New Biotech Rules

■ A soon-to-be-released White House document—designed to define the scope of federal agencies' jurisdiction over biotechnology products—will simplify the regulatory process, and may also require some agencies to alter their existing plans to monitor new pesticides and chemicals.

The 28-page document, which *Science* has obtained, prohibits special regulations for biotechnology products such as genetic therapies and recombinant drugs, food, and pesticides unless "the risk posed by the introduction [of the new product] is unreasonable." Regulators who have reviewed the document say it essentially formalizes existing policies at some agencies, but not at others.

For instance, the Food and Drug Administration (FDA) already treats drugs, food, and medical diagnostic kits made with biotech methods no differently from other products. Regulators at the Environmental Protection Agency (EPA), however, are worried that the new rule could derail an agency proposal for regulating biotech products more aggressively than conventional pesticides and chemicals by making it more difficult to collect data on new hazards. The document also appears to conflict with the way the Department of Agriculture regulates genetically altered crops and the way NIH reviews human gene therapies, since both agencies have given biotech products special attention.

Even as federal regulators sort out the implications of the new rule, the biotech industry says the Administration is on the right track. "In a word, we'll take it," says Richard Godown, president of the Industrial Biotechnology Association. And despite a 90-day moratorium on new regulations (*Science*, 14 February, p. 787), White House counsel C. Boyden Gray is said to be pushing the document through for final approval soon.

Biddle Takes His Case to Congress—in a New Way

■ Navy whistle-blower Paul Biddle has resigned from his job as the government accounts officer at Stanford, but he plans to carry on his crusade to protect the taxpayer's dollars in a new way—by running for Congress.

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Is this the face of the next freshman lawmaker from California?

Biddle says he decided it was time to move on, now that government accountants have backed his charge that Stanford has overcharged the government at least $200 million for research overhead. Although he had originally planned to return to the private sector as a certified public accountant, he says friends talked him into running for the Republican nomination to fill the House seat being vacated by Representative Tom Campbell (R–CA), who is now seeking a Senate seat.

As a government employee, Biddle can neither accept campaign contributions nor distribute literature until his resignation is effective on 1 March, but he says he has about 40 volunteers who are having no trouble collecting the 1000 signatures he needs to qualify for the June primary. He is also optimistic about his chances of bagging the seat: He says an informal poll of 100 households suggested he has better name recognition than the other four Republican candidates, and he claims Democrats have been calling to volunteer for his campaign as well. "The issues I speak to are things Democrats can rally to," Biddle says. His agenda, should he be elected: ferreting out fraud and waste in government spending. What else?

Gene Panel Goes Away

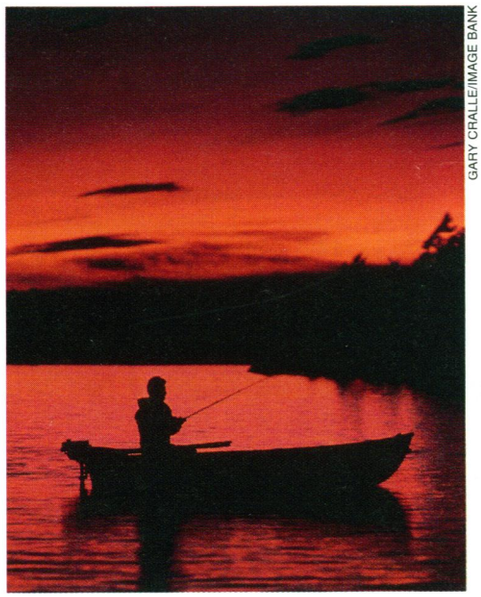
■ The process of getting federal approval for a human gene therapy experiment will be a lot easier in the future. At its last meeting on 11 February, NIH's Recombinant DNA Advisory Committee eliminated one step in the approval process by voting its gene therapy subcommittee out of existence. Now new protocols will go straight to the RAC (as it is known) for review. As a result, researchers will both save time and avoid the hassle of trying to satisfy two committees that traditionally have asked essentially the same questions.

Henry Miller, director of the biotechnology office at the Food and Drug Administration and an outspoken critic of excessive federal regulation for recombinant DNA technology, says the RAC has sufficient expertise to do the subcommittee's jobs. Besides, he says, the RAC has done almost nothing recently but deal with gene therapy protocols.

Senate Subcommittee to Examine Toxicity of Great Lakes Fish

■ An upcoming congressional hearing called by Senator John Glenn (D–OH) might be the first step toward congressionally mandated limits on pollutant residues in Great Lakes fish.

For years, marine biologists have noted that some fish in the Great Lakes—particularly coho salmon and whitefish—have accumulated high levels of toxic chemicals, including PCBs, DDT, mercury, and lead. A growing number of studies have linked reproductive abnormalities in wildlife and developmental problems in infants to the consumption of such contaminated fish. While state health authorities issue advisories when they find high levels of toxic chemicals in fish, such warnings provide only "an illusion of safety," says a Glenn staffer, particularly if the fish are shipped to out-of-state markets where consumers may be unaware of the risks.



GARY CRALLE/IMAGE BANK

Great Lakes sport fishing is one source of contaminated fish.

The hearing, scheduled for 7 April, won't be Glenn's maiden voyage into the realm of reproductive toxicity. Last fall, a Government Accounting Office report requested by Glenn found that federal agencies need to pay more attention to toxic substances that may affect the health of fetuses. Glenn may use the evidence he has gathered to justify more aggressive action on contaminated fish.

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