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# The International Treaty

ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE



## Items 8, 9, 10 and 11 of the Draft Provisional Agenda

### THIRD MEETING OF THE *AD HOC* ADVISORY TECHNICAL COMMITTEE ON THE STANDARD MATERIAL TRANSFER AGREEMENT AND THE MULTILATERAL SYSTEM

New Delhi, India, 26-28 June 2012

#### COMMERCIALIZATION OF A PRODUCT UNDER THE MULTILATERAL SYSTEM IN THE CONTEXT OF NOT-FOR-PROFIT PROJECTS UNDER ARTICLE 13 OF THE TREATY

#### AVAILABILITY WITHOUT RESTRICTION: GEOGRAPHICAL EXTENT OF THE RESTRICTION

#### COMMERCIALIZATION OF A PRODUCT UNDER THE MULTILATERAL SYSTEM: CALCULATION OF BENEFIT-SHARING PAYMENTS

#### AVAILABILITY WITHOUT RESTRICTION: SALE OF HYBRIDS<sup>1</sup>

## I. INTRODUCTION

1. The Secretariat received a number of questions from legal experts advising the Water Efficient Maize for Africa project (WEMA project). The questions relate to the operation of the Multilateral System and have potential system-wide policy relevance. In this regard, the Committee's advice and opinion are being sought.
2. In forwarding these questions and the related issues to the Secretariat for guidance, the advisers and experts of the WEMA project have emphasised the strong desire of the proponents of the project for transparency and to fully comply with their obligations under the Multilateral System, where relevant. They have also recognised the utility of the mechanisms established under the Treaty and value of the multilateral technical guidance that this Committee provides.
3. The Annex with the Appendices to this document reproduces the submission made by the WEMA advisers and experts to the Secretariat, for the consideration of the Committee. The submission contains some background information on the WEMA project, the related questions and hoped for answers. As all the four questions arise from the same project, they have been put together in one single document, without prejudice to any distinct advice and guidance that the Committee may wish to give on each question.

<sup>1</sup> In accordance with the request of the *Ad Hoc* Technical Advisory Committee, and the Terms of Reference established by the Governing Body, this document was prepared for the exclusive purpose of facilitating the Committee's deliberations. Any opinion or position expressed in the document is not to be attributed to the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture.

4. The Secretary has also agreed with the experts and advisers of the project to make themselves available during the discussion of these issues by the Committee to answer any questions, or provide any additional information that the Committee might require.

## ANNEX

### **SUBMISSION MADE BY THE WEMA PROJECT**

#### **I. BACKGROUND**

1. The WEMA project is developing new African drought-tolerant maize varieties, using conventional breeding, marker-assisted breeding, and biotechnology.<sup>2</sup> It will make drought-tolerant maize varieties available royalty and premium free to small-scale farmers in Sub-Saharan Africa. WEMA is an international public-private partnership coordinated by the African Agricultural Technology Foundation (AATF).<sup>3</sup> It consists of a consortium of a range of research and development partners including the International Maize and Wheat Improvement Center (CIMMYT), private sector operators, and the agricultural research systems of Kenya, Mozambique, South Africa, Tanzania and Uganda.
2. The varieties developed under WEMA will be distributed to African seed companies through AATF, without royalty, but will be made available to smallholder farmers, on sale, as part of the seed companies' business. The national agricultural research systems, farmers' groups, and seed companies participating in the project will contribute their expertise in field testing, seed multiplication, and distribution.
3. WEMA varieties may include germplasm sourced from one or more of the project partners. WEMA varieties may also include technologies that, while their use may be restricted in some countries, will either be made freely available or, at a minimum, will be made available on a royalty free basis in the specific countries targeted by WEMA.
4. Parts of the WEMA activities and products are expected to fall within the scope of the International Treaty. In the course of its development and implementation, so far, a number of issues have arisen for WEMA, which the WEMA partners believe will also be relevant to other similar charitable and non-profit agricultural research projects.

