

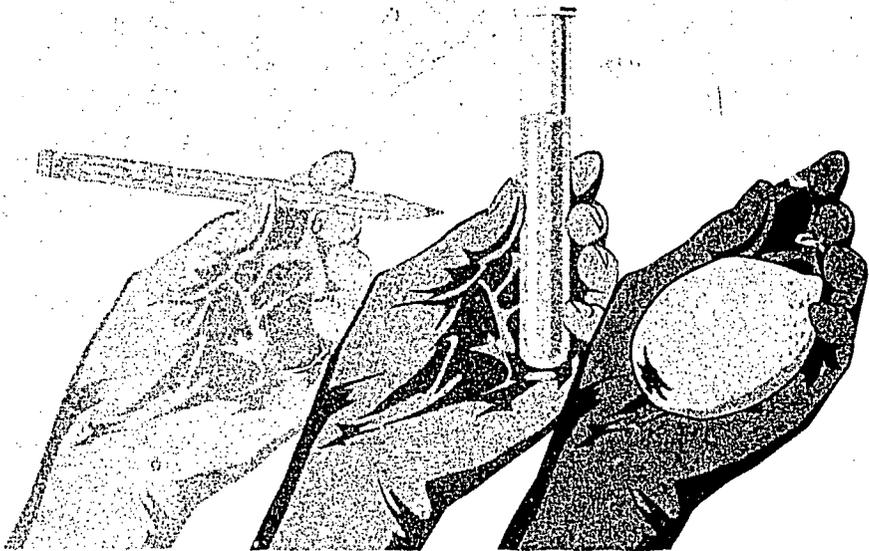
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roceedings of a workshop:

Biotechnology Policy and the CGIAR

The Hague, September 2-6, 1991



BIOTASK

isnar

The mandate of the International Service for National Agricultural Research (ISNAR) is to assist developing countries in bringing about lasting improvements in the performance of their national agricultural research systems and organizations. It does this by promoting appropriate agricultural research policies, sustainable research institutions, and improved research management. ISNAR's services to national research are ultimately intended to benefit producers and consumers in developing countries and to safeguard the natural environment for future generations.

ISNAR offers developing countries three types of service, supported by research and training:

- For a limited number of countries, ISNAR establishes long-term, comprehensive partnerships to support the development of sustainable national agricultural research systems and institutions.
- For a wider range of countries, ISNAR gives support for strengthening specific policy and management components within the research system or constituent entities.
- For all developing countries, as well as the international development community and other interested parties, ISNAR disseminates knowledge and information about national agricultural research.

ISNAR was established in 1979 by the Consultative Group on International Agricultural Research (CGIAR), on the basis of recommendations from an international task force. It began operating at its headquarters in The Hague, the Netherlands, on September 1, 1980.

ISNAR is a nonprofit autonomous institute, international in character, and apolitical in its management, staffing, and operations. It is financially supported by a number of the members of the CGIAR, an informal group of donors that includes countries, development banks, international organizations, and foundations. Of the 16 centers in the CGIAR system of international centers, ISNAR is the only one that focuses specifically on institutional development within national agricultural research systems.

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Introduction

1. A seminar on *Biotechnology Policy and the CGIAR* was held at the International Service for National Agricultural Research (ISNAR) in The Hague, the Netherlands from September 2-6, 1991. The seminar was cosponsored by the CGIAR Task Force on Biotechnology (BIOTASK) and ISNAR. Financial support was provided by the Government of the Netherlands. It was attended by some 70 participants from several national and regional agricultural research programs, bilateral and multilateral development agencies, international agricultural research centers, universities, and other public- and private-sector institutes involved in biotechnology. A copy of the agenda and a list of participants is attached (Annexes A and B).
2. The purpose of the meeting was to discuss *biosafety and intellectual property management*, especially in relation to the activities of the international agricultural research centers (IARCs). The meeting was shaped around these two topics which have emerged as important issues affecting the successful application of modern biotechnology to agriculture. Each topic was addressed by a series of short discussion papers giving a national, regional, or international perspective.
3. The meeting was opened by Dr. Hans Wessels (Chair of BIOTASK) who welcomed the participants to the meeting. The role of BIOTASK is to provide a forum for discussion as part of the CGIAR policy-development process. Dr. Wessels welcomed the presence at the seminar of several senior policymakers from national agricultural research systems (NARS). These policymakers are collaborating with ISNAR on biotechnology. The participants would help to clearly identify the biotechnology policy and management needs of national agricultural research systems. This is important because national needs in reference to the two theme topics might differ from those of the IARCs.
4. Dr. Wessels commented that rapid changes in the field of biotechnology have led some developing countries and international development agencies to view an advisory service on biotechnology and related issues as necessary. This could take the form of an independent advisory service to the NARS on matters of policy and management and on socioeconomic and technical issues. During the week, representatives of several countries, and bilateral and multilateral development agencies would be meeting to discuss the possible establishment of an "Intermediary Biotechnology Service." This service would function as a broker between the developing countries and the expertise of research laboratories in the field. Such a service would complement existing biotechnology networks as well as other initiatives. Its primary clients would be NARS, NGOs, private foundations, and farmers.
5. Dr. Christian Bonte-Friedheim, Director General of ISNAR, welcomed the participants. He stressed the importance of the seminar for increasing public awareness. This is critical for both biosafety and intellectual property management. It is important that activities in these two fields be transparent and that the public be well informed. ISNAR is pleased to be associated with this initiative as part of its work in the policy and management of biotechnology in NARS. ISNAR has been involved in this field since 1988 as one of the cosponsors of the World Bank/ISNAR/Australian Government Agricultural Biotechnology Study.
6. Participants visited Dutch biotechnology institutes in the Wageningen Agricultural Research complex. These include field sites where genetically engineered organisms have been released in

small-scale field trials. A second group visited a private biotechnology company associated with the University of Leiden.

7. The BIOTASK/ISNAR seminar was followed by a meeting at ISNAR on September 5 and 6 of IARC representatives. This meeting was convened by the IARC directors to formulate a draft policy statement on intellectual property management as it affects the international centers. The seminar provided an opportunity to discuss a range of diverse views with the IARC working group prior to their deliberations and preparation of the draft statement.
8. Intellectual property rights are being discussed in various international fora. These include the World Intellectual Property Organization (WIPO), the negotiations on the General Agreement on Trade and Tariffs (GATT), the International Union for the Protection of New Varieties of Plants (UPOV), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Conference on the Environment and Development (UNCED), and the negotiations on an International Convention on Biodiversity. The CGIAR is considering its policy on intellectual property, especially in relation to maintaining the free exchange of germ plasm among its collaborators, and ensuring greater access to new biotechnologies for the benefit of developing countries.
9. The CGIAR is also considering the role of biosafety in the work of the IARCs, their host countries, and their collaborating NARS. This matter is also the subject of much international debate in fora such as UNCED, EC, OECD, UNIDO, and FAO as the international harmonization of biosafety regulation is sought.
10. A second working group, on biotechnology country studies, met at ISNAR on September 5 and 6. This meeting was attended by several participants representing national programs and others collaborating with ISNAR on a series of biotechnology country studies in Colombia, Indonesia, Kenya, and Zimbabwe. A brief report on this meeting is provided in Annex C.

