Practical Considerations for Exercise 2

(to be distributed after the exercise has been completed)

After doing this exercise, participants should now be able to understand better some of the outstanding issues that will need to be resolved by the Contracting Parties, either individually or acting within the Treaty’s governing body.

General Issues

A number of issues were left unresolved by the Treaty at the time of its adoption. In some cases, these represented tough political issues on which political compromise could only be reached by using ambiguous wording. In all cases, final decisions regarding the meaning of the provisions may need to be taken by the Contracting Parties, acting individually or within the framework of the Treaty’s governing body. A number of these issues will arise, and need to be resolved, at the time of the drafting of the standard material transfer agreement (SMTA). In any case, it must be realized that the Treaty is a dynamic instrument, which is intended to grow with its implementation under the guidance of the governing body. In this context, it should be borne in mind that all decisions of the governing body need to be taken by consensus.

Specific observations

i. Issues of definition/interpretation
   a. ‘parts and components’ and ‘in the form received’ — Article 12.3(d)

   ‘PGRFA or their genetic parts or components’
   In Article 2 of the Treaty, the terms ‘PGRFA’ and ‘genetic material’ are defined. The same cannot be said, however, for the concept of ‘genetic parts or components’. While unclear, this term would presumably include genes, or any parts thereof, found in the accessed materials.

   If this is indeed so, then the wording of Article 12.3(d) would mean that no intellectual property rights that would limit facilitated access to the original plant genetic resources for food and agriculture (PGRFA) may be taken out over the material accessed from the multilateral system, or their genes or any parts thereof, ‘in the form received’ from the multilateral system.

   ‘In the form received’
   The words ‘in the form received’ would obviously mean that intellectual property rights that limit facilitated access cannot be taken out over the material as received from the multilateral system, as this would, by definition, limit facilitated access by other people to that material. Nor could such intellectual property rights be taken out over products derived from that material if the effect of those intellectual property rights were to limit access to the original material, or their genes or any parts thereof, in the form received.
However, what constitutes ‘in the form received’? Would this exclude genes isolated from the material received, because the PGRFA were not received in the form of isolated genes? Would the addition of a single ‘cosmetic’ gene (e.g., through transformation or conventional back-crossing) to an accession as received be sufficient to differentiate a new product from the material received through the multilateral system? Is inclusion of an essentially unaltered gene within a new construct sufficient?

Such issues are addressed in intellectual property law and practice, as reflected in relevant international agreements and national laws. They will presumably be addressed by countries in due course, either in their individual capacity within the context of their own system of intellectual property rights, or acting collectively in the governing body of the Treaty or other appropriate international forum. In the meantime, the ambiguities of Article 12.3(d) and, in particular, of the words ‘in the form received’ have caused a number of developed countries to stress their understanding, at the time of adoption of the Treaty, that the provision does not in any way modify or limit intellectual property rights as protected by intellectual agreements.1

In interpreting this paragraph, however, Contracting Parties may wish to consider the context of Article 12 as a whole, which appears to indicate that the reason for preventing intellectual property rights under certain circumstances is to ensure access for the purpose of research and breeding of the material received.

b. ‘under development . . . during the period of its development’ — Article 12.3(e)

As with proprietary information, Article 12 provides some exceptions to what kinds of genetic materials must be made available, and when. Genetic material ‘under development’ need not be made available during its period of development, although farmers and breeders can make it available if they choose. While the intention of Article 12.3(e) might be reasonably clear, the wording of this provision is somewhat flexible in that it does not specify what ‘under development’ means, nor does it define when the ‘period of development’ ends. The practical result, nevertheless, appears to be that breeders’ lines and farmers’ breeding material do not have to be released during the period that they are being developed and retained for use in producing a new variety. The provision follows the concept introduced into the International Undertaking under the third Agreed Interpretation of the International Undertaking in 1991 (Conference Resolution 3/91), which specified in its operative paragraph 2 ‘that breeders’ lines and farmers’ breeding material should only be available at the discretion of their developers during the period of development’. In Article 12.3(e), the explicit reference to breeders’ lines has been dropped, but breeders’ lines are of course included in the general reference to PGRFA under development.

More definitions are included in the text of the SMTA. Article 2 of the SMTA provides that Plant Genetic Resources for Food and Agriculture under Development means material derived from the Material (and, hence, distinct from it) that is not yet ready for commercialization and which the developer intends to further develop or to transfer to another person or entity for further development. The period of development for the Plant Genetic Resources for Food and Agriculture under Development shall be deemed to have ceased when those resources are commercialized as a Product. Plant Genetic Resources for Food and Agriculture under Development can, at the discretion of the developer, be passed on to other developers to complete the work of development. In such cases, the developer can attach additional conditions to the transfer, including the payment of a monetary consideration.

