

SAFEGUARDS IN A.I.D.  
BIOTECHNOLOGY ACTIVITIES IN AGRICULTURE

Comments of the  
RESEARCH ADVISORY COMMITTEE  
at its January 14-15, 1988 Meeting

Office of Research and University Relations  
Bureau for Science and Technology

January 15, 1988

REVIEW OF SAFEGUARDS IN A.I.D. BIOTECHNOLOGY

ACTIVITIES IN AGRICULTURE

Report to the A.I.D. Research Advisory Committee

Introduction

On September 4, 1987, an ad hoc panel of the Board on Science and Technology for International Development (BOSTID) of the National Research Council (NRC) met at the National Academy of Sciences headquarters in Washington to review the issue of safeguards in A.I.D. biotechnology activities in agriculture. The panel was convened at the request of the Office of Research and University Relations, Bureau for Science and Technology, Agency for International Development (A.I.D.), to provide its views to the A.I.D. Research Advisory Committee (RAC). Annex A lists all panel members and observers at the September 4th meeting.

In its request for a review of safeguards in A.I.D. agricultural biotechnology activities, the panel was asked to discuss the following problems and issues:

1. Should A.I.D. develop its own regulations on biotechnology, or should it adopt those in existence at other U.S. government agencies? What broad topics or subjects should be covered in such regulations for international activities?
2. Is there a need for A.I.D. to assist developing countries in the development of guidelines on biotechnology? Is an international effort necessary so that regulations in the U.S. and other industrialized countries and those of developing countries are consistent?
3. How should regulatory legislation relate to intellectual property rights, commercialization of product, and appropriate utilization of natural resources.
4. Given that A.I.D. is already supporting research and development aimed at the production of vaccines against animal diseases, what precautions should be taken before deliberately releasing genetically engineered animal vaccines in Africa?

This report summarizes the panel's discussions of the above issues for consideration by the RAC at its meeting in January 1988.

The panel specifically came to one general conclusion on the participation of the A.I.D. in regulatory aspects of agricultural biotechnology. That conclusion is designated the panel's "policy statement" as follows:

#### Policy Statement

Given the dynamic nature of biotechnology and its increasing role in A.I.D. projects, the Agency should endeavor to participate actively at all levels of biotechnology regulatory policy-making, both in the federal government and in the international arena, to ensure that the technology is wisely and safely implemented in furtherance of the A.I.D. mission to advance international development.

Discussion: Biotechnology can be seen as a set of tools allowing new approaches to address contemporary problems. It can provide especially relevant means for development that are both technologically appropriate and environmentally sound. It is important that A.I.D. assume the responsibility for promoting the availability and utilization of biotechnological know-how to achieve agricultural and industrial objectives of the developing countries and the United States.

State and federal mission and regulatory agencies involved in biotechnology are primarily concerned with safeguards as they affect U.S. opportunities. A.I.D., with international activities covering a broad range of programs and geographic regions, has a unique opportunity and responsibility to participate in development of regulatory guidance with developing countries that will integrate public health, environmental, ecological, and agricultural guidelines into a progressive and efficient biotechnological regulatory strategy for those countries.

The panel believes that a step in this direction has been taken with the recent establishment of the A.I.D. Intra-agency Biotechnology Standing Committee to furnish in-house consultation on technical, regulatory, and programmatic biotechnological issues and to provide liaison with other federal science and regulatory agencies concerned with biotechnology. However, because A.I.D. is primarily a development agency rather than a science agency and, therefore has a limited number of scientists on its staff, the panel sees a need for an additional, external multidisciplinary advisory group of scientists that are engaged in research and applications of biotechnology to provide the Agency with the best available technical advice on a variety of issues. Furthermore, AID should have a peer review mechanism for biotechnology research grant proposals submitted to the Agency for funding. That process must be a straight forward one which is made to operate efficiently. Such a review process would enhance the Agency's scientific credibility.

Problems and issues presented to the panel for discussion

1. Should A.I.D. develop its own regulations on biotechnology, or should it adopt those in existence at other U.S. government agencies? What broad topics or subjects should be covered in such regulations for international activities?

The panel sees no need for A.I.D. to develop its own set of safeguard regulations on biotechnology. Domestic guidelines already established by federal agencies such as FDA, USDA, NIH, and EPA and that currently are being used by A.I.D. provide adequate bases from which to proceed. There is no legal requirement for A.I.D. to follow these agency guidelines; however, because of the increasing number of agriculture projects underway with biotechnological components, both the Agency's Office of the Science Advisor and the Bureau for Science and Technology have been amending their contracts to include language that requires adherence to Federal guidelines. The panel feels that there is sufficient latitude in those guidelines to cover AID's international activities.

Emphasis also needs to be given to the importance of educating and informing public agencies and environmental groups about proposals for any introductions that may be planned. This should be done well in advance by the appropriate authorities in any given country. AID should include the requirement for public education as a part of its contractual agreements whenever U.S. agencies or companies are involved in one of the Agency's projects abroad.

