

**Issues in Genetic Resources No. 1, May 1994**

# Material transfer agreements in genetic resources exchange - the case of the International Agricultural Research Centres

**John H. Barton\* and Wolfgang E. Siebeck\*\***

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\* Professor-at-Law, Stanford Law School, USA and

\*\* Legal Consultant, Washington, DC, USA

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The Convention on Biological Diversity, which provides incentives for countries to exercise sovereign rights over genetic resources in their territories, has led several countries to develop policies and strategies governing the conservation and use of genetic diversity, including conditions for its release. A system is required to facilitate the unhindered movement of genetic resources and the fair and equitable sharing of benefits derived from their use. This publication, a contribution to the debate on these issues, suggests mechanisms by which these objectives might be achieved.





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## Foreword

The Centres of the Consultative Group on International Agricultural Research (CGIAR) collectively maintain the world's largest international collection of genetic resources. As this has been assembled in cooperation with countries and institutions world-wide, the Centres do not claim ownership of the materials: they are held in trust for the world community and are available without restriction to all *bona fide* users. The policy of unrestricted access has proven to be a very effective way for the CGIAR to meet the needs of its partners, particularly in developing countries.

There has been an increasing tendency for countries to develop national policies and strategies which, directly or indirectly, place restrictions on the free flow of genetic resources. This trend is supported by the recently concluded agreement on Trade Related Intellectual Property Rights (TRIPS) in the Uruguay round of negotiations under the General Agreement on Tariffs and Trade (GATT), which requires the implementation of intellectual property protection legislation over plant varieties by signatory nations. In the wake of the coming into force of the Convention on Biological Diversity many countries have also begun to develop national policies and legislation to govern the conditions under which access will be granted to the genetic diversity found within their borders

These developments threaten the free flow of genetic resources between nations and bring into question the role of the in-trust international collections of the CGIAR. The ability of these collections to continue to serve the needs of farmers and plant breeders throughout the world is dependent on the adoption of policies which allow unrestricted access while ensuring the benefits derived from their use are shared equitably.

This publication is a contribution to the current debate on the related questions of access to genetic resources and compensation for the exploitation of these resources. While the concept of Material Transfer Agreements, described in these pages, was primarily developed to meet the needs of the International Agricultural Research Institutes, it may also have promise as a mechanism for facilitating the exchange of genetic resources between countries. Under the proposed agreements, genetic resources would be made available to the CGIAR Centres - and thus to the global community based on the formal understanding that the material would not be subject to appropriation and that source nations would derive benefit from its provision, either collectively through participation in the multilateral system, or directly from the user of the germplasm.

A global strategy for the sustainable conservation and use of genetic resources requires the commitment of the world community to safeguard the total diversity of valuable plants. The success of this strategy in turn requires an understanding of the interdependence of nations in relation to plant genetic resources and a global commitment to ensure that the material remains accessible to those who need it. It is hoped that this study will provoke further thought and discussion on appropriate mechanisms to enable these goals to be achieved.

Geoffrey Hawtin  
Director General  
International Plant Genetic Resources Institute



## **I. Summary and Recommendations**

Material Transfer Agreements (MTAs) are routinely used by for-profit organizations to transfer genetic material. Increasingly they have gained acceptance also among public not-for-profit laboratories, particularly in the USA. They are contracts that can be tailored to the specific needs of the parties that conclude them. Should the International Agricultural Research Centres in the CGIAR use MTAs when they receive or distribute genetic material? To date there has been no need to do so. The Centres received genetic material without conditions, and could therefore release it without conditions.

In the wake of the negotiations of the Convention on Biological Diversity, adopted in 1992, which recognizes a country's sovereignty over plant genetic resources on its territory, several countries have begun developing policies on the release of germplasm. Such policies are expected to condition the release of genetic material from their territory upon recognition of their claims to compensation and technology access as defined in the Convention. This could lead to a hardening of the terms under which countries release genetic material to the Centres, unless the Centres can effectively safeguard the rights of source countries. This suggests the need to rethink the Centres' current policy of free and unconditional germplasm distribution, and to examine what the Centres could do to support the efforts of developing countries in realizing their claims to compensation and technology transfer under the Convention on Biological Diversity.

There is no doubt that the interest of the global community in a vigorous agricultural research activity is best served through a system that allows for the exchange of genetic material with minimal restrictions. The developing countries share this interest, because without making their genetic material available to the user community they will not realize their rights to compensation and access to technology.

The crucial question then is how to safeguard the interests of source countries without narrowing the exchange of genetic material. For the Centres, arrangements that require them to control the flow of material into and out of their collections would divert resources from agricultural research into administrative tasks.

In this situation, we basically see three possible responses for the Centres: (1) they would continue to freely distribute genetic material they currently hold and accept new material only from countries and sources that make it available without restrictions; their support to genetic resources conservation, agricultural breeding, and technology transfer would be seen as fulfilling the rights of developing countries under the Convention on Biological Diversity; (2) they would help maximize profits for developing nations from trading their genetic resources, by distributing Centre material under MTAs that require profit-sharing upon successful commercial exploitation, collect payments and place them in a fund to the benefit of source nations or all developing nations; or (3) they would facilitate the realization of source country rights to compensation and technology transfer without disrupting or jeopardizing the operation of their genetic resources collections.

We believe that Centres should pursue option (1) as long as they can maintain sufficient access to genetic resources from developing countries. However, we anticipate that for the reasons mentioned this will no longer, or not much longer, be acceptable to the developing world. At the same time, because it would divert scarce resources from research tasks, we cannot support option (2) under which the Centres would act as collection agents for source countries. We believe option (3) would represent a fair compromise. Although the Centres would not take responsibility for arranging compensation, they would significantly facilitate possibilities for source nations to realize access to technology and sharing of profits through negotiations with users.

In order to focus consideration of the compromise proposal, both within the CGIAR and within the broader community of source nations, user groups and the NGO community, we prepared a set of draft MTAs and a draft policy statement to be issued by individual Centres.

Under our proposal, a Centre would require a recipient

- to acknowledge the source nation's contribution in publications and variety descriptions
- to notify the Centre of any transfer of the material or its derivatives to a third party, and to require a similar restriction when transferring the material to that third party
- to file a report on pre-breeding/evaluation results
- in the event of successful commercialization of research products deriving from the material, to provide a reasonable share of net profits to the source nation in an amount and a form to be agreed upon between the recipient and that nation. This could be through payments, training assistance, technology transfer, or other forms of collaboration.
- to observe the following restrictions concerning intellectual property:
  - (a) not to seek rights on the material itself, and
  - (b) not to assert rights on derivatives in the territory of the source country and other developing countries, unless the recipient has actually marketed a product containing the technology in the source country and other developing countries within five years after issuance of such rights, or the derived material traces less than one fourth of its lineage to the material obtained from the Centre

The recipient's obligations should lapse after a period of, say, 30 years.

The Centre would be required

- to notify a recipient of the name and agency of the source nation that has provided the material, and of the possible interest that country may have in the material under the Convention on Biological Diversity.
- to track the destination of distributed germplasm to the first recipient (first-round releases). Either periodically or upon request, the Centre would advise the source nations of releases effected during a specified period. At the choice of the source nation this information would be available in hardcopy or machine-readable form.
- to monitor the filing of pre-breeding/evaluation data by recipients and make them available from its database to source nations on request.

Similarly to the recipient's obligations, a Centre's obligation to notify, track and monitor should also lapse after a period of, say, 30 years. A Centre may still want to maintain the procedures beyond such date, but should have the discretion to terminate them.

The proposed arrangements add substantial new commitments to the obligations the Centres already have as trustees. We do not see commitments to facilitate source country interests as interfering with their obligations as trustees: importantly, material obtained by the Centres on the proposed conditions would still be available worldwide for research and development. The added obligations on the Centres reflect the evolving international understanding of trusteeship and a task whose costs the Centres will have to bear in conducting their mission in a changing environment.

We believe that it is essential for the Centres to take a uniform approach in setting their policies as to what restrictions to accept on material obtained in the post-Convention era. Should any one Centre accept germplasm on terms more favourable to the source than do others, similar terms will be demanded of all Centres and by all suppliers. It would seem imperative that these terms be explained to and reviewed with a representative number of source nations and user organizations before they are applied.

Individual Centres should depart from the standard terms uniformly applied by all Centres only to the extent required by their genuinely different situations. Our analysis focused primarily on agricultural plants. Thus, a Centre such as ICLARM and the future international livestock development centre working with animal genetic material, or Centres such as ICRAF and CIFOR working with material that may have agricultural as well as medical applications, may have different needs. Only differences at this level should lead to special rules and policies.

The proposed set of form agreements and the rules and clauses may not satisfy the various interests involved. They may not go far enough for some developing countries, who want to present a stronger claim for compensation and technology transfer. The user industry may well oppose the proposed rules as too burdensome, and argue that

they cannot use material with the proposed strings attached. Yet, both sides should realize, that, imperfect as it is, the proposed compromise option offers benefits to both. It will allow the breeding industry continued access to the international germplasm collection effort; while for the source countries it levels the playing field by providing them access to information on users and breeding results they previously did not have, as well as facilitating compensation.

Beyond this, we realize that the future global collaboration in the exchange and development of germplasm, on which both the South and the North depend, will only work in a spirit of mutual understanding and fair play. Material transfer agreements can lay the basis for this collaboration but cannot replace the spirit.

## II. Introduction<sup>1</sup>

Genetic resources are the key raw material of the international Centres and their genebanks. These institutions collect, screen, sort, characterize, improve and distribute these resources. They make them available to users and researchers in developing and developed countries without restrictions. Most do not charge for the cost of handling the material. To date they have also enjoyed unrestricted access to germplasm from countries in both the developing and developed world.

There is broad concern that this era of free germplasm exchange is coming to a close. On the one hand, research in the private sector is playing a growing role, and this sector considers intellectual property protection for research products as essential for successful commercialization.<sup>2</sup> On the other hand, source nations, particularly among developing countries, are asserting control and ownership rights over germplasm found within their territories. This is a central implication of the United Nations Convention on Biological Diversity, signed at Rio de Janeiro in June 1992.

<sup>1</sup> The authors wish to thank Leanna M. Lamola (JD 1993, Drake University Law School) for her research assistance and Dan L. Bagatell (JD 1991, Stanford Law School) who prepared a background paper of great value under a Rockefeller Foundation grant to Stanford Law School.

<sup>2</sup> For general background see W. Reid *et al.*, *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development* (World Resources Institute, 1993); E. Brandt, "Sharing of Biological Research Materials: A University Perspective," 1 *University Int'l Prop. Rev.* 1 (No. 3, Fall 1993); J. Brinton, "Biotechnology Licensing: Issues from the University Perspective," 16 *AIPLA Q.J.* 479 (1988-89); G. Karny, "Biotechnology Licensing," *Licensing L. and Bus. Rep.*, May-June 1985 at 1; P. Kelly & E. Jaworski, "Agreements Covering Exchanges of Biological Materials," 3 *Trends in Biotechnology* 22 (1985); C. Lipsey *et al.*, "Protecting Trade Secrets in Biotechnology," in *Practising Law Institute, Protecting Trade Secrets* (1986); B. Rowland, "Legal Implications of Letter Licenses for Biotechnology," 1 *High Tech. L. J.* 99 (1986); R. Simpson & R. Sedjo, "Contracts for Transferring Rights to Indigenous Genetic Resources," *Resources*, No. 109 (Fall 1992); J. Woodley, "The Commercial Transfer of Biotechnology -- Considerations in Technology Licensing," *Intell. Prop. in Asia & the Pacific*, July-Dec. 1989 at 19; P.S. Baenziger, R.A. Kleese, R.F. Barnes (eds.), "Intellectual property Rights: Protection of Plant Materials", *Crop Science Society of America* (1993).

It is not the goal of this paper to contemplate whether such concerns are valid<sup>3</sup>; but rather to consider how the international Centres should react to such concerns, so as to have policies and instruments in hand when the need arises. Material transfer agreements (MTAs) may be the instrument of choice to protect the legitimate interests of the germplasm community and the Centres. Thus, the primary objective of this paper is to explore their possible utility for the international Centres.

The paper is structured as follows: Section III reviews the current use of MTAs, by whom and for what purpose. This is followed in Section IV by a discussion of key provisions typically found in MTAs. Section V then reviews the legal validity and enforceability of such agreements. The interest of the international Centres in negotiating MTAs, specific provisions they may want to incorporate in such instruments, and their implications for the Centres' handling of genetic material are discussed in Section VI. In Annex 1 we have suggested language which Centres may want to use in tailoring agreements to cover their specific needs, and a policy statement they might want to use in introducing these agreements. Annex 2 reviews statements on distribution policies issued by some International Centres.

### **III. Purpose and Use of MTAs**

#### **A. Legal Scope**

MTAs are a recent phenomenon, used in connection with the transfer of biological materials with potential commercial significance. They can be used for transfer of material for curation (e.g. storage in genebanks), for research, or for commercial use. Most often material is transferred for a combination of these purposes. As agreements, they may take a variety of forms — from letter statements accompanying a shipment of materials to detailed and formally negotiated contracts signed by both parties before a transfer is made. Their provisions may similarly vary, depending on the intentions of the parties. At one extreme, the provisions may be designed to avoid patent rights on the material or its components; at the other extreme, they may be designed to encourage patented inventions deriving from the material and to divide the benefits of such inventions.

