

Agenda Item 4
For Strategic Guidance

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Genetic resources policy issues for consideration by the CGIAR System Management Board

Introduction

1. The purpose of this paper is to provide the CGIAR System Management Board (SMB) with information about risks to CGIAR associated with three genetic resources policy-related issues as described in the following table:

Issue	Risk Family	Opportunities and Risk indicators
Issue 1: CGIAR response to Plant Treaty's Governing Body Resolution 4/2017	Poor execution undermines capability	Adequate use of intellectual property and licensing tools maximizes accessibility and/or impacts including via the production of International Public Goods
Issue 2: CGIAR Statements on biotechnology, gene editing and digital sequence information	Non-adherence to appropriate values	Ethical research practices employed to achieve research results, ethical behaviors by all staff and contractors
Issue 3: CGIAR engagement in process to improve Plant Treaty's multilateral system of access and benefit-sharing	CGIAR loses its central role in Agricultural Research for Development	Intellectual assets produced by CGIAR are managed innovatively and leveraged by the scientific and development communities

2. This paper also provides options for action by SMB, based on its consideration of the associated risks.

Issue No 1: CGIAR response to ITPGRFA Governing Body Resolution 4/2017 requesting Centers to provide information about Intellectual Property policies, licensing strategies, compliance with Intellectual Assets Principles

3. In April 2018, the SMB considered Resolution 4/2017 which was adopted by the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) which,

Invites the CGIAR System to provide the Governing Body, through the Secretary, with the annual reports concerning the status of the implementation of the CGIAR Principles on the

Management of Intellectual Assets that relate to germplasm that the CGIAR Centers manage under the framework of the International Treaty, including in cases where such germplasm, parts thereof, or information generated from the use of this germplasm are the subject matter of patent or plant variety protection applications, or are included in partnerships that qualify as restricted use or limited exclusivity agreements pursuant to the CGIAR Principles.¹

4. The SMB noted “the risk to CGIAR’s reputation/ability to operate if the Governing Body in 2019 finds that CGIAR Intellectual Assets Reports do not provide adequate information, and adopts a resolution to increase the power of Secretariat and GB to require information on an ad hoc basis from CGIAR.” The SMB also “recommended that the System Organization and CGIAR Centers work together to make additional information available to the Governing Body through expanded annual Intellectual Assets reports and/or other means.”
5. Since the SMB made these recommendations, the Policy Module and the CGIAR System Management Office (SMO) have worked with Centers to: a) increase the amount of relevant information that was included in the 2017 Annual CGIAR IA Management Report and that will be included in the 2018 CGAIR IA Management Report; b) support Centers to make more regular and detailed public disclosures, and c) develop webpages with consolidated information on Centers’ disclosures related to PGRFA under the Treaty framework. (More information about these efforts is included in Annex 1.)
6. There has been significant progress in terms of information generated and publicly shared in the 2017 Annual CGIAR Annual IA Management Report and in some Centers’ independent disclosures. However, some Centers have not yet made independent public disclosures about some of the Limited Exclusivity Agreements (LEA), Restricted Use Agreements (RUA) and intellectual property rights (IPR) that they reported in their annual report to the SMO covering 2017. As such, there is a risk that it will be perceived that Centers disclosures are not yet ‘caught up’ with the system-wide commitments pursuant to the CGIAR IA Principles.
7. The next meeting of the Governing Body will be November 11-15, 2019. In advance of that meeting, the CGIAR System will need to make a submission to the ITPGRFA Secretariat/Governing Body, in response to Resolution 2017.
8. The CGIAR submission to the Secretariat/Governing Body must include the CGIAR Annual Intellectual Assets Management Reports covering 2016², 2017 and 2018. Beyond that, we recommend providing an introductory, overview document which provides background information about System-wide efforts and mechanisms to promote transparency including the development of the IA principles, details about system-wide monitoring processes, links to reports pre-dating 2016, the IEA’s review in 2016 of the IA Principles and the webpages maintained by the SMO with links to Centers’ public disclosures.

