

tial hazards with genetically engineered microbes are, for the most part, the same as those for nonengineered microbes. (EPA has already regulated 13 microbial pesticides, which have not been genetically altered.) The agency is concerned, for example, about an organism's toxicity and virulence and its ability to reproduce, cause disease, and survive in the environment. Betz says, however, that genetically engineered microbes pose some additional problems and that EPA probably will require extra testing to determine safety. The additional testing would analyze, for example, the stability of the genetic material in an engineered microorganism and the traits to be expressed by the genetic alteration. As a result, EPA may require tests to evaluate these characteristics and information on the genetic engineering techniques used to produce the pesticide.

No one is questioning the agency's authority to regulate the commercial production of biological pesticides produced by genetic engineering. But EPA could land itself into controversy because—claiming authority under FIFRA—it intends to play a more active role in the oversight of the field-testing of genetically modified microbial pesticides. This is already a hotly debated area. NIH was recently sued for approving a University of California experiment that would have tested in the environment bacteria designed to prevent frost damage to plants.

The agency plans to change an existing regulation so that companies must notify the agency of their plans to field-test a genetically engineered pesticide. Currently, an application must be submitted to EPA if a pesticide is to be tested on 10 acres or more. But for genetically engineered microbes, EPA now plans to require an application no matter how small the test plot is. Betz said that the regulation is intended primarily to keep EPA informed of the testing.

EPA may already be testing the waters in this area. The Office of General Counsel recently concluded that the frost-preventing organism which University of California researchers want to test is indeed a pesticide. According to Anne Hollander, a policy analyst in the Office of Toxic Substances, the organism can be classified as a pesticide because it hinders a plant pest—its genetically nonmodified counterpart—from promoting the formation of ice crystals in plant tissue. The agency has not said whether it plans to require the California researchers to file for a permit.

Interpretation of the toxic substances act as it applies to biotechnology products is likely to be even more controver-

sial. The act gives EPA the power to regulate new chemicals, but does this mean that the agency can regulate organisms, for example, that could be used to clean up oil spills or to aid in the mining of ores? At a recent meeting of the Industrial Biotechnology Association, David Padwa, chairman of the board of Agrigenetics, asked Clay whether recombinant DNA is a chemical. "Yes," Clay responded. Padwa then asked, "Is recombinant DNA a new chemical?" Clay replied, "I think so."

Clay is not too perturbed about the fuzziness of TSCA's authority to regulate genetic engineering products and the



**EPA's Donald R. Clay**

*"Companies have already promised they'll sue me."*

possibility of future lawsuits. "It doesn't upset me. If I win, I win. If I lose, then Congress can legislate new law," he said later. Clay points out that Congress created TSCA to bridge the gaps in environmental regulation, so the act is a logical candidate to govern biotechnology.

Hollander points out that unlike pesticide law, TSCA places the burden of proof of safety on the agency, not the producers. Although companies must provide EPA with test data, the chemical's proposed uses, volume of production, worker exposure, and disposal, it is up to EPA to demonstrate that the new chemical poses an unreasonable risk.

EPA plans to rely on the expertise of the NIH advisory committee and other scientists as it sorts out its role in biotechnology. Clay says EPA is also forming a task force with other agencies to discuss the regulation of biotechnology and risk assessment related to environmental release of the microbes. Clay adds, "For a change, EPA is getting ahead of the game."—MARJORIE SUN

## Dingell Wants Action on NIH Authorization

In an unusual action, Energy and Commerce Committee chairman John Dingell (D-Mich.) has directed members of his committee to work out a legislative compromise to reauthorize the National Institutes of Health (NIH). But whether a deal can actually be struck before Congress recesses for the year is not clear.

Dingell rarely has intervened regarding NIH reauthorization, but this year the legislation is particularly contentious. Members of Dingell's committee have sponsored two vastly different NIH reauthorization bills. Dingell wants them to settle their differences before a House vote in order to smooth the way for its passage. A committee aide said that Dingell wants to avoid "a bidding war" in which legislators' pet projects could be tacked on as amendments to a controversial bill.

Chairman of the health and environment subcommittee, Henry Waxman (D-Calif.), is the sponsor of a controversial bill that would create numerous new programs at NIH. Two Republican committee members, James Broyhill of North Carolina and Edward Madigan of Illinois, have introduced a substitute bill that is a pared-down version of Waxman's bill and is the preference of general biomedical organizations such as the Association of American Medical Colleges. Both bills, however, provide the same funding levels.

So far, the legislators have not gotten very far. A subcommittee aide to Waxman declined to comment on the issue and an aide to the minority side said, "We just haven't been able to find a happy medium."

—MARJORIE SUN

## House Report Blasts DOE on Oak Ridge Pollution

A strongly worded report released by the House Science and Technology Committee on 3 November takes the Department of Energy (DOE) to task for mishandling a big mercury spill and related problems at an aging