Overview of Biotechnology Policy Issues

11. The opening session of the seminar was devoted to a paper by Prof. G. Junne of the University of Amsterdam, who gave an overview of the emerging issues in biotechnology relevant to developing countries.
12. For a number of reasons the global patent situation has changed considerably in recent years. This is partly due to the proliferation of participants conducting research at the global level.
13. Following the 1970 economic crisis, many of the large multinational companies, major investors in research, concentrated on their core business, relying more on subcontractors for ancillary products. This led to an increase in cooperative research, and necessitated protection of product and process information. Many of the new intercompany links were of a non-equity nature, which added to the need to protect partners not part of the parent company.
14. There has been an increasing tendency toward strategic alliances among firms in different countries. This has provided an opportunity to capture the benefits of technological change on an international scale in a much shorter time period than the traditional step-by-step marketing strategy. However, this type of cooperation also increases the need for protection.
15. Global research has been accelerated by international projects, such as EUREKA, an EEC-promoted project. There has also been an increase in cooperation between the private sector and universities brought about by the rapid development of advanced techniques.
16. The shift in the global research structure has heightened the degree of protection sought by the private-sector enterprises that invest heavily in research. This has led to a major increase in the rate of new patent applications. If this continues, licensing procedures may have to be simplified, possibly bringing about a new generation of problems. Companies may have to change their strategies to accommodate possible changes in export markets arising from the introduction of new technology. Some degree of license sharing may become necessary in order for them to retain momentum without having to again broaden their core businesses.
17. Prof. Junne pointed out that there is limited information available addressing the impact of intellectual property rights (IPR) in industrial and developing countries. In industrial countries, intellectual property rights act as a stimulant to research and development, to investment in the use of new technology, and to the diffusion of new technologies by making them commercially available to the public.
18. In contrast, some effects of IPR in developing countries may be less positive, or even negative. For example, the stimulatory effects of IPR on research and development may be limited for several reasons:
 - markets are often small and protected;
 - research is conducted mainly by the public rather than the private sector;
 - foreign firms active in this field often carry out development rather than research in-country, thus creating few new inventions for them to patent.

19. The stimulus of IPR with respect to investment in the use of new technology in developing countries might be limited by the following factors:
 - local investors tend to prefer "available" technology which is often cheaper and has lower maintenance costs;
 - markets are small and are often protected by entry barriers;
 - IPR tends to protect imports rather than products, and this might be an additional disincentive.

20. In stimulating the diffusion of new technology in developing countries, IPR may have limited effects because:
 - the channels for spreading new knowledge are often less developed;
 - patent information is published mainly in the markets of the North;
 - patent information in the North is more accessible;
 - diffusion depends on the willingness to grant licenses, but this may be limited in developing countries where the main object is to protect exports.

21. However, IPR could serve as a stimulus to the use of new technologies by encouraging cooperation with foreign companies.

22. In the discussion, several speakers stressed the need for case-by-case examinations of the likely costs and benefits of intellectual property rights for countries of different sizes and at different stages of economic development. Several Latin American countries, for example, have undertaken such studies and have decided to proceed with a patent system tailored to meet their particular situation. Also, Kenya has recently enacted a new patent law.

23. Prof. Junne also stressed the importance of biosafety in the context of the diffusion of biotechnology. Biosafety is important not only from the standpoint of the prevention of risks but also in order to gain public acceptance of the products of biotechnology. A recent EEC survey indicates that this acceptance bears little relationship to the public perception of risk but was, to some degree, correlated with the degree of public awareness. The survey also shows that, from the standpoint of biosafety, the public at large appears to place more confidence in the opinions of consumer and environmental organizations, than in the opinions of politicians, the public sector, or scientists.

24. Recent world events have increased concerns about biosecurity (the control of biological agents) at the expense of biosafety (containing their spread). Prof. Junne suggested that export controls on biotechnology in the future may be more burdensome for countries of the South than for those of the Eastern Block. This can hinder the diffusion of biotechnology products.

Biosafety

International Initiatives

25. Dr. Peter van der Meer, of the Dutch Ministry of the Environment, introduced the discussion on biosafety by drawing attention to the many national and international initiatives on biosafety in progress. Important international initiatives are OECD guidelines, the European Commission (EC) Directives on Containment and Release, the Inter-American Institute for Cooperation on Agriculture (IICA) guidelines for field releases in Latin America, the papers prepared by the Council of Europe, and a joint working group of UNIDO/UNEP/WHO/FAO. The environmentally sound management of biotechnology is also one of the 10 priority themes for the United Nations Conference on Environment and Development (UNCED), due to take place in Brazil in June 1992.
26. Proponents of these various initiatives all stressed three steps to avoid duplication with other initiatives — to review existing material, to identify common elements, and to define areas for further work. In his paper, Dr. van der Meer focused on the common elements found among the various international initiatives and on the many national biosafety guidelines and regulations that now exist.
27. He defined the following elements as being common to all:
 - considerations of the organism, including genetically manipulated organisms;
 - adherence to the step-by-step principle in developing an approach to biosafety;
 - recognition that risk assessment and risk management are complementary and necessary activities;
 - understanding of the difference between containment and release;
 - accepting the need for a clear and transparent framework for safety in biotechnology.
28. In considerations of the organism itself, it is important to recognize that biotechnology represents a continuum of techniques which people have practiced throughout history. Current discussions of biosafety tend to focus on genetically manipulated organisms (GMOs). If the organism and the techniques adopted are well understood, the predictability of the end product's behavior will be high and the risk involved in its use will be minimal.
29. With respect to the step-by-step process, there is a need to progress first from the laboratory to small-scale field trials, to larger-scale field trials, and then to commercial release. These steps need not be overly rigid. The degree of safety built into them should be related to the knowledge of the organism concerned. OECD-developed principles for risk management are now widely used. Field practices based on these principles allow some flexibility in containment and control practices.
30. Risk assessment involves a careful prior review of available information before the technology is applied. Risk management involves consideration of safety factors and careful monitoring once the organism is released.

31. With respect to containment, it is possible to categorize procedures based on past experience, and to set conditions and exemptions based on these. There is rather limited knowledge about release, and safety considerations often need to be established on a case-by-case basis.
32. Finally, in terms of establishing an overall framework for biosafety, it is important to be as transparent as possible to encourage investment in biotechnology. This might mean voluntary guidelines or legislation are required. Dr. van der Meer supported international harmonization of such guidelines. He was optimistic that additional moves in this direction might follow the UNCED deliberations, particularly with respect to risk assessment and management.
33. In the general discussion, Dr. Val Giddings (USDA) stressed that a flexible approach to biosafety is important because of the wide range of products involved. This view was endorsed by Dr. Peter Dart from the University of Queensland in Australia, who pointed out that most plant releases are modified plants rather than genetically engineered organisms. The discussion then turned to the experience being gained in individual countries in the development of national biosafety systems.

