

2016 CGIAR Intellectual Assets Management Report

Purpose

This document presents the 2016 CGIAR Intellectual Assets Management Report, prepared under the CGIAR Principles on the Management of Intellectual Assets (CGIAR IA Principles). This 2016 Report takes a revised format, reflecting the independent observations of the System Council Intellectual Property Group (SC IP Group)'s alongside the System Organization's 2016 reflections.

Action Required:

The Board is requested to review, and if thought appropriate, approve the 2016 CGIAR Intellectual Assets Management Report.

Distribution notice:

This document is an internal document of the System Management Board and should not be publicly shared until deliberations are complete.

Prepared by: CGIAR System Management Office



2016

CGIAR Intellectual Assets Management Report



Prepared by : CGIAR System Management Office



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Foreword

The 2016 CGIAR Intellectual Assets Management Report provides information on the fifth reporting cycle under the CGIAR Principles on the Management of Intellectual Assets¹ (CGIAR IA Principles). This 2016 Report takes a revised format, reflecting the benefit to the reader of presenting the System Council Intellectual Property Group (SC IP Group)'s independent observations² alongside the System Organization's 2016 reflections.

The report is based on the CGIAR Research Centers' (Centers) 2016 intellectual assets reports and subsequent follow-up with them following the review of these reports and discussions on their content between the CGIAR System Organization and the SC IP Group. It also takes into consideration activities conducted by the System Organization and the SC IP Group in 2016 related to implementation of the CGIAR IA Principles.

We value the insights provided by the SC IP Group including three recommendations for the System Organization to consider. We are in general alignment with Recommendations 1 and 2 based on 2016 experiences. Work planning in 2018 between the System Organization and the Centers will consider how to implement these in the most efficient way. Recommendation 3 requires further exploration with the Centers in view of the CGIAR System's revised governance and Centers taking prime responsibility for delivery of many of the shared services functions that underpin our collective efforts to deliver on CGIAR's and Center-own mandates. With a firm commitment to accountability and transparency in all that we as a System do, this Report also identifies how the SC IP Group's 2015 recommendations have been addressed.

By end 2017, the CGIAR System will adopt a Risk Management Framework. The appropriate use of intellectual assets and our focus to continue to maximize their global accessibility and impact will be one of its pillars, to highlight more expressly the strategic importance of effective intellectual assets management in the CGIAR System. A matter of key interest to the System Management Board as we implement a more strategic approach to our business planning cycle over the forthcoming years is to ensure that intellectual assets produced by CGIAR are managed innovatively, and leveraged by the scientific and development communities.

Marco Ferroni
Chair, System Management Board

2016 at a glance

100%

Center Compliance with Article 10.1 of the *CGIAR Principles on the Management of Intellectual Assets* – requiring delivering of a robust Center-specific Intellectual Asset report annually.



All 11 CGIAR Research Centers that host CGIAR Genebanks (termed Article 15 Centers, see Annex 2) have agreements with the Food and Agriculture Organization of the United Nations (FAO), placing their germplasm collections within the purview of the Multilateral System of Access and Benefit Sharing under the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty).

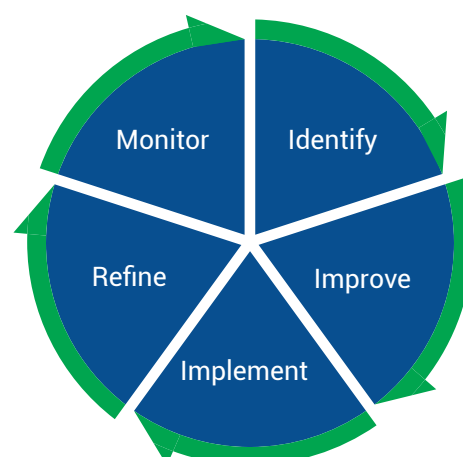


All Article 15 Centers have confirmed they have reported their 2016 Standard Material Transfer Agreement (SMTA) transfers to the Secretariat of the (International Treaty) as required pursuant to the International Treaty.

Additionally, the International Treaty Secretariat confirmed that CGIAR's Article 15 Centers have cleared a reporting backlog relating to previous years. **Over 3.9 million seed samples using 47,810 Standard Material Transfer Agreements have been transferred by CGIAR since the International Treaty came into force on 29 June 2004.** This significant achievement was acknowledged at the 7th meeting of the Governing Body of the International Treaty.

BETTER INTEGRATION OF INTELLECTUAL ASSETS MANAGEMENT IN THE CGIAR PORTFOLIO

All proposals for CGIAR Research Programs (CRPs) and Platforms comprising the 2017-2022 CGIAR Portfolio, which were approved by the System Council in 2016, incorporate effective intellectual assets management strategies designed to maximize global access and impact.



