



Product Stewardship and
Liability in the Context
of IPR:
Report of a Study

May 2010



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Correct citation: CGIAR ISPC (2010) *Product Stewardship and Liability in the Context of IPR: Report of a Study*. Rome, Italy: ISPC Secretariat.

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Independent Science and Partnership Council and CAS-IP
Joint Workshop on the
Associated Needs for Product Stewardship and Liability

PREFACE

to the Workshop Summary

The Independent Science and Partnership Council (ISPC) (and its forerunner the Science Council or SC) has been promoting awareness of Intellectual Property (IP) concerns in CGIAR Center research and seeking ways to encourage public private partnerships for the past few years¹. The issues surrounding the management of IP, which it might seem a strictly legal matter, are an integral part of the ISPC's mandate of promoting quality and relevance of science in the CGIAR as IP can have significant effects in access to cutting-edge science, in the maintenance of "international public goods" nature of the research products, and in the responsible conduct of scientific research with various partners.

The ISPC has prepared and disseminated strategic studies in this area and shared in the deliberations of the CGIAR Genetic Resource Policy Committee (GRPC) which addresses similar concerns. Following the recommendations of the Joint SC-GRPC studies on *IPR in the context of International Public Goods* (2006), the Science Council was requested by GRPC to undertake additional studies focusing on the issues of product stewardship and liability in close collaboration with the CGIAR's Central Advisory Service in IP (CAS-IP). This has led to two further studies to inform debate and the formulation of appropriate IP policy in the future: *Liability of CGIAR Centers & NARS partners under intellectual property and biosafety laws arising from the supply of biological resources* and *Recommended Stewardship Framework for the CGIAR*. The SC commissioned three experts as co-authors, who conducted desk studies and field visits to a number of CGIAR Centers during 2008-9.

As a follow-up dialogue to these studies, a consultation with the CGIAR Center research directors and experts from private sector companies was planned. The Alliance Deputies Executive (ADE, a committee of the research managers in the CGIAR) and the CGIAR Secretariat, had been considering separately to hold a workshop on research management practices with private sector representatives. Subsequently, the groups collaborated to organize a joint workshop, with the SC and CAS-IP documents on public-private partnership and associated needs for product stewardship and liability considered at the event held in Zurich, on 11-13 November and kindly hosted by the Syngenta Foundation. The outcomes of the workshop on public-private partnerships have been reported elsewhere²

This document consists of two parts:

¹ The major contribution of the late Mike Gale to the ISPC's and GRPC efforts in this area is acknowledged.

² http://www.cgiar.org/pdf/pscnov2009/workshop_final_report_nov2009.pdf

- A summary of the second part of the CGIAR workshop on public-private partnership, namely SC/CAS-IP joint Consultation on Associated Needs for Product Stewardship and Liability.
- CGIAR Strategic Studies on Liability and on Product Stewardship in the Context of IPR.

Associated Needs for Product Stewardship and Liability Workshop

SUMMARY

The SC/CAS-IP joint Consultation on Associated Needs for Product Stewardship and Liability was held in Zurich on 13 November 2009 as part of the CGIAR ADE-PSC Workshop on Public Private Partnerships. It focused on product stewardship and liability and provided a forum for examining the increased complexity of challenges linked to the sustainable use and distribution of CGIAR Center research products. Participation included CGIAR Research Directors from nine Centers and one Challenge Program, and representatives from industry (four participants), foundations (seven participants) and academia (four participants).

It is recognized that development and deployment of CGIAR products now involves regulatory challenges and legal liability - including IP-related challenges - that have not been faced in the past. The scope of this challenge is quite broad with respect to the variety of CGIAR products, the variation in regional, national and local impacts and the differences in levels of responsibility within the research, development and deployment domains. During the earlier part of the workshop, organized by the CGIAR Secretariat and the Alliance Deputy Executive on enhancing research productivity through public-private partnerships, the participants from foundations and the private sector frequently referred to the importance of CGIAR Centers maintaining their credibility and responsibility as research partners through clear product stewardship principles and mechanisms. Introductory remarks from *Dr. Marco Ferroni*, Executive Director of the Syngenta Foundation re-emphasized the importance of product stewardship in the context of discussion of public private partnerships from the earlier part of the workshop. *Haruko Okusu*, (SC Secretariat), and *Victoria Henson-Apollonio*, (CAS-IP), outlined the previous work of the ISPC and CAS-IP on issues of liability and IPRs in the CGIAR System. Summary presentations of background papers commissioned for the workshop by the CGIAR SC in consultation with CAS-IP were presented by the authors.

Prof. Michael Blakeney, Herchel Smith Professor of Intellectual Property Law at Queen Mary College, University of London and Professor of Law at the Faculty of Law of the University of Western Australia, focused on liability issues resulting from IPR infringement and Biosafety concerns related to negligence, breach of regulatory standards or contractual obligations and the potential of economic loss due to trade disruptions. Discussion covered financial vs. reputational liability and highlighted the importance of the reputational aspects for CGIAR Centers but particularly for the private sector partners, which reflected upon the concerns raised by a number of participants during Workshop Part 1. Prof. Blakeney also presented some examples of liability risk mitigation mechanism for farmers. Liability insurance and the use of compensation schemes are being considered, although they are both in nascent stages of implementation in the area of agriculture and, in particular, GM crops.

The second background paper presented by the author *Prof. Rebecca Bratspies* of the City University of New York (CUNY) Law School proposed a stewardship framework for the CGIAR. Prof. Bratspies drew attention to the potential of the FAO's Hazard Analysis and Critical Control Point (HACCP) Analysis approach as an example of a framework for distribution of products with an associated liability component. Prof. Bratspies identified the need to understand the administrative level at which responsibility for implementing any particular phase of a stewardship process occurred. *Dr. Vibha Dhawan*, Executive Director of The Energy and

Resources Institute (TERI), presented several illustrative case studies from developing countries, including useful stewardship contract texts from Indian cases.

In the discussions on stewardship, it became obvious that even the definition of stewardship is perceived differently by various stakeholders in the agricultural sector. In addition, the wide variety of products that may carry liability – from “brands” to agricultural machinery designed by CGIAR researchers, to GMOs – were highlighted. An example of the plastic bags used for post-harvest storage of grain and beans was described by the Research Director from IITA. Imitators of the technology were selling “counterfeits” whose inferior qualities meant that the beans put into inferior imitation bags were not protected against damage due to insect pests. Thus IITA’s reputation was at risk, as farmers were dismayed to experience post-harvest damage believing that their harvest should have been protected through using “IITA-endorsed” bags for storage.

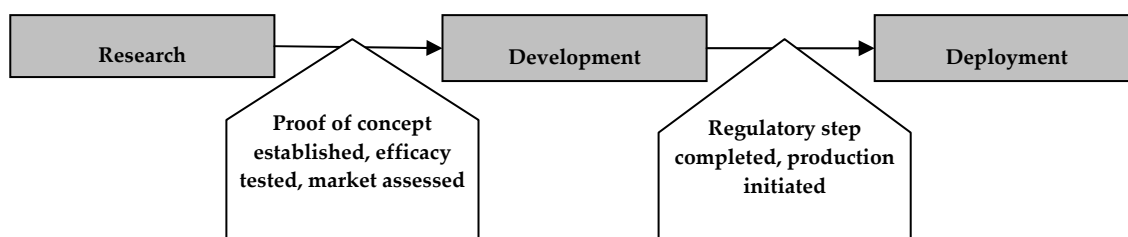
The afternoon session was designed to better garner inputs from the participants on questions related to types of products; operational levels of responsibility; candidate case studies from industry and the CGIAR Centers; funding propositions to finance stewardship; and capacity building requirements in the area of stewardship. Furthermore the participants were asked to provide reactions and comments on the recommendations included in the background document and provide ideas and guiding principles towards text for pro-poor stewardship agreements. The summary of this session, conducted in small groups followed by a plenary discussion, is summarised in the section below.

As a conclusion of the debates on IP and product stewardship, the participants agreed on the need to collect case studies and practices from the CGIAR Centers, including identification of established processes/procedural units such as seed health/phytosanitary sections that could provide models for stewardship management activities. CAS-IP has offered to lead this initiative in collaboration with the Center IP Managers/Focal points. The group also recommended that this stewardship study should then be followed up with the Center Research Directors. CAS-IP suggested a follow-up meeting for the discussion of these cases to be held in mid-2010, where a small group would be brought together to use these results in developing a CGIAR-wide plan for stewardship strategies that address changing institutional roles in partnership, identification of differing strategies for the array of products developed and deployed for the small holder farmer, and means to provide due diligence for stewardship through appropriate contract language.

SUMMARY OF BREAKOUT GROUPS AND PLENARY DISCUSSION SESSION

Definition

Although this was not part of the requested task, some breakout groups started their discussions by considering the definition of research, development, and deployment as they relate to the issue of product stewardship procedures. One group defined the division between each steps as follows:



Within the CGIAR, it was suggested that the distinction between the research and development stages were not as clear as in the private sector; rather, the R&D stage might be defined by *strategic research* and *adaptive research* stages. There was also some discussion on the balance between quality control measures and product stewardship. It was pointed out that setting excessively high seed quality control standards for small seed companies in developing countries often does not lead to product stewardship; rather, they discouraged any product stewardship mechanisms from functioning in a cost efficient manner.

A large number of CGIAR Center products were identified as requiring stewardship. They included *materials* (plant, livestock and fish germplasm; seeds; machinery; compounds and chemicals; laboratory equipment; software; vaccines and diagnostics), *knowledge, information and know-how* (models; databases; markers, library and other genomic tools; published information including blueprints and manuals; biosafety dossiers; policy recommendations; adapted technologies and practices; “general info and know-how”; training materials), and *capacity-building* (human resources; facilities; manuals; platforms such as BecA). One group chose to group them into those *entrusted to the CGIAR Centers* (e.g., germplasm under Annex I of ITPGRFA, databases) and those “*created*” by the Centers themselves (e.g., vaccines and diagnostics, crop management technologies), as they might potentially be subject to different stewardship processes. One group distinguished the technological products into three categories: *traditional technology, traditional biotechnology, and modern biotechnology*.

Failing to apply proper stewardship over these products could result in claims for: IP infringement; violation of rights in the use of traditional knowledge; genetic erosion; bystander damage (human health, crop, environment); problems with product performance (misleading ad, confusion, unintentional) and trade disruption; and non-compliance with regulations; contractual non-compliance.

Levels of operation

Most participants recognized that there is no choice but to implement improved stewardship approaches in the CGIAR; at least some form of general guiding principle and standard-setting would be necessary at the System level, while more detailed practicalities will necessarily be undertaken at the Center/program/platform level, and in some cases, at the project/partnership level. There are already experts and mechanisms in place at some of the Centers, such as a technology transfer office. A *centrally managed mechanism* would be beneficial to the CGIAR Centers, possibly in the form of technology transfer and patent office, legal advice or a platform/working group.

Numerous suggestions were put forward in relation to effective operationalization and enforcement of stewardship measures. Some noted that if the CGIAR wishes to work with the private sector, it should adopt procedures similar to the private sector (most of which have already been adopted by US universities and public research institutes). However, there is also a need for the CGIAR Centers to define the CGIAR’s *own minimum standards* considering all potential partners and practicability given the CGIAR’s organizational structure. Strategies must be developed for dealing with standards of partners that are higher (more stringent, perhaps in exchange of IPR) or lower (when judgment is needed, whether or not to accept any lower standard, or better, to consider need for capacity-building to bring up the standards). There is also a need to distinguish between “our products” and our products including other institution’s IP in applying those standards. At the deployment stage, some procedures might routinely be undertaken by partners (e.g., import registration, regulatory dossiers) while others might not be worthy of consideration – prioritization would therefore be an important aspect. In general, awareness of the importance of stewardship is still not sufficiently high in the CGIAR Centers,

downstream partners, as well as the donors. More work is needed in order to engender a higher level of commitment to support the implementation and enforcement of stewardship procedures.

Funding propositions

Most groups generally saw the donors to be responsible for funding stewardship measures, although judicious choice of partners could also be beneficial. At the R&D level, it was acceptable in the eyes of most private sector companies and foundations to build stewardship activities costs into research proposals, given appropriate costing and clarity/distinction of responsibilities. The private sector / foundations see this as a conscious effort by the researchers to consider product stewardship mechanisms, in particular the protection of intellectual property, from the project planning stage. A healthy IP protection of research products is seen as a positive product stewardship measure, since it can help maintain their public goods status (by allowing public disclosure and therefore preventing others from privatizing the goods in question) and potentially create bargaining chips to attract collaborators and leverage access to other technologies in PPP. Additional challenges arise when considering the costs for future and continuous stewardship obligations, such as for data management and germplasm conservation. Here, there might be a gap between donor and Center perceptions as to what costs are to be considered core/institutional costs of the Centers, which have been encouraged to opt for services based on full-cost recovery. Donor and System education will be required to ensure inclusion of stewardship costs in overhead cost rates and the inclusion of such rates into program budgets.

General comments and recommendations

- Stewardship lasts forever – each CGIAR Center must ask the question whether and how it should engage in research requiring stewardship as the first step. It should not be seen merely as a donor requirement or a barrier to deployment of research products.
- A stewardship strategy needs to be developed for the CGIAR, along with a possible centrally-managed (at the Shared Services level) stewardship mechanism, to set guiding principles and minimum standards.
- At the Center/program level, some form of Standard Operating Procedures (at all points where there is risk) must be developed, which could include procedures for handing over projects to product developers or to downstream partners.
- CGIAR can, and should be more rigorous in pursuing beneficial uses of product stewardship mechanisms, including IPRs, in its development-oriented research.
- A desk study is needed to compile existing mechanisms for quality control among the CGIAR Centers.

**PRODUCT STEWARDSHIP AND LIABILITY IN THE
CONTEXT OF IPR**

STUDY I

**Liability of CGIAR Centers and NARS partners under intellectual
property and biosafety laws arising from the supply of biological
resources**

Michael Blakeney

Queen Mary Intellectual Property Research Institute

University of London

RECOMMENDATIONS

Recommendation 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."

Recommendation 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.

Recommendation 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.

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

Recommendation 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.

Recommendation 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).

Recommendation 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.

Recommendation 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.

Recommendation 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.

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

Recommendation 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.

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

Recommendation 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.

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

A INTRODUCTION TO THE LIABILITY STUDY

The Terms of Reference for this study requires:

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 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.

This study is one of two commissioned by the Priorities and Strategies Portfolio of the Science Council of the CGIAR. It follows a recommendation of the Science Council and the Genetic Resource Policy Committee (GRPC) arising from their October 2006 commentary on three commissioned studies on intellectual property and its use in a public goods context.³ That commentary noted that "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."

As the introduction to the Terms of Reference indicates the study arises out of concerns about legal liability which might arise for CGIAR Centers from the use of technologies provided by private partners which may be embedded in CGIAR products. This liability may arise under intellectual property law and under biosafety laws.

Of course the question of biosafety liability and best practices for the CGIAR has already been anticipated by the May 2007 *Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers*. This study takes into account those recommendations.

B LIABILITY

This report examines the private and public law liability of CGIAR Centers and NARS partners arising from the use of proprietary technologies. This liability could typically arise in two areas: (i) liability for infringement of another's IP; and (ii) liability arising under biosafety laws from using CGIAR Center products incorporating proprietary technologies.

Typical liability for IP infringement in a CGIAR context will arise from: (i) the unauthorized use of another's proprietary technologies by a CGIAR Center; and (ii) the unauthorized supply of a CGIAR Center product to a NARS partner containing another's proprietary technology.

Typical liability involving a breach of biosafety laws in a CGIAR context will arise from: (i) the supply of a CGIAR Center product to a NARS partner containing a technology which breaches biosafety laws; (ii) the use by a CGIAR Center or NARS partner of a product incorporating a technology which gives rise to biosafety liability; and (iii) the accidental loss by a CGIAR Center or a NARS partner of a bio-unsafe substance.

This study addresses the possibility that because of its special legal status a CGIAR Center might be considered to exempt from IP and biosafety liability.

³ Science Council, CGIAR Research Strategies for IPG in a Context of IPR, Rome, Science Council Secretariat (October 2006), <http://www.sciencecouncil.cgiar.org/activities/spps/index.html>.

This study does not address the legal liability of farmers under IP or biosafety laws as this is beyond the scope of the Terms of Reference.

Where the supply of potentially IP infringing or bio-unsafe products occurs in a contractual situation, it is possible for the supply contract to provide for the exclusion of liability. It may also be possible to structure the supply transaction to insure against any liability.

Each of these matters is detailed below.

C INFRINGEMENT OF INTELLECTUAL PROPERTY

The principal categories of IP which will be relevant to CGIAR activities are:

- plant variety rights;
- patents;
- trademarks;
- geographical indications;
- industrial designs; and
- trade secrets.

The question of infringement of these rights will be determined by the national IP laws under which those rights are created. The IP categories listed above are summarized below and detailed in Annex 1, together with relevant infringement case laws.

1. Plant Variety Rights

Plant varieties are protected in most countries by specialist (*sui generis*) legislation modeled on the International Convention for the Protection of Plant Varieties (UPOV). The protection under this legislation is afforded to a “breeder” or persons claiming through the breeder who is defined in Article 1 (iv) of the UPOV Convention as the person who bred, or discovered or developed a variety”. “Breeding” is generally defined as including the discovery of a plant together with its use in selective propagation so as to achieve a result.

Generally, under plant variety rights (PVR) legislation the plant breeder is conferred an exclusive right to do or to license the following acts in relation to propagating material of the variety:

- produce or reproduce the material;
- condition the material for the purpose of propagation;
- offer the material for sale;
- sell the material;
- import the material;
- export the material;
- stock the material for the purposes described above.

The duration of PVR under legislation based on the UPOV Convention is 25 years in the case of trees and vines and 20 years for any other variety.

Plant variety protection is established after a registration process. A plant variety is considered to be registrable, if it has a breeder, is distinct, uniform, stable and has not been or has only recently been exploited. A plant variety is considered distinct if it is clearly distinguishable from any other variety

whose existence is a matter of common knowledge. It is uniform if, subject to the variation which may be expected from the particular features of its propagation, it is uniform in its relevant characteristics on propagation. A plant variety is stable if its relevant characteristics remain unchanged after repeated propagation. A plant variety is taken not to have been exploited if it or propagating material has not been sold to another person by or with the consent of the breeder.

Plant variety protection also extends to varieties which are “essentially derived” from protected varieties. Although in practice there is a fair degree of confusion as to the criteria to be applied in ascertaining whether a variety is essentially derived. Liability for infringement of plant variety rights can arise in a CGIAR context where germplasm is made available by a CGIAR Center to NARS or farmers, which turns out to be a protected variety or essentially derived from a protected variety.

Research exemption

The 1991 Act of the UPOV Convention (UPOV 1991) provides in Article 15(1) that the breeder’s right shall not extend to:

- i) acts done privately and for non-commercial purposes,
- ii) acts done for experimental purposes and
- iii) acts done for the purpose of breeding other varieties, and, ...[derived varieties aside], acts .. .[of commercial exploitation].. in respect of such other varieties.

Thus in general terms a CGIAR Center will not infringe a plant variety right where it uses a protected variety for further breeding.

In relation to the commercial exploitation of CGIAR breeding programs based on protected varieties infringement will occur where new varieties are considered to be “essentially derived” from protected varieties.

To deal with the potential liability for infringement CGIAR Centers will have to show that the new variety has a different origin for at least some of the traits which it shares with the original variety. A practical problem for breeders is the determination of the permitted closeness of a new variety with an original variety. Various offices responsible for the registration of plant variety rights⁴, as well as industry associations⁵ and scientists⁶ are attempting to agree norms for different crops. Ultimately, of course the question will be settled by litigation. Until that time CGIAR Centers have to bear in mind their potential liability for infringement arising from the use of protected varieties as breeding stock.