¹ The full text of the Resolution 4/2017 is available at: <http://www.fao.org/3/a-mv085e.pdf>

² The 2016 CGIAR Intellectual Assets Management Report was going through the final stages of being approved at the time of the 7th Session of the Governing Body. It was published on line after GB 7.

Option(s) for SMB guidance:

9. It is recommended that that the SMB:
- Request the SMO and the Policy Module, in consultation with Centers, to develop a streamlined, fit-for-purpose, and thorough reporting cycle process and templates as necessary for future annual IA compliance reports.
 - Request the SMO and the Policy Module, in consultation with Centers, to develop new or improved modalities or tools to further transparency in the area of intellectual assets management.
 - Direct all Centers to finalize and publish disclosures about RUAs, LEAs and IP applications flagged in the annual CGIAR Intellectual Assets Management Reports for 2017 and 2018 (and to share those disclosures with the SMO no later than July 2019 (i.e., 3 months before the GB meeting)).
 - Underscore, as it did in 2018, the potential risk to CGIAR’s reputation if the Governing Body in November 2019 i) finds that CGIAR IA Management Reports do not provide adequate information, and ii) adopts a resolution to increase the power of the Secretariat and the Governing Body to require more information from CGIAR.
 - Underscore that it is critically important that the CGIAR submission to the Governing Body in 2019 draws upon and presents Centers’ best practices in terms of compliance with the IA Principles and timely public disclosures.
 - Express appreciation for additional information included in the 2017 CGIAR IA Management Report, and thank those Centers (CIP, IRRI, CIMMYT) who provided additional information for the RUA, LEA and IP applications case studies/examples.
 - Encourage all Centers to proactively provide information about RUAs, LEAs and IP applications for inclusion as representative examples in future CGIAR IA Management reports (including 2018).
 - Recognize the usefulness of the ‘Guidance Note on CGIAR Research Center Public Disclosures related to the Management of Intellectual Assets’ and recommend that all Centers consider them when developing their disclosures.

Issue No. 2: Developing CGIAR statements on biotechnology, genome editing and digital sequence information

10. In 2017, the SMB requested the Genebank Platform Policy Module to review the CGIAR Internal Position on Biotechnology including GMOs (2014) in light of recent developments in genome editing. During its January 2018 meeting, the General Assembly of Centers determined that it would be most appropriate to have two CGIAR communication documents: one focusing on biotechnology including GMOs, and another focusing on genome editing in particular. In April 2018, the System Management Board recommended to Centers that they “revisit the guiding principles [for large scale sequencing projects] developed ad hoc in 2017” and “consider raising their profile (e.g., for a CGIAR Statement on genomic sequence information, conservation sustainable use and benefit sharing).”

11. The Policy Module coordinated a process for developing drafts of the first two CGIAR statements on biotechnology and genome editing, which it submitted to the DG Co-chair of the General Assembly in January 2019. (See Annex 1 for details of CGIAR scientists involved in developing the two drafts.)
12. The Policy Module will coordinate the development of a draft CGIAR statement on genomic sequence information for consideration of the Director Generals/General Assembly after receiving feedback about the two draft statements from the Director Generals/General Assembly (and possibly also the SMB).

Option(s) for SMB guidance:

13. It is recommended that the SMB:
 - Note the potential importance to the reputation of CGIAR to have clear statements related to CGIAR use of biotechnologies, genome editing, and genomic sequence information, and
 - Encourage the Centers to take necessary steps to finalize development of such statements over the course of 2019.

Issue No. 3: CGIAR's engagement in the intergovernmental process to enhance the functioning of the Plant Treaty's multilateral system of access and benefit-sharing

14. The ITPGRFA Governing Body launched a process to enhance the functioning of the multilateral system of access and benefit-sharing in 2013. Since then, there have been 8 meetings of the Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing (WG-EFMLS) and four informal complementary meetings of key stakeholders (including CGIAR). Past updates, reports prepared by the Genebank Platform Policy Module prepared for CGIAR are available.³ The 9th meeting of the WG-EFMLS will take place in June 2019, and the 8th Session of the Governing Body will be in November 2019.
15. For now, past guidance from DGs of Article 15 Centers and the SMB is sufficient to guide CGIAR engagement in these upcoming meetings. However, if new issues emerge, or the rate of negotiation accelerates such that the Governing Body may be in position to adopt a new set of measures by November 2019, the Policy Module will need to revert to Article 15 DGs and SMB for additional guidance in the interim period.