MORE EFFECTIVE MANAGEMENT OF INTELLECTUAL ASSETS IN THE NEW 2017-2022 CGIAR PORTFOLIO WHICH WAS APPROVED IN 2016

Strategic management of intellectual assets by Centers and their partners is essential for realizing CGIAR's global access and impact. The 2017-2022 CGIAR Portfolio seeks to promote more effective intellectual assets management practices through better integration and planning. Specifically, CGIAR Research Programs (CRPs) and Platforms address the following:

- relevance of intellectual asset management to the CRP or Platform, critical issues to address in implementation and anticipated challenges
- project planning and implementation
- key dissemination pathways for maximizing global impact
- operations
- coordination and decision-making
- indicative resources

RESTRICTED AGREEMENTS REPORTED IN 2016 *as further detailed on page 11*

0	4
Restricted Use Agreements	Limited Exclusivity Agreements

PLANT VARIETY PROTECTION AND PATENTS REPORTED IN 2016

0	6	2
Plant Variety Protection filings or authorizations	Provisional patent filings or authorizations	Non-provisional patent filings or authorizations

CGIAR'S 2016 engagement with International Treaty frameworks

The International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty) creates a framework for farmers, research organizations, NGOs, plant breeding and seed companies and governments to coordinate activities conserving, improving and sustainably using Plant Genetic Resources for Food and Agriculture (PGRFA) and to equitably share benefits derived from the use of those resources. CGIAR is committed to fully implementing and complying with the International Treaty.³

The Genebank Platform of the 2017-2022 CGIAR Portfolio contains a policy module, which is co- led by senior staff of Bioversity International (Bioversity) and the International Rice Research Institute (IRRI), which is responsible for coordinating CGIAR activities concerning genetic resource policy issues in international fora, including the activities discussed in the subsections below.

1

Farmers' Rights

Article 3 of the CGIAR IA Principles recognizes the indispensable role of farmers, indigenous communities, agricultural professionals and scientists in conserving and improving genetic resources. Furthermore, Centers are required to respect national and international efforts to protect and promote Farmers' Rights, as envisaged by the International Treaty, and to

support the development of appropriate policies and procedures for their recognition and promotion.

In 2016, CGIAR representatives actively participated in a variety of international fora addressing the access to and use of plant genetic resources for food and agriculture and Farmers' Rights. This primarily involved the various working groups and committees of the International Treaty pursuant to which CGIAR manages the materials in its genebanks and breeding programs.

In 2016, Bioversity published a number of articles highlighting its initiatives to promote and strengthen Farmers' Rights;⁴ to support community seedbanks;⁵

and in relation to community- based agricultural biodiversity management.⁶ The International Potato Center (CIP) organized decentralized meetings in potato growing communities in support of a national consultation by the Peruvian government to ensure that farmers' interests were directly taken into account in the review process. Additionally, a number of webinars were organized by the System Organization to raise awareness of Farmers' Rights under international treaty frameworks, including perceived tensions and sui-generis options for regulatory systems that allow greater flexibility to accommodate informal seed systems, and regarding the rights of farmers to save seed.⁷

2

CGIAR involvement in the review of options to enhance the functioning of the Multilateral System of the International Treaty (MLS)

At its 6th meeting in 2015, the Governing Body of the International Treaty extended the terms of reference of an Ad Hoc Open-ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing (WG-EFMLS), and expanded its mandate to consider issues concerning genetic sequence information and access and benefit-sharing.

The WG-EFMLS's ongoing deliberations – which were further discussed at the 7th meeting of the Governing Body of the International Treaty on 30 October – 3 November 2017 and will continue into the next biennium – could profoundly affect the day-to-day operations of the CGIAR genebanks and breeding programs.

Accordingly, CGIAR has continued to participate as an active observer in the WG-EFMLS to ensure that its views and needs are taken into account. CGIAR representatives comprising CGIAR IP focal points and genebank managers attended the 5th meeting of the WG-EFMLS, held in Geneva in July 2016. Certain modifications were proposed at the meeting regarding the identification of SMTA ancestry pursuant to Article 6.5 of the SMTA. Some of the modifications proposed were not supported by CGIAR Research Centers, prompting a CGIAR submission to draw attention to the operational difficulties associated with such changes.⁸ CGIAR's comments appear to have been favorably received by the International Treaty Secretariat and WG-EFMLS.

Meetings of the WG-EFMLS in 2017, leading up to the Governing Body's 7th meeting, have been particularly important for CGIAR, and submissions by CGIAR to the WG-EFMLS are anticipated to focus on a number of evolving issues being discussed in this fora, including: legal certainty and transaction costs associated with modifications to the SMTA; expansion of the coverage of the MLS; elements of a subscription system including termination of subscription and obligations; viability of a subscription system with upfront payment obligations alongside an accessed-based system with deferred payment obligations; differentiated mandatory payment rates and exemptions from payment obligations; access and benefit-sharing concerning genetic sequence information.

3

Secretariat's review of CGIAR practices related to use of the SMTA

At its 6th meeting in 2015, the Governing Body issued a resolution instructing the International Treaty Secretariat to work with CGIAR Research Centers to gather information on the content of the additional conditions they attach, if any, to the transfer of PGRFA under

Development, and to explore ways of facilitating implementation of the obligation under Article 6.5 of the SMTA to identify material received from the MLS in

Annex 1 to the SMTA. The Secretariat has since conducted a survey to gather this information from Centers and submitted a report⁹ of their observations to the 7th meeting of the Governing Body of the

4

Implementing the Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (Nagoya Protocol) entered into force in October 2014. Unlike the MLS established under the International Treaty, which allows facilitated access to certain PGRFA with a pre-established

framework for access and benefit-sharing, the Nagoya Protocol creates a bilateral system of access and benefit-sharing requiring prior informed consent and mutually agreed terms for benefit-sharing in regard to the access and use of genetic resources and associated traditional knowledge. CGIAR closely monitors regulatory developments concerning the access and transfer of PGRFA in the countries in which it operates, including regarding implementation of the Nagoya Protocol. In 2016, Bioversity obtained a permit to collect and export the seed and leaves of mahogany from community managed forests in the Maya Biosphere reserve of Guatemala. This is the first instance – of which the System Organization is aware – of a Center accessing materials under the Nagoya

Protocol. Bioversity documented the process,¹⁰ and this experience helped to inform draft guidelines that it prepared in 2016 concerning Center operations under the Nagoya Protocol. These guidelines are under development and are expected to be finalized in 2018.