1 See the statements made by the delegates of Australia, Canada, Japan, the USA, and the European Community at the time of adoption of the Treaty by the FAO Conference.
ii. The list of crops


   This definition is ambiguous. The governing body and individual Contracting Parties may need to decide on its exact meaning.

   b. Changing taxonomic understandings

   Aside from its substantive content, the text of Annex I is less than clear in certain regards, considering the state of biological science and changes in knowledge over time. For example, the Treaty acknowledges only implicitly the fact that taxonomists and breeders disagree about what is included within a particular crop gene pool. Knowledge of such groupings changes over time. It is questionable whether the materials under the multilateral system will expand and contract as taxonomic understandings of what constitutes a particular genus evolve. Assuming that the governing body will not want to undertake the cumbersome and costly task of constituting its own taxonomic authority, on what basis will Contracting Parties and centres decide whether questionable categories/materials are included or excluded? Practically speaking, how would the Treaty handle cases where materials considered today to be part of Annex I fall off the list by virtue of changes in taxonomic categories?

iii. Distributions to farmers for direct use for cultivation — Article 12.3(a)

   The Treaty provides that material made available through the multilateral system should be ‘provided solely for the purpose of utilization and conservation for research, breeding, and training’ for food and agriculture.

   Article 12.3(a) does not specifically allow nor sanction access for the purpose of direct use by farmers for cultivation. The negotiators clearly did not want genebanks to compete with ordinary distribution of seed or propagating material to farmers, and such access for direct use must be considered to be out of the ordinary. This situation occurs, for example, in cases where an accession is desired for a particular niche market (a colourful potato, for instance) and no further breeding work is needed, as well as in cases where the crop itself is the subject of little breeding work (e.g., pulses) or to enrich the genetic diversity in farmers’ fields for subsequent selection. Article 12.3(a) does not expressly provide for facilitated access for direct use or multiplication. This omission may be interpreted as an intentional exclusion of such a use from the scope of facilitated access under the multilateral system. The situation is of particular significance for, but by no means unique to, the CGIAR centres. The material transfer agreement (MTA) used under the FAO-CGIAR in-trust agreements allowed access for such purposes. In adopting the interim MTA to be used by the CG centres under the in-trust agreements with FAO, the FAO Commission on Genetic Resources for Food and Agriculture, at its Ninth Session (in 2002), agreed on the following footnote:

   This does not prevent the recipients from releasing the material for purposes of making it directly available to farmers or consumers for cultivation, provided that the other conditions set out in this MTA are complied with.

   A possible interpretation, which would not run counter to either the actual wording of Article 12.3(a) or the objectives of the Treaty, could be that while direct use for cultivation is not a use for which facilitated access can be demanded, the release of material for direct use for cultivation would not be prevented where this is in accordance with the objectives of
the Treaty and is necessary for the fulfilment of the mandates of the institutions concerned. This may happen more and more often as genebanks provide a safe haven for material used on-farm that is becoming increasingly threatened.

The whole issue of access for direct use for cultivation has recently been under discussion in the Treaty’s Ad Hoc Advisory Technical Committee on the Standard Material Transfer Agreement and the Multilateral System.2 In giving advice to the CG Centres, the Committee has concluded that there was no doubt that PGRFA that have been developed by the CG Centres from material accessed through the multilateral system can be released by the developer for direct cultivation. This is, after all, one of the rights of the developer. The Committee also saw no problems in the CG Centres transferring material that had been held in trust under the FAO/CGIAR in-trust agreements of 1994 to farmers for direct use. However, countries that have transferred PGRFA under the SMTA for the purpose of research and breeding may have a legitimate interest in seeing that the material is not used by the farmers of other countries for direct cultivation without further development, except with their express permission. In any case, the terms of the SMTA would preclude the use of material transferred under the SMTA for direct use for cultivation, as opposed to research and breeding. In many cases, of course, it is difficult to determine the line between direct use for cultivation and further breeding. The SMTA is not the correct instrument to be used in any case where material is to be transferred for direct use by farmers for cultivation. A simple declaration can be used instead, indicating that the material can be used for cultivation.