⁴ Eg Australia, Clarification of Plant Breeding Issues under the Plant Breeder’s Rights Act 1994, Report of the Expert Panel On Breeding, December 2002, <http://www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf>

⁵ Eg European Seed Association, ‘Access to Plant Genetic Resources and Intellectual Property in the European Union. Plant Variety Protection based on the UPOV Convention and Protection of Biotechnological Inventions based on Directive 98/44/EC’, Position Paper, 13.05.2004; International Seed Federation, Use of DNA markers for DUS testing, Essential Derivation and Identification, [http://www.worldseed.org/cms/medias/file/PositionPapers/OnIntellectualProperty/Use_of_DNA_markers_for_DUS_testing_Essential_Derivation_and_Identification_20060531_\(En\).pdf](http://www.worldseed.org/cms/medias/file/PositionPapers/OnIntellectualProperty/Use_of_DNA_markers_for_DUS_testing_Essential_Derivation_and_Identification_20060531_(En).pdf).

⁶ Eg M. Heckenberger, M. Bohn, D. Klein, and A. E. Melchinger, ‘Identification of Essentially Derived Varieties Obtained from Biparental Crosses of Homozygous Lines: II. Morphological Distances and Heterosis in Comparison with Simple Sequence Repeat and Amplified Fragment Length Polymorphism Data in Maize’ *Crop Sci.*, May 6, 2005; 45(3): 1132 – 1140; T. Borchert, J. Krueger and A.Hohe., ‘Implementation of a model for identifying Essentially Derived Varieties in vegetatively propagated *Calluna vulgaris* varieties’, *BMC Genetics* 2008, 9:56.

2. Patents

Introduction

Plant Variety Protection laws were developed in response to industry calls for *sui generis* protection for agricultural and horticultural innovation. The inclusion of a seed saving exception for farmers was a public policy safeguard which was an early reflection of food security concerns. As is mentioned above, this safeguard does not exist in patent statutes. It is thus important for CGIAR Center and NARS clients not to confuse the right to save seed under PVR laws with the prohibition against saving and reusing patented seed.

The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. Genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. The production of transgenic plants has become possible through the development of a number of enabling and transformation technologies. These technologies, together with the introduction of beneficial plant traits, have become the subject of intellectual property protection, as a consequence of the favourable decisions of courts in the USA and Europe. Thus in considering the IP liability of CGIAR Centers and NARS, account has to be taken both of the patenting of DNA, as well as of enabling technologies.

Infringement

The potential IP liability of farmers for the use of patented genetic material is illustrated in the US decision in *Monsanto Co. v. Scruggs*,⁷ and *Monsanto Co. v. Schmeiser*⁸ which are detailed in Annex 1 but which concerned the finding by courts in the USA and Canada respectively of the liability of farmers for saving and replanting patented seed.

Another possible area of liability for farmers arises from the possibility that GM crops which may be cultivated without infringing patent liability, might cause problems where those crops are exported into markets where the patent might be registered. This is illustrated in the *Monsanto Technology LLC v Cefetra BV and the State of Argentina*⁹ where Monsanto sought to enforce its patent rights in the Netherlands against GM soy beans exported from Argentina.

A similar action was brought against importers of Argentinean soy beans in the UK in *Monsanto Technology LLC v Cargill International S.A.*¹⁰

It might be argued that the position of CGIAR Centers and NARS are distinguishable from the position of farmers, as unlike the latter, they are not engaged in trade or commerce. This is not necessarily the case, as the research activities of CGIAR Centers and NARS might render them liable as being authorizers of patent infringements or being involved as accessories of infringing activities by farmers. The closest case authority on point is *Monsanto Co. v. Parr*¹¹ which concerned a finding of liability against a defendant who operated a seed and grain cleaning business. This cleaning process enabled cleaned seed to be replanted. The Court found that the seed cleaners activities facilitated breaches of Monsanto's patent by farmers.

There are some analogous cases from copyright law. In *University of New South Wales v. Moorhouse*¹² the High Court of Australia ruled that a university in providing unsupervised photocopying facilities for

⁷ 342 F. Supp 2d 584 (2004).

⁸ [2004] SCC 34.

⁹ District Court of The Hague 249983/HA ZA 05/2885, 19 March 2008.

¹⁰ [2007] EWHC 2257 (Pat)

¹¹ 2008 WL 1808365 (N.D. Ind. 2008)

¹² (1975) 133 CLR 1

students authorized copyright breaches by those students. Similarly in the *Napster* litigation in the USA¹³ the courts held that the provision of software which enabled the downloading of copyrighted music made the software provider liable as a contributor of copyright infringement by others. In other words, where a CGIAR Center has used the proprietary materials or technologies of others, even though it might provide its germplasm to farmers in non-commercial transactions, it might still be held vicariously liable for any infringing activities by those farmers.

Research Exception

An important contributor to effective agricultural research is the access which researchers may have to patented materials and technologies. A research exception permitting the use of protected materials for non-commercial research and product development purposes, exists under most patent laws. However, recent case law suggests that this exception has begun to narrow.

An experimental use exception was first laid down in US patent law in the early nineteenth century, holding that where it was held that a patented product may be used as an experiment, whether for gratification of scientific tastes, curiosity, or to ascertain the verity and exactness of the specification or for amusement, without an intent to use for profit, would not amount to patent infringement.¹⁴ This exception was held to be 'truly narrow' in *Roche Products, Inc v Bolar Pharmaceuticals Co., Inc*¹⁵ and the slightest commercial purpose or intention for carrying out an experiment has been held to be patent infringement.¹⁶ The scope of this exception was more recently explored in *Madey v Duke University*¹⁷ Madey employed by Duke University as a laboratory director owned two patents over an electron laser, which he had secured prior to his appointment at the University. After his services were terminated, Madey's patented equipment continued to be used by Duke University and he sued it for patent infringement. The University raised the experimental use exception defense. The Federal Circuit refused to allow the exception to exempt university research activities from infringing a patent, as it held that these research activities "unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects."

The narrowing of the experimental use defense in the USA is particularly problematic in the plant biotechnology research sector, where access to patented germplasm is crucial for innovation in crops which will be made available to the agricultural sector.

Most of the European case law concerned with the experimental use exception has developed in the pharmaceuticals area. The principal question in these cases is whether during the period of protection of a pharmaceutical patent, clinical tests may be conducted. Where a substance is protected as a pharmaceutical for a certain indication, two different kinds of test can occur during the duration of a patent. First, tests with the aim of finding new indications of pharmaceutical substances that have been patented only for one indication. Secondly, tests for market approval of a patented substance for an already patented indication during the protection of a pharmaceutical patent. If the latter kind of test is permitted, a competitor of a patentee can prepare for market approval well ahead of the expiration of the respective patent. Thus, upon the expiry of a patent, a generic equivalent of the formerly patented pharmaceutical can be marketed immediately without risk of patent infringement.

For example, in the UK section 60(5) (b) of the Patents Act, 1977 incorporates the experimental use defense using the same words as that of the CPC. Under this provision: (a) the acts must be done for experimental purposes; and (b) those purposes must relate to the subject matter of the invention. The

¹³ 55 U.S.P.Q. 2d 1780 (N.D. Cal. 2000); 57 U.S.P.Q. 2d 1729 (9th Cir. 2001).

¹⁴ *Whittemore v Cutter*, 29 Fed. Cas. 1120 (1813).

¹⁵ 733 F.2d 858 [Fed. Cir. 1984].

¹⁶ Eg see *Pfizer Inc. v International Rectifier Corp.*, 217 USPQ 157 (C.D. Cal. 1982); *Embrex, Inc. v Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).

¹⁷ 307 F.3d 1351 (Fed. Cir. 2002).

exception was considered by the court in *Monsanto v Stauffer*.¹⁸ Stauffer had developed a market variant 'Touchdown' of Monsanto's patented 'Roundup' product for which it had obtained provisional clearance from relevant authorities. In order to obtain final clearances, Stauffer had run tests at its own research farm and also organised a series of tests outside its research farm where interested parties could observe the results. Monsanto moved for an interlocutory injunction on the grounds of patent infringement. Both the Patent Court and Court of Appeal ruled that the outside tests could not qualify for an experimental use exception.

The Court, in *Smith Kline & French Laboratories Ltd v Evans Medical Ltd*¹⁹ observed that "what is or is not an experiment must depend upon the facts of each case but can include experiments designed with a commercial end in view."

The implications of these experimental use cases for the work of CGIAR Centers are first: to avail themselves of the defense, Centers should undertake the research within their own premises. Secondly, the research results/ products should not be made available by CGIAR Centers on a commercial basis.

Patenting of Plant Varieties

A subject which is of some significance for CGIAR Centers, NARS and farmers is the possibility that plant varieties might be patented. As we have seen the plant variety protection legislation provides an exception for farmers who save seed for future plantings and also there is an exception for researchers to develop further varieties. These exceptions are absent from patent legislation. Therefore where varieties can be patented both seed saving and future research might be compromised.

In the USA the Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act (PVPA) in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc.*²⁰ Pioneer held patents cover the manufacture, use, sale, and offer for sale of the company's inbred and hybrid corn seed products as well as certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts ... to regard each as effective".

3. Trade Marks

As the use of a registered trademark is often taken as a warranty of the quality of the goods or services supplied under that mark. The name, acronym or logo of a research institute is often a warranty of the quality of the services supplied by that institute. Its designation is worthy of protection, particularly because unauthorized traders may falsely represent an affiliation with the institute. Similarly, the products which are produced by an agricultural research institute may also be worthy of protection, e.g. the IRRI prefix for rice types developed at that institute. Similarly, the research institute may wish to protect its Internet domain name as a trade mark.

Collective and Certification Marks

A special type of registered trade mark is a collective mark which may be registered by an association whose members may use it if they comply with the requirements fixed in the regulations concerning the use of the collective mark. In the USA collective and certification marks are typically used by

¹⁸ [1985] RPC 515 CA.

¹⁹ [1989] F.S.R 513.

²⁰ 200 F.3d 1374 (Fed. Cir. 2000), cert. granted, 148 L. Ed. 2d 954 (2001)

agricultural producers in much the same way as geographical indications are used in Europe. US State governments typically encourage the registration of certification marks to encourage agricultural producers. For example, the certification mark VIDALIA is owned by the State of Georgia's Department of Agriculture and is "intended to be used by persons authorized by certifier, and ... in connection with which it is used are yellow Granex type onions and are grown by authorized growers within the Vidalia onion production area in Georgia as defined in the Georgia Vidalia Onion Act of 1986."²¹ Similarly, FLORIDA CITRUS is owned by the State of Florida's Department of Citrus and certifies that the goods bearing the mark "either consist of citrus fruit grown in the State of Florida, under specified standards, or are processed or manufactured wholly from such citrus fruit."²² Non-US agricultural producers have also registered certification marks in the USA. For example the Thai Ministry of Commerce of Thailand, has registered THAI HOM MALI RICE "harvested in Thailand per the standards set by the Ministry of Commerce of Thailand in "Regulations of the Department of Foreign Trade Re: Usage of the Certification Mark of Thai Hom Mali Rice."²³ Similarly, the Tea Board of India has registered DARJEELING to certify "that the tea contains at least 100% tea originating in the Darjeeling region of India and that the blend meets other specifications established by the certifier."²⁴

The leading US case involving the enforcement of a geographical indication as a certification mark is *Community of Roquefort v William Faehndrich, Inc*²⁵. This case held that the designation 'Roquefort' was not a generic designation of blue cheese and that the owner of the certification mark was entitled to prevent the use of the mark on all cheeses not made in the French city of that name.

4. Geographical Indications (GIs)

GIs are usually indications of source, in referring to the fact that a product originates in a specific geographical region. However, more usually a GI is a sign that indicates that a product originates in a specific geographic region only when the characteristic qualities of the product are due to the geographical environment, including natural and human factors.

The right to protect a geographical indication from wrongful appropriation is enjoyed by all traders from the particular geographical location, whereas a trademark is protected from wrongful appropriation at the suit of the registered proprietor of that mark. Generally, geographic indications are monitored and protected by producer associations from the relevant region.

Unlike trademarks, geographical indications are not freely transferable from one owner to another, as a user must have the appropriate association with the geographical region and must comply with the production practices of that region.

Geographical indications are obtained through registration. A specification is usually filed indicating the relevant geographical area and the product quality characteristics attributable to that area. The application for registration is usually filed by a body representing the producers of that area. This body will also usually be responsible for bringing actions against wrongful users of the GI.

5. Confidential Information (Including Trade Secrets)

Under intellectual property law information which has been originated by a person and which is not in the public domain and in relation to which efforts have been made to keep it confidential may be

²¹ U.S. Reg. No. 1709019.

²² U.S. Reg. No. 1559414.

²³ U.S. Reg. No. 2,816,123.

²⁴ U.S. Reg. No. 2,685,923.

²⁵ 303 F. 2d 494 (CA 2 1962).

protected by the law of confidence. For example, where plant breeding information has been kept confidential, the theft of that information in documentary form would be actionable. Similarly, it has been held that the theft of genetic material is actionable. For example in *Franklin v Giddins*²⁶, the Queensland Supreme Court was concerned with the theft by a defendant of budwood cuttings from the plaintiffs' orchard which enabled the defendant after grafting to grow Franklin Early White nectarines, in competition with the plaintiffs. The Court held this to involve a theft of confidential information embodied in the genetic composition of the budwood.

In *Pioneer Hi-Bred Int'l v. Holden Found Seeds*²⁷ the US Eighth Circuit Court of Appeals was concerned with a dispute between competing breeders of corn seed Pioneer and the defendant, Holden. Pioneer claimed that Holden had developed a seed from misappropriated seed which it claimed were its trade secrets. The Court ultimately, sustained its claim.

6. Copyright

Copyright law is concerned with the protection and exploitation of the expression of ideas in a tangible form. The central right which the law confers is to prevent unauthorized persons from copying a work. To be protected as copyright, ideas have to be expressed in an original way; that is they must have their origin in the labor of the creator. Works are protected irrespective of their quality. Works are also protected, typically from the date of publication and without any requirement of registration.

The relevance of copyright law to agricultural research is primarily in the suggestion that copyright might be asserted over the written representation of a gene or amino acid sequence in addition, or as an alternative, to applying for a patent or other intellectual property protection.

Originally, the subject matter of copyright protection was printed literary artistic and literary works. A "literary work" for the purposes of copyright law includes a table or compilation expressed in words, figures or symbols; and a computer program or compilation of computer programs. Consequently, copyright protection may cover scientific databases, as well as laboratory notebooks, academic writings and computer displays of information.

It has been suggested that the written representation of a sequence of modified DNA or protein may be protected as an original literary work under copyright law.²⁸

Copyright is infringed if a person does or authorizes the doing of any act falling within the copyright in a work without the copyright owner's permission. Such conduct must relate to the whole or a substantial part of the work.

Fair dealing for research or study

Most copyright laws except from copyright infringement certain acts of "fair dealing" in a copyright work for the purpose of research or study. Matters typically taken into account in determining whether the reproduction of the whole or a part of a work constitutes a fair dealing for the purpose of research or study typically include:

- the purpose and character of the dealing;
- the nature of the work or adaptation;

²⁶ (1978) Qd R 72.

²⁷ 35 F.3d 1226 (8th Cir. 1994).

²⁸ S. Coke, 'Copyright and Gene Technology' (2002) 10 *Journal of Law and Medicine* 97, 102, see also the discussion in See also the discussion in I Kayton, 'Copyright in Living Genetically Engineered Works' (1982) 50 *George Washington Law Review* 191; N Derzko, 'Protecting Genetic Sequences under the Canadian Copyright Act' (1993) 8 *Intellectual Property Journal* 31, 39.

- the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
- the effect of the dealing upon the potential market for, or the value of, the work or adaptation; and
- where only a part of the work is copied, the amount and substantiality of that part compared to the whole work or adaptation.

7. Data Base Rights

The European Database Directive, which was implemented in the UK in the Copyright and Rights in Databases Regulations, 1997 provide for the protection of material contained in databases against unauthorized extraction or reutilization. A “database” is defined as "a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means". Relevant databases in the context of food security will be breeding records and genetic databases comprising compilations of the sequences of genomes, including whole genomes, single genes and gene fragments, such as single nucleotide polymorphisms (SNPs) and expressed sequence tags (ESTs).²⁹

D. LIABILITY ARISING FROM THE ADVENTITIOUS PRESENCE OF GMOs

1. Introduction

Biosafety liability issues typically arise in situations where non-GM seed, crops or food is adulterated by the unintended presence of GMOs. As the table below indicates, this liability may arise in relation to: CGIAR Centers, NARS Centers, GM seed manufacturers/suppliers, farmers (GM, non-GM, organic and GM-free), contract harvesters, bulk handlers, local transporters, produce manufacturers and retailers.

Table I - 1 Key liability possibilities associated with the unintended presence of GMOs

CGIAR Centers, NARS Centers	Breach of Contractual Warranties Nuisance Negligence GM approval legislation Consumer Protection Legislation
GM Seed Manufacturers / Suppliers	Breach of Contractual Warranties Nuisance Negligence GM approval legislation Consumer Protection Legislation
GM Farmers	Infringement of a seed manufacturer’s intellectual property rights Breach of contractual warranties GM approval legislation Trespass Nuisance Negligence

²⁹ See E Baba, ‘From Conflict to Confluence: Protection of Databases Containing Genetic Information’ (2003) 30 *Syracuse Journal of International Law and Commerce* 121.

Non-GM, Organic and GM-free Farmers	Infringement of a seed manufacturer's intellectual property rights GM approval legislation Breach of contractual warranties Consumer Protection legislation (misleading and deceptive conduct re GM status)
Transporters and Harvesters	Breach of contractual warranties Trespass Negligence
Bulk Handlers	Breach of contractual warranties Consumer Protection legislation Negligence
Manufacturers / Retailers	Food Standards Code Consumer Protection legislation

The supply of GM germplasm by a CGIAR Center under the Standard Material Transfer Agreement (STMA), promulgated under the International Treaty on Plant Genetic Resources for Food and Agriculture is governed by Article 9.1 which provides that the Provider "makes no warranties as to the safety of or title to the Material, nor as to the accuracy or correctness of any passport or other data provided with the Material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Material being furnished. The phytosanitary condition of the Material is warranted only as described in any attached phytosanitary certificate. The Recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material."

Supply of germplasm by a CGIAR Center outside the International Treaty or by a NARS Center under an MTA would be considered a supply under a contract. In this situation one has to note both the express terms of the MTA, as well as any terms which might be implied by operation of law. As a CGIAR Center does not "sell" the seed which it provides to farmers the sale of goods legislation of most countries would not be applicable in implying terms and warranties in the supply transaction. On the other hand in a number of countries those terms and warranties might be implied in consumer protection legislation.

If an acquirer of germplasm seeks an express term that it is free of GM contamination, the supply of adulterated germplasm would be a clear breach of that contractual term, even where the contamination might have occurred in the seed in planting, growing, harvesting, transporting, and storing the crop. Where germplasm is acquired for use in organic farming, or for supply into markets which prohibit GM crops, the supply of contaminated germplasm would breach the implied warranty of fitness for purpose. This warranty is imposed where the supplier has reason to know of any particular purpose for which the goods are required and the acquirer relies on the seller's skill and judgment in providing the goods.

Legal liability arising from the possible contamination by GM crops of organic or other "GM free" crops under tort law was comprehensively examined by the Saskatchewan Court of Queen's Bench in *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc*.³⁰ The plaintiffs in this case claimed damages to organic grain farmers allegedly resulting from the development and commercial introduction into Canada of GM canola by the two defendants. The nature of the damage suffered by

³⁰ 2005 SQKB 225.

the plaintiffs was the loss of the principal foreign markets for organic grain: the United States, Japan and Europe.

A critical factor in the decision by the court to disallow the plaintiffs' claims was the determination by the Canadian Food Inspection Agency that the genetically modified canolas were not harmful. The damage alleged to organic grain farmers was "solely the damage resulting from loss of use of canola as an organic crop or for cleanup costs for fields "contaminated" by GM canola, due to standards imposed by organic certifiers or by foreign markets or individual customers for organic products."³¹

The legal bases of the plaintiffs' claims were that the defendants were liable in negligence, nuisance, trespass and for breach of statutory duty.

2. Negligence

Liability for negligence occurs where a legal duty to act as a reasonable and prudent person exists and is breached, and the breach of duty causes damages to others or their property. The principal elements of the tort of negligence are: (i) the defendant must owe a duty of care to the plaintiff; (ii) the defendant causes damage to the plaintiff; and (iii) that damage was reasonably foreseeable. With respect to GM crops a negligence claim could be brought by a person claiming personal damage based on an allergic response to food products containing GMOs. Negligence has been claimed in cases involving the contamination of organic crops by GM crops.

