NIHRAC

PLANT, ANIMAL CONTAINMENT GUIDES CLARIFIED

WASHINGTON, D.C.—During its September meeting, the National Institutes of Health Recombinant DNA Advisory Committee (NIHRAC) recommended changes in rDNA research guidelines covering experiments on "contained" plants and animals. The exercise, however, frequently found the group hovering between scientifically attractive and politically more feasible paths—with the committee generally choosing the latter course.

On another matter, although the committee rejected an amendment as "too broad" that was proposed by Jeremy Rifkin and the Foundation on Economic Trends (Washington, D.C.), it did appoint a group to examine jurisdiction over NIH-supported gene-splicing experiments conducted outside the U.S.

NIHRAC has been seeking to provide a sensible scientific lead to institutions whose scientists are doing rDNA experiments on higher plants and animals. Thus, draft documents (prepared by other federal agencies and describing stringent requirements for the design of greenhouses and animal facilities) were substantially relaxed and simplified. "We're saying that the fund of [field] experience with plant pathogens gives us confidence" in making these changes, explained Nina Federoff. A plant geneticist at Carnegie Institution of Washington (Baltimore, MD) and former committee member, Federoff helped revise the documents. If the committee's recommendations are approved by NIH director James Wyngaarden, researchers in many cases will merely need to inform their institutional biosafety committees (IBCs) that experiments have been done—rather than seek prior approval.

Although the committee considered exempting wide classes of animal and plant rDNA experiments from the guidelines, members reluctantly agreed against doing so. "It is better to loosen restrictions than try to get exemptions," Federoff pointed out.

Thus, for example, a proposal by the full committee in September 1986 to exempt from review virtually all rDNA gene deletion experiments has remained "dead in the water," according to NIHRAC executive secretary William Gartland, Jr. Attorneys have advised Wyngaarden that implementing the proposal requires a full-blown environmental assessment, a procedure that currently seems more burdensome than the relief being sought.

Microbiologist Bernard Davis of Harvard University Medical School (Boston, MA) argued that the guidelines have become "too complex" and may be "creating public confusion" rather than allaying out-dated fears about rDNA research. Indeed, officials representing the University of California (Berkeley) requested that the committee repeal the guidelines, suggesting that they expire by 1992 unless experience "proves their continuation is necessary." Although NIHRAC members agree that the guidelines could be improved by simplification, the committee did not consider this "sunset" proposal.

Activist Rifkin has demanded that NIHRAC clarify how its guidelines extend to research projects outside the United States, an inquiry that dates back to 1986 when scientists from Wistar Institute (Philadelphia, PA) tested a recombinant rabies vaccine in cattle in Argentina (see *Bio/Technology* **5**:13, Jan. '87). Although no NIH money was spent on the animal tests, Wistar scientists had developed the vaccine with NIH funding. Rifkin's attorney, Lee Rogers, says the guidelines should "deal with 'substantial support' by NIH of research abroad." The committee, however, remained undecided on the question, with some members concerned that trying to extend jurisdiction outside U.S. boundaries would be "presumptuous" and might have a "chilling effect" on research; others seemed to agree that this apparent loophole needs closing.

—Jeffrey L. Fox

NEW BUSINESS

CELLMARK STARTS U.S. FORENSICS SERVICE

WASHINGTON, D.C.—Cellmark Diagnostics, a new division of ICI Americas (Wilmington, DE), is introducing in the United States a DNA fingerprint method for analyzing forensic lab samples and determining family relations in paternity suits. The technique was developed by Alec Jeffreys, a geneticist at the University of Leicester (U.K.); it has been used widely in England for two years.

Cellmark (Germantown, MD) hopes to tap into a testing market that it estimates to be at least $75 million annually and expanding. Plans also call for developing tests to diagnose genetic diseases.

The molecular fingerprinting technology analyzes short, highly variable, but frequently repeated (or "stuttered") sequences of DNA that are scattered throughout people's genes. Jeffreys developed a probe method to highlight such regions, which, with the use of restriction enzymes, can illuminate differences in inheritance patterns between individuals. The sensitivity of the method is so great that only one to two drops of blood, about 10 hair roots, or a trace of semen is needed to conduct an analysis, Jeffreys says. In England, the method has been used by immigration officials to determine whether alleged family members are related, and by the police to establish the guilt or innocence of rape and murder suspects.

The Cellmark technique will enable U.S. law enforcement officials "to bypass constitutionally problematic procedures involving forcible blood letting or compelled semen sampling," says James E. Starrs, professor of law and forensic sciences at George Washington University (Washington, D.C.). Guarantees of privacy and against forced searches would not be violated in using the Cellmark method, he contends, because the tests can be done on such small samples. Moreover, although criminals can hide ordinary fingerprints, they "cannot so readily hide details of their DNA," he says.

Cellmark and its parent company see the DNA fingerprinting method as a way to break into the large and growing U.S. diagnostics market. The company initially is eyeing the market for paternity testing (about 50,000 U.S. tests annually) and rape and homicide forensics testing (about 110,000 tests each year), according to Cellmark president Robert Gottheiner. (A company colleague estimates that, with the availability of such a clear-cut procedure, the volume of paternity testing could soon quadruple.)

A single analysis will be priced from $500 to $800, Gottheiner says, and the Maryland lab is designed to handle up to 300 tests per day. The company plans to do all testing in-house, and thus expects eventually to open additional facilities in the Northeast or the West. **—JLF**