#### **II. COMMERCIALIZATION OF A PRODUCT UNDER THE MULTILATERAL SYSTEM IN THE CONTEXT OF NOT-FOR-PROFIT PROJECTS RELATED TO ARTICLE 13 OF THE TREATY**

5. Paragraphs 13.2(b) and 13.2(d)(i) of the Treaty envisage forms of benefit sharing other than monetary. Paragraph 13.2(b) provides for access to and transfer of technology. The partnership structure of WEMA, based on collaborative research and the sharing of germplasm and technologies, falls within the scope of these provisions. This is emphasised by the fact that no WEMA partner will earn any royalty from the provision of germplasm or technology and the fact that the mandate and structure of AATF is consistent with achievement of the provisions of 13.2(b).
6. Paragraph 13.2(d)(i) provides for the sharing of the benefits of commercialization other than monetary through private and public sector partnerships and collaboration in research and technology development. The public-private nature of both the WEMA research partnership and of its plan for the distribution of its varieties is also consistent with the objectives of 13.2(d)(i).
7. WEMA is largely typical of public and donor funded non-profit agricultural research projects. It is evident that, through paragraphs 13.2(b) and 13.2(d)(i), the Treaty envisages these projects as a form of benefit sharing.

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<sup>2</sup> <http://www.aatf-africa.org/wema>

<sup>3</sup> <http://www.aatf-africa.org>

8. No WEMA research partner will receive any royalty payment in compensation for its provision of germplasm or technology or for its research costs and contributions. All research costs are being met from donor funds and no other form of compensation is being given. However, the need to charge farmers for WEMA varieties only arises because of the costs and complexities of sustainable seed multiplication and distribution and the risk of undermining existing seed development and market activity with unfair competition. Furthermore, there is no free seed distribution network, except for those addressing emergencies, and the establishment of one would be extremely expensive, have no medium to long term sustainability and would undermine existing commercial activity. Similarly, even if the problem of distribution did not arise, it would be problematic to distribute at simple cost or for free because this would undermine existing seed companies in the region, as they could not compete with free or at cost products.

9. The provisions of Article 13.2(d)(ii) of the Treaty and Articles 6.7 and 6.8 of the Treaty are designed to ensure that developing country smallholder farmers benefit from the profits that agricultural research and development companies derive from publicly owned germplasm. The only profits that will be generated from the distribution of WEMA varieties to farmers will be made by the African seed companies and agro-dealers and their justification is that they make the distribution of improved seed to farmers possible. Expectedly, any benefit-sharing requirements related to these profits will be directly passed on to farmers through the Treaty benefit-sharing mechanism. Effectively therefore, in the case of WEMA, the Treaty's benefit sharing fund would be receiving payments, not from any income derived by the agricultural research and development partners, but from the benefits derived by the African smallholder farmers and small and medium enterprises that it is intended to benefit. This will, consequently, reduce the level of benefits that WEMA can generate for those smallholder farmers.

10. This situation is peculiar to many non-profit agricultural research projects. Projects exclusively designed to meet the objectives of Article 13.2(b), and possibly also 13.2(d)(i), are not commercial in nature but they fall within the standard material transfer agreement (SMTA)'s definition of commercialization because they do involve the sale of a product for monetary consideration. The sale for monetary consideration is essential in ensuring effective distribution to smallholder farmers without undermining small and medium enterprises within the region.

11. WEMA is, therefore, seeking advice on whether projects exclusively designed to meet the objectives of Article 13.2(b), and possibly also 13.2(d)(i) are also liable for monetary benefit sharing under Article 13.2(d)(ii). In *Appendix I*, the corresponding question to the Committee is set forth in more detail, together with a summary of the relevant facts from the WEMA project, and the hoped-for response by the WEMA project's experts.

### **III. AVAILABILITY WITHOUT RESTRICTION: GEOGRAPHICAL EXTENT OF THE RESTRICTION**

12. Article 13.2(d)(ii) of the Treaty provides that:

*... the standard Material Transfer Agreement ... shall include a requirement that a recipient who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall 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...*

Article 6.7 of the SMTA reproduces these provisions.

13. It is expected that some WEMA varieties will contain technologies that, in specific jurisdictions, are not available without restriction to others for further research and breeding. It is possible that this will include situations where the use of the particular technology is only restricted in countries other than those where the WEMA variety in question is distributed.

14. In most cases, and certainly in the case of WEMA, the form of restriction is likely to be some form of intellectual property right. With limited regional exceptions, intellectual property rights operate at the national level, which may allow for differentiated commercial strategies in various markets.