In *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc.*³² the court was not prepared to find a duty owed by the defendants (developers and marketers of GM canola) to the plaintiffs (organic grain farmers in Saskatchewan) to prevent or to minimize the extent of adventitious presence of their respective GM canola varieties on the plaintiffs' farmland or in their crops.

The principle of law which the Court applied was that which had been laid out by the House of Lords in *Anns v. Merton London Borough Council.*³³ It should be noted that the *Anns* principle defines the law of negligence in Canada and New Zealand, but it has been rejected in Australia and England. In Australia and England a three step test is applied. That test involves firstly, foreseeability, secondly, the existence of a relationship between the parties of "proximity" or "neighborhood" and finally, a consideration of policy to determine whether it is "fair, just and reasonable" to impose the duty of care in question. Thus the liability principles applied in *Hoffman v Monsanto* have to be distinguished from those which might be applied in other countries.

A similar result to that in *Hoffman v Monsanto* was the decision of the United States District Court for the Eastern District of Missouri in *Sample v. Monsanto Co.*³⁴ The plaintiffs argued that farmers, such as themselves, who did not grow genetically modified crops "lost revenue because the European community rejected Monsanto's genetically modified products and boycotted all American corn and soybean as a result."³⁵ The plaintiffs brought an action for negligence against Monsanto for introducing the non-genetically modified seeds into the market. Monsanto moved for summary judgment, arguing that the economic loss doctrine barred negligence claims that are not based on physical injury to persons or property. The Court ruled that as the plaintiffs did not sustain physical contamination or injury to their property, the economic loss doctrine precludes recovery of damages.

³¹ *Ibid.* at para.22.

³² 2005 SQKB 225.

³³ 1978] A.C. 728 (H.L.).

³⁴ 283 F.Supp.2d 1088 (E.D.Mo.2003).

³⁵ *Ibid.* at 1091.

The different approach to negligence in Australia, producing an opposite result to that in *Hoffman v Monsanto* was the Australian High Court decision in *Perre v. Apand Pty. Ltd*³⁶. The defendant had provided defective potato seed to Sparnons, commercial growers of potatoes and other vegetables. The seed caused an outbreak of bacterial wilt in Sparnons' potato crop. The plaintiff owned farms near the Sparnons' land and sold potatoes in the lucrative Western Australia market. Their potatoes were not directly affected by potato wilt, but legislation of Western Australia prohibited the import of potatoes that were grown within 20 kilometers of a bacterial wilt outbreak. The plaintiff's therefore lost the most lucrative market for their potatoes.

At trial and in the Court of Appeal the plaintiffs were unsuccessful, these Courts holding that, as the plaintiffs had suffered no physical damage, their claim was for pure economic loss and was not recoverable. The High Court ruled that where a defendant knows or ought reasonably to know that its conduct is likely to cause harm to the person or tangible property of the plaintiff unless it takes reasonable care to avoid that harm, the law will prima facie impose a duty on the defendant to take reasonable care to avoid the harm.³⁷ The loss to the plaintiffs was on the facts clearly foreseeable and they were known to be a vulnerable class.

The possibility of harm emanating from GM crops was considered recently by the United States Court of Appeals for the Ninth Circuit in *Geertson Seed Farms and others v. Forage Genetics, Inc and Monsanto Company and Others*.³⁸ This was not a tort action, but concerned decision by the Animal and Plant Health Inspection Service (APHIS), a division of the United States Department of Agriculture, concerning the environmental impact of Round-up Ready Alfalfa. APHIS had initially classified the genetically modified alfalfa as a regulated article under the National Environmental Policy Act (NEPA).

The Appeal Court agreed with the District Court that the harm to growers and consumers who wanted non-genetically engineered alfalfa outweighed the financial hardships to Monsanto and Forage Genetics and their growers.

The courts also agreed that in considering the public interest, while recognizing that agricultural biotechnology has social value, they held that it would be in the public interest to enjoin the expanded use of Roundup Ready alfalfa before its impact was studied, because failing to do so could potentially eliminate the availability of non-genetically engineered alfalfa.

A dissenting judgment in the Appeal Court noted that the facts were sharply disputed by the parties, including a dispute as to the risk of genetic contamination that could occur while APHIS prepared the EIS.

3. Nuisance

The tort of private nuisance is concerned with conditions or activities that cause physical injury or damage to land or that interfere with the use or enjoyment of land. The common law has distinguished between activities or conditions that cause physical injury or damage to another's land from activities and injuries that interfere with the use or enjoyment of land, without actual physical damage.

A nuisance claim in relation to GM corn was considered by the US District Court in Illinois in *In re StarLink Corn Products Liability Litigation, Marvin Kramer v. Aventis CropScience USA Holding Inc*.³⁹ The plaintiffs in that case sought to bring a class action claim against the defendant manufacturer and creator of genetically modified StarLink corn. It was alleged that StarLink had contaminated the entire

³⁶ (1999), 164 A.L.R. 606.

³⁷ Ibid at para 68.

³⁸ 2008 U.S. App. LEXIS 18752

³⁹ (2002), 212 F. Supp. 2d 828 (U.S. District Court, N.D. Illinois).

corn supply in many states resulting in increased farming costs and depressed corn prices. The genetic modification of StarLink corn caused it to produce a protein (Cry9C) toxic to certain insects and containing several attributes similar to known human allergens. Accordingly, the defendant had obtained only qualified approval for release for use for animal feed, ethanol production and seed increase by the Environmental Protection Agency (“EPA”) under the Federal Insecticide, Fungicide, and Rodenticide Act. The EPA prohibited its use for human consumption and imposed on the defendant manufacturer stringent requirements of warning and monitoring to ensure implementation of mandatory segregation methods in the cultivation, harvesting, handling, storage and transport of StarLink corn, including a mandatory 660-foot “buffer zone” around StarLink corn crops. It was alleged that the defendant had failed to comply with the EPA requirements resulting in the crosspollination and commingling of StarLink with non StarLink corn.

The plaintiffs’ actions included private nuisance, alleging that the defendant created a private nuisance by distributing corn seeds with the Cry9C protein, knowing that they would cross-pollinate with neighboring corn crops. The defendant moved to have the claim dismissed as disclosing no cause of action, arguing that they could not be liable for any nuisance caused by StarLink corn because they were no longer in control of the seeds once they were sold to farmers.

The Court first ruled that the cross-pollination of a crop from neighboring land constituted nuisance as the StarLink corn was not considered fit for human consumption.⁴⁰ On the question of whether liability in private nuisance could extend to a manufacturer after the point of sale, the Court relied on the American Restatement para. 834, stating that one can be liable in private nuisance “not only when he carries on the activity but also when he participates to a substantial extent in carrying it on.” The question was what counted as “participation to a substantial extent” in carrying on the nuisance beyond the point of sale. It was clear that the general rule was that liability for nuisance could not be imposed on the manufacturer in these circumstances. However, the Court pointed to a number of cases in which the normal pattern of nuisance liability (imposed on a neighboring land owner or occupier) had been extended. In the case of some manufacturers, the liability had been extended on the basis of foreseeability of the harm alleged coupled with some malfeasance on the part of the manufacturer. In this case, it was alleged that the defendant had itself violated the EPA’s mandates in failing to adequately warn of the need for segregation and to enforce farmers’ compliance with the EPA requirements. The Court concluded “All parties who substantially contribute to the nuisance are liable. The unique obligations imposed by the limited registration arguably put Aventis in a position to control the nuisance.”⁴¹

In *Hoffman v Monsanto* the court distinguished the *StarLink* decision on the grounds that it was not alleged that contamination of organic crops by GM canola was harmful per se or that it rendered the organic crops unfit for consumption or otherwise harmful. Nor was it alleged that the defendants failed in any way to conform to the requirements imposed on them. Indeed, it will be recalled that they had received federal approval for the unconfined release of the GM canola varieties. Thus there were no facts alleged in this case that could support a finding that the defendants substantially caused the nuisance alleged.

4. Trespass

To sustain a cause of action in trespass, the plaintiffs must establish intentional and direct interference with another’s possession of land, usually an unauthorized entry upon another’s land. It has been suggested by a number of scholars that planting a crop which, several months later, produced pollen

⁴⁰ *Ibid.*, at 841.

⁴¹ *Ibid.*, at 847.

which was carried by the wind onto a neighbor's property would not be a sufficiently 'direct' interference to satisfy the requirements of trespass to land.⁴²

5. Breach of Statutory Duty

Most countries have introduced environmental legislation or legislation, based on the Cartagena Protocol, to deal with the impacts of GM agriculture. A number of countries have also adopted GM labeling laws. Breaches of this legislation could render a defendant criminally liable, as well as liable for a civil action for breach of statutory duty.

A UK case in which biosafety concerns were raised in an agricultural context was: *R. v Watson, (On the application of) v Secretary of State for Environment, Transport & Regions & Anor*⁴³ Under Part VI of the UK Environmental Protection Act 1990 GM seed could not be released into the environment without a consent issued by the Secretary of State for the Environment Transport and the Regions under section 112 of the Act. Sharpes a firm of seedsmen had developed a genetically modified strain of maize seed known as T25. They wished to have a seed trial conducted. It was arranged that a body called "NIAB" should conduct a trial on land it occupied for the purpose of such trials. However, because T25 seeds were genetically modified organisms, before a consent could be given the Secretary of State had to be satisfied that the release would be safe. The Secretary of State was satisfied and granted a consent to Sharpes.

What was not realized when the consent was given was that the Applicant, whose farm was in the same area as NIAB's land, was an organic farmer and that a question could arise whether a crop of organic maize grown by him could be pollinated by pollen from the T25 plants. The Applicant was a member of the Soil Association which certified organic crops. The value of crops sold "organically grown," would be seriously depreciated, without this certification. The Applicant knew of the trial of T25 which was taking place and was warned by the Soil Association that if there was a risk of pollination from it his crop certification of it would be withdrawn. Faced with this warning the Applicant sowed his own crop, but at a point as far away as he could sow it from the land on which T25 was being grown - 2 km away, in fact. No question of risk to the Applicant's crop arose if the T25 plants were not allowed to flower. The question was taken up with the Secretary of State. He decided that it was appropriate to take a decision nearer the time as to whether the crop should be allowed to flower. He took advice from the body known as "ACRE" and decided to allow the trial to continue and not to prevent the plants from flowering.

The Applicant sought an order requiring the Secretary of State to prevent the crop from flowering. The Secretary of State has sought the advice of the Advisory Committee on Releases to the Environment (ACRE) on this matter. That advice stated that as the applicant's sweetcorn crop had been planted at a site approximately 2 km from the nearest genetically modified maize, ACRE consider the amount of cross-pollination was likely to be zero.

On this basis the Court ruled that the Secretary of State's decision was not open to challenge. However, if the risk of cross-pollination was higher, this case illustrates the possibility of liability for breach of statutory duty.

⁴² R. A. Repp, 'Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift' (2000) 36 *Idaho L Rev* 585; C. Flood, 'Pollen Drift and Potential Causes of Action' (2003) 28 *Iowa J Corp L* 473; T. N. Vollendorf, 'Genetically Modified Organisms: Someone is in the Kitchen with DNA – Who is responsible when someone gets burned?' (2001) 21 *Miss C L Rev* 4.

⁴³ [1998] EWHC Admin 737.

E THE CARTAGENA PROTOCOL

1 International Aspects

A number of international agreements and treaties are concerned with biosafety. These include the Convention on Biological Diversity (CBD) (1992), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (1994), the WTO Agreement on Technical Barriers to Trade (1994), the FAO International Plant Protection (1997), Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998) and the CBD Cartagena Protocol on Biosafety (2000). Additionally, there are a number of non-binding codes of practice and technical guidance documents including the World Conservation Union (IUCN) Position Statement on Translocation of Living Organisms (1987), Organization for Economic Co-operation and Development (OECD) Safety Considerations for Biotechnology (1992), the FAO International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources, the United Nations Industrial Development Organization (UNIDO) Voluntary Code of Conduct for the Release of Organisms into the Environment, the UNEP Technical Guidelines (1995) and the FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents (1996).⁴⁴

Of these the most important for CGIAR activities is the Cartagena Protocol on Biosafety, which was adopted on 29 January 2000 by the Conference of the Parties to the Convention on Biological Diversity as a supplementary agreement. The Protocol seeks to protect biological diversity from the potential risks posed by "living modified organisms" (LMOs) resulting from modern biotechnology. Among the principal provisions of the Protocol is the creation of an advance informed agreement (AIA) procedure that requires exporters to seek consent from an importing country before the first shipment of an LMO meant to be introduced into the environment. Shipments of LMO commodities that are intended for direct use as food, feed, or for processing, must be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment." The Protocol establishes a process for considering more detailed identification and documentation of LMO commodities in international trade. It also sets out information to be included on documentation accompanying LMOs destined for contained use, including any handling requirements and contact points for further information and for the consignee.

Annex I to the Protocol lists the following information which must be provided by the exporter of a LMO:

- a) Name, address and contact details of the exporter.
- b) Name, address and contact details of the importer.
- c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
- d) Intended date or dates of the transboundary movement, if known.
- e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

⁴⁴ For a comprehensive list of relevant legislation, see L. Glowka *The Role of Law in Realising the Potential and Avoiding the Risks of Modern Biotechnology. Selected Issues of Relevance to Food and Agriculture*, Rome, FAO International Commission on Genetic Resources for Food and Agriculture, 2002.

- f) Centers of origin and Centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
- j) Quantity or volume of the living modified organism to be transferred.
- k) A previous and existing risk assessment report consistent with Annex III.
- l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
- n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
- o) A declaration that the above-mentioned information is factually correct.

In the case of LMOs intended for direct use as food or feed, or for food processing, Annex II requires:

- a) The name and contact details of the applicant for a decision for domestic use.
- b) The name and contact details of the authority responsible for the decision.
- c) Name and identity of the living modified organism.
- d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
- e) Any unique identification of the living modified organism.
- f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient, organism or parental organisms related to biosafety.
- g) Centers of origin and Centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- i) Approved uses of the living modified organism.
- j) A risk assessment report consistent with Annex III.
- k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Annex III to the Protocol deals with the risk assessment to be made by competent authorities to make informed decisions regarding LMOs. As a general principle risk assessment should be carried out “in a

scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations” and carried out “on a case-by-case basis”. To fulfill its objective, clause 8 of Annex III requires that risk assessment entails, as appropriate, the following steps:

- a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
- b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
- c) An evaluation of the consequences should these adverse effects be realized;
- d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
- e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
- f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Among the matters to be taken into account in a risk assessment are the relevant technical and scientific details regarding the characteristics of the following subjects:

- a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, Centers of origin and Centers of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
- b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
- c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organisms or parental organisms;
- f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;
- g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and
- h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and Centers of origin of the likely potential receiving environment.

Under the national law of most countries the accession to a treaty does not have any effect until it is adopted by national ratifying and implementing legislation. Examples of national legislation which adopts the Cartagena Protocol are outlined in (b) below.

Where a country does not ratify or accede to the Biosafety Protocol, but is a party to the CBD, Article 19(4) creates a bilateral obligation for a contracting party to provide information on an LMO prior to providing it to another CBD party. This information includes (1) any available information on the regulatory measures taken by the exporting CBD Party and (2) any available information on the “potential adverse impact” of a particular LMO.

2 National Aspects

Typically two approaches or ‘regulatory styles’ have been identified in national legislation implementing Cartagena: (i) a process-based approach (exemplified by the EU regulatory system), and (ii) a product based approach (exemplified by the United States) focusing primarily on the end-use of the product rather than on the production process.⁴⁵ A United Nations University study, published in February 2008⁴⁶ has observed that in practice, many national regulatory systems and international instruments appear increasingly to reflect a ‘mixed’ approach, subjecting GMOs and GM products to both general and specific safety rules and standards.

The UNU study listed the following biosafety legislation.

Africa

Forty countries had ratified or acceded to the Cartagena Protocol on Biosafety.⁴⁷ A Model Law on Biosafety was developed under the auspices of the Organization for African Unity in 2001.⁴⁸ Member States were urged to use the Model Law in drafting their national legal frameworks for biosafety in order to create a harmonized Africa-wide biosafety system.⁴⁹

Asia and Pacific

By December 2007, thirty seven countries in the region had ratified or acceded to the Cartagena Protocol on Biosafety.⁵⁰ In addition, ASEAN nations have adopted non-binding guidelines which provide guidance for biosafety regimes in the absence of a national biosafety framework.⁵¹

⁴⁵ See C Dunlop, “GMOs and Regulatory Styles”, (2000) 9(2) *Environmental Politics*, 149.

⁴⁶ Sam Johnston, Catherine Monagle, Jessica Green with Ruth Mackenzie, *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?* Yokohama, United Nations University Institute of Advanced Studies, February 2008.

⁴⁷ Algeria, Benin, Botswana, Burkina Faso, Burundi, Comoros, Congo, Cote d’Ivoire, Djibouti, Gambia, Ghana, Guinea, Lesotho, Liberia, Madagascar, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, Sudan, Swaziland, Tanzania, Togo, See, <http://www.unep.org/biosafety/>.

⁴⁸ The text of the Model Law is available at:

http://www.africabio.com/policies/MODEL%20LAW%20ON%20BIOSAFETY_ff.htm.

⁴⁹ Decision on the Report of the Interim Chairperson on the Africa-wide Capacity Building in Biosafety, Doc. EX/CL/31(III) (Decision on the Third Ordinary Session of the Executive Council of the African Union, 4-8 July 2003, Maputo).

⁵⁰ Bangladesh, Bhutan, Cambodia, China, Cyprus, Democratic People’s Republic of Korea, Fiji, India, Indonesia, Iran, Islamic Republic of, Japan, Jordan, Kiribati, Kyrgyzstan, Lao People’s Democratic Republic, Malaysia, Maldives, Marshall Islands, Mongolia, Nauru, Niue, Oman, Palau, Papua New Guinea, Philippines, Qatar, Republic of Korea, Samoa, Saudi Arabia, Solomon Islands, Sri Lanka, Syrian Arab Republic, Tajikistan, Thailand, Tonga, Viet Nam, Yemen. See, www.cbd.int.

⁵¹ The guidelines can be accessed at <http://binas.unido.org/binas/regulations/ASEANGuidelines.pdf>.

Central and Eastern Europe

By December 2007, twenty countries in the region had ratified or acceded to the Cartagena Protocol.⁵² With the exception of Romania, no country permits the commercialization of GMOs. Bulgaria, Croatia and Romania have adopted GMO legislation. Eight countries in the region are Member States of the European Union and subject to its GMO legislation.⁵³

Latin American and the Caribbean

Legislation in this region has tended to lag behind the introduction of GM agriculture. For example In Brazil it was estimated that five million hectares of GMO crops were grown, but it was only in late March 2005 that Parliament passed a biosafety law that allowed for the legal commercial planting of GM crops. The UNU study notes that the regulatory environment across the region is variable.⁵⁴ Some countries, such as Brazil, have broad based biosafety legislation in place, covering transgenic plants, animals, micro-organisms, as well as bioethics and biotechnology. Others, such as Chile, Paraguay, Uruguay and Colombia have regulations that apply only to plants. Twenty five countries in the region have ratified or acceded to the Cartagena Protocol on Biosafety.⁵⁵

F. RISK MINIMIZATION STRATEGIES

1 Intellectual Property Infringement

As part of the international network of *ex situ* collections provided for in the International Treaty on Plant Genetic Resources for Food and Agriculture, CGIAR Centers agree not to claim legal ownership over the designated germplasm, or to seek any intellectual property rights over that germplasm or related information. The CGIAR Centers have also agreed to pass on the same obligations to all future recipients of designated germplasm not to claim ownership over the designated germplasm received, or to seek intellectual property rights over that germplasm or related information. Recipients also have to assume full responsibility for complying with the recipient nation's quarantine/biosafety regulations and rules as to import or release of genetic material.

The primary areas of potential IP liability for CGIAR Centers will arise in relation to alleged infringements of plant variety rights, patents and confidential information. These matters can usually be dealt with through contractual arrangements with the relevant rights holders in which permissions will be secured for the use of those proprietary rights. There are a number of examples of collaborations by CGIAR Centers with private partners in which arrangements were successfully made for the utilization of private IP rights, e.g. the Golden Rice project, and the Insect-Resistant Maize for Africa project.

