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Item 11 of the Provisional Agenda

SEVENTH SESSION OF THE GOVERNING BODY

Kigali, Rwanda, 30 October – 3 November 2017

Report on the Practice of the CGIAR Centers for Plant Genetic Resources for Food and Agriculture under Development

Executive Summary

At its Sixth Session, the Governing Body requested the Centers of the Consultative Group on International Agricultural Research (CGIAR Centres) that are signatories of agreements with the Governing Body, under Article 15 of the Treaty, to provide information on the additional terms and conditions that they apply when transferring Plant Genetic Resources for Food and Agriculture under Development. This document contains a synthesis of the information that the Centers provided, together with an analysis of such information in relation to the Standard Material Transfer Agreement and the Multilateral System of Access and Benefit-Sharing.

Guidance Sought

The Governing body is invited to consider the information provided in this document and provide any further guidance it deems appropriate, including requesting that the CGIAR Centers to regularly update information on additional terms and conditions for Plant Genetic Resources for Food and Agriculture under Development in their biennial reports to the Governing Body.

The Governing Body may also wish to consider requesting that the CGIAR System regularly update the Governing Body on the status of implementation of the CGIAR Principles on the Management of Intellectual Assets with respect to plant genetic resources for food and agriculture, which the CGIAR Centers manage under the framework of the International Treaty. In this regard, elements for a possible Resolution have been provided for the consideration of the Governing in the Appendix to this document.

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I. Introduction

1. Prior to the Sixth Session of the Governing Body, the CGIAR Centers that signed agreements with the Governing Body under Article 15 of the International Treaty provided information on their use of the Standard Material Transfer Agreement (SMTA) when transferring Plant Genetic Resources for Food and Agriculture under Development (PGRFAuD). Through Resolution 1/2015, the Governing Body welcomed the CGIAR Centers' use of the SMTA for the transfer of PGRFAuD that:

- 1) incorporate material previously held 'in trust' and placed within the purview of the Multilateral System (Multilateral System) by virtue of the agreements with the Governing Body under Article 15 of the International Treaty; or
- 2) incorporate material received by a Center under the SMTA or under another legal instrument that allows redistribution with the SMTA.
- 2. The Governing Body further requested the Secretariat, in cooperation with CGIAR Centers and other relevant CGIAR institutions and mechanisms, to:
 - 1) gather information on the content of additional conditions attached to the transfer of PGRFAuD:
 - 2) explore ways of facilitating implementation of the obligation of Article 6.5 of the SMTA to identify material received from the Multilateral System in Annex 1 to the SMTA;
 - 3) report back on the above to the Governing Body at this Seventh Session.
- 3. With reference to the request under 2) of paragraph 2 above, the CGIAR Centers made a submission to the sixth meeting of *the Ad Hoc* Open-Ended Working Group to Enhance the Functioning of the Multilateral System (Working Group) in March 2017, on the proposed revisions to the SMTA. In the submission, the CGIAR System Organization, on behalf of the CGIAR Centers that are signatories of Article 15 agreements, expressed their views on the identification of germplasm ancestors in Annex 1 to the SMTA, including for PGRFAuD. The Working Group's consideration of the specific issue, in the context of proposed revisions to the SMTA, is transmitted to this Seventh Session Governing Body in a separate document.
- 4. This document reviews the information that the CGIAR Centers provided in response to the request under 1) of paragraph 2 above. It also contains elements of a possible Resolution for consideration by the Governing Body.

II. Synthesis of submissions

- 5. Ten (10) CGIAR Centers responded to the request for information made by the Secretariat in September 2016. Four (4) Centers reported that they either do not apply any additional terms and conditions, or that PGRFAuD are not relevant to their operation, since no development of conserved germplasm through conventional or biotechnology-assisted breeding is carried out by those Centers.
- 6. The additional terms and conditions that the Centers reported on relate to both non-commercial and commercial aspects of germplasm development. The former are essentially to provide for data sharing and attribution/acknowledgement. The latter impose limitations on recipients in regard to product development and product release.

¹ See document IT/OWG-EFMLS-6/17/Inf.7, Submissions of Contracting Parties and Other Stakeholders on Matters to Be Discussed at the Sixth Meeting of the Working Group, Appendix 2. The document is available at http://www.fao.org/3/a-br413e.pdf

² Document IT/GB-7/17/7, Report of the Ad Hoc Open-Ended Working Group to Enhance the Functioning of the Multilateral System

7. The provision of data sharing clauses require the recipient to share with the provider, and consent to the provider's use of, various types of data, for example in publicly accessible databases. Such data may be derived from characterization or evaluation of the germplasm, or related to performance, and the needs and preferences of farmers.

