

To: Ismail Serageldin, Chairman, CGIAR

From: Walter Falcon, Chairman, CBC  
Geoffrey Hawtin, Chairman, CDC  
Louise Fresco, Director, SDR, FAO

Subject: Updated Documents on Genetic Resources

At this year's Mid Term Meeting in Brasilia, the Center Board Chairs and Directors General tabled eight documents related to genetic resources. In addition, both committees discussed a range of issues related to the implementation of the FAO-CGIAR Agreements. Several of the documents discussed at MTM represented work in progress. The plenary session of the MTM asked that additional work be done on these documents, especially with FAO, in order to clarify certain specific points.

Three documents are attached in response to that request. They are:

1. Guidelines for the Designation of Accessions under the FAO Agreements
2. Material Transfer Agreement
3. Second Joint Statement on the Agreement Placing CGIAR Germplasm Collections Under the Auspices of FAO

In consultation with the centers which maintain designated germplasm, IPGRI, as the lead center of the SGRP, worked closely with FAO, especially in regards to the Material Transfer Agreement and the Second Joint Statement. FAO has approved both documents (2 & 3). The documents presented here have now been endorsed for system-wide use by the CBC, CDC, and the Genetic Resources Policy Committee, and approved, as noted above, by FAO. These documents will be provided to the next meeting of the FAO Commission on Genetic Resources for Food and Agriculture.

Work is ongoing to develop further the Guiding Principles for the CGIAR Centers on Intellectual Property and Genetic Resources. An update will be provided at MTM-99.

## Guidelines for the Designation of Accessions under the FAO Agreements

### I. Background

In October 1994, FAO and eleven CGIAR Centres (those holding plant genetic resources, *ex situ*) signed Agreements placing collections of plant germplasm under the auspices of FAO, as part of the International Network of *Ex Situ* Collections. Centres hold germplasm designated under these Agreements “in trust for the benefit of the international community, in particular the developing countries in accordance with the International Undertaking on Plant Genetic Resources,” and the terms and conditions set out in the Agreements.

Under the Agreements, each relevant Centre is committed to a number of actions and principles, *inter alia*, it:

- “...undertakes to manage and administer the designated germplasm in accordance with internationally accepted standards, including, with respect to the storage, exchange and distribution of seeds, the international Genebank Standards endorsed by the Commission, as soon as possible applying the ‘preferred standards’ where these are specified, and ensuring that all designated germplasm is duplicated in order to ensure its safety.” (Article 5a)
- “...undertakes to make samples of the designated germplasm and related information available directly to users or through FAO, for the purpose of scientific research, plant breeding or genetic resource conservation, without restriction.” (Article 9)

Furthermore, each Centre agrees that:

- “The Centre shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over that germplasm or related information.” (Article 3b)
- “Where samples of the designated germplasm and/or related information are transferred to any other person or institution, the Centre shall ensure that such other person or institution, and any further entity receiving samples of the designated germplasm from such person or institution, are bound by the conditions set out in Article 3 (b) and, in the case of samples duplicated for safety purposes, to the provisions of Article 5 (a).” (Article 10)

To date, FAO and the CGIAR have issued two Joint Statements, which address various issues of interpretation and implementation of the Agreements. In these Statements, FAO and the CGIAR agree, *inter alia*:

- “With respect to the transfer of samples of designated germplasm, the requirement of Article 10 will be satisfied by arrangements, such as material

transfer agreements...” The wording of a standard material transfer agreement (MTA) for use by all Centres has been agreed by FAO and the CGIAR.

- That Centres will follow certain specified procedures when they have reason to believe that an MTA may have been violated.
- That Centres are not expected to meet unreasonable requests for germplasm (either in terms of quantity of accessions requested or the amount of material requested of a single accession), nor are they obliged to transfer material when such a transfer would pose a risk of introducing pests or diseases.