As has been mentioned above plant variety rights laws provide a research exception, which CGIAR Centers can make use of in relation protected varieties. Similarly, under patent laws an experimental use exception is available for CGIAR Centers in relation to materials which are protected by patents. These issues are best dealt with in the context of IP and biosafety management, which is addressed below.

⁵² Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Republic of Moldova, Romania, Serbia, Slovakia, Slovenia, The Former Yugoslav Republic of Macedonia and Ukraine. See, www.cbd.int.

⁵³ Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia.

⁵⁴ Johnston, et al, *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?* Yokohama, United Nations University Institute of Advanced Studies, February 2008, 29.

⁵⁵ Antigua and Barbuda, Argentina, Bahamas, Barbados, Chile, Costa Rica, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Peru, Saint Lucia, Suriname, Venezuela. See, www.unep.ch/biosafety/news/htm.

A potential liability issue is the incorporation, usually inadvertent, of third party intellectual property into CGIAR Center products. An obvious risk minimization strategy is for Centers to conduct periodic audits to identify any third party IP which is being used and to ensure in their IP management policies that Center personnel are aware of their IP obligations.

As part of their germplasm policies Centers generally make no warranties as to the safety or title of the germplasm, nor as to the accuracy or correctness of any passport or other data provided with the material. This will have the effect of minimizing Center IP liability for infringing acts which may be done by NARS or farmer recipients of Center germplasm. For example, the warranty clause in FAO's Standard Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture⁵⁶ provides:

The Provider makes no warranties as to the safety of or title to the Material, nor as to the accuracy or correctness of any passport or other data provided with the Material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Material being furnished. The phytosanitary condition of the Material is warranted only as described in any attached phytosanitary certificate. The Recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material.

Another useful precedent is that provided in Intellectual Property Management in Health and Agriculture Innovation: A Handbook of Best Practices⁵⁷.

Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Unless prohibited by law, Recipient assumes all liability for claims for damages against it by third parties which may arise from the use, storage or disposal of the Material except that, to the extent permitted by law, the Provider shall be liable to the Recipient when the damage is caused by the gross negligence or willful misconduct of the Provider.

If it is thought that this exclusion of liability is unduly harsh on NARS or farmers, CGIAR Centers could supply germplasm and other products, warranting the integrity of any IP incorporated in those products. In this situation, the Centers would be assuming the IP liability arising from the use of third party IP.

2. Biosafety Liability

CGIAR Centers

Under the Standard Material Transfer Agreement (SMTA)

The STMA, which was finalised in 2006 for use with germplasm under the FAO Treaty on Plant Genetic Resources for Food and Agriculture, provides in Article 9.1 that "the Provider makes no warranties as to the safety of or title to the material, nor as to the accuracy or correctness of any passport or other data provided with the material, neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the material being furnished and the recipient

⁵⁶ <ftp.fao.org/ag/cgrfa/gb1/SMTAe.pdf>.

⁵⁷ ISBN 978-4243-2026-4, available online at www.ipHandbook.com.

assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material."

However, the Guiding Principles for the Development of CGIAR Centers' Policies to address the Possibility of Unintentional Presence of Transgenes in Ex Situ collections, which were reported to the FAO Commission on Genetic Resources for Food and Agriculture⁵⁸ provides that Centers should "take proactive steps to determine the risk of the unintentional presence of exotic genes, including transgenes, in their ex situ collections."⁵⁹ The relevant Guiding Principles are adopted as recommendations in this report.

Recommendation 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."

Recommendation 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.

Recommendation 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.

⁵⁸ CGRFA-11/07/14 Rev.1, Rome, 11-15 June 2007.

⁵⁹ *Ibid.*, Art.6.

Recommendation 4

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

Recommendation 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.

Recommendation 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).

Recommendation 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.

Recommendations of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers, May 2007

In 2002 the CGIAR interim Science Council commissioned "a strategic study of biosafety across the CGIAR system, in order to shed light on current policies, procedures and practices and to make recommendations on future biosafety policies and practices across the CGIAR system."⁶⁰ Item 5 in the Terms of Reference for the Study was to make recommendation to the Science Council "on the possible future CGIAR policies and practices in biosafety to guide the Centers and their partners in the safe use of gene technology and its products."⁶¹ To a limited extent this covers part of the same field as the present study.

The Report adopts Cohen et al. (1999)⁶² identification of the four major elements for developing and implementing biosafety policies and practices. These recommendations are adopted as a recommendation of this Report.

Recommendation 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;

⁶⁰ Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers, May 2007, p.7.

⁶¹ Ibid., p.33.

⁶² Ibid., p.19 unfortunately Cohen et al (1999) is not included in the table of references, *ibid.*, p.34.

4. A feedback mechanism – for incorporating new information and revising the regulatory system.

It is suggested that the written guidelines may include the Terms of Reference (TORs) of biosafety committees and biosafety officers and specific text or documents on aspects of biosafety, including safety regulations in the laboratories, in the field, and in transit.

There is an obvious relationship between 1, 3 and 4, since the guidelines should be updated from time to time in light of any judicial interpretations of biosafety obligations, which should be picked up by the information system and the feedback mechanism. The latter involves a responsible body and procedures “to report on, monitor and adjust current research, events or regulatory systems.”⁶³

The findings of the Report includes the fact that “most Centers have prepared Institutional Biosafety Guidelines, primarily developed by Center staff, in accordance with the requirements of their respective host country national regulatory authorities.”⁶⁴

Recommendation 2 of the Report is the enhancement of capacity building in national biosafety policies and practices.⁶⁵ This recommendation includes the requirement that Centers to continue to support their partner countries: in building national capacity for framing regulations, implementing and monitoring them and that the “Centers activities in capacity building should be better coordinated with other bilateral and international programs, such as those being implemented by the UN agencies in response to the Cartagena Protocol on Biosafety.” The current study recommends that capacity building be extended to national and international legal regulation of biosafety.

The findings of the Report on biosafety practices at the Centers include the fact that “All Centers meet or exceed the capacity and requirements of their host country to govern the biosafety of LMOs.”⁶⁶ It is pointed out that some host countries are still developing their biosafety governance frameworks and regulatory capacity. However, the Report found that most of the Centers “are actively helping their host country to develop its biosafety governance frameworks”.⁶⁷ At this stage, Centers should monitor these legislative developments with a view to including them in the Centers’ Biosafety Guidelines.

*A useful approach for the CGIAR is that of the UK Advisory Committee on Releases into the Environment (ACRE) which in 2001 published **Guidance on Principles of Best Practice in the Design of Genetically Modified Plants**.*⁶⁸ *In Annex 1 to this guide for researchers is an outline of the Legal Framework for Decision Making on the Release and Marketing of GMOs in the EU which outlines “the legal framework against which decisions are made about the release and marketing of genetically modified organisms (GMOs) in the UK and EU.” Similar guides should be prepared by CGIAR Centers to outline the relevant legal framework in CGIAR client countries.*

Accidental Liability

To what extent would a CGIAR Center be liable for any accidental loss (including theft) or alteration of the third party IP during research, i.e., outside of supervisory procedures? Where the relevant legal liability arises from intentional activities, eg trespass and criminal statutes, the absence of knowledge of the relevant activities by the CGIAR Center would provide a complete defence.

Consequently, CGIAR Centers dealing with GM crops should ensure that they do not intentionally or through carelessness cause the movement of GM seeds or pollen from their property onto another’s.

⁶³ Ibid., p.19.

⁶⁴ Ibid., p.20.

⁶⁵ Ibid., p.21.

⁶⁶ Ibid., pp.24-25.

⁶⁷ Ibid., p.25.

⁶⁸ <http://www.defra.gov.uk/environment/acre/bestprac/guidance/index.htm>

Complying with licence conditions (if any) imposed by any GM approvals body and appropriate guidelines would assist in the avoidance of liability for trespass.

On the other hand where intention is not an element of the legal wrong, such as in negligence or nuisance, the CGIAR Center would be able to escape liability where it has put in place a system to avoid inadvertent harm. In situations where an activity is viewed as a nuisance even where all reasonable precautions have been taken, the court is less likely to characterize the conduct as unreasonable where all relevant license conditions and legislative requirements have been complied with.⁶⁹

In some countries, strict liability is imposed in relation to the breach of biosafety laws. In these situations although liability will be automatic, it will be possible for CGIAR Centers to mitigate the quantum of any penalty, through the establishment of systems and practices designed to prevent biosafety lapses. For example Centers could establish systems to provide for the testing of products to identify whether the presence of any GM material is within allowable thresholds or product standards. Under most regulatory statutes requirements for 'non-GM' crops are likely to include tolerance levels for the unintended presence of GMOS. Where a CGIAR Center becomes aware of volunteer GM plants growing on its property, it should contact the regulatory authority in the first instance.

Recommendation 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.

NARS

In addition to the best practices, being developed by CGIAR Centers mentioned above, NARS could also take account of the best practice testing guidelines for both phenotypic traits and genetic markers at points in the production and marketing chain provided under the Rules for Seed Testing of the International Seed Testing Association (ISTA) and the Association of Official Seed Analysts (AOSA), as well as by official regulatory agencies in both international and domestic jurisdictions.

Also of assistance are the protocols and policies developed by GM seed suppliers for the guidance of those using their products.⁷⁰ Compliance with these is likely to reduce liability arising under biosafety laws.

For example the Australian grains industry has developed guidelines for producing Canola seed for delivery to customers in the domestic and export markets.⁷¹ In accordance with these recommendations, farmers, when growing GM canola and/or non-GM canola, should incorporate and give attention to:

- maintaining complete farm records for all paddocks and crops;
- incorporating sound crop rotation and production practices in farm management;
- selecting crop varieties and seed treatments suitable for local conditions;
- using certified or quality assured seed for planting a crop in preference to farmer-saved planting seed;
- using farmer-saved planting seed grown only from a crop established with certified seed;

⁶⁹ See *Monsanto v Hoffman* supra and Maria Lee and Robert Burrell, 'Liability for the Escape of GM Seeds: Pursuing the "Victim"?' (2002) 65(4) *Modern Law Review* 517, 534

⁷⁰ Eg Monsanto's Canola Industry Stewardship Principles for coexistence of production systems and supply chains, May 2003, <http://www.jcci.unimelb.edu.au/GMCanola2007/CISP%201%20July%202003.pdf>.

⁷¹ *Ibid.*

- establishing base weed control and cultural practices on the weed spectrum and the herbicide resistance status;
- declaring and identifying product at first point of delivery in the supply chain;
- implementing farm hygiene practices in relation to:
 - farm equipment (spraying, seeding, cultivation, harvesting);
 - seed and grain handling, transport and storage; and
 - chemical storage and handling;
- incorporating integrated crop and weed management practices, such as:
 - consulting the Crop Management Plan for details before planting;
 - consulting the Stewardship Plans for non-GM herbicide tolerant crops;
 - rotating herbicide groups and modes of action, as well as cultural practices;
 - minimizing the adventitious presence of off-type seed or grain; and
 - minimizing gene flow.

Where a contractor is employed to implement a management practice (for example, crop spraying, windrowing, harvesting, transport), the grower must ensure the contractor is adequately informed of the standard required for undertaking the assigned task and, if required, can prove recommended procedures were followed. Growers, advisors and their staff must be adequately informed and trained and be aware of the recommendations for growing canola (for example, keeping records, cleaning machinery) for the optimal and safe management of the seed, crop and harvested product.

Outlined below are the risk minimization strategies in relation to the various civil actions which arise in a biosafety context.

3 Biosafety and IP Management

Although this paper addresses the liability of CGIAR Center arising from the use of genetic resources, similar principles will apply to the misuse of other proprietary information such as copyrighted or patented software codes and confidential information. Most Centers have dealt with these matters in the process of conducting IP audits and establishing systems for the management of their own and third party IP. As each of the Centers have established IP management systems and procedures, it should not be too difficult to extend these systems to the management of biosafety issues.

This report is part of a tripartite analysis of the responsible stewardship of biological resources by CGIAR Centers. This analysis will, no doubt, provide some useful suggestions for the management of these resources. Organizationally, there are obviously advantages in unifying the management of biological resources and the management of IP.

Following the IP precedent, it would be useful for CGIAR Centers to conduct biosafety management reviews, with a view to verifying the establishment of effective biosafety management procedures and structures at Centers. In order to ascertain the extent of knowledge of biosafety and biosafety management practices within Centers questionnaires could be administered to administrative staff and to senior research staff. These questionnaires could act as a base against which to measure the, hopefully burgeoning knowledge about biosafety within Centers and will be tested against subsequent surveys.

Recommendation 10

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

With the increasing significance of biosafety matters for Centers, it would seem to be important to establish a biosafety coordination office. This office could be responsible for coordinating both

biosafety and IP administration and procedures within Centers and would be responsible for external biosafety and IP liaison.

Recommendation 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.

The coordination of biosafety procedures would include: securing the biosafety compliance of staff and visitors; ensuring the inclusion of biosafety provisions in relevant third party agreements; ensuring the utilization of appropriate MTAs by Centers both as recipients and distributors of germplasm and biological tools; maintenance of a central repository of biosafety documents; maintenance of the Centers biosafety database; as well as general responsibility for biosafety consciousness raising.

Externally, the biosafety Coordinator would provide a biosafety dimension to negotiations with research collaborators, as well as liaising with the biosafety officials of CGIAR Centers and of the various biosafety organs of the CGIAR itself.

To supplement the general biosafety consciousness-raising activities mentioned above, it would be very useful for Center staff to be provided with access to biosafety principles in a handbook. This handbook could also be made available on-line.

Recommendation 12

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

CGIAR Center staff and visitors should be obliged to comply with Center biosafety policies.

Recommendation 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.

Recommendation 14

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

4. Other Liability

In the case of accidental release the question has been raised whether Centers might be vicariously liable for any damages for IP infringement and for biosafety breaches arising from actions against a company providing genetic material to a CGIAR Center. As a general matter the terms of a relationship between a provider company and a CGIAR Center will be determined by any contract between them. That contract can provide for a CGIAR Center to contribute to any payment of damages by the provider company. Equally, the CGIAR Center can provide for its immunity in any legal action against the provider company.

As a matter of practice it is open to the person bringing the action to select the relevant defendant. In all of the reported litigation thus far, the primary defendant has been the provider company. In all of the reported litigation the defendant company has not availed itself of any option which it might have had to join a grower as a defendant or as a contributor to any damages which might be imposed. Invariably in any supply of proprietary material, the rights holder will secure for itself the exclusive right to defend or conduct any litigation which calls an IP right into question.

It should be noted that in cases involving criminal liability, it is not possible either for a provider company or a CGIAR Center to obtain an indemnity from the other, as it is the policy of the criminal law not to permit any shifting of criminal liability.

5. Status of CGIAR Centers and Liability Arrangements

It has been suggested that CGIAR Centers and NARS should have immunity from liability because of their special status as international organizations working on developing International Public Goods.

This issue will invariably have been addressed during the Center-wide IP audit exercise. The liability of Centers will depend upon a combination of the provisions of their constitutive documents, their headquarter agreements and any specially enacted laws. The constitutive document, usually a constitution or memorandum of articles under the national company law of the host country will determine the question of general liability of a Center. As a matter of general practice an incorporated Center is liable for the acts of the "directing mind and will" of the corporation/Center. These persons are those identified in the by-laws/articles of association of the company as exercising its governing or directorial functions. In some circumstances, e.g. under environmental laws or consumer protection laws, liability may be imposed upon a corporation for the acts and omissions also of servants and agents. In this latter circumstance, liability can usually be avoided if the corporation has put in place a rigorous system of supervision of lower echelon personnel.

It is, of course, possible for the headquarters agreement to exempt a Center from liability under the laws of the host country. This will not assist Centers where their activities breach overseas laws. IP laws generally have only national effect. As we saw above in relation to the soy meal litigation, an activity might be innocuous in a home country where there is no enforceable IP right, but it becomes problematic when dealings are conducted in countries where those rights have been registered.

Where a Center is mostly involved in developing advanced lines which will then be transferred to NARS for breeding, the obligations for the Center will be dictated by the terms on which the transfer is made. IP or biosafety liability should be spelt out in the MTA. Similarly, where a product of research in a CGIAR Center is transferred from its headquarters to a field office in another country, with a view to being finally handed over to a NARS, again the question of IP or biosafety liability should be spelt out in the MTA. The notorious example of blight resistant rice developed by IRRI containing the *Xa21* gene patented by UC Davis⁷² is an example of the sort of difficulties which can arise in these situations. Use of the *Xa21* gene in IRRI client countries was unobjectionable, because of a licensing arrangement entered into between IRRI and UC Davis. However, exports by farmers in client countries to the USA, would have involved them in an infringement of the UC Davis patent. In that circumstance the CGIAR Center or NARS which provided those farmers with the patented gene could have been joined as defendants in the infringement action.

CGIAR Centers should attempt to avoid this kind of liability by making no warranty as to the title of any IP rights incorporated in materials provided by them to NARS.

Knowledge of IP liability issues in CGIAR Centers has been thrashed out over the last decade through the establishment and publication of IP policies in all CGIAR Centers and with the establishment of the CAS. The same approach should be taken with the establishment of biosafety policies.

A radical solution to these biosafety and IP liability issues is contained in the suggestion of Anatole Krattiger that the 15 CGIAR Centers be merged into a World Agricultural Organization (WAO) with a mandate to "re- focus its attention on two strategic areas: the poorer developing countries with weak agricultural research and extension programs, and crops of specific importance to resource poor and

⁷² U.S. patent 5,859,339, 12 January 1999.

subsistence farmers.”⁷³ He suggests that this will deal with what he describes as the “top heavy” institutional structure of the CGIAR and its limited research budget in comparison with the corporate sector.⁷⁴ The establishment of a new organization would permit the “channeling” of existing technologies to the specific needs and priorities of the least developed countries and regions and “would negotiate with technology owners and seek licenses with the right to sublicense on a crop-by-crop, market-by-market, or technology-by-technology basis”.⁷⁵

The reconstitution of the CGIAR as an international organization, presumably within the UN system would deal with the liability issue, as the CGIAR would then attract all of the immunities of an international organization.

6. Insurance⁷⁶

Insurance for GMOs is currently not generally available. Insurance is generally focused on sudden and accidental damage, for which the risks can be actuarially calculated. Insurance against diffuse environmental pollution such as GMOs might cause is more difficult to come by. In 2003 the London *Telegraph* reported a survey conducted by working farmer members of Farm, a campaign group, which found insurance companies unwilling to take on the risk of liability claims against farmers who grew GM crops.⁷⁷ An explanation given for this was that “GM could be like thalidomide - only after some time would the full extent of the problems be seen”. All the insurers surveyed felt that too little was known about the long-term effects on human health and the environment to be able to offer any form of cover for farmers growing GM crops. Insurance firms do not have claims histories to help them assess risks, or to assess the extent of precautions being put in place by companies, thus making it hard initially to set premiums.

Experience tends to build up over time, and the insurance market tends not to move into new areas rapidly. Initially the industry would aim to limit its own potential liability. The European Commission notes that capping is likely to improve the chances of early development of the insurance market but would erode the effective application of the ‘polluter pays’ principle.⁷⁸

The closest example which I have found to an insurance scheme covering GM liability is a scheme being developed for the FAO and the Thai Government on insurance for aquaculture farmers in Thailand. An FAO technical paper noted that there was a general perception that aquaculture was a high-risk activity involving greater risk than in other food production industries principally because its products are often raised outside the aquaculturists’ direct observation with increased susceptibility to disease outbreaks but requiring large investments from the aquaculturists.⁷⁹ As with GM agriculture in commercial aquaculture insurance is not widespread. The reasons for this, include: (i) the general lack of knowledge of aquaculture insurance operations among insurers in developing countries; (ii) limited awareness among aquaculturists in developing countries of the benefits of insurance; (iii) lack of stock control and other management skills and processes that are required for

⁷³ A. F. Krattiger, ‘How can intellectual property rights contribute to the food security of an increasingly globalized world while meeting the demands of farmers and breeders?’ http://www.infoagricar.ch/ipr-symposium/documents/Paper_Krattiger.pdf, 7.

⁷⁴ Ibid.

⁷⁵ Ibid.