- 8. In some cases, the additional terms involve requiring recipients to provide attribution and acknowledgement of funding agencies and developers of the germplasm, when publishing the results of research conducted on the PGRFAuD. In one instance, there is a requirement for a 30-day advance notice before publication.
- 9. Terms and conditions to control product development and release are applied with varying degrees of complexity, depending on the status of the germplasm (e.g. whether under active development through research and breeding, or close to release as a finished product). Some Centers applying this type of condition specify that all rights on PGRFAuD are maintained by the provider, and/or that the recipient is the owner of the resulting information and the derived material. Most of the Centers that transfer PGRFAuD prohibit their transfer to third parties without the consent of the providing CGIAR Center. In one case, the limitation to third party transfers of PGRFAuD is embedded in a research consortium, whose terms establish a time-limited exclusivity of preferred access for the private sector, in return for exclusive rights on material, publications and data sharing. In the consortium agreement, a research exemption for public sector partners is also established. The CGIAR Center that provided this information made reference to the compatibility between such research consortium, qualified as a limited exclusivity agreement, and the CGIAR Principles on the Management of Intellectual Assets (CGIAR IA Principles).³
- 10. Some of the Centers also require the recipient to negotiate a commercial licence with the providing CGIAR Center before the release of a product deriving from PGRFAuD, or equivalent to the PGRFAuD at the end of its development cycle. Some additional terms and conditions deal with ownership of, and applications for, intellectual property (IP) protection over essentially derived material (varieties). In one case, a CGIAR Center requires the recipient to provide seeds of elite germplasm (varieties) for inclusion in the genebank, and for use as parental germplasm in the Center's breeding programme.
- 11. In some instances, the transfer of PGRFAuD includes identified genes and DNA sequences, as well as associated genetic information and know-how. Some of this subject matter is marked as 'confidential' or 'proprietary'. In one case, traits in PGRFAuD are protected by IP rights and transferred with a licence for non-exclusive research to interested recipients. The terms of the licence prohibit sub-licensing or commercial exploitation, and require upfront and milestone payments, consortium membership, joint ownership of derived material and confidentiality.

The CGIAR System Organization publishes annual reports containing general and aggregated information on the CGIAR IA Principles, extracted from confidential consolidated reports to which only the CGIAR System Council IP Group is privy. The most recent public report, for year 2015, is available at:

http://library.cgiar.org/bitstream/handle/10947/4372/2015%20CGIAR%20IA%20Report.pdf? sequence = 4.

³ Under articles 6.2 and 6.3 of the CGIAR IA Principles, the CGIAR Consortium and/or Centers may grant limited exclusivity for commercialization of the respective intellectual assets they produce (Limited Exclusivity Agreements), subject to certain research and emergency use exemptions. The CGIAR Principles allow Centers to request approval from the CGIAR Consortium to deviate from these exemption requirements, if compelling reasons are provided. In 2013 (i.e. shortly after the CGIAR IA Principles were adopted), the CGIAR System Office presented the Principles to the *Ad Hoc* Technical Advisory Committee on the SMTA and the Multilateral System during its fourth meeting (see document IT/AC-SMTA-MLS 4/12/3, *The Policy and Principles of the Management of Intellectual Assets of the Consultative Group on International Agricultural Research*, available at http://www.fao.org/3/a-be502e.pdf). The Committee noted the need for transparency and availability of information on the application of the CGIAR IA Principles (see document, IT/AC-SMTA-MLS 4/12/Report, available at http://www.fao.org/3/a-be513e.pdf).

12. Regarding the form of the additional terms and conditions, all the reporting Centers use a document – in some cases an additional Material Transfer Agreement or a research licence, and in others, a consortium agreement – which is separate from the SMTA.