Additionally, Centers were involved in a number of workshops and initiatives in 2016 to promote mutually supportive implementation of the International Treaty and the Nagoya Protocol. These activities are coordinated under the framework of a Joint Program by FAO/Bioversity/International Treaty Secretariat to strengthen the capacity of national partners to implement the multilateral system.¹¹

2016 key topics and SC IP Group's observations and recommendations¹²

1

IP ASPECTS OF RESOURCE MOBILIZATION

System Organization 2016 reflections

Income-generating activities, including the charging of fees or royalties by Centers for providing access to their products and services, are explicitly permitted under certain conditions by the CGIAR IA Principles.¹³ Indeed, the CGIAR IA Principles provide that Centers

can charge reasonable fees beyond costs for providing access to their intellectual assets, on the condition that these commercial activities do not divert them from fulfilling the CGIAR vision. Furthermore, the CGIAR IA Principles require that the revenue generated by the Centers be used to support CGIAR activities and be transparently reported.

Income-generating activities represent a small proportion of Centers' activities overall, with the vast majority continuing to focus on ensuring that intellectual assets are managed so as to maximize global accessibility and impact, most commonly as international public goods. Some examples of activities involving revenue generation include:

- The International Institute of Tropical Agriculture (IITA) has continued to report growth in the commercialization of its Aflasafe™ technology, with the net income from its sales used: 1) to pay for research of national partners, further research on Aflasafe™; and 2) as working capital to upgrade, maintain and build manufacturing facilities. IITA has created a Business Incubator Unit to manage the production and commercialization of Aflasafe™ and NoduMax, another IITA registered technology that improves yields.

- The International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) filed a Patent Cooperation Treaty (PCT) application related to the induction of cytoplasmic male sterility in hybrid crop production, partly due to the commercial potential of the technology.
- CIP signed a conditional Limited Exclusivity Agreement with a breeding company for the collaborative breeding of five tropically adapted potato varieties, with the option to license the improved technology if it becomes commercially viable in the future.¹⁴
- IRRI reported the filing of a number of patents in 2016, some of which have potential commercial applications (as discussed below in Section 2).

As these income-generating activities continue to be considered by Centers as an additional source of funding, and as they potentially increase, it will be important to ensure that the Centers have a mutual understanding of the conditions under which fees or royalties can be charged, and that communications in this respect are carefully managed.

SC IP Group observations

The topic of resource mobilization is particularly relevant at this time, given the uncertain budgetary environment in some donor countries. Consistent with the CGIAR IA Principles, the SC IP Group does not consider the Centers' intellectual property (IP) related commercial activities to be mutually exclusive with the CGIAR vision. The Centers' ability to generate revenue arguably furthers the CGIAR System's sustainability, if that revenue is used strategically to continue funding CGIAR activities. However, commercial activities should not limit poor farmers' access to and use of CGIAR technology, or detract from Centers' primary missions. In addition, resource mobilization may trigger reputational risks, depending on the nature of the activity and the sensitivity surrounding the intellectual assets at issue. This may particularly be the case for Centers seeking patent protection related to the collections of PGRFA that Centers hold in-trust for the benefit of the international community, which is discussed in more detail below in Section 2.

SC IP GROUP RECOMMENDATION 1:

The SC IP Group recommends that the net income derived from Centers' business activities continue to be used in a way that is consistent with the CGIAR vision, and recommends general increased vigilance and monitoring by the System Management Board of the Centers' commercial activities to ensure that:

- 1.1 Net revenue from commercial activities is used to further the CGIAR vision;
- 1.2 Centers provide dissemination plans demonstrating how commercial activities reach poor, smallholder farmers, and that their access to the technologies is not limited in any way; and
- 1.3 Potential reputational risk issues are appropriately anticipated if possible, and proactively addressed.

2

PATENTS AND PLANT VARIETY PROTECTION

System Organization 2016 reflections

The CGIAR IA Principles require that Centers carefully consider whether to register/apply for (or allow third parties to register/apply for) patents and/or plant variety protection ('IP Applications') over the Centers' respective Intellectual Assets. The CGIAR IA Principles state

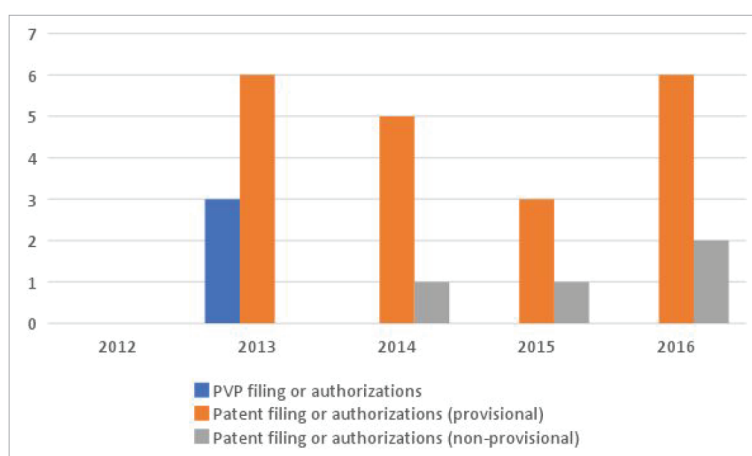
that "IP Applications shall not be made unless they are necessary for the further improvement of such Intellectual Assets or to enhance the scale or scope of impact on target beneficiaries, in furtherance of the CGIAR Vision".