⁷⁶ See, Agriculture and Environment Biotechnology Commission, AEBC/02/07, Liability Sub-group, Draft Paper on Issues for Discussion, <http://www.aebc.gov.uk/meetings/papers/aebc0207.htm>

⁷⁷ <http://www.telegraph.co.uk/news/uknews/1443522/No-insurance-cover-for-GM-crops-that-could-be-like-thalidomide.html>

⁷⁸ Agriculture and Environment Biotechnology Commission, Liability Sub Group, Draft Paper on Issues for Discussion, AEBC/02/07, <http://www.aebc.gov.uk/meetings/papers/aebc0207.htm>.

⁷⁹ Raymon van Anrooy, et al Review of the Current State of World Aquaculture Insurance. FAO Fisheries Technical Paper 493, 2006.

insurance cover eligibility, (iv) exclusion of small-scale aquaculturists from insurance; (v) lack of well-established village institutions, such as co-operatives, to act as insurance agents; (vi) lack of legal frameworks for fisheries insurance and lack of related government policies; (vii) difficulties in promoting insurance policies, designing sustainable insurance programs and co-ordinating the work of the agencies concerned; (viii) lack of staff within insurance institutions with knowledge of the sector; and (ix) some negative experiences by reinsurers that have borne substantial losses, for example, from algal blooms.⁸⁰

Some similarities with issues involving GM insurance can be immediately identified.

The FAO has appointed Global Compliance Assistance Pte Limited, a Singapore based insurance consultancy,⁸¹ to advise the Thai Government how to structure the risk transfer so that it can attract the capital of the world insurance/reinsurance market to Thai aquaculture industry. The CEO of this company has indicated his willingness to explore the development of an insurance scheme for GM agriculture.

The essence of insurance is that it spreads the risk in such a way that if a loss occurs to one or a number of the persons insured by a particular insurance company, the probability is that there will be enough policy holders who do not suffer a loss that the losses and the insurers expenses can be covered by the insurer's premium reserve. *Bernoulli's law* or the 'law of large numbers' forms the basis for the statistical expectation of loss upon which premium rates for insurance policies are calculated. Out of a large, diversified and homogeneous underwriting portfolio the claims burden should converge towards its expected value, in other words, in theory, the insurance company should be able to fairly accurately predict not by name but by number, the number of policyholders who will suffer a loss.

The problem comes when the conventional insurance market has insufficient knowledge or understanding of a particular risk, which results in a fear that the risk could be serious and unquantifiable. The insurance industry will only put its capital at risk where the risk, in its opinion, can be properly quantified and this quantification shows that it can be underwritten profitably. Until that point, it will not commit significant amounts of capital.

One approach where groups of persons require cover for risks that the conventional insurance market deems either "uninsurable" or will only write at prohibitive premiums is to form a *mutual* to provide such cover.

A mutual can be structured in various ways, but basically, it is an entity formed by a group of persons or companies exposed to some risk or contingency common to the group who are prepared to share financially with each other, on a proportionate basis, the cost of any loss incurred by an individual member, if the contingency occurs to the member. They are non-profit organizations. In other words, the group uses its own spread of risk, the same way as an insurance company does.

Most mutuals are formed notwithstanding the availability of conventional insurance alternatives, for example because:

- the members of the mutual have the perception that they are subsidizing through high premiums their conventional insurer's portfolio of relatively inferior risks;
- instability or inconsistency of the insurance markets;
- unacceptable or inconsistent pricing policies;

⁸⁰ Ibid. at 2

⁸¹ Contact particulars are: Max Fulton, Chief Executive Officer, Global Compliance Assistance Pte Limited, tel +65 63232363 (Singapore) Email: max.fulton@gca-compliance.com

- the relationship between premium and the cover provided (“the rate on line”) seems high;
- the failure of some high profile insurance carriers and the perceived financial insecurity of others ;
- the perception that some sectors of the conventional insurance market are becoming claims payment averse;
- insufficient flexibility of cover.

There are numbers of examples of mutuals that have been formed because there was no insurance available. For example, in a number of countries doctors are insured through mutuals for their professional indemnity risk for the very reason that they could not obtain insurance on the conventional market. Universities in a number of countries transfer their risk to a mutual and from there to the reinsurance market. While they do this in areas where conventional insurance is available in other cases the mutual covers risks that the conventional market will not. A good example of such a risk is clinical trials which are a vital part of university research but which the conventional market will not insure.

7. Compensation Funds

Another option which has been advanced to cover GM liability is compensation funds.⁸² While the risk pool is usually smaller compared to an insurance solution, such funds have the advantage of being tailored to the particular problems they address. Compensation funds have the procedural advantages of identifying the risk group in advance and the administration of the fund can be adjusted to their specific needs.

Another advantage is that the number of contributors to the fund is typically broader than in the classic insurance scheme. In addition to those immediately concerned can be added the State, Compensation funds are usually introduced to fill a gap in the insurance market. Thus in the case of GM where no insurance schemes appear to exist, for the reasons mentioned in the previous section, compensation funds may be established in order to at least serve as a temporary solution until the insurance market can take over.

There is some experience with GM compensation funds, particularly in the EU. The following summarises a 2007 survey of EU based schemes edited by Bernhard Koch.⁸³

Denmark was the first country to introduce legislation on a compensation fund for losses arising from GMO admixture. The Danish model foresees –initially for a period of five years – that GM crop growers shall pay 100 DKK per hectare of GM cultivation into a fund which shall be administered by the Danish Plant Directorate, a division of the Ministry of Agriculture. If in one given year claims should exceed the resources of the fund, they will nevertheless be satisfied. The excess monies will come from the State, but shall be recovered in the following year when the farmers’ contributions will be adjusted accordingly.

Non-GM farmers who suffer economic losses due to involuntary admixture but without contributory conduct of their own can claim compensation from the fund for the market price difference as well as for costs incurred for testing and sampling. Organic farmers can ask for further damages due to their special situation.

⁸² See Koch, B.A. (ed) (2007) *Liability and Compensation Schemes for Damage Resulting from the Presence of Genetically Modified Organisms in Non-GM Crops*. Vienna, European Centre of Tort and Insurance Law, http://ec.europa.eu/agriculture/analysis/external/liability_gmo/full_text_en.pdf 77ff.

⁸³ Ibid., Ch C.III.

Causation need not be proven strictly, a defined proximity in space and time between a GM field and the contaminated land suffices.

The competition authorities of the European Commission upheld the Danish regime because of the limited duration of the scheme, and because of the present unavailability of insurance cover on the European market.

The Portuguese compensation fund is also designed for an initial period of five years (but may be extended thereafter). It is limited to cases of adventitious presence of GMOs in conventional or organic crops above the labelling threshold of 0.9% only, while losses caused by the GM farmer's neglect of good farming practice has to be pursued on the basis of tort law.²⁰⁴ Monies are collected via a green tax on seeds (€ 4 per 80,000 seeds) though the fund may generate further income from investing amounts not used, but also from a 100 € fee per application, which is withheld if unsuccessful.

Applicants must prove causation at their own expenses and are only eligible if they have used certified seeds themselves. Claims must be delivered to the Directorate-General for Crop Production within the production (and contamination) year. As payments depend upon the means of the fund, compensation may be reduced proportionally if its resources should not suffice to pay out all approved amounts.

GM compensation funds have been designed in Belgium, Finland, France, Germany and the UK.

In July 2006 Defra announced its consideration of a compensation scheme as part of a consultation on proposals for managing the co-existence of GM with non-GM crops.⁸⁴ The terms of reference for this consultation were that stakeholders would be consulted on "options for providing compensation to non-GM farmers who suffer financial loss through no fault of their own", making it clear that any compensation would need to be funded by the GM sector itself, rather than by Government or non-GM producers.⁸⁵

The basic assumption of this consultation is that crops grown as non-GM (conventional or organic) could be worth less if they must be sold as 'GM', because they have a GM presence above the EU 0.9% labelling threshold. The potential need for a compensation system is predicated on non-GM crops trading at a premium. If the market does not distinguish between GM and non-GM crops no economic loss would occur to non-GM farmers and therefore redress would not be required.

The primary reason which Defra gives for its consideration compensation schemes is that the "application of the common law of negligence or private nuisance to GM cross-pollination is untested and uncertain".⁸⁶ Under UK law, applying EU co-existence rules Defra took the position that that redress for economic loss should only be available to farmers if the GM presence in a non-GM crop exceeds the 0.9% EU threshold as it would be "a disproportionate burden on the GM sector to make it liable for redress on the basis of a threshold stricter than the relevant legal standard."⁸⁷ A mitigating factor in for DEFRA is that if effective coexistence measures are in place, then the instances where non-GM growers might face a loss due to a GM presence above 0.9% should be very infrequent and that according to its regulatory impact analysis the value of any redress claim is likely to be relatively low.⁸⁸ It also envisaged that the redress scheme should only cover direct financial loss from individual incidents.

The potential economic losses identified by Defra arise from in which there is no market for the GM equivalent, in which case the loss would be the whole of the non-GM or organic price that has to be

⁸⁴ DEFRA, Consultation on proposals for managing the coexistence of GM, conventional and organic crops, London, DEFRA, 2006, available on www.defra.gov.uk.

⁸⁵ *Ibid.*, para 136.

⁸⁶ *Ibid.*, para 137.

⁸⁷ *Ibid.*

⁸⁸ *Ibid.*, para 139.

foregone. For crops like oilseed rape, beet or sweetcorn maize for processed food use, Defra assumes that in all normal circumstances the relevant unit of production when considering possible redress will be the crop obtained from a whole field, because farmers will trade these crops, as a minimum, on a whole field basis.⁸⁹ Where an organic forage crop has a GM presence above 0.9% the EU organic standards regulation prevent non-GM farmers in the UK from feeding this to their own animals thereby limiting the mitigation of loss.

Additional potential losses identified by Defra include those incurred in testing the affected crop for GM presence; the cost of storing the crop separately, or longer than intended, as a result of being unable to sell as originally intended; or extra transport costs as a result of having to treat the crop as GM rather than non-GM.⁹⁰ However, Defra pointed out that the more types of loss that are covered by a redress scheme, the more complicated and bureaucratic it may be to operate and that establishing the level of additional losses would entail further effort that could be disproportionate to the sum of money involved. Consequently, it recommended that if additional losses were to be covered, “to minimise bureaucracy the best approach might be to adopt a system of fixed or standard costs (e.g. for crop storage per day), avoiding the need to assess actual costs in detail.”⁹¹

Other types of loss which Defra did not think should be part of a redress mechanism were: (i) the loss by a farmer of subsequent business from a buyer as a result of being unable to fulfill a previous supply contract; (ii) the decision by a potential purchaser not to buy a particular non-GM crop, or pay a reduced price, if it has been grown in the general locality of a GM crop; (iii) the precautionary decision by a farmer not to grow a particular crop, to avoid the possibility of it being unacceptable because of its proximity to GM crops; and (iv) the loss of accreditation for a field or a farm by an organic certifying body.⁹² These losses resulting from voluntary standards or market-led decisions Defra considered should not be covered by the redress mechanism as compensation for these losses could still be sought through legal proceedings.

The eligibility criterion which Defra recommended for compensation is that redress should be limited to non-GM farmers who can demonstrate that there is a GM presence above 0.9% in their crop through no fault of their own and non-GM farmers may need to produce evidence, for example to confirm that:

- non-GM seed was used;
- the affected crop was destined for a premium non-GM or organic market;
- any obligations arising from the coexistence regime had been complied with;
- the finding of a GM presence above 0.9% was based on samples taken in accordance with a recognised protocol and tested at a suitable accredited laboratory.⁹³

Defra expects that there would need to be an adjudication process to determine the eligibility of redress claims, including an appeal or arbitration mechanism. This is considered below.

An interesting feature of the UK compensation scheme, compared with others in Europe is the Government’s decision that any compensation should be funded by the GM sector. Other options canvassed by Defra⁹⁴ are that compensation could be funded by:

⁸⁹ Ibid., para 142.

⁹⁰ Ibid., para 146.

⁹¹ Ibid., para 147.

⁹² Ibid., para 148.

⁹³ Ibid., para 150.

⁹⁴ Ibid., paras 156-157.

GM farmers who do not comply with the specified coexistence measures

This would have the advantage of placing the burden on those farmers most likely to be the cause of an excessive GM presence in neighbouring crops. This would provide a strong incentive for GM farmers to comply with coexistence measures, but it would not cover the situation where an excessive GM presence arises through no fault of a GM farmer, or where fault cannot be specifically attributed.

All farmers growing GM crops

This would spread the burden evenly among all GM growers. However, it does not have the advantage of the first option of providing a direct incentive for GM growers to comply with coexistence measures, and it could be said to penalise unfairly those farmers who do comply.

GM seed companies.

If GM seed companies were to fund a redress mechanism it would be a commercial matter between the companies and GM farmers to determine through their market relationship the precise allocation of the burden. For example, the seed companies could recover their costs through increased seed prices. It would also be open to them to recover some costs from GM farmers who have not complied with coexistence rules, by making compliance a condition of the GM seed contract. Making GM seed companies responsible would give them a clear incentive to ensure an effective coexistence regime. This in turn should increase confidence in the potential effectiveness of the regime and the degree of compliance with it.

In the latter situation Defra speculated that the burden could be applied equally on all GM seed companies, but alternatively the burden could be distributed according to market share, although this option might add administrative complexity.⁹⁵

An alternative model to a mandatory compensation scheme is for GM seed companies to set up and fund a voluntary redress mechanism. This could also be seen as a confidence-building measure. In the UK a voluntary redress charter is being developed by the Supply Chain Initiative on Modified Agricultural Crops (SCIMAC) which comprises the National Farmers Union, British Society of Plant Breeders, Crop Protection Association, Agricultural Industries Confederation and the British Sugar Beet Seed Producers Association. The SCIMAC plan involves the GM seed companies committing to a charter whose aim is to restore the market position of any non-GM farmer whose crop exceeds the 0.9% threshold through no fault of their own. The redress envisaged includes:

- direct replacement of affected produce (i.e. crop substitution)
- indirect replacement of affected produce (e.g. 'virtual' crop substitution, where affected produce is directed to an outlet and the claimant paid as if the crop were as originally intended)
- direct cash compensation
- compensation 'in kind'.⁹⁶

⁹⁵ Ibid., para. 157.

⁹⁶ See www.scimac.org.uk.

Annex 1

Case Studies

Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc. 2005 SQKB 225.

The plaintiffs in *Hoffman v Monsanto* claimed damages for organic grain farmers allegedly resulting from the development and commercial introduction into Canada of GM canola by the two defendants. The nature of the damage suffered by the plaintiffs was the loss of the principal foreign markets for organic grain: the United States, Japan and Europe.

It was not disputed that in field trials were conducted in Canada between 1990 and 1994 by AgrEvo Canada, the predecessor of Bayer Cropscience (BCS) for a gene which, when inserted in canola, rendered it resistant to glufosinate ammonium based herbicides such as Liberty, a herbicide marketed and sold by BCS. Approval for the unconfined release of "Liberty Link" canola was granted by the Canadian Food Inspection Agency in 1995. In 1996 Monsanto had been granted approval for the sale of its Roundup Ready (RuR) canola. By 2003 approximately 70 percent of all canola grown in Western Canada was either a Roundup Ready or Liberty Link variety.

Canola in general and Roundup Ready and Liberty Link varieties in particular are open-pollinated. As a result, there is inevitable pollen drift as a result of wind and cross-pollination can occur with non-GM ("conventional") canola grown nearby. This can result in the production of GM seeds in conventional canola, which can, in turn, result in GM progeny. Volunteer plants of GM canola can also result in fields where canola is not grown at all as a result, *inter alia*, of spillage of GM canola seeds from passing trucks, or from neighboring farmland where GM crops are cultivated. The resulting presence of GM canola or canola seed on cultivated land where it is not intentionally cultivated was referred to by the plaintiffs as "contamination of the environment". The term, "adventitious presence" was proposed by the defendants. This also included including mechanical mixing during the harvesting, processing, handling and storage of seed and grain.

A critical factor in the decision by the court to disallow the plaintiffs' claims was the determination by the Canadian Food Inspection Agency that the genetically modified canolas were not harmful. The damage alleged to organic grain farmers was "solely the damage resulting from loss of use of canola as an organic crop or for cleanup costs for fields "contaminated" by GM canola, due to standards imposed by organic certifiers or by foreign markets or individual customers for organic products."⁹⁷

The legal bases of the plaintiffs' claims were that the defendants were liable in negligence, nuisance, trespass and for breach of statutory duty.

The court was not prepared to find a duty owed by the defendants (developers and marketers of GM canola) to the plaintiffs (organic grain farmers in Saskatchewan) to prevent or to minimize the extent of adventitious presence of their respective GM canola varieties on the plaintiffs' farmland or in their crops. The principle of law which the Court applied was that which had been laid out by the House of Lords in *Anns v. Merton London Borough Council*.⁹⁸

In *Anns* Lord Wilberforce explained the test for negligence in the following terms:

First one has to ask whether as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity of neighborhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause the damage to the latter—in which case a *prima facie* duty of care arises. Secondly, if the first question is answered affirmatively, it is necessary to consider whether there are any considerations which ought to

⁹⁷ Ibid. at para.22.

⁹⁸ 1978] A.C. 728 (H.L.).

negative, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of it may give rise.⁹⁹

It should be noted that the *Anns* principle defines the law of negligence in Canada and New Zealand, but it has been rejected in Australia and England. In Australia in *Pyrenees Shire Council v Day*¹⁰⁰, the High Court advocated the three stage test which is now generally applied in England¹⁰¹. That test involves firstly, foreseeability, secondly, the existence of a relationship between the parties of "proximity" or "neighbourhood" and finally, a consideration of policy to determine whether it is "fair, just and reasonable" to impose the duty of care in question. Thus the liability principles applied in *Hoffman v Monsanto* have to be distinguished from those which would be applied in Australia and England.

Applying *Anns* Case the Saskatchewan court was not prepared to find that the defendants were in a sufficiently proximate relationship to the plaintiffs that it could be said that a duty of care was owed. Mere foreseeability of loss was not sufficient under the law of negligence to establish a *prima facie* duty of care.

The Court held that the plaintiffs had alleged facts sufficient to support a finding that it was reasonably foreseeable that release of the defendants' GM canola into the general environment would result in the adventitious presence of GMOs in the plaintiffs' crops and fields. The defendants' GM canola varieties were open-pollinated varieties which, due to the "natural" process of crosspollination can pollinate conventional canola conferring genetic modification upon the seed of the formerly conventional canola. However, the Court found that what was missing from the plaintiffs' claim was any specific allegation that the loss and damage to organic farmers (*viz.*, loss of the use of canola as a marketable organic commodity and loss of canola for use in crop rotation, plus the clean-up costs and loss of use of fields as a result of GM canola volunteers) was foreseeable.

The Court noted in addition, that there were policy considerations that, in accordance with the second leg of the test in *Anns* Case, would bar or limit the imposition of the duty of care alleged on the defendants. First, both defendants received approval of the federal government for the unconfined release of their GM canola varieties prior to their release. Thus the imposition by the courts of a duty of care not to release these substances into the environment would therefore appear to be in conflict with express governmental policy. Further, the alleged damage was not of physical harm to the plaintiffs' crops, but arises from the alleged inability to meet the requirements of organic certifiers or of foreign markets for organic canola. There was no allegation that GM canola was unhealthy or caused detrimental physical problems to humans or plant life.

Nuisance

The tort of private nuisance is concerned with conditions or activities that cause physical injury or damage to land or that interfere with the use or enjoyment of land. The common law has distinguished between activities or conditions that cause physical injury or damage to another's land from activities and injuries that interfere with the use or enjoyment of land, without actual physical damage.

In *Hoffman v Monsanto* the plaintiffs took the position that there had been physical damage to the land of organic farmers and to organic crops as a result, at least, of the presence of invading GM volunteer plants. The defendants argued that the damage alleged was not caused by the release of GM canola at all, but by the actions of third parties who had promulgated the standards affected by the inevitable adventitious presence of GM canola and by the decisions of individual organic farmers to seek to adhere to those standards. Secondly, the defendants pointed out that agricultural activity in Saskatchewan generally involves the production of open-pollinating crops, that the release of GM canola was subject to federal approval and that the growing of GM canola was widespread and was therefore a "usual and ordinary" activity. The Court, however, noted that the crops and land of organic farmers was effectively contaminated

⁹⁹ Ibid., at 751-52.

¹⁰⁰ (1998) 192 CLR 330 at 419-420.

