In memoriam: *This publication is dedicated to Wolfgang Siebeck*

Issues in Genetic Resources No. 4, June 1996

Access to Plant Genetic Resources and the Equitable Sharing of Benefits:

a contribution to the debate on systems for the exchange of germplasm

(a feasibility study prepared by the International Plant Genetic Resources Institute)

Abstract

There is a wide spectrum of options for genetic resources exchange systems, ranging from a strictly bilateral approach at one extreme, to an unstructured informal multilateral approach at the other. Between these two extremes lie a host of additional options which draw on elements from both ends of the spectrum.

In examining the extreme ends of the spectrum of options, the report points out that, at least for food crop germplasm, exclusively bilateral arrangements are likely to be excessively complicated given the large number of potential actors, the complex pedigrees of crop lines, the limited capacity of many partners to be able to negotiate favourable terms, and the relatively limited financial benefits that might accrue from such arrangements

At the other end of the spectrum lies an approach which characterises the current informal exchange system. This approach has been responsible for much of the food crop germplasm collected and exchanged internationally over the past two decades and has benefited both developing and developed countries. However, a lack of clarity concerning the rights and obligations associated with participation in the system and its conformity with the objectives of the Convention on Biological Diversity (CBD) relative to benefit-sharing has left it open to charges of non-transparency and has tended to discourage the involvement of some important stakeholders. Thus there appears to be a need for a more formal approach, although one that retains the essential features of the current system.

The report considers the possible structure of this more formal approach. It presents a flexible multilateral framework – referred to as the Multilateral System for Exchange (MUSE) – that would be governed by mutually agreed rules. MUSE is not an exchange system *per se*; rather it is the framework for a system, which could accommodate the broad range of options existing between the above-mentioned extremes of purely bilateral arrangements and informal multilateral approaches to exchange. For example,

MUSE could make provision for benefit-sharing on a bilateral basis under certain circumstances. Under another scenario, MUSE might include a fund as a mechanism for financial compensation in return for access and in recognition of the concept of Farmers' Rights. A combination of these scenarios might coexist within the MUSE framework and be applied according to circumstances. For instance, the scenario providing for bilateral negotiations might apply in the case of non-food crops only.

The policy basis for the MUSE framework would be set by general principles established in the CBD. The system would operate according to standard rules governing conditions of membership, terms of access to genetic resources, mechanisms for sharing benefits among participants, and relationships with non-members. The MUSE rules would provide formal clarification – and protection – of the rights and obligations associated with the exchange of PGR under the terms of the CBD and the revised International Undertaking.

If it is decided that the MUSE approach is worth pursuing further, a number of issues need more detailed study, e.g. the transaction costs involved in the various options. In the meantime, it is hoped that the IPGRI report will stimulate interest and contribute positively to the on-going debate on systems for germplasm exchange.

Issues in Genetic Resources *is an occasional series of papers published by IPGRI on important topics of interest to the genetic resources community.*

The International Plant Genetic Resources Institute (IPGRI) is an autonomous international scientific organization operating under the aegis of the Consultative Group on International Agricultural Research (CGIAR). The international status of IPGRI is conferred under an Establishment Agreement which, by December 1995, had been signed by the Governments of Australia, Belgium, Benin, Bolivia, Burkina Faso, Cameroon, China, Chile, Congo, Costa Rica, Côte d'Ivoire, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Greece, Guinea, Hungary, India, Iran, Israel, Italy, Jordan, Kenya, Mauritania, Morocco, Pakistan, Panama, Peru, Poland, Portugal, Romania, Russia, Senegal, Slovak Republic, Sudan, Switzerland, Syria, Tunisia, Turkey, Ukraine and Uganda. IPGRI's mandate is to advance the conservation and use of plant genetic resources for the benefit of present and future generations. IPGRI works in partnership with other organizations, undertaking research, training and the provision of scientific and technical advice and information, and has a particularly strong programme link with the Food and Agriculture Organization of the United Nations. Financial support for the agreed research agenda of IPGRI is provided by the Governments of Australia, Austria, Belgium, Canada, China, Denmark, France, Germany, India, Italy, Japan, the Republic of Korea, Mexico, the Netherlands, Norway, Spain, Sweden, Switzerland, the UK and the USA, and by the Asian Development Bank, IDRC, UNDP and the World Bank.

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Foreword

Genetic diversity within and among plants, animals and microorganisms provides the foundation for farming systems throughout the world. The continued existence of much of this diversity is threatened, yet it remains a fundamental resource that underpins our ability to tailor food production to meet future challenges - whether new pests or diseases, changing climates or the relentlessly increasing demands of an ever expanding human population. Our collective ability to meet these challenges will depend on our capacity to access and use a wide assortment of genes and genotypes. The failure to do so will impact all of the peoples of the world, but in particular those living under the most difficult conditions; often the very communities which have, over the millennia, developed the genetic resources which are so vital to us today. If they, in particular, are to gain from our efforts to identify and use genetic variability, it is imperative that we find ways to promote further the equitable sharing of the benefits derived from its use. This report, prepared at the request of the FAO Commission on Genetic Resources for Food and Agriculture, aims to contribute to the ongoing debate on how best to ensure that germplasm continues to be available internationally in the best interests of all.

The report considers a range of options, from the current, essentially unregulated system, through to a global germplasm exchange system based solely on bilateral agreements. A framework, referred to as the Multilateral System for Exchange (MUSE), is presented within which the many intermediate options between these two extremes can be considered. The report explores some of these options.

The report is based on the work of a Study Team which, during the course of its investigations, held a wide series of consultations with many stakeholders and interest groups. It operated under the guidance of a task force established by IPGRI and which included FAO staff members as observers. The leader of the Study Team was Mr. Wolfgang Siebeck who, sadly, passed away very shortly after the report was finalized. His contribution to the report was enormous, as it was to so many of the complex issues currently being addressed internationally in relation to genetic resources. This report is dedicated to his memory.

In outlining a range of different options and setting a possible framework for solutions, the report does not closely examine the transaction costs involved in implementing the different options. It is clear however that further work is needed in this area. IPGRI thus intends to further this aspect of the study over the coming months with the aim of providing a supplementary analysis by the time the report is considered by the Commission in December 1996.

I trust that this report, together with the proposed supplement, will prove to be a useful contribution to the debate in the FAO Commission regarding the revision of the International Undertaking on Plant Genetic Resources, as well as to the ongoing consideration of these, and related issues, in other fora.

Geoffrey Hawtin
Director General
IPGRI

June 1996

Summary

1. The 6th session of the FAO Commission on Plant Genetic Resources requested that IPGRI study the feasibility of possible systems for the exchange of plant genetic resources for food and agriculture (PGRFA)[1] and the equitable sharing of benefits. The following report is the result of that study. It seeks to provide the Commission with a set of options and their implications and thus to inform international negotiations concerning the revision of the International Undertaking on Plant Genetic Resources. As part of the study process a wide series of consultations was held with major stakeholder groups.

2. A fundamental justification for conserving and characterizing PGRFA is their potential for use in the development of improved crop varieties. These improved varieties are necessary to meet the food needs of a growing population and the demands of changing agro-ecological and social conditions. Plant breeding for sustainable agriculture is dependent on the existing diversity of PGRFA. Yet this diversity is currently underused and furthermore, is threatened by genetic erosion.

3. Important food crops are usually widely distributed and may be major staples in regions far from their origin. The dispersal and exchange of crops have gone on since the early spread of agriculture. The reliance of countries on introduced crops means that no country is self-sufficient in plant genetic resources. Even though many nations harbour significant genetic diversity in genebanks and on farmers' fields, they will still continue to require access to the diversity available elsewhere. The interdependence of countries with regard to PGRFA clearly points to the need for the international exchange of genetic resources and related information.

4. Farmers and professional breeders have traditionally relied on open access to genetic resources. In recent years, however, there has been a trend towards greater privatization of plant breeding and research, coupled with increasing pressures to enact stricter intellectual property legislation. At the same time, there is a growing recognition of the potential value of biodiversity to sustainable development. With the entry into force of the Convention on Biological Diversity (CBD), the

[1] According to the International Undertaking, plant genetic resources encompass: "cultivated varieties in current use and newly developed; obsolete cultivars; primitive varieties (landraces); wild and weedy species; near relatives of cultivated varieties; and special genetic stocks including elite and current breeder's lines and mutants." International Undertaking on Plant Genetic Resources, Article 2 i (a).

conservation imperative has received formal recognition, as have the sovereign rights of nations to control access to their biological diversity and to make it available under terms and conditions that are agreed mutually between providers and recipients. Among other things, these conditions permit providers of original material to negotiate a fair and equitable share of the benefits arising from its exploitation.

5. The Global Plan of Action (GPA), which will be one of the principal outputs of the upcoming FAO International Technical Conference on Plant Genetic Resources, will serve as an important tool for implementing the revised International Undertaking, and indeed the CBD itself, with regard to PGRFA. The effectiveness of the GPA will depend on strengthening international cooperation and ensuring continued access by all countries to the full range of crop genetic diversity.

6. International cooperation in the field of PGRFA can provide significant benefits including:
   - increased opportunities for developing joint conservation and use strategies and for sharing responsibilities and costs regionally and/or globally, including the provision of mechanisms for safety duplication;
   - the facilitation of research partnerships and the pooling of research resources needed to exploit particular genepools effectively;
   - access to greater amounts of germplasm than are available in any one country;
   - access to improved materials;
   - access to relevant technologies developed by partner countries;
   - a greater exposure of material to a wide range of environments, thereby leading to better understanding of its properties and hence, better exploitation of its potential;
   - access by providers to information, e.g. special traits or multilocation testing data, on material that they have supplied as well as on material supplied by partners;
   - more cost-effective means of exchanging information, e.g. through shared databases and information systems;
   - access to training at a range of specialized institutions.

7. In devising mechanisms for implementing the GPA, the revised International Undertaking and the CBD, it is important to consider the suitability of the two basic approaches to the exchange of genetic resources under given circumstances. Bilateral approaches are typically partnerships of two institutions or governments, generally formalized through a contract or memorandum of understanding. Multilateral approaches involve a number of countries and/or institutions that agree

collectively to terms and conditions for sharing materials and benefits. Both approaches have advantages and are consistent with the CBD.

8. Bilateral approaches may be most appropriate when a small number of countries have, or need access to, the genetic diversity of a particular species or group of species, and/or when highly expensive and specialized research gives a strong competitive advantage to a single or limited number of institutions. Such conditions may prevail in the case of some industrial crops and in certain sectors, for example pharmaceuticals.

9. Multilateral approaches may be most appropriate in situations where individual countries harbour only part of the genetic variability (i.e. the total genepool) of interest, and/or when farmers and professional breeders in many countries need access to particular resources. They are also appropriate when there is a high social stake in successful crop improvement and when the pooled efforts of many are likely to be more effective in promoting improvement than the efforts of a few. These conditions prevail for the majority of staple food crops.

10. The report examines three options for exchange systems:
- a strictly bilateral approach
- the current informal multilateral approach
- a multilateral framework governed by mutually agreed rules.

11. Exclusively bilateral arrangements have rarely been reported in the case of staple food crops but are likely to be extremely complicated given the large number of potential actors (and hence individual agreements) involved, the complex pedigrees of crop lines (and hence the difficulty of assessing and apportioning benefits), the limited capacity of many partners to be able to negotiate favourable terms, and the relatively limited financial benefits that might accrue from such arrangements. The report concludes that a strictly bilateral approach to the exchange of food crop germplasm is likely to be excessively cumbersome and thus does not consider this option at length.

12. The second option represents the current approach to exchange, an informal system which comprises national programmes and other partners, including CGIAR Centres, NGOs and the private sector. This approach is both flexible and cost-effective. It has been responsible for much of the food crop germplasm collected and exchanged internationally over the past two decades and has benefited both developing and developed countries. However, a lack of clarity

concerning the rights and obligations associated with participation in the system has left it open to charges of non-transparency and has tended to discourage the involvement of some important stakeholders, in particular, the informal sector. Thus there appears to be a need for a more formal approach, although one that retains the essential features of the current system.

13. The third broad option – referred to as MUSE[2] – describes such an approach: a flexible multilateral framework governed by mutually agreed rules. The CBD would set the context for MUSE and would provide the guiding principles for the system. The MUSE rules would provide formal clarification – and protection – of the rights and obligations associated with the exchange of PGR under the terms of the CBD and the revised International Undertaking.

14. The basic MUSE framework as described would retain the strengths of the current multilateral approach but would add to its transparency by clearly specifying the rights and obligations of all members. Such a framework could accommodate the broad range of alternatives existing between the above-mentioned extremes of purely bilateral arrangements and informal multilateral approaches to exchange. For example, MUSE could make provision for benefit-sharing on a bilateral basis under certain circumstances, typically upon commercialization. Another scenario might include a fund as a mechanism for financial compensation in return for access and in recognition of the concept of Farmers' Rights. A combination of these scenarios might coexist within the MUSE framework and be applied according to circumstances. For instance, the scenario providing for bilateral negotiations might apply in the case of non-food crops only.

15. Membership in MUSE would be voluntary and would be open to all stakeholders with an interest in PGRFA. These include farming and indigenous communities, government departments and institutions, genebanks, managers of protected areas, university departments, private charitable institutions, commercial institutions and companies, regional and international research institutions, inter-governmental organizations, non-governmental organizations, etc.

16. Countries wishing join MUSE would become party to an agreement. The FAO Commission on Genetic Resources for Food and Agriculture might consider negotiating such an agreement within the framework or as part of the revised International Undertaking. In accepting the MUSE

[2] A **MU**ltilateral **S**ystem for **E**xchange.

Agreement, members would agree to collaborate and to operate according to standard rules governing conditions of membership, terms of access to genetic resources, mechanisms for sharing benefits among participants, and relationships with non-members. The subsequent governance and monitoring of MUSE, including responsibility for revising the MUSE rules to meet changing needs, would rest with government members.

17. Conditions for non-government membership (private institutions, NGOs, farming and indigenous communities, etc.) would be set by the host country of the participating institute or organization whose responsibility it would be to determine how to implement and enforce these conditions at the national level. Governments might, for example, allow interested parties to join MUSE by entering into an agreement at the national level or with the system as a whole. The latter option might apply for institutes and organizations located in non-member countries or for international organizations such as the CGIAR. Once they have joined MUSE, non-government members would be bound by the same basic rules regulating access and benefit-sharing as are contained in the MUSE Agreement.

18. A system such as MUSE is likely to attract greater participation from the "informal sector" (non-governmental organizations, farmer and community groups, etc.) in mainstream genetic resources efforts than is currently the case. The MUSE rules would apply to all members and, to the extent that infringements could be detected, would be enforceable. All members would be free to pursue their own objectives as long as these were consistent with the rules of the system. At the operational level, MUSE would be characterized by a rich diversity of permanent and temporary alliances, implemented by a mixture of existing networks and new partnerships.

19. Because current arrangements for the exchange of genetic resources are not standardized (a notable exception being the standard agreements that accompany the release of materials from CGIAR genebanks), they tend to be made on a case-by-case basis. The adoption of standard terms and conditions under MUSE could greatly reduce – or avoid altogether – the necessity to conclude individual agreements for each transaction conducted between participants and could substantially reduce bureaucracy and transaction costs overall.

20. In addition to encouraging broader participation and increasing the transparency and cost-efficiency of international conservation efforts,

membership in MUSE would offer a wide range of benefits. It should be noted that these are not uniquely available under MUSE. Indeed, any form of international cooperation has the potential to provide such benefits, as noted above. The principal advantage of MUSE is that it would contain mutually agreed mechanisms for ensuring that these benefits are shared equitably among participants and for protecting the rights and enforcing the obligations of all.

21. The MUSE Agreement would define such areas as:

- the scope of the system in terms of genetic resources
- the terms under which access would be provided
- mechanisms for sharing benefits
- membership terms and conditions
- governance and decision-making mechanisms
- rules of membership and mechanisms for monitoring and enforcement
- mechanisms for interacting with non-members.

22. The report identifies a number of criteria that might be used to define the range of genetic resources that would be made available through MUSE (the "scope" of the system). Criteria for defining scope might include, among others: categories of plant genetic resources; conservation location (e.g. *in situ* or *ex situ*); intended use of the materials (e.g. whether they are to be used in crop improvement or for pharmaceutical purposes); whether the materials were collected before or after the entry into force of the Convention on Biological Diversity. The report notes that, at a minimum, MUSE should include all major staple food crops. Coverage might be on an inclusive basis (whereby a list would specify materials included in the scope) or an exclusive basis (whereby a list would specify what is not included).

23. In considering scenarios within the MUSE option, the report discusses the possibility of establishing a fund as a mechanism for financial compensation in return for access. This could be one of the mechanisms for recognizing Farmers' Rights. If a fund were to be included in MUSE, decisions would be needed on such matters as its establishment, governance, replenishment and disbursement. Special consideration would need to be given to developing mechanisms and guidelines for allocating the funds, and in particular, for ensuring that farmers and local communities receive adequate compensation. The fund issue is currently under discussion in other fora and therefore is not covered at length in the report.