In the 2015 CGIAR Intellectual Assets Management Report, the former Fund Council Intellectual Property Group made several recommendations on the justifications to be provided by Centers with regard to their patent applications. Centers followed up on these

in their 2016 intellectual asset reports, as further detailed in the section Implementation of recommendations from the 2015 CGIAR Intellectual Assets Management Report below.¹⁵

In their 2016 intellectual asset reports, Centers reported a total of six provisional patent applications¹⁶ and two non-provisional patent applications.¹⁷ No plant variety protection applications or registrations were reported. These are consistent with the number of filings observed in recent years, as illustrated in

Diagram 1 – Instances of filings of IP protection (patents and Plant Variety Protection)



Of the six provisional patent applications reported in 2016, the International Livestock Research Institute (ILRI) reported one PCT application, ICRISAT reported one provisional patent application in India, and IRRI reported two provisional patent applications in the USA¹⁸ and two PCT applications.¹⁹ In addition, IRRI reported non-provisional applications in the form of two PCT applications advancing to national filings (one in USA and Australia;²⁰ one in USA and Brazil²¹). Furthermore, IRRI reported on the discontinuation in 2016 of a provisional patent application, two PCT applications and a US utility patent application, each of which had been previously reported by IRRI with accompanying justifications.

The justifications for the patent applications reported by Centers in 2016 were deemed acceptable. However, as experienced in previous years, follow-up was

required by the System Organization in some instances to obtain sufficient information to reach this conclusion. This was in part due to different views on the extent to which Center justifications in support of patent applications should include development, dissemination and communication plans for the technology in question, particularly regarding technologies that are at an early stage of development. There was also a difference of opinion as to the extent to which such reports are required to include coverage of patent filing costs and actual and anticipated research and/or commercial licenses, irrespective of whether they are non-exclusive, as well as ongoing yearly updates on such licenses and costs. The System Organization is working with the SC IP Group and Centers to clarify expectations in this respect, and to set a precedent for reporting that strikes an appropriate balance between the priorities and needs of Centers and CGIAR's funders.

SC IP Group observations

In line with the CGIAR IA Principles, the SC IP Group takes the position that Centers should only seek patent protection strategically when it furthers the CGIAR vision, and that prompt public disclosure should follow the publication of non-provisional patent applications. Patent protection, particularly if related to the collections of PGRFA that Centers hold in-trust for the benefit of the international community, triggers issues of reputational risk, which are particularly sensitive given the range of funders' policies and stakeholders' interests and views. Such timely public disclosure is in line with the Open Access policy and global access principles, and furthers CGIAR's commitment to transparency. By getting ahead of funder and public scrutiny and telling the compelling story of how the patent protection will further the CGIAR vision, it also raises public awareness of the strategic importance of IP and mitigates the potential reputational risk to the System.

Overall, the SC IP Group is satisfied with the justifications provided by the Centers in support of their patent applications filed in 2016. It has, however, notified IRRI that future reporting related to some of its four 'early stage' provisional and PCT patent applications (specifically the provisional patent applications, when moving into national applications), will warrant further justifications and a proactive public communications strategy, in light of the sensitive nature and potential reputational risks, and taking into account the nature of the technology involved. An example is the patenting of traits derived from wild species. Reputational risks only increase over time, as a Center decides to continue with national phase applications for specific country patents, and as a patent protection become more robust.

The two national phase patent applications relate to GM/gene editing technologies. IRRI explained that these patent applications protect GM/genome editing applications and allow for future revenue generation in the countries where the patents are filed (i.e. Brazil and the USA). Given that these patents are entering the national phase, the SC IP Group expects more detailed justifications and information on dissemination strategies (as per the Fund Council IP Group recommendations in the 2014 and 2015 CGIAR Intellectual Assets Management Reports). This information has, so far, not been received. In response to the SC IP Group's follow-up questions, IRRI has indicated that it is presently working to establish a strong proof of concept and is not able to provide more detailed information at this stage, given that there are still many unknowns about the technology and its potential market penetration. In an effort to accommodate the SC IP Group's requests, IRRI has also shared its draft Intellectual Property, Commercialization and Communication Policy. The SC IP Group has reviewed this draft and supports its current contents.²²

SC IP GROUP RECOMMENDATION 2:

The SC IP Group recommends that Centers:

- 1) Publicly disclose all published patent applications on their website once they are registered in the applicable patent database(s), including information on how the patent protection will further the CGIAR vision.
- 2) Provide the required justifications for any patent application to the System Management Office and SC IP Group, including information on:
 - a. the nature of the technology;
 - b. the purpose of filing for patent protection, pursuant to the requirements in Article 6.4 of the CGIAR IA Principles;
 - c. the foreseen dissemination and global access strategy to ensure that they are consistent with the CGIAR IA Principles for national patent applications and, where possible, for provisional and PCT applications.
- 3) Track the scope of impact of the technology and sharing of benefits to advantage the poor, especially farmers in developing countries.
- 4) Flag potential reputational risk issues for patents that move into the national phase for the System Management Board, so that they are proactively addressed.