National Policies and Experience

Latin America

34. Dr. Walter Jaffe of the Inter-American Institute for Cooperation on Agriculture (IICA) and Dr. William Roca of the International Center for Tropical Agriculture (CIAT) had prepared a paper on the current status of biosafety in Latin America.
35. IICA has carried out a major study of policies in Latin America and has produced a set of biosafety guidelines for the region. For laboratory containment, these are based on the guidelines of the U.S. National Institutes of Health. For field release, IICA established a study group of 30 to 40 scientists, including representatives from North and South America, to work on developing appropriate guidelines. This approach is intended to facilitate harmonization of biosafety approaches throughout Latin America. While this may not be possible throughout the region as a whole, the prospects for harmonization at a subregional level appear promising, particularly in the five Southern Cone countries where IICA is closely associated with guidance on a series of economic initiatives.
36. Latin American governments recognize a need to incorporate biotechnology into the economy in order to retain competitiveness. However, current indigenous biotechnology capabilities are few and tend to be academically rather than industrially oriented. In these circumstances, the main source of the introduction of biotechnology is likely to be technology transfer. The pace of technology transfer has been hindered by biosafety considerations in countries such as Mexico and Chile. Thus, there is internal pressure to resolve those uncertainties in order to facilitate access to new technologies.
37. Biosafety needs to be considered part of both the broad policy for development and the more specific policy of strengthening the country's science and technology capabilities. Biosafety policy is necessary for safeguarding the public and the environment. It is also needed both to offer an adequate climate for foreign investment and to maintain public confidence in the new technology. Biotechnology is not presently confronted by an antagonistic environmental lobby in the region. There is an opportunity to develop a rational, regional approach to biosafety in Latin America.
38. From a review of scientific capability in the region, based on current publications, it appears that few Latin American institutes have a strong genetic engineering capability at the present time. Also, limited attention has been given to biosafety considerations. Furthermore, most existing biotechnology projects are in the private rather than the public sector.

39. In the current regulatory situation, most countries have neither guidelines nor regulations governing the release of genetically engineered organisms. In terms of containment, Brazil, Cuba, and Mexico have used laboratory guidelines based on those of the National Institutes of Health (NIH) in the United States. Mexico has also taken preparatory steps for legislation regarding genetically modified organisms. With respect to environmental release, little action has been taken so far. Mexico has a working group studying its first application for the release of a transgenic organism. In Cuba there is a discussion under way regarding the establishment of guidelines for biosafety with respect to release.
40. In terms of opportunities for biotechnology, the prospects in Latin America appear to be particularly good. There are opportunities for technology transfer from industrial countries.
41. However, these prospects are constrained by the limited expertise in the region and a regulatory infrastructure that has been weakened by economic factors. In such circumstances, the biosafety strategy has either been to adopt a wait-and-see approach until more experience accumulates outside the region, or to take a case-by-case approach permitting maximum flexibility through the absence of formal regulations. Current moves toward a subregional approach to the harmonization of biosafety policies were welcomed.

Asia: Philippines

42. Dr. William Padolina of the University of the Philippines at Los Baños spoke on biosafety policy development in the Philippines. Dr. Dely Gapsin (ISNAR) made additional comments in the light of her experience in developing biosafety policy at the Philippine Council for Agriculture, Forestry and Natural Resources Research and Development (PCARRD). Dr. Padolina also drew attention to the current number of international activities in biosafety. There are various initiatives, all of which have made progress but lack sufficient coordination.
43. In the Philippines, a Biotechnology Implementation Plan for the period 1991-1995 is being put in place. This provides research and development support for bioindustries, facilities for strengthening institutes working in biotechnology, funds for manpower training, and guidelines for environmental protection. In addition, the plan gives particular priority to six special research areas including the production of penicillin, diagnostics, tissue culture, the development of value-added products from coconuts, the disposal of urban wastes, and reforestation.
44. With respect to biosafety, an executive order signed by the President of the Philippines in October 1990 established a National Committee on Biosafety responsible to the Minister of Science and Technology. This committee has no policing powers of its own but is charged with making guidelines on risk assessment and management, relating biosafety to the existing quarantine system. The committee should, where necessary, offer advice on the formulation of new legislation. It is formed by representatives from a range of interested parties including government agencies and independent scientists.
45. In addition to the national committee on biosafety, any institute working on biotechnology should have an Institutional Biosafety Committee (IBC). The functions of this committee should parallel those of the national committee. Each IBC is charged with ensuring that its institute complies with the national guidelines. It is composed not only of staff from the institute but also independent persons from outside. One scientist at each institute is designated as the biotechnology safety officer. Research involving a biosafety element must be cleared by the IBC before it is passed to the national committee for approval. In normal circumstances such approval should take no more than eight weeks.
46. Public awareness of the national guidelines for biosafety is good in the Philippines. This is because the guidelines were the subject of public hearings conducted before any genetically modified organisms were released. The national guidelines have not involved new legislation. They cover exotic organisms as well as genetically modified organisms and deal with

biotechnology production and research. In this context, exotics include the products of conventional breeding for which specific exemptions may be permitted.

47. During the discussion, several speakers questioned the need for modern biotechnology (recombinant DNA technology) guidelines to include provisions for the products of conventional plant breeding. Dr. Padolina stressed that the inclusion of conventional breeding has presented no problems because the research products involved have usually had little difficulty in complying with the guidelines. It is, however, necessary to be flexible.
48. The need for flexibility was also stressed by Dr. Giddings (USDA) who said that in the United States Department of Agriculture the practice is to provide permits for release not more than 120 days after receipt of the application. Both in the United States and in the Philippines, permit applications are usually made after some preliminary discussions and consultation. The United States, however, has a large staff and budget for dealing with the approval of release permits. This enables a full-scale environmental assessment which might be difficult in many other countries.
49. A particular issue raised was the possibility that an applicant who had been denied a permit for release in a country with strict regulations could transfer his application elsewhere, where risk-assessment skills and experience were lower. Some participants feel that this possibility strengthened the case for the harmonization of international guidelines on release.

Africa: Kenya

50. The final paper in the second session came from Mr. Jeremiah Rutto and Mr. C. Kariuki of the Kenya Agricultural Research Institute (KARI). This paper outlined the present status of biotechnology in Kenya and discussed likely future directions. A biotechnology policy developed, but not yet released, by the National Advisory Committee on Biotechnology Advances and their Applications (NACBAA) was guided by the views of a national conference on plant and animal biotechnology held in Kenya in 1990.
51. In Kenya, work in biotechnology is being undertaken in several national and international institutes. Biosafety is largely handled at the institute level. General rules and regulations have been enacted in Kenya's law dealing with plant quarantine, public health, and environmental safety. These laws are based on those of industrial countries. It is considered desirable to develop a set of national biosafety guidelines tailored to the specific needs of the country. Such guidelines could be produced by a specialist committee with the responsibility for risk assessment and management. Such a committee could be closely linked to the proposed new National Biotechnology Center in Kenya in order to capitalize nationally on its experience and expertise.
52. Criteria for the importation of genetically modified organisms might include the following:
 - whether there is risk of the imported organism becoming a major pest,
 - whether the organism already exists in Kenya,
 - whether the modified organism is used elsewhere,
 - whether the containment facilities are secure,
 - whether field trials are proposed,
 - whether accidental escape can be contained.

IARC Approaches

Crop-related biosafety

53. Dr. John Dodds from the International Potato Center (CIP) outlined the approaches to biosafety taken by the international agricultural research centers concerned with crop improvement. He noted the spectrum of techniques available ranging from conventional breeding to molecular techniques.
54. The particular biosafety concerns of the IARCs are:
 - the location of most of the IARCs in the center of origin of their target crops;
 - the wide germ plasm distribution networks;
 - the need for the IARCs to cooperate with biosafety systems not only in their host country, but with many client countries;
 - the need for risk assessment procedures, including the potential for wide crosses with related species;
 - the question of liability;
 - the clarification of the role of the Institutional Biosafety Committee, now established in most IARCs with crop-improvement programs;
 - the relation of biosafety to quarantine, as in most IARCs there are efforts to integrate biosafety into the normal precautions and quarantine procedures used for intercountry movement of germ plasm;
 - the need for consumer acceptance, taking as an example the health care field, where several recombinant DNA products were put on the market with much less controversy than the agricultural field releases;
 - the need to make information available to the public, as the CGIAR could play a more active role in raising public awareness on biotechnology, including safety considerations.