Options for SMB guidance

16. It is recommended that the SMB:
 - note the importance to the CGIAR mission of a successful outcome of the intergovernmental process to enhance the functioning of the multilateral system, and

³ Examples are available [here](#), [here](#) and [here](#). More reports and updates are available upon request.

the importance of CGIAR engagement in that process as supported by the Genebank Platform Policy Module, and

- request the Policy Module to report back to it on the progress of negotiations after the 9th session of the WG-EFMLS which will be held in June.

Annex 1: Additional background information with respect to Issues 1, 2 and 3

Regarding issue 1: CGIAR response to Governing Body Resolution 4/2017

17. After the SMB provided its guidance in April 2017, the Policy Module has worked closely with the SMO to:

- Send a joint message to Center DGs underscoring the need for Centers to i) include more information in the Centers' annual intellectual assets (IA) management reports, ii) be more proactive in publishing their independent public disclosures concerning intellectual property applications, Limited Exclusivity Agreements (LEAs) and Restricted Use Agreements (RUAs) with respect to plant genetic resources developed by the Centers.
- Make presentations to the following groups within CGIAR concerning Resolution 4/2017, the new-found relevance of the annual IA Management Reports to the ITPGRFA Governing Body, the guidance provided by the SMB, and practical means for increasing information in the annual reports and in Centers' own public disclosures
 - CGIAR System Council Intellectual Property Group, May 2018
 - CGIAR Centers' Genebank Managers in April and November 2018
 - CGIAR Centers' Intellectual Property Focal Points (comprising CLIPNet), November 2018
- Review and suggest revisions to relevant sections of pre-publication drafts of the 2017 CGIAR IA Management Report to include more information of relevance to the Governing Body
- Develop the 'Guidance Note on CGIAR Research Center Public Disclosures related to the Management of Intellectual Assets' to help CGIAR Centers writing their public disclosures concerning LEAs, RUAs and intellectual property applications in ways that will respond to issues raised by the Governing Body. The Guidance Note is available [here](#). As part of the process for their development, the guidance note was presented to the CGIAR Genetic Resources Policy Working Group in January 2019, and to Centers' IP focal points in February 2019.

18. In addition, Resolution 4/2017 was considered at the 'Multistakeholder Consultation Meeting convened by the CGIAR Genebank Platform Policy Module' Paris, July 18-19, 2018. While the meeting did not develop consensus recommendations on these points, participants suggested CGIAR could consider the following options: invite a member of the System Council Intellectual Property (SCIP) group to attend future meetings of the multistakeholder consultation group to facilitate discussion with people outside the CGIAR; invite representative of the ITPGRFA Secretariat or Bureau to interact with SCIP group (bearing in mind confidentiality concerns), and/or include an agenda item for future System Council meetings concerning Centers' compliance with the IA Principles (to provide regional representatives on SC an opportunity to gain familiarity with principles, processes, outputs). The report of the multistakeholder consultation meeting is available [here](#).