¹⁰¹ See *Caparo Industries Plc v Dickman* [1990] 2 AC 605; *X (Minors) v Bedfordshire County Council* [1995] 2 AC 633; *Marc Rich & Co AG v Bishop Rock Marine Co Ltd* [1996] AC 211.

by the presence of GM canola and that it was not “plain and obvious that they cannot succeed in showing that the damage or interference they have alleged constitutes a legal nuisance.”¹⁰²

The defendants argue that they could not be liable unless the alleged nuisance emanated from land they occupied or controlled. The Court noted that although it is true that nuisance is typically a claim by one landowner or occupier against his neighbor, in Canada responsibility for private nuisance is not restricted to the occupiers of adjoining lands. However, as with the negligence claim, the Court considered that the damage suffered by the plaintiffs was caused by the European legislation, rather than by the introduction of GM canola.

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In *Hoffman v Monsanto* the plaintiffs took the position that there had been physical damage to the land of organic farmers and to organic crops as a result, at least, of the presence of invading GM volunteer plants. The defendants argued that the damage alleged was not caused by the release of GM canola at all, but by the actions of third parties who had promulgated the standards affected by the inevitable adventitious presence of GM canola and by the decisions of individual organic farmers to seek to adhere to those standards. Secondly, the defendants pointed out that agricultural activity in Saskatchewan generally involves the production of open-pollinating crops, that the release of GM canola was subject to federal approval and that the growing of GM canola was widespread and was therefore a “usual and ordinary” activity. The Court, however, noted that the crops and land of organic farmers was effectively contaminated by the presence of GM canola and that it was not “plain and obvious that they cannot succeed in showing that the damage or interference they have alleged constitutes a legal nuisance.”¹⁰³

The defendants argued that they could not be liable unless the alleged nuisance emanated from land they occupied or controlled. The Court noted that although it is true that nuisance is typically a claim by one landowner or occupier against his neighbor, in Canada responsibility for private nuisance is not restricted to the occupiers of adjoining lands. However, as with the negligence claim, the Court considered that the damage suffered by the plaintiffs was caused by the European legislation, rather than by the introduction of GM canola.

A nuisance claim in relation to GM corn was considered by the US District Court in Illinois in *In re StarLink Corn Products Liability Litigation, Marvyn Kramer v. Aventis CropScience USA Holding Inc.*¹⁰⁴ In *Hoffman v Monsanto* the court distinguished the *StarLink* decision on the grounds that it was not alleged that contamination of organic crops by GM canola was harmful per se or that it rendered the organic crops unfit for consumption or otherwise harmful. Nor was it alleged that the defendants failed in any way to conform to the requirements imposed on them. Indeed, it will be recalled that they had received federal approval for the unconfined release of the GM canola varieties. Thus there were no facts alleged in this case that could support a finding that the defendants substantially caused the nuisance alleged.

Trespass

In *Hoffman v Monsanto* the plaintiffs alleged that the defendants had released a self-propagating and proliferating product into the environment, without any, or in the alternative, inadequate, controls that they knew, or ought to have known, would eventually trespass on lands farmed by organic farmers. The plaintiffs cited authorities that suggested that a defendant should be liable in trespass when he has deliberately placed a contaminant (oil, soot, pesticide, etc.) so that natural forces, such as wind or water, has then carried onto neighboring land. However, the Court noted that the authority of a number of English and Canadian cases which required more direct interference with land for trespass to be established. The Court ruled that the commercial marketing and sale of GM canola seed that subsequently finds its way onto the land of another was not an action sufficiently direct to constitute trespass. It was only after conventional farmers grew GM canola varieties and with the intervention of natural processes (or because of the actions

¹⁰² Ibid., para 110.

¹⁰³ Ibid., para 110.

¹⁰⁴ (2002), 212 F. Supp. 2d 828 (U.S. District Court, N.D. Illinois).

of others who have processed or handled the seed) that the GM canola genes could find their way onto the land of organic grain farmers. This was insufficiently direct to lay at the door of the defendants. However, harvesting a crop where the spread of seed to adjoining fields is an immediate consequence of the harvesting could satisfy the directness requirement.

Breach of Statutory Duty

Hoffman v Monsanto also considered the possibility of the liability of a plant developer being responsible for adverse environmental effects in breach of The Canadian *Environmental Management and Protection Act, 2002*, (“EMPA, 2002”) and for failure to obtain an environmental assessment under *The Environmental Assessment Act 2002*, (“EAA”). The Court noted that this legislation applied only to discharges of substances that may cause an adverse effect, and did not apply to discharges authorized by governments or government agencies, (as was the release of GM canola).¹⁰⁵

Section 23 of the EMPA imposed civil liability on any person (a term which includes a corporate body) who proceeds with a “development” (a term defined in s. 2 (d)) for which ministerial approval is required without obtaining that approval. Section 8 of the Act requires ministerial approval before any person proceeds with any “development” unless a specific exemption is sought and obtained. Failure to comply with this section results in civil liability, under s. 23. The section makes the person who proceeds with the development without approval liable to any other person who has suffered loss, damage or injury as a result of the development without proof of negligence or intention to inflict loss, damage or injury. Further, the section imposes the burden of proving that any loss, damage or injury was not caused by a development on the person who proceeds with the development without ministerial approval.

The statement of claim in the case alleged that the defendants had tested, developed and commercially released GM canola to be grown on a widespread basis in Saskatchewan and that they did not obtain ministerial approval before doing so. The court did not consider that the testing, development and commercial release of GM canola constituted a “development” within the meaning of the Act.

In particular, the plaintiffs do not allege that GM canola is likely to have an effect on any unique, rare or endangered feature of the environment...; that the activities would likely substantially utilize any provincial resource; or that they would cause the emission of pollutants or by products that require handling and disposal in a manner not regulated by any other Act or regulation... It is not in my view plain and obvious that the plaintiffs could not prove that the development of GM canola caused widespread public concern because of potential environmental changes or that it is (or was) likely to have a significant impact on the environment, particularly given the relatively broad definition of “environment” in s. 2(e).

Of course in situations where the testing or release of GM seed is likely to cause “widespread public concern” then the EMPA might be applicable.

In re StarLink Corn Products Liability Litigation, Marvin Kramer v. Aventis CropScience USA Holding Inc (2002), 212 F. Supp. 2d 828 (U.S. District Court, N.D. Illinois)

The plaintiffs in that case sought to bring a class action claim against the defendant manufacturer and creator of genetically modified StarLink corn. It was alleged that StarLink had contaminated the entire corn supply in many states resulting in increased farming costs and depressed corn prices. The genetic modification of StarLink corn caused it to produce a protein (Cry9C) toxic to certain insects and containing several attributes similar to known human allergens. Accordingly, the defendant had obtained only qualified approval for release for use for animal feed, ethanol production and seed increase by the Environmental Protection Agency (“EPA”) under the Federal Insecticide, Fungicide, and Rodenticide Act. The EPA prohibited its use for human consumption and imposed on the defendant manufacturer stringent requirements of warning and monitoring to ensure implementation of mandatory segregation methods in the cultivation, harvesting, handling, storage and transport of StarLink corn, including a mandatory 660-

¹⁰⁵ 2005 SQKB 225 at para 165.

foot “buffer zone” around StarLink corn crops. It was alleged that the defendant had failed to comply with the EPA requirements resulting in the crosspollination and commingling of StarLink with non StarLink corn.

The plaintiffs’ actions included private nuisance, alleging that the defendant created a private nuisance by distributing corn seeds with the Cry9C protein, knowing that they would cross-pollinate with neighbouring corn crops. The defendant moved to have the claim dismissed as disclosing no cause of action, arguing that they could not be liable for any nuisance caused by StarLink corn because they were no longer in control of the seeds once they were sold to farmers.

The Court first ruled that the cross-pollination of a crop from neighboring land constituted nuisance as the StarLink corn was not considered fit for human consumption.¹⁰⁶ On the question of whether liability in private nuisance could extend to a manufacturer after the point of sale, the Court relied on the American Restatement para. 834, stating that one can be liable in private nuisance “not only when he carries on the activity but also when he participates to a substantial extent in carrying it on.” The question was what counted as “participation to a substantial extent” in carrying on the nuisance beyond the point of sale. It was clear that the general rule was that liability for nuisance could not be imposed on the manufacturer in these circumstances. However, the Court pointed to a number of cases in which the normal pattern of nuisance liability (imposed on a neighboring land owner or occupier) had been extended. In the case of some manufacturers, the liability had been extended on the basis of foreseeability of the harm alleged coupled with some malfeasance on the part of the manufacturer. In this case, it was alleged that the defendant had itself violated the EPA’s mandates in failing to adequately warn of the need for segregation and to enforce farmers’ compliance with the EPA requirements. The Court concluded “All parties who substantially contribute to the nuisance are liable. The unique obligations imposed by the limited registration arguably put Aventis in a position to control the nuisance.”¹⁰⁷

R. v Watson, (On the application of) v Secretary of State for Environment, Transport & Regions & Anor [1998] EWHC Admin 737.

Under Part VI of the UK Environmental Protection Act 1990 GM seed could not be released into the environment without a consent issued by the Secretary of State for the Environment Transport and the Regions under section 112 of the Act. Sharpes a firm of seedsmen had developed a genetically modified strain of maize seed known as T25. They wished to have a seed trial conducted so that if plants grown from the seed demonstrated the qualities required by Schedule 2 of The Seeds (National Lists of Varieties) (Amendment) Regulations 1982, the seed could be listed in the National List published in the Plant Varieties and Seeds Gazette published under the Plant Varieties Seeds Act 1964. Inclusion of a plant or seed in the National List is an aid to marketing it in the United Kingdom. Accordingly Sharpes made application for T25 to be included in the list. The Ministers arranged that a body called “NIAB” should conduct a trial on land it occupied for the purpose of such trials. However, because T25 seeds were genetically modified organisms, before a consent could be given the Secretary of State had to be satisfied that the release would be safe. The Secretary of State was satisfied and granted a consent to Sharpes.

What was not realized when the consent was given was that the Applicant, whose farm was in the same area as NIAB’s land, was an organic farmer and that a question could arise whether a crop of organic maize grown by him could be pollinated by pollen from the T25 plants. The Applicant was a member of the Soil Association which certified organic crops. The value of crops sold “organically grown,” would be seriously depreciated, without this certification. The Applicant knew of the trial of T25 which was taking place and was warned by the Soil Association that if there was a risk of pollination from it his crop certification of it would be withdrawn. Faced with this warning the Applicant sowed his own crop, but at a point as far away as he could sow it from the land on which T25 was being grown - 2 km away, in fact. No question of risk to the Applicant’s crop arose if the T25 plants were not allowed to flower. The question was taken up with the Secretary of State. He decided that it was appropriate to take a decision nearer the time as to whether the

¹⁰⁶ Ibid., at 841.

¹⁰⁷ Ibid., at 847.

crop should be allowed to flower. He took advice from the body known as "ACRE" and decided to allow the trial to continue and not to prevent the plants from flowering.

The Applicant sought an order requiring the Secretary of State to prevent the crop from flowering. The Secretary of State has sought the advice of the Advisory Committee on Releases to the Environment (ACRE) on this matter. That advice stated that as the applicant's sweet corn crop had been planted at a site approximately 2 km from the nearest genetically modified maize, ACRE consider the amount of cross-pollination was likely to be zero.

On this basis the Court ruled that the Secretary of State's decision was not open to challenge. However, if the risk of cross-pollination was higher, this case illustrates the possibility of liability for breach of statutory duty.

Geertson Seed Farms and others v. Forage Genetics, Inc and Monsanto Company and Others 2008 U.S. App. LEXIS 18752

This case concerned a decision by the Animal and Plant Health Inspection Service (APHIS), a division of the United States Department of Agriculture, concerning the environmental impact of Round-up Ready Alfalfa. APHIS had initially classified the genetically modified alfalfa as a regulated article under the National Environmental Policy Act (NEPA). After being petitioned by the manufacturer it had made a finding of no significant environmental impact and unconditionally deregulated the alfalfa.

In its Environmental Assessment ("EA") prepared in accordance with NEPA and its implementing regulations, APHIS explained that alfalfa is pollinated by insects, primarily bees, and that insect pollination has been documented as occurring up to 2 miles from the pollen source. However, with regard to the threat of possible genetic contamination of non-genetically engineered alfalfa, it explained that the National Organic Program mandates buffer zones around organic production operations, the size of which are decided by the organic producer and the certifying agent on a case-by-case basis. The EA concluded that it was therefore unlikely that Roundup Ready alfalfa would have a significant impact on organic farming.

In May 2007, the District Court had granted the plaintiffs a permanent injunction to prohibit all future planting of Roundup Ready alfalfa, as well as the harvesting of any Roundup Ready alfalfa seed already planted, pending the completion of an EIS and a new decision on deregulation. APHIS agreed that any future planting should be subject to certain conditions, including requiring isolation distances from other crops and requiring certain harvesting conditions to minimize gene flow to non-genetically engineered alfalfa seeds. The District Court found that genetic contamination had occurred. Monsanto and its licensee, Forage Genetics appealed the injunction, arguing it was too broad.

On appeal, the Court considered the principles of law which applied to the grant of a permanent injunction. It noted that applying these principles an injunction did not "automatically issue" when a NEPA violation is found and said that it was required to "engage in the traditional balance of harms analysis." With respect to harm, the court found that genetic contamination of organic and conventional alfalfa had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place. It held that such contamination was irreparable environmental harm because contamination cannot be reversed and farmers cannot replant alfalfa for two to four years after contaminated alfalfa has been removed.

The Appeal Court agreed with the District Court that the harm to growers and consumers who wanted non-genetically engineered alfalfa outweighed the financial hardships to Monsanto and Forage Genetics and their growers.

The courts also agreed that in considering the public interest, while recognizing that agricultural biotechnology has social value, they held that it would be in the public interest to enjoin the expanded use of Roundup Ready alfalfa before its impact was studied, because failing to do so could potentially eliminate the availability of non-genetically engineered alfalfa.

A dissenting judgment in the Appeal Court noted that the facts were sharply disputed by the parties, including a dispute as to the risk of genetic contamination that could occur while APHIS prepared the EIS.

Trade Secrets

Pioneer Hi-Bred Int'l v. Holden Found Seeds 35 F.3d 1226 (8th Cir. 1994).

This case was concerned with a dispute between competing breeders of corn seed Pioneer and the defendant, Holden. Pioneer claimed that Holden had developed a seed from misappropriated seed which it claimed were its trade secrets. Holden disputed the genetic similarity between its seed and Pioneer's H3H/H43SZ7. In an attempt to evaluate the parties' competing claims, the court oversaw three series of tests: electrophoresis, reverse phase high-performance liquid chromatography and growouts. Each test was supervised by the court, performed by independent experts, and monitored by the parties. Although the court found that each of the three tests had its own set of limitations and inadequacies they served to demonstrate the unlikelihood of Holden's explanation of the parentage of the seeds and the greater likelihood of Pioneer's theory of parentage. At first instance, the district court awarded Pioneer \$US46 million for misappropriation of its trade secrets.

The case is not a particularly good authority for the proposition that genetic information can qualify as trade secrets as Holden did not dispute this point, therefore the court assumed "without deciding that genetic messages can qualify for trade secret status." The appeal focussed upon the District Court's application of trade secrets doctrine. Under Iowa law, a plaintiff must generally show: (1) existence of a trade secret, (2) acquisition of the secret as a result of a confidential relationship, and (3) unauthorized use of a secret. Holden argued that it should not be liable for misappropriating Pioneer's seed because Pioneer failed: (1) to keep the genetic messages secret; (2) to prove that Holden actually possessed the protected genetic messages; and (3) to prove that Holden obtained the material by improper means.

Holden argued that H3H/H43SZ7 were not trade secrets because Pioneer failed to maintain their secrecy. The district court found that the genetic messages of H3H and H43SZ7 were trade secrets as the "formula" did not exist outside Pioneer's and its contractors' fields, and that Pioneer took reasonable precautions to protect the secrecy of the genetic message. Pioneer took several measures to preserve the secrecy of its inbreds. Growers operated under contracts which prohibited disclosure of the seed. Fields have no labels indicating what seed is being grown, and all seed bags were coded to avoid identification. Pioneer removed male inbred lines and commingled them with other corn, thereby frustrating those seeking to obtain the inbred seed. The Appeal Court considered there to be sufficient evidence to support the district court's finding that Pioneer took reasonable precautions to protect the secrecy of the genetic message of H3H/H43SZ7.

Holden contended that since none of the scientific tests could conclusively prove parentage, the District Court erred in finding possession. Holden points out particular shortcomings with each of the tests. The Appeal Court held that there was sufficient evidence to warrant a finding that Holden had derived its seed from H3H/H43SZ7.

The Appeal Court noted that a confidential relationship was not a prerequisite to a trade secret action, since a plaintiff may prevail in the absence of such a relationship by showing that the secret was obtained by improper means. The Appeal Court noted that Pioneer presented no direct evidence regarding how Holden obtained H3H/H43SZ7. However, direct evidence of industrial espionage was rarely available and not required.

The Appeal Court noted that the record displayed a long history of Holden attempts to obtain Pioneer's genetic material. These efforts included searching "friendly farms" for stray inbred plants. Although the court concluded that Pioneer has not specifically shown that these efforts were the exact source of Holden's seed the testimony supported such an inference. Holden's inadequate explanation of its faulty record-keeping and the untimely disposal of all its impugned seed also gave rise to an inference of misappropriation.

Monsanto Co. v. Scruggs, 342 F. Supp 2d 584 (2004)

This case concerned Monsanto's development of glyphosphate tolerant seeds. This was the basis of Monsanto's US patent 5,352,605 ("605 patent"). Monsanto used the art taught in the '605 patent to develop

genetically modified soybeans and cotton which were resistant to glyphosate herbicide. After developing the biotechnology Monsanto licensed it to seed companies, imposing two provisos: (i) it forbade seed companies from selling seed which contained Monsanto's biotechnology to growers unless the grower first signed a technology license agreements, reserving the patented technology to Monsanto and (ii) seed so sold could only be used by growers to grow a single commercial crop, i.e. growers could not save seed produced from a harvested crop for replanting during the following growing season.

Mitchell Scruggs, who had not signed a technology licensing agreement purchased a small quantity of Roundup Ready ("RuR") 5601 Asgrow soybeans from a seed company in Memphis. The seed was sufficient to plant approximately ten acres of soybeans. After the fall harvest, Mr. Scruggs retained the soybean seed from those ten acres; he cleaned it and saved it for planting during the 1997 crop season. Through saving seed from all subsequent crop seasons up to the year 2000, by 2000, Scruggs had enough saved RuR soybean seed to plant more than 8,000 acres. Similarly Scruggs purchased a small quantity cotton seed containing the Bollgard and RuR Ready traits. He retained the cotton seed from the fields he planted with the cotton seed and sent it to a facility for cleaning and delinting. By 2000, Scruggs had saved enough cottonseed to plant in excess of 2000 acres.

Monsanto claimed that its patent had been infringed by Scruggs.

The Court explained that patent infringement a patent is infringed if a single claim is infringed. In this case Monsanto relied both on the admission of Scruggs in purchasing its patented soybean and cotton seed and it relied on the results of a series of three scientific tests, to demonstrate that Scruggs' 2000 soybean and cotton crops contained patented Roundup Ready and Bollgard biotechnology.

The Court rejected Scruggs' defense that neither Monsanto's biotechnology nor the plants in their fields were covered by the '605 patent. Similarly the Court rejected Scruggs argument that the first sale by a patentee of an article embodying the invention, the patent rights were exhausted. The Court noted that Monsanto never made an unrestricted sale of its seed technology, as it licensed its technology to seed companies with a proviso: subsequent sales of seed containing its transgenic trait must be limited to growers who obtained a license from Monsanto and for only a single growing season.

The defendant in *Monsanto v Scruggs* was obviously compromised by the fact that he had directly purchased Monsanto's proprietary technology.