15. The case of WEMA highlights the issue regarding the provisions of Article 13.2(d)(ii) and the likely nature of the restrictions that Article refers to. The use of a given technology may only be restricted in key markets, such as the USA and the EU, and be freely available for research and further breeding in the rest of the world. Therefore, the question has arisen as to whether under Article 13.2(d)(ii) of the Treaty, as replicated in the SMTA, the owner of the rights to the technology in question would be liable for mandatory benefit sharing payments on global sales and not only those in the jurisdictions where use was restricted. In *Appendix II*, the corresponding question to the Committee is set forth, together with a summary of the relevant facts from the WEMA project and the hoped-for response by the WEMA project's experts.

#### **IV. COMMERCIALIZATION OF A PRODUCT UNDER THE MLS: CALCULATION OF BENEFIT-SHARING PAYMENTS**

16. WEMA is developing its varieties and then plans to licence a number of local seed companies in each of the target countries to multiply and distribute the seed through their established networks of agro-dealers. The reason for dealing with a limited number of seed companies under a licensing arrangement is to ensure quality control in seed production and to ensure effective management of the varieties. WEMA intends to provide access to its varieties free of charge and is exploring options to encourage retailers to keep prices reasonably low.

17. The SMTA requires the calculation of benefit sharing payments due when a product is "commercialized". The definition of commercialization is based upon sale "for monetary consideration on the open market". While the use of this concept under Articles 6.7 and 6.8 of the SMTA appears straightforward, that is, that the calculation should be made at the point of sale to the general public, some questions have arisen regarding the text and its application in practice, specifically in the context of the present case under consideration.

18. Textually, the alternative payment option described in Article 6.11 presents a specific challenge. Article 6.11 refers to payments on the sales of all products of the same crop, whether or not the products incorporate material from the Multilateral System or not. In this particular case, although this provision could be implemented at the level of the agro-dealers who sell directly to the public, but it is more readily understood as being directed at seed companies, who sell to agro-dealers rather than directly to the public. The possibility of benefit-sharing being calculated at the point of sale by seed companies to agro-dealers may also be supported by the provisions of paragraph 1(b) of Annex 2 of the SMTA.

19. The practical reason for querying the definition of sale "for monetary consideration" relates to the operation of the Multilateral System. WEMA expects to work with an average of about five seed companies in each of its target countries. However, each of these seed companies will have tens, if not hundreds, of agro-dealers in their distribution network. If benefit-sharing calculations are to be made at the level of the agro-dealers, instead of the seed companies, this will increase the bureaucratic processes and paperwork involved with the Multilateral System exponentially. This increase in bureaucracy, combined with the scale and nature of many agro-dealer operations, is likely to have a very negative impact on rates of compliance with benefit-sharing requirements.

20. WEMA understands that it would bear no legal responsibility for compliance by seed companies and agro-dealers handling its varieties but, as a non-profit project operating in the public interest, feels obliged to promote approaches that will encourage compliance wherever possible.

21. WEMA is also concerned about the impact that leaving benefit-sharing obligations at the agro-dealer level may have on pricing. While not wishing to destabilise or adversely affect the fragile seed industries and markets that exist in partner countries with excessively low prices, WEMA is also very concerned not to see its varieties, however successful, sold to farmers at excessively high prices. If agro-dealers are to be responsible for the calculation and subsequent payment of benefit sharing fees, this is likely to have an unpredictable impact upon the final price to farmers according to individual agro-dealers.

22. WEMA considers that if the calculation can be made at the point at which seed companies sell to agro-dealers, this will make the ultimate price impact to farmers more predictable. In addition, WEMA is exploring the possibility of using its licensing agreements with seed companies to monitor seed production volumes and, based on annual reports from these seed companies, either coordinating benefit-sharing payments by the seed companies or making the payments on their behalf. This would have the advantage for the Multilateral System of limiting bureaucracy and promoting compliance while, for WEMA, it would have the advantage of removing a potentially significant variability in pricing by agro-dealers.

23. WEMA is seeking the opinion and advice of the Committee regarding its understanding that the calculation of benefit sharing payments may best be made at points in the product distribution chain prior to the final sale of seed by agro-dealers to farmers. In *Appendix III*, the corresponding question to the Committee is set forth, together with a summary of the relevant facts from the WEMA project and the hoped-for response by the WEMA project's experts.

