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NIHRAC

LARGE-SCALE RULES, TRANSGENIC ANIMALS, INTERNATIONAL ISSUES

WASHINGTON, D.C.—During its June meeting, the Recombinant DNA Advisory Committee (NIHRAC) of the National Institutes of Health (NIH) (Bethesda, MD) carefully considered but could not agree on a proposal for extending its jurisdiction to cover experiments that are conducted outside the United States. The committee did, however, reach a consensus on broadening its review of research involving transgenic animals and on easing the stringent requirements for certain industrial-scale procedures.

If accepted by NIH director James Wyngaarden, NIHRAC's proposed sweeping changes for certain kinds of large-scale processes could have a major impact on food processors and pharmaceutical manufacturers.

Current industrial-scale containment guidelines call for process equipment to meet restrictions equivalent to laboratory-scale minimum containment conditions for handling the safest genetically engineered microbes. Representatives from industry, however, say that compliance with these still relatively strict engineering standards is inappropriate and unnecessarily costly. The committee agreed, recommending that—in most cases—large-scale process equipment for genetically engineered microbes can be the same as that used for safe parent strains. Following the same general logic, the committee also recommended approving several requests to ease restrictions on specific types of microorganism now used widely by industry.

The issue of whether NIHRAC should review research involving transgenic animals stems from recent health and safety concerns raised over insertion of genes from human pathogens into animals. "Right now, we're the only game in town" for dealing with this issue, says Gerard McGarrity, president of the Coriell Institute of Medical Research (Camden, NJ) and the new chairman of NIHRAC. After debating whether such amendments would expand the current guidelines too greatly, the committee decided the expansion was warranted.

The proposal that NIHRAC jurisdiction should somehow extend outside U.S. borders arose because of a still-disputed rabies vaccine trial conducted in Argentina in 1986 (see *Bio/Technology* 6:762, July '88). NIH sponsored the early work of Wistar

Institute (Philadelphia, PA) scientists on a genetically engineered, vaccinia-based rabies vaccine. Later, without further NIH funding or involvement, a derivative vaccine was tested on cows in Argentina. How far should compliance with the NIH recombinant DNA guidelines and review by NIHRAC extend in such cases?

Earlier this year, an NIHRAC working group considered a proposal, submitted by Jeremy Rifkin and his Foundation on Economic Trends (Washington, DC), to broadly extend NIH jurisdiction over such projects. The working group realized that—whatever its decisions—NIH jurisdiction necessarily is "limited" outside the United States, according to chairman Mitchell Cohen, an official from the Centers for Disease Control (Atlanta, GA). Moreover, neither paternalism nor neglect of responsibility was deemed an appropriate response. There is also "particular concern" within NIH regarding experiments involving either deliberate release of genetically engineered organisms or human gene therapy. Insofar as possible, those experiments should comply with sound scientific guidelines—either those crafted by NIHRAC or its equivalent in other countries. Experimental protocols should at least be brought to the attention of and, preferably, reviewed by health officials in the host country.

Amending current guidelines to achieve such goals proved beyond the full committee's reach during the June meeting, however. The committee has not yet found the appropriate language for an amendment, and rejected a proposal offered by Rifkin as worded too broadly. RAC members were concerned that it might force researchers to be responsible for policing all "downstream" project development or, perhaps worse, it could make the exchange of culture samples from central repositories a matter of NIHRAC review.

NIH attorney Robert Lanman's alternative proposal, although narrower in scope and clearer in detailing the limits of NIH jurisdiction, still would not cover the incident in Argentina. This led Harvard University Medical School (Boston, MA) microbiologist Bernard Davis to say, "I'll have to agree with Mr. Rifkin" in calling the alternate proposal inadequate. Thus, the committee referred the issue back to the working group.

—Jeffrey L. Fox