~~32916~~
128550

United States General Accounting Office
Washington, D.C. 20548

FOR RELEASE ON DELIVERY
Expected at 9:30 a.m.
Wednesday, December 4, 1985

Statement of
Brian P. Crowley
Senior Associate Director,
Resources, Community, and Economic Development Division
before the
Subcommittee on Investigations and Oversight
of the
House Committee on Science and Technology
on the
General Accounting Office's
Review of the Department of Agriculture's
Role in Regulating Biotechnology

Mr. Chairman and Members of the Subcommittee:

We are here today at your invitation to discuss our ongoing review of the Department of Agriculture's (USDA's) role in regulating biotechnology.

Our review is being done at the request of Chairman Don Fuqua of the full committee and builds on the work we did for our recently issued report to Chairman Fuqua entitled The U.S. Department of Agriculture's Biotechnology Research Efforts (GAO/RCED-86-39BR; Oct. 25, 1985). That report identified 778 biotechnology research projects funded by USDA during the 1984-85 time frame at a cost of $40.5 million. The report also identified

87 of the projects--being conducted in 28 states--that were expected to involve the deliberate release of genetically engineered organisms into the environment within 1 to 5 or more years. Such releases would be done for the purposes of further testing rather than being widespread applications.

Along this line, Chairman Fuqua also asked us to review USDA's programs in the biotechnology area, focusing on how such programs relate to decisionmaking concerning the deliberate release of genetically engineered organisms into the environment. He also asked us to look at the relationship that exists between USDA and other federal agencies with biotechnology responsibilities.

I'd like to make two overall points before I discuss the details on our work. First, this review has not yet been completed. Therefore, our observations today should be viewed as preliminary and subject to change.

Second, as the Chairman requested, our work focused on USDA, but the federal role in biotechnology regulation and research is much broader. Many federal agencies--in accordance with federal health, safety, and environmental laws--have responsibilities with respect to biotechnology research and the subsequent commercialization of the products or processes of that research. For example, the National Institutes of Health (NIH) has played a lead role in biotechnology since the 1970's when it established a Recombinant DNA Advisory Committee and in 1976 published Guidelines for Research Involving Recombinant DNA Molecules.

Other federal agencies include (1) the Food and Drug Administration (FDA), which has authority to regulate food and food additives, human and veterinary drugs, cosmetics, and biological products for medical uses, (2) the Department of Labor, which is authorized to require employers to provide safe working

conditions for employees working in biotechnology areas, and (3) EPA, which has broad authorities to address risk to public health and the environment.

In April 1984 a Working Group on Biotechnology--under the White House Cabinet Council on Natural Resources and the Environment and working through the Office of Science and Technology Policy (OSTP)--was organized to review the government process dealing with biotechnology; in December 1984 the working group published a proposal in the Federal Register for a coordinated framework for regulating biotechnology. We understand that this group is planning to publish this framework in final form in early 1986.

Also, the U.S. judicial process, through several lawsuits, has also had an impact. One suit claimed that NIH had failed to evaluate adequately the environmental impact of deliberate release experiments. Another lawsuit challenged the appropriateness of injecting sheep and pig embryos with DNA material from human growth genes.

USDA's PAST INVOLVEMENT AND PHILOSOPHICAL APPROACH TO REGULATING BIOTECHNOLOGY

USDA has taken an active part in developing and overseeing the new biotechnologies. USDA representatives were active participants at meetings and workshops in the early 1970's where policy decisions were made regarding the federal government's response to concerns about the risks associated with the new biotechnologies. USDA adopted the NIH guidelines and established an internal policy requiring compliance with them as a condition for receiving USDA research funds.

Until recently, the major concern centered on the safety of the biotechnology experiments in the laboratory and the assurances that appropriate containment precautions were being taken and that, even if the organisms used in the experiments did escape the laboratory, they could not survive and thus negatively affect the environment. The overriding fear was that an accidental release from the laboratory of some novel, pathogenic organism could have dire consequences. Our review to date suggests that some of this apprehension has since subsided, at least within the scientific community, as additional knowledge and experience have been gained. The overriding fear now seems to be centered on the deliberate release of a genetically engineered organism, or product, into the environment as a means of further testing.