As their name implies, MTAs are contractual agreements concluded between two or more parties. As contracts they enjoy the protection of the law in many nations: failure to perform what is promised is a breach of contract which gives one party the right to

<sup>3</sup> On this subject, see, for example, C. Fowler and P. Mooney, "Shattering - Food, Politics and the Loss of Genetic Diversity" (1990); J. Rifkin, "Biosphere Politics - A New Consciousness for a New Century" (1991); S. Kadidal, "Plants, Poverty, and Pharmaceutical Patents," 103 *Yale L.J.* 223 (1993); J.R. Kloppenburg, Jr.(ed.), *Seeds and Sovereignty* (1988); Siebeck, W.E., D.L. Plucknett, and K. Wright-Platais (1993) "Privatization of Research Through Intellectual Property Protection and its Potential Effects on Research at the International Centres". in D.R. Buxton *et al.* (eds.) *International Crop Science I*. Madison WI, 1993.

bring action against the other party, such as suing for damages. Unlike patents or copyrights, MTAs do not rest upon codified legal statutes defining specific rights and obligations. Instead, reflecting freedom of contract, parties to an MTA have wide discretion in setting the terms of their agreement and tailoring them to their specific needs.

MTAs are generally regarded as subject to trade secret law; the material transferred is the 'trade secret'. In those countries that protect trade secret contracts, MTAs offer a form of intellectual property protection that can go beyond that available under patent law. An MTA can, for example, cover material that is not patentable; it can (at least as a matter of law) be effective for longer than the typical patent term. At the same time, it is ineffective against independent development of similar material, and an MTA may lose legal force once the material involved becomes significantly disseminated, whether voluntarily or not.

In some countries, the material transferred under an MTA may also enjoy protection against certain forms of violation by third parties. Thus, a third party who obtains the material by theft or trickery may be liable for damages.<sup>4</sup> However, an MTA offers no protection against genuine independent development by a third party.

## **B. Who Uses MTAs**

MTAs have been pioneered by industry, are increasingly being used by public sector laboratories, particularly in the USA, and now also appear in international germplasm exchanges, including those from developing to industrial countries.

### *1. Industry*

MTAs are particularly useful in the biotechnology context where they typically cover exchanges for both research and possible commercialization. The specificity of biological materials gives them substantial value. For example, scientists from different firms may want to exchange material containing a gene suspected of coding for a particular physiological function, and to protect future commercial rights while allowing research to proceed. The patent system is not helpful to them, because the precise functions or sequence of the materials may not yet be known. Moreover, the patent system is expensive and requires disclosure. Thus, the scientists use a contractual arrangement which commits the parties to the exchange to confidentiality.

Among profit-oriented firms, these MTAs frequently arise in the context of cooperative research efforts by a *small group of firms* to develop a specific product.

<sup>4</sup> The Uniform Trade Secrets Act, adopted in several US states, provides for damages against a party who obtains a trade secret by "improper means," which includes "theft, bribery, misrepresentation, breach or inducement of a breach of a duty to maintain secrecy, and espionage through electronic or other means." Art. 1.

For example, a biotechnology firm collaborating with an industrial partner to develop a new process technology may exchange materials with that partner. Their agreement, laying out the structure of the cooperative research program, will typically authorize the exchange of biological materials, prohibit their transfer to third parties or use for purposes other than the collaboration, and define a mechanism for marketing the product that is expected to derive from the research program.

In such cases, the right and responsibility of patenting the product will be carefully spelled out, as will be the ownership rights in such a patent. These rights will generally be exclusive, for the whole purpose of the collaboration is to develop a new proprietary product. Often the most difficult problem is the allocation of rights to unexpected inventions — possibly valuable in new markets — that neither firm had considered.

The situation is different in *large research consortia* which include a significant portion of firms in a field. Although such consortia are often encouraged by governments, firms are more hesitant to share technology. Being competitors rather than collaborators, the firms will typically share only less valuable material. The logic of a consortium makes it almost automatic that each member of the consortium will receive a non-exclusive licence to any invention emerging from the effort. The commercial value of such a licence is often small so that firms may not attempt to obtain patents on such material. Such consortia tend to focus on relatively basic research, or on research that can benefit all members and for which costs can therefore be shared.

## 2. *Public Sector Laboratories*

Non-profit institutions such as government and some academic laboratories have a very different interest in MTAs. In some relatively traditional institutions, the institution desires primarily to ensure that the material remains in the public domain, while making sure that its association with the material is recognized. Thus, a national agricultural research institution may give a firm a non-exclusive right to use and multiply its material provided that certain quality standards are met and the material is identified as deriving from the public institution. In other cases, the institution may seek to require that the recipient not restrict access to use of the material or patent inventions (e.g. natural genes) that may derive from the material.

Two factors are leading public-sector research institutions to adopt different strategies. One is the sense that exclusivity may be desirable, and in fact necessary, to ensure that the material can actually be commercialized; this exclusivity may be most readily obtained through patents or other forms of intellectual property protection. This was the rationale behind the US legislation encouraging public sector institutions and grantees to file for intellectual property protection on their inventions.<sup>5</sup> Experience

<sup>5</sup> E.g. the Bayh-Dole Act, 35 U.S.C. §§ 200-210; and the Stevenson-Wydler Act, 15 U.S.C. §§ 3701-14.

had shown that firms would not use public sector inventions unless they could obtain a form of exclusivity that would recompense the costs involved in taking a public sector invention to the market. These costs (arising after the basic invention) are sometimes substantial. They include, for example, the development of large-scale production methods (scaling-up), testing to satisfy regulatory requirements and the support of a network of distributors.

Once this approach was in place, however, the public sector institutions and, particularly, universities, began to look to inventions as a basis for royalties. Since research materials often embody important commercial value, they would treat their transfer much the same as a transfer of patent rights. Thus, a university might give a new plant variety to industry on the basis of a full-scale, negotiated marketing agreement that includes specific royalty provisions. Where the value of the material is unclear, because it is not itself a marketable product but might be a major component of such a product, the university might provide the material under an agreement that would attempt to give it the right to negotiate for a share of the profits in products that derived from the material. In some cases, the university might seek 'reach-through royalties,' i.e. a percentage share of sales or profits from any products that might be developed through use of the transferred material (e.g. an important reagent) as a research tool. In some of these cases, the university set too high a price and, in effect, priced itself out of the market.

### *3. International Germplasm Exchange*

Following the practice of US corporations who routinely insist on using formal MTAs when transferring genetic material outside the USA, MTAs are beginning to be used by industry in Europe and Japan also in domestic and international exchanges. Form agreements in use appear to follow US precedents.

Public institutions outside the USA are also beginning to introduce form agreements to limit or preclude commercial use of material, or make it subject to a separate licensing agreement. These initiatives seem to be driven by the intention to comply with the provisions of the Convention on Biological Diversity.<sup>6</sup> At least one developing country has issued guidelines on germplasm exchange with foreign institutions.<sup>7</sup>

<sup>6</sup> Royal Botanic Gardens, Kew, UK, through a recently introduced policy, will control exploitation of genetic material it collects following the coming into force of the Biodiversity Convention. Commercialization will be subject to a licensing agreement. Kew intends to remit half of the licensing fee to the source country, or to an international fund should such a fund be set up under the Biodiversity Convention. (Linnington, pers. communication).

<sup>7</sup> Guidelines issued by the Turkish Plant Genetic Resources Research Institute specifically require recipients to provide feedback data and publication credit, and reserve the right to patents on the material for the Government of Turkey.



### C. Attempts at Formalizing Access to Germplasm

For some time efforts have been underway to formalize the exchange of genetic material. These have recently been boosted by international initiatives to codify the exchange of such material, especially in the United Nations Food and Agriculture Organization (FAO), and the United Nations Environment Program (UNEP).<sup>8</sup>

#### 1. *International Code of Conduct for Plant Germplasm Collecting And Transfer (FAO)*

In its recently approved 'International Code of Conduct for Plant Germplasm Collection and Transfer' FAO has set rules for plant exploration and collection.<sup>9</sup> The Code is voluntary but likely to provide the basis for collecting missions to developing countries. It recognizes nations' "sovereign rights over plant genetic resources in their territories" while encouraging them not to "unduly restrict" access to these resources. It sets out responsibilities of collectors, donors, curators, sponsors and users of germplasm, including procedures and rules for granting collectors' permits, and the need to deposit duplicates with the host country upon completion of a collection mission. Curators are, in particular, to "take practical steps, *inter alia* by the use of material transfer agreements" to promote the objectives of the code, "including the sharing of benefits derived from collected germplasm by the users with the local communities, farmers and host countries."

As possible forms of compensation the Code enumerates (Art. 14)

- “(a) facilitating access to new, improved varieties and other products, on mutually agreed terms;
- (b) support for research of relevance to conservation and utilization of plant genetic resources, including community-based, conventional and new technologies, as well as conservation strategies, for both *ex situ* and *in situ* conservation;

<sup>8</sup> For a discussion of the Biodiversity Convention see Section VI.A.2.b (page 28 below). The Commission of the European Union has prepared a draft decree aiming at better conservation, description and utilization of agrogenetic resources already available in member states. Collecting of new material would be limited to the territory of member states. Objectives are to establish an inventory of material collected (including the setting up of a databank); induce coordination among member states; and help rationalize existing collections (reduce duplicate storage). A standing committee of member states would ensure information flow and exchange of germplasm. The draft decree, at this point, does not set rules for such exchange. (Doc Com(93)337 fin. dated September 7, 1993).

<sup>9</sup> FAO Conference document C 93/REP/5 dated December 1993 (Draft Report - Part 5 - from Commission I), Twenty-seventh Session of the FAO Conference, Rome, 6-25 November 1993.

- (c) training, at both the institutional and farmer levels, to enhance local skills in genetic resources conservation, evaluation, development, propagation and use;
- (d) facilitate the transfer of appropriate technology for the conservation and use of plant genetic resources;
- (e) support for programmes to evaluate and enhance local landraces and other indigenous germplasm, so as to encourage the optimal use of plant genetic resources at national, subnational, and farmers' and community level and to encourage conservation;
- (f) any other appropriate support for farmers and communities for conservation of indigenous germplasm of the type collected by the mission, and
- (g) scientific and technical information obtained from the germplasm."

#### 2. U.S.A. National Institutes of Health (NIH)

Uncertainty over the legal validity of provisions in some MTAs, particularly more extreme 'reach-through royalty' provisions, gave rise to pressures in the United States to develop a more balanced form agreement for government sponsored research. Since 1990, the U.S.A. National Institutes of Health (NIH), in cooperation with other government agencies, universities, hospitals, research institutes, and the biotech and pharmaceutical industry, has developed a set of three form agreements. Drafts are currently undergoing a final review and are expected to be published in the NIH Guide.<sup>10</sup>

The three form agreements are designed for the following situations:

- a simple letter agreement for the transfer between non-profit institutions of biological material that does not have obvious commercial value
- a Uniform Biological Material Transfer Agreement (UBMTA) for use between non-profit institutions
- a UBMTA for transfer of biological material from industry to non-profit institutions.

The first two agreements represent reasonably balanced terms for transfer of materials from one non-profit institution to another. The third sets out similar terms under which the commercial provider of the material could be granted a licence to an invention resulting from the recipient's research. Reflecting their origin, the three formats are designed for the transfer of medically rather than agriculturally oriented materials.

<sup>10</sup> August 1993 drafts are available in J. Brinton, 'Uniform Biological Material Transfer Agreement(s)', *AUTM Manual, Part IX; Chapter 2 (Association of University Technology Managers, 1993)*.

The UBMTAs extend their coverage to ‘derivatives’ defined as substances genetically derived from the supplied material including modifications that are not obviously distinct from the supplied material. They do not provide for reach-through royalties on inventions and modification that go beyond the so defined derivatives.<sup>11</sup>

All three agreements require signature by both parties before material will be released. An earlier proposal, to establish relatively detailed umbrella agreements that could be referenced by a simple exchange of letters for a specific transfer of materials, was dropped.

### *3. U.S.A. National Cancer Institute (NCI)*

For screening in its drug discovery program, the National Cancer Institute (NCI) annually procures some 6000 samples of plants, marine organisms and microbes from developing countries. Under its letter-of-collection agreement, NCI “recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected”. NCI regularly files for patents on active agents isolated, and licenses them to pharmaceutical companies for production and marketing. The licensee is required to enter into an agreement with the source country on compensation.<sup>12</sup> NCI also offers its help, to transfer knowledge, expertise and technology related to drug discovery and development to the source country, to train its scientists and to collaborate with source country institutions in the discovery and development process.

NCI does not itself negotiate a licensing fee as part of its agreement with the pharmaceutical company, and leaves the determination of the compensation to negotiations between the source country and the licensee. No dispute has yet arisen where a source country and licensee could not agree on the level of compensation, and it remains to be seen whether in that case NCI could maintain a hands-off attitude.

<sup>11</sup> See discussion under IV.C (page 20).

<sup>12</sup> “Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the successful licensee to negotiate and enter into agreement(s) with the appropriate Source Country Government agency(ies). This agreement will address the concern on the part of the Source Country Government that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.” (§ 12 NCI Letter-of-Collection Agreement)

#### 4. *US Department of Agriculture - Agricultural Research Service (USDA-ARS)*

To comply with international agreements such as the Convention on Biological Diversity, the US National Plant Germplasm System (NPGS) is currently reviewing its policy of free distribution of genetic material.<sup>13</sup> According to one proposal, NPGS would, at the request of countries that place their genetic material in the NPGS, attach an identifier to such material. Material currently deposited in the NPGS would continue to be freely available, while material with a 'Source Recognition' (SR) identifier would only be released on condition that the recipient not distribute the material, that it credit the source country in publications, and that it enter into an agreement with the source country on the use of the material and fairly compensate the source country in case of commercial gain from the material or its derivatives, and that it provide NPGS with evaluation data on the material.

