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Food and Agriculture Organization of the United Nations

International Treaty on Plant Genetic Resources for Food and Agriculture

INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

TWELFTH MEETING OF THE AD HOC OPEN-ENDED WORKING GROUP TO ENHANCE THE FUNCTIONING OF THE MULTILATERAL SYSTEM

Rome, Italy, 16–19 September 2024

Submissions from Regions, Contracting Parties and Stakeholders

Note by the Secretary

At its Tenth Session, the Governing Body stressed the importance of an open and inclusive process and invited the Co-Chairs to seek written inputs or reports from all relevant stakeholders.

At the last meeting of the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System (Working Group), the Co-Chairs announced that they would invite written submissions from Regions, Contracting Parties and relevant stakeholders on elements of the "June 2019 draft package" other than the three "hotspots" (digital sequence information/genetic sequence data, expansion of Annex I, and payment structure and rates).

The Secretary accordingly issued Notification NCP GB11-005 on 30 April 2024, inviting Regions, Contracting Parties and relevant stakeholders to provide written submissions on these elements. The Notification specified that the submissions should focus on the provision of inputs and concrete proposals that may be considered to advance negotiations.

This document compiles the submissions received in reply to Notification NCP GB11-005, in the language and form in which they were received.

List of Appendixes

Points to Adapt in the MLS Resolution (Appendix 2 in IT/OWG-EFMLS-11/24/3)

Para 5: (Patents)

5. *Recognises* the need to ensure ~~the~~ access without restriction to any PGRFA, **[new] or their genetic parts or components**, in the form received from the MLS;

[new] Decides to establish a Ad Hoc Technical Committee on the implementation of Art. 12.3d

[new] Decides that the main task of the Committee will be to provide guidance for the effective implementation of Art. 12.3d of the Treaty and the enforcement of Art. 6.2 of the SMTA.

[new] Establishes a basis for the work of the Committee through the Terms of Reference contained in Annex x to this Resolution;

[new] calls on recipients of PGRFA to disclose use of Material from the Multilateral System in their patent applications.

[And/or include this with a stronger wording in a new Art. 6.2 bis of the SMTA: "The recipient shall disclose any use of Material accessed through this SMTA in its patent applications"]

Related articles:

Art. 12.3d d) Recipients shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System;

Reasoning: Article 12.3d is an essential article of the Treaty to preserve free access to material in the multilateral system. However, it has not yet been implemented. There is no clarity as to what form of patents a signatory to an SMTA is allowed to apply for and what not. In view of the increasing number of patents on native traits, this is a cause for concern.

Before the scope of the Multilateral System is extended, it must be ensured that Art. 12.3d is implemented correctly in future. Otherwise, an extended scope would lead to more patents and restrict access to the material for everyone - which contradicts the objective of the treaty.

Domestic Use:

New Paras (to be included in the Governing Body Resolution for the ENHANCEMENT OF THE MULTILATERAL SYSTEM OF ACCESS AND BENEFIT-SHARING OF THE INTERNATIONAL TREATY

The Governing Body,

Reaffirms Art. 12.4 of the Treaty, which states that faciliated access shall be provided pursuant to a standard material transfer agreement (MTA) and clarifies that this must be done in a non-discriminatory manner for both domestic and foreign users.

Urges all Contracting Parties that have not already done so, to provide access for the purpose of utilization and conservation for research, breeding and training for food and agriculture, only through the standard material transfer agreement and in a non-discriminatory manner for both domestic and foreign users.

Related Treaty Articles

11.2 The Multilateral System, as identified in Article 11.1, shall include all plant genetic resources for food and agriculture listed in Annex I that are under the management and control of the Contracting Parties and in the public domain.

12.1 The Contracting Parties agree that facilitated access to plant genetic resources for food
and agriculture under the Multilateral System, as defined in Article 11, shall be in accordance
with the provisions of this Treaty.

12.4 To this effect, facilitated access, in accordance with Articles 12.2 and 12.3 above, shall be provided pursuant to a standard material transfer agreement (MTA),

Funding strategy article 18.4 (f) on voluntary contributions. This element requires strengthenining the modalities of the strategy to promote such contributions.

Appendix 2

República Argentina - Poder Ejecutivo Nacional
AÑO DE LA DEFENSA DE LA VIDA, LA LIBERTAD Y LA PROPIEDAD

Nota

Número: NO-2024-55733883-APN-DAA#MRE

CIUDAD DE BUENOS AIRES
Martes 28 de Mayo de 2024

Referencia: Contribuciones para el proceso de mejora del funcionamiento del Sistema Multilateral. Aportes para la elaboración del texto de negociación de los co presidentes del Grupo de Trabajo Especial de Composición Abierta.

A: Secretaría TIRFAA (PGRFA-Treaty@fao.org),

Con Copia A: María Victoria Gandini (DAA#MRE), Lara Susana Fazzolari (DAA#MRE),

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De mi mayor consideración:

Estimados miembros de la Secretaría del Tratado Internacional sobre los Recursos Filogenéticos para la Alimentación y la Agricultura,

En respuesta a la notificación NCP GB11-005-Propuestas de mejora dl MLS, la República Argentina agradece la labor de los co presidentes del Grupo de Trabajo Especial de Composición Abierta para Mejorar el Funcionamiento del Sistema Multilateral (Grupo de Trabajo) y la remisión del informe de la undécima reunión del mismo realizada el pasado mes de abril en la ciudad de Roma.

Nuestro país reitera su compromiso con el proceso negociador que está realizando el Grupo de Trabajo con relación a la reforma del sistema multilateral. En este sentido, ratifica el "borrador de paquete de junio de 2019" como base de los trabajos y los debates en torno a los denominados "tres puntos críticos". A la luz de las dificultades experimentadas en el último período de negociación del año 2019, los debates mantenidos en la undécima reunión y la afirmación por parte de varios países que la apertura del anexo 1 se encuentra supeditada a un eficiente

mecanismo de distribución de beneficios, se sugiere trabajar de manera conjunta estos elementos evitando postergar el debate sobre los montos de las tasas de pago.

Asimismo, la República Argentina reafirma que los usos de los recursos fitogenéticos deben ser para la alimentación y la agricultura según lo establecido por el artículo 1 del Tratado Internacional a la vez que resalta la necesidad de salvaguardas y exclusiones en el proceso de reforma a fin que pueda garantizarse la adhesión a citado proceso la cual es una condición inexorable para nuestro país.

Finalmente, conforme al cronograma de trabajo descripto en el párrafo 27 del reporte del undécimo encuentro del Grupo de Trabajo, la Argentina solicita - nuevamente - la circulación tanto de los documentos de trabajo como informativos junto al texto de negociación que elaborarán los co presidentes con la debida antelación a la reunión que se realizará en septiembre en los seis (6) idiomas de la FAO. El cumplimiento de esta petición permitirá garantizar la transparencia y legitimidad del proceso en curso al permitir a los Estados Parte realizar las consultas pertinentes con los organismos, dependencias y actores relevantes al interior de sus fronteras posibilitando la presentación de posiciones nacionales en la duodécima reunión y asegurando así las condiciones para avanzar en el proceso negociador.

Sin otro particular saluda atte.

Digitally signed by GESTION DOCUMENTAL ELECTRONICA - GDE
Date: 2024.05.28 18:09:00 -03:00

Corina Beatriz Lehmann
Directora

Dirección de Asuntos Ambientales
Ministerio de Relaciones Exteriores, Comercio Internacional y Culto

Digitally signed by GESTION DOCUMENTAL ELECTRONICA - GDE
Date: 2024.05.28 18:09:01 -03:00

Appendix 3

Inputs for drafting the Co-Chairs' negotiating text for the process to Enhance the Functioning of the Multilateral System

Canada's Submission to the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture in response to Notification NCP GB11-005, April 30, 2024

Dear Treaty Secretariat,

Thank you for the opportunity to highlight an issue raised by Canada during previous formal meetings of the *Ad-H*oc Open-ended Working Group to Enhance the Functioning of the Multilateral System (OEWG-EFMLS) and at GB-10 in November 2023.

Canada feels it is important to facilitate access to MLS material for non-food and non-feed agricultural uses. Canada considers the possible legal ambiguity in Article 12.3(a) to be a relevant aspect that needs to be discussed by the OEWG-EFMLS.

Rationale:

- Support by the Treaty and its MLS for uses beyond food and feed would contribute to a transition to a green economy which is in line with objectives of the United Nations Environment Program (e.g. https://www.unep.org/resources/report/biofuels-and-environmental-impact-scientific-analysis-and-implications).
- Many crops are multi-purpose, with food, feed, and technical use outcomes. Examples include: the use of rapeseed special oil compositions; flax and cotton for fibre; linseed in nutraceuticals; camelina, maize and sugar cane for biofuels and ethanol; potato for technical starch; and ginger, oat and barley for medicinal purposes. It often is not possible to clearly predict all of the uses of a released cultivar which incorporates MLS material.
- Farmers can obtain benefits from multiple use outcomes from their crops.
- Removing restrictions to uses of crop cultivars incorporating MLS material would be helpful to support the sustainable use of plant genetic resources for food and agriculture, and contribute to the diversification of agricultural production.

