

Contribution of ISF to the establishment of a Material Transfer Agreement (MTA) for the Multilateral System (MS) provided for in Part IV of the International Treaty on Plant Genetic Resources for Food and Agriculture (PGRFA)

The ISF (formerly ASSINSEL) is in favor of facilitated access to PGRFA as an important source of breeding material for use in the development of new varieties of plants, as well as an equitable sharing with the Multilateral System of the benefits arising from the commercialization of such new varieties. As early as 1998, ISF adopted a position in favor of a Multilateral Agreement (Annex I) and, therefore, welcomes the signature of the International Treaty on PGRFA and the built-in Multilateral System, whilst regretting that the list of crops included is too limited and should be broadened as soon as possible.

As suggested in 1998 by ISF, the MTA is an essential part of the MS, in order to allow its fair implementation. It is the reason why the terms of that MTA are so important. Therefore ISF would like to contribute to the work of the Expert Group on the terms of the Standard MTA established in 2002 in answering, with the expertise in plant breeding of its members, the questions asked to that group of experts.

Before answering the questions, ISF strongly believes that the terms of the MTA must not change the spirit of the Treaty and, in particular, of the articles 12 and 13 that have been the subject of long and lively discussions, and were finally adopted by the 31st session of the FAO Conference in November 2001. According to the Treaty, mandatory benefit sharing occurs when a product is commercialized, except that whenever such a product is available without restriction to others for further research and breeding (Article 13.2.d(ii) of the Treaty). Thus the triggering conditions for mandatory benefit sharing are commercialization and non-availability of the product for further research and breeding. If one of these conditions is not fulfilled, there is no mandatory monetary benefit sharing, in addition to the benefit sharing by technology transfer.

In order to finalize the MTA that will be used within the MS, an expert group, whose terms of reference are attached (Annex II) has been established by FAO. The questions asked to the experts are of different nature : Technical on the one hand, Financial and Policy related on the other hand and, finally, dealing with implementation.

ISF contribution to answering those questions is as follows:

A. Technical questions

A.1 What constitutes commercialization in terms of Article 13.2.d(ii) of the Treaty ?

Commercialization triggering benefit sharing (BS) should be sale or licensing for sale, by the person having received the material for the MS and having developed a new product incorporating part of the received material, of the propagating material of that new product. It should be limited to those two acts.

The deposit of an application in order to obtain intellectual property protection cannot be considered as commercialization, as it does not involve any commercial act and does not generate any commercial benefits.

A.2 What means incorporation of material accessed under the MS?

Incorporation of material means any transfer of genetic parts or components of the material accessed under the MS pursuant to the terms of the MTA, be it through crosses or genetic engineering into a new product .

Different processes for incorporation may be taken into account when determining benefit sharing, such as:

- Crossing the material received with other genetic resources;
- transfer of one or several traits isolated from the material received to other genetic resources.

A.3 When would a product be considered to be available without restriction to others for further research and breeding ?

A product would be considered to be available without restriction to others for further research and breeding when any third party, having had access to the product lawfully, may use that product to develop new products without restriction. It is not considered a restriction on research and breeding if the variety may be used as an initial source of variation for the purpose of creating other varieties (e.g. pursuant to the breeder's exception under UPOV). Freedom to operate at research level does not preclude possible infringements (e.g. essential derivation in the sense of UPOV, scope of the claims of a patent) at commercialization level.

It must be noted that whether a product is available without restriction to others for further research and breeding must be analyzed on a case-by-case basis. A reasonable handling fee should not be considered as a restriction.

B. Financial and Policy questions

B.1 What should be the level, form and manner of payments in line with commercial practice ?

When possible, and unless otherwise agreed by the provider and the recipient, the level of benefit sharing should be defined *a priori*.

Any monetary benefit sharing should be based upon the relative contribution of the material accessed under the multilateral system to the commercial value of the product and according to common commercial practice¹.

An upfront payment at the time of signing the MTA is not recommended, as it would be difficult to account for the probability of developing a successful commercial product.

The form and manner of payment should be based on common commercial practice, e.g. the annual declaration by the recipient of the material of its annual turnover regarding the new product or the license at stake with the possible audit on prior written notice of his/her account books by a third independent and neutral party, under a confidentiality agreement.

B.2 Whether different levels of payment should be established for various categories of recipients who commercialize such products or for different sectors and, if so, what these levels, various categories of recipients and sectors should be ?

Different levels of payment should not be established as a principle as, in fact, all the recipients will have to pay a percentage of their turnover agreed on a case-by-case basis related to the new product and the selling price of that new product will be adapted to the various markets, taking into account the possible differences.

