*DELIBERATE-RELEASE REGULATIONS*

# SCOPE PROPOSAL GOES ANOTHER ROUND

WASHINGTON, D.C.—Last year U.S. federal officials issued a draft document on "scope" that outlined how key agencies would oversee deliberate-release experiments involving genetically engineered organisms (*Bio/Technology*, 8:706, Aug. '90). Recently, while reconsidering these issues, officials in the President's Office of Science and Technology Policy (OSTP) and the Biotechnology Working Group (BWG), a part of the President's Council on Competitiveness, rewrote the document.

A revision of the draft document—released inadvertently in May—still recommends that federal regulations should not unduly hamper biotechnology's economic potential. "Unless otherwise required by law, planned introductions of organisms into the environment shall not be subject to federal oversight absent substantial evidence that a significant and unreasonable risk may be posed," says the draft.

The scope document is not the only biotechnology policy statement floating around Washington. Under Vice President Dan Quayle's imprimatur, BWG has issued the "Principles for Federal Oversight of Biotechnology: Planned Introduction in the Environment of Organisms with Modified Hereditary Traits" (*Bio/Technology* 8:889, Oct. '90). It also released the lengthier "Report on National Biotechnology Policy" (*Bio/Technology* 9:322, April '91). Like the scope proposal, these policy statements stress limited regulation of biotechnology.

The scope draft states that regulating on a basis other than risk will "tend to discourage tremendously useful innovations." It defines unreasonable risk as one where "full social and environmental cost exceeds the cost of government intervention to redress it." In several places, the draft also proposes that federal agencies consider "social needs" when evaluating the risks of planned introductions. This phrasing, which unintentionally echoes the so-called "fourth hurdle" of social and economic acceptability suggested by the European Economic Community as a criterion for accepting biotechnology products, is said to derive from federal statutory language.

Gauging the significance of the revised scope document is no easy task in the contentious atmosphere currently surrounding it. Administration sources are annoyed that the revised scope statements were leaked. So they are reluctant to discuss what they say is a "draft that is not done, not reviewed, and won't be published as it is." Unofficially, administration sources point out that the draft attempts to remove "preposterous" exemptions cited in the 1990 scope document. That document suggested five process-based categories of organisms that could safely be tested in the environment without extensive regulatory assessments.

Administration sources downplay the controversy the document has stirred. "It's not prescriptive, because each agency has its own statutory authority," one official explains. "And that's not new. It's always been the case that agencies have some criteria to bring applicants in for review."

Critics say the draft document confuses rather than clarifies issues. It threatens to delay and perhaps scuttle—rather than expedite—review of deliberate-release proposals, they say. Rebecca Goldburg of the Environmental Defense Fund (New York, NY) says that the document "reflects a conservative ideology. But it's not doing anybody much good."

Furthermore, critics point out, the proposal seems to "pull the rug out" from draft rules for genetically engineered organisms being finalized by the Environmental Protection Agency (EPA). The agency is trying to meet its congressional mandate under the Toxic Substances Control Act and the Federal Insecticide, Fungicide, and Rodenticide Act. EPA officials fear that adherence to the new scope document will cost time. EPA rules, which are not yet issued, would be "more than acceptable, my industry contacts say," notes one official. "They've asked for clarity. They'd like to avoid having to act as regulatory guinea pigs."

The Association of Biotechnology Companies (ABC, Washington, DC) and the Industrial Biotechnology Association (IBA, Washington, DC) are trying to walk a careful line. In a joint statement on agricultural-biotechnology regulatory issues presented recently to the Administration, IBA and ABC plead for a "fast-track" approval process and avoidance of "duplicatory regulatory efforts." The statement also urges "prompt issuance" of regulations affecting biotechnology from federal agencies, including EPA and the Food and Drug Administration.

Furor over the scope document has "my phone ringing off the hook," says a congressional staffer. The issue appears to be part of a larger question that "invites investigation," he adds. Thus, in a concerted effort, members of Congress from both the House and Senate are considering asking the Government Accounting Office to investigate alleged "White House interference with science advice to the agencies." The problem goes beyond biotechnology and is of "epidemic proportions," the staffer asserts. "It's not a political question, but a matter of who's in charge of developing scientifically based regulations—political appointees or scientists."

**—Jeffrey L. Fox**

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With less unanimity, the committee decided to withdraw from further reviews of proposals involving deliberate release of genetically engineered organisms. Although most such proposals are reviewed either locally or by the U.S. Department of Agriculture or the Environmental Protection Agency, some jurisdictional ambiguity continues while agency regulations are refined. In practice, NIHRAC has not reviewed such a proposal for several years. Thus, committee members agreed that the guidelines should now be updated to reflect that changing reality. The decision is also part of a broader self-examination that the committee began last year and plans to resume more fully next fall.

All the gene-therapy proposals reviewed by NIHRAC entail use of genetic markers. Such markers are used to trace events in cells that are first removed from patients, then engineered with marker genes, and then replaced in patients. Typically, the gene-marking step is not itself therapeutic, although it may serve in some critical way to evaluate the course of other therapies. Because such marking procedures may carry some additional risk to patients, NIHRAC members are insisting that considerable care be devoted to the refinement of associated laboratory and clinical procedures, as well as consent forms presented to patients before they participate. In all the cases reviewed by NIHRAC so far, the patients face life-threatening conditions, and thus the medical procedures entail many risks besides the gene marking procedures.

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