

DELIBERATE RELEASE

FISH DRIFT BETWEEN AGENCIES' GUIDELINES

WASHINGTON, D.C.—Last March the Agricultural Biotechnology Research Advisory Committee (ABRAC) of the U.S. Department of Agriculture (USDA) reviewed a proposal from researchers at Auburn University (Auburn, AL) to test genetically engineered carp in outdoor ponds (*Bio/Technology* 7:424, May '89). Despite provisional committee approval, an official go-ahead from USDA had not come by the end of June, pending completion of an environmental assessment (EA). Fearing that the gene-stock adult carps might die if not provided with an outdoor habitat, Rex Dunham and his collaborators placed several fish in ponds without formal USDA approval; they also notified institutional biosafety officers at Auburn University and the National Institutes of Health Recombinant DNA Advisory Committee (NIHRAC) of their actions. This apparent confusion over which agency has jurisdiction over the test arises in part because key documents, including the ABRAC charter guidelines and an appendix to NIHRAC guidelines, are being refined.

An ABRAC working group met in June to answer criticisms aimed at the proposed "USDA Guidelines for Research with Genetically Modified Organisms Outside Contained Facilities" (*Bio/Technology* 7:123, Feb. '89). It focused on a scheme for classifying "unmodified organisms" according to relative safety categories—a classification that drew the most criticism from reviewers of the draft document. Although USDA officials expect to publish the revised guidelines soon, they now also are planning to prepare an environmental impact statement (EIS) to evaluate procedures under the proposed guidelines.

Preparing an EIS is a "long process," says Alvin Young, director of the Office of Agricultural Biotechnology. It entails holding public hearings, conducting several rounds of analysis and comment, and can end up costing several million dollars. Currently, the department has not allocated money for the task, but the threat of lawsuits likely will provide the necessary incentive to begin the project soon. While the EIS is pending, USDA will do smaller-scale EAs to support actions it reviews and endorses under the current proposed guidelines, Young says.

Both the ABRAC process and the Auburn outcome leave Margaret Mellon of the National Wildlife Federation (Washington, DC) uneasy.

Being the first such U.S. test of an engineered vertebrate, she notes, the vagueness of the review process is "disturbing," particularly as the same fish, depending on their age and degree of sexual maturity, seem to come under different federal agencies' jurisdictions. "The federal framework doesn't seem to be working very well in this case," Mellon asserts. "The jurisdiction isn't clear," Young

tained." And because the ponds are screened and fenced as well as guarded around the clock, the site may be considered "physically contained."

Young notes that the researchers "are under no requirement" to notify USDA of their activities—they did so voluntarily. Moreover, they have followed "stringent safety procedures" while placing the adult fish in outdoor ponds, even though the next

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agrees. "The Auburn situation is difficult because the formal guidelines are not yet in place."

By the end of June, USDA officials had nearly completed the EA evaluating the proposed Auburn University experiments involving carp endowed with extra copies of activated growth hormone genes, which may enable the fish to grow more efficiently in aquacultural settings. The draft EA concludes that the proposed experiments pose "no significant impact" to the environment, according to Young. It focuses on later experiments that will involve newly hatched fish—known as "fry"—to be conducted in ponds.

In anticipation of those tests, Auburn researchers have placed several mature genetically engineered carp in special ponds, isolating them while conditioning them for mating. Several factors suggest this preliminary step falls under NIHRAC guidelines, and is acceptable. While there's ambiguity about whether the guidelines would cover an "outdoor" test of the fish, they encompass tests of appropriately confined or contained genetically engineered organisms. These mature carp are segregated by sex, and therefore are "biologically con-

experiment with fry is the one ABRAC committee members said must be done under its restrictions.

Despite continued frustrations with efforts to publish the USDA guidelines, the "guidelines process is close to being ready to function," Young says. Although intended for researchers receiving USDA support, "there will be something for all ag researchers" in the document, he adds. Eventually, USDA plans to familiarize biosafety officers from across the country who oversee agricultural research with the guidelines "to get uniformity in adherence." Recently, officials at regulatory agencies, including the Animal and Plant Health Inspection Service within USDA as well as the Environmental Protection Agency, were "briefed" on the status of the guidelines.

Although officials from these agencies have doubted the need for guidelines that go beyond current regulations, Young contends that such guidelines are needed to "capture" research involving various new technologies. Moreover, "there is a need for public accountability [and for describing] the scientific principles for decision making," Young says. "It's not a black box." —Jeffrey L. Fox