24. Another scenario within MUSE might allow, under certain circumstances (typically when there are prospects for commercialization), an original provider of germplasm to enter into bilateral negotiations with a recipient for an appropriate share of benefits. This might be in the form of access to a commercialized product derived from the germplasm, or to technologies, royalty-free or on special terms; access to facilities, training or other services; or an appropriate share of royalties or profits arising from the product. The questions of when to enter into such negotiations and how to define "commercialization" are examined in Annex IV.

25. It is noted that in the case of commercialization of the seed of crop varieties included within the agreed scope of MUSE, profit-sharing arrangements are likely to give rise to relatively small revenues. In many cases, these could easily be consumed by the administrative and legal costs involved in negotiating benefit-sharing. However, if both providers and recipients of germplasm within MUSE determine that there are sufficient grounds to warrant bilateral negotiations, these could be carried out under standard, multilaterally agreed guidelines – thus significantly lowering costs – and possibly with legal assistance provided through the system. Options for allowing bilateral benefit-sharing within MUSE are examined in Annex IV.

26. In many countries, the signing of the Agreement would enable the MUSE terms to be enforced in that nation. In other cases, special legal arrangements would have to be made in order to be able to enforce the terms of the Agreement. These might take various forms, such as broad umbrella agreements, mechanisms for registering institutions with MUSE, or specific material transfer agreements (MTAs)[3] governing individual exchanges. Options for addressing this and related institutional issues are examined in an annex to the report.

27. By signing the MUSE Agreement, governments would agree in advance to standard terms of prior informed consent (PIC) and would operate on the basis of standard, mutually agreed terms (MAT) with respect to the exchange of all material included in the scope of the system. The PIC and rights of local communities and of other non-government holders of genetic resources would be established through instruments determining their participation in or relationship to MUSE, and in

[3] An MTA is a legally binding agreement between two or more parties that specifies the terms and conditions under which materials will be supplied and specifies the obligations of the recipient. The jurisdiction under which the MTA is governed, normally that of the recipient country, is specified in the agreement

accordance with national policy and legislation. Such instruments might in turn contain provisions for recognizing Farmers' Rights.

28. MUSE would facilitate access by all members to the materials within its scope. The collective benefits of participating in the system would also be available to all members. However special arrangements might be needed to ensure that communities and farmers providing germplasm to MUSE know where their materials are being held and how they, and other genetic resources, can be accessed. Any group or institution providing material to MUSE – whether or not they are formal participants in the system – would retain the right to have continued and unrestricted access to that material.

29. Genetic resources included in the system might be released to non-members only under certain arrangements. This would typically be through standard MTAs negotiated and agreed by all MUSE members. The conditions under which materials would be made available to non-members might be identical to the terms of access by members, or might place added obligations on recipients, such as the requirement to provide materials to the system in exchange, special requirements for the sharing of information, or a requirement to make research products available to members (or to a subgroup of members such as developing countries) on concessional terms.

30. A small secretariat would be required to ensure the effective management of MUSE. An information unit would also be needed to serve the needs of MUSE members. In addition, consideration could be given to establishing a service unit to help co-ordinate and facilitate various aspects of benefit-sharing, including the transfer of technology, and funding provided by donor agencies and others for specific projects and activities to be conducted within the framework of MUSE. Membership fees might be levied to cover the operational costs of running MUSE, including the secretariat and the information and service units.

31. If it is decided that the basic MUSE option or any of its scenarios are worth pursuing further, a number of questions need more detailed study, including the likely costs of the system, as well as various issues related to benefit-sharing, governance and implications of the system for national legislation.

32. The future development of agricultural systems world-wide requires that PGRFA remain accessible, are available under terms and conditions designed to ensure conservation and continued sustainable use, and that

the benefits arising from that use are shared equitably. It is hoped that the options considered in this report will stimulate interest and contribute positively to the ongoing debate on these issues.

Organization of the Paper

Part I of the paper sets the broad context for the study and outlines a number of approaches to the exchange of genetic resources. Chapter I provides the background to the study and Chapter II reviews alternative exchange models, the uses and relevance of these options in specific situations, and their respective costs and benefits. The Multilateral System for Exchange (MUSE), a multilateral framework guided by a set of mutually agreed regulations, is introduced in this chapter.

Part II of the paper examines the MUSE option, and possible scenarios, in more detail. Chapter III describes the institutional framework and the benefits associated with participation in the system. The possible scope of the system is addressed in Chapter IV. Chapter V presents conclusions and recommendations for future action. A more detailed analysis of possible mechanisms for implementing aspects of MUSE is given in Annex IV.

Part I. Introduction, Context and Options

Chapter I. Introduction

Origin of the Study

1. At its Sixth Session in June 1994, the FAO Commission on Plant Genetic Resources invited Dr. Geoffrey Hawtin, Director-General of IPGRI[4], to outline the technical and policy problems inherent in managing the plant genetic resources[5] collections held in trust by the CGIAR Centres.[6] These collections form part of the FAO Network of *Ex Situ* Collections.[7] In the course of his presentation, Dr. Hawtin described a possible approach to facilitating access to plant genetic resources and promoting the equitable sharing of the benefits arising from their use. The Commission requested Dr. Hawtin to prepare a note based on his intervention (see Annex I).

2. The Commission is currently considering the revision of the FAO International Undertaking on Plant Genetic Resources to bring it in line with the Convention on Biological Diversity (CBD).[8] Members felt that the approach proposed by Dr. Hawtin for the exchange of germplasm

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[4]The International Plant Genetic Resources Institute, one of the 16 international agricultural research institutes of the Consultative Group on International Agricultural Research (CGIAR).

[5] According to the International Undertaking on Plant Genetic Resources, plant genetic resources encompass: "cultivated varieties in current use and newly developed; obsolete cultivars; primitive varieties (landraces); wild and weedy species; near relatives of cultivated varieties; and special genetic stocks including elite and current breeder's lines and mutants". International Undertaking on Plant Genetic Resources, Article 2 i (a).

[6] Established in 1971, the CGIAR is an association of countries, international and regional organizations, and private foundations dedicated to supporting a system of agricultural research centres and programmes around the world. Sixteen centres are currently sponsored by the Group.

[7] In 1983, FAO established an International Network of *Ex Situ* Collections as an integral part of the Global System for the Conservation and Utilization of Plant Genetic Resources. The objectives of the network are to ensure safe conservation and promote unrestricted availability and sustainable use of plant genetic resources, by providing a framework for sharing of benefits and burdens. Several countries have indicated their interest in joining the Network.
In October 1994, the FAO signed agreements with 12 of the Centres of the CGIAR, in which the Centres agreed to continue to hold designated germplasm in trust and to make it available for research, not to file for intellectual property protection on the material and related information, and to ensure that any recipient of the material must assume the same responsibility. The agreements only cover collections assembled prior to the entry into force of the Convention on Biological Diversity.

[8] The International Undertaking, adopted in 1983, is a non-binding set of rules that promotes international conservation efforts aimed to stem the rapid erosion of the genetic diversity of crop plants. Resolution 8/83 of the Twenty-second Session of the FAO Conference. Rome, 5-23 November 1983.

could contribute to the Commission's deliberations on the Undertaking and therefore requested IPGRI to prepare "an in-depth study, for the consideration of the Commission, of various possible systems which would be compatible with the Convention on Biological Diversity, analyzed in terms of their likely efficiency, practicality and cost-effectiveness."

3. IPGRI appointed a Study Team to assist in carrying out the in-depth study. The work was supervised by a Task Force composed of senior IPGRI staff and two observers from FAO. The Study Team included experts in the conservation and exchange of plant genetic resources, the CGIAR system, the CBD and law (see Annex II for the terms of reference and composition of the Study Team and Task Force). During the course of the study, the Team consulted with governments, non-governmental organizations and the private sector in several fora, including the Second Conference of the Parties to the Convention on Biological Diversity (see Annex III). This report draws heavily on those contributions.

Objective of the Report

4. This report seeks to provide the Commission on Genetic Resources for Food and Agriculture[9] with a set of options and their implications, to inform negotiations concerning the revision of the International Undertaking on Plant Genetic Resources.

[9] By Resolution 3/95 of the Twenty-eighth Session of the FAO Conference, the Commission on Plant Genetic Resources became the Commission on Genetic Resources for Food and Agriculture.

Interdependence and the History of Exchange of PGRFA

5. Throughout history, crops have traveled beyond national borders, carried abroad by ecological and social interactions, shifting populations and explorers. As a result, both developed and developing countries rely on introduced crops for a large part of their production and consumption. In many countries, crops originating in other parts of the world have become a national dietary staple and a major export. For example, North America is almost completely dependent on species originally domesticated in other regions for its food and industrial crops. Sub-Saharan Africa depends on species domesticated elsewhere for 87% of its crops. It is estimated that 69% of developing countries acquire more than half of their crop production from crops domesticated in other regions.[10] Even countries that are particularly rich in biological diversity still rely heavily on crops and hence, to a considerable extent, genetic resources, originating in other parts of the world. In Brazil, for example, nearly half the population's energy from plant sources comes from the three major cereals – rice, wheat and maize – all of which originated in other parts of the world.[11]

Percentage of total regional food production based on crops originating in other regions of diversity[12]

Region	% of Production accounted for by non-native crops
West Central Asia	31
Indochina	34
Hindustan	49
Latin America	56
Chino-Japan	62
Africa	88
Euro-Siberia	91
Mediterranean	99
Australia	100
North America	100

6. The reliance of countries on introduced crops means that no country is self-sufficient in genetic resources. While many countries hold large amounts of plant genetic diversity in genebanks and on farmers' fields,

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10 Wood, D. 1988a. Crop Germplasm: Common Heritage or Farmers' Heritage? *In* Seeds and Sovereignty (J.R. Kloppenburg, Jr., ed.). Duke University Press.
Wood, D. 1988b. Introduced Crops in Developing Countries -- a Sustainable Agriculture? Food Policy 167-177 (May 1988).

11 Cooper, D., Engels, J., and Frison, E. 1994. A Multilateral System for Plant Genetic Resources: Imperatives, Achievements and Challenges. Issues in Plant Genetic Resources No. 2, May 1994. International Plant Genetic Resources Institute, Rome, Italy.

12 Cooper *et al.*, 1994.

they will continue to require access to the diversity available elsewhere for genes with useful traits for crop improvement and to guard against the risks of over-reliance on too narrow a genetic base. The interdependence of countries with regard to genetic resources highlights the need for the international exchange of germplasm and related information.

7. To date, most plant genetic resources have changed hands informally among breeders and researchers. Formal contracts such as material transfer agreements (MTAs)[13] are a more recent phenomenon and are still relatively rare. They are usually signed when genetic material is exchanged as part of a collaborative research programme. Protected varieties are, in general, freely available under PVP legislation for use in further breeding and research.[14] In some countries, varieties and other genetic material can be protected by utility patents.

8. Governments have hitherto exercised little or no control over the exchange of genetic resources of major food crops. Countries have generally permitted collecting missions on the condition that their own scientists participate and that samples of collected material (and related information) are provided for storage at a local facility. The practice of free exchange is apparently still observed by many genebanks in industrialized and developing countries. As recently as 1990, for example, the US Congress voted into law a provision according to which genetic material assembled by its National Genetic Resources Programme is freely available to any country upon request.[15]

9. The genetic resources collections housed in the genebanks of the CGIAR have been assembled with the participation of the countries providing the material, on the understanding that it will be made available to the research community world-wide. For this reason, and because the use of

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[13] An MTA is a legally binding agreement between two or more parties that specifies the terms and conditions under which materials will be supplied and specifies the obligations of the recipient. The jurisdiction under which the MTA is governed, normally that of the recipient country, is specified in the agreement.

[14] However, the concept of “essential derivation” introduced in the 1991 revision of the UPOV Convention invokes the principle of compensation to the owner of the original variety when the genome of a derived variety is characterized by relatively few genetic changes, typically the substitution of a single gene.

[15] Sec. 1632(a)(4) of Public Law 101-624 of November 28, 1990 reads: "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 program assembles."

plant genetic resources is central to their crop improvement programmes, the Centres have followed a policy of allowing unrestricted access to the plant genetic resources in their collections.[16]

10. The current informal exchange 'system' comprises national programmes and other partners, including CGIAR Centres, NGOs and the private sector. It provides a good example of a multilateral approach to the conservation and use of genetic resources. This system has been responsible for much of the food crop germplasm collected and exchanged internationally over the past two decades.

The CGIAR

11. The CGIAR Centres play a key role in the conservation and use of livestock, fish and plant genetic resources, including forestry and agroforestry species. Over the past three decades, the Centres have collectively assembled what is believed to be the world's largest international *ex situ* collection of the genetic resources of food and fodder crops of importance to developing countries. These comprise some 500 000 accessions, including wild species, landraces, improved varieties and genetic stocks, housed in modern genebank facilities. The majority of the materials from the collections are duplicated at national, regional and other international research institutes. The Centres will continue to expand their in-trust collections with the aim of conserving the major diversity of the genepools concerned, either by increasing the holdings at the Centres themselves, or through collaborative arrangements with other genebanks.

12. The CGIAR Centres promote and facilitate the exchange of landraces, promising varieties and elite breeding lines with national agricultural research systems (NARS) and other partners for their evaluation and use in different ecosystems. Each year, nearly 150 000 germplasm accessions from the in-trust collections and 500 000 samples of improved material are distributed by the Centres, the large majority going to developing countries. Like the genetic resources themselves, all related information is available without restriction.

13. The CGIAR promotes the development of sustainable agricultural systems through research and assistance to national programmes. Many of the Centres assist NARS to develop their own programmes for the conservation and use of plant genetic resources through joint collecting,

[16] TAC Document GAR/TAC/88/4 "CGIAR Policy on Plant Genetic Resources", Rome, February 1988.

evaluation, repatriation of materials, regeneration of accessions and storage of duplicates of NARS collections.

14. A primary objective of the CGIAR is to develop new products and technologies, including biotechnologies, and to make them, and related information, available without restriction to developing countries. Training is a key component of the CGIAR's activities. Since 1971, the Centres have trained approximately 30 000 developing-country scientists and technicians in genetic resources conservation and use and related topics.

The Users of PGRFA

15. From the dawn of agriculture, farmers and indigenous communities have selected suitable plants from genetically diverse populations and have propagated them by seed or other forms of planting material. Plant breeding covers a range of activities, from relatively simple selection to the use of sophisticated techniques such as genetic engineering. The skill of the breeder lies, for the most part, in choosing the parents and in selecting the desired recombinants from a large population of material.

16. The overriding justification for collecting, conserving and evaluating PGRFA is to ensure their availability for use in the development of improved crop varieties. The most obvious use of plant genetic resources involves the introduction of desired characteristics into existing crops. However, this first entails extensive screening to discover the particular traits of interest, a process which requires the "use" of many thousands of genebank accessions.[17] In the long term, breeding programmes would be at risk if they lacked sufficient genetic variation to respond to changing situations, e.g. new diseases or variants of pathogens or other changing ecological factors.

[17] The importance of ensuring that the full range of genetic diversity is available in genebanks is illustrated by the following typical example from IRRI. In the search for accessions with resistance to whitebacked planthopper, 48 554 accessions of *O. sativa* were tested from which 401 were selected as resistant and 437 accessions of wild rice were tested from which 202 were selected as resistant. [Chang. T.T., 1989. The Case for Large Collections. *In* The Use of Plant Genetic Resources (A.H.D. Brown, O.H. Frankel, D.R. Marshall and J.T. Williams, eds.). Cambridge University Press.]

Plant Breeding

17. Modern plant breeding involves crossing parents with complementary characteristics to generate a population of genetically recombined plants, a small proportion of which, it is hoped, will provide the particular assemblage of genes required. In a modern variety, genes from a very large number of parents, from many different countries or regions, may be combined (see VEERY figure, page 24).

18. In the early stages of breeding, scientists may screen thousands of germplasm samples in search of useful new traits. Using this material, crosses are made giving rise to thousands of different gene combinations. These are narrowed down by selection, generally of individual plants or lines, over several generations. The overwhelming majority of combinations are discarded during this process. In the later stages, multilocation evaluation normally takes place to determine the degree of adaptation of the remaining lines to the target environments. At the end of the process, the breeder normally submits a small number of lines for independent evaluation before they are released to the farmer.

19. Sometimes crosses are made that are not intended to deliver a variety directly, but rather to produce improved parents for further crossing ('pre-breeding'). Much of the use of PGRFA takes this form.

20. The development of new varieties depends on the use of genetic resources over a long period: the whole process of breeding and releasing a new variety can take at least 10 years and often takes longer. The rice variety IR36, for example, has 15 landraces and one wild species in its heritage and was the result of some 20 years of breeding work.

21. Molecular biological techniques are providing new tools for plant breeding. Genes can now be transferred across species barriers or even from the animal kingdom into plants. Although to date relatively few varieties have been developed through such gene transfers, the number of successes will undoubtedly increase in the future. The potential contribution of the new techniques is enormous.