The establishment of different levels of payments as a principle would:

- Lead to high administrative burden
- Allow for a payback/subsidy scheme at national level
- Create anti-competitive conditions
- Be fraud sensitive.

¹ The non-exhaustive parameters usually taken into account in common commercial practice are:

- The cost of R&D to develop the new product using the material accessed under the MS and the degree/level of intellectual property covering the other components/research processes involved in the development of the new product.
- The competitive environment.
- The historic cost of equivalent similar material/technology.
- Country specific regulations capping royalty payment.

B.3 Whether to exempt small farmers in developing countries and in countries with economies in transition from the payments, and if so, who qualifies as such a small farmer ?

Asked like that, the question is not relevant as, in fact, it is not the farmers that will have to pay to the global fund but the seller of the product to the farmers. That question is a duplication of the previous one, with an emphasis on small farmers as a specific category of “different sectors”.

Exempting small farmers would imply that either the seller of the product should receive subsidies from the global fund (or government) in order to be able to sell the seed at a lower price to that category of customers or that the small farmers would receive the subsidy directly if they are paying the full market price for the seed. In any case, the system would be extremely complex, cumbersome, costly to implement and also fraud-sensitive.

If the principle of exempting small farmers from the payments would be retained by the Governing Body of the Treaty, despite the obvious difficulties, the definition of small farmers should be made on a country-by-country basis, a small farmer in Bolivia being not the same as a small farmer in India or in Poland.

B.4 How will monetary and other benefits be defined, for the purpose of the standard MTA ?

It seems that this question is already addressed in question B.1 and that the parameters listed in B.1 should allow to define the benefits for the purpose of the standard MTA.

C. Implementation questions

C.1 By what means will the MTA ensure the application of Article 12.3 ?

By incorporating literally in the MTA the terms of the Article 12.3(a), (d), (f) and (g)².

C.2 What terms should be included in the MTA, so that recipients are bound by it on acceptance of the material from the MS ?

A copy of the MTA signed by an authorized representative of the recipient should be returned to the providing center prior to the receipt of the material or the MTA should otherwise be accepted as binding in a manner recognized by relevant governing law. That is enough to have the recipient bound by the MTA, according to contractual law.

² Within article 12.3, paragraph (d) is subject of different interpretation. The interpretation of ISF is attached (Annex III).

One must be aware that contractual laws are national and the MTA may have to be adapted on a country-by-country basis to avoid clauses that could be unlawful in a given country. In any case, the following sentence should be inserted in all MTAs: “Severability: if any term, condition or provision of this MTA or application thereof is judicially or otherwise determined to be invalid, unenforceable or contrary to law, the remaining terms, conditions and/or provisions of the MTA will remain in full force and effect”.

Annex I

Position on Access to Plant Genetic Resources for Food and Agriculture and the Equitable Sharing of Benefits Arising from their Use

(Adopted in June 1998)

Farmers and breeders have traditionally relied on open access to genetic resources, including improved commercialized varieties protected under the UPOV Convention. However, recently, with the entry into force of the Convention on Biological Diversity (CBD) the sovereign rights of nations to control access to their biological diversity has received formal recognition. There is evidence that the principles of sovereign rights and benefit-sharing, in absence of an international agreement, are leading to greater restrictions on the exchange of genetic resources.

Restriction of exchange of genetic resources is a major concern, in particular for exchanges between the less developed countries, some of them being poor in genetic resources and financial resources. It is less worrying for commercial plant breeders because:

- centres of origin are often less important than centres of secondary diversification which have developed themselves according to shifts of population during the last millenniums. For a given crop, those centres of secondary and sometimes tertiary diversification, exist in all countries where the crop is of economic importance, often far from the original area of domestication.
- genetic diversity in land races and wild species represents resources with limited present value for breeding purposes for most species. These resources require a great deal of time and effort to explore and find potentially useful traits for integration into improved varieties. Breeders cannot usually justify paying significant amounts of money to have access to exotic germplasm that is not quite thoroughly evaluated and which has not yet been enhanced or adapted to specific agricultural environments in which the farmers, who are the breeders' customers, are seeking new, better adapted and productive varieties.
- new technologies could free the breeders from the use of exotic germplasm for development of new resistance and quality traits.

However, from a public interest point of view, ASSINSEL considers that the current trend of restricting access to genetic resources for food and agriculture should be regulated by the establishment of a multilateral agreement between countries in order to reverse the current trend of restrictions. That multilateral agreement could provide for the possibility of bilateral agreements.

I. A Multilateral Agreement

I.1. Scope of the Agreement

All genetic resources with importance for present and future food security and agriculture in general should be included in the agreement, at the level of genera and species: food crops, including also vegetables and fruits, forage crops and mixed industrial/food crops. For each genus and species the genetic resources would consist of wild relatives, landraces, obsolete varieties and commercial varieties which are in the public domain. (For the list of genera and species, see CGRFA/IUND/4, Rev.1, pp. 40-43).