3

LIMITED EXCLUSIVITY AGREEMENTS AND RESTRICTED USE AGREEMENTS

System Organization 2016 reflections

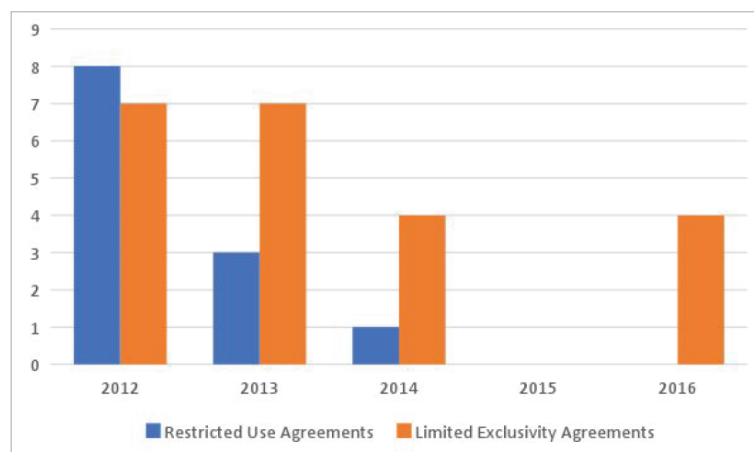
Centers and their partners typically disseminate the outputs of their research and development activities as international public goods. Use by Centers of the dissemination pathways permitted under the CGIAR IA Principles, which involve limited restrictions to global accessibility designed to maximize impact, remain relatively infrequent.

Limited Exclusivity Agreements arise pursuant to Section 6.2 of the CGIAR IA Principles, which permit Centers to grant limited exclusivity for commercialization of the Intellectual Assets they produce, subject to certain research and emergency use exemptions, and provided that certain conditions are fulfilled.

Restricted Use Agreements arise pursuant to Section 6.3 of the CGIAR IA Principles, which permit Centers to acquire and use third party Intellectual Assets that restrict the global accessibility of the products/services resulting from the use of such Intellectual Assets for commercialization, research and development, provided that certain conditions are fulfilled.

In 2016, only four Limited Exclusivity Agreements were reported, and no Restricted Use Agreement was reported. These small numbers are consistent with the equally small numbers observed in the years 2012 through 2015, as illustrated in Diagram 2.

Diagram 2 – Instances of Limited Exclusivity Agreements and Restricted Use Agreements



The justifications for the Limited Exclusivity Agreements reported by Centers in 2016 were deemed acceptable by the System Organization. However, as experienced in previous years, follow-up was required by the System Organization in some instances to obtain sufficient information to reach this conclusion.

System Council IP Group observations

The SC IP Group is pleased to note that the Centers provided appropriate justifications and comprehensive information with respect to the four Limited Exclusivity Agreements signed in 2016, including descriptions of the project, the exclusivity arrangement, and the rationale for how the target beneficiary markets were reached. It is important to note that some of the Limited Exclusivity Agreements reported include options to grant limited exclusivity in the future if the improved technology is commercially viable. The SC IP Group also welcomes the Centers' reporting of these 'conditional' Limited Exclusivity Agreements. While at this stage, these agreements do not directly limit exclusivity, they do include contractual terms that may govern future use, license and exclusivity. The SC IP Group therefore commends the Centers for reporting on these more indirect limitations on exclusivity. In any event, Centers also need to ensure that the terms of any options they grant comply with the CGIAR IA Principles, i.e., limited scope of the exclusivity in terms of geography, duration, etc.

4

IP CAPACITY

System Organization 2016 reflections

Intellectual assets/IP management capacity has remained relatively stable in Centers and the System Organization since an initial increase following adoption of the CGIAR IA Principles in 2012. At the System Organization, intellectual assets management capacity is

assessed to require a 50% full-time equivalent support. Subsequent recruitments of IP and business development specialists have modestly strengthened this capacity at Centers. Further strengthening of, and better coordination between IP and business

development specialists across the System is needed to meet the partnership and scale-up demands of the CGIAR Portfolio 2017-2022, and to address the evolving opportunities and risks faced by Centers in relation to intellectual assets management.

System Council IP Group observations

The System Council is pleased to see that some Centers have increased IP capacity. However, the IP capacity of the System Organization appears to have decreased to one part-time IP lawyer in 2016, apparently as a result of the legal demands created by the transition. The SC IP Group is concerned whether this decreased IP capacity may affect future work at the System Organization in support of the IA Principles and System-wide IP leadership.

SC IP GROUP RECOMMENDATION 3:

The SC IP Group recommends that the System Organization increase its IP capacity to:

- 4.1 Coordinate more CLIPnet events that further a community of practice and cross-fertilization among Centers. This is in line with previous years' recommendations.
- 4.2 Support Centers that may have less IP capacity to remain in compliance with the SMTA, the CGIAR IA Principles, other treaties and IP related initiatives.

- 4.3 Support the Centers in providing sufficiently comprehensive justifications for patenting that include dissemination and global access strategies in their public disclosures and justifications.

- 4.4 Provide advice and support regarding the Centers' commercial activities to ensure that reputational risks are addressed appropriately, and in a timely manner.