III. Analysis

- 13. The analysis of the information provided by the CGIAR Centers requires recognition of their modus operandi relative to national and commercial breeders. Generally, the CGIAR Centers do not directly release or commercialize the varieties that they breed. They transfer PGRFAuD to their partners. To accommodate this, and issue a licence for the product, additional terms and conditions are often added for PGRFAuD, requiring the recipient to ask for a licence if the material is deemed ready for release and commercialization.
- 14. Based on the information provided by the CGIAR Centers, the Secretariat notes three issues for possible consideration by the Governing Body, in the exercise of policy guidance to the CGIAR Centers pursuant to the agreements under Article 15 of the International Treaty. These considerations can be made on the relation between additional terms and conditions for PGRFAuD, and the SMTA and other rules of the Multilateral System.
- 15. The first consideration relates to commercial licences in cases where a product derived from PGRFAuD is commercialized. The royalties that these licences may require would add to the monetary benefit-sharing provisions of the SMTA in cases of commercialized products that are restricted for further research and breeding. The SMTA foresees the payment of monetary consideration for PGRFAuD, even if not explicitly in the form of royalties on Products that derive from PGRFAuD. It may even be inferred that monetary consideration is embodied in the entire concept of PGRFAuD, which are meant to reflect the fact that payments and other conditions are effected as germplasm is passed down the development chain. The possible issue is whether an additional payment scheme could, in practical terms, constitute a disincentive to accessing improved germplasm under the Multilateral System. The recipient who commercializes a Product would be subject to payments to the providing CGIAR Center, in addition to monetary benefit-sharing into the Benefit-sharing Fund (BSF), if the conditions for triggering such benefit-sharing occur. For the time being, no payments from commercialized Products have been made into the Benefit-sharing Fund, and there is no requirement for providers of PGRFAuD – including the CGIAR Centers – to report or share any income generated by the transfer of such PGRFAuD, including from the commercialization of Products that incorporate PGRFAuD. The sustainability of this current structure may need to be further examined based on existing practices, including by the industry.
- 16. The licensing arrangements being implemented by some CGIAR Centers reflect the fact that, although the SMTA is meant to be applied until a product is released for commercialization (i.e. at the point of sale of a product on the open market), the agreement relates to research, breeding and training only, and thus does not apply to direct and commercial use. Some CGIAR Centers respond to this situation by adding terms and conditions requiring the recipient to return to them for a commercial licence, so they can change the status from PGRFAuD to Product, and issue a commercial licence.
- 17. The second consideration relates to restrictions to third party transfers of PGRFAuD. The SMTA establishes that the transfer of PGRFAuD is at the discretion of the developer. As the Ad Hoc Technical Committee on the SMTA and the Multilateral System noted in one of its opinions given in year 2012, the developer (or the chain of developers) of PGRFAuD has the full discretion as to whether or not to make these resources available, from their initial transfer until the time of the commercialization of a product that incorporates them. As the Committee further noted, this restriction is to enable normal commercial practice to take place regarding sales of improved material and commercial cooperation in the seed sector. This includes the ability of the purchaser of an improved

material, or of breeders cooperating in the development of an improved material, to exclude others from access to their material.⁴

- 18. The practice of the CGIAR Centers is to exercise discretion as first developer of the germplasm with regard to subsequent transfers of the PGRFAuD by subsequent developers to third parties. The consent of the initial developer, i.e. the providing CGIAR Center, is required for those subsequent transfers. This practice is presumably motivated by the need to control further research and development, geographically or otherwise, and could entail a limitation to the downstream flow of germplasm incorporating PGRFAuD. If the Multilateral System is intended to facilitate incremental research and breeding, ostensibly on as wide a scale as possible, restricting the circulation of improved germplasm that incorporates material accessed from the Multilateral System to the discretion of the first developer could be seen as limiting further research and breeding. Although the practice appears to be legitimate, based on the current text of the SMTA, the rationale for these provisions may need to be kept under review as the rules of the system evolve.
- 19. The third consideration relates to the case of transfer of proprietary assets in PGRFAuD. One Center explicitly mentioned a proprietary trait (i.e., for which national patent applications have been filed), intended for use in F1 hybrids, which is licensed for research on a non-exclusive basis. However, it is not clear whether or not the licence entails the transfer of PGRFAuD with the SMTA, which would also guarantee monetary benefit-sharing in cases where a Product is developed and commercialized. Patent claims may refer to processes, e.g. breeding processes, whose adoption may not necessarily require the use of physical material from which those processes have been developed. A possible question is whether the licensing of proprietary traits for optimization (i.e. research) would always entail the transfer of germplasm with the SMTA, inter alia for the triggering of benefit-sharing provisions, in cases where the traits are proved to be useful in the breeding of new commercial varieties and, presumably, a subsequent commercial licence is negotiated with the CGIAR Center. If the transfer of physical material with the SMTA is not necessary to use the proprietary traits in commercial breeding, the benefit-sharing conditions of the SMTA would not apply, unless they are reproduced in the licence.

IV. Consideration of PGRFAuD in the context of enhancement of the Multilateral System

- 20. The Governing Body may wish to note that, in the current biennium, the Working Group dealt with proposals for amendments to the SMTA, which are of direct relevance to the management of PGRFAuD, including by the CGIAR Centers.
- 21. As referred to in paragraph 3 above, the proposals for the identifier of PGRFAuD and the identifier of the Material from which PGRFAuD are derived, are being considered for Annex 1 to the SMTA.
- 22. In the Annex to the SMTA that would provide the option for a possible subscription system, the term 'product' (as distinct from the 'Product') is being proposed, which would include the

 $^{^4\} See\ document\ IT/AC-SMTA-MLS\ 2/10/Report,\ \textit{Appendix}\ 2,\ available\ at\ http://www.fao.org/3/a-be065e.pdf$

⁵ The CGIAR IA Principles allow for the CGIAR Centers to seek patents on and/or plant variety protection (PVP) of their intellectual assets when necessary for the further improvement of such intellectual assets, or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision (Article 6.4.2). The CGIAR System Council IP Group reviews such justification.