More clarity to Article 12.3(a) of the Plant Treaty is required to avoid varied interpretations. Article 6.1 of the Standard Material Transfer Agreement would also need to be considered.

We would be grateful if you could address this issue in the Co-Chairs' negotiating text.

With kind regards,

Axel Diederichsen

National Focal Point to the International Treaty on Plant Genetic Resources for Food and Agriculture for Canada
Saskatoon, Saskatchewan

May 27, 2024

Appendix 4

Elements to consider in developing draft negotiating texts:

A submission from CGIAR to the Co-Chairs of the Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing

A. Introduction

In November 2022, the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty) decided to resume negotiations under the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing (WG-EFMLS). These negotiations had been suspended in 2019. The Governing Body decided that the resumed negotiations should begin with the 'package of measures' that had been developed by the WG-EFMLS as of June 2019. That package includes: a) the draft revised standard material transfer agreement (SMTA), b) the draft revised Annex 1 to the Plant Treaty, and c) the draft Resolution to be adopted by the Governing Body at the same times as it adopts the revised SMTA and Annex 1. The Governing Body also agreed that the resumed WG-EFMLS should initially focus on three so-called 'hotspots' that had contributed to the suspension of negotiations in 2019. Those 'hotspots' are: 1) benefit sharing from the use of digital sequence information/genomic sequence information (DSI/GSD); 2) expansion of the list of crops included in the scope of the multilateral system, and 3) optional new approaches and rates for monetary benefit sharing.

The 11th meeting of the WG-EFMLS, April 15-17, 2024, focused primarily on the three 'hotspots'.

Following that 11th meeting, the Plant Treaty Secretariat issued a call for written submissions from contracting parties and stakeholders concerning any other issues – other than the 3 'hotspots' – that the Co-chairs of the WG-EFMLS should take into consideration as they develop revised draft texts of the SMTA, Annex 1, and the draft Resolution, to be used as a basis for negotiations during the 12th meeting of the WG-EFMLS in September, 2024.

We understand that the Co-chairs prefer not to 'reopen' those sections of text of the draft revised SMTA, draft revised Annex 1 and draft revised Resolution that were agreed in principle ('Agreed Ad Ref") by negotiators in 2019. Our approach to developing this submission therefore is to focus primarily on issues that are linked to sections of the 2019 texts that were *not* 'Agreed Ad Ref' or which are not reflected at all in those texts. In a few exceptional circumstances, we note where it might be useful or necessary to revisit portions of text that were 'Agreed Ad Ref' in 2019.

Our comments are limited to the draft revised Resolution, and the draft revised SMTA as included in Appendix 2 of document entitled "The 'June 2019 Package': Note by the Co-Chairs", IT/OWG-EFMLS-11/24/3,[1] which was prepared for the 11th session of the WGEFMLS.

[1] Available at https://openknowledge.fao.org/server/api/core/bitstreams/8bb2f7a9-fee5-4809-a5bc-5674a5c9cf17/content

B. Regarding suggested additions to the draft Resolution.

Comments in this section follow the order of the paragraphs in the draft Resolution.

Under the section entitled 'Potential elements for the revised SMTA'

The four paragraphs numbered 4-5 QUINQUIES (not 'Agreed Ad Ref') are meant to address concerns about preserving the rights of farmers, researchers and others to continue to access and use, without restriction, plant genetic resources from the multilateral system. SMTA Article 6.2 was designed to address this concern. However, there are persistent concerns raised by contracting parties and stakeholders that intellectual property rights can be, and have been, used to prohibit plant breeders from using materials accessed from the multilateral system, including their genetic parts and components, for further breeding work. As a trust building measure, to address these concerns, it would be useful for the Resolution to:

- *confirm* that the exercise or attempted exercise of intellectual property rights or other rights by recipients of PGRFA from the multilateral system, to limit the use by others of those same materials, including their genetic parts and components, for research training and breeding is contrary to the intended purpose of article 6.2 of the SMTA.

This paragraph could either replace, or be inserted after, 5 QUINQUIES.

Paragraph 7 BIS (not 'Agreed Ad Ref') states that Article 15 institutions should require recipients of 'in trust' materials to make genetic sequence data available. SMTA Article 6.9 states that "[t]he Recipient shall make available to the Multilateral System, through the information system provided for in Article 17 of the Treaty, all *non-confidential* information that results from research and development carried out on the Material ... (emphasis added)." The qualifier of 'non-confidential' means is it is not mandatory for recipients to share sequence data derived from the materials received. Article 15 organizations cannot simply add such a condition to the SMTA when transferring in trust materials. Of course, in situations where Article 15 institutions are involved as partners in large research consortia, we can attempt to use our leverage as partners to ask other partners to voluntarily agree to such conditions. But apart from these situations, to comply with the intention of this draft paragraph, SMTA Article 6.9 would need to be revised (or another subparagraph under Article 6 would need to be added) including an obligation for recipients to publicly share all DSI data derived from PGRFA received under the SMTA. If such a revision was made to the SMTA, it could be limited to SMTAs used by Article 15 Centers only (to comply with the spirit of Para 7 BIS). However, we feel it should apply to all PGRFA in the multilateral system. NB: the revised draft SMTA, para 9, at line 46, page 19, (not 'Agreed Ad Ref'), in 'Note from the Co-Chairs', includes a clause -- "[and all genetic sequence data]" – that appears intended to have this effect.

Paragraph 8. We very much appreciate the recognition of the potential limits of the abilities of genebanks to respond to large requests, as expressed in this 'Agreed Ad Ref' paragraph. We do not

propose to revise the single sentence that constitutes paragraph 8. However, we propose adding a sentence to address the risk that genebanks could be considered responsible if a subscriber withdraws from their subscription on the basis of not getting requested PGRFA, as anticipated in SMTA Annex 3 para 4. SMTA Annex 3, para 4 is not 'Agreed Ad Ref' but if it is later agreed to by the contracting parties, we propose adding the following new para 8 BIS in the draft resolution:

- Genebanks that make good faith efforts to respond to such requests – even if they are unable to provide the material requested – will not be considered responsible if a subscriber withdraws from a subscription on the basis of not getting requested PGRFA pursuant to SMTA Annex 3, para 4 bis.

Paragraphs 14-15 (not Agreed Ad Ref) are about exemptions from payment obligations. CGIAR proposed the option reflected in paragraph 14 to exempt subscribers whose annual seed sales fall below a threshold. It was confirmed by the representative of IHS Markit Agribusiness Consulting during WG-EFMLS 11 that companies whose seed sales are less than 10 million USD/year collectively constitute less than 5% of global seed sales, and possibly as little as 1% of global seed sales. In light of: i) the administrative costs associated with monitoring and ensuring payments from this 'long tail' of companies, ii) the low combined total payments they would make, and iii) the importance of relieving small size companies from administrative burdens and legal uncertainty, we suggest contracting parties consider establishing a threshold whereby companies whose annual seed sales are less than 10 million USD are exempt from the obligation to make subscription payments.

Under the section entitled 'Potential elements related to PGRFA information'

(NB: none of the paragraphs included in this section are Agreed Ad Ref.)

The title of this subsection should be revised to refer to either a) 'digital sequence information' to be consistent with the terminology used in, *inter alia*, the UN Convention on Biological Diversity, the Kunming-Montreal Global Biodiversity Framework, and the Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, or b) 'digital sequence information/genomic sequence data' to be consistent with how terminology has evolved since 2019 under the framework of the Plant Treaty.

As several delegates stated during the 11th session of the EFMLS, there should be additional paragraphs included in the draft Resolution relating to the governance of DSI. (Until now, focus has been almost entirely on developing triggers and modalities for monetary benefit sharing from the use of DSI.) This new text should

- affirm the importance of maintaining open access to DSI/GSD, given its importance for agricultural research and plant breeding;
- underscore that DSI data should be managed in conformance with the FAIR[2] (findable, accessible, interoperable, reusable) data management principles,

[2] See https://www.nature.com/articles/sdata201618

- request the Secretariat to conduct a study or develop a pilot project on options for integrating CARE[3] data principles in the management of DSI associated with PGRFA in the multilateral system and report back to the 12th Session of the Governing Body;
- affirm that DSI/GSD data related to PGRFA in the multilateral system should not be subject to intellectual property rights or other forms of protection that would limit their availability and use of such data by others, or the genetic resources from which that data was derived.

