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STATEMENT FOR THE RECORD BY
BRIAN P. CROWLEY
RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION

FOR THE
SUBCOMMITTEE ON TOXIC SUBSTANCES AND ENVIRONMENTAL QUALITY
OF THE
SENATE COMMITTEE ON ENVIRONMENT AND PUBLIC WORKS

ON THE
GENERAL ACCOUNTING OFFICE'S
REVIEWS OF THE DEPARTMENT OF AGRICULTURE'S
BIOTECHNOLOGY RESEARCH EFFORTS AND
REGULATORY PROGRAMS AND ACTIVITIES

Mr. Chairman and Members of the Subcommittee:

At your request, we are providing this statement to assist you in deliberating the preparedness of the federal government to oversee and regulate biotechnology. The statement highlights two of our recently issued reports having to do with the U.S. Department of Agriculture's (USDA's) biotechnology research efforts and its regulatory programs and activities. These reports resulted from work done at the request of Chairman Don Fuqua, House Commmittee on Science and Technology.

The first report, The U.S. Department of Agriculture's Biotechnology Research Efforts (GAO/RCED-86-39BR, Oct. 25,1985), provided a previously unavailable inventory of biotechnology

research projects conducted or sponsored by USDA in fiscal years 1984 or 1985. Some 778 research projects were identified at an annual cost to USDA of $40.5 million. Of these projects, 87 were expected by the researchers to involve the deliberate release of genetically engineered organisms into the environment within 1 to 5 or more years. The 87 projects were being conducted in 28 states. Such releases are to be done for the purpose of further testing rather than for the purpose of achieving widespread applications.

In conjunction with the above, Chairman Fuqua also asked us to review USDA programs and activities that relate to biotechnology and how such efforts relate to decisonmaking concerning the deliberate release of genetically engineered organisms into the environment. This work is the subject of our recently issued report entitled Biotechnology: Agriculture's Regulatory System Needs Clarification (GAO/RCED-86-59, March 25, 1986). It is from this latter report that we have drawn the remainder of the remarks that are presented to you in this statement.

BACKGROUND/RESULTS IN BRIEF

Little or no evidence exists that harmful, genetically engineered organisms have been created, but few experts believe that the new biotechnologies (particularly the technique of prime interest and concern known as "recombinant DNA") are without risk. This potential risk and biotechnology's broad application have led several federal agencies, including USDA, to regulate the research and commercialization of biotechnology.

USDA helped formulate early policy decisions concerning recombinant DNA research and has helped develop the new biotechnologies. Its future involvement is likewise expected (1) to be significant because much of the research in biotechnology is agriculturally oriented and (2) to intensify because regulatory responsibilities of the National Institutes

of Health-Recombinant DNA Advisory Committee--the federal government's primary overseer of biotechnology until recently--are now shifting to various federal agencies, including USDA. Although this is the case, USDA had not--as of November 1985--formulated a biotechnology regulatory structure (particularly with regard to deliberate releases of genetically engineered organisms into the environment) or provided its Agriculture Recombinant DNA Research Committee with the authority and direction it needed to effectively act as the Department's focal point for biotechnology matters. In addition, USDA had done little to communicate to the Congress and the public both the benefits and risks of biotechnology as well as its plans to minimize those risks.

USDA PHILOSOPHY TOWARDS REGULATING BIOTECHNOLOGY

USDA has stated often that it is capable of regulating and minimizing the associated risks of the new biotechnologies because of its (1) many years of research and accumulation of extensive knowledge and (2) cautious approach to the containment, testing, and deliberate release of organisms into the environment. In addition, it has stated that products developed from the new biotechnologies will be similar to conventional products and can be similarly regulated.