5

Policies related to intellectual asset management

Centers' ongoing policy development and revisions reported in 2016 demonstrate that they continue to strive to improve their policy framework across a broad range of topics related to implementation of the CGIAR IA Principles, including: compliance with the Nagoya Protocol's

access and benefit-sharing requirements concerning genetic resources and traditional knowledge (ILRI and Bioversity); research ethics and informed consent (ICARDA); images and human dignity (ILRI);

germplasm, genome editing and biosafety (CIMMYT); public private partnerships (IRRI and World Fish); open access and data management (World Fish, CIMMYT, CIP).

Implementation of recommendations from the 2015 Intellectual Assets Management Report

This section provides updates on the five recommendations of the SC IP Group presented in the 2015 CGIAR Intellectual Assets Management Report.

Recommendation 1

Part 1: *"That all Centers – and IRRI in particular -- develop and report on their market and dissemination strategy plans in line with the CGIAR Vision as part of the 'justifications' for any patent application and, where possible, for any provisional or PCT patent application in the future."*

The System Organization updated the Q&A tool that provides best practice guidance to Centers to clarify expectations regarding the justifications to be provided by Centers in support of patent applications. All Centers that reported patent filings or registrations in 2016 included information concerning their market and dissemination strategy plans as part of their justifications.

Part 2: *"IRRI should also follow specific recommendations outlined in Section 8.2.3 [of the 2015 CGIAR Intellectual Asset Management Report]²³ with respect to the patent application on methods associated with increased grain yield involving a novel 'SPIKE' gene."*

In its 2015 report, IRRI reported national stage filings in 7 countries on its previously reported PCT application regarding a method for producing a rice plant with improved grain yield, specifically replicating the gene SPIKE²⁴ – a gene that IRRI identified from a rice landrace. While the 2015 CGIAR Intellectual Assets Management Report explained why IRRI's justification was satisfactory at that early stage of patent protection, the report strongly encouraged IRRI to pursue a transparent and proactive communication strategy with respect to this patent, given the sensitivities surrounding the protection of a method related to a 'native trait'. In response to this, IRRI initiated discussions at senior management and board level to consider an appropriate balance between disclosures for transparency and operational needs for managing confidential or commercially sensitive

information. As part of this process, it established a specialized committee of IRRI's board of trustees to develop policies and protocols governing IRRI's management of IP and commercialization. In addition, after IRRI's patenting of the SPIKE gene triggered questions from donor countries, members of FAO and civil society organizations, representatives of IRRI, the System Organization and Bioversity coordinated a response which satisfactorily addressed the issues raised, and IRRI posted information on its general approach to intellectual asset management on its website.²⁵ This was recently updated to include an Intellectual Property, Commercialization and Communication Policy approved in October 2017 by IRRI's board of trustees.²⁶

In its 2016 report, IRRI provided the following updates regarding the SPIKE gene patent:

- 1) The final version of an Intellectual Property Management Agreement with the Japan International Research Center for Agricultural Science (JIRCAS), its co-owner on the technology and IP, was signed in February 2017.
- 2) IRRI decided to a) pursue the SPIKE gene patent application only in Japan (JIRCAS), India, the Philippines and the USA because those countries provide better environments in which to conclude commercial licensing agreements; and b) let the patent applications lapse in Thailand and Vietnam.
- 3) IRRI signed several non-exclusive R&D licensing agreements with third parties.

IRRI shared the final executed agreement with JIRCAS concerning the ownership and management of the IP involved in the SPIKE trait. Additionally, IRRI provided updates regarding the development of the technology, including the research and commercial license agreements that it had concluded, or was in the process of negotiating.

SC IP Group observations

The SC IP Group is pleased to confirm that the terms of IRRI's IP Management Agreement with JIRCAS protect dissemination pathways of the technology to reach target beneficiaries and preserve ample latitude for IRRI to advance the CGIAR vision and strategy of providing broad access to IRRI's intellectual assets. The SC IP Group regrets that IRRI, despite the recommendations given in the 2015 IA report, did not pursue a pro-active communication strategy regarding this patent given the sensitivities surrounding the protection of a method related to a 'native trait'. The SC IP Group continues to insist that IRRI provide more public information on how this patent will further the CGIAR vision, and to share with the System Office and SC IP Group a more detailed dissemination plan and/or global access strategy.

Recommendation 2

"That as part of the annual reporting process, the System Organization provide in its consolidated report a section on all patent protection sought by Centers."

The System Organization provided the SC IP Group with access to a register that it maintains and periodically updates, which tracks patent applications, registrations and updates reported by Centers.

Recommendation 3

"That Centers continue to share their IP related policies, best practices and effective IP strategies and models with the System Organization and other Centers."

The System Organization continued to update the online portal and repository it maintains to facilitate sharing by IP Focal points of their Center's IP related policies, best practices, templates, models, etc.

Recommendation 4

"That the System Organization's report include a section on how the Centers and System Organization have implemented the SC IP Group's recommendations included in the prior year's review."

The inclusion of this section in the current report addresses this recommendation.

Recommendation 5

"That Centers are strongly encouraged to include in their annual Center IA Reports, a status report of their IP Portfolio, material updates concerning the progress of the Limited Exclusivity Agreements, Restricted Use Agreements and patents/PVPs they have previously reported (i.e. as part of their Part 1 general reporting concerning partnerships or dissemination pathways, or in Part 2 if the update contains confidential information). Such updates should include progress against any development, dissemination, risk management and/or communications plans (or other material attribute) that forms part of the justifications approved by the System Organization and the SC IP Group, and should also include public communications made in this regard."

