BIOSAFETY COMMITTEES

EPA CONSIDERS DECENTRALIZED REVIEW...

WASHINGTON, D.C.—In planning for the anticipated enlarged volume of proposals to deliberately release genetically engineered organisms into the environment, officials at the Environmental Protection Agency (EPA) recently suggested decentralizing the process (see *Bio/Technology* **5**:1273–1277, Dec. '87). Specifically, they recommended creating institutional-level "environmental biosafety committees" (EBCs), modeled on the National Institutes of Health (NIH) system of voluntary institutional biosafety committees (IBCs). During a day-long meeting in January, an EPA advisory panel greeted the proposal with considerable criticism but eventually gave its lukewarm endorsement to "the concept" of EBCs.

During the meeting, EPA's Biotechnology Science Advisory Committee (BSAC) discussed some serious apprehensions about the agency's proposal for establishing EBCs. For example, Paul Boyer, who directs the Biotechnology Research and Education Program at the University of California (Los Angeles), sent comments directly to the agency. He wrote that "the creation of additional review committees may incorrectly add to the public perception that products of biotechnology are inherently dangerous and need close regulation."

BSAC members—who are drawn from academic institutions, other government agencies, and public interest groups—urged EPA officials to carefully consider several concerns about EBCs. These include questions about the authority to be vested in EBC members; their relation to EPA; appeal, certification, and enforcement procedures; scientific guidelines for committees to follow; and potential unevenness between committees at different institutions.

In particular, BSAC members repeatedly raised the concern that, if an individual EBC were established strictly as an institutional committee, it would seem to embody a serious conflict of interest. In simple terms, even with several members drawn from the community outside an institution, a committee whose majority consists of insiders will be passing judgment on a proposal from a fellow employee. "I can see EBCs in universities, but I have more trouble seeing how they would operate in companies," says BSAC member Robert Colwell, an ecologist from the University of California (Berkeley).

John Moore, EPA Assistant Director for Pesticides and Toxic Substances, tried to respond to some of the committee's concerns. For instance, he told BSAC that he envisions EBCs as having fairly broad powers in deciding whether jurisdiction over a particular genetic engineering proposal resides with a local committee or, instead, should be referred to EPA. Although in theory a corporate EBC should be as workable as the company's IBC (now a generally accepted concept for both corporations and universities), "in reality it will be viewed differently by the public, and we can't ignore that," Moore says. In some cases, companies may choose not to rely on EBCs but to seek the agency's stamp of approval directly.

Colwell suggested establishing *regional* EBCs—in part, to overcome potential conflict-of-interest problems but also to reduce the number of new committees that might need to be formed. His recommendation, however, was quickly rejected by most other BSAC members. "That is a horrible idea," commented University of Maryland (College Park) scientist Rita Colwell, who chairs BSAC.

As an alternative to either a rapid build-up of EBCs or of regional committees, EPA and the first participating institutions "could pyramid" the EBCs, starting with just a few but gradually building the number as they are needed, proposed Robert McKinney from NIH. Ultimately, BSAC left EPA officials to grapple with such practical matters. "We are endorsing a concept, not a mechanism," McKinney pointed out.

In another development, Robert Colwell presented draft guidelines to the committee recommending how EPA could better deal with the issue of confidential business information when evaluating deliberate release proposals. **—Jeffrey L. Fox**

NEW REPORT

...WHILE GAO SURVEYS BIOSAFETY

WASHINGTON, D.C.—In mid-January, the U.S. General Accounting Office (GAO) quietly released *Biotechnology: Role of Institutional Biosafety Committees* (IBCs). Although the GAO report* is compact and its conclusions bland, it represents the most extensive survey to date of IBCs, the principal model for environmental biosafety committees (EBCs) recently proposed by the Environmental Protection Agency (EPA).

The GAO report treats the proposed expansion in jurisdiction of biosafety committees very cautiously. The relationship between IBCs and the National Institutes of Health (NIH), which established the current system, is "well understood," the report notes. However, "the relationship between some biosafety committees and the federal agencies...involved in reviewing proposals for the use of genetically engineered organisms in the environment, such as EPA and USDA, has yet to be defined."

The new report also stresses that, despite some recent trends toward diversification, IBCs are "predominantly composed of members with backgrounds in genetic engineering." Moreover, it states, "opinions differ" about how well other federal agencies could use the "present capabilities of the committees"—not to mention the IBC structure—in the regulatory process, particularly in "adequately review[ing] release proposals." Some federal officials said that, by adding experts from other disciplines, the "capabilities of the committees can be improved." But current committee chairpersons cite considerable confusion on this issue—with many of them indicating "little need to change their membership" to address changing duties.

IBC chairpersons give the appearance of not paying particularly close attention to the biotechnology regulatory scene. Of those surveyed by questionnaire in May 1987, only 25 percent from the public sector—and 55 percent from the private sector—had reviewed the federal "Coordinated Framework for Regulation of Biotechnology," which was published in June 1986. Nonetheless, biosafety committees have "generally complied with the NIH guidelines," the GAO report notes. Indeed, although only about half the private-sector companies surveyed have registered their IBCs with NIH (registration is voluntary), those that have done so appear to "follow the [NIH recombinant DNA] guidelines more closely than [do] their public-sector counterparts." **—JLF**

**The GAO report, RCED-88-64BR, can be obtained from the U.S. General Accounting Office, P.O. Box 6015, Gaithersburg, MD 20877. The first five copies are free, with additional copies available at $2.00 each.*