With respect to the final bullet point, it is worth noting that the report of the WG-EFMLS 11 states that "Any solution should not restrict facilitated access to PGRFA or open access to DSI/GSD on PGRFA ..." [4] For CGIAR Centers, these data management principles are particularly important given our responsibility to manage 'in trust' materials on behalf of the international community, including adding value to them through research. That said, it is logical that these same data management principles should apply for all DSI/GSD derived from all Annex 1 PGRFA in the multilateral system.

Paragraph 32 urges contracting parties, and invites natural and legal persons, holding information associated with PGRFA to make such information publicly accessible. Article 15 institutions should also be urged or requested to share such information.

Paragraph 33 encourages users of PGRFA from the multilateral system to make new information generated on these PGRFA publicly available. One option, as mentioned above, would be to add this requirement in paragraph 6 of the SMTA, making it mandatory. In this case, it may be useful to distinguish which kinds of data recipients should be required to share. It is not necessary to define DSI per se, but it would contribute to legal certainty to list the kinds of information to which this obligation applies, for example, passport data, genomic sequence data.

Paragraphs 33 also encourages users of PGRFA to support capacity building efforts so that DSI can be used and shared to achieve the objectives of the Plant Treaty and food security. In this context, we note that, in 2023, as part of Resolution 16/2023, the 10th Session of the Governing Body

> "Welcomes and acknowledges the technical assistance ... undertaken by the CGIAR Centers in order to reduce the existing gap on capacity regarding generation, access to and use of DSI/GSD and recommends that this work be continued and strengthened."

Capacity strengthening to help developing countries and countries with economies in transition to generate, store, use and share DSI is essential in its own right. It is also a potentially very important 'trust-building measure' that should be considered as a complementary component of the overall package of measures to enhance the multilateral system of access and benefit-sharing. For this reason, CGIAR is currently consulting with the Plant Treaty Secretariat and a number of national and regional programs about options for following-up on the recommendation in Resolution 16/2023 to scale up DSI-related capacity strengthening. We therefore suggest adding the following sentence at the end of Para 33:

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[3] See https://www.gida-global.org/care

[4] The full report is available at https://openknowledge.fao.org/server/api/core/bitstreams/8ffa72f6-126e-48cd-b576-51f0e7d4032a/content

- *encourages* the CGIAR and Plant Treaty Secretariat, in partnership with other organizations, including regional organizations, to develop a Flagship Program on DSI Capacity Sharing under the framework of the Plant Treaty's Capacity Strengthening Strategy.

Under a proposed new section on benefit-sharing

We suggest adding a new section to the Resolution dealing with Benefit sharing. We make this suggestion partly because paragraph 15 ALT addresses the disbursement of funds from the International Benefit-sharing Fund, but it is included at the end of the section dealing with revisions to the SMTA. It does not fit there. Furthermore, there are other issues related to benefit sharing that should be addressed in the Resolution.

CGIAR has heard from a range of national partners over the years that they feel they are missing out on benefit-sharing under the multilateral system because their proposals for projects to be supported by the Plant Treaty's International Benefit-sharing fund have not been selected to date. To address tensions associated with this issue, we suggest that the resolution should state that the Governing Body

- *decides,* as a trust-building measure, that some portion of funds from the International Benefit-share fund will be set aside for commissioned projects in countries whose proposals have repeatedly not been selected through the competitive process.

Another possible trust building measure -- to address some contracting parties' and stakeholders' concerns that insufficient PGRFA is actually being made available to date through the multilateral system-- would be for the Governing Body to:

- *decide* that eligibility for funding (or to a portion of funding) from the International Benefit-sharing Fund will depend upon countries' making materials available through the multilateral system, or taking demonstrable steps to doing so, or explaining through notifications to the Secretariat/Governing Body why they are unable to do so (e.g., they have no collections, or the materials are not viable, they do not have enough stock multiplied to be able to send out samples, etc).

An added benefit of this approach is that it would help to identify outstanding capacity building needs for countries to be able to operate under the Plant Treaty framework.

Another trust building measure would be for seed companies to deposit samples of plant varieties, for which IP protections have expired, in national or international collections, thereby making them available through the multilateral system. Of course, recipients are already encouraged to do exactly this under SMTA Article 6.9. And the desire to encourage such deposits is also partly behind the planned review under Plant Treaty Article 11.4, of whether natural and legal persons should continue to enjoy facilitated access. The Article 11.4 review will finally be started at GB 11 in 2025. The status of that review will no doubt have an impact on how this issue can or should be addressed in this Resolution. In the meantime, we suggest including a 'place holder' clause along the following lines in the draft Resolution:

- *strongly encourages* natural and legal persons to deposit samples of plant varieties that are no longer subject to IPR protection, or that are subject to forms of IPR protection that do not restrict their availability for further research, breeding and training, in national or international genebanks, thereby making them available through the multilateral system of access and benefit-sharing.

Under a proposed new section on relationship to other agreements

The Resolution should include a section addressing the relationship between access and benefit sharing under the Plant Treaty (for both PGRFA and DSI), and benefit sharing for DSI under the Kunming-Montreal Global Biodiversity Framework (for DSI). That said, we acknowledge that, since we don't yet know for certain what benefit sharing formula either system will eventually adopt, it is too early to suggest detailed text for this section. So again, we are suggesting the creation of a 'placeholder' section in the Resolution.

We would like to take advantage of this opportunity to suggest a few principles that we feel should inform the relationship between the two systems that are eventually adopted. First, the two systems should recognize each other, and be mutually supportive. Second, ideally, they should adopt benefit-sharing formula that are sufficiently similar (i.e., based on sales of product portfolios) so that it would be relatively easy to know to which system benefit-sharing payments are due. Ideally, for a single product, a user should not be obliged to make payments to more than one benefit-sharing system. But they should, nonetheless, have the advantage of access to all open access DSI (regardless of the kinds of genetic resources from which it was derived). For example, if a Plant Treaty subscriber makes payments on their portfolio of Annex 1 products under the MLS, they should have access to all DSI, including from pathogens that may be necessary for part of the upstream research and development of the commercialized pathogen-resistant Annex 1 varieties/products. And they would not be obliged to make payments under the CBD/KMGBF *because the products are Annex 1 PGRFA Products*. Alternatively, if a company uses PGRFA-derived DSI as part of its research to develop commercial biocontrol agents for crop pathogens, and makes payments to the multilateral benefit-sharing mechanism established under the CBD/KMGBF, it should have access to the open access DSI it needs (including DSI derived from Annex 1 PGRFA), without making additional payments under the Plant Treaty.

C. Regarding suggested additions to the draft SMTA

The fourth paragraph of the Preamble of the SMTA, on lines 21-23 (not 'Agreed Ad Ref') explicitly recognizes the diversity of legal systems with respect to national procedural rules, etc. While this statement may be true, we are not sure why it is being added at this time. It risks sounding like an invitation for countries to move away from the spirit of harmonization and standardization that the Plant Treaty and the SMTA have so far embraced when it comes to dispute resolution through, for example, its reference to the UNIDROIT Principle of International Commercial Contracts in Article 7. Genebanks sending and receiving materials from multiple countries cannot afford to become experts in each country's legal system. As providers of PGRFA to recipients in over 140 countries with the SMTA, CGIAR underscores the importance of maximizing standardization and harmonization of dispute resolution procedures to reduce transaction costs.

Article 6.1 (agreed ad ref) is the same text as currently exists in the SMTA. However, since the SMTA was adopted in 2006, there has been growing interest on the part of agricultural research, civil society and farmer organizations to experiment with materials from national and international genebanks, to see if they perform well 'in the form received' and to scale up 'direct use in production' of those materials, including potentially, commercial production, in the event that they do perform well. The TAC-SMTA/MLS has opined that "PGRFA received under the SMTA can be made available to farmers for direct use for cultivation only if there is a separate express permission allowing for such distribution from the provider that include the material in the multilateral system." Over time, an increasing proportion of materials conserved in genebanks around the world will have been previously received under an SMTA, meaning that an increasing proportion of materials will not be available for direct use without obtaining the permission foreseen by the TAC-SMTA/MLS. The negotiations to enhance the multilateral system provide an opportunity to revisit and expand the potential range of uses by recipients of materials, as listed in Paragraph 6.1 of the SMTA. Expanding the permitted uses of materials to include direct use would promote both sustainable use and food security. It would also increase monetary benefit sharing (assuming that such sales triggered mandatory payments to the benefit sharing fund). This issue can be addressed by adding 'direct use in production' in SMTA article 6.1 as follows:

- The Recipient undertakes that the Material shall be used or conserved only for the purposes of research, breeding, ~~and~~ training and direct use in production for food and agriculture.

