

Workshop of the Alliance Deputy Executive (ADE) of the CGIAR Centers Dialogue and the Private Sector Committee (PSC)

Workshop II (13 November 2009):

Associated Needs for Product Stewardship and Liability

Background information and summaries of the two studies

Context

Discussions in Workshop II will be based on two studies that have been commissioned by the CGIAR Science Council (SC) in consultation with the Central Advisory Service for Intellectual Property (CAS-IP). These studies follow a recommendation of SC and the Genetic Resource Policy Committee (GRPC) arising from the commentary on three commissioned studies on intellectual property and its use in a public goods context in 2006,¹ where it was noted that “Guidelines to credible product stewardship regimes” on the responsible management of third party IP are needed, development of which should be “based on CGIAR and NARS experience to date and the expectations of the private and public sector IP donors”. Furthermore, “issues regarding liability” should be part of the intellectual property guidelines which are formulated for the CGIAR system “in order to ensure clearer understanding of liability at CGIAR and NARS level.”

According to the Terms of Reference, the objectives of the studies are:

(1) Clear product stewardship guidelines for Centers wishing to use third party IP for technologies/products with an IPG nature. It will outline various types of product stewardship required/expected by the private and public sector IP providers, and how Centers can work to meet such requirements/expectations. It will also clarify the requirements for NARs partners, who will act as the primary conduit for delivering the products of innovations stemming from the IP to the poor.

(2) A definition and detailed description of ‘liability’ for use by CGIAR Centers and NARs partners. The study will highlight different types of liability issues of likely concern by the Centers and their NARs partners, and will provide clear guidelines for any procedures needed to be implemented to provide the optimal ‘liability environment’ in Centers and partners. Such a study will investigate case law, to the extent possible, that is in the record, especially in jurisdictions where the CGIAR operates. The study will also address the feasibility of using mechanisms such as insurances, designed to mitigate liability risk.

(3) A definition and detailed description of ‘liability’ for use by CGIAR Centers and NARs partners. The study will highlight different types of liability issues of likely concern by the Centers, their NARs partners and farmers/growers, and will provide clear guidelines for any procedures needed to be implemented to provide the optimal ‘liability

¹ Science Council, *CGIAR Research Strategies for IPG in a Context of IPR*, Rome, Science Council Secretariat (October 2006), available at <http://www.sciencecouncil.cgiar.org>.

environment' in Centers and partners. Such a study will investigate case law, to the extent possible that is in the record, especially in jurisdictions where the CGIAR operates. The study will also address the feasibility of using mechanisms such as insurances, designed to mitigate liability risk as well as conducting a survey of liability pre-emption jurisprudence that would apply to transgenic crop germplasm.

Objectives of the workshop

In this workshop, the participants will review the working drafts of the two studies (available at <http://www.sciencecouncil.cgiar.org/home/priorities-strategies/en/>) in order to consider the elements for an optimal management and stewardship arrangement for the CGIAR Centers when dealing with products of third party IP. More specifically, the workshop aims to come up with the following:

- A guideline, or a list of minimum standards and optional elements, which outline the necessary processes/procedures for CGIAR Centers in working with products regulated by third party IP (and/or biosafety constraints), in order to have effective oversight and management of associated risks.
- A list of issues and conditions to consider when developing appropriate two-way stewardship agreements, which go beyond the simplistic approach of placing the major responsibility at the grower/farmer level, and which respects the IPG nature of CGIAR research.

The discussion might involve types of product stewardship required/expected by the private and public sector IP providers; and how to deal with confidentiality, statutory regimes, biosafety, competitive pressures, monitoring and impact assessment, uneven IP protection worldwide, and segmented markets in defined territories.

Recommendations and conclusions from the background studies

Study I: Liability of CGIAR Centers and NARS partners under intellectual property and biosafety laws arising from the supply of biological resources
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Summary of recommendations

- 1 CGIAR Centers implement the *Guiding Principles for the Development of CGIAR Centers' Policies to address the Possibility of Unintentional Presence of Transgenes in Ex Situ collections*, and "take proactive steps to determine the risk of the unintentional presence of exotic genes, including transgenes, in their *ex situ* collections."