The Policy Context

22. The question of access to PGRFA has been at the heart of the debate surrounding plant genetic resources for more than 15 years. The International Undertaking originally subscribed to the concept of free

exchange.[18] The need for clarification concerning the application of this principle led the FAO Commission to adopt two resolutions providing an "agreed interpretation".[19] Plant Breeders' Rights (PBR) were explicitly recognized to be "not incompatible with the Undertaking", thereby acknowledging that this intellectual property right does not prevent free access to germplasm for breeding and research purposes. In addition, the Commission agreed that "breeders' lines and farmers' breeding material should only be available at the discretion of the developers during the period of development". This provision brought the Undertaking into conformity with national laws on private property. The "agreed interpretation" also stated that the term "free access" does not necessarily mean free of charge. The FAO Commission later acknowledged that access to genetic resources requires further clarification, and made it one of the primary issues to be resolved during the current round of negotiations.

23. In recent years, there has been a further erosion of the concept of free exchange, as countries have exerted greater control over their genetic resources and have introduced more conditions for access to them. Subsequent modifications of the Undertaking have further restricted the original concept of free access and common heritage.[20]

24. The Convention on Biological Diversity (CBD)[21] reaffirms national sovereignty over genetic resources. It states that authority to determine access to genetic resources rests with national governments and that access,

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18 "This Undertaking is based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." International Undertaking on Plant Genetic Resources, Article 1.

19 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.

20 Annex II allows that farmers and breeders may decide whether to make the resources they develop available to others and Annex III states that nations have sovereign rights over their plant genetic resources.

21 The Convention on Biological Diversity, adopted by the Earth Summit in Rio de Janeiro in June 1992, and in force since 29 December 1993, is part of a comprehensive international attempt to combat a broad range of environmental problems, including global warming, the destruction of tropical forests, and the need to preserve the world's biological resources on which the survival of humanity depends. The Convention attempts to balance the interests of the South and the North. It envisages a partnership whereby all countries conserve their genetic material and make it available, in addition to providing access to relevant technologies and a share in the benefits arising from the use of biodiversity. In contrast to the International Undertaking, it represents a binding commitment on the countries that have ratified it. As of 1 March 1996, the Convention had been ratified by 144 countries.

where granted, should be subject to the prior informed consent of the providing country on mutually agreed terms. The Convention thus provides an international legal framework for regulating access and encourages users to share benefits with countries providing genetic resources.

25. The Global Plan of Action (GPA), which will be one of the chief outputs of the forthcoming International Technical Conference on Plant Genetic Resources,[22] will serve as a tool for implementing the CBD with regard to PGRFA. The GPA, which has conservation and use of genetic resources as its chief aims, is expected to target resources to global priorities and to increase the effectiveness of international conservation efforts. The successful implementation of the GPA will depend upon the continued availability of PGRFA. This will in turn rest upon the accommodation of the principles of sovereign rights and benefit-sharing in any future system of germplasm exchange.

26. There are concerns that these principles might lead to greater restrictions on the exchange of genetic resources. While the Convention clearly seeks to facilitate access, it also recognizes that "the authority to determine access to genetic resources rests with national governments". In response, a number of countries have already started to regulate germplasm transfers. For example, African nations have imposed a temporary ban on the transfer of any biological resources not covered by existing conventions and where prior informed consent is not in effect.[23] Other countries have introduced specific control mechanisms (e.g. the Philippines[24]) or are negotiating regional exchange arrangements that would control the release of genetic material from member states to outsiders (e.g. the Andean Pact countries).

27. Given these concerns and current political realities, it appears that the current informal approach to exchange is no longer broadly acceptable. It is

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22 The International Technical Conference on Plant Genetic Resources, scheduled for June 1996, will provide a major intergovernmental forum for considering the first Report on the State of the World's Plant Genetic Resources and a Global Plan of Action. The Conference will address both the conservation and use of plant genetic resources for food and agriculture.

23 African Common Perspectives and Position on the Convention on Biological Diversity. AMCEN / Conventions / CBD1. 26 October 1994.

24 Philippines Presidential Executive Order no. 247, adopted 18 May 1995, requires research agreements between collectors and the government concerning the provision of information and samples, technology cooperation and benefit-sharing. All research "directly or indirectly intended for commercial purposes" requires the more stringent Commercial Research agreement. Prior informed consent is required from concerned local and indigenous communities.

critical therefore that agreement be reached on an effective system for the exchange of PGRFA. Such a system should help ensure efficient conservation, promote access and use, and ensure an equitable sharing of any benefits arising from the commercial exploitation of PGRFA. It should conform to both the letter and the spirit of the CBD and should aim to minimize transaction costs while maximizing efficiency and effectiveness. In response to its mandate from the FAO Commission, this study will explore the feasibility of a number of approaches to exchange, taking into account the requirements and concerns of all stakeholders, including farmers and community groups.

Pedigree of VEERY wheat (*Triticum vulgare*) released by CIMMYT in 1977.

Chapter II. System Options

1. A fundamental aim of sustainable agricultural development is to meet the nutritional requirements of a global population that is expected to increase from 5.5 billion (thousand million) to 8.5 billion by 2025[25]. Genetic resources for food and agriculture lie at the heart of sustainable agricultural development. They provide both the means to ensure food security (at an individual, community, national or international level) and to enhance the role of agriculture as an engine for economic development. Any system for the exchange of genetic resources and the equitable sharing of benefits must support continuing efforts to achieve these goals.

2. In the context of discussions on germplasm exchange, it is necessary to distinguish between plants with potential use in industry, and plant genetic resources for food and agriculture. In the use of genetic resources for pharmaceutical purposes, for example, a chemical compound may be identified, extracted and then synthesized in a laboratory anywhere in the world. The source of the useful gene or compound in this case is normally clear. Also, there are distinct commercial interests involved in the development of industrial products, with proven markets and the prospect of large profits. This has tended to lead to a situation where scientists are reluctant to share information or material and where secrecy and intellectual property protection are the norm.

3. PGRFA present a very different situation. Unlike the single active compound in many pharmaceuticals, a new crop line is likely to have a complicated pedigree and to owe its effectiveness to the combination of genes originating from many ancestors. Even if a pharmaceutical is not entirely synthesized, the bulk manufacture of the product will involve large-scale operations in a chemical factory. While genetic engineering in a lab may contribute to crop development, the end product is grown in farmers' fields. Another distinction is that 80% of the seed required for planting in developing countries is saved by farmers or exchanged by them[26] rather than purchased on the commercial market, with the result that the global market for seed is comparatively small.[27]

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25 Agenda 21, Chapter 14.

26 The World Seed Market: Development and Strategy. A Study by Rabobank Nederland Agribusiness Research. Utrecht, The Netherlands. 1994.

27 The world market for commercial seed in 1990 was valued at $15 billion of which $1.75 billion accounted for horticultural seed. The World Seed Market - Developments and Strategy,

Criteria for an Effective Exchange System

4. While there have been attempts to quantify the benefits currently flowing internationally to both providers and users of germplasm, this information is far from comprehensive. Nevertheless, the qualitative benefits of international cooperation are well known. To be effective, any system for the international exchange of genetic resources should, at a minimum, provide the same range of benefits as are currently available, including:

- **opportunities for more comprehensive and cost-effective conservation**

5. Approximately 6.1 million samples are presently maintained in *ex situ* collections,[28] at an annual average cost of US$50 per sample,[29] resulting in an annual cost of US$305 million world-wide. These costs are bound to rise in the coming years as more material is collected and systematically duplicated for security reasons. Given the conservation responsibilities imposed on countries by the CBD, there is likely to be an increased demand for the development of cost-effective approaches to *ex situ* conservation at the national level. Greater attention is also expected to be given to conserving PGRFA *in situ* and to supporting traditional conservation activities by farming communities.

6. International cooperation provides countries with increased opportunities for developing joint conservation and use strategies and for sharing responsibilities and costs regionally and/or globally. These strategies might include arrangements to meet national storage or safety duplication needs through international cooperation.

7. The in-trust collections of the CGIAR provide a very significant resource to the international community. In addition to supplying germplasm to breeding programmes, the Centres provide a range of related services, for example the restoration of genetic resources which have been lost (see box below).

Rabobank Nederland, 1994. By contrast, the global market for pharmaceutical products is $235 billion per annum. ten Kate, K.., Biopiracy or green petroleum? Expectations and Best Practice in Bioprospecting. Overseas Development Administration, London. 1995

28 FAO (1996) Report on the State of the World's Plant Genetic Resources, Document CGRFA-EX2/96/2 of the Second Extraordinary Session of the FAO Commission on Genetic Resources for Food and Agriculture, April 22-27, 1996.

29 Keystone International Dialogue Series on Plant Genetic Resources. Oslo Plenary Session. Final Consensus Report: Global Initiative for the Security and Sustainable Use of Plant Genetic Resources. Oslo, Norway. Third Plenary Session. May 31-June 4, 1991.

Restoration of germplasm

The value of shared conservation efforts is evident in the joint effort carried out by the International Rice Research Institute (IRRI) and national programs in Asia. Since 1981, IRRI has restored hundreds of rice samples to Nepal, Pakistan, Thailand, Philippines and Sri Lanka. More recently, 5311 duplicated accessions of traditional cultivars – jointly collected in Assam and neighbouring regions in northeast India – were sent back to national facilities in India. Much of the original Assam collection had deteriorated or had been lost.[30]

- **access to genetic resources from different sources for use in research and breeding**

8. A principal benefit of international collaboration is that it allows participants to gain access to a wider range of genetic material than can be found within their borders. Landraces and wild relatives of major food crops are often distributed over wide geographical areas in their regions of diversity. Facilitated access and international collaboration is particularly critical for collecting and screening these materials, some of which contain useful traits that are still to be identified and are at risk of extinction.

- **access to improved germplasm**

9. As noted in the previous chapter, plant breeding is a complex and lengthy process. Relatively few national institutes have adequate resources to devote to developing improved genetic materials. For example, more than 50% of African countries identify lack of funds as the major constraint to their breeding activities while 45% of the Near Eastern countries report lack of human resources as the major constraint.[31]

10. International cooperation can provide access to improved germplasm that meets users' needs for specific characteristics. For countries without fully developed breeding programmes, cooperation enables them to gain access to a range of varieties for testing under local conditions. It also can facilitate the introduction of new crops to enrich existing agricultural systems.

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30 Geneflow, IPGRI. 1995.

31 FAO (1996) Report on the State of the World's Plant Genetic Resources, Document CGRFA-EX2/96/2 of the Second Extraordinary Session of the FAO Commission on Genetic Resources for Food and Agriculture, April 22-27, 1996.

- **access to information and technologies**

11. Despite the revolution in data-gathering and dissemination that has occurred over the past decade, information on genetic resources is still unevenly distributed around the world. Some institutions maintain advanced databases and are linked into international information networks. Many others, particularly in developing countries, have limited facilities for refining and maintaining databases, and little or no opportunity to exchange information on an international basis. International collaboration offers significant opportunities to right this imbalance by facilitating access by collaborators to global information resources.

12. The scientific and technical basis for many areas of genetic resources conservation remains weak, despite recent important advances. International cooperation provides better opportunities for joint efforts to devise solutions to common needs, such as low-cost seed storage techniques and the refinement of sampling strategies for collecting and regeneration. It also provides opportunities for the transfer of relevant technologies developed by partner countries which can be refined and adapted to meet national needs.

- **participation in joint research**

13. Thousands of researchers throughout the world are already working to produce the knowledge required to conserve and use genetic resources. But their numbers are small in relation to the task, and in many countries their efforts are severely handicapped by lack of funds.
14. International collaboration in research and the sharing of research results is a cost-effective means to build capacities in national programmes and to develop a stronger scientific basis for conservation efforts world-wide.

- **access to training**

15. In addition its direct benefits, training is an ideal means to effect technology transfer, as well as being one of the most important steps towards building strong national programmes. Many different branches of science are involved in plant genetic resources efforts and a lack of expertise in any one of them can prevent a country from realizing the full value of its biological assets.

16. It is unlikely that any single national institute will have the capacity to train people in all aspects of plant genetic resources conservation and use. An international approach to training allows countries and institutions facing similar challenges to share the costs and burdens of

developing training courses and to pool resources and expertise to meet common needs and problems.

Types of International Cooperation

17. International cooperation in the conservation, use and exchange of crop germplasm can occur on either a bilateral or a multilateral basis. Bilateral arrangements refer to partnerships negotiated between two parties for their mutual benefit and generally formalized through a contract or memorandum of understanding. Multilateral arrangements involve several parties sharing the costs and benefits of collaboration. As noted above, current multilateral arrangements for the exchange of genetic resources and information are generally conducted without a formal agreement outlining terms and conditions.

18. Bilateral arrangements have long been used in industry, typically taking the form of material transfer agreements (MTAs) which govern the exchange of genetic resources. There are also bilateral exchange agreements between governments, for example the agreement between Brazil and Malaysia to exchange *Hevea* (rubber) (see below).

A Bilateral Agreement: Brazil–Malaysia Agreement on *Hevea*

19. In 1995, the Brazilian Agriculture Research Corporation (EMBRAPA) and the Rubber Research Institute of Malaysia (RRIM) signed an agreement whereby EMBRAPA would exchange Brazilian wild materials of the genus *Hevea* for elite clones of *Hevea braziliensis* developed by RRIM. A collecting expedition was carried out in the Brazilian Amazon under the terms of national legislation. These require that at least 50% of collected materials must remain in Brazil and that a Brazilian institution must participate in field explorations. Improved clones selected by RRIM from these materials can be transferred to third parties only after EMBRAPA's authorization. In exchange for the wild materials collected in the Amazon, RRIM has sent nearly 80 elite clones to EMBRAPA. The materials negotiated under this agreement can only be used for scientific and technological development.[32]

20. As noted in Chapter 1, an informal multilateral system has been in place for many years exchanging more than 650 000 accessions every year. Materials from this system have found their way into the bulk of

[32] Information provided by Brazilian National Research Center for Genetic Resources and Biotechnology (CENARGEN).

existing crops and have benefited both developing and developed countries. For example, wheat varieties containing germplasm developed by the International Center for the Improvement of Maize and Wheat (CIMMYT) are grown in virtually all wheat-growing countries of the world and cover 81% of the wheat-growing area in Latin America,[33] 60% of the wheat lands in South Africa and 34% in the USA.[34]

Characteristics of Bilateral and Multilateral Systems

21. Both bilateral and multilateral systems have advantages and disadvantages making one or the other approach preferable in a given situation. For example, the limited focus of bilateral arrangements allows partners to reach agreement and deliver results more quickly than is generally possible within the context of a larger partnership. A comparatively rapid turnaround may be suitable in situations where, for example, the speed of product development confers a competitive advantage.

22. Bilateral arrangements often have the advantage of flexibility; their structures, rules and goals can be easily and quickly modified to respond to changing needs. A bilateral agreement can be tailored to the needs and circumstances of the parties and can deliver targeted and highly focused results. Parties collaborate based on their shared objectives, and are able to exploit their respective comparative advantages without risk of diluting their efforts through the need to collaborate with partners that have less in common.

23. Bilateral partnerships can be created for specific purposes and then dissolved, without the need for permanent institutional structures. Thus bilateral arrangements frequently have lower overhead costs than multilateral approaches to exchange.

24. Bilateral arrangements are often used to ensure safe conservation, for example when one genebank arranges with another to hold a duplicate set of material. Multilateral systems, however, also offer opportunities for developing common and cost-effective conservation strategies, and for coordination and mutual support among partners.

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[33] For further information on the impact of CGIAR Centre-developed germplasm in Latin America, see CIAT, CIMMYT, CIP, 1992. The Role of CIAT, CIMMYT and CIP in Agricultural Research in Latin America and the Caribbean: Relevance and Results (unpublished).

[34] Tribe, Derek. Feeding and Greening the World. The Role of International Agricultural Research. CAB International. Wallingford, UK. page 224.

25. For species with a wide distribution of genetic diversity, as is the case with most major food crop species, any one country might contain only a small fraction of the total diversity. A multilateral system offers participants access to a far greater range of germplasm than is generally possible in bilateral arrangements. For example, the world's largest and most complete collection of rice – located at the International Rice Research Institute (IRRI) in the Philippines – comprises more than 80 000 samples from 111 countries. The collection includes, for example, 8454 samples from Indonesia, 799 samples from Sierra Leone and 849 samples from Brazil.[35] These countries – and all others – have ready access to the entire collection. For any one country to have access to the same range of rice diversity through bilateral arrangements, it would be necessary to conclude agreements with 110 countries. For all countries represented in the IRRI collection to have access to this material, a total of 12 210 bilateral agreements would be necessary.