Recipients of material so identified would have to agree in writing to conform with these conditions. Upon request, NPGS would notify a source nation of releases of SR material, but would leave it to that nation to pursue possible claims against the recipient. NPGS would not act as agent or collector for the source nation. NPGS' advanced data management facility, the Genetic Resources Information Network (GRIN), is expected to handle the additional data-processing requirements resulting from operating the proposed two-tier system.

#### 5. *Private Sector Initiatives*

A novel arrangement was concluded in 1991 between Merck & Co., the largest US pharmaceutical producer, and Costa Rica Biodiversity Institute (INBio). Under the agreement, INBio, a publicly chartered non-profit organization, will provide Merck against payment of \$1.35 million and provision of field equipment, with an unspecified number of probes (plants, insects, microbes) at Merck's choice over a period of two years. Merck has the right to patent inventions it makes from Costa Rican material, and will pay INBio an undisclosed percentage of sales revenues. INBio intends to use the proceed in its ongoing Biodiversity program.

Such arrangements, of interest to countries rich in biological diversity such as Costa Rica, offer the potential of adding value to genetic material by developing the infrastructure to collect, screen, characterize and store germplasm.

Reflecting the negotiating pattern of the Merck-INBio arrangements, the World Resources Institute (WRI) has developed a model contract for Biodiversity prospecting

<sup>13</sup> Sec. 1632(a)(4) of Public Law 101-624 of November 28, 1990: "The Secretary [of Agriculture], ... shall (4) make available upon request, without charge and without regard to the country from which such request originates, the genetic material which the programme assembles."

to be concluded between pharmaceutical companies and a developing country.<sup>14</sup> The model contract provides for an initial collection fee, and a royalty on pharmaceutical products that may be derived from the genetic material taken from the developing country.

#### **IV. Typical Provisions of Material Transfer Agreements**

This section reviews clauses typically found in MTAs.

##### **A. Use Permitted 'For Research Purposes Only'**

Probably the most common pattern in the non-profit sector in industrial countries are agreements that permit the free use of materials for 'research purposes',<sup>15</sup> with the possible implication that there is an obligation to negotiate a division of royalties should commercial products become obtainable from the materials. This pattern is typical when the provider of materials is willing to provide the material for scientific purposes, but wants to protect all possible commercial rights.

The exact meaning of 'research purposes' has not been fully clarified.<sup>16</sup> Although little has been written in this area, at least one commentator<sup>17</sup> takes such research to include not only research oriented toward purely academic purposes but also research oriented ultimately toward product development. This interpretation is supported by the basic logic of such an agreement: One who takes the material for research use with an obligation to negotiate royalties in the event of commercial use should be allowed to carry out research up to the point of commercialization, at which point royalties must be paid. In case of a public sector recipient, such as an agricultural research university, distribution for use by farmers would be the equivalent of commercialization and the recipient's obligations in such a situation should be spelled out; research prior to that point would certainly be permitted under such an agreement.

<sup>14</sup> Downes, D. *et al. Biodiversity Prospecting Contract* in: Biodiversity Prospecting: Using Genetic Resources for Sustainable Development, World Resources Institute, 1993.

<sup>15</sup> E.g. "The Biological Material will be used for research purposes only". NIH draft letter UBMTA for non-profit to non-profit transfer, article 2.

<sup>16</sup> The issue is *not* the same as that involved in the research exemption in patent law. That exemption is a right to use a patented invention for certain (generally academic) research purposes and follows statutory or case law criteria. Here, the issue is the interpretation to be given to a term frequently used in a contract. The parties could, if they chose, insert a detailed definition of their choice.

<sup>17</sup> B. Rowland, 'Legal Implications of Letter Licenses for Biotechnology,' 1 *High Tech. L. J.* 99 (1986).

### **B. Obligation to Share Royalties or Profits**

Although it is possible (and typical in some commercial contexts) that a transfer agreement would precisely specify a distribution of the profits from commercial use of the materials transferred, the more common pattern is to leave the negotiation of this distribution to take place later in the event that there are profits.<sup>18</sup> Mainly because few MTAs have yet led to commercial products, there has been no judicial interpretation of these clauses. Some have undoubtedly led to agreements. One alleged verbal agreement led to a dispute settled out of court.<sup>19</sup>

A duty to negotiate will not necessarily lead to an agreement. No one can predict the bargaining power that the two parties will have in such a negotiation. But the existence of a vaguely defined obligation to negotiate may deter a firm from making substantial investments to commercialize a product unless it is more precisely defined. At the time of the initial transfer, however, it is normally impossible to define a reasonable royalty, especially in situations where a product may be derived from materials obtained from more than one source. To meet such situations, agreements often include arbitration procedures to define a reasonable royalty, should the parties be unable to do so.

### **C. Derivative Material**

Of importance in an MTA is the scope of the subject matter covered by it, on which the provider seeks to protect its rights. In addition to the supplied material itself, such protection normally extends to its derivatives.

However, to determine what is a derivative and what is not, is often difficult, yet critical. Consider the example of a gene found within a specimen supplied by a genebank. The terms of the agreement apply to the natural genes found within the specimen. But what if the recipient wishes to patent or use commercially what is essentially the same gene, but with the codons modified to improve expression in a different host? What if the gene found in the supplied material is not itself patented but is used as a probe to identify a similar gene in another species which is then patented? It is relatively easy to negotiate in advance an answer to such questions, but failure to face them then can lead to serious later dispute.

The typical approach to this problem is to negotiate a definition of 'derived product' and to make the commitments of the MTA apply to such derived products as well as to

<sup>18</sup> E.g. "If RECIPIENT desires to use the MATERIAL or Modifications for ... profit-making or commercial purposes, RECIPIENT agrees, in advance of such use, to negotiate in good faith with PROVIDER to establish the terms of a commercial license. It is understood by RECIPIENT that PROVIDER shall have no obligation to grant such a license to RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others". NIH draft UBMTA, nonprofit to non-profit, art. 5 (b).

<sup>19</sup> *Hoffman-LaRoche v. Golde*, No. 80-3601-AJZ (N.D. Cal, filed Sept. 11, 1980).

the supplied material itself. Thus, genes or portions of genes found in progeny of the supplied material might be covered by the MTA, while new products found by using the material as a reagent might not.

Although the obligation to negotiate royalties thus applies only to inventions deriving directly from the transferred material, some agreements attempt to 'reach-through' and secure royalties on a broader category of products.<sup>20</sup> Such provisions have frequently been found unacceptable by recipients; there may also be questions as to their legal validity under competition law.

#### **D. Obligation Not to Seek Patents**

Another provision that might be included in an MTA prevents patenting of the transferred material or of certain kinds of derived products.<sup>21</sup> Many genebanks might like, for example, to supply material under terms that prohibit protection of the transferred material, or of genes found in it. This can be done by provisions that state, for example, that the recipient shall take no measures to patent the material, or genes found in the material. Commercial recipients interested in locating and developing such genes, may, of course, be unwilling to accept the material under such conditions. In those cases in which the material is fully characterized, publication would, of course, prevent patenting of the material itself. In order to prevent the patenting of genes isolated from material supplied by a genebank, it would, however, be necessary that the relevant genes had been sequenced and the relevant genetic data published as well. If this has not been done, only an MTA clause can bar the recipient from patenting.<sup>22</sup>

A patent obtained in violation of such an agreement would almost certainly not be, for that reason, invalid. The supplier of the material would, however, be able to obtain damages for breach of the promise not to patent, and would also be able to obtain a compulsory, royalty-free licence to use the material. These points follow from the law

<sup>20</sup> E.g., in the case of a culture of a disease organism, "The recipient's obligation to pay royalties to the provider of this culture shall extend to any products produced that may in any way use the transferred organism. This shall include resistant organisms that have been identified by use of the transferred organism".

<sup>21</sup> E.g. "Recipient will not patent the transferred material or any material or gene derived from it".

<sup>22</sup> United States law provides a procedure, "Statutory Invention Registration," 35 U.S.C. §157, under which a patent like registration can be used to keep an invention in the public domain and protect the inventor against another's later independent invention. There have been no cases under this provision, and it is not clear when use of this provision is preferable to publication.

governing the parallel situation in which an employee obtains a patent after making a valid contract to transfer patent rights to his or her employer.<sup>23</sup>

### **E. Obligation to Share Intellectual Property Rights**

An alternative approach to patent rights is suggested by the commercial practice found in the small-group product-oriented research cooperation described earlier.<sup>24</sup> Because partners in such collaboration expect patentable results to arise from their collaboration and the exchange of material, they will generally agree from the outset how to allocate rights. One party might, for instance, receive exclusive rights in one market, while the other party might receive rights in another market. Or the parties might divide royalties evenly or in proportion to their research investments.

### **F. Obligation to Grant a Licence (Grant-Back Clause)**

Private sector research groups are frequently concerned with protecting their competitive position in the event that the recipient of the material develops a patent or makes a related invention. Under a 'grant-back' clause, some providers seek to ensure the right to use such patented inventions.<sup>25</sup> In this way, they protect their competitive position in the event that the licensee develops a major improvement. The detailed analysis of these provisions can be complex; in some cases, they have given rise to concerns under competition law, arising from fears that they may be used to extend a provider's dominant market position.

### **G. Mutual Assistance**

MTAs frequently include provisions designed to prevent access to the material by third parties, so as to make sure that the material does not reach parties not bound by the confidentiality commitments. Such provisions may, for instance, require the recipient

<sup>23</sup> "The basic starting point in the law of employee/employer patent rights [in the United States] is the principle that the inventor owns the patent rights even though the invention was conceived and/or reduced to practice while the inventor was employed. Three caveats apply to this general rule. The first is that an express contract between the parties can vest ownership in the employer [in many nations]. Secondly, the employer will have ownership if the employee was specifically hired to exercise his inventive faculties. Finally, even if the employer does not have ownership rights in the invention, he may still have a non-exclusive, nontransferable royalty-free license ('shop right') to use the patented invention;" P. Van Slyke & M. Friedman, 'Employer's Rights to Inventions and Patents of Its Officers, Directors and Employees,' 18 *AIPLA Qlty. J* 127, 132 (1990). (Some nations regulate the allocation of patent rights between employees and employers.)

<sup>24</sup> See section III.B.1 (page 12).

<sup>25</sup> "Recipient will give provider a non-exclusive, royalty-free license under any inventions it may patent that derive from the transferred material or improvements or derivatives thereof".



to separate research activities on the transferred material from other research, and to introduce control procedures to restrict the number of staff that will have access to it.

#### **H. Deferment of Publications and Reporting Obligations to Facilitate Patenting**

If patents are expected to result from research on the transferred material, MTAs may stipulate that intended publications based on the material be deferred for a stated time (typically one to three months) so that patent rights can be protected by application in the interim. The agreement may also require parties to report to each other on any actions they may take with respect to patents so as to protect their mutual rights to royalties, and to facilitate patent applications in case the nonpatenting party has information needed in the application.

#### **I. Acknowledgement**

It is common, especially in the academic context, to require the recipient to provide acknowledgement — the equivalent of a literature citation — of the contributions of the material supplied, in connection with any publication that may result from use of the material.<sup>26</sup>

#### **J. Warranties**

A final category of typical terms concerns liabilities that may be associated with the material. This is particularly important with respect to transgenic material, where the supplier does not want to be liable for the recipient's failure to obtain appropriate biosafety clearance. The recipient should normally be under an obligation to obtain such approval and indemnify the supplier in the event of such problems. MTAs may also include guarantees that the materials are not covered by patents, or conversely, disclaim any liability in the event that they infringe a third party's patent.

### **V. Legal Validity and Enforceability of MTAs**

#### **A. Enforceability**

Although there have been no cases turning on the validity of an MTA, such an agreement (if accepted by both parties) is enforceable in countries that respect trade secret law. In the USA, this is laid down in the Uniform Trade Secrets Act. A possible general exception could arise from competition law that restricts use of private

<sup>26</sup> "You agree to acknowledge the source of the Biological Material in any publications reporting on your use of it". NSF draft letter UBMTA, non-profit to non-profit, art. 4.

agreements to achieve intellectual property goals far beyond those created by statutes such as the patent and copyright acts.<sup>27</sup> Of the clauses discussed above, the one most likely to be challenged on these grounds would be a very broad 'reach-through' clause demanded by a holder of material considered very valuable.

Some developing nations have traditionally restricted trade secrecy provisions both because of antitrust concerns just described and fears that trade secrecy provisions limit public access to inventions and thus give the public less than does the patent system. Brazil, for example, has experimented with a system under which trade secrets would be made public five years after the date of the agreement, a proposal strongly resisted by those considering the transfer of technology to Brazil under a trade secret agreement. In addition, the terms of the trade secret and confidentiality agreements that employers can require from their employees are often regulated.