It should be recognized that A.I.D. projects in biotechnology will catalyze, or drive the need for appropriate action. A.I.D. projects at the Mission level may establish precedents for creation of international regulations and guidelines in the future.

2. Is there a need for A.I.D. to assist developing countries in the development of guidelines on biotechnology? Is an international effort necessary so that regulations in the U.S. and other industrialized countries and those of developing countries are consistent?

Assisting developing countries prepare guidelines on biotechnology is entirely consistent with A.I.D.'s objective to help strengthen capacity building. It should be emphasized, however, that because of special environmental, ecological or even political situations, the strict adherence to U.S. guidelines may not be appropriate or wise. Guidelines recommended must provide necessary safeguards without being too restrictive, or they will be ignored.

International cooperation can promote the acceptance of sound and reasonable guidelines for regulation of biotechnology. Such cooperation has been very successful in the past. For example, an international consensus on pesticides use was achieved through the World Bank's adoption of the U.S. pesticide guidelines and agricultural quarantine was widely accepted after standards were developed by Australian scientists in FAO. The role of international organizations can be very positive. Generally, developing countries more readily accept guidance from international agencies.

3. How should regulatory legislation relate to intellectual property rights, commercialization of product, and appropriate utilization of natural resources?

This is an important issue because of the fact that biotechnology is likely to be heavily developed in the private sector.

There is already a large private sector component interacting with the developing countries on behalf of A.I.D. With the existing patchwork of U.S. federal, state, and local regulations for commercialization as an example, it is obvious that this will be a difficult issue to deal with in relation to the various developing country situations. Caution must be exercised to ensure that regulations are not excessively restrictive. It should be remembered that biotechnology transfer is a two-way street. Regulations should not hinder the flow of biotechnology know-how to the U.S. and should be consistent with the Department of Agriculture policies on access to genetic resources. The United States needs to maintain access to the genetic diversity abroad, including developing countries, and also to the expertise of foreign scientists. The Department of Commerce has been doing studies on biotechnology in Japan and in some of the European countries, and has prepared a position paper on biotechnology activities throughout the world. It is important for A.I.D. and the Department of Commerce to maintain close ties regarding biotechnology in order to avoid working at cross purposes.

4. Given that A.I.D. is already supporting research and development aimed at production of vaccines against animal diseases, what precautions should be taken before deliberately releasing genetically engineered animal vaccines in Africa?

Without considerable deliberation and advice from animal disease experts, the panel does not feel qualified to make specific suggestions at this time about this complex and controversial issue. However, in general the panel urges that A.I.D. work closely with the relevant countries in

Africa to make sure that safety questions and environmental concerns are considered. In cases of planned use of animal vaccines, special agreements on guidelines for their use should be carefully worked out to protect against liability.

#### Recommendations

- An ongoing, multi-disciplinary external advisory committee should be established to provide A.I.D. with the necessary up-to-date, expert technical advice on biotechnology issues. (The importance of including ecologists on the committee was noted, and the inclusion of representatives from developing countries might be considered.) Economy requires that members of the committee know the experience of other agencies and that AID adopt policies employing that experience. Drawing on the advice of this committee, AID will find it useful to adopt regulations concerning biotechnology that can be enforced by an officer of the Agency.
- In addition to regulation by rule, AID might institute a peer review for scientific merit of biotechnology proposals that the appropriate officer of AID believes requires such review. If, in addition, the AID officer enforcing regulations wishes a view on the scientific merit of a matter, he may, of course, seek it from the peer reviewer. Again, in the interest of economy, the committee members should know the experience of other agencies and AID should adopt policies employing that experience.

- A.I.D. should be represented on the federal inter-agency biotechnology committee. A.I.D. with its involvement with biotechnology concerns in the developing world can bring to the inter-agency committee a dimension that is now lacking.
- A.I.D. should work with international organizations on issues of biotechnology regulations such as the Biotechnology unit of the Science and Technology Policy Division of the Organization for Economic Cooperation and Development (OECD) that has already undertaken the development of biotechnology regulatory guidelines for member countries. Another suggestion is that appropriate A.I.D. persons contact the International Council of Scientific Unions (ICSU) through the National Academy of Sciences' Office of International Affairs. (ICSU has in the past developed guidelines for the free circulation of scientists and maybe exploring guidelines for biotechnology.) A.I.D. should also maintain close contact with the Technical Advisory Committee (TAC) of the Consultative Group of International Agricultural Research Centers (CGIAR), which is in the process of formulating a statement on biotechnology concerns.
- The RAC should review the subject of international safeguards in A.I.D. biotechnology in agriculture once again in 12 to 18 months to determine how RAC might be of further assistance to the Agency on this important topic.

Annex A

Discussion Meeting  
Safeguards in AID Agricultural Biotechnology Activities  
September 4, 1987

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