⁶ In literature, the issue as to whether the use of publicly available germplasm may be affected by a patent involving a particular native trait has been analysed, for instance in relation to alternative accessions that may contain the trait described in the patents claims, by being identical to or by common ancestry with the source of the protected trait. van de Wiel C., Lotz B., de Bakker E. (2016). *Intellectual Property Rights and Native Traits in Plant Breeding*. Wageningen: Wageningen Foundation DLO.

royalties generated from the transfer of PGRFAuD (see Annex 3, clause 3 of the revised SMTA as proposed by the Working Group at its Sixth Meeting).⁷

V. Guidance Sought

- 23. In considering the above information and discussions on PGRFAuD, the Governing Body may wish to note that the management of PGRFAuD is of paramount relevance for the functioning of the Multilateral System, and in particular for the generation of benefits through the development of germplasm. Given the wide range of practices regarding additional terms and conditions for PGRFAuD, and considering that several CGIAR Centers have crop breeding programmes developing germplasm in the Multilateral System that is characterized as PGRFAuD, the Governing Body may request that the CGIAR Centers continue to include (as they started doing in 2015) information on the scope and content of additional terms and conditions in their biennial reports on implementation of the Article 15 agreements to the Governing Body. This continued, regular reporting would give the Governing Body important insights into the distribution and use of improved germplasm in the Multilateral System by the CGIAR Centers. In so doing, it would enable the effective exercise of policy guidance, as provided for in the agreements with the Governing Body. It could also lead, in the future, to the development of a comprehensive set of best practices on additional terms and conditions for PGRFAuD, not only for the CGIAR, but for all users of materials in the Multilateral System. In addition, it may be useful to develop best practices for promoting non-monetary benefit-sharing, for example in the form of access to and transfer of technology.
- 24. Given the apparent relevance of mechanisms for the management of intellectual assets by CGIAR Centers to PGRFAuD practices, the Governing Body may also invite the CGIAR System to ensure regular communication to the Governing Body and, on an intersessional basis, to the Contracting Parties through the Secretariat on the status of the implementation of the CGIAR Intellectual Assets Principles, as it relates to germplasm in the Multilateral System, including in cases where such germplasm (or parts thereof) is the subject matter of patent or plant variety protection applications, or is included in partnerships that qualify as restricted use or limited exclusivity agreements. This communication could, for example, be effected by extracting and elaborating relevant information from the annual reports.
- 25. The Governing Body is invited to provide any guidance it considers appropriate in regard to the range of issues raised in this document, taking into account the elements for a possible Resolution provided in the *Appendix* to this document.

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⁷ The report of the meeting (IT/OWG-EFMLS-6/17/Report), which includes the revised SMTA in *Appendix* 2, is available at: http://www.fao.org/3/a-br666e.pdf

⁸ See footnote 3 above. The CGIAR IA Principles are currently undergoing independent review.

Appendix: Elements for a possible Resolution (to be integrated into DRAFT RESOLUTION **/2017 on the Multilateral System)

THE GOVERNING BODY:

Recalling the provisions of Article 15.1 a) of the International Treaty;

Recalling further the provisions of Articles 6.5 and 6.6 of the SMTA;

Recalling Resolution 1/2015;

Noting the continuing relevance of the CGIAR Principles on the Management of Intellectual Assets to implementation of the obligations of CGIAR Centers pursuant to the agreements concluded with the Governing Body under Article 15 of the International Treaty,

- 1) **Thanks** the CGIAR Centers that have submitted information on the content of additional conditions to the transfer of plant genetic resources for food and agriculture under development and invites the Centers to continue providing updated information in their biennial reports to the Governing Body on implementation of the agreements concluded under Article 15 of the International Treaty;
- 2) *Invites* the CGIAR System to provide the Governing Body, through the Secretariat, with information on the status of the implementation of the CGIAR Principles on the Management of Intellectual Assets, as it relates to germplasm that the CGIAR Centers manage under the framework of the International Treaty, including in cases where such germplasm, or parts thereof, is the subject matter of patent or plant variety protection applications, or is included in partnerships that qualify as restricted use or limited exclusivity agreements pursuant to the CGIAR Principles.