However, the current trend in developing nations is to move toward stronger enforcement of trade secret agreements. Mexico, for example, has just shifted to full protection. The terms of the intellectual property section of the Uruguay Round will require recognition of trade secret agreements.<sup>28</sup>

### **B. Prior Agreement vs. Letter Included with Material**

A difficult question — especially because of its implications for the administrative costs of implementing MTAs — is whether, in order to be legally enforceable, the MTA has to be signed by both parties prior to the transfer of the genetic material, or whether a simple letter included with the transferred material is sufficient to establish an enforceable agreement. This letter would state the terms on which the transfer is conducted, and include a statement such as "By retaining the material, recipient agrees to the terms of this letter agreement".

<sup>27</sup> Thus, in *Kewanee Oil Co. vs. Bicon Corp.*, 416 US 470 (1974), the US Supreme Court considered whether a state's trade secret law violated the federal patent law policy favouring the disclosure of inventions. It analyzed the issue carefully before upholding the state trade secret law.

<sup>28</sup> Article 39, paragraph 2, of the 'Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods' (the TRIPS Agreement) proposed within the Uruguay Round of Multilateral Trade Negotiations states:

"Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

- . is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- . has commercial value because it is secret; and
- . has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret".

Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, doc. MTN/FA, 15 December 1993.

In general, the terms of such a letter agreement would establish the contractual relationship, unless the recipient proposes terms which 'materially' differ from those contained in the letter agreement. If they do, the recipient's response, even if it is worded as acceptance ("I accept your offer on the following conditions"), is considered as a new offer, to be accepted or rejected by the original offeror. Public policy considerations, such as consumer protection, have influenced legislation and jurisprudence in various countries.

In the USA, if the acceptance of such a letter is contested, the courts are divided on the interpretation of the relevant provisions of the Uniform Commercial Code.<sup>29</sup> The terms of the letter are more likely to be seen as accepted if the shipper allows for the return of the supplied material and the recipient if s/he fails to understand the precise terms of the letter does not make use of this possibility. They are also more likely to be held up within a community whose members are aware of their respective trading practices and policies. In civil law countries, legislation and jurisprudence tend to interpret such agreements as validly concluded.<sup>30</sup>

<sup>29</sup> In evaluating the force of such a letter, courts are likely to turn to § 2-207 of the Uniform Commercial Code, whose first two paragraphs state:

- "(1) A definite and reasonable expression of acceptance or a written confirmation which is sent within a reasonable time operates as an acceptance even though it: states terms additional to or different from those offered or agreed upon, unless acceptance is expressly made conditional on assent to the additional or different terms.
- (2) The additional terms are to be construed as proposals for addition to the contract. Between merchants such terms become part of the contract unless:
- (a) the offer expressly limits acceptance to the terms of the offer; (b) they materially alter it; or
  - (c) notification of objection to them has already been given or is given within a reasonable time after notice of them is received".

In applying this provision, the recipient's request for the material is interpreted as an offer, and the cover letter as its acceptance or confirmation that may include terms restricting the recipient's use of the material. Form language in the cover letter may attempt to make acceptance expressly conditional on the recipient's assent to these restrictions. The fundamental question then becomes whether these restrictions are 'material'. Although many of the disputes interpreting this section involve issues such as whether an agreement to arbitrate is a material alteration, one recent case involved interpretation of the liability limitations that were contained in a software package and were meant to be effective upon opening that package. The court rejected these limitations and decided in favour of the buyer, *Arizona Retail Systems, Inc. vs. The Software Link, Inc.*, 831 F. Supp 759 (DC Ariz. 1993).

<sup>30</sup> Under French law, for example, the general principle (as in Anglo-Saxon law) is that silence is not acceptance. But, reflecting the emphasis of Article 1108 of the French Civil Code on consent of the party to be bound (rather than on offer and acceptance), the exceptions can be rather flexibly stated and can arise through professional customs and ongoing business relationships, F. Chabas, *Leçons de Droit Civil* 123-25 (7ième éd., 1985). Thus, if well publicized within the relevant community, a provider's policy can be enforced through a simple transmittal letter.

The situation would be less clear in disputes that arise the Convention for the International Sale of Goods.<sup>31</sup>

### C. Monitoring Requirements

There is no legal requirement for the provider of the materials to verify whether the recipient is living up to obligations included in the agreement; enforceability does not depend on vigilance. Of course, rights not exercised become meaningless in practice — without some form of monitoring or tracking, an MTA may be effectively meaningless.

## VI. The Case of the International Centres

### A. The Demise of the Free-Flow Paradigm?

#### 1. Germplasm Exchange Under the Free-Flow Rule

Because the use of plant genetic resources is central to their mission, the international Centres have traditionally subscribed to a policy of free exchange of germplasm.<sup>32</sup> Germplasm from their collections is freely available to scientists in the public and private sectors throughout the world, who can use it without restrictions, for research or commercially. There is an expectation, based on rules of ethics, that the recipient will reciprocate in kind, if a Centre asks for material, and few seem to be the cases where reciprocity has been denied. This has been the rule in Centre relations with partner institutions in both developing and developed countries.

Germany passed a law in 1976 to contain the broad interpretation until then given by courts to the presumptive application of statements of policies and general conditions to business deals with non-merchants ('Gesetz zur Regelung der Allgemeinen Geschäftsbedingungen' of December 9, 1976, BGBl. 1, 3317). According to §2(1), general conditions set by one party will rule relations between parties if the issuer advises recipient of the existence of such conditions at the time the contract is concluded; (2) recipient has the possibility of taking note of the conditions; and (3) agrees with them. While (1) and (2) have to be proven by the issuer, implicit agreement on (3) is presumed if the recipient does not object (Palandt, Kommentar zum Bürgerlichen Gesetzbuch, 52. Auflage, Anmerkung 4 zu §2 AGB). By contrast, within the trading community, the onus to prove that recipient was unaware of conditions and did not have access to them is reversed. Applied to a recipient of Centre material, even if we assume that s/he is considered a 'non-merchant', notifying the policy statement to a recipient at least once, and referring to it in subsequent transmittal letters would be sufficient to make them part of the contract.

<sup>31</sup> Article 19 (2) states: "...a reply to an offer which purports to be an acceptance but contains additional or different terms which do not materially alter the terms of the offer constitutes an acceptance, unless the offeror, without undue delay, objects orally to the discrepancy or dispatches a notice to that effect. If he does not so object the terms of the contract are the terms of the offer with the modifications contained in the acceptance". (United Nations Convention on Contracts for the International Sale of Goods, entered into force January 1, 1988.) Although this would seem to favour the provider (acceptor) more than does its analogue under the US Uniform Commercial Code, the provision goes on to provide a broad definition of material alteration; under this broad definition, typical provisions of an MTA would almost certainly be held material.

<sup>32</sup> TAC Document AGR/TAC:IAR/88/4 'CGIAR Policy on Plant Genetic Resources', Rome, February 1988.

There has been little interference with the free-flow rule from regulatory authorities. Except for phytosanitary controls and quarantine regulations, the international Centres have usually been able to exchange and distribute germplasm unimpeded by government controls. Countries generally, and often routinely, permitted collecting missions, in which Centres, as a matter of policy, invited local scientists to participate and provided samples of collected material for storage at a local facility.

Also intellectual property protection to date has not affected the exchange of germplasm by the Centres. International research collaboration sponsored by the Centres, based on the free exchange of germplasm, and bringing together the world's best expertise in plant breeding, provided the basis for the Green Revolution, and accomplished, without patents or plant breeders' rights, one of the great technological breakthroughs of modern days.

## *2. Towards a Controlled Exchange of Germplasm*

Understandably then, the international Centres are little inclined to abandon the free-flow paradigm. They have a lot to lose, and probably little to gain. Moreover, there is a strong argument that for food crops, at least, a free-flow regime is to the benefit of developing nations. But trade rules are changing: countries, particularly the suppliers of germplasm among developing countries, are beginning to assert sovereign control over their germplasm resources; while industry in developed countries claims intellectual property rights over improvements of plant germplasm achieved through breeding or biotechnological manipulations.

### *a. International Undertaking on Plant Genetic Resources*

Efforts have been underway for some time to internationally codify the access to, and use of, plant genetic resources. In 1983, the Food and Agriculture Organization of the United Nations (FAO) established the International Undertaking on Plant Genetic Resources.<sup>33</sup> Essentially, this was an attempt, through international conservation efforts, to stop or slow the rapid and uncontrolled disappearance of crop plant species resulting from genetic erosion.

The International Undertaking originally subscribed to the rule of free exchange of plant genetic resources which it recognized as 'a heritage of mankind'. In subsequent years, however, disagreement over the scope of intellectual property protection, and specifically over whether breeder's lines and material protected by plant breeders' rights - under the rule of the Undertaking - should be available without restriction, led to

<sup>33</sup> Resolution 8/83 of the Twenty-second Session of the FAO Conference, Rome, 5-23 November 1983. In 1990, the USA joined the FAO Commission on Plant Genetic Resources which administers the Undertaking, but has not signed the Undertaking.

a narrowing of the free exchange principle. In 1989, FAO adopted two resolutions<sup>34</sup> providing an 'agreed interpretation' according to which plant breeders' rights were not incompatible with the Undertaking, meaning that such materials remained outside the Undertaking. In exchange for this concession to industrial countries, developing countries won endorsement of the concept of farmers' rights.<sup>35</sup> Farmers' rights are not individual rights in a legal sense, but a moral commitment by the industrial countries to reward "the enormous contribution that farmers of all regions have made to the conservation and development of plant genetic resources". However, a multilateral system to compensate farmers and farming communities for their contributions was never put in place.

The 1989 'agreed interpretations' on farmers' rights and plant breeders' rights marked the first time that a *quid-pro-quo* rationale was explicitly introduced into the discussion on access to germplasm. In 1991, the free-flow principle was further qualified through another resolution<sup>36</sup> which, while still recognizing the common heritage principle, subordinated it "to the sovereignty of the states over their plant genetic resources". The same resolution anticipates further limitations of the free availability rule to come, by declaring that "conditions of access to plant genetic resources need further clarification".

#### *b. The Convention on Biological Diversity*

The Convention on Biological Diversity of 1992 represents an attempt to establish a blueprint for the preservation of the world's biological resources, including those of agriculture. While recognizing the intrinsic value of biological diversity of all life forms, and the critical importance of conservation and sustainable use of plant genetic resources, the Convention requires developed and developing countries to conserve and manage their biological resources; formally recognizes sovereign control by individual nations over biological resources on their territories but requires countries to facilitate access to genetic resources; requires industrial countries to allow and facilitate access to their technologies on mutually agreed terms, but recognizes the primacy of intellectual property protection as the limiting factor in such releases; and provides a

<sup>34</sup> Resolutions 4/89 and 5/89 adopted by the Twenty-fifth Session of the FAO Conference, Rome, 11-29 November, 1989 and incorporated into the International Undertaking as Annexes I and II, respectively.

<sup>35</sup> "Farmers' rights mean rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centers of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers..". (Resolutions 5/89 *ibid*).

<sup>36</sup> Resolution 3/91 adopted by the Twenty-sixth Session of the FAO Conference, Rome, 9-28 November 1991 (now Annex 3 to the International Undertaking)

financial mechanism, to be subscribed to primarily by the developed countries, to fund developing country expenses on conservation and access to technology.

The Convention distinguishes genetic resources already collected from those that will be collected in accordance with the Convention. Article 15.3 limits sovereign rights to genetic resources to those which a *country of origin* provides, or other countries acquire, in accordance with the Convention. Article 2 defines the 'country of origin' as the country which possesses those genetic resources in *in situ* conditions. Thus the Convention effectively creates no obligations with respect to genetic material collected prior to coming into force of the Convention (even if that material is stored in an international Centre within the territory of the country of origin). On the other hand, any material collected on or after December 29, 1993, when the Convention entered into force, in a country that: has become a party to the Convention, will be subject to the national sovereignty provisions of the Convention.

In the wake of the negotiations of the Convention on Biological Diversity several countries have begun developing policies on the release of germplasm.

#### *c. The TRIPS Agreement of the Uruguay Round*

While developing countries' demands for control over their genetic resources grew stronger in FAO and in the negotiations leading up to the Convention on Biological Diversity, negotiations advanced in parallel for stronger protection of man-made improvements and inventions. From the outset, strengthened protection of intellectual property in developing countries was a key objective advanced by the industrial nations in the recently completed GATT Round of Multilateral Trade Negotiations, known as the Uruguay Round. For a long time, developing countries opposed those demands, but because of the trading benefits they expected to obtain in other areas of the trade pact, and also because many of them, of their own interest, began to move towards stronger protection of intellectual property, developing countries relented and agreed to submit to the 'Agreement on Trade-Related Intellectual Property Rights' (the TRIPS Code) which goes far beyond what developing countries previously had been ready to accept under international agreements. The TRIPS Code<sup>37</sup> requires countries:

- to protect trade secrets (Art. 39);
- to protect any invention (process or product) in all fields of technology (Art 27);
- to protect varieties. Countries can exempt plants from 'patentable subject-matter' but have to protect varieties, either through patents or a *sui generis* system (Art 27 (3));

<sup>37</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, *supra* n. 28.

- to provide enforcement procedures (Arts. 41-49).

To bring their legislation into compliance with these commitments, the Code grants developing countries a grace period of five years which on certain conditions can be extended by another five years, and for least developed countries by ten years (Arts. 65-66).

Implications for genetic resources management by individual developing countries under the Code commitments remain to be assessed. With strengthened national protection of intellectual property, countries with a growing indigenous breeding and research capability will have broader control over improved material, in addition to the control that the Convention on Biological Diversity grants them over their native germplasm. By contrast, countries with no such capacity are less likely to see benefits from protecting intellectual property.

