journal *Ambio* which contained new estimates on the climatic effects of nuclear war by Paul J. Crutzen of the Max Planck Institute. This led to the TTAPS effort, which was reviewed by scientists from around the world at a meeting in Cambridge, Massachusetts, last spring.

Russian scientists, who have been doing their own calculations, are also believed to be in fundamental agreement. This was dramatically illustrated at the meeting by a satellite hookup which showed Ehrlich and Sagan exchanging conclusions with four high-ranking members of the Soviet Academy of Sciences.

To what degree, if any, might this new perspective on nuclear war affect the deliberations of strategic planners? The overall impression from the conference is that nuclear war on any scale would be worse than anything it was meant to avoid. As keynote speaker Donald Kennedy of Stanford said, "It is no longer acceptable to think of sequelae in minutes, days, or even months. What biologists are telling us today is that the proper time scale is years."

Science asked several government spokesmen for their reactions to the scientists' findings. The general response is summed up by a Department of Defense official who said, "So what?" The government already knows nuclear war would be absolutely devastating, and the real question is how to prevent it. A State Department official was asked what the meaning of deterrence—that is, the threat of using a weapon—would be if its actual use would be suicidal. He said it's still a deterrent if the Russians believe we would use it. He added that if the Russians believed that we believed a first strike would be suicidal, they might relax a little and not put so much into their own first strike capabilities.

The only agency that seems to have been affected by the findings is the Federal Emergency Management Agency. A FEMA spokesman said that while they were unmoved by the physicians' message, which they thought "exaggerated," they were worried about problems of food supply, which appear to be "even more profound than we had anticipated." He said the problems of cold and dark were for the long-term planners and not part of FEMA's primary responsibility. In keeping with FEMA's job, which is to act as though every catastrophe is manageable, the spokesman pointed out that even in the worst case, only 5 percent of the nation's land area would be blown up; that 75 percent of what would be needed for a nuclear attack was already done for other assorted disasters; and that the United States has a much better transportation system than the Russians for pre-attack evacuation.

A National Academy of Sciences committee headed by George Carrier of Harvard University is currently winding up a 9-month study of the long-term atmospheric effects of nuclear war, commissioned by the Defense Nuclear Agency, which Sagan said is substantially in accord with his colleagues' findings.

Whether or not the government sees the information as significant, there is definitely an accelerating concern among scientists. The International Council of Scientific Unions is starting a 2-year study for which a series of meetings, starting this month, is being held in Stockholm. A scientific symposium is also planned in Tokyo.

It would appear that growing numbers are coming to agree with biologist Thomas Eisner of Cornell University who said at the meeting: "I no longer feel that a single biologist in this country or the world can be exempt from becoming involved in these issues."

—CONSTANCE HOLDEN

EPA Revs Up to Regulate Biotechnology

The agency's general counsel has already ruled that bacteria designed to prevent frost damage to plants are pesticides

With the likelihood that biotechnology research will soon be bearing commercial fruit, the Environmental Protection Agency (EPA) is gearing up to regulate some potentially important products of genetic engineering. Its entry into an already controversial area is creating anxiety in the biotechnology industry, and its authority is likely to be challenged in court.

EPA is moving to fill a gap in the federal government's power to monitor biotechnology. Currently, the recombinant DNA advisory committee at the National Institutes of Health (NIH) is the principal oversight group for genetic engineering research. It administers safety guidelines laid down by NIH. But the guidelines are binding only for federally funded researchers and do not address broader issues concerning the environmental impact or the health risks associated with commercial activities. Compliance by companies is voluntary. EPA believes it has the power to regulate industry and is even preparing to exercise some authority over the field-testing of pesticides produced by genetic engineering techniques. This could potentially put it in the business of regulating research.

Exactly how the agency will go about regulating biotechnology is not yet clear. EPA officials say the policy is still being worked out. During the past several months, they have been meeting with representatives of biotechnology companies to exchange ideas and, so far, both sides describe the discussion as open and cordial. By early next year, EPA plans to publish in the *Federal Register* a list of its concerns about genetically modified organisms and their impact on the environment. The list will be circulated to solicit public comments on the agency's potential regulatory role.

Donald R. Clay, acting assistant administrator of the office of pesticides and toxic substances, argues that EPA has clear authority to regulate genetically engineered pesticides under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). He also believes the agency can regulate some other applications of biotechnology, such as the use of genetically modified organisms to break down oil slicks, under the Toxic Substances Control Act (TSCA). But this is a controversial interpretation of the statute. "Companies have already promised that they'll sue me if I regulate under TSCA," Clay said in an interview.

EPA expects that applications to manufacture genetically engineered microbial pesticides will be filed in the next year or two. To meet requirements of FIFRA, companies will have to submit extensive test data to demonstrate that the organisms will not pose unacceptable environmental and health hazards.

According to Frederick Betz, a biologist and EPA policy analyst, the poten-

tial hazards with genetically engineered microbes are, for the most part, the same as those for nonengineered microbes. (EPA has already regulated 13 microbial pesticides, which have not been genetically altered.) The agency is concerned, for example, about an organism's toxicity and virulence and its ability to reproduce, cause disease, and survive in the environment. Betz says, however, that genetically engineered microbes pose some additional problems and that EPA probably will require extra testing to determine safety. The additional testing would analyze, for example, the stability of the genetic material in an engineered microorganism and the traits to be expressed by the genetic alteration. As a result, EPA may require tests to evaluate these characteristics and information on the genetic engineering techniques used to produce the pesticide.