26. The previous point demonstrates a clear advantage of multilateral arrangements for crops with wide geographical distribution. This advantage is even greater if one considers a range of crop species. Countries with limited genetic diversity of one crop might well hold a large proportion of the diversity of another. Access to the required germplasm might be difficult to arrange bilaterally, especially if the institutions involved are only interested in a narrow range of species. Certain institutions in West Asia, for example, might need access to rice germplasm from Southeast Asia, while some Southeast Asian institutions might need access to sweet potato germplasm from Latin America where yet others might be more interested in wheat germplasm from West Asia.

27. Multilateral approaches are likely to provide greater opportunities for exchanging and screening genetic resources than bilateral arrangements. Evaluation of data from a large number of environments leads to a better understanding of the properties of the exchanged material, adding significantly to its value and increasing the chances that it will be used.

28. Sometimes the characteristics of a sample are known in advance (e.g. as a result of local or indigenous knowledge, or an earlier screening). In such cases, direct bilateral negotiations between the holder of the

[35] Report of the External Review Panel on CGIAR Genebank Operations, International Rice Research Institute (IRRI). December 1995

germplasm and the recipient may be the most efficient and appropriate means of allowing access on mutually agreed terms. However, more commonly, the existence of genes conferring the desired characteristic is completely unknown, or perhaps only conjectured.

29. The search for useful genes and chemicals may involve the screening of a large number of species, and thousands or tens of thousands of different samples. In the search for naturally occurring chemicals for pharmaceutical use, access to species and genetic diversity might best be gained through bilateral agreements with species-rich countries. Plant breeders, however, generally screen a large number of genetically diverse samples of a single crop species. Given the wide geographic distribution of genetic diversity of most major food crop species, bilateral agreements would thus have to be concluded with a large number of countries or institutions in order to gain access to a significant proportion of the genepool for screening, a prerequisite to progress in breeding.

30. Germplasm is only truly useful when accompanied by information. The information that makes an accession attractive to researchers includes passport data,[36] characterization data,[37] evaluation data[38] and ethnobotanical information.[39] Bilateral arrangements can, and often do, include provisions for sharing information. As they are limited to two partners, bilateral arrangements offer far greater confidentiality than is generally possible with multilateral arrangements. They are thus well suited to maintaining the secrecy that may surround the development of certain products, or when proprietary information or technologies are shared.

31. A multilateral system, on the other hand, can provide greater opportunities for pooling efforts on characterization and evaluation. It provides access to a wider range of information than is available bilaterally, and offers opportunities to use information cost-effectively, avoiding duplication and unnecessary expense by sharing databases, for example.

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[36] Passport data include information on the origin of the material, the date of collection and environmental conditions.

[37] Characterization data include morphological, biochemical and molecular information.

[38] Evaluation data include information on yield potential, phenology and pest and disease resistance.

[39] Ethnobotanical information relates to local uses and locally observed traits.

32. The release of materials from genebanks is easier and more cost-effective if standard conditions can be applied to their acquisition and distribution. While it would be possible for genebanks to negotiate the terms of release bilaterally, they might be forced to turn down materials if it were not possible to reach agreement on the terms. A better approach would allow the negotiation of multilateral agreements concerning standard terms and conditions covering the exchange of materials held in partner genebanks. It should be noted that, in general, current arrangements for the exchange of genetic resources are not standardized, an exception being the standard agreements that accompany the release of materials from CGIAR genebanks.

33. Crop varieties typically contain genes from many different sources. Modern varieties, especially those with a long history of breeding, may have scores of lines in their parentage, originating from farms, local communities and breeding programmes in many countries (see VEERY box). To negotiate specific benefit-sharing arrangements with every country of origin would be daunting. To negotiate with individual farmers or communities would be virtually impossible. The enormous costs of such negotiations and the implementation of multiple benefit-sharing arrangements, would almost certainly result in a drastic reduction of the use of new germplasm. The consequence would be an even greater recycling of existing germplasm than already occurs, leading to a further narrowing of the genetic base of crop varieties. Such an effect runs counter to the widely held belief that sustainable agricultural production and food security world-wide are best served by broadening the genetic base of crop production. Multilateral approaches to exchanging germplasm and benefit-sharing could prevent such a situation and might even lead to greater use of genetic resources and a broadening of the genetic base of crops.

34. In rare instances, a patented product – such as a new pharmaceutical drug – which derives from a compound found by screening plants may produce annual sales of several hundreds of millions of dollars. This situation might lend itself to bilateral negotiations between provider and user. However, the probability that an individual sample of a natural product will proceed through screening, elucidation of structure and activity, bulk manufacture of the active compound or its analogue, preclinical and clinical trials, and marketing is extremely low: in the order of one in ten thousand.[40] The process can cost several hundred

[40] ten Kate, Kerry, Biopiracy or green petroleum? Expectations and Best Practice in Bioprospecting, Overseas Development Administration, London. 1995.

million dollars and may take fifteen years or more to complete. Nevertheless, the high value of the profits and the relatively few stakeholders amongst whom they would be shared could merit the transaction costs involved in bilateral arrangements.

35. Most crop varieties, however, have modest annual sales in the tens or hundreds of thousands of dollars and are likely to have a pedigree combining genes from many sources. For crops, the profits from any bilaterally negotiated sharing of benefits or royalties arising from a commercialized variety are likely to be extremely small, especially given the large number of potential stakeholders.[41] In most cases, the cost of negotiating and monitoring and the payment of legal fees would consume a major part, if not all, of the potential revenues. Commercial endeavours would then become unattractive.

36. Bilateral arrangements offer opportunities for developing specific research partnerships and training activities. Multilateral arrangements have also proven to be highly effective in fostering a supportive climate for innovation, as well as in promoting collaborative research and providing training opportunities at a wide range of specialized institutions. However, in the case of multilateral arrangements, these benefits are less likely to be directly linked to the provision of access to specified germplasm. One example of successful multilateral collaboration is the development of core collections which aim to promote the use of genetic resources contained in large collections (see below).

Core Collections

37. A core collection consists of a limited set of accessions usually containing less than 10% of the total number of samples in a collection. Despite their relatively small size, core collections are expected to contain over 70% of the total genetic variation found in the collection. Core collections can be based on a single international or national collection or on a number of different collections. Core collections can lead to more rational germplasm conservation and use through:

* identifying gaps in the collection
* assigning priorities in regeneration
* promoting rational characterization and evaluation
* assisting breeders in searching for useful traits
* facilitating germplasm distribution.

[41] See Annex IV.

38. Core collections are not seen as a mechanism for reducing the total size of collections. The diversity present in the remaining samples, which is not present in the core collection, represents a resource that cannot be discarded.

39. A number of core collections have been established and more are planned. The CIAT *Phaseolus* core collection contains 1500 accessions out of a total of 24 000. There is currently an international initiative underway to develop a barley core collection which will contain about 2000 accessions, or approximately 4% of the 50 000 barley accessions held around the world that are assumed to be unique.[42]

40. In summary, both bilateral and multilateral approaches have their place. Bilateral approaches are likely to be appropriate when a limited number of countries or institutions share or need access to genetic diversity, or when highly expensive and specialized research gives a strong competitive advantage to a single or limited number of partners. Such conditions may prevail, for example, in the case of some industrial crops such as rubber and in certain sectors, for example pharmaceuticals.

41. Multilateral approaches may be more appropriate in situations where many countries share the total genepool of a crop, when breeders in many countries need to access the genetic resources, and when broad cooperation to meet global goals such as food security may be more effective than the efforts of a few individuals or institutions. These conditions prevail for the majority of staple food crops, for which exclusively bilateral arrangements could become inordinately complex and costly and might well hamper progress on breeding and research.

The Options

42. The options for exchange systems fall into three broad categories: a strictly bilateral approach, an informal multilateral approach and a multilateral framework guided by mutually agreed rules.

43. Exclusively bilateral arrangements have rarely been reported in the case of staple food crops but are certain to be extremely complicated for the reasons given above. Strictly bilateral approaches to the exchange of food crop germplasm are therefore likely to prove excessively

[42] T. Hodgkin, Th. J. L. van Hintum and B. A. U. Morales, editors. "Core Collections of Plant Genetic Resources". John Morley and Sons, 1995. Copublished by IPGRI and Sayce Publications, UK.

cumbersome and thus this option is not given further consideration in the report.

44. A second option characterizes the current approach to the exchange of germplasm, an informal system comprising national programmes and other partners, including CGIAR Centres, NGOs and the private sector. This approach is extremely flexible and cost-effective. It has had remarkable success in pushing forward the frontiers of genetic resource science over the past two decades. However, a lack of clarity concerning the rights and obligations associated with participation in the system has left it open to charges of non-transparency. In addition, some countries are concerned that the current approach does not meet the requirements of the CBD with regard to its provisions for access and benefit-sharing. Thus there appears to be a need for a more formalized approach to exchange, although one that retains the essential features of the current system.

45. The third broad option (henceforth referred to as "MUSE" [43]) describes such an approach: a flexible multilateral framework governed by mutually agreed rules. The CBD would set the context for MUSE and would provide the guiding principles for the system. The MUSE rules would provide formal clarification – and protection – of the rights and obligations associated with the exchange of PGR under the terms of the CBD.

46. At the heart of the MUSE option lie the objectives of facilitating access and sharing benefits on a multilateral basis. However, the MUSE framework could accommodate any one or a number of the alternatives existing between the extremes of purely bilateral arrangements and an informal multilateral approach to exchange. For example, MUSE could make provision for benefit-sharing on a bilateral basis under certain circumstances, typically upon commercialization.[44] Another scenario might include a fund as a mechanism for financial compensation in return for access and in recognition of the concept of Farmers' Rights. Yet another approach might be to decide that the costs and effort of sharing financial benefits arising from the commercialization of crop germplasm would outweigh any potential advantages, and instead to restrict benefit-sharing to such things as access to germplasm, information, technology and training. A combination of these scenarios might coexist within the MUSE framework and be applied according to

[43] A **Mu**ltilateral **S**ystem for **E**xchange.

[44] See also Annex IV.

circumstances. For instance, the scenario providing for bilateral negotiations might apply in the case of non-food crops only.

47. Whatever form it might take, MUSE would operate according to standard rules governing conditions of membership, terms of access to genetic resources, mechanisms for sharing benefits among participants, and relationships with non-members. To preserve the chief benefit of the current system – its flexibility – these rules should be the absolute minimum required to guarantee that the rights and obligations of all stakeholders are respected. At the same time, they must be adequate to support a framework for the successful implementation of the CBD and the Global Plan of Action. The table on the following pages sets out the advantages and disadvantages of options of systems of exchange.

System of Exchange	Advantages	Disadvantages
Option 1: Strictly Bilateral	• flexibility • quick response • enables partners to exploit specific comparative advantages • low overheads	• access to smaller range of diversity than multilaterally • multiple agreements needed to gain access to range of materials available under a multilateral system • without multilaterally agreed framework, each transaction must be subject to individual agreement • cumbersome and complicated
Option 2: Informal Multilateral (the current approach)	• flexibility • informality • many participants happy with *status quo* • access to wider range of diversity than bilaterally • access to information, training, etc. • pooling of efforts allows comple-mentarity, efficiency and cost-effectiveness	• some participants dissatisfied with the benefits available under the current system and the way they are shared – increasingly affecting open exchange and access • lack of clarity on ownership, conditions for access and benefit-sharing • uncertainty creates delays and expense • lack of transparency • since rights and obligations are unclear, transactions often need individual agreements: cumbersome
Option 3 Formal Multilateral (“MUSE”)l	• clarity with respect to rights and obligations of	• challenge of defining MUSE rules and procedures

members, especially on ownership, access and benefit-sharing
- value added to multilateral benefits, fairness in sharing them and mechanisms for delivery
- attractive to wider range of stakeholders
- increased access and exchange
- greater transparency
- within basic framework, considerable flexibility of methods of implementation
- reduced transaction costs

- challenging of devising workable benefit-sharing options and keeping transaction costs minimal
- effort of changing *status quo*
- political, legal and institutional challenge of implementing MUSE at national and local levels
- difficulties of monitoring and enforcement

48. The following chapter further explores elements of the MUSE option, including the benefits associated with participation in the system and possible scenarios within the basic MUSE framework. Chapter IV concerns the possible range of biological materials that could be made available through the system.

Part II. A Multilateral System for Exchange (MUSE)

Chapter III. Options for Implementing a Multilateral System for Exchange (MUSE)

Membership

1. Membership in MUSE would be voluntary and would be open to any country, organization or institution which has something to offer and to gain from the system and which agrees to abide by the rules, including those of the individual networks in which it participates. Members might include farmers' organizations, indigenous and local community groups, government institutions, private sector not-for-profit institutions and for-profit companies, national and international non-governmental organizations, university departments, regional institutions and international organizations such as the CGIAR.

The Framework

2. The Convention on Biological Diversity would set the guiding principles for MUSE in areas such as access to genetic resources on mutually agreed terms, prior informed consent and the equitable sharing of benefits.

3. Countries wishing to join MUSE would sign an agreement. The FAO Commission on Genetic Resources for Food and Agriculture might consider negotiating such an agreement within the context of the revised International Undertaking on Plant Genetic Resources. In signing the MUSE Agreement, countries would agree to collaborate and to operate according to standard rules governing conditions of membership, terms of access to that subset of genetic resources that members decide to include in the scope of the system (see Chapter IV), mechanisms for sharing benefits among participants, and relationships with non-members. The subsequent governance and monitoring of MUSE, including responsibility for revising the MUSE rules to meet changing needs, would rest with government members.

4. By acceding to the Agreement, signatory states would agree to the MUSE provisions on prior informed consent (PIC)[45] and mutually

[45] To give prior informed consent is to agree, before it occurs, to an event whose implications have been disclosed in advance. It is a legal procedure that recognizes the right of individuals or States to exert control over events affecting them or resources within their control.
The CBD introduces a requirement for Contracting Parties to provide genetic resources on the basis of prior informed consent. The Convention does not define prior informed consent; however, Article 15 stipulates that the authority to determine access is subject to national

agreed terms (MAT),[46] thus meeting the requirements of the Convention. When countries with no legislation on germplasm exchange ratify the Agreement, in most cases its provisions would automatically become national law. However, certain countries may be unable to adhere to the MUSE Agreement without adapting or introducing national laws and regulations to bring them in line with the Agreement. An institution based in a non-member country where national legislation runs counter to the MUSE Agreement might not be eligible for membership.[47]

5. The state is sovereign over all the plant genetic resources in its jurisdiction. However, many of these resources will be under private ownership, so that a state's agreement to participate in MUSE may not be sufficient to determine access to all of the materials within its borders. Publicly held material covered by the scope of the system would logically enter MUSE as a condition of a country's decision to join the system. The situation regarding other materials within a country, however, may vary from country to country, the determination of who has the right to negotiate access to material within a country's borders being a matter for national legislation. The PIC of local communities and of other non-government holders of genetic resources would therefore be established through instruments determining their participation in or relationship to MUSE, and in accordance with national policy and legislation. Such instruments might in turn contain provisions for recognizing Farmers' Rights.

6. Conditions for non-government members (private institutions, NGOs, farmers and indigenous communities, etc.) would be set by government members, whose responsibility it would then be to determine how best to implement and enforce these conditions at the national level. Governments might, for example, allow institutions to join MUSE by entering into an agreement at the national level or with the system as a whole. The latter option might apply for institutes and organizations

legislation, so the definition of prior informed consent, and the decision whether to require or dispense with it, is a matter for national law.

46 Mutual agreement on terms for access allows providers of genetic resources to control the terms and conditions of their use. These terms are generally negotiated as part of the process of securing prior informed consent. Just as for PIC, mutually agreed terms are required by the Convention although their definition is left to national policy. MAT may include provisions for the uses that may be made of the genetic resources provided, the sharing of benefits arising from these uses, ownership and intellectual property rights and obligations not to pass the resources or their derivatives on to third parties without securing similar undertakings from them.

47 This would generally be the case when national legislation on PIC and MAT is more restrictive than that contained in the MUSE Agreement.

located in non-member countries or for international organizations such as the CGIAR. Once they have joined MUSE, non-government members would be bound by the same basic rules regulating access and benefit-sharing as are contained in the MUSE Agreement.

7. All MUSE members would be free to pursue their own objectives as long as these were consistent with the guiding principles and the rules of the system. Within MUSE, institutions and organizations would collaborate in a wide variety of arrangements. These arrangements would be guided by operational procedures formulated by the collaborators and based on the needs and circumstances of the networks, institutions and genepools involved. The institutional arrangements within MUSE would be flexible. They would provide a framework for the many networks that already exist and would enable new networks to evolve to meet new needs and opportunities.

8. MUSE would facilitate access by its members to all materials included in its scope. The scope, which would be agreed by members, might include both pre- and post-CBD materials, pre-CBD materials alone, or post-CBD materials only. Likewise, there are a number of options for the type of materials and the range of genepools to be covered by the system. For example, MUSE might include only the genepools of crops of importance to global food security. Alternatively, the system might only cover food and other genetic resources that do not fall into that category, leaving food security crops outside of the scope of MUSE. (See Chapter IV for a detailed discussion of scope).