#### *d. Responses of the CGIAR*

The international Centres are caught in this thrust towards greater control over genetic resources. Being too small a player to stem the trend they may have to adjust.

For some time, policy reviews and discussions within the Centres' community have reflected the growing concerns with which these developments are viewed. Several initiatives were launched in response.

In 1982, the CGIAR began looking at the possible effects of intellectual property rights on its germplasm operations. Efforts at different stages involved its Technical Advisory Committee and its Centre Directors, and helped the Group to rationalize the legal basis for its germplasm holdings, to establish preliminary principles on intellectual property management, and to set tentative rules on how it expected users to handle germplasm distributed by a Centre. A brief review of the discussions follows which led to the adoption of a working paper by the CGIAR donors in May 1992.

Upon recommendation of TAC, the CGIAR in 1988 adopted its current policy on Plant Genetic Resources,<sup>38</sup> determining that its Centres hold their germplasm collections in trust and defining among attendant Centre obligations the duty to distribute germplasm freely for research purposes.

In November 1990, a workshop convened by ICRISAT and the CGIAR Secretariat reviewed the need for observing intellectual property in Centre operations. The resulting report contained recommendations for restrictions in germplasm distribution from Centre genebanks and their breeding and research programmes. Specifically, it proposed that all germplasm releases by Centres be covered by agreements. While all germplasm

<sup>38</sup> TAC Document AGR/TAC:IAR/88/4 'CGIAR Policy on Plant Genetic Resources', Rome, February 1988; 'CGIAR Policy on Plant Genetic Resources'. 1989. IBPGR, Rome.



should remain 'readily available' on a non-discriminatory basis, the workshop suggested that in order to protect access, landraces and wild taxa be distributed under what it called 'creative agreements' for the distribution of such germplasm (without specifying, however, what such agreements should provide for). All other material would be distributed under MTAs requiring recipients to use the material only for research, and also requiring that this restriction be attached to any further distribution of the material and its derivatives, while any commercial use would require a prior licence.<sup>39</sup>

At a meeting in The Hague in September 1991, the Centre Directors' *ad hoc* Working Group on Intellectual Property recommended adoption of a policy to ensure that developing countries share in financial benefits obtained by the private sector from commercializing genetic material provided to CGIAR Centres by developing countries. Concerned that the use of MTAs might weaken the free flow of genetic resources, the Working Group, nonetheless, recognized that without such agreements it would be difficult to ensure that such profits would be shared. Specifically, it proposed that with respect to genetic resources and other research products, the Centres should transfer materials only under an agreement which reserves the right to a share of any commercial returns arising in the developed countries. Recipients should be required to negotiate with the Centre a share of profits to be returned to the Centre which the Centre would apply to conservation and use of genetic resources in developing countries. The Centre should also ensure that innovations deriving from the material become available on a royalty-free basis for use by the Centres (plural) and in the developing world.

At Centres' Week in October 1991, the Centre Directors issued 'Suggested Principles for a Future CGIAR Policy on Intellectual Property Rights'<sup>40</sup> in which they confirmed the CGIAR's adherence to the principle of unrestricted availability of its plant genetic resources. The principles spelt out conditions in which Centres would or would not seek intellectual property for themselves (never on 'naturally occurring genes', and on other products only exceptionally in order to ensure access to technology, without, however, seeking financial gains), but was silent on user's rights to seek intellectual property protection on genetic resources obtained from a Centre.

<sup>39</sup> *Managing Intellectual Property at the International Agricultural Research Centres*. Summary Report of a Workshop on Consequences of Intellectual Property Rights for the International Agricultural Research Centres, held at ICRISAT 19-21 Nov 1990, ICRISAT, 1991.

<sup>40</sup> These Principles were re-issued with minor modifications by a Centre Directors' meeting in June 1992. The Inter-Centre Working Group on Genetic Resources (ICWG-PR) which consists of the heads of Centre genebanks, recently also proposed a number of elements to be included in the Centre Directors Guiding Principles. Among them is a recommendation that genebank material will be made available on condition that the recipient take no steps restricting their further availability to other interested parties.

Following a meeting in Rome in January 1992, a joint TAC/Centre Directors' Working Group on Intellectual Property developed a combined statement on intellectual property, biosafety and conservation of plant genetic resources. Specifically on germplasm distribution, it recommended that, except to NARS (who would continue to receive genebank material without any forms and restrictions), all material would be distributed under MTAs. With regard to genebank material, these would spell out that any useful genes discovered in the material or derived from it could not be withheld from the country from which the material originated, and that the Centres (plural) could not be prevented from using the material. A user desiring to commercialize such material or any derivatives would have to negotiate with the Centre. Breeding material could be made available to NARS on an exclusive basis in order to grant the NARS an opportunity to obtain a financial return and to augment scarce financial resources. Users of breeding material in an industrial country, whether private or public, would be allowed to seek plant variety protection provided (a) it did not restrain future use of the material by the Centres, and (b) financial gains were paid into an international fund for the benefit of developing countries.

At its meeting in Istanbul in May 1992, the CGIAR unanimously adopted a 'working document' which was not a definite policy statement but was to reflect current practices and to represent broadly held views within the CGIAR system. It mirrors the 'Suggested Principles' issued by the Centre Directors in November 1991; it recognized 'farmers' rights'; but except for affirming the continued free availability of genebank material, it did not touch on the question of what users can do with genebank and enhanced material. The possibility of forestalling intellectual property protection by users of Centre material was not addressed. The minutes of the meeting state that Centres and their Boards of Trustees bear the responsibility for developing particular policies and procedures relating to the major issues dealt with in the working document.

Several Centres have since adopted policies (see Annex 2) which provide for the use of MTAs in the transfer of germplasm. CIAT and IRRI are actually applying them, though infrequently, for the release of germplasm to private-sector users. Release conditions vary widely, from 'research only' restrictions for all material (ICRISAT), and prohibition to seek any or some forms of intellectual property (CIMMYT), to free distribution, with a Centre explicitly retaining the right to distribute the same material to others (IITA, IRRI).

#### **B. Open or Limited Access - Whose Interests are at Stake?**

It is useful to briefly reflect on the competing interests apparent in the debate over who controls the flow of plant genetic resources.

### *1. The Global Community*

There is an overriding interest of the world community in fighting poverty and human want. Germplasm-based agricultural research is a critical and, one could argue, the most promising avenue to enlarge the Earth's food resources and production in order to feed its growing population in a sustainable fashion. In addition to conserving the diminishing genepool, this calls for maximizing the utilization of genetic resources in research. A system as open and free as possible to exchange these resources is the best guaranty that these goals can be met.

### *2. Developing Countries*

As evidenced by the Green Revolution, the free-exchange paradigm has benefitted developing nations by encouraging public and private sector plant breeding. At the same time, many developing countries argue that the free-exchange paradigm has worked to their disadvantage by allowing the North access to their genetic diversity without adequate and fair compensation. It is the goal of the Convention on Biological Diversity to level the playing field by giving the South access to the technological and financial resources of the North. The developing countries, on whose territory the bulk of the Earth's still unexploited plant genetic resources is located, now hope to obtain a fairer deal.

The developing countries are facing a dilemma in achieving this goal: in order to tender their genetic material they have to display it to potential bidders. Hiding it in the backyard will arouse the interest of few and be a poor strategy.

At times, the interest of developing countries in releasing their germplasm is obscured by unrealistic expectations about its 'market potential'. One factor often overlooked in this discussion is that while there is substantial commercial interest in 'biodiversity prospecting' among pharmaceutical companies for plants containing materials of possible medical relevance, prospects of important commercial gains in the agricultural sector are less luring. Understandings such as the one concluded between Costa Rica INBio and Merck & Co.<sup>41</sup> appear unlikely to become appropriate models for agricultural research. There are two reasons. The first is financial: profits from a pharmaceutical product are likely to be substantially larger than those from a new variety. The second is inherent in the input structure of the two forms of research. The typical plant-derived pharmaceutical is a compound extracted directly or indirectly from a specific plant found or harvested in one nation; and benefits would consequently be shared with that one nation. In the agricultural case, however, the typical market variety can be traced to material from many nations, requiring numerous agreements to divide a probably small profit among a large number of countries.

<sup>41</sup> See III.C.5 (page 18 above).

Both limited 'market potential' and lack of a 'marketing infrastructure' leave developing countries little choice: to realize their newly recognized rights under the Convention on Biological Diversity, they have to participate in the international exchange of germplasm. But they will want to do so against assurances that those to whom they entrust it will support and facilitate their claims to technology access and compensation.

### *3. Germplasm Users*

The germplasm user community has an equally strong interest in the continued international germplasm exchange and the availability of public genebank services from which it can draw samples already screened and characterized. Neither the public nor the private sectors, however, will willingly accept use restrictions, particularly if they entail conditional payment obligations. Users should, however, be expected to cooperate in the transfer of knowledge and technology to source countries where they can do so. They may be less reluctant though, to cooperate in the transfer of knowledge and technology as long as this does not erode profits and limit their intellectual property rights.

### *4. International Centres*

The interest of the international Centres is twofold: they want a minimum of bureaucratic procedure in handling genebank material, and must maintain their access to genetic material.

In the past, Centres have acquired genetic material through collecting missions or donations, generally with a minimum of formality. Collecting missions were conducted on the basis of simple exchanges of letters which documented timing, scope and funding of a mission, vouched that any movement of germplasm would comply with phytosanitary regulations and that precautions would be taken to avoid accidental introduction of pests and diseases. The letters also indicated where duplicate specimens were to be deposited. Some letter agreements also requested that the host country authority acknowledge through signature of the letter that the material collected should be freely available.<sup>42</sup> No further conditions were spelt out.

Germplasm donations seem to have been effected with even less formality.

<sup>42</sup> "In accordance with the IBPGR principle that all material collected under its funding should be fully and freely available to all who can use it, your signature below indicates your full agreement with this principle, and that it will be observed". Letter between IBPGR and INSA Vietnam of 28 August 1992.

Several Centres received donations when they were established; such donations still account for a large part of currently held accessions.<sup>43</sup>

To the extent that in future they may have to accept new rules on the exchange of germplasm they will want to limit legal formalities and standardize procedures as much as possible. In fact, this should be a shared concern of all actors as they should be equally interested in containing transaction costs.

But of critical interest to the continued effective conduct of their mission will be the Centres' future access to genetic material from developing nations. That access will depend on whether developing countries consider the transfer of germplasm into Centre genebanks as being in their own interest, and whether they perceive the Centres as effectively protecting their interest.

### C. Options for the International Centres

How far, then, can the Centres move away from the current free-exchange system in order to meet the interests of the developing countries, without jeopardizing the flow and use of genetic material, and limiting their own effectiveness? Is there a way to reconcile these competing interests?

There are, basically, three options. They vary in the detail, but each has an internal logic. They differ primarily in the extent to which they impose restrictions on the flow of germplasm.

The first option would be to maintain as much and as long as possible the free flow approach. Under this *Free-Flow Option* Centres would decline imposing any form of control on the flow of genetic material out of Centre collections. Their argument would be that they are there to support the developing world through their research effort and that under the free-flow option they can do this more effectively than in a controlled system. They could also point to the fact that they annually leverage substantial funds for their research effort which should be seen as one form of compensation to satisfy developing country demands under the Convention on Biological Diversity. In addition,

<sup>43</sup> Through three workshops in 1977, 1983 and 1990 and work plans agreed at these workshops, IRRI conducted a systematic and comprehensive collection effort which almost doubled the number of accessions at IRRI's International Rice Germplasm Centre (IRGC). The initiative was supported by all major rice-growing countries which provided duplicates of their collections, while gaps were filled through joint collecting efforts. The free exchange of germplasm, information and experience among participating nations was one of the basic tenets of this endeavour. (see International Rice Research Institute. Proceedings of the Workshop on the Genetic Conservation of Rice. IRRI 1978; *1983 Rice Germplasm Conservation Workshop*. IRRI 1983; *Rice Germplasm - Collecting, Preservation, Use*. Proceedings of Third International Workshop, 10-12 May 1990. IRRI 1991. See also M. Jackson and R. Huggan *Sharing the Diversity of Rice to Feed the World*. *diversity* 9(3):22-25 1993).

they would continue to support the quest of developing countries for other forms of compensation<sup>44</sup>, primarily in the form of improved technology access and increased support for biodiversity conservation and utilization in developing nations. This interpretation of compensation requirements would be in line with the 1993 FAO International Code of Conduct for Plant Germplasm Collecting and Transfer which suggests, compensation to primarily take the form of increased international support for conservation, technology development and technology transfer activities.<sup>45</sup> There would be no need for an MTA under this option.

Under a second option, Centres would go all the way to help developing countries to realize their rights under the Convention on Biological Diversity. We call it the *Institutional Compensation Option*. Centres would seek to maximize financial return from genetic material for developing nations. To this end, they would be prepared to accept genetic material from source countries under conditions which would require the Centres to assume responsibility for negotiating and collecting compensation on the source nations' behalf. Payments could either be directed to individual source countries, or deposited into an international fund.

A third option represents a compromise. Under this *Compensation Assistance Option* Centres would do all that they can, at defensible cost and without disrupting their genebank operations, to introduce a measure of control over germplasm releases designed to preserve and support the claims of source nations to compensation which the source nations, in turn, would have to pursue with ultimate users. The Centres would not themselves negotiate agreements, but distribute material under MTAs that would, to the extent reasonable and possible, protect the source nations' rights.