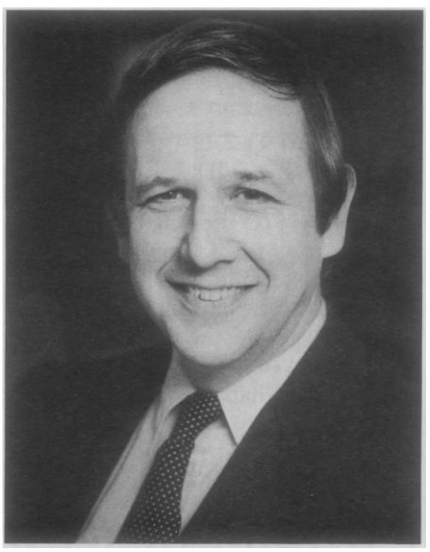
No one is questioning the agency's authority to regulate the commercial production of biological pesticides produced by genetic engineering. But EPA could land itself into controversy because—claiming authority under FIFRA—it intends to play a more active role in the oversight of the field-testing of genetically modified microbial pesticides. This is already a hotly debated area. NIH was recently sued for approving a University of California experiment that would have tested in the environment bacteria designed to prevent frost damage to plants.

The agency plans to change an existing regulation so that companies must notify the agency of their plans to field-test a genetically engineered pesticide. Currently, an application must be submitted to EPA if a pesticide is to be tested on 10 acres or more. But for genetically engineered microbes, EPA now plans to require an application no matter how small the test plot is. Betz said that the regulation is intended primarily to keep EPA informed of the testing.

EPA may already be testing the waters in this area. The Office of General Counsel recently concluded that the frost-preventing organism which University of California researchers want to test is indeed a pesticide. According to Anne Hollander, a policy analyst in the Office of Toxic Substances, the organism can be classified as a pesticide because it hinders a plant pest—its genetically nonmodified counterpart—from promoting the formation of ice crystals in plant tissue. The agency has not said whether it plans to require the California researchers to file for a permit.

Interpretation of the toxic substances act as it applies to biotechnology products is likely to be even more controversial. The act gives EPA the power to regulate new chemicals, but does this mean that the agency can regulate organisms, for example, that could be used to clean up oil spills or to aid in the mining of ores? At a recent meeting of the Industrial Biotechnology Association, David Padwa, chairman of the board of Agrigenetics, asked Clay whether recombinant DNA is a chemical. "Yes," Clay responded. Padwa then asked, "Is recombinant DNA a new chemical?" Clay replied, "I think so."

Clay is not too perturbed about the fuzziness of TSCA's authority to regulate genetic engineering products and the possibility of future lawsuits. "It doesn't upset me. If I win, I win. If I lose, then Congress can legislate new law," he said later. Clay points out that Congress created TSCA to bridge the gaps in environmental regulation, so the act is a logical candidate to govern biotechnology.



EPA's Donald R. Clay

"Companies have already promised they'll sue me."

Hollander points out that unlike pesticide law, TSCA places the burden of proof of safety on the agency, not the producers. Although companies must provide EPA with test data, the chemical's proposed uses, volume of production, worker exposure, and disposal, it is up to EPA to demonstrate that the new chemical poses an unreasonable risk.

EPA plans to rely on the expertise of the NIH advisory committee and other scientists as it sorts out its role in biotechnology. Clay says EPA is also forming a task force with other agencies to discuss the regulation of biotechnology and risk assessment related to environmental release of the microbes. Clay adds, "For a change, EPA is getting ahead of the game."—**MARJORIE SUN**

Dingell Wants Action on NIH Authorization

In an unusual action, Energy and Commerce Committee chairman John Dingell (D–Mich.) has directed members of his committee to work out a legislative compromise to reauthorize the National Institutes of Health (NIH). But whether a deal can actually be struck before Congress recesses for the year is not clear.

Dingell rarely has intervened regarding NIH reauthorization, but this year the legislation is particularly contentious. Members of Dingell's committee have sponsored two vastly different NIH reauthorization bills. Dingell wants them to settle their differences before a House vote in order to smooth the way for its passage. A committee aide said that Dingell wants to avoid "a bidding war" in which legislators' pet projects could be tacked on as amendments to a controversial bill.

Chairman of the health and environment subcommittee, Henry Waxman (D–Calif.), is the sponsor of a controversial bill that would create numerous new programs at NIH. Two Republican committee members, James Broyhill of North Carolina and Edward Madigan of Illinois, have introduced a substitute bill that is a pared-down version of Waxman's bill and is the preference of general biomedical organizations such as the Association of American Medical Colleges. Both bills, however, provide the same funding levels.

So far, the legislators have not gotten very far. A subcommittee aide to Waxman declined to comment on the issue and an aide to the minority side said, "We just haven't been able to find a happy medium."

—**MARJORIE SUN**

House Report Blasts DOE on Oak Ridge Pollution

A strongly worded report released by the House Science and Technology Committee on 3 November takes the Department of Energy (DOE) to task for mishandling a big mercury spill and related problems at an aging