Until the past year, much of the federal government's oversight of biotechnology research was done by the NIH Recombinant DNA Advisory Committee. Now, however, NIH wants to reduce its role and shift some of its responsibilities to agencies that are more directly involved in specific subject matters. USDA has thus received during the past year several requests or inquiries from private companies concerning proposed releases of agriculturally related genetically engineered organisms into the environment.

Over the years, USDA officials have expressed confidence in their abilities to regulate the new biotechnologies. They said that the agricultural and forestry products developed by these technologies will be basically similar to products of more conventional technology. They also said that USDA's existing regulatory authorities, combined with the NIH guidelines, are generally adequate and appropriate for regulating biotechnology.

USDA officials also cited USDA's overall experience in agricultural research for over 100 years, which they regard as directly applicable to the new biotechnologies, and which has

resulted in immense accumulations of scientific background and knowledge that help guide today's researchers. USDA officials contend that USDA has historically exercised considerable caution with respect to containing and testing potentially harmful organisms and in safely releasing into the environment some 7,500 new varieties of organisms that it determined to be beneficial.

USDA's REGULATORY STRUCTURE

One of our objectives was to determine whether USDA's biotechnology regulatory structure, particularly as it relates to deliberate releases into the environment, was clearly defined and operational. USDA's biotechnology involvement has generally been handled by various USDA agencies, most of which were established before the advent of the new biotechnologies and which have other regulatory and/or research responsibilities. These include the Animal and Plant Health Inspection Service (APHIS), which is responsible for protecting the nation's animal and plant resources from diseases and pests, and the Agricultural Research Service (ARS), Cooperative State Research Service (CSRS), and Office of Grants and Program Systems (OGPS), which conduct and/or oversee much of USDA's agricultural research effort. Also, USDA's Agriculture Recombinant DNA Research Committee (ARRC) was established in 1976 to support the NIH Recombinant DNA Advisory Committee and to oversee and coordinate matters within USDA relating to biotechnology.

Although APHIS, ARS, CSRS, OGPS, and the ARRC are the primary players in USDA with respect to biotechnology regulation, the specific roles of each have not been clearly defined, particularly in regard to deliberate releases into the environment. This has resulted in certain initiatives being independently advanced by some of these agencies and in some signs of struggle within USDA over who is to do what and when. Examples of these independent initiatives, as well as some actions that have recently been taken to help clarify USDA's overall regulatory role, are as follows.

APHIS is the USDA regulatory agency that has had and undoubtedly will have the largest role in regulating biotechnology products. As of November 1985, APHIS' Veterinary Services had approved and licensed for marketing 10 veterinary biologicals produced by the new biotechnologies to treat or diagnose diseases. An APHIS microbiologist told us that dozens of additional genetically engineered biologicals were being considered for approval. He said that APHIS does not expect that the products thus far licensed or under review would be challenged in the same sense that experiments involving, for example, bacteria designed to impede frost formation on plants have been challenged in the courts. This is because none of these products involve live organisms being injected into animals. Such injections are generally not considered to constitute deliberate releases of genetically engineered organisms into the environment. The microbiologist told us that the use of live organisms in similar injections in the future will require more caution and some regulatory or procedural changes.

In another part of APHIS, Plant Protection and Quarantine responded to a company seeking to release a genetically engineered tobacco plant into the environment for experimental purposes. In a June 1985 letter from APHIS to the company APHIS stated that it found no problem with the proposed field test. According to a company spokesperson, the wording of the letter placed a large share of the responsibility for the release on the company. The company official said that his company had decided to hold off the intended tobacco planting for another year. He expected USDA to issue more detailed regulations in the interim, and he was also expecting a response from the NIH Recombinant DNA Advisory Committee regarding the same experiment.

At about the same time, USDA was considering one additional request for deliberate release. This request also involved a genetically engineered tobacco plant. Perhaps as an indication of the uncertainty and inconsistency that exist with respect to USDA's regulation of biotechnology, this request was being handled primarily by the ARRC, as opposed to APHIS, which handled the first request. According to the Chairman of the ARRC, the company submitting the second request had preferred that the ARRC handle it, rather than APHIS.