- 2 As part of their risk analysis, when collecting or acquiring new accessions Centers should consider the following regarding testing:
 - a. whether transgenic events (commercial and research) in the relevant taxa are likely to be present in the area of collecting or acquisition;
 - b. the distance between the collecting site and areas where transgenic events (commercial and research) are situated; or
 - c. whether germplasm providers can provide adequate documentation of their germplasm management practices with respect to the material in question.

- 3 With respect to existing accessions, Centers' testing procedures should be guided by the following criteria:
 - a. No testing would be required when:
 - i. there are no transgenic events (commercial or research) in the relevant taxa at the present time;
 - ii. there were no transgenic events (commercial or research) in the relevant taxa at the time of acquisition (*e.g.*, maize prior to 1996);
 - iii. it is determined that, unless there are other factors, there is no presence of transgenic events within a distance that would allow for introgression; or
 - iv. there are transgenic events (commercial or research) present, however, proper management practices have been followed and documented in the management of the accession,
 - b. Tests should be undertaken when there are transgenic events (commercial or research) present and good management practices cannot be demonstrated.
 - c. Once an accession has been determined to either not require testing or has tested negative, the Center will follow best practice regeneration and maintenance procedures to maintain the genetic integrity, as for all accessions.

- 4 If and when transgenes are detected in an accession Centers will take appropriate steps to prevent introgression of those transgenes to other accessions.

- 5 To facilitate risk analysis Centers should establish and maintain a database on the global status of GM research and development for the crops within their collections and that the database should be posted on a publicly accessible website.

- 6 Upon request by the recipients of materials Centers should provide information describing procedures and tests that they have followed for the accession concerned and all data resulting from any testing should be properly documented and made publicly available as soon as it is considered scientifically reliable (*e.g.*, by posting on the Center's web site). A

- 7 Centers will inform the relevant authority of the country of collecting or acquisition of the material in question when transgenes are found and the Center will also inform the relevant authority of the country in which the Center is located.

- 8 Centers should establish:
 1. Written guidelines – to clearly define the structure of the biosafety system, the roles and responsibilities of those involved and the review process;
 2. Regulatory authorities – comprising well trained individuals in the host country, who are confident about their decision-making ability and to ensure the support of their institutions;
 3. An information system – enabling the biosafety evaluation process to be based on up-to-date and relevant scientific information and the concerns of the community; and to ensure that biosafety data and procedures are recorded and archived;
 4. A feedback mechanism – for incorporating new information and revising the regulatory system.

- 9 In all situations where a CGIAR Center provides products or materials under a MTA or a contract a provision should be inserted excluding the Center from any IP or biosafety liability which may arise from the use of that material.

- 10 CGIAR Centers to conduct biosafety management reviews, with a view to verifying the establishment of effective biosafety management procedures and structures at Centers.

- 11 CGIAR Centers should establish a biosafety coordination office, responsible for coordinating both biosafety and IP administration and procedures within Centers and would be responsible for external biosafety and IP liaison.

- 12 CGIAR Center staff should be provided with access to the biosafety policies of Centers in a handbook.

- 13 Service contracts with staff should notify their obligation to comply with Center biosafety policies and should identify the responsibility and authority of the Biosafety Coordination Office and refer to the Biosafety Handbook as the primary source of information about Center biosafety policies and procedures.

- 14 All visitors to CGIAR Centers should be obliged to execute a biosafety agreement, similar to that executed by Center staff.

Study II: A Recommended Stewardship Framework for the CGIAR

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Summary of Conclusions

Since the mid 1960s, it has been generally accepted that advances in agricultural technology, particularly better crop cultivars, improved livestock and new information systems, play a key role in transforming traditional agriculture (Schulz 1964). This insight remains true today: despite radical transformations in the international context for agriculture, agricultural

advances still offer a pathway out of poverty to millions of rural poor (World Bank 2008; Sunding and Zilberman 2000). One such transformation has been the dramatic growth of the role that private, rather than public goods play in the science-based development of agricultural technology. This report grew out of Science Council's recognition that the CGIAR System needs a strategic framework for harnessing this global shift towards private ownership of the fruits of agricultural research.