Despite the obvious virtues of the Free-Flow Option, we anticipate that the lack of compensation will no longer, or at least not much longer, be acceptable to the developing world. By contrast, the administrative cost of the institutional compensation option would claim a substantial share of Centre budgets, as Centres would have to develop or procure expensive legal and negotiating capabilities. It should be discarded on those grounds.

The foregoing would leave the Compensation Assistance Option which should be broadly acceptable; it would allow the Centres to operate within a multilateral germplasm exchange protocol should such a protocol be established under the Convention on Biological Diversity, or under FAO. Should the international community decide at one point to develop an international fund to support germplasm conservation, this would

<sup>44</sup> The CGIAR and its Centres have formally recognized the institutions of 'farmers' rights' as defined in the FAO. See section VI.A.2.a, VI.A.2.d (pages 27, 32).

<sup>45</sup> see quote in III.C.1 (page 15).

be compatible with the Compensation Assistance Option. Centres would support and facilitate the operation of such fund but not act as its collection agents.

#### **D. Compatibility with Trusteeship**

In 1988, the CGIAR adopted its policy statement on plant genetic resources<sup>46</sup>, stating that its Centres are holding their genebank material 'in trust', and make it available to researchers without restrictions. This declaration did not constitute a legal act, but recognized the arrangements under which Centres had previously received such material into their custody.<sup>47</sup> An important question is whether and to which extent the Centres' trusteeship obligations would allow them to support the interests of source countries under the proposed Compensation Assistance Option.

Trusteeship is a form of holding material for the benefit of a third party, the beneficiary. Trustees can do almost anything with the subject matter entrusted to them as long as they do so in accordance with the understanding of those who entrusted the material to them and act in pursuance of the interest and to the benefit of the beneficiary. Thus, control and condition on the use of Centre's genebank material could be imposed consistently with the trusteeship as long as they are in a pattern that might reasonably have been contemplated by the provider of the material and serve the interest of the beneficiary.

In the definition generally used in the CGIAR, the beneficiary of the CGIAR trust is the global research community, acting in the interest of the developing countries. Adopting this definition of beneficiary interest, any condition that could potentially slow the flow of germplasm, the progress of research and the access of the beneficiary to the research product would be incompatible with the CGIAR trust concept. Similarly, it would be incompatible with the trust concept for the Centres themselves to seek to profit from the material in the genebanks.

This leads us to conclude that it is compatible with the current interpretation of the Centres' trust obligations if the Centres provide an opportunity for source nations to benefit from the genetic material they have contributed to Centre's genebank collections by ensuring that recipients are aware of possible rights and obligations associated with

<sup>46</sup> The statement (footnote 38) defines policy in regard of distribution of germplasm and the status of the collections as follows: "*Supply of Germplasm*. It is the policy of the CGIAR that Centres should supply from active collections the germplasm requested by any *bona fide* research worker anywhere in the world, provided adequate stocks are held at the time the request is received. [...] The CGIAR encourages all countries to support the unrestricted interchange of germplasm throughout the world". Under the heading 'Ownership' it states: "It is the CGIAR policy that collections assembled as the result of international collaboration should not become the property of any single nation, but should be held in trust for the use of present and future generations of research workers in all countries throughout the world".

<sup>47</sup> W.E. Siebeck and J.H. Barton. *The Implications of Applying the Legal Concepts of Trust to Germplasm Collections at CGIAR Research Centres*. 1992. *Diversity* 8(3): 29-35 (1992).

the material, and by providing source nations with the information on which they may pursue their claims.

This, then, provides the criteria to gauge what conditions Centres can accept, and subsequently reflect in MTAs under which they distribute the material. The following section of this paper examines on which terms and conditions Centres can accept material into their genebank collections in consonance with the above considerations and, based on the Compensation Assistance Option, proposes a structure of MTAs reflected in the draft form agreements in Annex 1.

### **E. Proposed Agreements for the IARCs**

In international germplasm exchange the Centres operate at both the receiving and supplying ends: they receive material from donors in developing and developed countries, out of existing collections or through collecting missions. And they distribute it to developing and developed countries, in its original make-up (which we will here refer to as 'trust material') or genetically improved (which we will refer to as 'research products').

The conditions under which Centres accept material obviously have to reflect the conditions under which they release it; otherwise, they would not be able to live up to their commitments to source nations. Detailed provisions for release may, however, vary according to the use to be made of the material (research or commercial use) and the character of the partner to whom the material is transferred (NARS or developed-world entity).

#### *1. Release Conditions*

The following paragraphs consider specific release terms.

##### *a. Prior Source Country Consent*

A source country might ask a Centre to obtain its prior approval before releasing material collected on its territory to a subsequent user. If all source countries put the same condition, this would require obtaining approval for distribution of some 150 000 samples per year. If it could be done at all, the resource requirements to implement such a system would be enormous, and could not be justified. Alternatively, if the burden to file for source country consent were placed with the user who then would have to present the country's consent agreement to the Centre in order to obtain the sample, this would ease the administrative burden on the Centre. As a consequence, breeders in that case are unlikely to use the material; this could, in turn, limit their contribution to meeting global food needs.

For these reasons, Centres should not accept such release conditions.



*b. Distribution for 'Research only'*

A 'research-only' provision would allow the Centre to distribute material immediately, i.e. without prior consultation with the provider. A recipient could use the material for research, but would have to obtain permission to commercialize (and would therefore have to negotiate). The recipient would also not be permitted to pass the material or derivatives to third parties without permission, to be sought either directly from the provider or through the Centre. Such provision fits a collaborative set-up where a limited amount of (mostly proprietary) material is introduced and researched. However, in breeding activity involving large numbers of samples of germplasm a 'research-only' clause would be difficult to police.

Its effectiveness would depend, in large part, on the good will of recipients. We do not doubt that most recipients would try to honor the obligation. Often, however, the obligation may be ignored or simply overlooked, especially when parentage in a new variety is small. It should also be noted that when seeking permission to commercialize a breeder would not disclose the make-up of a hybrid's parental lines.

We therefore would recommend against Centres' accepting material on this condition.

*c. Request not to Distribute Material to Third Parties*

Although such a provision is typical in the medical context, we are concerned that a refusal to allow distribution to third parties would seriously disrupt the exchange of plant germplasm among scientists. In the medical sector, it is typical for one firm to study material from one source, while, in the agricultural sector, it is typical for a variety to include parents from many sources.

If recipients had to seek approval from the Centre or the source country every time they passed on genetic material, if not ignored such obligation would cause burdensome paperwork. A practicable arrangement would be to request the recipient that he or she advise the third party of the interest of the source country in the material and of the Centre's contractual request for an evaluation report (see below) every time material is passed on, and at the same time notify the Centre when such transfer takes place. We believe this to be the better approach even if this obligation will at times be overlooked or ignored.

*d. Reporting of Pre-Breeding/Evaluation Results*

Centres traditionally expect recipients to report evaluation results, particularly on breeding material they sent out for testing. However, there is at present no contractual obligation to that effect, and the response seems to be sporadic. At the same time, there appears to be considerable, and perhaps growing, interest among source country providers in obtaining and using such information in their own breeding programmes. Access to pre-breeding information would be an important factor in aiding technology sharing under the Convention on Biological Diversity.

We believe that Centres should systematically require recipients to report such information so that they can make it available to source countries, either periodically or on request. This should be a commitment they give when accepting trust material into their collections.

With computerization of genebank data, it should also be possible for Centres to monitor whether recipients live up to their obligations, and should consider terminating distribution to recipients who become notorious for ignoring such commitment.

*e. Acknowledgement of Origin*

Centres should also require users to acknowledge the source country origin of materials in their scientific publications or in published descriptions of their marketed varieties. This would promote transparency and a modicum of openness in international germplasm exchange. It could also help source countries in pursuing their interests in terms of technology access and compensation.

*f. Profit-Sharing Clause*

Through a clause in an MTA, a Centre could require the recipient to share a profit from successful commercial exploitation of a product derived from source material. Such clause would be legally valid and the Centre could sue the recipient in case of non-conformance. This appears to be the approach of the National Cancer Institute, where the Institute expects to work with private firms under licensing arrangements.<sup>48</sup>

For the international Centres, who distribute material to a large number of recipients, the difficulty of monitoring and the expense of negotiations suggest that such a commitment will be impracticable at best. In line with the Compensation Assistance Option we therefore believe it to be preferable to formulate such a clause as an obligation of the recipient to be enforced by the source nation. Centres would do what they can to protect the source nation's rights by including appropriate language in the MTA, and by stating their policy goals clearly and publicly.<sup>49</sup>

<sup>48</sup> See section III.C.3 (page 17).

<sup>49</sup> Some may argue that a full-fledged legal commitment of the recipient to the Centre would allow the Centre to sue the recipient in the rare event that windfall profits are derived from genetic material provided by one or several known source countries. Our response would be that: in such case the source country or countries should take full responsibility for launching legal proceedings; different jurisdictional systems provide for various ways for the Centre to support such proceedings.

*g. No-Patent or Grant-Back Clause*

Some developing countries oppose any form of intellectual property on genetic material.<sup>50</sup> Even after complying with the TRIPS agreement by legislating some form of plant breeders' rights protection, many will still oppose patenting of plant material including genes. A difficult question is whether a Centre should or could promise to such nations to prevent such intellectual property protection by subsequent users and place a condition in an MTA to that effect. Such promise may allay fears of some source nations that they would not be allowed a share in the commercial value of a patent, or access to its protected technology. Also, in the interest of a free flow of resources, one might argue for a prohibition on patenting of genetic material itself. The possibility of patenting 'naturally occurring genes' has been precluded in policy pronouncements issued by some Centres and the CGIAR.<sup>51</sup>

While a Centre can, and should, enjoin a user not to seek protection that would restrict the availability of the material itself, it would, however, be unrealistic to expect the Centre to check attempts by users to patent derivatives. A stipulation to that effect cannot be policed and would thus not seem very meaningful. One plausible compromise would be to permit patenting of derivatives, but ensure that such patent rights are not exercised to the detriment of developing nations, or the international Centres. This would not prevent a firm from making profits from the genetic material, but would preserve access to the technology for developing nations and the international agricultural research community, while triggering the profit-sharing provisions discussed<sup>52</sup> above.

Even so, some users in industry (especially those with substantial markets in developing nations) may be reluctant to accept material on terms that restrict their right to use a patent in developing countries. For that case, the MTA might allow them to use intellectual property to protect their invention in developing countries provided they market it within a reasonable period (say, five years) after the patent was issued and at

<sup>50</sup> In only a few developing nations is there currently a possibility of protecting patent rights, for few grant patents on genes or plant varieties. This will change as developing nations expand their intellectual property systems to comply with the Uruguay Round Agreement. The TRIPS Agreement (*supra* n. 28) states that parties may exclude from patentability "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the [Multilateral Trade Organization]". Article 27 (3) (b).

<sup>51</sup> See section VI.A.2.d (page 31) above. This formulation presumably allows patents on genes and gene fragments once they have been removed from the original and implanted into a different host organism.

<sup>52</sup> See Section VI.E.1.f. (page 40).

a reasonable price. This would meet the interests of developing countries in obtaining access to the new technology. The intellectual property rights would presumably be enforceable during the first five years after issue. Should the firm not market its invention within that period, Centres and others would be free to use the invention in these countries. It should be the responsibility of the interested government, and not of the Centres, to ensure that a price actually is 'reasonable'.<sup>53</sup>

#### *h. Tracking and Monitoring Responsibilities*

Centres have always logged releases from both their genebank collections and their breeding programmes. Logs show accession numbers linked to passport data, as well as the country of origin, and the recipient's name, institute and country. While most logs are kept in the form of paper files, going back as many as 40 years, Centres have in recent years begun to store such data electronically.

Distributions beyond the first recipient, however, could not be tracked. Even if the first recipient were formally barred from transferring the material and derivatives without the Centre's or the provider's agreement, there would be no practical way for a Centre to effectively police unauthorized second-round releases. Similarly, a Centre will be in no position to monitor what recipients are doing with the distributed material, whether they are still experimenting with it, have commercialized products from it, or whether they have passed it on in its original or modified forms.

We recommend that Centres accept a tracking responsibility for first-round distribution, but not beyond. The only monitoring responsibility the Centres can reasonably discharge - proposed above - would be a periodic check on the return of evaluation reports with the possibility of terminating further distribution to a neglectful recipient.

#### *i. Storage-Only Provision*

Some developing countries are apparently reluctant to deposit material with Centre genebanks for distribution, and instead may want to offer it for storage only, a type of *ex situ* conservation frequently referred to as 'black-box storage'. Under such an arrangement a genebank provides space only, without assuming responsibility for maintenance of the material.

<sup>53</sup> This should meet the concern that a patent-holder could try to sell the invention in developing country markets at prices which farmers, and especially small farmers cannot afford. While this would not seem to be a very likely scenario (why should a firm offer its product at a price only a few can pay?), a country should consider granting a compulsory licence to a local producer. Under Article 31 of the TRIPS Agreement, such a licence is permitted, albeit subject to a number of conditions. Note that this situation can develop only in countries that protect such patents.

Such an arrangement should be considered outside the Centres' trust responsibility as currently defined and would deviate far from the concept of a genebank as a service to the scientific community.<sup>54</sup> It would seem appropriate only as a temporary back-up facility for countries which do not have technically reliable storage facilities, or in an emergency situation requiring temporary storage for their collections. However, in no case should Centres assume trustee responsibilities for such material, or offer assistance in characterizing and evaluating it.