On their own initiative, Centres designate germplasm to be included in the International Network and under the terms and conditions of the Agreements with FAO. Germplasm acquires its status as “designated” germplasm at the moment the Centre determines that it considers it as such, and is willing to manage it in accordance with the FAO Agreements. Every two years, Centres are required to provide FAO with an updated list of designated germplasm. It is recognised in the second Joint Statement that in certain circumstances, specific designated germplasm will cease to be considered as designated (e.g., loss of viability of an accession, and administrative situations such as the discovery that an accession identifier previously provided FAO does not actually correspond to a physical sample, etc.)

The Agreements call for the Centres to append a list of "designated germplasm" included in the International Network, and to update the list every two years as new accessions are added to the collections.

These Guidelines for Designation have been developed on the initiative of and through the System Wide Programme on Genetic Resources >and endorsed by the Inter-Centre Working Group on Genetic Resources< (brackets to be removed following endorsement). The promulgation of these Guidelines demonstrates that Centres accept a certain responsibility towards the international community to designate materials under the Agreements with FAO in a consistent and transparent manner, and on the basis of clearly enunciated criteria. While these Guidelines are aimed at helping Centres determine whether to designate materials under the FAO Agreements and at making that decision-making process more transparent to the general public, it should be noted that a number of other documents have relevance to the Agreements themselves and to their implementation, *inter alia*, the FAO/CGIAR-agreed Material Transfer Agreement (MTA), the first and second “Joint Statement(s) of FAO and the CGIAR Centres on the Agreement Placing CGIAR Germplasm Collections Under the Auspices of FAO,” and certain other CGIAR policies and statements concerning plant genetic resources and intellectual property rights.

## II. Criteria To Consider In Determining Whether Material Should Be Designated

For decades, Centres have safeguarded genetic diversity and attempted to develop it in the public interest. Centres have never claimed to own this genetic material. In keeping with this tradition and practice, Centres now designate material if it is eligible for designation (i.e., not acquired with restrictions preventing a Centre from managing it in accordance with the FAO Agreements), and, as noted below, if the Centre is prepared to manage it in accordance with the Agreements. Centres should not consider the value or potential usefulness of the material, nor attempt to make any value judgement about whether the material should be in the public domain, or not, when deciding whether to designate an accession.

The understanding and principle underlying the Agreements with FAO is that each Centre will designate all accessions (see Section III, below, for more detail) that are part of their holdings, or are subsequently acquired, which have not already been designated by another Centre or institution and which will be administered and managed by the Centre in compliance with the terms and conditions of the Agreement with FAO.

In designating germplasm, Centres commit themselves to:

- A. long term conservation
- B. unrestricted availability

The CGIAR Policy on Genetic Resources (1989) declared for the first time that collections were being held “in trust” for the world community. Implicit in such a declaration - and explicit in the Agreements with FAO - is the understanding that Centres do not claim ownership of this genetic material. Thus, Centres have a responsibility to designate all germplasm which (1) they undertake to conserve under accepted standards (in most cases, long-term); and (2) they can make available without restriction for “scientific research, plant breeding or genetic resource conservation”. (See section V below, for a more detailed treatment of how Centres should interpret the term, “without restriction”).

## III. Types of Germplasm to be Designated

Accessions which a Centre is prepared to conserve long-term and make available without restriction should be designated irrespective of whether they are wild species, landraces, farmer varieties, obsolete varieties, advanced varieties, breeding lines, genetic stocks, etc.). In cases where materials have been received with the understanding that they will be conserved and will remain available, it is incumbent upon the Centre to designate them. It is understood that Centres may have sound scientific and management reasons for not designating all breeding lines, experimental populations, genetic stocks, or products of breeding programmes such as advanced cultivars. Commitment to long-term conservation and unrestricted

availability may not be appropriate in all such cases. In such circumstances, the material in question would not be designated. Non-designation, however, would not prevent the Centre from making the material available appropriately and at the proper time in furtherance of Centre and CGIAR goals and principles.

Accessions held by Centres for others under “black box” arrangements should not be designated. (Some Centres hold “black box” collections - collections of others who may be temporarily unable to care for the material. In these cases, the Centre typically conserves the material, but usually does not open, examine, test or engage in research on the materials. While the Centre may be committed to long-term storage of such materials, the Centre has no right or authority to designate them.)