The agreement should include pre- and post-CBD, in-situ and ex-situ collections. (The inclusion of the pre-CBD collections is acceptable only if the other principles laid down in this document are accepted).

I.2. Access to genetic resources and benefit sharing

I.2.1. Access

In order to be as practical as possible, all materials covered by the agreement should be "freely" available under similar terms of access. "Free access" does not mean "without cost". In case of in-situ collections, in particular for wild relatives, the country of origin should facilitate the organization of collecting missions based on mutually agreed terms.

The Material Transfer Agreement (MTA) should include the following provisions:

- The recipient will neither claim legal ownership nor apply for intellectual property protection for the germplasm received, per se. Such a protection should be impossible anyway, or very difficult to obtain, the criteria for protectability being not met.
- The material supplied may be used by the recipient without restriction for breeding purposes. Recipients may protect, if criteria for protectability are met, the products of such breeding through plant variety protection that is consistent with the provision of UPOV, through any other sui generis system or through patents, according to national laws.
- Cells, organelles, genes or molecular constructs isolated from the material may be protected by the recipient through patents, if the criteria for patentability are met.

I.2.2. Benefit sharing

One of the main benefits of being a member of the multilateral agreement is to have access to genetic resources at a global level, as well as to improved plant varieties protected through plant variety protection or any sui generis system including a breeder's exception clause.

In the event of protection through patents, limiting free access to the new genetic resource, ASSINSEL members are prepared to study a system in which the owners of the patents would contribute to a fund* established for collecting, maintaining, evaluating and enhancing genetic resources. The mechanism for implementing that system would need to be discussed. However, we have to be aware of the difficulties which would be met in implementing such a system:

- It is extremely difficult to determine the contribution, which might be rather small, of the supplied germplasm in the final product and hence to reach an objective basis for calculating benefits.
- 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 giving to chance to the germplasm provider to block the commercialization of the protected product, thus jeopardizing the investment already made. One option would be to determine a range of minimum and maximum levels of benefits, binding on all members, that would apply if provider and user were unable to reach an agreement.

I.3. Benefit of a Multilateral Agreement

A global system can be effectively developed only on a multilateral basis. That would condition the realization of the global Plan of Action.

Multilateral approaches offer opportunities for developing common and cost-effective conservation strategies, and for coordination and mutual support among partners.

A multilateral approach offers participants access to a far greater range of germplasm than is generally possible in bilateral arrangements. Thus multilateral arrangements are preferable for crops with wide geographical distribution. This advantage is even greater if one considers multilateral agreements covering a range of crop species.

Multilateral approaches are likely to provide greater opportunities for exchanging and screening genetic resources than bilateral arrangements. The 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.

Multilateral approaches provide access to a wider range of information than is available bilaterally and offer opportunities to use information cost-effectively, avoiding duplication of efforts and unnecessary expense by sharing databases, for example.

* the mentioned fund is the fund the establishment of which is presently under discussion by Governments under Article 12 of the draft revised International Undertaking on Plant Genetic Resources for Food and Agriculture

Multilateral arrangements have 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. In the case of multilateral arrangements, these benefits are less likely to be directly linked to the provision of access to specified germplasm.

A multilateral approach, with a globally agreed M.T.A. will decrease the complexity and probably high costs of individual transactions.

I.4. Implementation of the Agreement

The establishment of a global exchange system will require agreements on exchange principle. A Material Transfer Agreement will have to be adopted. This will involve countries and the CGIAR becoming party to an intergovernmental agreement governing conditions of membership, terms of access to genetic resources, mechanisms for sharing benefits among participants and relationships with non-members. (Exchange of material with non-parties to the agreement should be allowed under specific conditions).

In terms of practical implementation, the framework of the system should be flexible enough to allow the participation of non-government members such as private organizations, NGOs, farming and indigenous communities. Conditions for such a participation would need to be set by the host country of the above-mentioned organizations.

The multilateral agreement should have very low implementing costs and little to no impediments that are associated with its bureaucracy.

II. Bilateral Agreements

Bilateral approaches may be most appropriate for instance when a small number of countries have, or need, access to 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 as, for example, rubber.

In addition, bilateral agreements can be tailored to the needs of the parties, they can be created for specific purposes and then dissolved without the need of heavy structures; they may offer greater confidentiality.

For these reasons, ASSINSEL, whilst preferring a broad multilateral agreement, acknowledges the necessity to open opportunity for possible bilateral agreements. However, these bilateral agreements should be established according to guidelines defined within the overall framework of the multilateral agreement.