*j. Time and Application Limits*

In parallel to statutory time limits on the protection of intellectual property such as patents and copyrights, we believe that material obtained by Centres under release conditions, should, after a certain period, become generally available, that is, without an MTA.

The draft form agreements therefore include language that all intellectual-property oriented obligations lapse after 30 years. This time limit is obviously subject to negotiation. Thirty years reflect the fact that patent systems are moving globally toward a 20-year term. At the same time, there have been cases in which materials are found to be useful after spending 20 years or more in a genebank. Hence we chose a somewhat longer time.

We also included a limitation that a source plant should be accounted for if it makes up one-fourth or more of a plant that is actually marketed and that it should not be accounted for if it makes up less of the marketed plant. Again, the choice of one-fourth is arbitrary and may be reviewed from time to time, but is comparable to practice within the commercial breeding community. Clearly, such a limitation should not apply in the event that a breeding parent is used for one specific gene, whether introduced into the marketed plant by backcrossing or by genetic engineering.

*k. Recommended Release Conditions*

To summarize: when accepting genetic material subject to the Convention on Biological Diversity into their collections, Centres should agree to release it under the following conditions:

That the Centre would require a recipient to acknowledge the source nation's contribution in any publications or variety descriptions

<sup>54</sup> Such an arrangement has been suggested to one Centre as an alternative to in-trust storage. In an unrelated case, two African Centres have been requested by a Southern African regional group of countries not to distribute recently collected material outside that group until it has been assessed for possible commercially valuable traits.

- to notify the Centre of any transfer of the material or its derivatives to a third party, and to require a similar restriction when transferring the material to that third party
- to issue to the Centre a report on pre-breeding/evaluation results
- in the event of successful commercialization of research products deriving from the material, to provide a reasonable share of net profits to the source nation in a form to be agreed upon between the recipient and that nation. This could be through payments, training assistance, technology transfer, or other forms of collaboration.
- to observe the following restrictions concerning intellectual property<sup>55</sup>:
  - (a) not to seek rights on the material itself, and
  - (b) not to assert rights on derivatives (through the third generation) against nationals of the source country, other developing countries, the issuing Centre or other CGIAR Centres, unless it has actually marketed a product containing the technology in the relevant developing country within five years after issuance of such rights, these obligations should lapse after a period of, say, 30 years; and that the Centre itself would:
    - notify a recipient of the name and agency of the source nation that has provided the material, and of the possible interest that country may have in the material under the Convention on Biological Diversity
    - track the destination of distributed germplasm to the first recipient (first-round releases). Either periodically or upon request, it would advise the source nations of releases effected during a specified period. At the choice of the source nation this information would be available in hardcopy or machine-readable form
    - monitor the filing of pre-breeding/evaluation data by recipients and make them available from its database to source nations.

Similarly to the recipient's obligations, a Centre's obligation to notify, track and monitor should also lapse after a period of, say, 30 years. A Centre may still want to maintain the procedures beyond such date, but should have the discretion to terminate them.

## 2. Three Model Agreements

Based on the frequency at which they are likely to occur and on the need for special terms, three typical transfer situations can be chosen and distinguished.

<sup>55</sup> The International Centres are currently negotiating an agreement with FAO which would place plant genetic material they hold in trust under FAO's auspices as part of FAO's network of *ex situ* collections to be established under the International Undertaking. Under the proposed agreement the Centres would not seek intellectual property rights on the genetic material itself, and would ensure that recipients are bound by the same commitment. This commitment would not extend to derivatives. Our above proposal would be consistent with these provisions.

Each calls for different rules and conditions. For these three situations we have proposed form agreements. There will be other situations which Centres may also want to cover through agreements for which we believe agreements can be developed by modifying the proposed form agreements. The three form agreements would cover:

- the acquisition of germplasm
- the distribution of genetic material
- the distribution of research products to NARS.

*a. MTA for Acquisition of Germplasm*

Form agreement 'A' for acquiring germplasm would reference the conditions which a Centre would apply in distributing the acquired germplasm. Although this can be done by attaching the actual forms to be used in distributing the material, it is probably more transparent to reference the Centre's policy statement which describes the overall Centre policy. This would facilitate future changes in release policies.

In addition, the MTA would set out the Centres own rights and obligations, and limitations thereof, namely

- the Centre's obligations as a trustee to safeguard and maintain the material to the highest technical standards
- its right to use the material in its own research and breeding programmes
- its intention not to exercise intellectual property rights over the material itself, and not to exercise any such rights on derivatives against developing country nations
- provisions concerning the conduct of the acquisition (collecting mission or donation) of the genetic material.

There should be no time limit on these obligations, including the trusteeship obligations.

*b. MTA for Distribution of Genetic Material*

Save for the release of research products to NARS for which we will propose a special agreement, all distribution of germplasm, whether trust or enhanced material, should be covered in one and the same agreement. There is also no need to differentiate between types of recipient, whether in the private or public sector, profit or not-for-profit organization, and in developing or developed countries. In this regard, current CGIAR policy of releasing material to any *bona fide* researcher would be maintained. Under form agreement 'B', a Centre would identify the interests of source nations. The language is designed to allow for the fact that the distributed material may contain components collected from different source nations at different times, before or after the entry into force of the Convention.<sup>56</sup>

<sup>56</sup> It is not designed to protect rights of suppliers of proprietary material incorporated in Centre material; modifications would be necessary in such case. See discussion in section IVE3 (page 44).

*c. MTA for Distribution of Research Products to NARS*

For distribution of research products to NARS we propose Form Agreement 'C'. NARS are the continual collaborators of the International Centres. They provide the link between the Centres' mission and that mission's primary beneficiary, the developing-country farmer. The functions of the international Centres and NARS are complementary, or are becoming increasingly so, as NARS gain in research capacity and capability. Eventually, the international Centres will discharge strategic research tasks, while NARS will adapt the resulting research products in their national breeding and enhancement programmes.

This close collaboration suggests, that: germplasm exchange can be largely based on mutual trust, justifying a modified MTA. There are also other considerations that may justify a simpler type of transfer agreement in relation to NARS. First, since the thrust of the Convention on Biological Diversity was to level the playing field between the North and the South, it is likely that source countries in the South will be less concerned with the strict application of the Convention's tenets if genetic material is exchanged within the South.<sup>57</sup> The second argument for a simpler MTA with NARS is that many NARS are likely to find it difficult to fulfill complex notification and pass-through commitments. Third, as NARS mostly distribute material directly to farmers, such commitments should not be required.

Consequently, we propose that distributions to the NARS include a reduced notification requirement that only applies when a NARS distributes material for further breeding work. We further believe that it will not be necessary to include restrictions on intellectual property. As noted above, in many developing countries such rights could not be enforced at this point. Moreover, in countries where NARS could file for protection, licensing of protected material to private sector breeders and distributors could improve prospects for marketing such material.<sup>58</sup>

<sup>57</sup> Given the reluctance or refusal by some developing countries to release industrial crop germplasm to other developing countries, this assumption may be questionable.

<sup>58</sup> This proposal was included in the recommendations of the TAC/Centre Directors' Working Group on Intellectual Property adopted at its meeting in Rome in January 1992 (see section IVA2d, page 28).



### *3. Distribution of Germplasm under Research Collaboration with the Private Sector*

Several Centres have been contracting with private research institutions for the supply of advanced biotechnology processes and proprietary genetic material. Typically, in such research collaboration, the Centre will use basic genetic material either from its genebank or its breeding program, while the partner will provide a proprietary technology. Research work may be carried out at the Centre's or the collaborators research facilities or both. The need to enter into technology supply arrangements is likely to grow if the developing world is to receive the benefit of genes and gene technology patented in the developed world.

When acquiring proprietary material under collaboration agreements with advanced laboratories, the Centres may have to accept distribution limitations and restrictions they would not accept for material to be received into their genebanks. This will pose a new and different set of problems. In such case, the Centres will have to respect restrictions imposed by the supplier of such material, but they should be careful in determining what restrictions they can accept.

Because each collaboration will be different, we do not suggest developing a form agreement for such research collaboration. We expect, in fact, that in most cases Centres will have to negotiate on the basis of form agreements proposed by the technology supplier. Some thoughts follow on what terms and conditions Centres may, or should not, accept in such collaboration agreements.

Among the reasonable restrictions would be a requirement not to pass proprietary research materials to third parties while the collaborative research is in progress, and to return such material to the provider if the research does not lead to a product.

If the research is expected to result in product development, Centres should also be willing to respect the interests of the supplier in developed-country markets, while insisting that the Centre will be allowed to distribute the product in developing countries. This means that a Centre would commit itself not to release products including, or developed from, proprietary materials to developed-nation firms, and in particular not to pass any material containing a proprietary gene to firms, that would adapt them for developed world markets.

Concerning the distribution of such material to NARS for use in developing countries, Centres should negotiate for a royalty-free licence, or at most accept agreements authorizing payment of a nominal royalty on products used in developing nations. They should ensure that they can make such material available to NARS under a sublicensing agreement which, in turn, would set out the terms under which NARS would be authorized to make material available in their markets. In no case should the Centres agree to collect royalties from a NARS on behalf of their collaborator; nor should they collect royalties from a NARS with respect to their own contributions to a research product.

## F. Implications for the Centres

### 1. *The Need for a Uniform Approach*

It would seem essential for the Centres to take a uniform approach in their decisions as to what restrictions to accept on material obtained in the post-Convention era. Should any one Centre accept germplasm on terms more favourable to the source than do others, similar terms will be demanded of all Centres and by all suppliers. It would seem imperative that these terms be explained to, and reviewed with, a representative number of source nations and user organizations before they are actually used. Any differences should only be those associated with genuinely different situations. Thus, the analysis here focused primarily on agricultural plants. A Centre such as ICLARM or the future African Livestock Centre, working with animal germplasm, or Centres such as ICRAF and CIFOR, working with material that may have agricultural as well as medical applications, may have legitimately different needs — but it is only differences at this level that should lead to special approaches.

### 2. *Signature of Form Agreements*

In general, the legal arrangements for the Centres should be kept as simple as possible. In the case of collecting expeditions, it will be appropriate to use a full rather than a letter agreement, to be signed by both sides. As these expeditions are relatively infrequent, establishing a formal agreement should not pose an undue burden.

In the case of distributions of germplasm under Form Agreements 'B' and 'C', however, administrative costs would become overwhelming if separate agreements were to be sought and signed by both sides before distribution. Hence, even though the approach may not always be enforceable, we recommend using a policy statement to the genetic resources community, coupled with a form letter restating the conditions governing the distribution of germplasm.

### 3. *Description of Material in MTAs*

All Centres currently include with their releases the passport data of the material which show the country from which it was collected or otherwise obtained. In the cover letter for a transfer, any other genetic or fingerprint information should also be included to the extent available, if only as a benefit to the recipient. Although it is not essential to reference this information, it could assist should there be a later dispute as to whether the transferred material was actually used in a marketed product.

The Centres, however, should not place themselves in a position of guaranteeing the source of the material; otherwise, they would be opening themselves to unnecessary liabilities. This is particularly the case where the actual origin of the material is unknown or subject to dispute — i.e. the material was collected in a disputed territory, or the collected organism had only recently been introduced into the nation from which it was collected.

#### *4. Material to be Covered by MTAs*

All material subject to the Convention on Biological Diversity, i.e. germplasm collected after 29 December 1993, together with material reasonably describable as derived from such germplasm, should be covered under the proposed procedure. It does not matter whether this material is in a base or a working collection, or even whether it is in a genebank at all. As long as the material falls under the regime of the Convention, there is a clear obligation to the source nation.

The Centres may, however, want to consider whether MTAs should be applied to all material distributed by a Centre, including material that does not fall under the Convention on Biological Diversity. As the form agreement would note the time of collection of the source material, it would be clear whether there is a legal obligation to source nations. Even when there is no obligation because the material was acquired prior to 29 December 1993, a Centre may elect to provide information on the source country to the user, and on the user to the source nation. In favour of such an approach is the possibility of providing an additional benefit to source nations, if only in the form of the information gained from the recipient of the material. Moreover, there may be an advantage in instituting one uniform procedure for all distribution rather than using different procedures according to the date of accession. However, for some of this material, particularly from early donations, the actual source or time of collection may be unknown. While we believe that either approach is reasonable, we drafted our sample forms on the assumption that they would be used with all transfers.

Special arrangements will be necessary for material derived under special technology collaboration agreements; these arrangements will depend on the terms of the specific collaboration.

#### *5. Warranties and Liability Limitations*

In order to protect the Centres, we believe that a form agreement should include liability limitations to ensure that the Centres are not committing themselves to the safety of the material (even stronger disclaimers and procedures would be required should the Centres distribute transgenic material). Moreover, Centres should guard against any liability for possible misidentification of the source nation of the material.

### *6. Policing Requirements*

As noted above, it would be impractical, if not impossible, for the Centres to undertake monitoring responsibilities beyond tracking first-round distributions and filing of pre-breeding reports. Neither should they undertake the litigation in case of violations of distribution agreements. This would be the responsibility of the source nation involved.

### *7. Aspects not Covered in Proposed Form Agreements*

There are three important aspects we have not considered. One is the choice of law clause, the second the need for an arbitration clause. Needs for such clauses will vary from Centre to Centre. At the same time, it would be preferable if all agreements could reference the law of one specific nation, and thus be interpreted uniformly.