Animal-related biosafety

55. Dr. John Doyle (ILRAD) provided some practical insight into what is involved in managing a biotech laboratory in Kenya under acceptable guidelines for good laboratory practices. He described practicing suitable safety procedures as simply part of the "cost of doing business" in molecular biology.
56. The linkages between ILRAD and the host country (Kenya) with regard to biosafety were discussed. ILRAD follows the appropriate Kenyan regulations where these exist. Where they do not, ILRAD works on the basis of the Swiss guidelines of good laboratory practice, as these are acceptable worldwide. In this context, the institutional biosafety committee at ILRAD covers not only recombinant DNA research, but also the use of radioactive materials and other dangerous chemicals.

Plenary Discussion

57. In the discussion on biosafety, there was support for the development of rational biosafety policies at the national level. The three national/regional papers indicated that experience in biosafety is accumulating in the developing countries. While a number of countries have been examining the need for new legislation in this area, those participating in the seminar were basing their biosafety policies on existing legislation, especially quarantine legislation, within

which appropriate guidelines could be developed. This use of existing legislation was adopted by a number of OECD countries. It contrasts with that of the EC where new legislation will shortly be enacted. The main reason for new EC legislation is that national legislation is not compatible among the member countries.

58. The existence of national guidelines and National Biotechnology Committees in both the Philippines and Kenya is relevant to the IARCs because both countries host IARCs. The IARCs in these countries may wish to share their experiences in working with host-country biosafety systems with other centers and other NARS. Given the need for flexibility, this may be a useful discussion topic within the IARCs.
59. Risk management was referred to by several speakers. However, little had been said about how it should be dealt with. Dr. Giddings referred to USDA having a US \$6 million budget for full-scale environmental assessment of all potential releases. Obviously, few governments can afford this kind of expenditure. The comments made on the need for simplifying and crafting approval procedures based on worldwide experience were important.
60. Dr. Jaffe made the point that the economic situation in many Latin American countries has led to budget reductions for regulatory services. The services have limited capacity to assess risks even if biosafety guidelines are available. Some degree of international harmonization of guidelines would be helpful. Dr. van der Meer suggested that the UNCED process could be useful in fostering the international harmonization of guidelines. Dr. Jaffe illustrated how a regional approach was being used — especially in the Southern Cone countries of Latin America. Mr. Rutto (Kenya) suggested that a regional approach might be appropriate in terms of biosafety and biological control in Eastern Africa.
61. A lengthy discussion included the subject of whether the CGIAR system needed a system-wide policy on biosafety or if this could be better handled by the individual IARCs, as is presently done.
62. A potential difficulty discussed at length was the situation where an IARC, its host country, and its client countries each have different biosafety policies and procedures. Regional or global harmonization of biosafety guidelines, possibly based on the OECD guidelines, would thus be advantageous to the CGIAR system. Any policies or procedures adopted by the CGIAR and its IARCs should be sufficiently flexible to adapt to emerging international harmonization.
63. The meeting consensus was that the details of biosafety policy and procedures were best handled by the individual centers in the context of their research programs, their mandate crops, and the current status of biosafety policy and procedures in their host and client countries.
64. It would be useful if the CGIAR could make a public statement regarding the key principles it expected to see included in the biosafety policies and practices of CGIAR-supported IARCs. Such a statement is important, as the issue of biosafety is important to the environmental and development communities in many donor countries. CGIAR donor members would find it helpful to have a CGIAR system-wide statement to which they could refer. A preliminary statement of principles prepared for discussion at the meeting is attached as Annex D.

Intellectual Property Management

International Initiatives

65. Dr. Jeroen van Wijk of the University of Amsterdam gave an overview of the international debates on intellectual property being conducted by the World Intellectual Property Organization (WIPO), in the GATT negotiations, and in the negotiations for a new UPOV convention. Significant developments are summarized in Tables 1-4.

Table 1: Comparison of Main Provisions of Plant Breeders' Rights Under UPOV 1978 and 1991, and Patent Laws in General.

Provisions	UPOV 1978	UPOV 1991	Patent Law
Protection Coverage	Plant Varieties of Nationally Defined Species	Plant Varieties of all Genera and Species	Inventions
Requirements	<ul style="list-style-type: none"> • Distinctness • Uniformity • Stability 	<ul style="list-style-type: none"> • Novelty • Distinctness • Uniformity • Stability 	<ul style="list-style-type: none"> • Novelty • Inventiveness • Nonobviousness
Protection Term	Min. 15 years	Min. 20 years	17-20 years (OECD)
Protection Scope	Commercial Use of Reproductive Material of the Variety	Commercial Use of All Material of the Variety	Commercial Use of Protected Matter
Breeders' Exemption	Yes	Not for Essentially Derived Varieties	No
Farmers' Privilege	In Practice: Yes	Up to National Laws	No
Prohibition of Double Protection	Any Species Eligible for PBR Protection Cannot be Patented	None	None

Source: J. van Wijk, University of Amsterdam

Table 2: Patenting Living Material in the United States and in Europe

	United States	Europe
Micro-organisms	1980	1973
Transgenic plants	1985	1989
Triploid oysters	1987	
Transgenic mammal	1988	1991
Human cell lines	1989/90	
Human genes	1990	

Source: J. van Wijk, University of Amsterdam

Table 3: New Minimum Standard for Global Patent Protection

1. Patent term for 20 years.
2. Protection of products directly obtained by patented processes and of products per se
3. Compulsory licensing only in limited cases.
4. Adequate enforcement possibilities.
5. No exclusions from patentability.

Table 4: Three Routes to Upgrade the Global Patent Standard

U.S. Trade Act: "Special 301" provisions
GATT "TRIPs"
WIPO "Harmonization"

Options for the IARCs

66. The discussion of intellectual property management within the CGIAR system was built around a working paper prepared by Prof. John Barton of Stanford University and Dr. Wolfgang Siebeck of the World Bank. The paper, entitled *Intellectual Property Issues for the International Agricultural Research Centers: What are the Options?*, was presented by Dr. Siebeck. The executive summary and conclusions are given in Annex E.

