"REGULATORY NEVER-NEVER LAND"

USDA SNARLS AT TRANSGENIC CATFISH

WASHINGTON, D.C.—A rescued version of the Agricultural Biotechnology Research Advisory Committee (ABRAC) of the U.S. Department of Agriculture (USDA, Washington, DC) recently gave limited approval to a proposal to study transgenic catfish in outdoor ponds. The panel, however, grilled principal investigator Rex Dunham of Auburn University (Auburn, AL) with more intensity than expected, arguing that his experiments were not well designed and that only the rigor of his confinement precautions qualified the proposal for approval.

Yet there still is no mandate for any federal review of such experiments, nor is there a requirement that anyone, including USDA officials, heed ABRAC's advice. The whole topic resides in a "regulatory never-never land," according to some observers (box).

Dunham and his collaborators approached USDA last October, seeking approval to release 100,000 transgenic catfish fry into specially designed outdoor ponds on the Auburn campus. The fish carry a growth-hormone gene from rainbow trout. Dunham is trying to learn whether the transgenic fish grow faster and more efficiently than ordinary catfish, which are farmed intensively throughout the South.

Similar experiments

In 1990, Dunham came before ABRAC seeking advice on similar experiments involving transgenic carp (*Bio/Technology* 8:286, April '90). Then, as now, his main support—and funding—has come from USDA's Cooperative State Research Service (CSRS), which evaluated the carp proposal and prepared an environmental assessment of it. Although the experiments were given tentative approval, Dunham did not begin them until new confinement ponds were built at Auburn. The outdoor facility is specially designed to reduce drastically any likelihood that fish could escape and establish themselves in surrounding waterways. The carp experiments are still underway at Auburn.

Soon after receiving Dunham's proposal last October, CSRS assembled an *ad hoc* advisory panel of fisheries experts, six of whom met in January. Several of these panel members also appeared before ABRAC to summarize their findings. The panel "agreed that the experiments, if conducted as described, would not have a significant impact on the human environment," says Charles Brown of USDA's Animal and Plant Health Inspection Service (APHIS), who chaired the panel. "How-

ever, we're not agreed on every issue, and we want studies before there is any commercial use of transgenic catfish on a large scale."

Getting a go ahead

After hearing the panel's advice as well as a lengthy description of the proposal by Dunham, a majority of ABRAC members also concluded that the experiment could go ahead "because the confinement design and protocols are sufficient to prevent escape of the fish into the environment." However, several ABRAC members criticized the proposed experiments, suggesting that

they might not qualify for federal support if judged by peer reviewers.

Moreover, ABRAC member Edward Bruggemann of the National Audubon Society (Washington, DC) raised several additional concerns about the way in which Dunham's proposal is being reviewed. Evaluation should be "step wise," he says, arguing that Dunham and USDA officials should wait to assess the transgenic-carp experiments before beginning the supposedly parallel outdoor phase of the catfish research. "It's important for USDA to have a better process for evaluating these applications," Dunham says. —Jeffrey L. Fox

ABRAC STILL SEEKING A NICHE

USDA Secretary Edward Madigan rechartered ABRAC earlier this year, retrieving the panel from a threatened state of dormancy. He also appointed 15 new members to the panel.

USDA officials, moreover, are again trying to issue a definitive version of ABRAC guidelines. Early last year, a draft version of the guidelines was presented for public comment (*Bio/Technology* 9:326, April '91). Now retitled "Guidelines for Research Involving Planned Introduction into the Environment of Genetically Modified Organisms," the revised draft document consists principally of a scheme for "assessing the safety" and "designing confinement" for research projects that entail the deliberate release of genetically engineered organisms. Indeed, the current draft guidelines outline an elaborate classification system for such projects.

But the ABRAC guidelines still raise more questions than they answer. No one can say just how or when the guidelines will be implemented and to whom they will apply. And the guidelines provide no sanctions and say nothing about the consequences that might follow if researchers flout ABRAC advice.

The ABRAC document is currently being reviewed by Administration officials, including those in the Office of Management and Budget (OMB). OMB officials may just block the guidelines. If, instead, they adopt it as "policy," it

will remain "without sanctions," an insider notes. With the advent of the recent "scope" policy statement from the Bush Administration, there is little likelihood that the ABRAC guidelines will be given any regulatory or quasi-regulatory teeth. Biotechnology products are now considered "innocent until proven guilty," explains Alvin Young, director

of USDA's Office of Agricultural Biotechnology and ABRAC's executive secretary.

Still, ABRAC members are being asked to continue reviewing biotechnology research proposals—but only as they are presented voluntarily, and even though the scope policy declares that such research should be presumed to pose no risk.

Meanwhile it remains true that "no

federal agency has formally declared jurisdiction over transgenic fish," says regulatory specialist Maryln Cordle of USDA. As a courtesy to CSRS, Dunham brought the carp and the more recent catfish proposals there first, she notes. On both occasions CSRS asked Dunham also to appear before ABRAC.

In addition, officials considered but evidently rejected an alternative approach of having Dunham present his protocol to APHIS for review. "We don't assume that's an appropriate mechanism for transgenic fish," Cordle notes, adding that if APHIS were consulted, it could conceivably issue some form of "courtesy permit." —JLF

ABRAC is being asked to review biotech research proposals, even though "scope" says such research should pose no risk.