Monsanto Co. v. Parr 2008 WL 1808365 (N.D. Ind. 2008)

The defendant, Parr, in that case operated a seed and grain cleaning business in Indiana. Seed cleaning is a process where a harvested crop is run through a mechanical cleaner that sifts trash such as stems, leaves, dirt, and broken/split seed from the whole seed. The primary reason for cleaning seed is to have it prepared for replanting. Monsanto was concerned that Parr's activities would facilitate the saving and planting of its patented RuR seed and it wrote to Parr requesting that he cease any actions which would induce farmers to breach its patent. From 2002 through 2007, approximately 87.3% to 94.3% of the soybeans planted in Indiana contain Monsanto's patented RuR trait and the Court noted the strong likelihood that seed cleaned by Parr for replanting would infringe Monsanto's patent.

Monsanto Co. V. McFarling, 302 F.3d 1291 (Fed. Cir. 2002).

Monsanto required that sellers of the patented seeds obtained from purchasers a "Technology Agreement," in which they agreed that the seeds were to be used "for planting a commercial crop only in a single season" that the purchaser would not "save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting." Mr. McFarling, a farmer in Mississippi, purchased RuR soybean seed in 1997 and again in 1998; he signed the Technology Agreement. He saved 1,500 bushels of the patented soybeans from his harvest during one season, and instead of selling these soybeans as crop he planted them as seed in the next season. He repeated this activity in the following growing season. This saved seed retained the genetic modifications of the RuR seed. Mr McFarling did not dispute that he violated the terms of the Technology Agreement but claimed that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following

season, violated the seed saving provision of the US Plant Variety Protection Act (PVPA), which permits farmers to save seeds of plants registered under the PVPA. The Court held that Monsanto was entitled to rely upon its patent rights in relation to the seed and that Mr. McFarling had infringed its patent and that those patent rights were not affected by the PVPA.

Monsanto Canada, Inc. v. Schmeiser [2004] 1 S.C.R. 902, 2004 SCC 34.

In 1993, Monsanto US was issued Canadian Letters Patent No. 1,313,830 ("the '830 patent") for an invention termed "Glyphosate-Resistant Plants." The '830 patent granted Monsanto US the exclusive right, privilege and liberty of making, constructing, using and selling the invention for the full term of the patent. Monsanto Canada was a licensee under the '830 patent. The invention was used by Monsanto in Canola and marketed under the trade name "Roundup Ready (RuR) Canola." Schmeiser grew canola commercially in Saskatchewan. He had never purchased RuR Canola nor did he obtain a license to plant it. Yet, in 1998, tests revealed that 95 to 98 percent of his 1,000 acres of canola crop was made up of RuR plants. The origin of the plants is unclear. They may have been derived from RuR seed that blew onto or near Schmeiser's land, and was then collected from plants that survived after Schmeiser sprayed Roundup herbicide around the power poles and in the ditches along the roadway bordering four of his fields.

Monsanto brought an action for patent infringement claiming that by planting glyphosate-resistant seeds Schmeiser was said to use, reproduce and create genes, cells, plants and seeds containing the genes and cells claimed in the plaintiffs' patent.

The trial judge rejected each of these arguments, in finding that Schmeiser had infringed Monsanto's patent. He held that the fact that replication of the gene may occur in the natural course of events, without human intervention after insertion of the gene in the original plant cells, and plants, produced for seed, did not in itself preclude registration as an invention under the Canadian Patent Act the creation of the gene and the process for inserting the gene. He considered that there was no evidence that the patent was obtained for an illicit purpose. Finally, there was nothing in the PIRA which precluded an inventor from seeking registration under the Patent Act.

The Trial Judge observed that Schmeiser had grown canola from seed which he knew was Roundup tolerant. He ruled that the growth of the seed, reproducing the patented gene and cell, and sale of the harvested crop constituted taking the essence of Monsanto's invention, using it, without permission and in so doing infringed the patent.

The case was appealed to the Federal Court of Appeal, where it was heard by a court of nine judges. By a majority of 5:4 the appeal court ruled that Schmeiser had infringed Monsanto's valid patent. The majority, comprising: McLachlin C.J. and Justices Major, Binnie, Deschamps and Fish ruled that in determining whether Schmeiser had infringed s. 42 of the *Patent Act* by "using" the patented cell and gene, the word "use" was interpreted taking into account its plain meaning, the purpose of s. 42, its context, and the case law. In this case, Schmeiser's saving and planting seed, then harvesting and selling plants that contained the patented cells and genes appeared to the Court, on a common sense view, to constitute "utilization" of the patented material for production and advantage, within the meaning of s. 42. By cultivating a plant containing the patented gene and composed of the patented cells without license, Schmeiser deprived Monsanto of the full enjoyment of the monopoly.

The Court noted that Canadian case law had established that an infringement occurred where a defendant's commercial or business activity involving a thing of which a patented part is a component. Infringement therefore did not require use of the gene or cell in isolation. Infringement also did not require that Schmeiser had used RuR herbicide as an aid to cultivation. Schmeiser did not provide sufficient evidence to rebut the presumption of use. The argument that the infringing seed had merely grown, as the result of wind pollination, or through the pollinating activities of birds and bees was rejected by the majority Judges as denying "the realities of modern agriculture." What was at stake in this case was sowing and cultivation, "which necessarily involves deliberate and careful activity on the part of the farmer". He actively cultivated RuR Canola as part of his business operations, thus in light of all of the relevant considerations, Schmeiser had used the patented genes and cells, and infringement was established.

Annex 2

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**PRODUCT STEWARDSHIP AND LIABILITY IN THE
CONTEXT OF IPR**

STUDY II

**A Recommended Stewardship Framework for the Consultative
Group on International Agricultural Research (CGIAR)**

Rebecca M. Bratspies

The City University of New York School of Law, USA

and

Vibha Dhawan

The Energy and Resources Institute, India

LIST OF ACRONYMS

AATF	African Agricultural Technology Foundation
BIO	Bio Industry Organization
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CGIAR	Consultative Groups on International Agricultural Research
CIMMYT	Centro Internacional de Mejoramiento de Maiz y Trigo
FAO	Food and Agricultural Organisation
GMO	Genetically Modified Organism
HACCP	Hazard Analysis and Critical Control Point
IP	Intellectual Property
IPG	International Public Goods
IPR	Intellectual Property Rights
IRMA	Insect-Resistant Maize for Africa
ISPC	Independent Science and Partnership Council
ITPGREA	International Treaty on Plant Genetic Resources for Food and Agriculture
KARI	Kenyan Agricultural Research Institute
KEPHIS	Kenya Plant Health Inspectorate Services
LMO	Living Modified Organism
MTA	Material Transfer Agreement
NARS	National Agricultural Research Systems
PIPRA	Public Intellectual Property Resource for Agriculture
PSI	Product Stewardship Institute
SC	Science Council (of the CGIAR)
SME	Small and Medium Enterprises
SMTA	Standard Material Transfer Agreement
TRIPS	(Agreement on) Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Plant Varieties
WEMA	Water Efficient Maize for Africa
WTO	World Trade Organization
WHO	World Health Organization

A PURPOSES OF THIS REPORT

- To develop a stewardship framework for Consultative Group on International Agricultural Research (CGIAR) activities that encompasses, but is not limited to stewardship of genetically modified organisms through all stages of product development, distribution and use;
- To ensure that CGIAR scientists can deploy the best science and technical solutions in order to further CGIAR's poverty reduction and food security mission;
- To develop a strategy for minimizing the risks to farmers, the environment, individual CGIAR Centers and the CGIAR System from adoption of new agricultural technologies;
- To promote sustainable management by enhancing scientific, technological, and institutional policies surrounding stewardship of CGIAR products;
- To develop understanding of public law requirements governing responsible stewardship of transgenics and other regulated technologies.¹⁰⁸

B SUMMARY OF CONCLUSIONS

Recommendation 1: The CGIAR Centers should develop a coordinated, System-wide stewardship framework in order to promote a more structured and predictable approach to stewardship. This coordinated framework should employ a HACCP-based risk analysis framework to facilitate cooperative activities with private industry, research universities, and national partners. This framework should be specific enough to provide useful guidance, yet flexible enough to permit innovative solutions to project management problems.

- a) Focus should be on shaping institutional routines, behaviors and practices to cultivate the kind of stewardship environment that PPPs demand, and to promote efficiency, coherence and collaboration across the CGIAR system as a whole. This stewardship framework should include plans for:
 - i) data management
 - ii) material traceability
 - iii) containment protocols
 - iv) confidentiality
- b) This systemic approach should ensure that stewardship concerns are included in the initial conception of any project, rather than as an add-on at later stages.
- c) A new HACCP-based stewardship analysis should be conducted for each project, and should be keyed to the unique aspects of that project. At a minimum this analysis should address both System-wide, Center-level, and Project-based concerns.
- d) This framework should be designed so that scientists, administrators or other CGIAR System personnel will be able to implement it without undue burden.

¹⁰⁸ Other regulatory considerations addressed in this report include compliance with national laws, implementing the Convention on Biological Diversity, and satisfying the International Treaty on Plant Genetic Resources for Food and Agriculture, as well as compliance with domestic phytosanitary laws and laws regulating the use of agricultural chemicals such as pesticides/herbicides.

Recommendation 2: The CGIAR Centers should engage in knowledge coordination in order to develop an integrated, institutional learning mechanism capable of capturing, distilling, and conveying stewardship information.

- a) The CGIAR should invest in research-to-distribution stewardship planning.
- b) The CGIAR should institute standardized protocols that provide for a consistent approach to research and development involving transgenic, novel or IP-protected varieties.
- c) Awareness of stewardship obligations should be integrated with information and should travel with that information (as well as with the seeds themselves) throughout the research, development, and deployment processes. Focus should be on managing and communicating information effectively.

Recommendation 3: The CGIAR should consider centralizing and standardizing negotiations over access to privately held IP rights.

- a) As part of this process, the CGIAR should consider standardization of the legal documents and protocols associated with managing novel crops and other proprietary intellectual property. Any such standardization should focus on the core commonalities and leave room for document language to be tailored to the diversity of projects the CGIAR undertakes.
- b) Agreements for access to technology should be reduced to writing, and negotiations for use (as opposed to research) rights should occur before a project commences. Attention should be paid to negotiating System-wide rights of use.
- c) Each such negotiation should be viewed as an opportunity for institutional learning that will help the CGIAR develop further its capacity to negotiate International Public Goods (IPG)-compatible agreements with private partners.

Recommendation 4: Stewardship capacity-building and joint implementation with national partners should be part of the System-wide stewardship planning process. The CGIAR Centers should use this collaborative opportunity to develop a consistent approach to stewardship that furthers development of and access to IPGs.

Recommendation 5: The CGIAR should learn what data and information already exists within the System. There is the need to create a plan to ensure identification of, and access to this information, possibly through an integrated, searchable, data management system. Focus should be on:

- a. Developing templates and other forms of standardization to make data and information useful in multiple contexts;
- b. Using standardization to reduce the administrative burdens on researchers and individual CGIAR Centers associated with implementing the stewardship framework;
- c. Integrating stewardship information into the process of data generation, storage and retrieval, in order to improve awareness of regulatory requirements, as well as best practices;
- d. Leaving room for individual Centers to tailor their information management and stewardship strategies to account for specific circumstances, as well as practical application and implementation concerns.

C EXECUTIVE SUMMARY

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). Despite radical transformations in the process of agricultural research, this insight remains true today. Agricultural advances still offer a pathway out of poverty to millions of rural poor (World Bank 2008; Sunding and Zilberman 2000). As the single-largest pro-poor international agricultural research institution (Chataway, Smith and Wield 2007) the CGIAR is uniquely positioned to make that happen.

However, the landscape of agricultural research has changed dramatically, both with respect to the technologies involved, and the nature of available funding sources. Increasingly, private, rather than public goods play a central role 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.

For all its influence and importance as the largest producer of public goods for international agriculture, the CGIAR System still accounts for only a small fraction of total global agricultural research. Indeed, the CGIAR represents just 1.5% of the \$23 billion (2000 prices) global public-sector investment in agricultural research and development, and just 0.9% of combined global public and private agricultural research and development spending (Pardey et al. 2006).¹⁰⁹ Collaborations with private industry can expand the CGIAR's reach. By harnessing the results of that vast private investment for pro-poor development, these collaborations can leverage the CGIAR's limited resources more effectively.

The CGIAR System will increasingly seek 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. Others are embedded in traditional knowledge, which the CGIAR has a duty to respect. 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 research, and to become more involved 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 and the traditional knowledge rights of indigenous communities, as well as the wider environment, and the workers involved in the project. CGIAR must develop such a stewardship program,¹¹⁰ whilst at the same time not compromising its broader

¹⁰⁹ Developed countries, as a group, account for over 40% the public investment in agricultural research and development worldwide (and almost 80 percent of all science spending) (Pardey, et al. 2006). In 2000, global spending on agricultural research and development was \$36 billion—about 36% of which was performed by private firms and the remaining 64% by public agencies. Notably, about 93% of that private R&D was performed in rich countries, where some 54% of the agricultural R&D is private. (Pardey, et al. 2006)

¹¹⁰The dictionary definition of stewardship is “the careful management of something entrusted to one’s care.” (Merriam-Webster undated). The private agricultural-biotechnology sector defines product stewardship to be: ‘the responsible management of a product from its inception through to its ultimate use and beyond’ (BIO 2008; CropLife 2005). Civil society typically describes stewardship as taking shared responsibility for the impacts to human health and the natural environment that result from the

mission. The scope of appropriate stewardship raises some of the most pressing and problematic issues of institutional agricultural research and development. This report therefore tries to address not only the relevant substantive questions, but also to flag a set of related questions about how the CGIAR might internalize change, and might engage with broader networks.

To begin with, it is important to acknowledge that 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 System-wide commitment to defined stewardship practices. This must change. The CGIAR needs an institutionalized 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. Establishing a System-wide stewardship plan will ensure consistency and minimize the costs associated with stewardship activities. The CGIAR would also 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. The significant restructuring that the CGIAR is currently engaged in offers an opportunity to include stewardship concerns within the newly-configured Mega Programs from the very beginning.

This report proposes a stewardship framework that could be adopted at the CGIAR System level and operationalized by the Centers on a project-by-project basis.¹¹¹ To that end, 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 adapt the hazard identification and control process (HACCP) technique to create 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

production, use, and end-of-life management of a product (PSI 2008). This report adopts a definition of stewardship that incorporates both the management issues identified by industry and the shared responsibility emphasized by civil society, but goes beyond both to view stewardship as an overarching management vision that shapes processes for managing information and intellectual property rights, as well as for addressing the environmental, health and safety issues surrounding the products themselves. Thus, as used in this paper, the term stewardship encompasses careful management not only of the farm and the broader environment, but also of the information and intellectual property rights bound up with certain crops.

¹¹¹ Depending on how the CGIAR restructuring takes shape, it might make sense to have a different stewardship framework for each mega program, rather than one overall CGIAR stewardship framework. Even if that is the case, there will be significant overlaps. Developing the frameworks together will make the most efficient use of time and money. Moreover, if the stewardship frameworks are developed together, there is little risk that different programs will impose conflicting obligations, and the possibility of synergies can be fully explored.

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.¹¹² 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. It also highlights the capacities that will need to be developed at the Center, System and partner levels in order to achieve effective stewardship.

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 CGIAR 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. One important aspect of this stewardship framework is that it 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.

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 internalizing best practices for protecting the environment, workers and consumers in a fashion that respects the IP rights of private sector partners and traditional knowledge holders.

D BACKGROUND

Global food insecurity is a collective challenge. Attaining food security for a world population projected to reach nine billion people by 2050 is a daunting task (U.S. Census Bureau 2008). New knowledge created by investment in agricultural research, coupled with investment in the human capital of farmers, is a major engine driving improved agricultural production. For many countries advances in agricultural production have been an essential precursor to broader economic development. The CGIAR has historically been at the forefront of this evolution (Strong 1996). Its successes have been notable. However, with increasing population and growing detrimental impacts from severe climate changes, the Millennium Development Goals of halving poverty by 2015 seems increasingly out of reach (United Nations 2008). Currently, almost 17% of the world’s population suffers from food insecurity (FAO 2006). Furthermore, the 2008 crisis of soaring food prices underscored the fragility of the global system of food production and trade (FAO 2008).

At the same time that the challenges are growing, there are also some encouraging signs. Advances in agricultural biotechnology offer promise for responding to a panoply of biotic

¹¹² The microlevel proposals in this report are offered solely as guidance. The precise contours of the ultimate stewardship program will require input from multiple constituencies within the CGIAR itself.

and abiotic stresses, including drought, salinization and insects. If time and research bear out this early promise, these crops may play an important part in resolving food insecurity. However, significant changes in the global legal regime governing intellectual property, mean that more and more of this new technology is privately owned under legal regimes that give exclusive rights to the IP holder. Many of these private IP holders have indicated a willingness to provide the CGIAR with royalty-free access to their proprietary technologies (Chojecki 2006), but only on the condition that the CGIAR System attain a satisfactory level of stewardship with regard to IP protection, crop deployment, and other related issues.

1 The Legal Backdrop

Article 27.3(b) of the Trade-Related Aspects of Intellectual Property (TRIPS) Agreement requires WTO member states to adopt a scheme for plant variety¹¹³ protection either via patents or by an effective *sui generis* system. The breeder's rights spelled out in the International Union for the Protection of New Plant Varieties (UPOV) represent one of the possibilities for codifying intellectual property claims to plants. Of course only 67 states are parties to UPOV, (UPOV 2009) contrasting with 153 members of the WTO, of which the TRIPS agreement is part (WTO undated_a). The TRIPS agreement imposed a staggered deadline for complying with its provisions, including Article 27.3. Many of the countries in which the CGIAR System operates are on the list of "least-developed countries" given the longest time-line to come into compliance with TRIPS requirements (WTO undated). (See Table 1). Many states are struggling to meet even these extended timelines. These states do not yet have clear laws governing intellectual property rights for plant varieties and related technologies, including agricultural biotechnology products. Some states have no plant variety registration system at all, and many have only rudimentary patent, trademark and copyright protection laws.

The Convention on Biological Diversity, (CBD), has also had a dramatic impact on agricultural research. In particular Article 8j, which emphasized sovereign control over natural resources, made "authority to determine access to genetic resources, subject to national legislation."¹¹⁴ The CBD emphasized sovereign control of natural resources, including biodiversity. One outgrowth of the CBD was renewed attention to sovereignty

¹¹³ The UPOV Convention Article 1(vi) defines "plant variety" as: "a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be:

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged."

The legal term "plant variety" as it appears in UPOV, TRIPS and related legal instruments, is therefore different from the botanical term "variety" or "cultivar". For the purpose of this document, the scientific term "cultivar" is used in the context of agricultural research, while "plant variety" when referring to the legal requirements.

¹¹⁴ Article 8j of the Convention on Biological Diversity provides that :

"Each Contracting Party shall, as far as possible and as appropriate:

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

issues with regard to the CGIAR “designated germplasm” the world’s largest *ex situ* germplasm collection. The CGIAR collection, which predated the CBD, seemed contrary to the sovereign ownership of biodiversity principle enshrined in the CBD. The ensuing discussions resulted in an agreement between the FAO and the CGIAR placing that germplasm under the auspices of the FAO as part of the International Network of *Ex Situ* Collections. The agreement specified that the collections are held in trust on behalf of humanity. Access is available to all who need it, and the ability to claim IP rights in that germplasm is restricted. This approach was ultimately confirmed in the International Treaty on Plant Genetic Resources for Food and Agriculture, (ITPGRFA), which also created a mechanism for an equitable benefit sharing, and adopted a Standard Material Transfer Agreement (SMTA).

More recently, the Cartagena Protocol to the Convention on Biological Diversity imposes fairly stringent restrictions over the transport of what it calls “Living Modified Organisms” (LMOs), which are also often referred to as genetically modified organisms (GMOs) or transgenics. Currently the Cartagena Protocol has 148 members, including many states listed in the TRIPS agreement as “least-developed” (CBD 2008). Unfortunately, much of the capacity-building surrounding implementation of the Cartagena Protocol seems to be proceeding slowly (CBD 2006).

Collectively, TRIPS, the CBD, the ITPGRFA and the Cartagena Protocol, have changed the international environment for agricultural research. In addition, many states have also negotiated bilateral or regional trade agreements that increase IP protection beyond the levels required under the TRIPS agreement (El-Said 2005). These changes to the international legal rules of ownership rights and associated regulatory regimes took place against a burgeoning investment in agricultural research by the private sector. Indeed, private investment in agricultural research has at least tripled over the last two decades (Pardey, Alston and Piggett 2006; Fuglie, et al 1996).