USDA researchers have expressed some concern about APHIS' biotechnology regulatory role. For example, one researcher told us that the level of research expertise available in the field for dealing with specialized agricultural and biotechnological problems exceeds anything that can be assembled in a centralized regulatory framework such as APHIS'. In this regard, the research side of USDA, particularly CSRS, has been developing what is called the National Biological Impact Assessment Program (NBIAP). Still in the conceptual stage, the NBIAP was being proposed as a means to assess the biological impact of the release of organisms containing recombinant DNA. As proposed, it would describe various procedures involving research, field testing, and commercial release of new products in agriculture and would be organized using scientific expertise in the existing national agricultural research network.

An APHIS official described the NBIAP proposal as being of high quality and importance but stated that the NBIAP cannot serve as the final regulatory authority because of the legal responsibilities APHIS is obligated to enforce.

In a June 7, 1985, letter to OSTP, USDA's Assistant Secretary for Science and Education referred to extensive discussions within USDA regarding the regulatory uncertainties that were being experienced. The letter delineated research and regulatory responsibilities within USDA and proposed that requests submitted

to USDA involving recombinant DNA research or regulation be sent initially to the ARRC. The letter acknowledged, however, that USDA's biotechnology program was a developing one, yet to be further refined. USDA officials we talked with regarded the letter as a breakthrough in resolving key differences within the USDA over how to regulate biotechnology.

In an ARRC meeting held later in June 1985, members discussed how to formalize the ARRC's operations. The discussion resulted in a few specific steps being taken toward greater formalization. For example, a decision was made to establish a subcommittee that would work towards transforming the NBIAP from a concept into a working system. The discussion also involved several other topics that were left unsettled. For example, no action was taken on a proposal to formalize guidelines to facilitate the ARRC's review of requests for deliberate release. Also, despite the June 7, 1985, letter, the discussion reflected continued uncertainty about who in USDA should be the initial focal point for requests for deliberate release and other matters relating to agricultural biotechnology.

As these examples indicate, USDA has been rather deliberate and perhaps even slow in defining clearly the regulatory structure under which it will handle requests for deliberate releases and there are a number of reasons for this. First, USDA has taken the position that its existing regulatory structure relating to plants, animals, and microorganisms has been generally sufficient and appropriate for regulating genetically engineered organisms. USDA also does not want to impose overly restrictive, cumbersome regulations that might stifle growth in biotechnology or in the industries that have sprung from that research.

Second, USDA officials told us that the timing of USDA's decisionmaking in biotechnology is being influenced by OSTP's and other agencies' involvement. OSTP expects to issue a revised version of the December 1984 regulatory proposal early in 1986.

We also noted instances where the ARRC had put off certain actions because of some committee members' desire to wait and see what EPA was going to do.

Third, we were told by one USDA official, and sensed from several meetings we attended at USDA, that there was a high level of concern about lawsuits that have been filed by biotechnology opponents. We sense that USDA wants to proceed carefully because of the expected legal challenges to its future actions.

Information we obtained indicated that in October 1985, USDA was considering establishing in early 1986 a Committee on Biotechnology in Agriculture to replace the ARRC which would be a more formal and strengthened central committee for biotechnology within USDA. The new committee is expected to be consistent with OSTP's expected pronouncement in early 1986 regarding a coordinated framework for regulating biotechnology.

As the above discussion shows, USDA's biotechnology regulatory structure has been undergoing change in recent months and there is apparently more to come. In our opinion, the various initiatives represent steps in the right direction and set more firmly in place the general framework under which USDA will regulate biotechnology. However, USDA does not yet have the procedural details and specificities expected in a regulatory structure--procedures that not only minimize questions about who is expected to do what and when, but that also are flexible enough to encompass a wide range of biotechnological research and product developments.

USDA's RELATIONSHIP WITH OTHER FEDERAL AGENCIES

We were also asked to examine the relationship between USDA and other federal agencies involved in regulating biotechnology.