National and Regional Approaches

Latin America

67. Dr. Jaffe (IICA) presented the first paper in this session entitled *Intellectual Property Rights in Agriculture: A Perspective from Latin America and the Caribbean*.
68. Dr. Jaffe reviewed the status of breeding and biotechnology capabilities in Latin America. Most plant breeding is carried out in the public sector, meaning that the NARS, supported by the IARCs, play a crucial role. In a few countries a seed industry exists. In many cases it is in the hands of multinational companies who dominate particularly the market for hybrid seed. Varieties for high-value agricultural export commodities such as flowers, fruits, and vegetables are almost all imported, as are genetic stocks for the livestock industry.
69. A small biotechnology-based industry exists in the region. Most of its activities are in micropropagation. Biotechnology resources are located mainly in academic institutions; in some countries, these have considerably advanced biotechnology capabilities.
70. Within the general context of the intellectual property rights discussion it is important to recognize that many countries in the region are now implementing new economic development strategies to replace their traditional import-substitution approach. These new strategies include characteristics important in the context of IPR.
71. First, through reduction or elimination of tariffs and other trade barriers, the economies of these countries are becoming more open. This policy has been pursued in conjunction with the development of a number of regional and subregional trade initiatives. The accelerated trend towards free trade highlights the need for harmonization of IPR legislation, either within trade groups, or internationally.
72. Second, the role of the state in economic development is being revised in almost every country. Widespread privatization of state enterprises and other economic activities is one result of this. Because these embrace the production of seeds and other agricultural inputs by public-sector institutions, a need is emerging for intellectual property regulations that will facilitate private/public-sector relations.
73. Third, the new economic strategies often call for export-led growth which often involves agricultural or agroindustrial products. This requires market access. Increased competition in many markets, combined with a lack of a strong local plant breeding industry, makes access to advanced technologies a crucial aspect to the success of agricultural development strategies in the region. This access will increasingly depend on the existence of internationally accepted IPR protection.
74. The current status of IPR in agriculture in Latin America and the Caribbean is rather weak for biological processes and products. Presently plant breeders' rights (PBR) exist only in Argentina, Venezuela, and Chile. Under pressure from both local industry and outside countries, particularly the United States, this situation is changing rapidly. A new patent law has been passed in Mexico. New laws are under discussion in several other countries. Brazil and

Colombia are discussing the implementation of plant breeders' rights. It seems likely that a number of countries are moving towards adoption of UPOV or a similar model for plant variety protection. A number of discussions are taking place within a regional context, so that some form of harmonization of IPR appears probable in Latin America.

75. In many countries, one constraint to the introduction of IPR in the agricultural sector is the absence of systematic information about IPR in agriculture. This is particularly relevant in terms of analyzing the likely impact of IPR on national and regional research and development and on the local seed industry.
76. There appears to be a general consensus, particularly in the seed and plant propagation industry, on the need to introduce some form of plant breeders' rights (PBR). This seems to be associated with an increasing willingness to consider adherence to the terms of the original UPOV convention. There are, however, some doubts about the proposed changes to UPOV in 1992.
77. Changes in attitude regarding IPR and PBR are related to regional concerns about increasing privatization of agricultural technology, both in terms of access and the use of indigenous plants and animals. How to take local advantage of the increased value of these resources is an issue, in addition to financing for their conservation and characterization.

Africa

78. Dr. Calestous Juma, Executive Director of the African Center for Technology Studies (ACTS), spoke about Biotechnology Management in Africa: Changing Perceptions on Intellectual Property Management.
79. There has been considerable interest in the application of biotechnology in Africa, despite the absence of policies to promote the use of these techniques. The growth in interest has been accompanied by changes in perceptions about the role of intellectual property protection in development.
80. Dr. Juma argued that the emerging views on intellectual property issues differ qualitatively from the perceptions of the 1970s and 1980s. The changes have resulted from the growing recognition of the importance of scientific research and conservation of biological diversity for long-term economic development. These need to be encouraged through economic incentives and other related measures. Environmental issues are being extended into the domain of biotechnology research and development. This is occurring in a manner that could influence criteria for patentability.
81. Traditional arguments against intellectual property protection in several African countries are giving way to approaches that attempt to broaden the regimes of protection. This has arisen from interest among developing countries in treating genetic resources as sovereign resources having intrinsic value. Some African countries, notably Kenya, have perceived the establishment of intellectual property institutions, such as a patent office, as a route for gaining access to scientific information. This latter role may be at least as important as the traditional role of filing patents. The challenge for international research institutions will now be how to balance traditional views of open exchange of intellectual property, with the new perception of genetic resources as sovereign rights. With regard to the latter, it is important to gain a better understanding of traditional property rights, particularly in pastoral societies where traditional law may be more widely used than modern law.
82. Many industrial countries are arguing for harmonization in intellectual property legislation. It is likely that some countries will introduce independent legislation on genetic resources, complicating the issue of intellectual property protection. There is a risk that the introduction of germ-plasm-related clauses in legislation on issues such as intellectual property and cultural heritage will impinge on biotechnology development. The environmental issues referred to

earlier have only recently acquired legitimacy as issues of public concern. They were not previously considered on a par with issues such as health, safety, and morality. The broadening of public-interest concerns to include environmental issues adds yet another obstacle to the establishment of intellectual property rights through measures such as patents.

Asia

83. Dr. H. Krishan Jain of ISNAR addressed the question of plant breeding rights in India, where there is currently no form of IPR protection. Plant breeding in India has traditionally been in the public sector, where the policy has been to develop a large number of varieties suitable for different agroecological situations. This approach optimizes farmer income and thus is preferable to the introduction of a small number of widely used high-yielding varieties. The situation is now coming under pressure due to the development of a local seed industry. Dr. Jain considered that much of the progress in the development of high-yielding varieties had been facilitated by the free exchange of genetic material. This could be undermined by IPR legislation.
84. A number of questions about the practicality of new legislation were raised. These touched on ownership of the benefits of material held in gene banks, and how these benefits should be assessed and distributed. Dr. Jain considered the valuable component of new germ plasm to lie in the molecular biology techniques rather than in the source material. Dr. Torres (Colombia) commented on the difficulty in assessing benefits. He said that about 90 percent of the value of crop production in Colombia came from imported varieties and that, although there was a megadiversity of genetic material in the country, it was not necessarily an advantage in terms of the output value of agricultural production.

International Approaches

IARC experience

85. Dr. Doyle gave a brief review of ILRAD's experience in applying for a patent to protect a new recombinant vaccine it developed in partnership with a private pharmaceutical company. ILRAD's Board of Management had decided some years ago that, given the fact that most of ILRAD's research program was in the field of molecular biology, it was necessary for the center to be able to seek patent protection for its inventions. This protection was particularly important if it was to collaborate seriously with other public and private research agencies. Patent protection was to facilitate access to new technologies emerging from advanced laboratories, and ensure that potentially useful techniques could be applied to African animal health problems in a timely manner.

Large-company experience

86. Mr. Tim Roberts of ICI Seeds outlined the approach taken by private companies in protecting their inventions. A lively discussion ensued on the desirability of the IARCs exchanging material with private companies under material exchange agreements which ensured return to the IARCs, should any of the material prove to be commercially useful. Such agreements are now common practice among plant breeders. It is to the advantage of the centers to use such agreements as a standard requirement for interchange with advanced laboratories.

Small-company experience

87. Dr. Jan von Rompaey of Plant Genetic Systems (PGS), Belgium, described several existing collaborative arrangements between IARCs and PGS as examples of collaboration with a new

biotechnology company. One option was that the IARC could be responsible for distributing the resulting product in the developing world, while the company would market the product in industrial countries. This may be possible for a commodity such as potato with world-wide markets. It was less relevant for subsistence food crops such as cassava, with no markets in OECD countries.

CGIAR Policy Development

88. The wide-ranging discussion on IPR at the seminar formed the basis for the working group which met at ISNAR on September 5 and 6 to formulate a draft policy statement on intellectual property issues. This statement was considered by the Center Directors, TAC, CGIAR and BIOTASK, in October 1991 during International Centers Week in Washington, D.C. A revised statement will be considered by the CGIAR at its meeting in May 1992.