MUSE Guiding Principles, Rules and Procedures

Policy

MUSE guiding principles set by:

The CBD, governing:

- recognition of sovereignty over genetic resources;
- access on mutually agreed terms;
- prior informed consent (PIC);
- equitable sharing of benefits.

Oversight

MUSE rules set by:

Intergovernmental Body, governing:

- terms of the MUSE Agreement;
- scope of MUSE;
- terms of access and release;
- standard terms for PIC/MAT
- rights and obligations of members;
- sanctions for non-compliance;
- interaction with non-members.

Membership

Conditions for government membership set by:

Terms of the MUSE Agreement

Conditions for non-government membership set by:

National governments, governing:

- nature of instrument binding member to MUSE rules;
- PIC/MAT of non-governmental participants;
- enforceability of MUSE rules.

Implementation

Operational procedures set by:

networks and other institutional groupings, governing:

- mechanisms for germplasm exchange;
- implementation of sanctions;
- drafting of individual MTAs if required.

Germplasm Exchange in MUSE

9. There are three situations that would arise with regard to the exchange of genetic resources within the context of MUSE. Material already included in the scope of the system will be exchanged among members, new material will come into the system, and material held in MUSE will be transferred to non-member institutes or to countries outside of the system. Access to materials covered by the system would be cost-free, or at most involve a small service charge.

Exchange of MUSE Material between Members

10. Any transfer among members of material already in the system will be according to the terms of the MUSE Agreement. There will be no need for a separate legal instrument when the terms of the Agreement can be enforced in the recipient member's country. If this is not the case, legally binding agreements, such as MTAs, will be required.

Introduction of New Material into MUSE

11. New material would be introduced into the MUSE mainly through collecting in the field or directly from institutions outside of the system. Countries would specify which entities are entitled to give their prior informed consent to member institutes fielding collecting missions. Materials would only enter the system if the provider is willing or able to make it available under the standard PIC/MAT terms contained in the MUSE Agreement. This would generally be the case in member countries where national legislation would be consistent with the Agreement. If it is not possible to obtain PIC/MAT terms consistent with the MUSE Agreement, either because of national legislation or because the provider is unwilling to agree, the materials would remain outside of the system.

12. An MTA would be required in all cases where material is obtained from non-member countries or from institutes outside the system. This agreement would specify that materials provided by the non-member henceforth become part of the system through the member collector/recipient as intermediary. The non-member provider would have continued access to the material supplied as well as any information on the material that is generated by the recipients or from within the system generally.

13. The MTA would be based on the terms of access set out in the MUSE Agreement and would be of a standard form, to be negotiated by government members of MUSE. The standard MTA would require the user to share benefits (information, a negotiated share of royalties,

leaseback, etc.) with the provider. It would allow recompense if a provider discovered that a user had derived benefits from the commercial use of material or a derivative of material that they provided, but had not notified the provider of this fact, nor offered to share any benefits.[48] If the terms of the MTA are inconsistent with national legislation regarding PIC/MAT, the agreement would be invalid and the material would not be eligible to enter the system.

Transfer of MUSE Material to Non-member Countries or Institutes

14. Genetic resources contained within the scope of the MUSE system could be transferred to non-member countries or institutes on the basis of standard MTAs according to the terms set out in the MUSE Agreement. Such terms might include the requirement that the recipient make information available on the material, would enter into bilateral benefit-sharing negotiations under specified conditions, and would only pass materials on to third parties under an MTA specifying equivalent conditions. Non-member recipients might bear additional obligations to those applying to members; for example, a requirement to provide genetic resources and information to MUSE, or to make research products available to members (or a subgroup of members such as developing countries) on concessional terms.

Infrastructure

15. A small secretariat would be required to ensure the effective management of MUSE. An information service could also be established to serve the needs of MUSE members, by for example maintaining electronic information services[49] and producing and/or distributing other materials such as newsletters, journals and abstract bulletins. The secretariat and information service could either be attached to an existing organization or could operate through a dispersed system by which individual institutions would agree to provide specific services, perhaps in return for certain concessions, such as a reduction of membership fees if it were decided to levy such fees. The information service would work closely with, or could even be part of, the Clearing

[48] If the original provider were not party to the contract with the delinquent user and so could not enforce it, the provider would initiate a claim against the entity with which it made the original MTA and so on down the chain, each successive recipient ceding his/her rights to the original provider until either the provider could initiate legal action against the delinquent user or, if the chain has broken, against the entity that failed to pass on the benefit-sharing obligations (see also Annex IV).

[49] The CGIAR is currently linking its Centre databases on plant genetic resources electronically and developing the means to provide access to them internationally. The CGIAR data system, known as SINGER (The System-Wide Information Network on Genetic Resources) might form the hub of a larger network within MUSE that integrates and links databases made available by other members.

House Mechanism being established under the Convention on Biological Diversity.

Funding MUSE

16. All countries, organizations and institutions joining MUSE could be required to pay a membership fee to cover the operational costs of running MUSE, including the secretariat and the information unit. Any remaining funds might be used to support special services, such as training, workshops, etc. A differential rate might be applied to members according to whether they were located in developed or developing countries, whether they were primarily providers or users of germplasm, or whether they were non-government members located in member or non-member countries.

Collective Benefits

17. Wide participation in MUSE would depend on the merit of the system relative to available alternatives. Providers of germplasm need an incentive to supply materials to the system; otherwise they are likely to prefer to exchange material bilaterally or by some other means. Recipients of germplasm will be motivated to join the system in order to have access to material for developing new products. However, they will only find membership of interest if the conditions of access and the transaction costs involved are favourable compared with alternative sources of supply.

18. As previously noted, international cooperation in the field of genetic resources can give rise to a wide range of benefits. Participation in a multilateral exchange system has particular advantages in the case of food crop genetic resources and these have been enumerated at length in earlier sections of the report. It should be noted that these advantages are not uniquely available under the MUSE option. The principal – and unique – value of MUSE lies in its clarification of the nature of benefits available under the system, the establishment of rules and procedures governing access and benefit-sharing, and the creation of mechanisms allowing members greater opportunities for collaboration and more information on how to access the MUSE benefits. The relative transparency afforded by a more formal approach to exchange is likely to give rise to a number of key benefits as described below.

• broadening the base of participation

19. Participation in a multilateral system – whether regulated or not – is theoretically open to all stakeholders with an interest in PGRFA, something to offer and something to gain by participating in the system.

These include farmers' organizations, indigenous and local community groups, government institutions, private sector not-for-profit institutions and for-profit companies, national and international non-governmental organizations, university departments, regional institutions and international organizations such as the CGIAR.

20. The current approach to multilateral exchange is fundamentally informal in nature. For this reason, its success largely depends on the existence of good will and trust among those involved. This has tended to limit participation to institutions that know each other well and that have a long history of working together. Other stakeholders – such as farmers and grassroots organizations and institutions that have not previously participated in the current exchange system – may not know of its existence or may not know how it functions and how they could benefit by participation. Furthermore, a lack of clarity concerning the basis for access and benefit-sharing, the possibility of intellectual property protection being imposed on altered materials, and the fact that the position on these issues is not codified in rules upon which stakeholders can rely, mean that there is no guarantee that stakeholders would benefit fairly and appropriately from participation. This has created reluctance on the part of some stakeholders to become involved in the current system so that, ironically, the very informality of the present approach has led to a rather more closed and restricted system than is probably desirable.

21. The Convention on Biological Diversity explicitly recognizes the important role of indigenous and local communities in the conservation and sustainable use of biological diversity. A regulated exchange system such as MUSE could prove a useful means of encouraging the participation of these groups in the global effort. Such a system would be ordered by a set of rules which, while minimal, would apply to all members and, to the extent possible, would be enforceable. The result would be a more open and transparent system in which the rights and obligations of all members would be clearly specified and protected by the system. This is likely to make participation more attractive to stakeholders who have not engaged in the current system, such as farmers' groups, etc. Perhaps more importantly, it would acknowledge the right of these groups to participate fully in international exchange systems and the obligation to ensure that they receive a fair share of benefits as a result of their participation.

22. The advantages of a more broadly based exchange system could be significant. For example, the likelihood that MUSE will be attractive to new partners such as farmers' groups and indigenous communities

should lead to increased opportunities for integrating on-farm conservation into the global genetic resources effort. In addition, by improving links with these groups, MUSE would offer the potential to promote community breeding efforts and participatory breeding approaches involving both government and non-government members in new partnerships. Indeed, mechanisms to promote such partnerships might be explicitly created within the context of MUSE.

- **increased access to genetic resources**

23. A fundamental benefit of the MUSE approach is that members would have access to an enormous range of germplasm (including improved materials) – far more than they contribute individually and more than they could hope to gain from simple bilateral exchanges or informal multilateral arrangements. This in turn would lead to the increased likelihood of germplasm being used, as it would be readily available to a wider range of potential users.

24. All providers of material, whether or not they have formally joined the system, would retain the right to have continued and unrestricted access to their material. Special arrangements might be needed to ensure that communities and farmers groups providing germplasm to MUSE know where their materials are being held and how they, and other genetic resources, can be accessed.

- **reduced transaction costs**

25. Because current arrangements for the exchange of genetic resources are not standardized, they tend to be made on a case-by-case basis. Even the exchange system currently used by the CGIAR requires that each transaction be treated individually, albeit under standard terms.[50] The adoption of standard terms and conditions under MUSE could greatly reduce the necessity for concluding individual agreements between members exchanging materials within the scope of the system and is therefore likely to substantially reduce transaction costs overall.

- **adding value to the benefits of multilateral collaboration**

26. Scientific institutes have long cooperated multilaterally in the conservation and exploitation of genetic resources. Such cooperation has most often been carried out within the context of formal and informal

[50] Each shipment of material from the Centres is accompanied by a statement explaining the rights and obligations of recipients, an order form which must be signed by the recipient and which represents his/her agreement to abide by these obligations, and a shipment notice which specifies the terms under which the materials are being sent.

networks defined on a regional or a crop basis. Rules of procedure guide the activities of participants within these networks but they are not standardized across networks and may differ greatly with regard to their requirements in terms of access and benefit-sharing.

27. The establishment of common guidelines and principles under MUSE would not eliminate the need for network-specific rules to cover many of the operations within networks. However, it is likely that it would promote and facilitate greater cooperation between networks with interests in similar crops, eco-regions, conservation methodologies, etc. Indeed, as common rules would apply to all MUSE members, it is possible to envisage collaboration among almost any grouping of institutions, NGOs, farmers' organizations, indigenous community groups, universities, international centres and private-sector organizations.

28. The MUSE option would provide a formal structure for addressing the development of joint conservation strategies and for sharing the risks and responsibilities, the benefits and burdens of conservation activities. It would provide enhanced opportunities for pooling the resources – genetic, human, and institutional – necessary to conserve and exploit particular genepools effectively and efficiently.

29. As noted above, the MUSE structure would promote and sustain strong linkages among system members. This would allow the development of system-wide information networks which would facilitate access by members to certain categories of technology and information, both on the germplasm contributed by a member himself/herself as well as that provided by others. Additional information would become available as a result of activities such as screening trials conducted by recipient members, and jointly conducted multilocational trials.

30. Finally, if it is decided to adopt one or more of the scenarios possible within MUSE (see below) the system could facilitate bilateral sharing of financial benefits through the adoption of agreed rules and procedures. In addition, the system could facilitate access to multilateral funding to support joint activities.

The Scenarios

31. As noted in Chapter II, within the broad MUSE framework there is scope for allowing all benefits to be shared multilaterally or for allowing benefit-sharing on a bilateral basis under certain circumstances. Alternatively (or in addition), MUSE might include a fund as a mechanism for financial compensation in return for access and in

recognition of the concept of Farmers' Rights. These possible scenarios within the basic MUSE model are discussed below.

Scenario #1: a fund

32. Members might wish to consider establishing a fund to compensate germplasm providers. This would require careful negotiation. While not essential to the successful implementation of MUSE, the existence of a fund could provide an added incentive for some to join. Some see such a fund as a mechanism for giving tangible recognition for Farmers' Rights. Others have doubts as to its feasibility, or at least as to the extent that it could prove a significant source of funds. If MUSE members agreed to establish a fund, they would have to consider mechanisms for its establishment, governance, replenishment and allocation. The possibility of establishing such a fund is currently under debate in other fora, notably FAO, and several proposals to establish funding mechanisms have been tabled.[51] They will not be expanded upon here.

Scenario #2: provision for delivering bilateral benefits[52]

33. MUSE would deliver multilateral benefits on the basis of the MUSE Agreement and through mechanisms built into the system. While bilateral benefit-sharing might be possible within the context of the system, these arrangements would be the responsibility of individual members. They would be carried out, however, according to rules established by MUSE.

- **access to and transfer of proprietary technology**

34. A bilateral arrangement could provide the opportunity for the transfer of proprietary technologies to the provider of the material. This might often be more attractive to both providers and users than negotiating an appropriate share of what might frequently be insignificant royalty fees. (see below). If users anticipate that their primary market for a particular product or variety will be found in industrial countries, they might agree to its production and sale in developing countries at no, or a notional, royalty. This is unlikely to be an attractive option, however, if a product is being produced for developing-country markets.

- **capacity-building and technical cooperation**

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51 M.S. Swaminathan, for example, proposes a levy on seed sales. This would increase seed royalties from an average of 12 to 15 per cent with the difference contributing to a fund for Farmers' Rights. See Swaminathan, M.S. (Ed). "Farmers' Rights and Plant Genetic Resources. MacMillan India Ltd. 1995".

52 See Annex IV for a discussion of the legal and institutional issues relating to this scenario.

35. There are many other opportunities for bilateral benefit-sharing that are consistent with the spirit and the law of the Convention on Biological Diversity. These include agreements to conduct joint research, to exchange scientists and train research personnel. In addition, users might agree to contribute hardware and software or to produce seed of a new variety in the providing country. In such a case, the primary intention might be to develop the research capacity of the provider. The details of these arrangements would be negotiated bilaterally with rules and guidelines provided by the MUSE Agreement.

- **financial benefits**

36. In certain cases, users might agree to share financial benefits directly with providers within the framework of MUSE. This would require assessing the value of the supplied germplasm to a particular research product. To the extent that these generally confidential arrangements are public knowledge, pharmaceutical companies have agreed to offer providers of genetic resources royalties on sales that are normally in the range of 0.5% to 10%. These royalties would be shared between the original provider or any intermediaries or collaborators who have added value to the raw genetic resources. The original provider often receives between 5% and 50% of the 0.5% to 10% royalty (i.e. perhaps as little of 0.025% of sales).[53]

37. Details of any financial benefit-sharing arrangements concerning the use of plant genetic resources in agricultural research have yet to be publicized. The market for agricultural research products is comparatively small, and the profit potential limited.[54] In addition, an introduced line might account for only a tiny percentage of a variety's

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53 ten Kate, K. 1995, Biopiracy or Green Petroleum? Expectations and Best Practice in Bioprospecting. Overseas Development Administration, London.

54 The world market for commercial seed in 1990 was valued at $15 billion of which $1.75 billion accounted for horticultural seed. (The World Seed Market - Developments and Strategy, Rabobank Nederland, 1994). Assuming a high profitability of 4% on total sales, total industry profits would amount to $530 million. If a generous 10% or $53 million (more than twice the share used in a typical pharmaceutical agreement) were shared among providers; and two highly successful varieties of each of 15 major crops were in the market of each of the world's 10 major seed markets in any year (2x15x10=300), this would amount to an average share of $175 000 per successful variety which then would have to be shared by several providers of source material. On the basis of less optimistic projections about total industry profits, more realistic assumptions about the number of successful varieties (five instead of two), and considering that the major part of the genome of any new variety is likely to come from elite germplasm already in the possession of the breeder, the amount available to be shared per successful variety would probably be minuscule and would be absorbed by transaction costs.

genetic make-up, making it very difficult to determine its contribution and hence to arrive at an objective basis for calculating benefits.[55]

Scenario #3: combined scenarios

38. A combination of the scenarios described above could coexist within the MUSE framework and be applied according to the specific circumstances. For example, the provision for bilateral benefit-sharing might apply in the case of non-food crops only.

[55] See Hardon, J.J. , Vosman B. and Th. J.J. van Hinthum. Identifying Genetic Resources and their Origins: the Capabilities and Limitations of Modern Genetics and Legal systems, Background Study Paper No.4, FAO/CPGR-Ex 1/94/Rep.

Chapter IV. Scope

1. The implementation of a formal exchange system – MUSE – will require the definition of the range of biological materials ("the scope") that would be available through the system.[56] Criteria for defining scope might include, among others: categories of plant genetic resources; method of conservation; intended use of the materials; and/or whether the materials were collected before or after the entry into force of the Convention on Biological Diversity.

2. If the range of genetic resources available in the system is inadequate, MUSE is unlikely to be attractive to potential members. Ideally, MUSE members would include most countries holding significant amounts of genetic diversity, whether by virtue of their location in centres of diversity or as a result of their conservation and breeding activities.