We found many instances of interaction between USDA and other agencies such as EPA, FDA, NIH, the National Science Foundation (NSF), and OSTP. As noted earlier, USDA has been involved in dealing with concerns about recombinant DNA for over 10 years and much of this involvement has been in conjunction with NIH. USDA's Agriculture Recombinant DNA Research Committee, coordinates research policies and activities not only between USDA and NIH, but also between USDA and NSF.

With regard to regulation USDA and FDA signed a memorandum of understanding in 1982 that resolved jurisdictional questions involving animal biological products. In 1984 a memorandum of understanding between USDA and EPA defined certain general principles of cooperation, coordination, and communication between the two agencies.

One other important instance in which USDA and other federal agencies were working together on biotechnology matters was the establishment in 1984 of the Cabinet Council's Working Group on Biotechnology, whose members come from over 15 departments and agencies.

Although considerable interaction has taken place between USDA and the various other federal agencies, there have been instances of disagreement. But the agencies seem to be able to work things out together. For example, USDA questioned the approach to biotechnology regulation that EPA was taking in its statement of policy published in the December 31, 1984, Federal Register. Under the direction of OSTP, USDA and EPA have been negotiating at the staff level to sort out these differences.

USDA's COMMUNICATION OF ITS VIEWS ON BIOTECHNOLOGY

While reviewing the above issues, we noted that USDA has not been very effective in communicating to the public USDA's views on biotechnology and on the regulatory role it will play. Such communication becomes increasingly important as more biotechnology research moves from small-scale, contained laboratory experiments into experiments involving deliberate releases of genetically engineered organisms into the environment. USDA is expected to play a prominent role in these releases because many of them will involve agriculture in some way. As the number of proposals for release grow, USDA will increasingly become a focal point for public concern about biotechnology activities.

Historically, many of USDA's activities were not matters that received close public scrutiny; therefore, the need to explain them did not arise. USDA officials told us that in the 100 years USDA has been involved in agricultural research, there have been relatively few expressions of concern about what it was doing. According to these officials, USDA has been surprised by the excitement and concern about biotechnology. Recently, however, USDA has begun to recognize the need and has taken steps to inform the public of its biotechnology activities.

We believe that as USDA continues to communicate its position, it will be confronted by the fundamental problem of convincing the public that it is sensitive to the issue of risk and can manage risk effectively. This issue raises important questions and concerns. For example, the prospect of releases of genetically altered organisms (such as bacteria) that may perhaps cover large agricultural regions has stirred considerable concern that any mistakes could be costly and very difficult, if not impossible, to correct. A leading scientist involved in studying bacteria told a conference at the National Academy of Sciences

that he felt uncomfortable with the present uncertainties. Some critics have cited the revolutionary nature of biotechnology, comparing the splitting of the gene with the splitting of the atom, and have tried to persuade the public to look further into the future at the potential, long-term risks of biotechnology.

However, in the various documents that we reviewed and in USDA presentations that we attended, we noted USDA's emphasis on biotechnology's potential benefits. On the other hand, USDA's discussion about biotechnology's potential risks or the reasons it believes certain risks are less significant than some critics allege were not as apparent or prevalent. For instance, we found few references in USDA literature to the possibility of long-term risks. In our opinion, any sign of a pattern of communication that puts too much emphasis on the potential benefits and too little emphasis on the plans for dealing with possible risks creates an impression that the communicator is not sensitive to the risks.

- - - -

As noted earlier, we are preparing a report that will address the above issues in more detail, and we plan to send it to USDA and others for comment shortly. To sum up our observations, we believe USDA needs to get its biotechnology regulatory structure in place. It has already been involved with the licensing of a number of genetically engineered products, and it has recently begun to receive requests for approval to release genetically engineered organisms into the environment. USDA's work load can only be expected to intensify as many companies with substantial investments in biotechnology research begin to push toward commercializing their research products. USDA can facilitate this process only if its regulatory structure is in place, sufficiently defined, and made known to all who must comply with or are otherwise interested in it.

This concludes my statement. We will be glad to respond to any questions.

32916