Annex A: Seminar Program

Sunday 1 September

18:00-20:00

Welcome Reception Park Hotel

Molenstraat 53, The Hague

Monday 2 September

Biotechnology and Biosafety, Opening Session

08:00-09:00

Registration

ISNAR, 6th Floor

09:00-09:15

Opening Remarks
Ir. H. Wessels, Chair., BIOTASK

Dr. Christian Bonte-Friedheim,
Director General, ISNAR

09:15-10:00

Keynote address

Prof. G. Junne, University of
Amsterdam

10:00-10:30

Coffee

National Policies and Experiences in Biosafety, Chair., Dr. Val Giddings, USDA

10:30-11:00

Overview of global initiatives on
biosafety systems

Dr. P. van der Meer
Dutch Ministry of the Environment

11:00-11:30

Biosafety policy development in
Latin America

Dr. W. Jaffe, IICA, and Dr. W.
Roca, CIAT

11:30-12:00

Biosafety policy development in the
Philippines

Prof. W. Padolina, UPLB, and Dr.
D. Gapsin, ISNAR

12:00-13:30

Lunch

13:30-14:00

Biosafety policy development in Kenya

Mr. J. Rutto, KARI

IARC Approaches to Biosafety, Chair., Prof. C. Chetsanga

14:00-14:45

Plant biosafety policy and procedures at
the IARCs

Dr. J. Dodds, CIP

14:45-15:30

Animal biosafety at ILRAD

Dr. J. Doyle, ILRAD

15:30-16:00

Coffee

Plenary Discussion, Chair., Dr. V. Giddings, USDA

16:00-17:30

CGIAR policy on biosafety

Panel Discussion

Tuesday 3 September

Field Visits

09:00-17:00

Group 1: Visit to Dutch biotechnology institutes in Wageningen and field sites for release of genetically engineered organisms.

09:00-12:00	Group 2: Visit to Mogen, University of Leiden	
12:00-14:00	Lunch	ISNAR
14:00-17:30	Group 2: Working Group on Intermediate Biotechnology Service	Ministry of Development Cooperation, The Hague
19:00-22:00	Seminar Dinner	Goude Hoofd, Groenmarkt 13, The Hague

Wednesday 4 September

CGIAR Policy on Intellectual Property

IPR Policy Issues, Chair., Dr. H.K. Jain

08:30-08:45	Introduction	Dr. Lukas Brader, Chair., Center Directors, Ad-Hoc Committee on Intellectual Property
08:45-09:15	Overview of international activities on intellectual property	Dr. J. van Wijk, University of Amsterdam
09:15-09:45	Selected international activities	Prof. J. Barton, Stanford University
09:45-10:15	Options and issues on intellectual property for the CGIAR	Prof. W. Siebeck, World Bank
10:15-10:30	Coffee	

Regional Approaches, Chair., Prof. Yongyuth Yuthavong

10:30-11:00	Intellectual property rights in agriculture: a perspective from Latin America and the Caribbean	Dr. W. Jaffe, IICA
11:00-11:30	Biotechnology management in Africa: changing perceptions on intellectual property management	Dr. C. Juma, ACTS
11:30-12:00	Perspectives on intellectual property in India relevant to the CGIAR	Dr. M. Sharma
12:00-13:30	Lunch	

IARC Experiences, Chair., Prof. Norah Olembo

13:30-14:00	ILRAD's experience in patenting rDNA vaccines	Dr. J. Doyle, ILRAD
14:00-14:30	Intellectual property protection for plants: an industry view	Mr. T. Roberts, ICI Seeds
14:30-15:00	Intellectual property management — perspective of a new biotechnology company	Dr. van Rompaey, Plant Genetic Systems
15:00-15:30	Coffee	

Plenary Discussion

15:30-17:30	Forum on CGIAR policy development on intellectual property	Panel Discussion, Chair., Dr. L. Brader, IITA
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Annex C: Report on the Biotechnology Country Studies Working Group

ISNAR, The Hague, September 5-6, 1991

Introduction

ISNAR, with support from the Government of the Netherlands, is conducting biotechnology country studies in Colombia, Indonesia, Kenya, and Zimbabwe. Participants of these four countries were present at the BIOTASK/ISNAR seminar on Biotechnology Policy and the CGIAR. Their contributions were valuable in developing CGIAR policies towards biosafety and intellectual property.

The seminar was followed by a two-day workshop at which the experience of the participants in developing biotechnology policy, programs, and procedures was discussed in detail from a national perspective.

The country studies provide an overview of current and planned public- and private-sector activities in agricultural biotechnology. The studies address the following issues:

- the current status of biotechnology efforts,
- agricultural and policy constraints,
- the potential for biotechnology, and
- priority areas in which donors can assist.

On the basis of the studies, there was a discussion of government policies, biosafety, intellectual property, information, and priorities for small-scale farmers, in relation to biotechnology.

Indonesia

Dr. Ibrahim Manwan, Director of the Central Research Institute of Food Crops, of the Agency for Agricultural Research and Development (AARD), presented a report on agricultural biotechnology in Indonesia.

Indonesia has been formulating its biotechnology policy since 1985 with the support of the Ministry of Research and Technology. A National Committee on Biotechnology coordinated its implementation. Dr. Manwan is national coordinator for agricultural biotechnology. With regard to intellectual property, the Indonesian patent law excludes plant and animal varieties, in general, and food crops, in particular, from patent protection.

Indonesia appreciates the need for national biosafety guidelines because the country wants to cooperate with foreign companies. A major effort in biotechnology capacity building and manpower training is supported primarily through a World Bank loan.

Major bilateral support comes from JICA (Japan) and USAID. There are also smaller bilateral programs with several other donors, including Australia (AIDAB/ACIAR), France, and the Rockefeller Foundation.

The problem of setting priorities in a dual agricultural economy was raised during the discussion. As yet, there is limited back-up support for biological applications for small-scale farmers. This is primarily because biotechnology's potential is little known by the extension services.

Zimbabwe

Prof. C. Chetsanga, Chair of the National Scientific Research Council in Zimbabwe, and Vice-Chancellor of the University of Zimbabwe, presented a paper on the current status of agricultural biotechnology in Zimbabwe. The main constraints on the application of biotechnology in Zimbabwe are:

- lack of manpower and training,
- limited access to technology,
- limited access to equipment, and
- restricted access to information.

There are no biosafety guidelines in Zimbabwe. The Research Council of Zimbabwe is preparing guidelines on request from the university and private companies wishing clarification on future regulations before making investments in biotechnology.

Zimbabwe is a member of ARIPO, the regional patent organization, and a member of WIPO. Plant and animal varieties are presently excluded from patenting. In the near future, Zimbabwe is likely to support patents in biotechnology.

In the discussion, the need was stressed for countries to define a framework for collaborative research focused on a limited number of topics. Priorities must be based on the national comparative advantage. For some countries with a shortage of manpower trained in biotechnology, it may be preferable to concentrate on the application of technology developed elsewhere, instead of developing national high-tech research capacity.

Kenya

Prof. Norah Olembo, Chair of the Department of Biochemistry, University of Nairobi, presented a paper on agricultural biotechnology in Kenya. Mr. Jeremiah Rutto (KARI) gave an additional presentation on KARI's programs.