## **V. AVAILABILITY WITHOUT RESTRICTION: SALE OF HYBRIDS**

24. The text of the Treaty does not make reference to "restrictions on further research and breeding" being exclusively related to intellectual property rights, nor does it make any distinction among the possible forms of "restrictions". The negotiating history of the text seems to support this point, with explicit reference having been made to contractual and other non-intellectual property based forms of restriction.

25. A significant proportion of, and likely all, WEMA varieties will be hybrids. Some of these varieties will likely be developed with inputs from protected varieties or using proprietary technologies. The question arises as to whether they, both those with or without intellectual property protection, should be treated in the same manner in regard to their availability for further research and breeding.

26. In *Appendix IV*, the corresponding question to the Committee is set forth, together with a summary of the relevant facts from the WEMA project and the hoped-for response by the WEMA project's experts.

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*Appendix I*

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**COMMERCIALIZATION OF A PRODUCT UNDER THE MLS IN THE CONTEXT OF  
NOT-FOR-PROFIT PROJECTS UNDER ARTICLE 13 OF THE TREATY**

*A. Question*

- Can the Water Efficient Maize for Africa project (WEMA) be considered as non-commercial despite the fact that it fits the definition of ‘commercialization’ provided for in the SMTA?  
**OR,**
- Can a project exclusively designed to meet the objectives of Article 13.2(b), and possibly also 13.2(d)(i), not be liable for mandatory benefit sharing under Article 13.2(d)(ii) even though it falls within the definition of commercialization used in the SMTA?

*B. Facts*

i) WEMA is a charitably supported, non-profit, project delivering new maize varieties to smallholder farmers in Africa

- WEMA’s research and development partners will not charge any royalty, fee or cost recovery, or demand any other form of payment, for the provision of seed to seed companies in the target countries. This includes the fact that there will be no cost associated with the donation of proprietary germplasm and technologies from the private sector partner. I.e. germplasm will be free at the point of delivery to seed companies.
- WEMA’s public-private research and development structure is a technology transfer mechanism, as envisaged by Article 13.2(b) of the Treaty, that supports farmers, NARS and the private sector in the target countries.
- WEMA’s support to seed companies through the provision of improved varieties at no cost is a form of non-monetary commercial benefit sharing, as envisaged by Article 13.2(d)(i) of the Treaty.
- The provisions of Article 13.2(d)(ii) of the Treaty and Articles 6.7 and 6.8 of the Treaty are designed to ensure that developing country smallholder farmers benefit from the profits that agricultural research and development companies derive from publicly owned germplasm.
- WEMA is typical of a large number of public and donor funded non-profit agricultural research projects, where any additional expenses can only be paid for from research budgets or charged to farmers.

ii) The SMTA has a very broad definition of ‘commercialization’ that focuses on the distribution of products rather than on the Treaty’s priority of the use of PGRFA in the research and development of those products.

- The SMTA defines commercialization as follows:
 

**“To commercialize”** means to sell a **Product** or **Products** for monetary consideration on the open market, and **“commercialization”** has a corresponding meaning. **Commercialization** shall not include any form of transfer of **Plant Genetic Resources for Food and Agriculture under Development**.
- Even though, WEMA varieties will be free at the point of delivery to seed companies, they will fall within the definition of commercialization because of the costs of multiplication and distribution.

iii) WEMA varieties can only be multiplied and distributed through commercial networks

- Seed companies licensed by WEMA are expected to multiply the seed according to market demand, and possibly develop their own hybrids based on WEMA inbred lines, and then distribute through their established retail networks. They will not be funded by WEMA and will have to charge retailers for the seed they supply.
- There are relatively limited options for the broad distribution of seed in developing countries. The most effective established networks are through private agro-dealers and, in some countries, through agricultural extension systems.
- The use of agricultural extension systems would require significant investment, would undermine the development of the private sector and would not be sustainable without external funding.
- The use of private agro-dealers requires that they be able to charge for their service and, to avoid undermining the existing commercial market, their prices need to be comparable with ordinary hybrid prices.
- WEMA will monitor pricing patterns and will encourage seed companies and retailers to pass research and development savings onto farmers, although it is recognised that it is legally challenging to control pricing patterns in most jurisdictions.

*C. Hoped for responses*

- WEMA varieties are not subject to benefit sharing because they are provided free of charge as a product at the point of delivery to seed companies and the obligations under the SMTA are exhausted in that transaction.
- Improved varieties that are developed exclusively using public or charitable sources of funding and that are provided free of charge to seed companies or retailers in developing countries, and for which any sale for monetary consideration is exclusively related to the process of multiplication and distribution, do not fall within the requirement for benefit sharing under paragraphs 6.7 and 6.8 of the SMTA.