3. Defining the optimum scope for MUSE is a challenge. There are advantages and disadvantages to the various possible criteria for determining the categories of genetic resources to be included and excluded from the scope of the system. The rationale for distinguishing between these categories, the institutional and economic implications of the different potential bases for managing exchange and for enforcing the terms of MUSE all contribute to this difficulty. At a minimum, however, to attract broad participation, MUSE might include the genepools of food crops of greatest importance to global food security. Some options for scope are explored below.

Scope Defined Comprehensively

4. The comprehensive option would include all species and categories of plant genetic resources.[57] Under this option, MUSE would become the sole basis for access to plants, covering all locations in which they are found – from *ex situ* collections to rainforests – and all uses – from industrial to agricultural.

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[56] The issue of scope with regard to exchange systems has arisen in various fora and is currently under discussion by the FAO Commission on Genetic Resources for Food and Agriculture. See also Plant Genetic Resources for Food and Agriculture: Towards a Multilateral Agreement: Proceedings from an Informal International Consultation held in Stockholm, 1-2 March 1995. Edited by Carl-Gustaf Thornstrom, SAREC Documentation. Conference report 1995:1.

[57] For example, wild relatives, primitive and modern varieties, landraces, breeding materials and genetic stocks.

5. This approach has the advantage of simplicity. It is unlikely, however, to be attractive to some governments and companies that for commercial reasons normally limit access to certain species and/or categories of plant genetic resources – typically industrial crops or breeding lines.

Scope Defined by Taxon or Genepool

6. Members might choose to define the scope of the system according to a list of taxa, based on such criteria as relevance for food security, social and economic importance, geographic distribution and the risk of genetic erosion. Given the disparity of genetic diversity among countries and their different needs for and uses of genetic material, the determination of an internationally acceptable, taxonomically based scope for MUSE would require careful negotiation, as would the taxonomic basis for the list, whether genepool, genus, species or other taxonomic class.

7. Genepool-based lists can be difficult to define. For many crops, reliable information about the flow of genes between and among species is limited and the distinction between taxa is often difficult to draw, making the definition of many genepools somewhat arbitrary. A list of genera, rather than a list of species, may be more appropriate in many circumstances, for example when genes from related species have the potential to contribute significantly to the improvement of the crop species in question. This is increasingly the case with the growing ability to make inter-specific crosses and to transfer genes across species boundaries. Another option would be to combine both species and genera in defining the scope of the system.

8. If the scope is defined by taxon or genepool, materials might be brought into the system on an inclusive basis (i.e. a list would specify materials included in the scope) or on an exclusive basis (i.e. a list would specify what is not included). In either case, the list could be subject to periodic review.

9. It may be difficult to compile an exclusive list since taxonomic information about many species is inadequate and in many countries good inventories of native species are lacking. New species are frequently being discovered and taxonomic classifications are continuously being revised. In addition, negotiators may see such an approach as too open-ended. An inclusive list may be easier to compile, although the danger exists that valuable species might be overlooked. One possible approach might be to assemble a list that includes the plant species which constitute the major food commodities required to meet

national and global nutritional needs.[58] Expert working groups might then be convened to define the related species that would most usefully constitute the genepool of each commodity in question.

10. The choice of such commodities could reflect current practice in the networks involving the CGIAR Centres and their partners. The Centres exchange genetic resources of approximately 25 major food crops, as well as forages and multipurpose trees. The materials currently covered by the CGIAR mandate could form the initial basis for developing the scope of MUSE. The scope could be expanded by adding new food and other crops, over time and as agreed by members. A decision would be needed on whether forages and multipurpose trees should be included.[59]

Scope Defined by Category of Germplasm

11. The scope of the system could be based on different classes or categories of germplasm. These include:
    - wild species
    - wild relatives of crop species
    - landraces
    - primitive and obsolete varieties
    - modern varieties
    - breeding lines and experimental populations
    - lines with specific genetic and cytogenetic characteristics.

12. The above categories vary in the degree of "improvement" (i.e. the degree of human interference) involved in their development, in actual or potential legal ownership status and in strategic or commercial value.

13. In some situations, the availability of certain categories may be restricted. For example, the International Undertaking states that the availability of breeding material is left to the discretion of the plant breeder concerned.[60] The same might be the case with regard to material held by farmers or farming communities. Genetic stocks are not usually

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58 Prescott-Allen, R and Prescott-Allen, C. How many plants feed the world? Conservation Biology, 4 (4): 365-374, December 1990.

59 There is already some experience of defining scope by taxon or genepool. During its Sixth Session in June 1995, the FAO Commission initiated discussions on the coverage of biological materials during the renegotiation of the International Undertaking. A number of draft lists defining the scope by different criteria were tabled. The difficulty of reaching agreement on various categories of resource, such as forest species, indicates that the initial scope may best be limited to food crops.

60 CPGR 6/95/7 Rev.1 FAO.

deposited in genebanks since they typically form part of research collections. Members might therefore choose to limit the scope of the system to materials whose exchange is not already restricted in some way. At a minimum, however, the scope might reasonably include all material currently available for exchange.

Scope Defined by Date of Collection (pre- or post-CBD)

14. Material collected or obtained prior to the entry into force of the Convention on Biological Diversity (29 December 1993[61]) is not covered by its provisions on access and benefit-sharing.[62] Consequently, this date could serve as a point of reference for determining scope. For example, MUSE might include only pre-CBD materials as a means to resolve the outstanding question of access to *ex situ* collections not acquired in accordance with the Convention.[63] Alternatively, MUSE might include only post-CBD materials, so that the system would be in full conformity with the Convention. This would leave pre-CBD materials outside the scope of MUSE (including the bulk of collections held *ex situ*) and subject to exchange as at present.

15. A third option might be to include both pre- and post-CBD materials in the scope of MUSE. From a purely practical standpoint, this option has certain advantages. The necessity to treat material collected before the coming into force of the Convention differently from that collected after would impose significant practical difficulties on *ex situ* genebanks. Added costs would be incurred in monitoring origins and in dispatching samples under different terms and conditions based on the time of acquisition.

16. In addition, copies of the same gene are likely to be found in accessions acquired both before and after 29 December 1993. It would be impossible to prove that a gene had been obtained from material collected pre-CBD, and thus did not give rise to need to share benefits, or from post-CBD material, and did.

17. Arbitration of conflicts over breeding materials composed of both pre- and post-CBD accessions could prove difficult as well, since breeding is a step-by-step process that incorporates new genes in previously

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61 The Convention entered into force upon ratification by the 30th signatory, Mongolia. It only enters into force in other countries subsequently on the date upon which they ratify.

62 Article 15.3.

63 Nairobi Final Act of the Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity, Resolution 3.

developed or existing genetic materials. Including both pre- and post-CBD materials in MUSE would avoid these difficulties altogether.

Scope Defined by Conservation Method (*ex situ* or *in situ*)

18. This option distinguishes between genetic resources held *ex situ*[64] and *in situ*[65] as a means to determine the scope of the system.

19. *In situ* conservation is essential for several reasons. First, genetic resources held *in situ* continue to evolve in response to changing environmental conditions, making them extremely useful to plant breeders. Material conserved *ex situ* normally maintains its genetic makeup. Second, certain genetic resources – notably recalcitrant-seeded and clonally propagated species – are currently difficult and expensive to conserve *ex situ*. Even if it were possible, the financial and institutional resources needed to conserve all of the genetic diversity of such crop resources *ex situ* are simply not available.

20. Most of the genetic resources held in genebanks obtained their characteristic properties while growing *in situ*, frequently as a result of human intervention on farmers' fields. The fact that these materials have been collected and conserved *ex situ* at some point in time would therefore not appear to be a useful distinction. Indeed, genetic resources do not generally proceed directly from *in situ* regimes into the hands of end users but first pass through an *ex situ* genebank and plant breeding programmes. The difficulty of proving a gene's origin – discussed in the section on pre-and post-CBD material above – would seem to apply in this case as well.

21. While there appear to be few arguments in favour of excluding materials from MUSE based on the method of their conservation, in practice it is likely that more participants in MUSE would have control over *ex situ* than over *in situ* resources. While local communities and indigenous groups, which often control *in situ* resources, would be eligible to join MUSE, they may choose not to do so (see Chapter III). Thus "ownership" rather than conservation method *per se* would appear to be the more important factor (see next section).

Scope Defined by Ownership

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64 As seed, pollen, *in vitro* or in field genebanks.

65 On farm or in natural habitats.

22. The Convention on Biological Diversity recognizes the sovereignty of nations over the genetic resources found within their borders. Countries differ in the manner in which they recognize ownership rights over genetic resources by the individuals, groups or institutions that are the actual holders or guardians of the material.

23. The ownership option defines the scope of the system according to the type of institute that holds the material. Institutes fall into two broad categories: public (under the direct control of government) and private (representing a company, non-governmental organization, community group, individual, or some other entity beyond the direct control of government).

24. **Publicly owned material:** Assuming national legislation is not to the contrary, any government institution holding collections of genetic resources should be able to make them available to the system for exchange. Governmental membership in MUSE would imply that all materials held by the government and included in the scope of MUSE would be brought into the system. If so agreed, this could include *in situ* resources under governmental control, for example in national parks.

25. **Privately owned material:** A significant proportion of the genetic diversity currently used in breeding activities is in private hands and governments may choose to regard this as the property of the holding institute. Likewise, governments may recognize ownership or other rights of farmers and indigenous communities over the materials on their lands or territories. A country's membership in MUSE would not guarantee that such material will be placed at the disposal of the system since the permission of these private groups would be needed. Similarly, member countries might not be willing or able to require private non-members to share benefits arising from the use of material already in their collections. Options for addressing this issue are explored in Chapter III.

Scope Defined by Intended Use

26. Genetic resources frequently have multiple uses. For example, certain food crops can also be used in industry or for medicinal purposes. The guar or cluster bean (*Cyamopsis tetragonolobus*) is grown as a garden vegetable on the Indian subcontinent but plays a number of other roles, including medicinal. Several species of the yam (genus *Dioscorea*) are used in medicines as well as for food. This is also the case for some trees,

such as the coconut, which serves many purposes in addition to its use as food.

27. Genetic resources might be included in MUSE for certain uses only, such as breeding for food production. The designated use of the material could be specified in the terms and conditions for germplasm access and release. Standard PIC and MAT agreements (as defined in the MUSE Agreement) would cover access to material for the agreed purposes only and would note that any other use, for example pharmaceutical research and development, would require renegotiation – on a bilateral basis – possibly leading to different benefit-sharing obligations.

Scope Defined by Mixed Options

28. MUSE members might choose to combine any of the above options in determining the scope of the system. For example, the scope might be defined not just by taxon, but also by intended use and nature of ownership. Needless to say, combining a number of options will narrow the scope of the system and might require more complex monitoring systems.

Chapter V. Conclusions and Next Steps

Conclusions

1. This report describes three basic options for regulating access to plant genetic resources for food and agriculture. It concludes that the first, a strictly bilateral approach, is virtually unworkable with regard to PGRFA. The second, the current informal multilateral approach, has significant strengths; however, a lack of clarity with regard to the rights and obligations associated with participation in the system has tended to discourage the involvement of important stakeholders, in particular, farmers and community groups. In addition, some countries are concerned that the current approach does not meet the requirements of the CBD with regard to its provisions for access and benefit-sharing.

2. The third option – MUSE – retains the essential elements of the current approach within the framework of a system guided by a set of mutually agreed rules. Within this framework, MUSE could accommodate a broad range of alternatives existing between the extremes of purely bilateral and informal multilateral approaches to exchange. Possible scenarios within the MUSE option are presented; these include the establishment of a fund and/or mechanisms allowing the bilateral negotiation and sharing of benefits under certain prescribed circumstances. A combination of these scenarios might coexist within the basic MUSE framework and be applied according to circumstances.

3. The report notes that there are significant advantages to be gained from the broadest possible participation in MUSE and it explores various means whereby countries and a wide range of institutions – from both member and non-member countries – could participate as full partners in the system.

4. The major benefits to be derived from MUSE – for both providers and recipients of germplasm – are described, as are mechanisms by which these benefits could be shared. The report explains the desirability of using standard terms for obtaining prior informed consent, and of reaching mutual agreement on standard terms for access.

5. Finally, institutional issues are addressed. The guiding principles for the system would be set by the Convention on Biological Diversity. The MUSE Agreement, comprising membership rules and describing the scope of the system, would be determined by governments. The governance and monitoring of MUSE, including responsibility for

revising the MUSE rules to meet changing needs, would rest with government members. Conditions for non-government membership would be set by the host country of the participating institute or organization and the report describes a number of ways in which such groups might sign onto the system. Once they have joined MUSE, non-government members would be subject to the same basic rules regulating access and benefit-sharing as are contained in the MUSE Agreement.

6. At the implementation level of MUSE, a wide variety of networking and other partnership arrangements would be possible. Each of these arrangements would be regulated by procedures appropriate to the needs and circumstances of the parties and genepools concerned, but they would in every case conform to the broad terms and conditions of the MUSE rules. Existing crop and regional networks, as well as other existing and new partnership arrangements, could all be accommodated within the MUSE framework.

7. To be acceptable, any system for regulating access to PGRFA must be consistent with the Convention on Biological Diversity. To be effective, it must be flexible and cost-efficient. The three basic options presented in the report are all consistent with the CBD. However, they vary in terms of their flexibility and cost-effectiveness. As we have seen, although individual bilateral arrangements are easily adaptable and generally have low transaction costs, an exchange system based on bilateral arrangements alone would be cumbersome in the extreme. The current multilateral approach to exchange is highly cost-effective in that it allows for the pooling of resources, technologies and talent. Its flexibility is far greater than that which would be possible under a system involving purely bilateral arrangements. However, it is less effective than it might be, owing to the fact that uncertainties and practices with regard to access and benefit-sharing deter potential participants from making their genetic resources available and from collaborating in international efforts to exchange germplasm, information and technology. This points to the need for change in the current system.

8. MUSE endeavours to combine the advantages of the various approaches. It describes an open and transparent system in which the rights and obligations of all members would be clearly specified and protected by the system. The basic MUSE option is likely to be at least as cost-effective as the current multilateral approach, and for the same reasons. The imposition of a simple structural framework on the system might even result in further cost savings, by for example, eliminating the need to prepare MTAs to cover individual transactions and the pooling

of resources to meet the costs of conservation, technology transfer and capacity-building. The transaction costs of some of the MUSE scenarios need further study before their cost-effectiveness is fully known (see Next Steps below). However, allowing a combination of the MUSE scenarios to coexist within the basic system framework and applying them according to circumstances (e.g. according to the particular genepool concerned) could result in an exchange system that is both cost-effective and eminently adaptable.

Next Steps

9. If it is agreed that the basic MUSE option, and/or any of its scenarios, are worth pursuing, a number of issues will need further study. For example:

10. ● The Study Team was only able to provide a qualitative assessment of the benefits accruing from the current system. The benefits available to the system might well increase under the MUSE option. However, in order to evaluate the potential of MUSE to improve upon the current system, it will be important to undertake studies to evaluate needs and to determine in more detail the kinds of benefits desired by various groups of providers (local communities, national genebanks, governments, etc.).

11. ● The MUSE scenario allowing bilateral benefit-sharing would require guidelines for negotiations on profit-sharing, and for establishing maximum levels of potential benefits/liabilities for different circumstances. Further research would be needed before such guidelines could be developed.

12. ● In addition, it will be necessary to study in detail the transaction costs – such as initial and continuing investments in human resources and equipment – for a range of activities. These include recording and monitoring releases, drafting, negotiating and implementing MTAs or other transfer mechanisms, tracking and monitoring the use of materials, and enforcement of agreements, which may entail litigation. The Study Team was unable to conduct such an analysis due to the lack of relevant data at the national and institutional levels. Such information will be required to assess these costs and take the analysis further.

13. ● Further study would be needed on issues such as the governance of MUSE and associated bodies, the implications of MUSE for national legislation, the form and legal feasibility of material transfer

arrangements such as the MTAs described in Annex IV, and possible formats for standardizing terms and procedures for obtaining prior informed consent and mutual agreement on terms of access.

14. The future development of sustainable agricultural systems world-wide requires that plant genetic resources for food and agriculture remain accessible, and are available under terms and conditions that ensure that the benefits arising from their use are shared fairly and equitably. To this end, it is hoped that the options considered in this report will make a useful contribution to the ongoing debate.

Annex I.

STATEMENT TO THE SIXTH SESSION OF THE COMMISSION ON PLANT GENETIC RESOURCES, BY DR. G. HAWTIN, DIRECTOR GENERAL, INTERNATIONAL PLANT GENETIC RESOURCES INSTITUTE (IPGRI), 28 JUNE 1995, ON APPROACHES TO FACILITATING ACCESS TO PLANT GENETIC RESOURCES AND PROMOTING THE EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR COMMERCIAL EXPLOITATION, WITHIN THE CONTEXT OF THE CGIAR.