The System Organization updated the Q&A tool to clarify expectations on the provision by Centers of updates regarding previously reported arrangements. Some Centers included updates in their 2016 reports. The System Organization is currently developing a tool to assist Centers in providing periodic updates in a more consistent manner.

Reflecting on 2017 and beyond

Review of CGIAR IA Principles

The CGIAR IA Principles have recently been the subject of a review carried out by the Independent Evaluation Arrangement (IEA), the purpose of which is "to assess whether the [CGIAR] IA Principles and their implementation is advancing the achievement of their intended purpose to maximize the global accessibility and impact of CGIAR research".²⁷ The review assesses the appropriateness and effectiveness of the policy, as well as the efficiency and transparency of its implementation. It also assesses the oversight exercised by the System Organization, the SC IP Group and the System Council. The System Organization looks forward to considering and responding to the findings and recommendations of this review in consultation with Centers.

Oversight arrangements

There is an opportunity to look into, and potentially adjust, the role of the SC IP Group, taking into account the revised governance structure of the CGIAR System and, in particular, the function of the standing committees of the System Council and System Management Board. In this respect, it will be important to understand how oversight of compliance with the CGIAR IA Principles fits into the Risk Management Framework which is being developed for the CGIAR System. This is particularly relevant considering the reputational risks involved in IP commercialization or patent protections, and the appropriate linkage of the SC IP Group within the principle of providing 'combined assurance'.

SC IP Group observations

These potential adjustments to the oversight role of the SC IP Group should be done in consultation with the SC IP Group members and more importantly with donors, and should adhere to the principles of independence and access to Centers' information. These principles guided the donors' creation of the SC IP Group to ensure proper oversight and transparency. The SC IP Group welcomes the opportunity to provide comments on alignment of the SC IP Group's oversight function with the CGIAR System Risk Management Framework.

Annex 1

Mandate and composition of the SC IP Group

The role of the System Council Intellectual Property Group (SC IP Group) is to facilitate coordination between the System Council and the CGIAR System Organization (System Organization) by working in cooperation with the System Organization with regard to implementation of the CGIAR IA Principles, and advising the System Council in order to enable it to provide adequate oversight of intellectual asset management in CGIAR.

The SC IP Group receives all 15 Centers' intellectual asset reports, which include information and justifications about the Centers' Limited Exclusivity Agreements, Restricted Use Agreements, and patent and plant variety protection applications.

In order to safeguard the sensitive or confidential nature of the material contained in these reports, or of additional information requested by the SC IP Group, this information is received on an in-confidence basis

by the SC IP Group. The SC IP Group then filters this internal information to produce high level observations and strategic recommendations to both the System Organization and the System Council.

Through to 31 December 2017, the SC IP Group comprises the following three members, who serve in their personal capacity and not as representatives of their affiliated organizations:

- Paul Figueroa, USAID (Chair)
- Aline Flower, Bill and Melinda Gates Foundation
- Bram De Jonge, Wageningen University

SC IP Group members are appointed by the System Council for a two-year term on the basis of demonstrated expertise and practical experience in the management of intellectual assets and IP rights. They may serve for more than one term.

Annex 2

The Article 15 Centers

All 11 CGIAR Research Centers that host germplasm collections in CGIAR Genebanks (termed Article 15 Centers) have agreements with the Food and Agriculture Organization of the United Nations (FAO) placing these collections within the purview of the

Multilateral System of Access and Benefit-sharing of the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty). Pursuant to these agreements, Article 15 Centers hold and manage these collections in trust, for the benefit of humanity.

The Article 15 Centers are:

Center (short name)	Center (full name)
AfricaRice	Africa Rice Center
Bioversity	Bioversity International
CIAT	International Center for Tropical Agriculture
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
ICARDA	International Center for Agricultural Research in Dry Areas
ICRAF	World Agroforestry Center
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute
IRRI	International Rice Research Institute

Annex 3

Glossary

AfricaRice	Africa Rice Center
Bioversity	Bioversity International
Centers	Independent research organizations that are recognized as CGIAR Research Centers as defined in the CGIAR System Framework (presently comprising AfricaRice, Bioversity International, CIFOR, ICARDA, CIAT, ICRISAT, IFPRI, IITA, ILRI, CIMMYT, CIP, IRRI, IWMI, ICRAF and WorldFish)
CGIAR System	When taken together as a collective whole, the CGIAR System refers to the Research Centers, the Funders, the System Council, the CGIAR System Organization, advisory bodies and CGIAR Research, as defined in the CGIAR System Framework
CGIAR IA Principles	CGIAR Principles on the Management of Intellectual Assets
CIAT	International Center for Tropical Agriculture
CIFOR	Center for International Forestry Research
CIMMYT	International Maize and Wheat Improvement Center
CIP	International Potato Center
CLIPnet	CGIAR Legal and IP Network
CRP	CGIAR Research Program
FC IP Group	Fund Council Intellectual Property Group
IA	Intellectual assets
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
ICARDA	International Center for Agricultural Research in Dry Areas
ICRAF	World Agroforestry Center
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
IFPRI	International Food Policy Research Institute
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute
International Treaty	International Treaty on Plant Genetic Resources for Food and Agriculture
IP	Intellectual property
IRRI	International Rice Research Institute
IWMI	International Water Management Institute