The national policy for biotechnology is defined in three fora:

- the Ministry of Research, Science and Technology,
- the National Council for Science and Technology,
- the National Advisory Committee on Biotechnology.

In the past few years there have been several workshops on biotechnology in Kenya (e.g., Plant Biotechnology Workshop in 1989, and the National Conference on Plant and Animal Biotechnology in 1990).

Many institutes are becoming involved in biotechnology: KARI; University of Nairobi; Kenyatta, Egerton, and Moi Universities; and ICRAF, ILRAD, and ICIPE. There is scope for greater private investment in biotechnology. There was a workshop on university-industry cooperation in June 1991.

In the discussion, Dr. Calestous Juma, of the African Center for Technology Studies (ACTS), Nairobi, discussed the constraints to implementing the stated biotechnology policies in Kenya. Although the Science and Technology Policy is intended to support biotechnology, surrounding policies frustrate the future of the science.

Customs regulations, for example, are impediments to the import of fragile restriction enzymes. And this was unfortunately a common situation in developing countries in general. An integrated research policy, including infrastructural aspects, strategic alliances, and market analyses is needed.

Colombia

Dr. Ricardo Torres, Research and Development Policy Advisor of Colciencias, presented a paper on the status of agricultural biotechnology in Colombia.

The Colombian policy on biotechnology focuses on capacity building (human resource development), establishment of regulations (biosafety and IPR), and an institutional framework (joint ventures), in order to develop priority products. Colombia aims to produce efficient agricultural biotechnology products for the local market and for export.

Although Colombia has several research institutes, the potential for biotechnology is underestimated because of the lack of high-level specialists. University-industry cooperation is weak. An IPR committee is investigating the adoption of IPR laws in order to obtain foreign technology through international cooperation. At present, there is no specific biotechnology policy for small-scale farmers.

Plenary Discussion

Government policy

Although short-term results are needed to maintain political support, major outcomes of biotechnology will take 10 to 20 years. In the meantime a pro-science climate is needed. Dr. Juma (ACTS) said that governmental biotechnology policies are too often restricted to specific research institutes and neglect to create an enabling environment for innovations. Such an environment could be created through tax laws, venture capital, and tax-free equipment imports. Technology investors in Singapore, for example, can obtain up to 200 percent tax deduction.

Biosafety

Two conflicting perspectives determine the discussion on biosafety guidelines — the national sovereignty of developing countries with respect to laws and regulations, and the need for harmonized biosafety regulations in order to stimulate biotechnology transfer. The best approach is global harmonization according to OECD, IICA, NIH, or comparable guidelines. Biosafety regulations will be a consistent part of the management aspects of a biotechnology program. Its financial consequences should be an integral part of the project budget. Development agencies should take this into account in project preparation.

Intellectual property

The impact of IPR policies on developing countries was discussed in depth. Several participants believed that germ plasm has political value. A large stock of germ plasm derived from developing countries is stored in international gene banks. Developing countries want to claim

their historic rights to their natural resources to balance the new IPR laws. This issue is being considered in the preparations for UNCED, and in the intergovernment negotiations for a convention on biodiversity.

Information

Access to information was identified as a key factor in the development of biotechnology. There was a discussion on the usefulness of networks. The consensus was that networks cannot be installed from above but must grow from the mutual objectives of scientists.

Priorities in biotechnology for small-scale farmers

There were two presentations on the possibility of targeting biotechnology more directly to the needs of small-scale farmers.

Dr. J. Bunders of the Free University (Amsterdam) presented the "interactive bottom-up approach" which can be used in the identification of biotechnology for small-scale farmers. She acknowledged the fact that one cannot focus only on small-scale farmers because the global population increase requires yield increases through the use of advanced systems.

Meanwhile, biotechnologies are used by few small-scale farmers. The supposed trickle-down effect did not work. Dr. Bunders proposed that local teams of farmers, scientists, and policymakers should identify guidelines for the selection of biotechnology priorities.

Dr. Krishan Jain (ISNAR) argued that modern agriculture is under discussion. The NARS are under operational constraints and while the biotechnology policies in NARS are short-term, it will take 20 to 30 years before modern biotechnology reaches the majority of small-scale farmers. NARS should focus in the meantime on intermediate technologies with a high income-generating factor. In the case of biotechnology, this would mean that developing countries should focus on the more conventional biotechnologies, such as biological nitrogen fixation and tissue culture. These do not require huge new centers, but can make use of existing equipment and resources. Advanced biotechnology innovations should be bought from abroad.

Discussion participants commented that biotechnology will not solve inequalities between small-scale and large-scale farmers. One could try to focus on smallholder constraints through such programs as disease-resistance breeding for smallholder crops.

According to Dr. Jain only the larger developing countries can afford to build local high-tech capacity. There is a danger that new biotechnology institutes will become white elephants. On the other hand, local capacity is needed to absorb technology and help define local biotechnology research policy.

Conclusions

1. Government policies are needed which do not stimulate biotechnology in isolation, but include organizational and infrastructural aspects. Scientists should educate policymakers through national scientific research councils.
2. The development of biotechnology for small-scale farmers must be an integrated process, including marketing and processing of primary products. Technology should be sustainable in relation to environmental conditions, and should take absorption capacity into account.

3. Presently, intermediate-level biotechnology may be the best option for some developing countries. High tech is not always the most appropriate.
4. Copies of the country studies can be obtained from ISNAR. DGIS will use these studies in the identification of priorities in its biotechnology program in the four countries mentioned.

Annex D: Draft CGIAR Statement on Biosafety

1. The CGIAR system sees the need for an overview statement as to the current status of biosafety at the IARCs, the guidelines which they follow, and the desirable approaches to ensure that the IARCs maintain "good laboratory practice," and incorporate new developments in biosafety into their policies and procedures in a timely manner.
2. The CGIAR system is implementing a tiered system of responsibilities for biosafety. The components of the CG system concerned with biosafety are:
 - the international agricultural research centers (IARCs),
 - national agricultural research systems (NARS),
 - the Consultative Group of bilateral and multilateral development agencies,
 - the Technical Advisory Committee (TAC) to the CGIAR.
3. The principles for biosafety procedures at the IARCs are:
 - The IARCs should follow the national biosafety guidelines of their host country where these exist.
 - In the absence of national guidelines, the IARC should develop its own self-regulating guidelines based on internationally accepted guidelines such as those developed by the OECD.
 - The IARCs should encourage their national collaborators to adopt a regional approach to biosafety, in order to foster the international harmonization of biosafety policy and procedures.
 - The CGIAR should be supportive of the attempts in various fora to foster international harmonization of biosafety policy and procedures.
 - In Latin America, the IARCs should consider adopting the IICA recommendations, which propose a regional approach to biosafety.
4. Guidelines should be framed so as to support existing regulatory agencies and existing legislation as much as possible.
5. The IARCs should adopt biosafety systems which give maximum flexibility, in order to enable new scientific developments to be incorporated into the systems as quickly as possible.
6. The IARCs need to continue to keep abreast of new developments in biosafety, including risk assessment procedures. This information may best be provided on a system-wide basis.
7. ISNAR has a special responsibility in relation to the NARS. ISNAR should keep itself informed of recent developments in biosafety and should be able to advise NARS on the establishment of appropriate biosafety systems (either directly, or indirectly by referral to other specialized sources of advice).