Furthermore, Centres should endeavour to designate particular accessions only once - confusion will result if accessions and their duplicates stored at other Centres are all designated.

A. Accessions acquired by the Centre before the coming into force of the Convention on Biological Diversity (29 December 1993)

In the vast majority of cases, materials acquired before 29 December 1993 were, in fact, acquired with the understanding that they would enter the collection of the Centre, be conserved, and be made available to all bona fide users. Such materials should be designated. In some cases (e.g. advanced products of formal breeding programmes), materials may have been acquired with certain restrictions regarding their use or distribution. Such materials should not be designated, as the Centre could not meet the requirements of the Agreements with FAO.

B. Accessions acquired by the Centre after the coming into force of the Convention on Biological Diversity (29 December 1993)

Materials acquired after the coming into force of the CBD can and ordinarily should be designated under the Agreements with FAO provided they have been acquired with the understanding that they will remain in the “public domain” and that the Centre will conserve them and make them available without restriction as called for in the FAO Agreements. In such a case, the same principles guiding the designation of pre-CBD materials apply: the Centre must intend to manage and administer the material in accordance with the FAO Agreements. Central to the decision to designate post-CBD acquired material (as with pre-CBD acquired materials) is that the Centre be willing to commit to long-term conservation and unrestricted availability.

It is understood that acquisition of materials should be based on the express written permission of the relevant government authority. Centres should seek to determine which institute or agency has this legal authority. If materials are acquired with restrictions on their access or use, then it follows that they cannot be designated. Materials held with such restrictions cannot be considered as being kept by the Centre “in trust for benefit of the international community....” (Article 3a)

#### IV. Conservation of Designated Germplasm

The FAO-CGIAR Agreements state: "The Centre undertakes to manage and administer the designated germplasm in accordance with internationally accepted standards, including, with respect to the storage, exchange and distribution of seeds, the international genebank standards endorsed by the Commission, as soon as possible applying the "preferred standards where these are specified, and ensuring that all the designated germplasm is duplicated in order to ensure its safety." (Article 5) This means, in effect, that Centres must endeavour to conserve materials in a manner consistent with international standards, adopting "preferred standards" (i.e., those most appropriate for long-term conservation of the material in question) as quickly as possible.

The decision about whether or not to designate material should be made without regard to the form in which the material is to be conserved (seed, *in vitro* culture, whole plant, other) or the current/initial technical conditions of storage (long-term, medium-term, cryopreserved, etc.).

#### V. Availability of Designated Germplasm and Related Information

Designation can only apply to accessions that are available without administrative, legal or policy restriction. In other words, the availability of germplasm cannot be limited by contractual agreements with the supplier of the germplasm, by intellectual property laws, or by any policy or administrative regulation of the Centre (with the exception of relevant health and quarantine regulations).

Accessions should be designated irrespective of any current technical constraints to making them physically available. In a Second Joint Statement issued by FAO and the CGIAR, it was agreed that Centres could not be expected to fill all requests for materials immediately, or fill requests for unreasonable numbers of accessions or quantity of seed or clones, for example. It was agreed that Centres should not distribute designated germplasm when such distribution posed a risk of introducing pests and/or diseases. In other words, it is understood that certain factors may constrain the ability of a Centre to distribute designated materials - the fact that an accession may be temporarily unavailable does not affect the decision to designate it, or its status as designated later. The Agreements with FAO call for a good faith approach to the Agreements on both the part of the party requesting materials and the Centres. (See the Second Joint Statement for more detailed information on this subject.)

## **MATERIAL TRANSFER AGREEMENT (MTA)**

The material contained herein is being furnished by [Centre] under the following conditions:

### **Designated Germplasm**

[Centre] is making the material described in the attached list available as part of its policy of maximizing the utilization of genetic material for research. The material was either developed by [Centre]; or was acquired prior to the entry into force of the Convention on Biological Diversity; or if it was acquired after the entering into force of the Convention on Biological Diversity, it was obtained with the understanding that it could be made freely available for any agricultural research or breeding purposes.

The material is held in trust under the terms of an agreement between [Centre] and FAO, and the recipient has no rights to obtain Intellectual Property Rights (IPR) on the germplasm or related information.