Article 6.2 (not 'Agreed Ad Ref'). As noted in the discussion of the draft Resolution above, Article 6.2 could be revised to apply to IPRs over DSI in addition to genetic materials, for example, as follows.

- The Recipient shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under this Agreement, or its genetic parts or components, in the form received from the Multilateral System, and/or to DSI/GSD derived therefrom.

Article 6.9 (not 'Agreed Ad Ref'). As noted in the discussion of the draft Resolution above, Article 6.9 could be revised to require recipients to make DSI/GSD (or some more precise listing of kinds of data derived from the material received) publicly available.

Submission by Germany to notification „NCP GB11-005 – MLS enhancement submission“

Germany appreciates that the negotiations to enhance the MLS have been taken up again and that the „June 2019 draft package“ serves as basis for these negotiations. The EFMLS working group had reached significant consensus in its meeting in June 2019 on major issues relevant for the enhancement process.

The current negotiations focus initially on the three „hotspots“ DSI, expansion of Annex I, and structure and payment rates. These are three essential elements that deserve thorough discussions and reaching consensus on how they will be addressed in the enhancement package.

The ongoing negotiations provide the opportunity to also address issues of the MLS not strictly related to the enhancement, which are however very relevant for the full and effective implementation of the MLS, from which the implementation of an enhanced system will benefit.

Two aspects deserve clarification in our view in addition to the three hotspots:

1) Use of the SMTA for domestic transfer of material
2) Transfer and use of PGRFA under the MLS for direct use for cultivation

1) Use of the SMTA for domestic transfer of material

In order to provide equal conditions for all providers and users of material contained in the MLS, the provision of MLS material to users should be carried out by using a SMTA also in cases where the material is transferred to domestic users. This would also support the aim of enhancing the monetary benefits generated by the system, as no provision of MLS material for the purposes defined under the Treaty would be carried out anymore without SMTA, and hence without a potential monetary benefit deriving from the use of the resource going un-recorded and being lost to the system.

Potential ways of addressing this issue might either be by including appropriate text in the resolution, and/or by adding relevant language to Article 4 – general provisions of the SMTA.

2) Transfer and use of PGRFA under the MLS for direct use for cultivation

Article 6.1 of the SMTA does not address direct use for cultivation of material provided from the MLS. This generates legal uncertainty to providers, and genebanks might refrain from seconding requests for material, if direct use is the purpose of request. The conserved material should be put to the broadest use possible, and one important use of the material can be the direct use in cultivation by farmers where possible.
It is therefore our suggestion that legal clarity should be provided in the enhanced system, whether and how the transfer and use of PGRFA for direct cultivation under the MLS is possible.

The co-chairs might wish to charge legal experts to further examine these two aspects based on the opinions provided by the Standing Group of Legal Experts (SGLE) and to elaborate possible solutions.

Appendix 6

International Seed Federation
Seed is Life

ISF Input to Treaty Notification NCP GB11-005 on the MLS enhancement process

7 JUNE 2024

PREPARED BY THE
International Seed Federation

The International Seed Federation (ISF) is providing the present submission in response to the Notification NCP GB11-005 dated April 30, 2024. As requested in the notification, the present input is focused on issues beyond the three hot spots, which were discussed in-depth during the 11th meeting of the Open-ended Working Group.

General remarks:

The global seed sector has contributed to the enhancement process of the Multilateral System since it was launched by providing valuable suggestions and clear proposals for all the discussions within the Open-ended Working Group. Our intention has been, and remains, to create greater awareness of the commercial seed sector's operational principles needed to improve the MLS. Our goal has always been to make the MLS more attractive to all plant breeders and, at the same time, achieve the goals laid out by the Governing Body at its 5th meeting. In that vein, ISF is providing this submission with comments meant to aid the Co-Chairs in their efforts to re-draft the proposal for an SMTA for review and discussion in September.

Specific comments on non-"hot spot" elements of the June 2019 version of the SMTA:

Article 2 - Definitions:

We note that in the 2019 June version of the SMTA there are several definitions for which alternative texts exist. At this point we do not wish to express preferences as far as those alternatives are concerned, since we understand that – in any case – the redrafting exercise will attempt to consolidate text and eliminate alternatives. Therefore, we await the Co-Chairs' text and will provide any detailed observations of the definitions at a later date. We nevertheless wish to draw the Co-Chairs' attention to the importance of Article 2 for the whole of the SMTA, as a non-"hot spot" issue. It is of key importance that the terms and the language used in the definitions are clear and reflect the realities of the seed business. This is especially important for definitions like "Commercialization", "Product", and "Sales". As such, we are making ourselves available to the Co-Chairs if they wish to consult in an informal and transparent manner during their drafting process.

Article 6 – Rights and obligations of the recipient:

Article 6.1:

We recall that during the 11th meeting of the OEWG-EFMLS the proposal from Canada to broaden the scope of application of the MLS and the SMTA to industrial uses was briefly discussed. In this regard, we would like to note that the SMTA is the mandated agreement for transactions covered by the scope of the MLS. We hope not to see the enhancement process delayed or derailed by a new negotiation on Article 6.1 of the SMTA.

Article 6.8:

As an outcome of the negotiations that took place between 2013 and 2019, benefit sharing payments under Article 6.8 would become mandatory. In other words, in case a subscription system is put in place together with a commercialization-based option, any user choosing the commercialization-based option who successfully commercializes a product incorporating MLS material, will have certain mandatory monetary benefit sharing obligations. We wish to invite the Co-Chairs to pay due attention to the flexibility this important proposed change in Article 6.8 offers to users of MLS material and the benefits it will generate for the benefit sharing fund.

Impact to in-kind services:

It is a well-known fact that seed companies engage in various non-monetary benefit sharing activities in order to support conservation of plant genetic resources. As part of these activities, seed companies commonly get preselected sets of material from gene banks, which is identified by gene bank curators as critical for seed increase. Very often, the material also needs additional characterization, such as taxonomic classification, phenotypic description, etc. Seed companies then regenerate and/or characterize the material as an in-kind service to gene banks. Fresh seed stock of the material, with the characterization information, is subsequently returned to the gene bank. While being of immense importance for the maintenance of global germplasm collections, this activity is of limited commercial or R&D relevance for seed companies. In almost all cases to date, these transactions have been conducted under the terms and conditions of the SMTA. Under the current system this does not raise any issues. However, the Co-Chairs will need to pay due attention to make sure that such activities can continue in the future MLS, as they are vital for the local / national gene bank.

Impact on Collaborations/Exchange of material:

Another important element that requires attention from the Co-Chairs in their proposal of the new MLS, is the exchange of material by or between breeders in both the public and private sectors. According to the terms and conditions of the SMTA, both material and material under development have to be transferred with an SMTA.
While this paragraph has significant overlap with a “hot spot” issue, we feel it is important to make the following points. With some species, it is common for companies to have so-called crossing agreements with each other, which means that they exchange pre-commercial breeding lines with the aim of building on each other’s breeding progress. In case such breeding material incorporates MLS material, the exchange needs to be done under the terms and conditions of the SMTA. The economic consequences of future benefit sharing modalities and payment mechanisms of the MLS may have a significant impact on breeders’ ability to exchange materials with others. This may also create a hurdle for collaborations between private seed sector actors and public entities such as universities or public research institutes, including for capacity building and non-commercial technology transfer. We believe that the Co-chairs must not underestimate the importance of such cooperations amongst breeders for innovation and progress in breeding. Therefore, we invite the Co-Chairs to think through carefully what implications the future MLS may have on such activities and how the biggest freedom to operate and cooperate could be sustained.

Annex 2:

We understand that all details of the different benefit sharing modalities are still to be further elaborated in the revised Co-Chairs text. Nevertheless, in relation to point 3(c) of Annex 2, we would like to underline that the genetic contribution of the material to the final product, as a threshold for payment obligations, has been a long-standing and much needed improvement to the SMTA. We underscore that it continues to be one of our priorities. We appreciate that currently it is not decided whether or not a single access option will be retained, however, we wish to signal to the Co-Chairs that changes to the numbers determined for the threshold of incorporation or their removal could significantly impact the attractiveness of the future system.

Article 8.5 – Sanctions:

Article 8.5 foresees a liability of the recipient for damages in case of a proven breach of Article 6.1 or 6.2. In order to comply with the need to provide legal certainty to users of the system and also to those who might be involved in any dispute settlement, we invite the Co-Chairs to determine the framework as unambiguously as possible to avoid spending unnecessary resources on dispute settlement, whereas those resources are clearly much needed for innovation.

