

Regulatory Structure for Biotechnology Proposed

Mindful that biotechnology companies will soon market an abundance of new products and that foreign competition will be intense, the federal government recently issued a report that proposes, it hopes, a coherent regulatory policy to foster this maturing industry. In the report, the federal government outlines how its agencies plan to review and regulate these products, which include drugs, chemicals, pesticides, and organisms. The report suggests, for example, that several federal agencies establish their own review groups similar to the existing Recombinant DNA Advisory Committee at the National Institutes of Health (NIH).

The White House Office of Science and Technology Policy, which is coordinating the government-wide effort, published the report in the 31 December *Federal Register*. Recent court decisions barring certain biotechnology experiments have heightened concern about the regulation of gene-splicing products. The 51-page report describes how the Food and Drug Administration, the Environmental Protection Agency, and the U.S. Department of Agriculture plan to apply current laws, regulations, and guidelines as they pertain to research, development, marketing, shipment, use, or disposal of biotechnology products. The comment period is open until 1 April.

The report proposes a new structure to review biotechnology processes and products. The NIH advisory committee currently reviews proposals for recombinant DNA experiments at federally funded institutions. Companies voluntarily submit research proposals. The federal government now proposes to clone the NIH committee and establish similar committees at the Environmental Protection Agency, the Food and Drug Administration, the U.S. Department of Agriculture, and the National Science Foundation. Each agency committee would principally include scientists experienced in biotechnology. The NIH committee would continue to review gene-splicing experiments related to biomedical research. At the National Science Foundation, which funds a

substantial amount of genetic engineering research, a review committee would be established to examine the potential environmental effects of basic biotechnology research on a case-by-case basis.

All the agency committees would report to a parent committee, a biotechnology science board. The board, comprised of two members from each committee, would be created to ensure scientific consistency among the agencies and address broad issues in the science of genetic engineering. It would be chartered by the Department of Health and Human Services and report to the assistant secretary of health.

Other than that, the report contains no major surprises because the agencies have openly discussed their proposals while the report was being prepared during the past 6 months. The three regulatory agencies say that existing law provides them adequate authority to regulate and that no new legislation is needed. Each says that biotechnology products will be regulated basically by the same laws and regulations that govern similar products produced by conventional methods. Biotechnology products, however, will be reviewed case by case.

The proposed policy by EPA hedges on a point on which the agency previously has taken a stronger position. The agency has indicated that it would exercise oversight authority over biotechnology products manufactured by a variety of genetic engineering techniques, but now EPA has drawn back a little at the urging of the Office of Management and Budget. EPA now says it is not clear whether several of these techniques are actually subject to regulation and is seeking comment. The techniques in question include transformation, transduction, transfection, conjugation, and methods of plasmid transfer. EPA also says that it believes products of gene deletion should be subject to federal law governing toxic substances, but it asks for more discussion. An example of such a product, EPA says, is a bacterium modified by University of California researchers to prevent frost formation on plants. In this case, however, EPA has said that the bacterium, considered a microbial pesticide, would also be subject to pesticide law.

—MARJORIE SUN

U.S. Instruments Fly on Soviet Spacecraft

A unique episode in U.S.-Soviet scientific cooperation was revealed last month by astronomers at the University of Chicago. For more than a year, a team led by astrophysicist John Simpson has been working closely with Soviet scientists to put U.S. instruments aboard twin Soviet spacecraft that will rendezvous with Halley's comet in 1986. The collaboration was announced when the spacecraft were successfully launched shortly before Christmas.

The chance to fly the instruments aboard the Soviet Vega spacecraft arose in a surprising way. Simpson had developed a highly sensitive method for measuring the density and mass distribution of dust particles in a comet's tail, but because the United States had decided not to send a spacecraft to explore Halley's comet, there seemed little chance that it would be used.

Simpson went to an international symposium in Holland in September 1983 to describe the method, in the hopes that the European Space Agency could find room for an instrument on a spacecraft it is planning to send to Halley's comet. The European plans were already too far along to accommodate Simpson's experiment, however.

About a month after the symposium, Simpson got a surprise when he received a telex from the head of the Soviet space institute, inviting him to fly the instruments on the Vega spacecraft.

The Reagan Administration signaled its approval in March, and Simpson secured a grant of some \$300,000 from the National Aeronautics and Space Administration. Two months later, he personally delivered a working prototype of the instruments to the Soviet Union. The two spacecraft carrying the analyzers were launched on 15 and 22 December, and they will rendezvous with the comet in March 1986.

A direct telex link was established between Simpson's lab and Moscow to help plan and design the instruments, modify the software for the spacecraft's computers, and ensure that the instruments would fit in with