringent than the other, and it will evaluate modified microbes according to their potential pathogenicity, for example, or whether they are indigenous to the specific area where they will be released into the environment. Virtually all genetically engineered organisms would be subject to some form of review.

The guidelines focus on the nature of a product, rather than the way it is made.

The agency would abbreviate its evaluation for organisms that are non-pathogenic and have been altered, for example, by the deletion of genes, the addition of genes from the same genus, or the addition of a "well-characterized, non-coding sequence" from a pathogenic microbe. But an organism from a species that includes strains that are pathogenic in themselves would undergo more extensive review. EPA also says that microbes will be scrutinized more closely if genetic material from a different genus has been added to an organism.

Under EPA's pesticides rules, all genetically engineered microbes to be used as microbial pesticides will be evaluated. And, under the toxic substances regulations, EPA will require at least some information regarding any outdoor release of a modified organism.

EPA has already reviewed three applications by academic and industry researchers to conduct field tests of genetically engineered microbes, and, under the revised guidelines, would not have done anything different in its evaluation.

At USDA, oversight of biotechnology is shared by two branches, the Animal and Plant Health Inspection Service and the Science and Education office. The inspection service proposes to regulate genetically altered plant pests according to the same rules as naturally occurring plant pests. The Science and Education office, which oversees agricultural research, proposes a plan to regulate genetic engineering experiments under rules that are parallel to the guidelines established by the recombinant DNA committee at the NIH, according to Terry Medley, senior attorney in USDA's Office of General Counsel.

USDA will also form three new advisory groups on biotechnology: The Office of Agricultural Biotechnology will have full time staff to handle genetic engineering issues on a day-to-day basis; a panel called the National Biological Impact Assessment Program will evaluate the environmental fate of altered organisms and will serve both USDA and EPA; and a panel will be set up to advise the inspection service.

The guidelines do not address a few issues that have been under discussion among the agencies, but have not yet been resolved. There is no clear definition of what constitutes deliberate release, for example. The guidelines also do not elaborate standards for greenhouse containment, a topic which is being discussed by the agencies. John Moore, EPA assistant administrator for pesticides and toxic substances, says that deliberate release is "very difficult to define, but we deal with it generally by requiring notification of field tests." The issue of greenhouse containment will be discussed in the future, he remarks.

Robert Nicholas, a Washington attorney who represents biotechnology companies and has been active in public policy issues involving biotechnology, said that the new guidelines are an improvement over the original document. USDA offers more significant details about their proposed guidelines, and EPA clarifies its policy. "They leave many questions unanswered," he says, but the guidelines represent "a major step." ■ MARJORIE SUN