1. During its Sixth Session, the Commission on Plant Genetic Resources invited the Director General of IPGRI to outline the CGIAR's perception of the interlinked technical and policy problems it faced in managing the *ex situ collections* held in trust by the Centres, which they had now brought into the Network under the auspices of FAO. The Commission believed that the information he had given verbally was of value for its work, and requested him to prepare for its consideration a note containing this information. The present note responds to that request, and outlines some of the ideas under discussion within the Consultative Group on International Agricultural Research (CGIAR) concerning the possible development of a multilateral framework for plant genetic resources, its implications for the germplasm collections held in trust by the Centres of the CGIAR, and its possible application to a wider agreement on terms of access.

Background

2. With the coming into force of the Convention on Biological Diversity (CBD), the Centres of the CGIAR have been giving attention to how they might operate in the future to meet the terms and conditions of the Convention, particularly with respect to ownership, access on mutually agreed terms, and the fair and equitable sharing of benefits arising from the commercial exploitation of plant genetic resources. In the pre-Convention period, the Centres collectively have assembled what is probably the world's largest *ex situ* collection of genetic resources of food and fodder crops of importance to developing-country agriculture. These collections have been assembled with the full participation and knowledge of the countries (primarily developing countries) providing the germplasm, that the materials would be made available to the world community. In October

1994 the Centres signed agreements with FAO bringing the collections under the auspices of FAO. In these agreements the Centres undertake to make the germplasm and information on it available to users, and agree not to take out intellectual property protection on the materials and to ensure that recipients of samples are bound by the same obligation.

3. The agreements only cover the existing collections, i.e. collections that were assembled prior to the coming into force of the CBD. It is of particular concern to the Centres and to their partners, particularly the National Agricultural Research Systems (NARS) in developing countries, that agreement be reached quickly on future arrangements to ensure continued and easy access to plant germplasm, at low transaction cost, under the terms of the CBD. The CGIAR regards plant genetic resources to be of fundamental importance as a resource for development. While their conservation is essential for the future, it is even more important to ensure that they are available for use today, by farmers, plant breeders and others who would seek to use them as a basis for sustainable agricultural development.

The general approach

4. In order to promote the continued availability of PGRFA under the terms of the CBD, it is proposed that a system be developed, within a multilateral framework, which would both respect the principle of access on mutually agreed terms, although these would be multilaterally agreed, and provide mechanisms for the sharing of benefits. Countries would agree to place their PGRFA into such a system based on Prior Informed Consent, and access to samples of these resources would be ‘unrestricted’ (unpaid, at point of access, but regulated through a legal mechanism such as a material transfer agreement) for all other countries which are parties to the system. Such ‘unrestricted’ access would be limited to those countries.

5. All PGRFA in the system could be used, without payment, for research and for not-for-profit purposes. However, in cases where profits are generated through the commercial exploitation of the resources, there would be an obligation on users of samples of PGRFA to negotiate a share of the profits with countries of origin for material collected after the entry into force of the CBD. The definitions of ‘not-for-profit use’ and ‘commercial use’ would need to be agreed.

6. Material obtained prior to the coming into force of the Convention would either continue to be distributed on the present basis, or on the condition that any benefits derived from commercial use could be put into the envisaged international fund for the implementation of Farmers' Rights. In

the latter case, this could be limited only to material where the country of origin is unknown.

7. All participating countries (but with special emphasis on developing countries) would be eligible for support from an international funding mechanism, in order to promote conservation and utilization of PGRFA, as elaborated in the Global Plan of Action, once it is adopted. Developed-country parties to the system would contribute financially to the funding mechanism, in addition to making their own PGRFA available.

8. Countries placing their material into the system would get several types of benefits:
   * access to technologies of use in agricultural development, including improved materials and biotechnologies, particularly through the involvement of international organizations in the system.
   * access to other countries' PGRFA as well as other benefits from the multilateral system,
   * access to funds and other support through the Global System, and
   * shares of profits derived from particular samples of PGRFA, in cases where country of origin is known and the product is commercialized.

Some comments and observations

9. Access to PGRFA in the system would essentially be 'unrestricted' for research and not-for-profit use. However, it would be regulated in line with the provisions in the CBD for Prior Informed Consent (PIC) and access on mutually agreed terms. This requirement might be implemented through a material transfer agreement or other appropriate legal mechanisms (e.g. it might be possible to negotiate 'umbrella' country agreements) to ensure that benefits can be shared on a fair and equitable basis in cases where research leads to commercialization.

10. As noted, the definition of 'not-for-profit use' and 'commercial use' need to be agreed. For example, 'not-for-profit use' might include farmer-to-farmer exchanges, and varieties bred by public institutions which are made available without profit. 'Commercial use' might include all cases where profits are involved, or might be limited to cases where IPR protection is employed. Enforcement in the latter case might be easier.

11. It might be necessary to have a minimum 'cut-off' point, in terms of the contribution of material from a specific accession to a commercial variety, for sharing benefits. It might not be worthwhile, for example, negotiating with multiple countries of origin the sharing of benefits from a relatively

unprofitable new variety with a complex pedigree. In any case, the international community will have to weigh the transaction costs against the possible benefits. In such cases it might be better for a share of profits to be paid according to a standard formula in line with internationally agreed guidelines, or into the proposed international fund. In other cases, for example when a single sample contributes a characteristic of major significance (such as resistance to an important disease), the share of benefits awarded to a country of origin might exceed that normally granted purely on the basis of the theoretical overall percentage contribution of genes to the genome.

12. Clearly negotiations on the equitable sharing of benefits are likely to be very complex and recipients of germplasm are likely to want to know their potential liability in advance of conducting any expensive research. It will thus be important to establish internationally accepted guidelines for such negotiations on benefit-sharing that are as simple as possible, and reasonable in terms of the benefits that may result. In addition, consideration should be given to the provision of legal assistance to countries with a limited capacity in this regard.

13. For the particular case of materials obtained prior to the coming into force of the CBD there are several options:

14. ● the materials would continue to be distributed and used freely, subject only to the provisions of the agreements with FAO concerning IPRs, i.e. that the holders of international collections would not take out any IPRs on the germplasm and would pass this obligation on to any recipients of the material;

15. ● in cases of commercialization, the users of the germplasm could negotiate, within the framework of the Global System, with the holder of an international collection for sharing profits, with the proceeds going into the international fund;

16. ● in cases where the country of origin is known, a similar arrangement could be put in place so that the country of origin would negotiate a share of profits.

17. With respect to sharing financial benefits, the proposed multilateral system would increase the probability of materials placed in the system being used, and therefore of benefits being realized and shared, owing to their wider availability for screening and evaluation. However, in most cases such financial benefits are unlikely to be large, which again underlines the importance of analyzing the transaction costs involved. Other advantages

accruing to countries participating in the proposed multilateral system include:

* access to information on the performance and characteristics of the germplasm they have placed in the system;
* added security of PGRFA, through duplication and through its wider dissemination;
* access to improved materials developed through the use, for non-profit purposes, of material placed in the system;
* access to opportunities for capacity-building, e.g. provision of facilities and training.

18. A fundamental decision would be required as to the species coverage of any multilateral agreement of the type presented here. Should it cover all PGRFA, all food crop genepools, or just crops of critical importance for food security? Should there be list of all the taxa to be included, or would it be better to include all PGRFA and agree on certain exclusions? Given the scope for bilateral negotiations on the sharing of benefits within the proposed system, it would seem desirable for the system to be as inclusive as possible. Indeed, there would be strong incentives to join a well-designed system. As a minimum, however, the system could make a start based on the commodity genepools covered by the CGIAR. However, thought needs to be given to situations where it would be agreed to exclude a particular taxon, and to the possibility, and the consequences, of a country opting out of the system for certain taxa but participating with respect to others.

19. Developed countries which are not particularly rich in PGRFA and are thus heavily dependent on PGRFA from outside their borders, would still have full access to genetic resources under the proposed system. A fully bilateral system with restrictions at point of access risks leaving them with few opportunities to access the resources they need.

20. The effectiveness of any system, whether multilateral or bilateral, would depend to a considerable extent on mutual goodwill, and the willingness of all the participating countries to make it work, recognizing that a fully effective and equitable system is in the best interests of all. Appropriate legal instruments, whether material transfer agreements or other mechanisms, would need to be developed. Other possibilities for helping to ensure compliance could also be explored, e.g. it might be possible to include in IPR legislation the requirement to disclose the origin of component genetic resources in all IPR applications. Good documentation systems would also assist in the monitoring of the movement of materials and thus help to minimize infringements.

Conclusion

21. In conclusion, the CGIAR regards it as a high priority that agreement be reached on an effective multilateral framework for PGRFA. Such a system should help ensure efficient conservation, promote access and use, and ensure an equitable sharing of any benefits arising from the commercial exploitation of PGRFA. It should conform to both the letter and the spirit of the CBD and should aim to minimize transaction costs while maximizing efficiency and effectiveness. Although many details remain to be resolved, a system such as the one outlined here would meet such criteria, if developed and shaped by the international community, working together.

Annex II.

Terms of Reference for and Composition of the IPGRI Multilateral Study Team and Task Force

1. The sixth session of the FAO Commission on Plant Genetic Resources for Food and Agriculture (FAO-CPGRFA) held in Rome 19-30 June 1995, requested that IPGRI prepare an in-depth study, for its consideration in April 1996, of the various possible multilateral systems compatible with the Convention on Biological Diversity (CBD), analyzed in terms of practicality, efficiency and cost-effectiveness. To comply with this request, IPGRI established a team of four consultants: Mr. Wolfgang Siebeck (Germany), Dr. Marcio de Miranda Santos (Brazil), Dr. Graham Jenkins (UK) and Ms Kerry ten Kate (UK) with the required legal and technical skills to conduct such a study. The work of the team was supported by an IPGRI Task Force made up of senior IPGRI staff: Ms. Ruth Raymond, Dr. Jan Engels, Dr. Dick van Sloten, Dr. Emile Frison and Dr. George Ayad (Chair) and included two observers from FAO: Dr. Jose Esquinas-Alcazar and Mr. Gerald Moore. Based upon the findings contained in this study, IPGRI plans to submit a report to the FAO-CGRFA in April 1996.

Terms of Reference

2. Under the general supervision of the Director General and the direct supervision of the chairman of the IPGRI Task Force on the multilateral study, the Study Team members will:

3. ● submit, to IPGRI, an in-depth factual study on the various possible technical options, including the establishment of international fund, and their legal implications for a multilateral system that would facilitate access to genetic resources for food and agriculture on mutually agreed terms while offering ways and means of equitable and fair sharing of benefits arising from the use of these genetic resources in commercial and /or non-commercial purposes to developing countries (countries of origin) differentiating if necessary between developed and developing countries.

4. Components of such a study may include:
   - Introduction: bilateral as compared to multilateral approaches: nature and pros and cons of each within the context of national and international legislation/treaties and practices, why a multilateral system is needed.
   - Multilateral approaches including the following elements:
   - Scope: Plant Genetic Resources for Food and Agriculture (PGRFA), designate some species? (criteria of selection, industrial crops, pharmaceutical species, forest tree species, etc., case of multiple uses of many species), designate all species?, etc.
   - Membership and governance of a multilateral system: governmental institutions, UN organizations, non-governmental institutions including the private sector; governance system of the multilateral system.
   - Modalities of sharing benefits: cut-off point (i.e. patented material, IPR-protected material?)
   - Distinction between commercial and non-commercial uses.
   - Distinction between agricultural and non-agricultural uses.
   - Which benefits to share?
   - How to share different types of benefits?
   - Funding mechanisms: for instance an international fund–who donates funds?; nature of fund–obligatory, voluntary, taxes on seed sales; how should funds be used, e.g. direct support to genebanks, to breeding programmes; capacity-building including the transfer of technology; other funding mechanisms; governance of the various funding mechanisms.
   - Role of IPGRI and the CGIAR.
   - Role of the FAO Commission on Plant Genetic Resources for Food and Agriculture (FAO-CPGRFA) and the International Technical Conference on Plant Genetic Resources.
   - FAO/CGIAR Centres agreements. How will the multilateral system impact upon the agreements signed for the designated germplasm and for the next four years and on potential agreements?

5. Utilize as basic sources of information for the study such documents as: The FAO Undertaking for Plant Genetic Resources, The Convention on Biological Diversity (CBD), IPGRI's paper to the Sixth Session of the FAO-CPGR (28 June 1995); IPGRI Issues in Genetic Resources No. 2, by D. Cooper *et al.*, 1994, The SAREC consultation on multilateral systems (Stockholm, May 1995) and IPGRI Issues in Genetic Resources No. 1, by Barton and Siebeck, May 1994.

6. In the initial phase, submit for IPGRI's approval a workplan for the Study Team's activities including the brainstorming consultation and travel with a view to composing a first draft of the study in late November/early December 1995 and final IPGRI-approved version in January 1996.

7. To consult with, through visits, contacts and attendance of relevant meetings, as wide a range of national programmes, NGOs, the private sector, international organizations such as UPOV, WIPO, The FAO-CGRFA and the CBD secretariats, CGIAR and non-CGIAR Centres, as possible in the course of synthesizing the various options contained in the study so as to reflect actual examples. Relevant meetings would include some of the subregional meetings of the FAO International Technical Conference.

8. To fully document in the study all sources of various forms of information reported for each option and the basis for the legal implication of these options, e.g. figures, data in catalogues and tables, statistics, public and non-public institutional reports, etc.

Annex III.

Informal Consultation Process Undertaken by the Study Team

Date and venue	Institutions visited / Meetings attended and persons met
I. Consultations held at IPGRI and FAO, Rome, Italy	
6 September 1995, IPGRI	Mr. Roger Smith, Royal Botanic Gardens, Kew, UK
7 September 1995, FAO	Dr. Jose Esquinas-Alcazar, Executive Secretary, The FAO Commission on Plant Genetic Resources for Food and Agriculture (FAO-CPGRFA) Dr. David Cooper, FAO / ICPPGR Messrs. Gerald Moore, Legal Counsel, FAO; Luis Bompin, Legal Office, FAO
12 September 1995, FAO	Dr. Cary Fowler, Project Manager, FAO / International Conference and Programme on Plant Genetic Resources (ICPPGR)
6-12 September 1995, IPGRI	IPGRI steering committee members and other IPGRI senior staff
II. Consultations held in Nitra, Slovakia	
24-26 September 1995	The European Regional meeting of ICPPGR attended by country representatives
III. Consultations held in the UK	
10 October 1995, The British Society of Plant Breeders, London, UK	Meeting with the Board of the British Society of Plant Breeders
IV. Consultations held in	

Date and venue	Institutions visited / Meetings attended and persons met
Switzerland	
16 October 1995, The Secretariat of the Convention on Biological Diversity (SCBD), Geneva	Dr. Calestous Juma, Executive Secretary, Secretariat of the Convention on Biological Diversity (SCBD), Dr. Arturo Martinez, Senior Officer (Biological Resources), SCBD and Susan Bragdon, Legal Officer, SCBD
17 October 1995, The World Conservation Union (IUCN), Gland	Dr. Jeffrey McNeely, Chief Scientist (Biodiversity), The World Conservation Union (IUCN), Gland
17 October 1995, Association Internationale des Seléctionneurs (ASSINSEL), Nyon	Dr. Bernard Le Buanec, Secretary General, Association Internationale des Seléctionneurs (ASSINSEL), Nyon
18 October 1995, Union for the Protection of Plant Varieties (UPOV), Geneva	Dr. Barry Greengrass, Deputy Secretary General, UPOV
V. Consultations held in Stockholm, Sweden	
19 October 1995, The Swedish International Development Cooperation	Drs. Peter Hartelius, Swedish International Development Agency (SIDA); Karen Gerhardt (SAREC); Bo Bengtsson, The Swedish Academy of Sciences; Carl-Gustaf Thornstrom, (SAREC); and Ulf Svensson (Ministry of Agriculture)
VI. Consultations held in Washington DC, USA	
23 October 1995, The CGIAR Secretariat, The World Bank	Presentation to the CGIAR Genetic Resources Policy Committee chaired by Dr. M.S. Swaminathan
24 October 1995, The CGIAR Secretariat	Meeting with Dr. Don Duvick, Iowa State