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*Appendix II*

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**AVAILABILITY WITHOUT RESTRICTION: GEOGRAPHICAL EXTENT OF THE RESTRICTION***A. Question*

- Is paragraph 6.7 of the SMTA applicable where a product contains a technology whose use for research, training or breeding is restricted in a jurisdiction other than that where the product is to be distributed?

*B. Facts*

- WEMA varieties are expected to incorporate private sector owned PGRFA and technologies that have been donated for use in targeted countries.
- Generally, these PGRFA and technologies will be freely available for use in research, training or breeding in WEMA targeted countries.
- These PGRFA and technologies may not be freely available for use in research, training or breeding in some jurisdictions (predominantly developed countries). The form of restriction is likely to be some form of intellectual property right. With limited regional exceptions, intellectual property rights operate at the national level, which allows for differentiated commercial strategies in various markets.
- Does Article 13.2(d)(ii), particularly as it is interpreted in the SMTA:
  - i) Create liability for mandatory benefit sharing only on sales in jurisdictions where the use of the product is restricted, or
  - ii) Create a liability for mandatory benefit sharing on global sales, including in jurisdictions where there is no restriction?
- If Article 6.7 of the SMTA is read as creating a global liability, this creates a perverse incentive for technology and germplasm owners to impose the maximum level of restrictions on subsequent use and to avoid any research partnerships involving material from the Multilateral System.

*C. Hoped for responses*

- Liability under paragraph 6.7 of the SMTA is limited to sales in jurisdictions where a restriction on use exists and in other jurisdictions, where there is no restriction, paragraph 6.8 applies.

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*Appendix III*

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**COMMERCIALIZATION OF A PRODUCT UNDER THE MLS: CALCULATION OF  
BENEFIT-SHARING PAYMENTS***A. Question*

- Can the calculation of benefit sharing payments be made, and the application of paragraphs 6.7 and 6.8 of the SMTA be exhausted, at points in the product distribution chain prior to the final sale of seed by agro-dealers to farmers?

*B. Facts*

- The SMTA requires the calculation of benefit sharing payments due when a product is 'commercialized'. The definition of commercialization is based upon sale "for monetary consideration on the open market".
- Paragraph 6.11 of the SMTA refers to payments on the sales of all products of the same crop. This provision could be implemented at the level of the agro-dealers who sell directly to the public but is more readily understood as being directed at breeders or seed companies, who sell to other seed companies or agro-dealers rather than directly to the public. The possibility of benefit sharing being calculated at the point of sale by seed companies to agro-dealers may also be supported by the provisions of paragraph 1(b) of Annex 2 of the SMTA.
- A product, in the sense of a fully developed and field ready variety, may be sold at a variety of points in the product distribution chain that may not be considered as 'sale on the open market', including,
  - a breeding company may sell to a seed company, and
  - a seed company may sell to wholesalers or agro-dealers.
- The bureaucracy of exclusively dealing with agro-dealers, combined with the scale and nature of many agro-dealer operations, is likely to have a very negative impact on rates of compliance with benefit sharing requirements.

*C. Hoped for responses*

- Benefit sharing payments do not have to be based on sales to the general public and may be calculated at any point where there is a sale of a product, even if the offer of sale is only made to a limited group or on a wholesale basis.

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*Appendix IV*

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**AVAILABILITY WITHOUT RESTRICTION: SALE OF HYBRIDS***A. Question*

- If a genetic trait protected by intellectual property rights and contractual limits on use is introduced to a hybrid that is also marketed in an unprotected non-modified form, does the restriction on the use of the modified form affect the unmodified form?

*B. Facts*

- The development of varieties using modern biotechnology techniques is invariably based on the use of elite, usually hybrid, varieties developed using traditional breeding techniques.
- Traditionally developed hybrid varieties are rarely protected by legal means.
- Varieties incorporating genetic material introduced through the use of modern biotechnology are usually protected by both intellectual property rights and through contractual restrictions on purchasers.

*C. Hoped for responses*

- The sale of an unprotected hybrid variety is completely distinct from, and unaffected by, the sale of a form of that hybrid variety incorporating additional technology that is not available to others for further research and breeding without restriction.