19. The 2017 CGIAR IA Management Report was published in October 2018.⁴ Compared to earlier years' reports, it includes additional information in the form of:
- expanded examples of Centers' LEAs, RUAs, and patents applications in 2017, (one example of each) with information about the innovations/assets concerned, the problems they are meant to address, why the LEA or IPR were necessary for the further development of the assets concerned or to increase their impact, anticipated distribution strategies, and so on, and
 - the guidance SMB provided in April 2017 with respect to responding to Resolution 4/2017.
20. CGIAR Centers were required to submit their annual IA reports covering 2018 to the SMO by February 28, 2019. The SMO will use those reports to develop the 2018 CGIAR IA Management Report, which will be published in Q3 of 2019. The SMO will work with Centers to ensure that all pertinent information is included in the 2018 report and will consult where necessary to request additional information.
21. Meanwhile, the SMO continues to review the disclosures that Centers share with it and provides support to improve them when necessary. Of course, since the SMO does not know the details of all relevant activities of Centers, it can only reach and out assist if a Center gets in touch on an ad hoc basis, or after it includes information about RUAs, LEAs and IP applications in their annual reports to the SMO. The 2017 Annual CGIAR IA Management report flagged some outstanding disclosures from Centers that the SMO has been following up on with the Centers concerned. In some cases, Centers may make passing references in publications to technologies that are subject to restrictive licenses or intellectual property protections, or about activities that imply that Centers' intellectual assets are being subject to restrictions in the context of larger projects or cooperation agreements. But those publications do not include all the information recommended in communications whose primary purpose is to publicly communicate the arrangements the Centers are entering into pursuant to the IA guidelines.
22. Based on Centers' annual reports covering 2018, the SMO will proactively follow up where they note that disclosures would be timely.
23. In support of transparency, the SMO maintains a webpage which provides links to Centers' public disclosures as provided by Centers. At present, this webpage is not exhaustive and may be perceived to have gaps, particularly by people who have read the CGIAR Annual IA Management Reports. There is no 'hard and fast' rule about when Centers should publish disclosures; however, to protect against the risk to the reputation of CGIAR, it is clearly important for Centers to publish such disclosures before the information ends up being noticed and published about – in potentially inflammatory ways – by some other entity.

⁴ <https://www.cgiar.org/wp/wp-content/uploads/2018/10/CGIAR-2017-Intellectual-Assets-Report.pdf>

24. The SMO is working with the Centers to develop fit-for-purpose mechanisms to improve the IA reporting cycle. During this process, the group will identify how to collect information for inclusion in the annual IA reports as well as complementary modes of public disclosure.

Regarding Issue No. 2: developing CGIAR Statements on biotechnology, genome editing and digital sequence information

25. Early drafts of the draft biotechnology and genome editing statements were developed by a small group including Dave Ellis (CIP), Isabel Lopez Noriega (Bioversity, Policy Module), Rodrigo Sara (consultant, previously with SMO), Ruaraidh Sackville Hamilton (IRRI, Policy Module), Michael Halewood (Bioversity, Policy Module), Marc Ghislain (CIP), David Spielman (IFPRI), Kevin Pixley (CIMMYT), Thomas Payne (CIMMYT), and Joe Tohme (CIAT). Those drafts were then reviewed by the CGIAR Genetic Resources Policy Working Group which includes the groups/scientists listed in table 1. Thereafter, the drafts were revised a third time by members of the initial small drafting group.

Table 1: composition of the CGIAR GR Policy Working Group

CRP/Platform/CoP	No.	Representatives	Centre
Excellence in Breeding	1	Marianne Bänziger	CIMMYT
Big Data	1	Andy Jarvis/Brian King	CIAT
Social scientist network	1	David Spielman	IFPRI
SO	1	Sabrina Segal	SO
Genebank managers – Article 15 Group Executive	3	Dave Ellis/Noelle Angelin Tom Payne Mariana Yazbek	CIP CIMMYT ICARDA
IP focal points/CLIPNet	2	Carolina Roa Teresa Gresl	CIAT CIMMYT
Forest GR	1	Ramni Jamnadass	ICRAF
Science leader group (DDGs, CRP leaders)	-	Marianne Bänziger	-
Policy Module	3	Michael Halewood, Isabel Lopez Ruaraidh Sackville Hamilton	Bioversity IRRI
total	13		

26. It is anticipated that the process of engagement of experts from across CGIAR to develop a draft statement on genomic sequence information will provide opportunities to raise awareness about, and promote, the SMB’s additional guidance in April 2017 that Centers should “[b]uild in and demonstrate/communicate benefit-sharing for developing countries and farmers in genomic sequencing projects, and collectively across the CGIAR System.”