Final Comment

We urge the Co-chairs to keep in mind that reasonable, user-based payments may not meet the expectations of many Parties for the funds needed to support the conservation and sustainable use of PGRFA globally. These expectations could be a significant obstacle in achieving the enhancements needed to make the MLS workable, effective, and sustainable in the long-term. Further on, plant breeders already make important contributions to the conservation and sustainable use of PGRFA through their activities. The financial contribution expected to be made by them should take this into account. We therefore encourage the Co-chairs to do their best to bring Parties and stakeholders to reasonable and realistic financial expectations in this process.

Appendix 7

Japan's submission on Reference number NCP GB11-005 (MLS enhancement submissions)

To: ITPGRFA Secretariat

More than 150 countries and regions are already members of the ITPGRFA, and member states and secretaries are entitled to be praised for this remarkable accomplishment. However, some regions and countries have not yet joined this treaty. Greater number of country's commitment is required to make PGRFA a more robust and efficient mechanism. , we would like to discuss the steps that Contracting Parties should take in addition to the three hotspots in the future.

FROM:

Ms. Azumi YOSHIOKA

Global Environmental Affairs Office,

MIDORI Sustainable Food Systems Strategy Division,

Minister' s Secretariat,

Ministry of Agriculture, Forestry and Fisheries

REVIEW ON THE "JUNE 2019 DRAFT PACKAGE" OF THE MULTILATERAL SYSTEM OF INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE (ITPGRFA)" BY NATIONAL INSTITUTES OF BIOTECHNOLOGY MALAYSIA.

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is indeed an essential global agreement that upholds the principles of conservation, sustainable use, and fair sharing of plant genetic resources, thereby contributing significantly to global food security and agricultural development. It serves as a vital framework for preserving plant genetic diversity, fostering international collaboration, and promoting equitable benefit-sharing.

However, in the context of Malaysia, where biodiversity is exceptionally rich and diverse, it is imperative to ensure that our unique genetic resources are adequately protected and secured while deriving benefits from their utilization. Therefore, it is crucial for Malaysia to approach the implementation of the treaty with a keen focus on safeguarding our biodiversity and ensuring that our national interests are effectively represented and upheld.

Referring to the June 2019 Draft Package (https://shorturl.at/oKL46), here are our comments as follows:

1."ITEM 4. CO-CHAIRS' PROPOSAL ON ENHANCING THE FUNCTIONING OF THE MULTILATERAL SYSTEM. #No.21."

In our opinion, digital sequence information/genetic sequence data (DSI/GSD) could raises several important issues and few points need to be considered:

1. Equitable benefit sharing: The recognition that benefits from the use of DSI/GSD on genetic resources should be shared fairly and equitably reflects a growing awareness of the need to address issues of access and benefit sharing in the realm of genetic resources. However, determining what constitutes fair and equitable sharing can be challenging, especially considering the diverse interests and stakeholders involved.
2. Policy complexity: The evolving international policy landscape surrounding DSI/GSD underscores the complexity of regulating information that can have significant implications for biodiversity, biotechnology, and beyond. Developing effective policies requires navigating a myriad of legal, ethical, and technical considerations.
3. Definitional clarity: The divergence of opinions regarding the need for a definition of DSI/GSD highlights the ambiguity surrounding the term. Clarifying this definition is crucial for ensuring consistent interpretation and implementation of policies related to DSI/GSD.
4. Monetary benefit-sharing mechanisms: The mention of subscription options as a potential solution for monetary benefit-sharing raises questions about the feasibility

and effectiveness of such mechanisms. Further exploration is needed to understand how subscription models could be structured to ensure fair compensation for the use of DSI/GSD while also promoting innovation and access.

5. Gap Analysis: Examining how the "June 2019 draft package" deals with DSI/GSD and identifying remaining gaps is a critical step in enhancing policy measures related to genetic resources. Addressing these gaps will require concerted efforts from policymakers, scientists, industry stakeholders, and civil society to develop comprehensive and inclusive frameworks.

2. ITEM 5. DEVELOPMENTS IN OTHER RELEVANT FORA, INCLUDING OUTCOMES OF COP-15 OF THE CONVENTION ON BIOLOGICAL DIVERSITY. #No.26.

Malaysia acknowledges the importance of monitoring developments in other relevant forums of the United Nations, particularly in regard to Digital Sequence Information (DSI) and Genetic Sequence Data (GSD). While recognizing the recommendation for continued collaboration between the Secretariats of the International Treaty and the Convention on Biological Diversity (CBD), Malaysia emphasizes the paramount importance of safeguarding its rich biodiversity. As a nation blessed with diverse plant genetic resources, Malaysia stresses the need for strong coordination within Contracting Parties to ensure that any policies and decisions made at the international level consider the unique context and interests of Malaysia. It is imperative that solutions proposed by the International Treaty align with Malaysia's national priorities, including the protection and sustainable management of its biodiversity.

Furthermore, Malaysia emphasizes the significance of addressing intellectual property rights (IPR) issues related to plant genetic resources. The potential implications of unauthorized access to genetic materials and the patenting of traditional knowledge associated with plant varieties must be acknowledged and addressed. Malaysia calls for greater recognition of the contributions of local communities and indigenous peoples to the conservation and development of plant genetic resources, and for mechanisms to ensure that their rights are respected and protected.

Malaysia urges for proactive measures to be taken to address potential challenges or threats posed by emerging policies and frameworks, particularly those related to DSI/GSD. This includes advocating for robust mechanisms for monitoring and regulating the exchange of genetic materials to prevent unauthorized access and biopiracy, as well as ensuring that biosafety measures are in place and compliance with regulations.

Malaysian Pepper Board (MPB) currently offers access to two genetic databases dedicated to black pepper. These databases represent genetic repositories which are accessible through the official MPB website.

However, MBP wishes to make known the existence of the regulatory framework governing the utilization of genetic resources sourced from Sarawak. Based on Sarawak Biodiversity Ordinance of 1997, any exchange, whether for research or commercial purposes, of seeds, seedlings, or cuttings originating from Sarawak, is subject to legal compliance with this ordinance. Adherence to these regulations is essential to ensuring the ethical and legal utilization of genetic resources from this region.

Furthermore, in the context of the pepper industry, varietal differences are the major key factor in producing pepper product with different quality. Malaysia has the advantage in terms of varietal diversity, especially variety with good aroma properties. Thus, the sharing of genetic resources or planting materials may threaten the industry in the long run.

Near East Suggestions

Referring to your notification letter regarding the regions invitation to provide written submissions on elements of the June draft package other than the three hotspots (digital sequence information/genetic sequence data, expansion of Annex1, and payment structure and rates) provided by the Governing body in resolution 3/2023. The Near East region highlights the following points to that maybe considered to advance the negotiations on these elements:

1. Enhance collaboration with other treaty intercessional groups and underscore the necessity to liaise closely with the:

•Standing committee on the funding strategy and Resource Mobilization (funding committee) for:

- Updating the methodologies and discussing the targets for the Funding Strategy and the Benefit-sharing Fund.
- Considering non-monetary benefit sharing (the discussion of a method for measuring non–monetary benefit sharing for developing countries and the high –income countries contracting parties that lack experiences (strategy development ,training, technology transfer, etc.))
- Considering monetary benefit-sharing fund, involving the food processing industry in the benefit-sharing fund as this sector is one of the main beneficiaries of PGRFA
- Reaffirming that benefits arising from the use, including commercial, of plant genetic resources for food and agriculture under the Multilateral System shall be shared fairly and equitably through the exchange of information, access to and transfer of technology, capacity-building, and the sharing of monetary and other benefits arising from commercialization, as provided for in Article 13.2 of the treaty
- Compliance committee, to assure availability of the material contained in the Multilateral System .
-

2. Enhance collaboration with other instrumental bodies, on top of which the Convention on Biological Diversity at international, regional and national levels , particularly in implementing its Kunming- Montreal global biodiversity framework and its targets especially targets of sharing interest between the 2 conventions and the related long-term strategic framework for funding ,capacity building and development .In addition to strengthening collaboration with Crop Trust in conserving and making crop diversity available for use globally under the MLS.

3. Prompting voluntary contributions made by Contracting Parties (especially Contracting Parties that are developed countries), the private sector, NGOs and other sources to the Benefit-sharing Fund, as an important trust-building measure in light of the enhancement of the Multilateral System.

4. Invite contracting parties, especially developed country contracting parties, to provide resources and support to developing country contracting parties to build capacities in conservation and sustainable use of PGRFA.

5. The rights of farmers to conserve exchange and use the material that is available in the Multilateral System. In addition, excepting the public institutions involved in research and breeding in developing countries from any payment obligations arising out of access and use of Material from the Multilateral System.