The recipient may reproduce the seed and use the material for agricultural research and breeding purposes and may distribute it to other parties provided the recipient is also willing to accept the conditions of this agreement<sup>1</sup>.

The recipient, therefore, hereby agrees not to claim ownership over the germplasm to be received, nor to seek IPR over that germplasm or related information. He/She further agrees to ensure that any subsequent person or institution to whom he/she may make samples of the germplasm available, is bound by the same provision and undertakes to pass on the same obligations to future recipients of the germplasm.

[Centre] makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, availability, or purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's quarantine/biosafety regulations and rules as to import or release of genetic material.

Upon request, [Centre] will furnish information that may be available in addition to whatever is furnished with the seed. Recipients are requested to furnish [Centre] performance data collected during evaluations.

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<sup>1</sup> This does not prevent the recipient from releasing or reproducing the seed for purposes of making it directly available to farmers or consumers for cultivation, provided that the other conditions set out in the MTA are complied with.

The material is supplied expressly conditional on acceptance of the terms of this agreement. The recipient's acceptance of the material constitutes acceptance of the terms of this Agreement.

## SECOND JOINT STATEMENT OF FAO AND THE CGIAR CENTRES ON THE AGREEMENT PLACING CGIAR GERmplasm COLLECTIONS UNDER THE AUSPICES OF FAO

A Joint Statement issued by FAO and the CGIAR in conjunction with the signing of the FAO-CGIAR Agreements placing CGIAR Germplasm Collections under the auspices of FAO observed that:

The parties to the Agreement recognize that the conclusion of the Agreements represents but one stage of a continuing, dynamic process and agree to continue the dialogue in the context of the implementation of the Convention on Biological Diversity and the FAO Global System on Plant Genetic Resources. They will consult from time to time to review these matters and to consider such modification as may be appropriate in the circumstances.

FAO and the CGIAR have consulted frequently since the Agreements were concluded in 1994 in order to review the implementation of the Agreements.

The Parties understand and agree that:

While Centres distribute germplasm designated under the FAO/CGIAR Agreements through Material Transfer Agreements which prohibit the recipient, or any subsequent recipient, from taking out intellectual property rights, the CGIAR cannot guarantee that recipients will abide by the terms of the MTA. Violations may take place. However, in such cases the Parties commit themselves to taking appropriate remedial action, in accordance with the following agreed procedures:

When Centres become aware of a possible violation of their MTAs by a recipient of germplasm, the Centres will henceforth voluntarily undertake the following actions in response to the perceived violation.

1. The Centres will request an explanation. Upon failure to receive a satisfactory and timely explanation for the situation from the germplasm recipient, the Centres will notify the recipient that a violation is thought to have occurred and request that the recipient cease and desist in its efforts to obtain intellectual property rights over the material, or renounce such rights or ownership if they have already been granted or claimed.
2. The Centres will notify the proper regulatory body in the relevant country of the possibility that the MTA has been violated, and bring to their attention the fact that the grant of intellectual property rights may, therefore, have been inappropriate in the case of the material obtained from the CGIAR.
3. The Centres will notify IPGRI and the FAO Commission on Genetic Resources for Food and Agriculture, through its Secretariat, of the possible violation of the MTA under the Agreements with FAO.

The Centres reserve the right to take other action, including legal action, as they might deem feasible and appropriate to enforce the MTAs and preserve the integrity of the Agreements with FAO. In this regard, it would be the intent of the Centres to work in cooperation with FAO, under whose auspices the materials are held in trust by the CGIAR for the benefit of the international community.

The Centres recognize that many accessions designated under the Agreements with FAO, were distributed to plant breeders and researchers prior to designation in keeping with the CGIAR policy for providing "unrestricted availability" to germplasm - as noted in the Preamble of Agreements. In dealing with this situation, Centres will request and urge that no intellectual property rights be sought for designated germplasm that was distributed prior to its designation under the FAO-CGIAR Agreement.

Periodic reports will be presented to the Commission on Genetic Resources for Food and Agriculture on the actions taken in support of the objectives of the Agreements between the CGIAR Centres and FAO.

