PAINSTAKING PROCESS

BACKDOOR RELEASE OF EPA DRAFT RULES

WASHINGTON, D.C.—Officials of the U.S. Environmental Protection Agency (EPA) recently nudged into public view their current draft rules for the deliberate release of genetically engineered organisms. However, this exposure came as a glimpse through a side door instead of by official publication in the *Federal Register*. The latest effort—part of a painstaking process to develop regulations—continues to frustrate various factions concerned with biotechnology, including EPA officials and their critics.

The biotechnology industry seems to support the current draft rules—at least, lukewarmly—whereas universities are emerging as the most vocal opponents. Although EPA proposals under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA) recently progressed to the Office of Management and Budget (OMB), those proposed under the Toxic Substances Control Act (TSCA) remain behind at the agency for now but could move to OMB this fall. Both sets are said to be in considerable jeopardy.

Until the draft FIFRA rules reached OMB, they stood a better chance of being published in the *Federal Register* and obtaining a formal public review. However, some observers say, the proposals now seem unlikely to emerge from OMB anytime soon. The recent airing of an Administration proposal to change the underlying scope of the entire deliberate release issue appears to undercut the logic behind the FIFRA proposals and threatens to hold matters up until scope is settled (*Bio/Technology* **9**:603, July '91). In addition, the Administration's Biotechnology Working Group currently has no leader, which is a practical impediment to the release of biotechnology regulatory proposals from EPA or other agencies.

TSCA applies broadly to new, commercially used chemicals. Since 1986, EPA officials have construed TSCA to apply also to new genetically engineered organisms—in effect, designating them to be chemicals—that are being developed for commercial purposes. Questions about what is genuinely "new" and "commercial" continue to challenge EPA officials, scientific advisors outside the agency, and critics of the agency's efforts.

In July, EPA convened its Biotechnology Science Advisory Committee (BSAC) and invited public comment on the latest draft TSCA rules. Before the summer, the rules were being developed in private by agency officials to correspond to the Administration's scope definitions proposed in 1990 (*Bio/Technology* **8**:706, Aug. '90). By widely distributing the current draft and discussing it publicly under BSAC auspices, the agency has at least temporarily sidestepped some of the usual OMB hurdles, as well as any questions that may arise if the Administration chooses the newly proposed version of scope. Eventually—this fall, EPA officials say—the current draft rules under TSCA will be revised and sent to OMB.

Despite this effort to expedite agency rule-making procedures, uncertainty about both the timing and content for publication, much less acceptance of a final set of TSCA rules, remains high. Although BSAC members generally praised the draft rules, their questions and those of other representatives of the public fortify a sense that considerable debate lies ahead.

The most vehement criticisms of the current version of the proposed rules came from several university representatives who attended the July meeting of BSAC. Susanne Huttner, director of the Systemwide Biotechnology Research and Education Program of the University of California (Los Angeles, CA), says the proposed EPA rules would create a "regulatory net that extends beyond issues of risk" and thus would become "an unnecessary and scientifically unwarranted burden on biotechnology research." The rules would have "a serious impact on research in academia," adds Sue Markland Day of the University of Tennessee (Knoxville, TN). "Most important, they would give the EPA reviewer veto power over research."

This lingering confusion over which federal agencies or other local bodies are to review university-based deliberate-release research proposals appears to be intensifying dissatisfaction with the current draft rules. Some of that confusion extends to BSAC members, who admit that jurisdiction between EPA and the Recombinant DNA Advisory Committee of the National Institutes of Health on such matters is no longer clear. Several committee members suggest that the agency take particular care to spell out its proposals for regulating research and for developing exemptions from that review. There is even some sentiment to conduct such reviews regionally. —**Jeffrey L. Fox**