6. Ensure the efficient and transparent implementation of the Multilateral System.

NOTIFICATION NCP GB11-005 – MLS ENHANCEMENT SUBMISSIONS

29 May 2024

Dear Mr Nnadozie,

Subject: Submission from Pacific Island Contracting Parties on elements of the "June 2019 draft package"2 *other than* the three "hotspots"

1. The question of "Direct release"

The Multilateral System (MLS) of the Treaty facilitates for the access of Plant Genetic Resources for Food and Agriculture (PGRFA). The terms and conditions of this facilitated access are captured in Treaty Special Material Transfer Agreement (SMTA) as a binding agreement between the Provider and the Receiver of the PGRFA. The PGRFA accessed under the SMTA can only be used for the purpose of breeding, research or training.

Contracting Parties in the Pacific Islands, along with many other developing countries, demonstrate limited capacity for plant breeding, including basic conventional methods. Therefore, the utilisation of MLS material to derive new 'products' as currently defined under the SMTA is not feasible. It is essential to adapt the SMTA's definitions and provisions to enable the direct application of these resources in agricultural practices aimed at enhancing food security and environmental resilience as predominant in most developing SWP countries.

Food security and livelihoods in Pacific Island Countries are severely threatened by the effects of Global Climate change and traditional food systems need to adapt to the changes. Diversification with integration of new crops but also better adapted crop varieties is an important strategy to counter those threats.

Without the necessary capacity to conduct plant breeding, the only other available option to increase the diversity in crops and varieties is for public institutions as the main and often only institutions with some capacity to conduct agricultural research, is to introduce new crops and crop varieties, evaluate, select and directly release such accessions as improved varieties to farmers. The most important provider for this diverse PGRFA are the Consultative Group of International Agricultural Research (CGIAR) Centres and other international and regional genebanks like the Centre for Pacific Crops and Trees (CePaCT), as the Pacific's main regional genebank. This is not only for the diverse PGRFA available in their collections but also because such centres are deemed safe and secure by National Quarantine Services to import "seed". Access of PGRFA from other lesser known genebanks often involve costly import risk assessments to satisfy requirements by National Quarantine Services to import this PGRFA.

However, since this material can only be supplied using a SMTA by CGIAR and other international genebanks and a direct release of PGRFA in its original form accessed from the MLS under a SMTA is generally not allowed, Pacific Island Countries and other developing countries face a major dilemma in accessing and using PGRFA necessary for addressing their food security needs.

The current assumptions embedded within the SMTA favour crops that are amenable to easy breeding and rapid commercialisation. This framework neglects the unique agricultural challenges faced by Pacific Island Countries, where many crops essential for local food systems are difficult to breed (e.g. banana or yam) and classify under traditional marketable paradigms. Some crops have very long breeding cycles (e.g. coconut and breadfruit) or the contribution of MLS material in the

“final product” is difficult to ascertain (e.g. sweetpotato improvement using polycross nurseries). Therefore, an amendment to the SMTA is necessary to broaden the definition of 'products' to include those derived through direct use applications, ensuring equitable benefits to all Contracting Parties.

Pacific Island Countries have donated thousands of accessions into the MLS, many of them actually introduced into the current international genebanks before the Convention on Biological Diversity (CBD) or Treaty came into force, yet the lack of plant breeding capacity as the only mechanism to create a “product” in the definition of the current SMTA is severely limiting the use of the MLS and poses questions of what the benefits are for Pacific Island Countries of being a Contracting Party to the Treaty.

In light of the outlined challenges, Pacific Island Countries kindly requests the Co-Chairs and the ad Hoc Working Group to revise the SMTA to incorporate a 'Direct release' option. This revision should include strict guidelines and monitoring mechanisms to ensure that such releases are used solely to address local food security and adaptive needs, and not for commercial exploitation. Furthermore, the definition of 'Product' within the SMTA should be expanded to accommodate the realities of agricultural development in regions facing significant climatic and ecological challenges.

2. Submission on Hotspot issues

a) Expansion of Annex 1:
The Region is in general support of the expansion of Annex 1 to include all PGRFA given that there are several qualifying conditions for this expansion. However, there is a need for a clear definition of non-food crops to guide Contracting Parties and Genebanks in using appropriate instruments for facilitation of access to PGRFA. E.g. are coffee, cocoa, noni, spices etc food crops or not. What is the main criteria that would make a PGRFA a non-food crop?

b) Digital Sequence Information (DSI)/Genetic Sequence Data (GSD) Access and Benefit Sharing:
The Region supports the development of a Treaty specific Access and Benefit Sharing (ABS) solution. However, the Region shares the concerns expressed by other Contracting Parties and representatives of Civil Society and Farmer Groups on “unauthorised” patents or other access restrictions imposed on the DSI/GSD generated from the physical PGRFA in the MLS, in particular patents on genes conferring traits specific to the physical resource accessed. This may require a further clarification on Article 12.3 (d) “that no Intellectual Property rights can be taken out on “genetic parts or components” of the physical resource” and if that includes the DSI/GSD derived from it.

Yours sincerely

Birte Nass-Komolong on behalf of Pacific Island Contracting Parties

We would like to thank you, the Working Group members, for your productive work and constructive spirit. We also thank the Co-chairs for their commitment and wise guidance, which facilitated the successful conclusion of the tasks it requested from the Working Group.
During the meeting April 16-18, 2024, Co-Chairs prepared an overview of the "June 2019 draft package" and presented its main content. The "June 2019 draft package" covers all three elements referred to in Resolution 3/2022: a draft text for an amendment to Annex I of the International Treaty, a revised draft of Standard Material Transfer Agreement (SMTA), and a draft resolution of the Governing Body with proposed implementation measures.
At its Ninth Session the Governing Body had decided that the resumed process for the enhancement of the Multilateral System should build upon previous progress and achievements both in terms of structure and content and address, in a balanced manner, all three blocks of the package of measures developed previously (revised SMTA; expansion of Annex I; implementation measures through a Resolution). At its Tenth Session, the Governing Body considered the Checkpoint Report of the Co-Chairs on progress regarding the process for the enhancement of the functioning of the Multilateral System and requested the Co-Chairs to give special attention to the three identified "hotspots", namely digital sequence information/genetic sequence data (DSI/GSD), expansion of Annex I, and payment structure and rates (which are not the subject of this submission).

1) With regard to the draft **amendment to Annex I of the Treaty**, our position is that the optimal solution would be to include all taxa of food and agricultural importance from gene resource collections under state management and not covered by intellectual property rights. The group of plants should include, for example, herbs, among others, spice herbs, aromatic herbs, herbs with unique medicinal properties (medicinal plant raw material), herbs with preservative properties (antioxidative and antimicrobial properties) and improving the organoleptic properties of food and products used for food production (herbal substances that correct taste, smell, consistency, etc.).
2) In terms of the draft revised **SMTA (Standard Material Transfer Agreement),** we are of the opinion that the possibility of a single access option should absolutely remain. The individual fee is a good solution for scientific units. It may be difficult to obtain multi-year funding for the subscription system. On the other hand, it is quite simple to plan and account for a single access to MLS in the costs of a research project.

   <u>In addition, we would like to pose a few questions regarding this section:</u>
   In the draft SMTA, in Article 6.5 e), there is a stipulation that materials "under development" in which there is less than 12.5% MLS material and at the same time do not contain commercially significant features (trait of commercial value, page 19 of the "Draft Package") introduced from the material. On what basis will the presence or absence of this significant feature be evaluated? If the material is, for example, a line containing a resistance gene and there is a marker for it, the situation is simple. If, on the other hand, it is a breeding line with many commercially important traits improved with, for example, with New Genomic Techniques - how to verify this? What to do in a situation where the commercial value of a trait may be debatable (Null-Lox trait in a feed barley variety).

What would be **the method of verification** if the trait of commercial value was contributed by material from MLS? Only molecular markers?

3) Comments on **a draft resolution** of the Governing Body with proposed implementation measures:

page 8

In **point (b)** "Enhancing the functioning of the Multilateral System by additional measures", we agree with it. However, we propose to add the words: "among others, by involving scientific units, including state research institutes, in the activities".

Apart from these comments, the text of the draft resolution of the Governing Body with proposed implementation measures, is appropriate and acceptable.

Point 14 (page 10). We prefer the first option:

"*Emphasizes the importance of the Multilateral System to enable access to plant genetic resources for food and agriculture to a wide range of users, in particular family farmers, indigenous peoples, small plant breeding companies and public institutions, and in doing so, agrees to exempt from the requirements of benefit-sharing in the revised Standard Material Transfer Agreement users that have less than [XX] seed sales a year and requests each Contracting Party to inform the Governing Body how these terms are defined in its respective national jurisdiction*" - this option is more precise, simple and transparent. We assume that if the sales level is set high enough, Polish breeding companies could potentially benefit from the exemption.