In considering the text of the Agreement, the common understanding of the parties concerning certain of its provisions is, as follows:

Under the terms of the Agreements (Article 9), the Centres undertake "to make samples of the designated germplasm available directly to users or through FAO for the purpose of scientific research, plant breeding or genetic resource conservation, without restriction." It is implicit in this undertaking that users will make only reasonable requests for these specific purposes, and that the liability of the Centres would not extend to the fulfillment of unreasonable requests.

Sound management practices as well as practical or even biological constraints (such as seed availability or the health status of a sample) may at times make it difficult or inappropriate for centres to provide germplasm designated under the Agreements for the purposes spelled out in Article 9. It is understood that centres must use some discretion in determining the size and number of samples to be provided at any given time to a particular recipient. Centres are not obligated to distribute seed or other designated materials when such distributions would reduce stocks below accepted levels for conservation purposes, or when the request is for such a number of samples or quantity of a particular accession as to pose an undue burden on the financial or technical resources of the centre or on its ability to meet requests from others. In such cases, the center may ask that the recipient cover the actual costs of multiplying the relevant accessions. In cases of limited supplies, immediate availability of materials cannot be guaranteed. Such availability will follow a process of multiplication. Centers are not obligated to supply quantities of a sample which exceed basic requirements for the purposes stated in Article 9. Recipients are advised that they may need to undertake their own seed multiplication when existing sample sizes are small (such as in the case with many accessions of wild relatives)

or when demand for a particular sample exceeds supply. In filing requests for material for conservation purposes alone, users are invited to note the Global Plan of Action's objectives of "safeguarding as much existing unique and valuable diversity as possible in *ex situ* collections," while reducing "unnecessary and unplanned redundancy in current programmes."

In cases when a centre cannot fully or immediately meet a request, the centre will enter into a discussion with the requesting entity to develop and agree upon a plan and schedule for the supply of materials. This process might establish an agreed list of accessions to which priority would be given.

Some designated accessions cannot be multiplied without considerable cost. For example, certain accessions of woody species may take upwards of 10 hectares of land and 30 years to multiply. Similarly, supplying materials of vegetatively propagated species can involve very time-consuming and expensive procedures. While centres endeavour to supply materials free of cost, in such circumstances it would be unreasonable to expect that centres could guarantee unlimited quantities or immediate availability of all designated germplasm. Users are encouraged to exercise good judgement and appropriate constraint in requests for such materials. At their discretion, centres may request that users cover all or part of the costs involved in multiplication.

Centres are neither obligated nor advised to distribute samples that do not meet health or quarantine standards, or whose transfer could pose the danger of a spread of pests or disease. Centres will inform those requesting materials of the danger which might be posed by invasiveness in those cases where they perceive such dangers to be significant, and of the need for the prior informed consent of the recipient Government for the import of such materials. Materials will then be supplied upon receipt of such prior informed consent.

Article 2 provides that "The list of designated germplasm will be updated every two years as new accessions are added to the collection." This does not preclude Centres from adding new germplasm to the list of designated germplasm without having to wait for the biennial updating of the lists. In such cases, the status of particular germplasm as "designated germplasm" becomes effective immediately upon a centre's determining that it is designating the germplasm under the Agreement and managing the germplasm under the terms of the Agreement. The additional designations will be consolidated into updated lists, which will be notified to FAO every two years or more frequently as may be appropriate.

As management and information systems improve and as genomic information about accessions becomes available, centres will update the list of materials covered under the Agreements. In addition to adding new materials, centres may find, for example, that particular accessions have been designated more than once; that an accession's registration number conveyed to FAO on the list of designated germplasm referred to in Article 2, may be incorrect or no longer correspond to an actual accession in the

centre's genebank; or that an accession may, through natural or accidental causes, have lost viability. Logically, such "accessions" will no longer be considered as designated under the terms of the Agreement. The Center or Centers concerned will notify FAO of any proposals for the deletion of accessions from the list of designated germplasm for such reasons and will provide FAO with a statement of the reasons therefore.