Regarding Issue No. 3: CGIAR engagement in intergovernmental process to enhance the functioning of the multilateral system of access and benefit-sharing

27. The process launched by the ITPGRFA Governing Body in 2013 to enhance the functioning of the multilateral system was prompted largely by the fact that no mandatory payments were made

by commercial users to the international benefit-sharing fund during the first 11 years of the ITPGRFA's operation. To date, there has only been one mandatory payment (triggered by the mandatory benefit sharing conditions included in the standard material transfer agreement (SMTA)).

28. The continued and improved functioning of the ITPGRFA is critically important to CGIAR as it provides a legal basis for CGIAR Centers' transfers of genetic material to developing countries in pursuit of the CGIAR mission. CGIAR benefits developing countries primarily through the so-called "non-monetary" benefit-sharing mechanisms recognized by the ITPGRFA, i.e. (1) delivering superior varieties; (2) sharing information; (3) mediating access to and transfer of appropriate technologies; and (4) building capacity. CGIAR recognizes/respects contracting parties' desire to increase monetary benefit-sharing. However, CGIAR is also cognizant of the risk that revisions to the SMTA intended to generate additional monetary payments from users could inadvertently undermine the use of the multilateral system and the non-monetary benefits that accrue to developing countries through the work of CGIAR.
29. The mandate of the 9th Session of the WG-EFMLS in June 2019 is to finalize a set of measures to enhance the multilateral system for consideration/adoption by the Governing Body in November, 2019. That series of measures would include i) a revised SMTA reflecting new monetary benefit-sharing arrangements designed to increase the flow of money to the international benefit sharing fund from commercial users, ii) agreement on a schedule and process for increasing the scope of PGRFA included in the multilateral system. However, contracting parties are so far apart on a range of issues that is unlikely that the Governing Body will be able to finalize the process. Instead, it will probably have to resolve upon a process to continue negotiations into the next biennium.
30. A major twist introduced over the course of the negotiations is the demand by developing regions that the package of measures adopted by the Governing Body should include mandatory benefit sharing from commercial users of genomic sequence information, effectively extending the scope of the multilateral system from material genetic resources to include associated genomic information. This demand reflects increasingly widespread concern, in particular on the part of developing countries, that technically advanced users may be able to profit from digital genomic sequence information (DSI) without triggering that clause in the SMTA that would obligate them to make payments to the international benefit-sharing fund (because monetary benefit-sharing under the SMTA is triggered by use of material genetic resources). The issue of DSI-related benefit sharing has become a central challenge for the ongoing negotiations. It is also featuring prominently in meetings of the Convention on Biological Diversity, Nagoya Protocol, and the UN FAO Commission on Genetic Resources for Food and Agriculture. This is also a major concern to CGIAR, which increasingly relies on the use of DSI in its work with benefit developing countries. If negotiations lead to inappropriate decisions, the ability of CGIAR to deliver its mission could be severely compromised.
31. In the past, CGIAR has recognized the potential strategic importance of the creation and adoption of a subscription system, whereby subscribers agree to pay a percentage of seed sales for crops in the multilateral system in exchange for access to all PGRFA in the MLS. The

subscription system has the possibility of generating up-front payments from subscribers and substantially lowering users' track and trace-related transaction costs. It could also potentially serve as the basis for addressing outstanding demands for benefit sharing from the use of genetic sequence information, as noted by SMB in April 2017.

32. CGIAR has promoted the introduction of a threshold for subscription payments, whereby subscribers whose seed sales fall below X USD/year (rate to be determined) would be exempt from making subscription payments. Most regions are supportive of this concept, aware as they are of the risk of driving off non-profit and small commercial enterprises from using the multilateral system. However, over the course of the last 6 months, some contracting parties have promoted the idea that all subscribers should be required to submit annual financial statements to the ITPGRFA Secretariat confirming their seed sales. This represents an obligation and transaction cost that many traditional recipients of materials from CGIAR Centers cannot meet. To this end, CGIAR has advocated that annual financial reporting requirements – if imposed – should not be required for recipients whose seed sales fall below the set threshold.