Point 15 (page 10). We prefer the first option:

"Requests the Committee of the Funding Strategy to prepare possible criteria for allocation of funds by the Benefit-sharing Fund, that could take into account, inter alia, payments made by entities in a given country; whether a country has ratified the amended Annex I and is actively sharing the material through the Multilateral System and has made its material fully available" - this option is more precise, simple and transparent.

Point 31 (page 12) – We agree with the sentence: "*Reaffirms that, in accordance with Treaty Article 12.3.c, all available passport data and, subject to applicable law, any other associated non-confidential descriptive information, shall be made available with the plant genetic resources for food and agriculture provided under the Multilateral System*".

but we would like to supplement it with a scientific (agricultural research) point of view:

1. Identification of the samples at the strictest possible taxonomic level – species, subspecies, variety (sequence information/genetic sequence data).
2. Origin of samples to be provided, informing the place of the *in situ* obtaining, even when obtained from *ex situ* sources.
3. Information about the samples and the storage conditions.
4. The number of containers, volume and weight. This is information that is relevant to the Gene Bank and, if known, can be provided when submitting material to the CGIAR institution (the corresponding form in the database).

Others points are appropriate.

ARTICLE 1 — PARTIES TO THE AGREEMENT (page 15)

All points are appropriate for SMTA.

ARTICLE 2 — DEFINITIONS (page 15)

All definitions are corrected.

Page 16. We prefer second definition:

"Sales" means the gross income received by the Recipient and its affiliates in the form of license fees [for Plant Genetic Resources for Food and Agriculture] and from commercialization. [and from commercial use of genetic sequence data.]

Justification:

This definition is an extension of that included in the current SMTA. The proposed changes result from planning to expand passport data to include the results of genetic sequencing tests. The intellectual property (or patent) of the authors of the breeding plant variety may be sold under license (licensing is one of the forms of commercialization and the license agreement is a bilateral agreement). In Poland, the exclusive right to the variety is granted by the Research Centre for Cultivar Testing (Centralny Ośrodek Badania – Odmian Roślin Uprawnych COBORU), COBORU also has a list of protected varieties and their breeders and licensees who have received licenses. In Poland, the exclusive right to a variety is hereditary.

Second definition is more narrow. PGRFA research, breeding and commercialization could be only a part of company activity.

However, theoretically, in the case of licenses granted under specific contracts, it is easy to determine the volume of production. In the case of charging on the basis of the amount of product produced, we may have to deal with quite a large error, for example, part of the product produced may not be used for seeding purposes and reclassified as feed or food.

Page 16. We prefer second definition:

"To commercialize" means to exchange Plant Genetic Resources for Food and Agriculture [or any associated information including genetic sequence data] 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, nor shall it include the sale of commodities and other products used for food, feed and processing.]

Justification:

The meaning of this definition is included in the applicable SMTA (Standard Material Transfer Agreement). In this context "Plant Genetic Resources for Food and Agriculture" means "Product" obtained after the breeding process.

For propagation materials, the target commercialization is the sale of materials used for seeding/planting and production of the next generation.

PGRFA from MLS is used by scientific institutions for research. Breeding companies use its genetic potential for creating new varieties and sell seeds, the main income being licence fees.

*) Products for food, feed and processing are sold by farmers who usually do not use PGRFA from MLS.
*) Breeding companies also sell grain for feed, this is usually the resulting post-cleaning remnants and mixed untreated grain from trials. The genetic potential of such material, however, does not therefore classify it as PGRFA.

Moreover, the glossary could be completed in the following definitions:
- **Legal entity**: consists of a group of people or goods, endowed legal own personality and legally constituted.
- **Natural person**: any person capable of acquiring civil rights and duties.
- **Research** - experimental or theoretical activity carried out on genetic resources or associated traditional knowledge with the objective of building new knowledge by means of a systematic process that creates and tests hypothesis, describes and interprets fundamentals of observed phenomena and facts.
- **Technological development** - systematic work on genetic heritage or associated traditional knowledge based on existing procedures resulting from research or from practical experience carried out with the objectives of developing new materials, products or devices, or improving or developing new processes, for economic exploitation.
- **Associated Traditional Knowledge** - information or practice of indigenous population, traditional community, or traditional farmers about the properties, or the direct or indirect uses associated with genetic heritage.
- **Product notification** - declaration document required prior to economic exploitation of a finished product or reproductive material originating from access to genetic resources or to associated traditional knowledge in which the user declares compliance with the requirements of this Act and indicates the modality of benefit-sharing, when applicable, to be established in the benefit- sharing agreement.
- **Shipment** - transfer of a sample of genetic heritage, intended for access, to an institution located abroad, in which responsibility for the sample is transferred to the recipient institution.

ARTICLE 3 — SUBJECT MATTER OF THE MATERIAL TRANSFER AGREEMENT
The sentence is correct.
ARTICLE 4 — GENERAL PROVISIONS
All points are appropriate for SMTA.
ARTICLE 5 — RIGHTS AND OBLIGATIONS OF THE PROVIDER
All points are appropriate for SMTA.
ARTICLE 6 — RIGHTS AND OBLIGATIONS OF THE RECIPIENT
All points are appropriate for SMTA.
ARTICLE 7 — APPLICABLE LAW
The sentence is correct.
ARTICLE 8 — DISPUTE SETTLEMENT
All points are appropriate for SMTA.
ARTICLE 9 — ADDITIONAL ITEMS

All points are appropriate for SMTA.

ARTICLE 10 — SIGNATURE/ACCEPTANCE

The sentence is correct.

Annex 3. It is correct.

Annex 4. It is correct.

Additional remarks:

We accept the provisions allowing selected entities to be exempted from fees. Those participants in the system who should be allowed to use it free of charge should be properly recognized. Farmers, scientific units and small and medium-sized enterprises (SMEs) or those below a designated (low) production level. Here it should be noted that potentially Polish breeding companies will not be able to benefit from this mechanism. According to the EU definition on SMEs, these companies do not qualify. An opportunity may lie in negotiating an appropriate level of seed production.

We also draw your attention to the subscription fee rates. On page 10 of the "Draft Package," (item 14) there is mention of fee exemption below a certain value of seed sales. In contrast, App.2, Annex 3: Terms and conditions of the subscription system, Monetary Benefit Sharing, page 27 of the "Draft Package") mentions % rates on sales of PGRFA products.

Maybe it is a mental shortcut on page 10, but it seems that the basis for calculating the fee rate and fee exemption should be the same. In addition, the principle of exemption from fees below a certain amount of seed sales automatically exempts research institutions, universities from subscription fees, but it may also be the case that material that is not seed but is PGRFA (tissue cultures, seed potatoes...) will be collected, crossed and multiplied and then sold.

In addition, we want to draw attention to another aspect.

Area which is less exploited are **the rights of farmers to PGR conservation**.

It is necessary to explore opportunities and the possibility of strengthening multilateral access and benefit-sharing funding mechanism with focus on local communities.

It is vital to ensure that, notwithstanding the obligations and conditions laid down in the revised Standard Material Transfer Agreement, rights of farmers and indigenous communities to conserve, exchange and use the material that is available in the Multilateral System are preserved; and the public institutions involved in research and breeding in the developing countries are exempted from any payment obligations arising out of access and use of material from Multilateral System.

Additional thoughts on the payment system

The proposal for a one-time extension of the annex to all species seems better and more logical. Gradual extension to individual species can not only be lengthy, but given the need to ratify the treaty changes, there is a concern that it will not be up to date in all countries. In such cases it will be a big problem for the breeder to check each time what is the status in a given country.

The MLS subscription system as presented is beneficial for those who obtain materials for breeding work on a regular basis, and it seems that it may be better and more efficient than the CBD/Nagoya Protocol. Access is also easier due to the standardization of SMTAs and exchange rules which allow for quick access to materials. However, domestic breeders use the materials that the Treaty regulates very infrequently, and with the exorbitant subscription price, it would be valuable to be able to get single access. For the sake of such breeders, of whom there are probably more in Europe, we support the idea of single access.

The subscription system of payments related to the commercialization of products obtained using the PGRFA is more attractive from the point of view of the administrative burden, because under this system the Subscriber makes annual benefit sharing payments based on product sales over a period of 10 years. This system will also enable more precise and long-term forecasting of proceeds to the Benefit Sharing Fund. However, since payment rates and other payment-related issues, such as fee waiver options, have yet to be determined, it is difficult to assess at this stage whether the introduction of a subscription system will actually increase the benefits of the Multilateral System. High subscription fee rates may be a limiting factor in the use of the PGRFA, especially by users who only want access to a single species rather than an entire group of plants. Given this, in our view, **it would be more beneficial to include both a subscription system and single access.**
Whichever payment system is in place, the key issue is to have regulations in place to enforce it.

By submitting this contribution, Poland declares that it will continue to participate in this important process of enhancing the MLS and will look forward to the new material that will be prepared by the Co-Chairs for the group's meeting in September.