8. **Bilateral and multilateral development agencies need to consider providing additional support for risk assessments, where the IARCs or NARS have novel products ready for widespread release. This support may come from funds earmarked for environmental issues.**

9. **Bilateral and multilateral development agencies need to consider providing training opportunities to those in individual countries responsible for the development and implementation of national biosafety systems.**

10. **The guiding principle in the development of biosafety policies and procedures should not be what is possible to regulate, but rather what is essential to regulate.**

Annex E: What Are the Options?

Intellectual Property Issues for the International Agricultural Research Centers: What are the Options?

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Executive Summary

Many of the international agricultural research centers are increasingly concerned about whether they ought to protect their innovations as intellectual property, a protection they have rarely sought in the past. Three developments feed this concern: (1) the rise of biotechnology and its growing importance for the Centers' research; (2) the "privatization" of agricultural research, meaning the increasing importance of private industry in agricultural research as well as the growing practice of public research institutions of protecting their innovations against use by unauthorized third parties; and (3) the tightening of national and international legislation and conventions that protect intellectual property.

This study has been commissioned by the CGIAR Secretariat, in consultation with the chairman of the Group of Center Directors. Its purpose is to review whether the above concerns suggest a need to modify the current "open-door policy" of the Centers with respect to germ plasm distribution and the release of innovations developed at the Centers, and, more broadly, to evaluate the options available to the Centers.

The study reviews the trends in biotechnology research and in intellectual property law described above. It then considers the factors affecting four policy issues for the Centers, both in general and in the context of specific categories of Centers:

- To what extent can the current open-door policy be retained?
- What is the feasibility of income generation from patenting and licensing?
- Would proprietary protection hinder or help in bringing research results to the farmer?
- What are the benefits and risks of cooperating with developed-nation industry to obtain access to patented biotechnologies?

Conclusions

Our review leads to the following conclusions:

1. The trend within the international research community to protect intellectual property has advanced too far to be ignored by any CGIAR Center. The Centers will increasingly find that the

technology they need is subject to intellectual property protection and that an effective way to disseminate their innovations will be through private-sector collaborators, often under exclusive rights. Moreover, as many developing countries are likely to adopt or strengthen intellectual property protection over the next several years, breeders will seek protection also in developing countries for advanced material of importance to their markets in both industrial and developing countries, e.g., soybeans.

2. Much of the activity of the Centers can continue without intellectual property protection and without breaking with the Centers' traditions of open scientific exchange. This will be particularly true for Centers working in countries that have not extended intellectual property protection to plants and biotechnology and for Centers whose mandate crops have little commercial interest for industrial country markets.
3. Under current policy, Centers should not restrict the flow and release of unimproved germ plasm including germ plasm which has been screened and characterized. They may wish to consider changing to a policy of safeguarding their bargaining position by requesting a material transfer agreement to be routinely signed by institutions that will not reciprocate a Centers' free exchange policy. In contrast, Centers may consider licensing their improved germ plasm to breeders and producers who intend to market it in industrial countries with little or no additional breeding.
4. Only rarely will intellectual property protection and commercialization in industrial countries be a lucrative option for the Centers. However, Centers scoring research advances in areas of high commercial interest should consider acquisition of patents in industrial countries, not so much as defense against seeing their innovations appropriated by third parties (that is better done through publication) but as bargaining chips to maintain access to proprietary technologies. There might be cases in which a Center should patent an exceptionally important invention as a source of income, but these would be rare.
5. As it will be imperative for the Centers to continually gain access to new proprietary technologies of potential use to developing countries, they will require understanding of patents and licensing; acceptance of commercial materials subject to restricted use will also entail acceptance of restrictions on the free intersystem exchange of materials.
6. Finally, each Center should carefully review the institutional linkages by which its innovations reach the farmer and should protect its innovations when such protection is likely to help in marketing the innovations to developing-country farmers.

In order to help the Centers in defining and executing such policies, we recommend that:

1. The CGIAR should establish a set of intellectual property policies and guidelines, within which individual Centers would define their own rules and procedures. Such a policy statement should lay down the ground rules to which the Centers will adhere when structuring their "upstream" relations with technology providers and research collaborators. It might also sketch out the new partnerships Centers are looking for in their "downstream" relations with breeders and the seed industry in developing countries. The policy statement should consistently reflect the position the Group and its Centers take on related issues (e.g., on genetic conservation and biodiversity) and should therefore also serve to contain the risk that expanding intellectual property protection will eventually slow the flow of germ plasm.
2. Individual Centers should draw up their own rules and procedures to provide for the following:
 - i. germ plasm distribution;
 - ii. standard networking arrangements likely to be needed to bring in outside technologies and, to the extent reasonably predictable, the kinds of proprietary restrictions that may be accepted, and of Center innovations they would consider patenting;

- iii. in-house procedures for controlling proprietary information, employee agreements, relationships with patent counsel, periodic reviews of intellectual property changes in host and other countries, and reviews of intellectual property trends affecting their mandate crops.
3. At least in an initial phase, and until Centers have built up sufficient capacity to manage their intellectual property, they should consider the creation of a central facility to provide basic advice and to refer Centers to legal counsel appropriate to their specific concerns. Such a facility should also allow Centers and their staff in charge of intellectual property management to exchange information and experiences on patent and plant variety matters. During the start-up of this new activity, Centers should arrange, perhaps with the help of other international agencies and intellectual property groups, workshops to help their scientists, their staff working on intellectual property issues, and their colleagues from national programs, to understand the basic concepts as well as the costs and benefits associated with intellectual property, and to ensure that the technical aspects of the law not hinder their mission.

The study also includes an annex outlining in-house policies and procedures for implementing a patent program and a tabulated overview of intellectual property protection in developed and developing countries.

Annex F: Acronyms and Abbreviations

- AARD:** Agency for Agricultural Research and Development
- ACTS:** African Center for Technology Studies
- BIOTASK:** CGIAR Task Force on Biotechnology
- CIAT:** International Center for Tropical Agriculture
- CIP:** International Potato Center
- CGIAR:** Consultative Group on International Agricultural Research
- FAO:** Food and Agriculture Organization of the United Nations
- GATT:** General Agreement on Trade and Tariffs
- GMO:** genetically manipulated organisms
- IARC:** International Agricultural Research Center
- IBC:** institutional biosafety committee
- IICA:** Inter-American Institute for Cooperation on Agriculture
- ILRAD:** International Laboratory for Research on Animal Diseases
- IPR:** intellectual property rights
- ISNAR:** International Service for National Agricultural Research
- KARI:** Kenya Agricultural Research Institute
- NACBAA:** National Advisory Committee on Biotechnology (Kenya)
- NARS:** National Agricultural Research Systems
- NIH:** National Institutes of Health
- NGOs:** nongovernmental organizations
- OECD:** Organization for Economic Cooperation and Development
- PBR:** plant breeders' rights
- PCARRD:** Philippine Council for Agriculture, Forestry and Natural Resources
Research and Development
- PGS:** Plant Genetic Systems (Belgium)
- UNCED:** United Nations Conference on Environment and Development

UPOV: International Union for the Protection of New Varieties of Plants

UNCED: United Nations Conference on the Environment and Development

UNCTAD: United Nations Conference on Trade and Development

UNIDO: United Nations Industrial Development Organization

UNEP: United Nations Environment Programme

USDA: United States Department of Agriculture

WIPO: World Intellectual Property Organization