MLS	Multilateral System of Access and Benefit-sharing of the International Treaty on Plant Genetic Resources for Food and Agriculture
Nagoya Protocol	Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity
PCT	Patent Cooperation Treaty
PGRFA	Plant Genetic Resources for Food and Agriculture, which are defined in Article 2 of the SMTA as "any genetic material of plant origin of actual or potential value for food and agriculture"
PGRFA under Development	"Material derived from the Material, and hence distinct from it, that is not yet ready for commercialization and which the developer intends to further develop or to transfer to another person or entity for further development" as defined in Article 2 of the SMTA
PVP	Plant variety protection
Q&A	Question and answer
SC IP Group	System Council Intellectual Property Group
SMTA	Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture
WG-EFMLS	Working Group to Enhance the Functioning of the International Treaty's MLS

Endnotes

- 1 Available at
<https://library.cgiar.org/bitstream/handle/10947/4486/CGIAR%20IA%20Principles.pdf?sequence=1>.
- 2 See mandate and composition of the SC IP Group in Annex 1.
- 3 As reflected in Section 4.2 of the CGIAR IA Principles.
- 4 Available at
https://www.bioversityinternational.org/fileadmin/user_upload/BI_Contributions_Lopez.pdf.
- 5 Available at
https://www.bioversityinternational.org/fileadmin/user_upload/Supporting_Community_Seedbanks_Clancy.pdf.
- 6 Available at
https://www.bioversityinternational.org/fileadmin/user_upload/Realizing_Farmers_Rights_Clancy.pdf.
- 7 The 2016 webinar series is accessible via
<https://sites.google.com/a/cgxchange.org/clip-net/webinars-archive/2016>
- 8 The CGIAR submission is available at <http://www.fao.org/3/a-br413e.pdf>
- 9 The Secretariat's Report on the Practice of the CGIAR Centers for Plant Genetic Resources for Food and Agriculture under Development is available at <http://www.fao.org/3/a-mu281e.pdf>
- 10 An abstract is available at <https://cgspace.cgiar/handle/10568/78144>
- 11 Further information regarding these activities is available in a CGIAR report submitted to the Governing Body for its 7th meeting on 30 October – 3 November 2017, in Kigali, Rwanda.
- 12 The findings, opinions and recommendations discussed in more detail hereafter represent the SC IP Group members' professional views in their advisory role to the System Council and do not necessarily reflect the views of the organizations or entities with which the members are affiliated.
- 13 Article 7 of the CGIAR IA Principles.
- 14 The agreement concerns a joint breeding project where both parties contribute their gene pool and know-how to develop new varieties adapted to sub-tropical conditions. The objective is to have new varieties available to farmers via commercialization, with a benefit-sharing scheme which will involve monetary returns to HZPC, CIP as well as the Benefit-Sharing Fund of the International Treaty on Plant Genetic Resources for Food and Agriculture. A press statement about the collaboration is available at <https://cipotato.org/press-room/blog/experts-link-improve-south-asias-potatoes/>.
- 15 See Recommendation 1.
- 16 Provisional patent applications lock in a priority date and require an additional filing to mature into a patent registration (e.g. PCT applications and national level provisional applications as are available in certain countries such as USA and Australia).

- 17 Non-provisional patent applications are capable of advancing directly to registration if approved (e.g. PCT patent applications advancing to national filings; national non-provisional applications such as non-provisional utility applications in USA).
- 18 On Plants Exhibiting Resistance to Herbicides, Methods of Producing Same and Uses Thereof, and Development of Non-Transgenic Salt Tolerant Rice Breeding Lines through Inter-Specific Gene Transfer from *Oriza Coarctata*.
- 19 On Increased Hybrid Seed Production through Higher Outcrossing Rate in Cytoplasmic Male Sterile Rice and Related Materials and Methods, and Semi-Dwarf Drought Tolerant Rice and Related Materials and Methods.
- 20 On Drought-Resistant Cereal Grasses and Related Materials and Methods, and Anaerobic Germination-Tolerant Plants and Related Materials and Methods.
- 21 On Anaerobic Germination-Tolerant Plants and Related Materials and Methods.
- 22 IRRI's Intellectual Property, Commercialization and Communication Policy has since been approved by IRRI's Board of Trustees and is available at <http://irri.org/images/downloads/Approved-IPC- Policy-291017.pdf>
- 23 Section 8.2.3 of the 2015 CGIAR Intellectual Asset report provides that "given the sensitive nature of the patent, i.e., seeking protection of a method related to a native trait derived from a landrace, the FC IP Group strongly encourages IRRI to a) share its final agreement with JIRCAS with the Consortium upon execution, along with any other licensing agreements concerning the patented method that may be signed in the future; b) promote and track the scope of impact of the technology and sharing of benefits to advantage the poor, especially farmers in developing countries; and c) pursue a transparent and pro-active public communications strategy with respect to its IP management in this regard".
- 24 The application sought to patent a method described as follows:
 a) providing a first rice plant comprising a gene SPIKE;
 b) transferring a nucleic acid encoding gene SPIKE from the first rice plant to a second rice plant;
 c) analyzing the second rice plant for the gene SPIKE;
 d) identifying and selecting a second rice plant comprising the gene SPIKE and exhibiting improved grain yield when compared to the second rice plant prior to the transfer.
- 25 Available at <http://irri.org/our-impact/technology-transfer>
- 26 Available at <http://irri.org/images/downloads/Approved-IPC- Policy-291017.pdf>
- 27 The terms of reference of the IEA's review are available at <http://iea.cgiar.org/evaluating/review-of-intellectual-assets-principles-of-cgiar/>

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