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Federal Department of Economic Affairs,
Education and Research EAER

Federal Office for Agriculture FOAG
International Affairs and Food Systems

Appendix 13

Submission from Switzerland:

Inputs for drafting the Co-Chairs' negotiating text for enhancing the MLS -

Non-hotspot issues

General comment

Switzerland would like to thank the co-Chairs for the opportunity to make a submission. Since the start of the process to enhance the multilateral system of the ITPGRFA (eMLS), Switzerland has been, and remains, committed to contribute to building a more efficient and operational solution.

Firstly, we would like to stress the need and urgency to improve the current system, particularly given the increasing complexity of the legal environment over genetic resources and the very special character of the MLS. The eMLS process is a unique chance to build a future-proof system for PGRFA and all the stakeholders dealing with them.

Switzerland advocates for a simple solution that works in the large majority of cases and that is practical and workable, equitable and transparent, that provides legal certainty and is aligned with general practices and needs of providers and users of PGRFA. We need to collectively seize this momentum to arrive at such a solution at GB11, and we look forward to continue working with the co-Chairs and working group towards achieving this goal which is in our grasp.

Non-hotspot elements for the co-Chairs' proposal

1. *Revised SMTA*

   As a general comment, we would like to highlight that the revised SMTA needs to be practical for all actors of the sector while drawing lessons on the experiences gained after many years of implementing the current SMTA. In particular:

   a. Definitions: In the June 2019 draft SMTA, the definition of Sales and Commercialization (Article 2) are still bracketed; it is important that the proposed definition is fully understandable by the private sector and compatible with its general practices.

   b. Reporting requirements should be clearly defined for both providers and recipients, taking particular care that small entities are able to adequately fulfill them.

   c. Clarify the terms for withdrawing from the subscription system

At this stage, the "June 2019" SMTA is difficult to read, as depending on the model chosen (subscription only or subscription and single access) different articles as well as different annexes apply. In order to fully understand the revised SMTA and facilitate further discussions, we would encourage the co-Chairs to present a clean version of the SMTA focusing on the subscription mechanism only, with the understanding that nothing is off the table at this point in the negotiation process.

2. *Resolution*

We encourage the co-Chairs to pay particular attention to the following elements:

- A simple transition phase that allows to build trust and that provides legal certainty as well as incentives for joining the new system, both for Contracting Parties (CP) and users.

- Clear rules on what happens to existing SMTAs rights and obligations once a user becomes a subscriber.

Dear Co-chairs,

This message is provided in response to notification NCP GB11-005, inviting submissions on non-hotspot elements of the "June 2019 draft package". The United States appreciates the opportunity to provide input for the co-chairs consideration in developing a draft negotiating text.

The suggestions provided below draw from previous U.S. submissions, and focus on elements identified as needing further work in the reports from two virtual consultations organized by the government of Switzerland ahead of GB-9.

Dual system: subscription and single access options -

The United States remains of the view that it is necessary to maintain the single access option (6.7 and 6.8) for the MLS to align with Treaty article 13.2 d)ii.

As floated at WG-EFMLS-11, it might be possible to consider an upper limit on the number of unique accessions that an individual or institution may access through the MLS within one calendar year under the single access option. For users accessing materials through the MLS in excess of this limit would be required to do so through a subscription. This would incentivize use of the subscription model while simultaneously preserving the single access option.

Threshold for exemption from payment under the subscription option -

For exemptions from payments under the Subscription Option, we support using a simple approach that exempts users whose annual sales do not reach a certain threshold, for example USD $5,000,000 per year.

Definitions –

The United States reiterates support for the following definitions to be included in Article 2 of the SMTA:

Definitions of Sales:

"Sales" means gross income received by the Recipient and its respective affiliates from licensing PGRFA to third parties and from commercialization.

Definition of Affiliates:

"One corporate body is affiliated with another corporate body if one of them is the subsidiary of the other or both are subsidiaries of the same corporate body or each of them is controlled by the same legal person"

Definition of Trait of commercial value:

“Trait of Commercial Value” means any inheritable and measurable trait that confers significant commercial value to a Product, including but not limited to agronomic traits, traits conferring resistance to biotic or abiotic stresses, traits that enhance the nutritional or processing value of harvested commodities, and any other traits used to describe a Product for the purpose of promoting its commercialization.

Thank you for your consideration of these proposals.

With kind regards,

Katlyn Scholl
Foreign Affaris Office
Office of Conservation and Water
U.S. Department of State

Ministerio
de Ganadería,
Agricultura y Pesca

Dirección General
de Recursos Naturales

Montevideo, 31 de mayo 2024.-

Estimado secretario del TIRFAA
Sr. Kent Nnadozie
Estimados Copresidentes del Grupo de Trabajo Especial de
Composición Abierta para Mejorar el Funcionamiento del Sistema Multilateral
Estimados de la secretaria del TIRFAA

Con sumo agrado nos dirigimos ante Uds., en respuesta a la notificación sobre el "*Proceso de mejora del funcionamiento del Sistema Multilateral. Invitación a presentar aportaciones para la elaboración del texto de negociación de los Copresidentes*", con fecha 30 de abril de 2024.

En referencia al párrafo 11 se solicita al grupo de trabajo que oriente a las partes contratantes sobre el término *"que están bajo la administración y el control de las partes contratantes y son del dominio público".*

En referencia al Apéndice 2 del citado documento, teniendo presente lo referido en el párrafo 27, se proponen los siguientes textos alternativos, marcando en negrita texto a incluir y tachado como propuesta a eliminar:

En referencias a las fechas, se propone cambiar por el siguiente texto: **a partir del 1° de julio del año siguiente al órgano rector que aprobó el nuevo ANTM.**

4. *Decide* que, sin perjuicio de las obligaciones y condiciones establecidas en el ANTM revisado, se preserven los derechos de los agricultores y las comunidades indígenas de conservar, intercambiar y utilizar el material disponible en el Sistema multilateral, y que las instituciones públicas **estatales y no estatales** que participan en actividades de investigación**, capacitación** y mejoramiento en los

países en desarrollo estén exentas de la obligaciones de pago derivadas del acceso al material del Sistema multilateral y la utilización del mismo.

7. BIS No queda claro el fundamento de porque una persona física o jurídica receptor de un material de un centro CGIAR, deba realizar un genotipado, esto tiene un costo o tramitación complicado para determinados receptores. Se sugiere eliminar.

Por seguridad jurídica y contralor de las partes contratantes se proponen: 14 ALT y 14 ALT BIS

15. *Pide* al Comité sobre la Estrategia de financiación que elabore ~~posibles~~ criterios para la asignación de recursos financieros por el Fondo de distribución de beneficios, **para la consideración del órgano rector** ~~que podrían tomar en cuenta~~, **teniendo en cuenta** entre otras cosas, ~~los pagos realizados por entidades de un país determinado~~; ~~el hecho de~~ que **sea beneficiaria una entidad de** un país **que** haya ratificado el Anexo I enmendado **y** ~~o~~ que comparta activamente ~~el~~ material a través del Sistema multilateral ~~y haya puesto a disposición todo su material.~~

23. Se solicita mayor claridad jurídica en el texto de este parrafo en referencia a si los cultivos o especies anexadas sean solo en *conservación ex situ*, mientras que las del actual Anexo 1, seguirán incluyendo tanto *ex situ* como *in situ.*

26. En este párrafo surge la siguiente duda: ¿Como funcionaria el órgano rector, solamente en el sistema multilateral habría dos instancias y en los otros temas funcionaria como un órgano rector?

27**.** Se sugiere aclaración jurídica al respecto de lo expuesto en este parrafo, en referencia a los siguientes temas: ¿Cuál es el tiempo que se maneja para el número mínimo de ratificaciones para que entre en vigor el Tratado enmendado?

¿En ese tiempo si un país quiere ratificar solo podrá hacerlo al Tratado enmendado? ¿Una vez que entre en vigor el Tratado enmendado, si un país no lo ha ratificado aún, rige el Tratado en su versión original?

32. Insta a las Partes Contratantes e invita a las personas físicas y jurídicas que posean información relacionada con los recursos **fito**genéticos para la alimentación y la agricultura a poner dicha información a disposición del público, por ejemplo, mediante su vinculación al Sistema mundial de información.

34. Invita a las Partes Contratantes, en especial las que son países desarrollados, a proporcionar recursos y apoyo a las Partes Contratantes que son países en desarrollo y a las Partes Contratantes con economías en transición para fomentar la capacidad en materia de acceso a la información asociada con los recursos **fito**genéticos para la alimentación y la agricultura, y de utilización de dicha información.

37. Se solicita una opinión de la legalidad de los puntos mencionados en este párrafo.