As it seeks to further its food security and sustainable farming missions, the CGIAR System will need access to the new technologies that are transforming agricultural research and product development. Many of these new technologies are covered by intellectual property (IP) rights held by private entities. The CGIAR will therefore increasingly be engaging with the private sector as it seeks access to these privately-held, IP-protected technologies. CGIAR centers are also likely to increase their collaborations with private sector partners in product development and distribution. As the CGIAR builds these partnerships, it will be called upon to demonstrate that it has a rigorous and credible stewardship program in place; one capable of protecting the IP rights of the CGIAR's private partners as well as the environment, and the workers involved in the project. CGIAR must develop such a stewardship program, whilst at the same time not compromising its broader mission.

Many CGIAR Centers already engage in significant stewardship activities. However, these activities tend to be ad hoc and project-centered, and do not represent a systemic commitment to defined stewardship practices. This must change. The CGIAR needs an institution-wide stewardship program that sets a clear standard of excellence. Such a program must start from a common, System-wide set of stewardship commitments, while still retaining the flexibility to tailor specific stewardship requirements to the nature of a particular project, the regulatory environment in which it occurs, and the private needs of the IP holder. Moreover, the CGIAR System as a whole would benefit from a coordinated plan for navigating complex legal, contractual and regulatory frameworks surrounding transgenics, and other regulated technologies. Such an approach would facilitate strategic planning and risk management at both the System and Center levels.

This report set out to develop a stewardship regime that could be adopted at the CGIAR System level and operationalized by the Centers on a project-by-project basis. With that in mind, this report contains two sets of observations and recommendations. The first uses a macro-level, systems-based approach to identify key structural components that currently inhibit or facilitate effective stewardship within the CGIAR. The second, more micro-level recommendations propose a streamlined stewardship framework to promote cooperative activities with private industry, research universities, and national agriculture research systems (NARS).

The two proposals are interrelated. The system-wide recommendations focus on governance structures and integrated processes. There are two primary system-wide recommendations. First, the CGIAR should employ a hazard identification and control process technique to develop a comprehensive system-wide stewardship plan. Such a plan should focus on two broad concepts: effective knowledge management and control over materials. Developing a consistent and compatible platform for compiling, storing and accessing stewardship information across the CGIAR System may be an integral part of this process. Second, the

CGIAR should develop what lawyers call a “form file:” a set of proposed legal documents and forms that can be used as a resource by Centers negotiating with private entities for access to IP-protected materials. This resource will empower Centers in their negotiations by giving them examples of ‘pro-poor’ language to include in their negotiated agreements.

The micro-level recommendations sketch out the contours of what such a stewardship framework might look like. This part of the report includes a list of proposed measures to institutionalize the routines, behaviors and practices needed to create the stewardship culture that cooperative activities will demand. The proposed stewardship framework is specific enough to provide useful guidance, yet flexible enough to permit innovative solutions to particular project management problems. Building in the kind of fluidity needed to respond to new innovations and situations was a priority. At the same time, these recommendations are intended to offer an approach to stewardship that scientists, administrators or other System personnel will be able to implement without undue burden. To that end, the proposed stewardship framework will help researchers integrate stewardship into the standard operating procedures for crop development and deployment. This framework is forward-looking and can be used to help researchers identify, at early stages of crop development, what the necessary interaction with national regulatory systems will be, thus enabling them to pro-actively collect and develop data that will ultimately be submitted for regulatory review. This report also highlights the capacities that will need to be developed at the Center, System and partner levels in order to achieve effective stewardship.

At all times, this proposal focuses on constructing and structuring a stewardship regime that will further CGIAR’s poverty alleviation mission even as it enables partnerships with holders of proprietary materials and knowledge. Thus the proposed stewardship regime reflects both a commitment to using technology to create international public goods (IPGs), and to cultivating a culture that respects the IP rights of private sector partners.