While the advice of the Committee is directed only to the CG Centres, the principles concerned would seem to be of general applicability to all users of germplasm from the multilateral system.

iv. Transfers of non-Annex I crops

The multilateral system covers only those crops included in Annex 1. What then happens to non-Annex 1 materials, and by what regime should they be governed? In principle, it would seem that the answer would be that they are governed primarily by the CBD, insofar as that Convention is applicable. Some countries, in the exercise of their sovereign rights, have chosen to extend the use of the SMTA to non-Annex 1 crops. The Treaty’s governing body has authorized the CG centres to make non-Annex 1 material available in accordance with the SMTA with explanatory footnotes.

v. Restoration of PGRFA

Article 15.1(b)(ii) allows for the restoration of genetic resources to Contracting Parties that supplied the materials to the CG centre, without resort to an MTA. A provision similar to this is found in the 1994 ‘in-trust’ agreements with FAO, with the exception that the current agreements with FAO speak of repatriation to the ‘country that provided such germplasm’. This may not necessarily be the country where the material was collected from in situ conditions. Indeed, this provision may give rise to practical difficulties in implementation, as it is understood that CG centres may not always know where the material was collected in in situ conditions. The practical impact of this distinction between

the two agreements (i.e., the ‘in-trust’ agreements and the new agreements with the governing body) might not be substantial. The material will be available in any case; the question is simply whether an MTA should be required. Under the Treaty, ‘restoration’ applies only to countries from which the material was collected in *in situ* conditions; otherwise, access is handled under the normal rules governing access, pursuant to Articles 12 and 13. The right of restoration is also accorded only to Contracting Parties. Non-Contracting Parties would have no such rights under the Treaty, although the provisions of the Treaty would not appear to prohibit such restoration.

The issue is now being considered by the Ad Hoc Committee on the SMTA and may well be referred to the governing body for decision. In principle, it would appear that restoration of PGRFA should not be considered ‘facilitated access’ and thus would not require an SMTA.

**vi. Non-Parties**

The issue of how non-Parties should be treated became controversial during the course of negotiations, particularly from the point of view of access to materials under the multilateral system. The question was whether the Treaty should dictate the use of different, and potentially discriminatory, treatment of non-Parties. In the end, no specific provision was included, which leaves this matter up to each individual Contracting Party. There is no provision that would require Contracting Parties to deny access to PGRFA listed in Annex I to countries that have not agreed to be bound by the Treaty, nor is there anything that would require them to grant such access. The provisions of Article 11.3 and 11.4 (which deal with decisions as to whether access should continue to be facilitated for persons that have not included their PGRFA in the multilateral system) refer only to natural and legal entities under the jurisdiction of Contracting Parties and not to non-Contracting Parties.

Article 31 of the Treaty, in dealing with non-Parties, therefore confines itself to stating that Contracting Parties are to encourage any member of FAO, or other State that is not a Party to this Treaty, to become a Party. This is intended to achieve as broad a coverage of the Treaty’s provisions as possible.

**vii. Practical issues related to implementation:**

*Management issues, ‘black box’, intra- & inter-institutional transfers, etc.*

Many practical issues that will need to be ironed out by the governing body will arise in the implementation of the Treaty. Some of these issues arose in the course of the implementation of the FAO/CG ‘in-trust’ agreements and were handled for the most part by bilateral negotiations between the FAO Secretariat and the CG centres. These matters and their resolution were then reported to the FAO Commission in a series of joint statements. A similar procedure is envisaged for implementation of the agreements between the Centres and the Treaty’s governing body, to be entered into under Article 15.1 of the Treaty.

The issue of ‘black-box’ material is particularly sensitive. This is material that has been acquired, by Contracting Parties and by the CG centres, under conditions that do not allow its free distribution and availability. In general, it would appear that the Treaty, in recognizing that access to material is subject to property rights, would not force either Contracting Parties or CG centres to forego respect of such conditions.

Intra- and inter-institutional transfers also raise a number of questions. In general, inter-institutional transfers between CG centres that have signed agreements with the
governing body should always be covered, as each centre is a separate legal entity. Normally intra-institutional transfers, such as the use of in-trust material from the genebank collection for research and breeding, would not be covered from a legal point of view. But the centres may wish to adopt a practice of treating such transfers as being within the scope of the Treaty. Similar issues arise with respect to transfers from one entity to another within the borders of a single Contracting Party. There are two views as to whether such transfers are covered by the Treaty.

viii. **Amendments to the Treaty and Annex 1**

Amendments to the Treaty and its annexes must be adopted by consensus. Whether consensus can be reached on an eventual extension of the scope of the multilateral system will depend, essentially, on the confidence that the Contracting Parties have in the multilateral system and the benefits that are seen to be derived from it.