USDA'S REGULATORY STRUCTURE NEEDS CLEARER DEFINITION

USDA has few programs or activities that relate exclusively to biotechnology; rather, its oversight in this area has been handled by agencies within the Department that were established before the new biotechnologies and that have other regulatory and/or research responsibilities. In addition, the Agriculture Recombinant DNA Research Committee was established in 1976 to oversee and coordinate matters relating to recombinant DNA research. Despite such mechanisms and certain recent initiatives to overcome regulatory uncertainty, we concluded

that USDA needed a clearer definition of its regulatory structure, particularly with regard to approving requests to deliberately release genetically engineered organisms into the environment. For instance, the first two such requests submitted to USDA for approval were handled by two different groups within USDA, although the requests were essentially identical. In general, agencies within USDA were struggling for regulatory control, questions remained as to which agency was responsible for what, and the Agriculture Recombinant DNA Research Committee--USDA's designated focal point for biotechnology--lacked authority and direction.

USDA has been hesitant in developing a well-defined regulatory structure because (1) it did not want to impose cumbersome regulations that might stifle growth in biotechnology, (2) the timing and pace of its actions have been influenced by the White House's Office of Science and Technology Policy, which has been examining biotechnology regulation and coordinating the actions of many federal agencies, and (3) several lawsuits filed by opponents of biotechnology have created some anxiety.

Recently, USDA has set more firmly in place a general framework under which it will regulate biotechnology. Still needed at the time of our review, however, were procedural details and specificities expected in a regulatory structure--procedures that minimize questions regarding who is responsible for what but that are are flexible enough to encompass an expected wide range of biotechnology research and product development. USDA also needed to more clearly establish the authority and duties of the Agriculture Recombinant DNA Research Committee, thus giving it the power to effectively act as USDA's focal point for biotechnology.

REDUCING CONCERNS THROUGH IMPROVED COMMUNICATION

The need for USDA to inform the Congress and the public about the benefits and potential risks of biotechnology is expected to intensify as many experiments in biotechnology move toward environmental release. Such communication would (1) lessen the fears aroused by experiments involving deliberate releases of genetically engineered organisms and (2) result in more informed discussions about the speed and/or restrictions under which biotechnology is allowed to proceed.

RECOMMENDATIONS

We recommended in our most recent report that USDA:

--Complete the development of a formalized, well-defined regulatory structure over biotechnology, particularly with regard to deliberate releases of genetically engineered organisms into the environment. We believe such a structure should be sufficiently detailed to minimize questions about who in USDA is responsible for decisions in particular areas and flexible enough to encompass the wide range of biotechnological research and product development expected. It should clearly identify the regulatory procedures for handling requests to license biotechnology products and approve the deliberate release of genetically engineered organisms into the environment. These procedures should help ensure the consistent handling and treatment of such requests.

--Provide the Agriculture Recombinant DNA Research Committee (or any successor to this committee) with the authority, prestige, and sense of direction it needs to effectively act as USDA's focal point for biotechnology. The committee should have the power to resolve

differences that may arise with regard to biotechnology within USDA (e.g., between the regulators and researchers) and to act on USDA's behalf in resolving differences between USDA and other federal agencies, such as the National Institutes of Health, Environmental Protection Agency, and Food and Drug Administration.

--Look for and take advantage of opportunities to improve and increase the communication of its views on biotechnology, both in terms of the benefits to be derived and the risks that must be considered and managed. The purpose of such communication should be to foster a more open, frank, and informed discussion about USDA's views on biotechnology.

In commenting on this report, USDA raised a number of points related to the report's contents. However, USDA's comments did not specifically address our recommendations.

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In closing, we believe that the time has come for USDA to have its biotechnology regulatory structure in place. It has already dealt with the licensing of a number of genetically engineered veterinary biologicals, and it has begun to receive requests for approval to release genetically engineered organisms into the environment for further testing purposes. USDA's workload can only be expected to intensify as many more small-scale, contained experiments conducted thus far in research laboratories progress to the point where further testing in the environment is desired, or, where companies with substantial investments in biotechnology research begin to push towards the licensing and commercialization of the products that have thus been produced. USDA can facilitate these processes, thus generating the benefits of biotechnology and at the same time safeguarding the public and the environment from risk, 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.