Date and venue	Institutions visited / Meetings attended and persons met
26 October 1995, USDA / ARS 1 November 1995, The CGIAR Secretariat, The World Bank	University Meeting with Mr. Pat Roy Mooney, Executive Director, Rural Advancement Foundation International (RAFI) Meeting with USDA staff, chaired by Dr. Henry Shands Informal meeting of CGIAR donors, sponsored and arranged by Sweden (SIDA / SAREC) during International Centers Week
VII. Consultations held in the UK 30 October 1995, Ministry of Agriculture, Forestry and Fisheries (MAFF), London	Mr. John Suich and Ms. Susan Buckingham, Ministry of Agriculture, Fisheries and Food (MAFF), London
VIII. Consultations held in Jakarta, Indonesia 6-17 November, 1995 during the Conference of the Parties (COP) to the CBD	**A.** Informal meetings with government delegations of the following countries in their personal capacities: **Canada** Dr. Brad Fraleigh **Brazil** Mr. Enio Cordeiro, Dr. Maria Jose Amstalden Sampaio, Dr. Lidio Coradin **Spain** Mr. Santiago Castroveijo Bolivar **France** Dr. Michel Chauvet **UK** Mr. John Suich **Malaysia** Prof. Dr. Zakri A. Hamid **USA** Ms. Vanessa Laird, Dr. Robert Bertram, Dr. John Mutuszack **India** Dr. Gidda Venkata Sarat Babu **Argentina** Ms. Monica Liliana Araujo **Germany** Dr. Wilbert Himminghofen **Indonesia** Dr. Setijati Sastrapradja **Colombia** Mr. Fernando Casas **Ethiopia** Mr. Girma Hailu **Philippines** Mr. Antonio La Vina **B.** Meeting with representatives of NGOs:

Date and venue	Institutions visited / Meetings attended and persons met
	Mr. Paul I. Borja, CBDC-SEARICE, Philippines Mr. Jake Tan, CADI, Philippines Mr. Abet Gavino, SEARICE, Philippines Mr. Witoon L., TREE, Thailand Mr. Crissy Romeno, SEARICE, Philippines Mr. Generoso Deal Cruz, CONSERVE, Philippines Mr. Neth Dant, SEARICE, Philippines Mr. Arma Bertuso, SEARICE, Philippines Mr. Frank Magnifico, CONSERVE, Philippines Mr. Romeo Quijand, PAN PHILS/ University of the Philippines College of Medicine, Philippines Mr. Marcos Juing, BASDA, Sarawak, Malaysia Dr. Walter Reid, World Resources Institute (WRI), USA Mr. Brendan Tobin, Sociedad Peruana de Derechos Ambiental, Peru Ms. Kritsada Boonchai, Local Development Institute (LDI), Thailand Ms. Janie Lasimbang, Partners of Community Organizations , Sabah, Malaysia Mr. Pat Roy Mooney, RAFI, Canada Ms. Kerry ten Kate, Royal Botanic Gardens, Kew, UK Mr. Sam Johnston, University of Cambridge, UK Mr. Nelson Alvarez, GRAIN, Spain Ms. Gudrun Henne, German NGO Working Group on Biodiversity, Germany **C.** Presentations to and participation in workshops: “Intellectual Property Rights: Threat to Biodiversity and Society”, 6 November “Intellectual Property Rights and Access to Genetic Resources: Follow-up to the Global Biodiversity Forum”, 9 November “Agrobiodiversity Workshop (Sweden): The IPGRI multilateral study, the FAO Leipzig

Date and venue	Institutions visited / Meetings attended and persons met
	Conference and issues for COP3", 13 November
IX. Consultations on the development of the report	The following provided comments on the draft report: Prof. Donald N. Duvick Affiliate Professor of Plant Breeding Dept. of Agronomy Iowa State University 6837 N.W. Beaver Drive P.O. Box 446 Johnston, Iowa 50131, USA Dr. Stephen Smith Pioneer HiBred Int., Inc. P.O. Box 1004 7300 N.W. 62nd Ave. Johnston, Iowa 50131, USA Mr. John H. Barton 1240 Harwalt Drive Los Altos, CA 94024, USA Dr. Carl-Gustaf Thornstrom Department for Research Cooperation - SAREC SIDA S-10525 Stockholm, Sweden Mr. Pat Mooney Rural Advancement Foundation International Suite 504, 71 Bank Street Ottawa, Ontario KIP5N2, Canada Mr. Henk Hobbelink Genetic Resources Action International (GRAIN) Girona 25, pral E-08010 Barcelona, Spain Dr. Tim Roberts Intellectual Property Manager

Date and venue	Institutions visited / Meetings attended and persons met
	Zeneca Seeds Jealotts Hill Research Station Warfield, Bracknell, Berkshire RG12 2JP, UK Dr. Tewolde Egyiabher Biodiversity Institute Addis Ababa, Ethiopia Dr. Wilbert Himminghofen Federal Ministry for Nutrition, Agriculture & Forestry Postfach 140270 53107 Bonn, Germany Dr. Michel Chauvet Bureau for Genetic Resources Paris, France Mr. Dan Lesnick BUCO-Agrar Koordination Wohlersallee 18 D-22767 Hamburg, Germany Dr. Henry Shands Deputy of Administration Agriculture Research Service (ARS) USDA / BARC Beltsville, MD, USA Dr. Bernard LeBuanec Secretary General International Association of Plant Breeders Chemin du Reposoir 7 CH-1260 Nyon, Switzerland Mr. Carlos Correa Universidad de Buenos Aires Buenos Aires, Argentina Dr. R. S. Rana Former Director NBPGR (India)

Date and venue	Institutions visited / Meetings attended and persons met
	D-43, Indraprastha Apts Flat 1, Section 14, Rohini New Delhi -110085, India Professor Tim Reeves Director General CIMMYT Mexico DF, Mexico Dr. Brad Fraleigh Research Coordination Central Experimental Farm 7th floor, Sir John Carling Bldg. Ottawa, Ontario KIA0G5, Canada Dr. Jochen de Haas Federal Ministry for Economic Collaboration (BMZ) Head of Division 223 Postfach 120322 53045 Bonn, Germany Dr. Michael Flitner BUCO-Agrar Koordination Wohlersallee 18 D-22767 Hamburg, Germany
X. Consultations with the CGIAR/IARCs	1. The Inter-Center Working Group on Genetic Resources (ICWG-GR), summary / draft discussed in Lima, Peru, Januray 1996 2. The CGIAR Genetic Resources Policy Committee, draft summary and full study report circulated for discussion in February and April 1996, respectively

Annex IV.

Provisions for Bilateral Benefit-Sharing within MUSE

Trigger points for bilateral benefit-sharing

1. If it were decided to include a bilateral element in MUSE, negotiations between a germplasm provider and recipient on benefit-sharing – including whether or not to share benefits – could arise at various points as a product is developed from the material. The earliest moment for negotiation would be when the material was first sent to the user, and the latest, when the product derived from the material was put on the market and generated sales. Aspects of benefit-sharing such as joint participation in research might most appropriately be negotiated early in the product development cycle, whereas the sharing of any royalties arising from sales of the final product could be finalized when it became apparent that the product was likely to give rise to commercial profits. Between these two extremes, negotiations might occur when the user has determined that the material is interesting enough to warrant further research and development, or when a user files for intellectual property protection.

2. The value of the germplasm provided may be assessed differently at the various stages of product development. Initially, when little is known about possible traits and the ultimate use of the material, the assessment of benefits will be more difficult than later in the research and development process when its value will become more apparent, albeit still difficult to quantify. It may also become clear at this point that the material is not useful, either because no product is developed, or because the final product does not make use of it. In either case, no financial benefits are to be shared.

Which events could trigger negotiations on benefit-sharing?

- User obtains material
- User introduces material into research/breeding programme
- Research determines useful traits in material
- User decides to develop product from material
- User files for intellectual property protection
- User starts field trials
- User brings product to market
- Sales start to generate financial benefits

Difficulties associated with bilateral benefit-sharing

3. Bilateral benefit-sharing arrangements will be subject to practical difficulties and some costs. Negotiating an appropriate share of financial benefits, for example, will require evaluating the contribution of the provided germplasm to the market value of the new product. This is a tremendously difficult and complex process (see below) and may, in some cases, require protracted and costly arbitration.

The challenge of calculating economic benefits

4. A market has developed for plants, microorganisms and animals as the source of new pharmaceuticals, with a range of prices per sample and royalties on sales. However, there is little experience of this form of benefit-sharing in the agricultural field.

5. Crops differ from pharmaceutical products in a number of ways. The global market for pharmaceuticals is some $235 billion per annum, to which products derived from natural sources may contribute between 25% and 40%.[66] By contrast, the global market for seeds is $15 billion. Normally less than 20% of the germplasm used for plant breeding is obtained from newly introduced landraces and wild species. The balance comes from commercially available material.[67]

6. A naturally derived pharmaceutical will typically be based on an active compound discovered in a single sample. The probability of an individual sample becoming a marketed medicine is around 1 in 10 000.[68] The probability that a single accession used in a breeding

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66 ten Kate, K. 1995, Biopiracy or green petroleum? Expectations and Best Practice in Bioprospecting. Overseas Development Administration, London.

67 In a survey of the source of germplasm for various crop groups for 20 plant breeding and seed companies (Cambridge and WCMC, 1994), the companies surveyed obtained 81.5% of all their germplasm from commercial cultivars, compared with 1% from wild species maintained *in situ*, 1.4% from *in situ* landraces, 2.5% from wild species held in *ex situ* genebanks, and 1.6% from landraces maintained in genebanks (Cambridge University Faculty of Economics and Politics and the World Conservation Monitoring Centre, draft, June 1994, Sustainable Utilisation for Global, National and Community Benefit: an Analysis of Utilisation and Biodiversity Conservation. Case Study: the Use of Plant Genetic Resources in Agriculture).

68 1 in 10 000 samples is likely to result in a marketable drug. This figure needs some qualification. The ratio of 1:10,000 is much cited for the probability of identifying a 'lead' from a pure chemical compound, rather than from a sample or extract from a higher plant, microorganism, etc. Perhaps one in four 'leads' may result in marketable products. At a 1986 OECD workshop, participants including representatives from pharmaceutical companies agreed that the probability that any given plant would produce a marketable prescription drug ranged between 1:1000 and 1:10 000, given that each plant contains many compounds to be screened (Principe 1991). Between 1:50 000 and 1:1 000 000 tests (i.e. combinations of different extracts against different screens) are estimated to result in viable commercial (ten Kate, K. 1995, Biopiracy or Green Petroleum? Expectations and Best Practice in Bioprospecting. Overseas Development Administration, London. 1995).

programme will ultimately contribute to a new crop line is much higher, but the new crop line will not be derived from a single accession. Rather, it will have a complex pedigree to which large numbers of cultivated varieties and wild species have contributed.

7. To add to the complications, it may be impossible to determine which lines have interbred with those under investigation, and which, of the many parents involved, have contributed valuable traits to the genome of the final 'new' variety. Even if the genes contributing useful characteristics were to be identified, and their source known, calculating the economic value of their contribution would be virtually impossible. Is a single gene that offers disease resistance – perhaps one in 10 000 genes in the plant as a whole – worth only 1/10000 of the plant's value?

8. The concept of 'commercialization' would itself need to be strictly defined within the context of negotiations on benefit-sharing. Should it refer to all sales or just the sale of seeds? Would it only cover those sales intended to bring profit? What about sales made on a concessional basis in a highly subsidized seed production and marketing situation, as is often the case with government-bred varieties in developing countries? What about situations where a new product is not sold but bartered for goods and services?

9. Another significant issue needing resolution is the extent to which benefit-sharing obligations would be transferred through a chain of varieties. Would the obligation stop with the first release? Would it thereafter be transferred to the breeder of the new variety? Or would obligations to share benefits continue through successive varieties, with the actual share of benefits decreasing as the original germplasm came to constitute an ever decreasing proportion of the ancestry of the new varieties produced?[69]

10. According to UPOV rules, released varieties can be used as parents of new varieties bred by others without authorization from the original breeder, providing the new variety differs sufficiently from the original (the so-called Breeders' Exemption).[70] The principle of carry-over

[69] See Barton/Siebeck. 1994, p. 43.

[70] According to the 1978 UPOV Convention, Article 15.3, "Authorization by the breeder shall not be required either for the utilization of the variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties. Such authorization shall be required, however, when the repeated use of the variety is necessary for the commercial production of another variety". This provision was modified by the 1991 version of

obligations, if accepted within the context of MUSE, would thus introduce a new principle that is not required under UPOV rules.

11. One way to simplify matters might be for MUSE members to agree to consider bilateral benefit-sharing only when a commercialized variety, or a single gene or gene-construct derived from the introduced material, comes under intellectual property protection. However, if such an agreement were to include Plant Breeders' Rights in addition to patents, this would still not resolve the problem of the Breeders' Exemption addressed above. The simplest way around this would be to allow bilateral benefit-sharing only in the event that a user were to take out a patent on the product developed from the material. However, since other forms of IPR (notably Plant Breeders' Rights and Trade Secrets) are commonly used by the seed industry, this approach would considerably limit opportunities for the sharing of benefits.

12. The difficulties involved in evaluating benefits fairly late in product development raise another potential problem. Companies might not support a requirement to negotiate benefit-sharing late in the research and development process (e.g. after a patent has been applied for) if this would offer providers the chance to withhold their ultimate consent to commercialization, thus jeopardizing the investments already made. One option would be to determine a range of minimum and maximum levels of benefits – binding on all MUSE members – which would apply if provider and user were unable to reach an alternative agreement.

Monitoring

13. The simplest solution to the question of monitoring might be to require users to initiate negotiations on benefit-sharing under the terms of the MUSE Agreement. However, providers would still need to monitor the use of their genetic resources as a means to identify infringements and thus to enforce the terms of release. While monitoring use is not an easy task, and may ultimately be impossible in many situations, there are ways in which it can be facilitated. A number of possible tools are discussed below.

14. Logging releases when material leaves a genebank would be a useful means of tracking initial use. The log would include a description of the material, the date, and the identity of the recipient. However, transfers to subsequent users would not be recorded unless requested in advance, and given the large number of samples distributed, and the frequency

the Convention which states that a new variety must differ significantly from a variety covered by Plant Breeders' Rights in order not to require the authorization of the original breeder.

with which material changes hands, there is a considerable risk that such a request would often be overlooked or ignored.

15. Another possible tool for monitoring use involves the application of molecular and chemical techniques such as genetic fingerprinting. Their use would facilitate the comparison of genetic materials and could allow providers to determine with a reasonably high degree of probability whether suspected products were derived from material originating with them. However, these techniques need further development before they can be used routinely and, at least at present, they are inordinately costly to use on a routine basis.[71]

16. A third option would be to introduce regulations requiring that all applicants filing for a patent or plant variety right identify the provider of genetic material from which a patent was derived or a variety developed.[72] In most countries, this would not require a change of patent or variety laws. By searching patent and plant variety databases, providers would be able to learn where and how their material had been used.

17. Identical genes may be found in more than one source and given the small size of individual germplasm samples needed, it is difficult, if not impossible, to monitor the origin and use of the full range of material used in crop improvement programmes. For these reasons, any system for monitoring the use of genetic resources will inevitably have to rely to a large degree upon the methodical records and honesty of breeders.

Transaction costs

18. There are three stages at which transaction costs might be incurred. First, agreements need to be put in place, such as MTAs or other legal instruments which oblige users to share benefits, combined with a requirement to disclose the origin of genetic material. Within MUSE, these agreements could be standardized under the Agreement and so

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[71] IPGRI Workshop on Conservation of PGRFA and the Use of Molecular Methods, 9-11 October 1995 (in press).

[72] Tobin and Kothari propose that patent and variety offices require evidence of prior informed consent as part of the filing for and granting of the relevant right. See Tobin, Brendan (1995) "Ensuring Prior Informed Consent - the Need for a Multilateral Approach". Paper presented at workshop on regulating access to genetic resources, the Global Biodiversity Forum, Hotel Indonesia, Jakarta, 4-5. November, 1995. See also Kothari, Ashish (1995) "Equitable Access to Biodiversity Resources and Benefits: Options for Action, and the Indian Follow-up". Paper presented at workshop on regulating access to genetic resources, the Global Biodiversity Forum, Hotel Indonesia, Jakarta, 4-5 November, 1995.

would not entail considerable cost. Once the material has entered the system, transfers within MUSE would be carried out under the terms of the Agreement. Transfers by member recipients to non-member users would be permitted, but these would require the new user to sign the standard MTA and to abide by its terms. Multiple transfers of the provided material would thus result in a 'chain' of MTAs with identical terms and linking every subsequent user with the original provider.

19. A second stage would involve pursuing a claim by tracing the path traveled by the material from the original provider to the final user. This could well be expensive and require the search of databases and patent registers.

20. Yet greater transaction costs would arise at a third stage when it comes to the actual settling of a claim. This could involve expensive litigation prompted because the chain of MTAs has collapsed and an intermediary user has become liable for damages, or because the original provider and the user disagree on the actual terms of benefit-sharing, or because the user or intermediary has failed to abide by the terms of the MUSE Agreement. As noted above, monitoring the origin and use of genetic materials is very difficult and attempts to collect the evidence necessary to substantiate a claim are likely to be quite costly.

Legal assistance and negotiating guidelines for bilateral agreements within MUSE

21. It might well be necessary for MUSE to adopt rules for bilateral settlement procedures. These could include guidelines and procedures for estimating the contribution of germplasm used in a new variety and for establishing its value to the resulting variety. Rules for arbitration should also be established. Consideration might be given to the establishment of a system for legal assistance on which a developing country could draw in pursuing bilateral benefit-sharing.