A third and important issue is the definition of 'developing nations,' when used in the form agreements. The question arises, for instance, whether the successor states of the Former Soviet Union and Eastern European nations should be treated as developed or developing countries.

### *8. Applicability of Form Agreements to Others*

Although our form agreements are designed for use by the international Centres, with some adaptations a nation could use these in negotiating agreements for exchange of genetic material with other countries.

### *9. Suggestions for Further Steps*

Assuming that the suggestions in this paper are considered generally appropriate, it is essential to review the suggested draft agreements within the CGIAR system, with source nations, users and the NGO community.

## **G. Assessment**

The proposed set of form agreements and the rules and clauses contained therein are unlikely to satisfy the multiple interests we have earlier identified. They may not go far enough for some developing countries, who want to present a stronger claim for compensation. The user community, particularly in industry, should be expected to argue that the proposed rules are too burdensome and that they will not use material with the proposed strings attached.

It should, however, be realized by both sides, that, as presented, this imperfect compromise offers benefits to both. It offers the breeding industry continued access to the international collection effort; while for the source countries it does level the playing field by providing them access to information on users and breeding results they previously did not have, as well as a possibility of compensation.

Beyond this, we realize that the future global collaboration in the exchange and development of germplasm, on which both the South and the North depend, will only work in a spirit of mutual understanding and fair play. Material transfer agreements can lay the basis for such collaboration but cannot replace the spirit.



## **ANNEX 1: Suggested Form Agreements and Policy Statement**

### **FORM AGREEMENT 'A' FOR ACQUISITION OF GERmplasm:**

1. **[Nation]** grants germplasm to **[Centre]** under the following terms and conditions.
2. **[Nation]** warrants that the germplasm comes from within its territory and that it is legally free to provide the germplasm to **[Centre]**.
3. **[Centre]** will hold the material in trust, place it in its genebank, maintain it, periodically regenerate it, duplicate it for security reasons and provide state-of-the-art long-term conservation.
4. **[Centre]** will make the material available to any user under an agreement as described in the attached policy statement, with terms intended (a) to indicate to recipient that **[Nation]** may have an interest in the material, (b) to require the recipient to notify **[Centre]** as to any further destination of the material, and (c) to restrict the recipient from obtaining intellectual property rights on the material itself and asserting such rights on derivatives against a developing-nation user.
5. **[Centre]** is free to improve and breed with the material in any fashion. Should **[Centre]** develop advanced varieties or separate genes from the material, it will not exercise any patent rights it may obtain against **[Nation]** or any developing nation.
6. The **[Centre's]** obligations at (a) to (c) of paragraph 4 of this agreement shall expire at the end of 30 years.

## FORM AGREEMENT 'B' FOR DISTRIBUTION OF GENETIC MATERIAL

1. This material is or derives (in part or in total) from material collected in or provided to the **[Centre]** by **[Nations]** and was collected [before/after] the entry into force of the United Nations Convention on Biological diversity and thus [is not/is] subject to the rights that **[Nation]** has under the Convention. In case of successful commercialization of any gene deriving directly from material provided by **[Nation]** and subject to the Convention or of any plant tracing one-fourth or more of its lineage to such material, **[Recipient]** is subject to an obligation to provide a reasonable compensation to the source nation in a form to be agreed upon between the recipient and that nation. This could be through payments, training assistance, technology transfer, or other forms of collaboration.
2. **[Centre]** is notifying **[Nations]** as to this transfer.
3. **[Recipient]** will provide **[Centre]** with the results of any evaluation trials it may perform. Upon request, these will be passed on by **[Centre]** to **[Nations]**.
4. **[Recipient]** shall not obtain any form of intellectual property protection on this material.
5. Should **[Recipient]** pursue intellectual property protection on any gene or other invention deriving from the material or any plant tracing one-fourth or more of its lineage to the material, it may not assert the resulting rights against anyone in a developing nation after five years from the date of grant of the intellectual property right, unless, during that time, it has made the invention available within the nation at a reasonable price. **[Recipient]** will ensure that any third party who takes the material or material owing one-fourth or more of its lineage to the material, or receives a licence under a patent that **[Recipient]** may obtain from the material, will be subject to a similar obligation. For the purposes of this paragraph, 'developing nations' include ....
6. Should **[Recipient]** provide the material, genes derived directly from it, or material tracing one-fourth or more of its lineage to the material to any entity other than for distribution to farmers, it shall notify **[Centre]** of the transfer.
7. **[Centre]** makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material.
8. **[Recipient]**'s obligations with respect to acquiring intellectual property rights and with respect to any obligations it may have to **[Nations]** shall expire at the end of 30 years.
9. Material is supplied expressly conditional on **[Recipient]**'s acceptance of the terms of this letter. **[Recipient]**'s retention of the material constitutes such acceptance.



**FORM AGREEMENT 'C' FOR DISTRIBUTION OF CENTRE RESEARCH PRODUCTS TO NARS:**

1. This material derives (in part or in total) from material collected in or provided to the [Centre] by [Nations].
2. [Centre] is notifying [Nations] as to this transfer.
3. [NARS] will (a) make the material and material derived from it available at nominal cost to its farmers, or (b) make it available on an exclusive basis to a firm that will distribute it to its farmers according to national law, provided that such distribution shall be on terms favourable to the farmers.
4. Should NARS provide the material or close derivatives to any entity other than for distribution to its farmers, it shall notify the recipient that the material includes material provided by [Nations], that it may be subject to compensation obligations, and shall notify [Centre] of the transfer.
5. [NARS] will provide [Centre] with the results of any evaluation trials it may perform. These may be passed on by [Centre] to [Nation].
6. [Centre] makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other information supplied with the material.
7. [NARS]'s obligations with respect to any compensation obligations it may have to [Nations] shall expire at the end of 30 years.
8. Material is supplied expressly conditional on [NARS]'s acceptance of the terms of this letter. [NARS]'s retention of the material constitutes such acceptance.

## POLICY STATEMENT ON MATERIAL TRANSFER AGREEMENTS

[Centre] holds large quantities of germplasm in trust; it distributes this germplasm to third parties for agricultural research and it works with the germplasm in its own research. This research and its products are the primary benefit that [Centre] provides to the developing world.

Following the entry into force of the United Nations Convention on Biological Diversity on 29 December 1993, [Centre] will recognize the specific rights of source nations supplying germplasm to [Centre] in its germplasm release policy. This policy duly reflects the concerns of source nations and of their farmers who have been improving the material over historical time. [Centre] is also cognizant of the costs of elaborate legal documentation and of the need to focus its own resources on research.

It therefore adopts, the following policy:

- (1) In any transfer of germplasm, whether material in its genebank or material improved by its own research, but without making warranty as to the genetic make-up of the transferred material, [Centre] will notify the recipient of the identity of nations that may have an interest in the material.
- (2) [Centre] will require the recipient to (a) acknowledge the source of the material in any publications reporting on its use or descriptions of marketed varieties derived thereof; and (b) notify it of any transfer of the material or its derivatives to a third party, to request that third party to also notify such transfer, and to issue to [Centre] a report on evaluation results.
- (3) [Centre] will track the destination of release germplasm to the first recipient (first-round releases). Either periodically or upon request, it will advise the source nation of releases effected during a specified period. At the choice of the source nation, this information would be available in hardcopy or machine-readable form. On the same terms, [Centre] will provide prebreeding/evaluation data from its database.
- (4) [Centre] will not claim intellectual property rights over the material held in trust.
- (5) [Centre] will also require that the recipient is not to obtain intellectual property rights on the material as supplied, and that any plant breeders rights in derivative lines or patents on genes or similar inventions deriving from the material are to be asserted in a developing nation only if the relevant material or material containing the relevant invention is made available in the particular developing

nation at a reasonable price within five years from the time of grant of the property right.

- (6) **[Centre]** will advise the recipient that the material may be subject to the Convention on Biological Diversity and that, in case of successful commercialization of research products deriving from the material, the recipient is subject to an obligation to provide a reasonable share of net profits to the source nation in a form to be agreed upon between the recipient and that nation. This could be through payments, training assistance, technology transfer, or other forms of collaboration.
- (7) The 5th and 6th obligations will reach genes derived from the material and plants incorporating one-fourth or more of the source material. They will expire after 30 years.
- (8) This policy will be attached to a cover letter agreement to be dispatched with the material.

The **[Centre]** recognizes that its policy at paragraph (6) may not necessarily create a formal legal obligation under all nation's legal systems on the part of the recipient to compensate source nations from any profits. The **[Centre]**, however, will seek to state the commitment in a way likely to be honoured by both legal systems and recipients, and believes that the use of the **[Centre's]** resources to undertake the legal and accounting work to enforce a legal obligation would be far less beneficial to developing nations than use of its resources for research.

The **[Centre]** will not accept genebank material on any terms other than these.



## **ANNEX 2: CGIAR Centres Current Germplasm Distribution Policies**

Five Centres have to date issued policies (some described as interim policies) specifically dealing with the distribution of germplasm, either from their genebanks, or their breeding and research programmes.

### **CIAT**

CIAT's 'Interim Policy on Intellectual Property' of April 1993 allows for restrictions on germplasm release in three cases: (1) to prevent appropriation of CIAT research products; (2) to protect intellectual property of research collaborators; and (3) to enable commercialization of CIAT research products through others. Genebank material will be distributed under MTAs on condition that recipient will "not appropriate these public goods". New varieties developed from material can be protected under IPR. (And so can apparently all other derivatives.) The statement further proposes that MTAs will be drafted, and that rules will be set to prevent appropriation of individual genes. The statement also proposes three remedies if a recipient violates the provisions of an MTA: such violation would (1) void the MTA; (2) make the recipient ineligible for future distribution; and (3) entail legal action by CIAT.

CIAT has since developed an MTA for the distribution of materials used for soil cover in coffee and cacao plantations. It requires the recipient (1) not to seek protection of the material or essentially derived varieties; and (2) not to transfer it to third parties without CIAT's authorization. Its duration would be indefinite.<sup>59</sup>

### **CIMMYT**

The 'CIMMYT Policy on Intellectual Property' was approved by its Board of Trustees 31 March 1993. It stipulates that "plant genetic resources held in trust will be made available to recipients who agree to take no steps that restrict the further availability of those resources in their original form to other interested parties".

A draft policy on 'Distribution and Release of CIMMYT Maize Germplasm Products' is available in an October 1993 version. According to it, genebank material will be available on condition that use (presumably in its original form) will not be restricted to others. Inbred lines and source populations will be supplied on request without release conditions; if supplies of such material are limited, it will be supplied, in order of priority, first to NARS, then to developing-country private sector, and last to developed-country

<sup>59</sup> "It is impractical to specify a time limit for this agreement because the genetic structure of the biological material, the object of this agreement, could be modified in the future through technology developments. Therefore, the present agreement is indefinite". (§ 4 CIAT MTA for material for use as soil cover in coffee and cocoa plantations).

private-sector recipients; material developed through collaborative trials will be available to collaborators; material developed by CIMMYT will be available to scientific collaborators; material obtained from others will be distributed only with the consent of the originator.

On 3 August 1993, CIMMYT issued a 'Policy on Use of Bread Wheat, Durum Wheat, *Triticale* and Barley Germplasm Distributed by CIMMYT - Reaffirmation of a Long Standing Policy'. According to it, genebank material is freely available (note that CIMMYT also holds 'obsolete varieties' in its genebank, i.e. material no longer in active breeding programmes, which is also freely available). Breeding material is distributed as follows: segregating populations ( $F_2$  -  $F_5$ ) are distributed without conditions. Advanced lines ( $F_6$  and higher) are distributed on condition that no Plant Breeders' Right will be obtained without CIMMYT's permission. No non-CIMMYT material obtained from CIMMYT can be transferred without permission by the originator.

### **ICRISAT**

According to ICRISAT's Interim Guidelines, genebank material will be distributed without restriction to governmental recipients in developing countries, but to all others for research purposes only. Governmental recipients will be requested to add the same restriction when transferring material to third parties. Breeding material and other ICRISAT research products will be distributed to users in developing countries in accordance with existing agreements with these countries. All others would receive the material for research only. Commercialization would require a licence to safeguard the interests of developing countries. For-profit users would be required to pay a reasonable royalty.

### **IITA**

A 'Statement on Intellectual Property Management at IITA' was issued in April 1993 after endorsement by IITA's Board of Trustees. According to it, genebank material will be distributed without restriction, while breeding material is distributed on condition that it not be used exclusively by a single organization. (This limitation may be intended to preclude a recipient from obtaining intellectual property rights on the material itself; however, as long as it was shared with at least one other organization, e.g. through a licence, the clause would appear to allow the recipient to obtain protection, also on the material itself.)

Some IITA research products (microorganisms and arthropods) will be made available for research purposes only.

**IRRI**

According to 'The Policy of the International Rice Research Institute (IRRI) on Rice Genetic Resources and Intellectual Property Rights' of April 1993, trust material is available without restriction. "IRRI is opposed to the application of patent legislation to plant genetic resources (genotypes and/or genes) held in trust".

A second policy statement, 'The Policy of the International Rice Research Institute (IRRI) on Hybrid Rice and Intellectual Property Rights' also issued in April 1993 also states that all breeding material is freely available. IRRI retains the right to distribute to others. It requests recognition of the use of its material when a variety is released by a recipient.

IRRI uses an MTA for distribution of enhanced material to private seed companies. It requires acknowledgement of the source country and cost-free sharing of varieties derived by the recipient.