Annex II

TERMS OF REFERENCE FOR THE EXPERT GROUP ON THE TERMS OF THE STANDARD MATERIAL TRANSFER AGREEMENT

I. Scope of the Work

1. The Expert Group shall develop and propose recommendations, which may be considered by the Interim Committee for the Treaty, on the terms of the standard Material Transfer Agreement (MTA), in accordance with Article 12.4 of the International Treaty.

2. The Expert Group is also asked to provide advice, and, where appropriate, to propose options and/or elements for inclusion in the standard MTA on, *inter alia*:

- What should be the level, form and manner of payments in line with commercial practice?
- Whether different levels of payment should be established for various categories of recipients who commercialize such products or for different sectors and, if so, what those levels, various categories of recipients and sectors should be?
- Whether to exempt small farmers in developing countries and in countries with economies in transition from the payments, and if so, who qualifies as such as a small farmer?
- What constitutes commercialization in terms of Article 13.2d (ii) of the Treaty?
- What constitutes incorporation of material accessed from the Multilateral System?
- When would a product be considered to be available without restriction to others for further research and breeding?
- How will monetary and other benefits be defined, for the purposes of the standard MTA?
- By what means will the MTA ensure the application of Article 12.3?
- What terms should be included in the MTA, so that recipients are bound by it on acceptance of the material from the MLS?

3. The Expert Group examine and report on all options identified, reflecting all views, with the associated implications.
4. The Expert Group shall be composed of experts nominated by Governments, with technical or legal expertise with respect to the exchange of plant genetic resources for food and agriculture and relevant commercial practice.
5. The group shall reflect an appropriate balance between developed and developing countries, with each FAO region being represented.

II. Composition of the Expert Group

6. The Expert Group shall comprise 24 members, as follows: four members each from Europe, Africa, Asia, Latin America and Caribbean, and the Near East, and two members each from North America and South West Pacific. Each region will appoint, in addition, an equivalent number of advisors to the members of the Expert Group. It is suggested that advisors may include *inter alia*, representatives from governments, industry, academia and civil society.
7. The CGIAR is invited to nominate one representative to participate in its technical capacity in the work of the Expert Group.
8. WIPO and UPOV will be invited to send one representative each to provide technical assistance, at the request of the Expert Group.

III. Schedule for the completion by the Expert Group of its functions

The regions were requested to nominate their experts before the end of the year 2002, so that the meeting of the Expert Group may be held, if possible, within the first half of 2003, subject to the availability of adequate extra-budgetary resources. The Expert Group would report on progress to the next meeting of the Interim Committee for the Treaty, which could then decide whether further meetings of the Expert Group are required.

Annex III

Interpretation of article 12.3(d) of the International Treaty on Plant Genetic Resources for Food and Agriculture

Article 12.3.d of the recently adopted treaty on Plant genetic resources for food and agriculture states that "Recipients [of PGRFA accessed from the Multilateral System] shall not claim any intellectual property or other rights that limit the facilitated access to the PGRFA, or their genetic parts or components, in the form received from the Multilateral System".

The first draft of that article was "Recipients [of PGRFA accessed from the Multilateral System] shall not claim any intellectual property or other rights that limit the facilitated access to the PGRFA received from the M.S."

Then a group of countries, not in favor of patenting gene sequences proposed to add the words "or their genetic parts or components", causing long and lively discussions.

In order to balance the new additional wording another group of countries, considering that it should be possible to protect gene sequences isolated from the plant material received, provided that they comply with patentability requirements, proposed a new addition: "in the form received" leading to the final adopted wording.

During the final meeting in Rome, in October/November 2001, the President of the Commission on GRFA indicated clearly that, as the second addition was balancing the first one there was no reason to continue to discuss that article.

For those reasons ASSINSEL interpret the article 12.3.d as follows:

- It is not possible to claim any intellectual property or other rights that limit the facilitated access to the PGRFA, or their genetic parts or components, in their form received from the Multilateral System.
- It is possible to claim intellectual property or other rights that limit access to the genetic parts or components isolated or inherited from the material received, provided of course that the patentability criteria are fulfilled and in particular the utility one in case of patent. A genetic sequence as such, without proved industrial activity, should not be patentable. However, the rights granted should in no case limit access to the initial genetic material.

In addition any other interpretation would be inconsistent within art. 13 stating that : "A recipient who commercializes a product that is a PGRFA and that incorporates material accessed from the Multilateral System, should pay [.....] an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding". That means clearly that a person who has incorporated material accessed from the Multilateral System into a product which is a new PGRFA may claim property rights or other rights that limit access to that new PGRFA.