REGULATION

MORE U.S. DELIBERATE RELEASE DELIBERATIONS

WASHINGTON, D.C.—The effort to refine key terms governing sensitive biotechnology issues continues at the federal level. Developing a clearer, more precise definition of "deliberate release into the environment" of genetically engineered organisms has become the dominant challenge. In December, for example, two working groups tackled the problem independently. At both the National Institutes of Health's Recombinant DNA Advisory Committee (NIHRAC) and the U.S. Environmental Protection Agency (EPA), subcommittees tried to address the concerns both of biotechnology's critics and its proponents.

EPA sought an improved definition of deliberate release to help the agency flag products that require review. Right now, EPA policy requires review of any "significant new use" of a microbe in the environment, research and development of a commercial product, or organisms falling under jurisdiction of the Toxic Substances Control Act. EPA has called on a science advisory panel of outside experts to help agency staff members draft a definition that will screen out the mass trivial applications while catching the important cases for review.

'Flushing Out' Options

As it improves its definitions, EPA is also trying to leave a carefully documented record of its deliberations—in case of litigation. Earlier lawsuits have taught the agency that its internal decision-making may become fodder for scrutiny and interpretation—or misinterpretation—in court.

The advisory panel, chaired by James Tiedje of Michigan State University (East Lansing), framed two broad options for EPA: define deliberate release in terms of containment levels deemed necessary for handling any particular microorganism; or assign relative numerical values to a set of criteria so that a total score exceeding a certain threshold value will trigger an agency review.

Both options need considerable expansion (one panel member calls it "flushing out") before the agency can pick one (or a third alternative) to assess risk, economic impact, and benefits for projects coming under regulatory review. Even then, it could prove difficult to establish a definition that is both simple (requiring something short of a full-blown risk assessment) and complete (so that researchers can tell in advance when an EPA evaluation will be necessary).

Some Releases Better Than Others

Meanwhile an NIHRAC working group has pondered whether to change its own established definitions for deliberate (or "planned") release of genetically engineered organisms into the environment—or whether new exemptions should be added to the current NIH guidelines for recombinant DNA research without changing the basic definition. Although the full NIHRAC will likely see proposals of both sorts when it next meets on February 2, there is some feeling that, legally, it is better to introduce exemptions than to amend fundamental principles.

Central to this effort by the NIH working group, according to one of its members, is to bring about a wider realization that certain whole classes of environmental release experiments pose less of a concern than do others. "We're trying to get the outside world to distinguish between recombinant DNA experiments that create something new and those that don't," a panel member explains. Most RAC members now agree that certain manipulations, such as gene deletions or single base changes within an organism's DNA, occur naturally all the time. Hence, trying to oversee or prohibit such manipulations is a useless exercise.

Expedited Review

The committee also is looking for ways to expedite review of high-value, low-risk tests of genetically engineered organisms that nominally involve deliberate release, such as tests of live vaccines or other experiments injecting genetically engineered material into large animals or plants. Refining definitions in this way would have little or no effect on plans for gene therapy experiments, however, which promise to be one of the NIHRAC's major future concerns.

Presumably any of the improved definitions also must be made compatible with those being refined by still other federal agencies—a task that is being addressed by the Biotechnology Science Coordinating Committee. **—Jeffrey L. Fox**

INDUSTRY-ACADEMIA RESEARCH

MORE COLLABORATIONS IN BRITISH BIOTECH

LONDON—Four British pharmaceutical companies have joined 11 U.K. universities and polytechnics to fund a £1.4-million genetic manipulation program over the next three years. Their purpose is to boost and diversify antibiotic production.

Coordinated by the Biotechnology Directorate of the Science and Engineering Research Council (SERC) and the Biotechnology Unit of the Department of Trade and Industry, the unique U.K.-government-sponsored program is centered on the creation of novel strains of *Penicillium*, *Aspergillus*, streptomycetes, and other producers of valuable secondary metabolites. It will exploit techniques such as those evolved in recent years by David Hopwood and his colleagues at the John Innes Institute (Norwich) as the basis for engineering "hybrid antibiotics." The program manager is Iain Hunter of the University of Glasgow. Among other campuses involved are Manchester University Institute of Science and Technology, where researchers are studying the genetic switches mediating between antibiotic and biomass production; and University College London, where there is particular interest in methods of increasing plasmid stability. Participating companies in this program of pre-competitive research (which parallels SERC's Protein Engineering Club, established last year) are Apcel (Slough), Beecham (Surrey), Glaxo (Middlesex), and Imperial Chemical Industries.

Coincidentally, University College London is expected to pair with the University of Birmingham in a quite separate biotech initiative. The two campuses are slated as joint headquarters for a new U.K. Biochemical Engineering Center focused on product recovery, advanced bioreactor control techniques, and other aspects of bioprocessing. Still evolving, the plan is for SERC to provide core funding for work financed in part by contracts with industrial companies. Total funding for the four-year program is anticipated to be between £2.5 million and £3 million, though all specific projects will have to go through SERC's normal refereeing machinery before being approved.

—Bernard Dixon