The CGIAR needs a strategy for engagement with the private sector in order to harness for its resource poor stakeholders, the outputs of these huge private sector investments. A coherent, overarching stewardship regime will need to be a key component of this strategy. Unfortunately, the regulatory vacuum that exists in many states in which the CGIAR operates will complicate the development of such a regime. Rather than relying on state regulation to define the contours of stewardship obligations in many of these states, the CGIAR will likely find itself in the position of creating and imposing its own stewardship program. In some cases, that stewardship program may become a model for other actors within those states.

Going forward, CGIAR centers must be prepared not only to develop products created with the tools of modern biotechnology from laboratory to farm and market, but also to serve as a platform for transferring this technology (and best practices for its stewardship) from multinational private entities to NARS and local small and medium enterprises (SMEs). Because stewardship agreements between the CGIAR Centers and private IP holders are likely to include obligations that will ultimately be fulfilled by NARS, SMEs, and farmers, rather than by CGIAR Centers, part of that process must be a focus on enhancing NARS, SMEs, and farmers’ capacities to appropriately oversee use of these technologies, particularly with regard to transgenics but also for conventional technologies with important risk dimensions.¹¹⁵ As a result, attention to developing this capacity will be

¹¹⁵ One possible standard for such technologies might be the Canadian definition of “novel foods”, which includes any “plant, animal or microorganism [that] exhibits characteristics that were not previously observed in that plant, animal or microorganism.” Division 28 of Canada’s Food Regulations, C.R.C 870

a critical component of any CGIAR stewardship regime. The CGIAR finds itself being expected to go beyond its traditional research role and to participate in capacity-building with regard to national regulatory systems and biosafety.

In assessing local capacity; it will not be enough to look simply at laws and regulations on the books.¹¹⁶ There will also be a need to assess the corroboration between legal pronouncements and the reality on the ground. For example: in 2002, as part of the World Sustainability Summit in South Africa, Ghana prepared a report touting its moves to develop a biosafety infrastructure. In particular, Ghana inaugurated its National Biosafety Committee—a multi-disciplinary body tasked with overseeing environmentally sound management of biotechnology. (United Nations 2002) Unfortunately, subsequent reports (Alhassan 2003) indicate that the biotechnology committee seldom meets. Likewise, another initiative announced with great fanfare in 2000, the Strategic Alliance for Biotechnology Research in African Development (SABRAD) had trouble procuring funds and thus radically scaled back operations (Alhassan 2003). Ghana is not unique in this respect. Many states do not have regulatory systems capable of shepherding a transgenic agricultural product through an approval process, and lack the monitoring and oversight capabilities critical to successfully employing such crops. Even in Kenya, where the International Maize and Wheat Improvement Center (CIMMYT) has been working extensively with local partners to develop transgenic maize for almost decade, biotechnology research was, until very recently, on somewhat tenuous legal footing. In 1998 Kenya adopted Guidelines for biosafety in biotechnology research. These guidelines authorized research but not commercialization of genetically modified crops. It was only in December of 2008 that Kenya’s parliament finally passed the Biosafety Bill that had been pending for years. The bill was signed into law in February 2009.

Much of the groundwork for this newly-adopted law, as well as the capacity to implement it, grew out of research collaboration on *Bt*-maize between Kenya Agricultural Research Institute (KARI), Kenya Plant Health Inspectorate Services (KEPHIS) and CIMMYT. The process of field-testing *Bt*-maize helped Kenya develop what have become standard operating procedures for GMO field testing. The CIMMYT-KARI application and compliance documents have formed the basis for Kenya’s regulatory approval process, and their laboratory facility has become the standard. In short, the *Bt*-maize project helped Kenya institutionalize best practices for regulating transgenic crops, and built CIMMYT’s capacity to address issues of IP and biosafety regulatory regimes.¹¹⁷ There is a need for this kind of capacity building across many of the countries in which the CGIAR System operates, and within the CGIAR Centers themselves.

Given the tremendous investments of time, money and other resources that went into making this collaboration succeed, it is probably not realistic to use the Kenya *Bt*-maize experience as a model for how such collaborations will be structured in every country in which the CGIAR System operates. Nevertheless, the KEPHIS-KARI-CIMMYT collaboration may offer instructive lessons, both from the collaboration’s successes and

(2008) focuses on Novel Foods. While genetically modified organisms fall within this definition, so do many of the more innovative uses of conventional technologies.

¹¹⁶ It is an unfortunate reality that it is easier to draft a law than to implement it. Stewardship must be thought of an instrumental rather than formal process, and even the best of laws are only as good as the actions taken to implement them. Thus, even when operating in states with a putative legal framework for managing biosafety, stewardship and IP protection, Center or System involvement in assisting NARS, SMEs and other state partners with developing stewardship implementation plans and capacities with regard to CGIAR-related projects may still be warranted.

¹¹⁷ This is true even though product development stalled on “freedom to operate” issues and access to proprietary biotechnology.

from its failures. For example, despite notable successes in capacity-building, the project encountered freedom-to-operate problems at a late stage in the research process. Thus, the collaboration's experience underscores the need to obtain full rights to use IP protected materials, rather than just research rights, from a project's inception. On the positive side of the ledger, the capacity that KEPHIS developed during this process may suggest models for how the CGIAR System might interact with regulators in other, similarly-situated states. Much of the institutional capacity built through this collaboration is likely transferable to other projects and other Centers.

Other collaborations will also develop potentially transferable expertise on a host of stewardship issues. The CGIAR System would be well-advised to develop an institutional learning mechanism for capturing, distilling and conveying this stewardship information internally. Even when some of the details of the agreement between a Center and a private partner are covered by a confidentiality agreement, the project will still generate significant stewardship lessons that could be shared across the CGIAR System without compromising the private concerns that prompted the confidentiality agreement in the first place.¹¹⁸ The macro and micro-level recommendations contained in this report are a starting point for cultivating the kind of institutional memory and capacity needed to make this knowledge transfer happen.

One thing is clear, if the CGIAR is going to obtain access to privately-owned technologies and intellectual assets, the CGIAR will have to satisfy private owners that the decision to entrust these assets to the Centers and subsequent developers and distributors working with the Centers, is well-placed. As part of creating agricultural products for use in developing countries, the CGIAR may be asked to make representations, or even commitments, about state and NARS capacity to address issues relating to biosafety and crop containment. When the proposed site of testing or deployment does not have a fully developed regulatory system for biotechnology, making those assurances will be more difficult. As such, the CGIAR has a stake in making sure that these state partners have the necessary capacity. Indeed, in order to fulfill its agreements with private IP-rights holders, the CGIAR may find itself assisting and advising national partners as they build domestic capacity in the areas of stewardship risk assessment and risk management. If the CGIAR already has a System-wide stewardship framework in place, it will be better positioned to offer suggestions or models in response to such requests. Of course, the regional organizations described in Annex II of this report might be better candidates for actually taking on the task of helping states construct the needed domestic stewardship regimes.

2 Industry-Based Visions of Stewardship

Discussions about proper stewardship take place against a backdrop of normative ambiguity: there is no settled definition of stewardship. Civil society and the private sector often differ about the scope and content of stewardship obligations. Given the kinds of partnerships and cooperative ventures into which the CGIAR routinely enters, the System will need to be cognizant of both sets of concerns. Of course, the CGIAR shares many of the same goals that motivate private industry stewardship plans, and that animate civil society. In particular, the CGIAR shares the need for a stewardship system that comports with applicable regulatory requirements. Like privately-developed stewardship plans, the

¹¹⁸ Those negotiating for access to technologies on behalf of the CGIAR should be attuned to this point. Indeed, draft contract language specifically addressing this ability to share stewardship lessons across the CGIAR System and with national partners would be a good candidate for the System-wide form file described elsewhere in this proposal.

CGIAR's stewardship plan must incorporate best practices for managing new technologies, and must identify and develop performance indicators to enable effective measurement of successful implementation. Such a system will require impact monitoring by every level within the CGIAR System, from the first field-tests to the ultimate farmer end-users. To be successful, the resulting stewardship planning must extend from the laboratory to the field and beyond. The expansive definition of stewardship described above (see note 2) captures these concerns and adds an additional set of stewardship issues derived from the public goods mission of the CGIAR.

Industry literature dealing with stewardship tends to rely heavily on individual contract-based stewardship commitments from seed purchasers and farmers (Monsanto 2008). These commitments take the form of legally binding "grower agreements" which require individual farmers to take primary responsibility for stewardship activities (Monsanto 2008; Dow AgroSciences undated; BASF 2004). As these agreements are typically structured, it is the farmers themselves who are required to employ and make certifications about stewardship methods, and who accept responsibility for stewardship failures. With contractual stewardship obligations in place, private IP-rights holders focus their resources on policing those contracts, and have developed a reputation of vigorously pursuing available contract and tort law remedies for any deviation.

A necessary backdrop for these stewardship agreements is thus a strong legal regime of contract enforcement. Such a backdrop may or may not be present in the places in which the CGIAR System operates. As a result, concerns about the legal culture in stakeholder countries can be a significant obstacle as the CGIAR seeks to negotiate access to proprietary technologies. Moreover, this allocation of stewardship responsibilities is unlikely to be the most suitable approach for the clientele CGIAR serves, or for uses the CGIAR hopes to make of these products. As a result, the CGIAR System's stewardship plans will necessarily differ from the approaches favored by private industry, particularly private industry operating in industrialized countries.

Obligations built into industry-drafted stewardship agreements may not be appropriate for the poverty-alleviation context in which the CGIAR operates. Some contractual obligations are clearly intended to ensure that farmers have methods for avoiding the development of insect or weed resistance, preventing the unintended spread of transgenes, and ensuring preservation of identity (Monsanto 2008; BIO 2008; CropLife 2005). These concerns will resonate regardless of context. However, in addition to commitments on these fronts, private stewardship contracts typically include a laundry list of additional provisions intended to protect the IP-rights holder's property rights. Such provisions include: restrictions on the ability to transfer any IP-protected materials, including seeds, to third parties; confidentiality requirements; bans on seed saving; prohibitions on the sale of seed; commitments to sell the resulting products only within designated markets, or to use only designated silos or millers; choice of law rules; and acceptance of arbitration to resolve disputes (Monsanto 2008).

These concerns may be less appropriate for the CGIAR System context, and may include commitments that the CGIAR and its national partners may be unwilling or unable to fulfill, or that place undue burdens on resource poor farmers in developing countries. One size may not fit all and the answers to these questions may be different for different Centers and/or for different projects. The CGIAR System would benefit from developing a common understanding of which IP stewardship parameters can be tailored to specific projects in order to meet the particular concerns of that project's partners, and which parameters need more centralized treatment. For the issues amenable to centralized

treatment, draft contract language should be developed and made available to the Centers through a form file repository.

Even without endorsing the proliferation of IP claims in this area, the CGIAR System must develop the capacity to navigate the developing IPR system in order to best advance its poverty alleviation mission. As of 2006, only a small percentage of the CGIAR's collaborations occurred with private sector entities (CGIAR Science Council 2006) Given the private sector's key role in agricultural research, increasing alliances, collaborations, or partnerships with private IP holders may offer the CGIAR new opportunities to promote the needs of resource-poor farmers and to adapt new technologies to promote sustainability and food security in developing countries. Indeed, some researchers affiliated with the CGIAR and its constituent centers have expressed interest in accessing technologies and information, particularly involving agricultural biotechnology, currently protected by IP rights owned by private industry or public research institutions (Wollweber 2005). And, there are a number of such projects already in existence, including CIMMYT's participation in the Water Efficient Maize for Africa (WEMA), the Golden Rice, and the StrigAway Maize projects. (These projects and others are described in more detail in Annex I.) One lesson from the CGIAR's existing projects is that different models of cooperation and collaboration may be appropriate for different situations. Regardless of the form that cooperation takes, however, the stewardship points outlined in this report will need to be addressed.

Going forward, it would be worth paying attention to the relationship between these, and similar cooperative agreements, and the ITPGRFA Standard Material Transfer Agreement (SMTA). Industry is likely to be concerned about its ability to assert property rights over innovations developed as part of public-private collaborations with the CGIAR and its national partners. This concern will be heightened when the final product of such collaborations incorporates IP-protected proprietary materials shared with the CGIAR on preferential terms. Private entities will also likely seek clarity about the relationship between such collaborations and the equitable sharing provisions under the ITPGRFA. These concerns may be rooted in the desire to avoid having to compete with collaboratively-derived products within established markets rather than with a desire for ownership rights that would compromise any CGIAR activities.

The CGIAR would be well advised to come to a central understanding of how the System intends to respond to such questions, and to do so before facing them in the context of a negotiation over access to a particular proprietary technology. Among the possible resolutions are: articulation of a standard System-wide position; identifying a range of acceptable alternatives and leaving choice among these alternatives to the negotiators of a particular project; or a conclusion that this question is best resolved on a case-by-case basis. Each approach has both merits and weaknesses. Selecting a System-wide approach will therefore necessitate discussions among a wide-range of internal stakeholders about the comparative advantages of consistency versus flexibility on this point. Given the degree of passion that surrounds this question, as reflected in the language of Article 8j of the CBD, this is an issue likely to remain relevant in the future.

Industry representatives have also expressed concerns about the CGIAR's ability and willingness to engage in the level of stewardship necessary to meet their concerns (Chojecki 2006). These concerns tend to focus on three general areas: 1) that CGIAR operates in places where the legal environment will not provide adequate recourse to protect their intellectual property; 2) that CGIAR does not have the capacity or will to protect their intellectual property; 3) that their good name will be associated with failed or controversial projects (Chojecki 2006). The CGIAR System must be prepared to satisfy these IP holders that

information, resources and technologies can safely be shared with CGIAR researchers. One major source of tension is likely to be differing norms about confidentiality. While some degree of confidentiality is likely to be necessary in working with IP-protected material, the CGIAR should think long and hard about the consequences of agreeing to broad confidentiality provisions. Most industry-drafted confidentiality provisions are broader than they need to be. The CGIAR should devote some resources to developing appropriate confidentiality language that will satisfy the reasonable confidentiality needs of private partners, while also preserving space for the kinds of publication and exchange necessary to the creation of IPGs. Again, such language could be developed and stored in the proposed System-wide “form file” repository so that individual Centers have ready access.

At the same time it works to meet the needs of its industry partners, the CGIAR must also be proactive about developing a stewardship regime compatible with the System’s poverty alleviation and food security mission. In doing so, there is much the CGIAR can learn from private sector stewardship models. But, the CGIAR’s unique global mandate means that simply transposing stewardship plans from the private sector to the CGIAR System will not work. Despite this caveat, in developing a stewardship plan the CGIAR need not write on *tabula rasa*. Existing cooperation agreements between various CGIAR Centers and private actors can be instructive both for models of successful partnership, and for some pitfalls to avoid. (See Box 1, and Annex I) Each such negotiation should be viewed as an opportunity for institutional learning that will help the CGIAR develop further its capacity to negotiate IPG-compatible agreements with private partners.

Box 1. Example of cooperation agreements between CGIAR Centers and private actors

CIMMYT’s participation in WEMA and IRMA projects offers some instruction about the kinds of stewardship issues that might be part of any agreement with private IP holders. For example, both have tailored confidentiality agreements with an eye toward preserving the ability to publish results. This is a model to copy going forward. Sometimes, however, the lessons will be cautionary. For example, CIMMYT’s participation in the StrigAway project underscores some of the reasons why blanket adoption of industry-proposed language might not be appropriate for the CGIAR. Provision 8 of CIMMYT’s Material Transfer Agreement for StrigAway (CIMMYT undated) provides in full:

8. Germplasm that the recipient derives from the material by one or more crosses of the material with other germplasm (including germplasm obtained from CIMMYT), or that results from some other genetic modification of the material by the recipient, may be distributed, transferred, released and commercialized by the recipient without obtaining CIMMYT’s consent, provided:
 - a. The recipient and any other party receiving such germplasm from the recipient use “StrigAway®” technology when seed-dressing with Imidazolinone the material and any germplasm that the recipient derives from the material by one or more crosses of the material with other germplasm, or that results from some other genetic modification of the material by the recipient.
 - b. Seed-dressing with Imidazolinone is only used with germplasm homozygous for the Imidazolinone resistance trait.¹¹⁹

These provisions raise some concerns. First, the limitation to use “StrigAway” technology in sub-section (a) is written with reference to a trademark. Unlike patents, trademarks do not expire. So long as trademarks are in use, they remain valid. As a result, this provision

¹¹⁹ The full Material Transfer Agreement is available at http://www.cimmyt.org/english/wps/obtain_seed/Cmls/MTA-IRMaizeNon-DesignatedResGermplasm.pdf

commits users of the imidazolinone-coating technology to purchase proprietary, rather than less expensive generic chemical ingredients so long as the trademark remains in effect; potentially forever. That means that long after any patents on imidazolinone have expired, and the chemical is in the public domain, anyone using the StrigAway germplasm developed by, or derived from this project will be obligated to purchase proprietary chemicals. While the CGIAR System may think it appropriate to include exclusivity provision in certain of its projects, as a monetary incentive for private parties to share critical technologies, such incentives should not outlive the patent rights, and certainly should not be unending.

Subsection (b) raises a different concern. While it clearly imposes a limit on the use of the seed-dressing technique, left unclear is who has the responsibility of determining that the germplasm in question is homozygous for the imidazolinone resistance trait. There are no phenotypic differences between germplasm heterozygous and homozygous for this particular trait. Thus compliance with this provision will require some relatively complex analysis of the relevant germplasm. While the restriction makes good biological sense, this provision, as written, could impose an inappropriate burden on SMEs or even on individual farmers. As mentioned above, industry stewardship agreements used in developed countries routinely impose significant burdens on growers. Transferring this method of allocating responsibility to farmers in developing countries may be inappropriate.

E DETAILS OF RECOMMENDATIONS

A stewardship plan capable of responding to the complex and diverse institutional challenges posed by biosafety¹²⁰ and IP management requirements will take a significant commitment. Stewardship must be incorporated into practices not only on a System-wide basis, but also within each Center, and each project undertaken. Stewardship will be everyone's responsibility. The CGIAR must develop stewardship processes tailored to the IPG context in which it operates, and focused on increasing meaningful access to new technology solutions for resource poor farmers.

This study proposes that the CGIAR as a whole adopt an administrative system that includes an iterated, system-based decisional framework, along the lines embodied in the FAO's Hazard Analysis and Critical Control Point (HACCP) Analysis (FAO undated).¹²¹ Such an approach first identifies key decision points in the development and distribution of new crops. At each such decision point, there is a standardized method for reflection, planning and deliberative decision-making. The results of this reflection feed back into the product development process. Private industry has used HACCP-based analysis to develop their product stewardship system for agricultural biotechnology. (BIO 2008) With some adaptation, that same HACCP-based stewardship methodology can form the basis of a stewardship framework for the CGIAR System.

As described above in more detail, the concerns driving industry stewardship requirements include: confidentiality; compliance with domestic statutory regimes;

¹²⁰ As used in this report, Biosafety means the use of biological materials, products and applications in a fashion that does not compromise human health, biodiversity, and environmental sustainability.

¹²¹ The principles of the Hazard Analysis and Critical Control Point (HACCP) system have been adopted by the Codex Alimentarius Commission and guidelines to its application are provided in an Annex to the General Principles of Food Hygiene (FAO and WHO, 2003). The HACCP approach has been widely adopted in the context of food safety. Many NARS and SMEs will therefore already be familiar with how it works. This is additional advantage of using this approach as the basis for the CGIAR's stewardship framework.

biosafety; competitive market pressures, particularly segmented markets in defined territories. The CGIAR System shares many of those same concerns, and must be prepared to respond to all of them. This proposed stewardship framework, if properly operationalized, can achieve that goal. To that end, this Stewardship framework offers a consistent, easy-to-implement methodology for addressing issues of biosafety, confidentiality, and IP rights. It provides both a conceptual framework and concrete guidance for managing biotechnologies and other proprietary technologies. The adapted HACCP outline described below is intended for illustrative purposes only—it provides examples of the kinds of stewardship issues that can arise at each phase of the research-development-deployment chain. To truly embrace the HACCP-based approach, the CGIAR will need to ensure that its stewardship framework captures the array of stewardship concerns that might occur at each stage of the CGIAR's work. This means soliciting input from internal stakeholders, and tailoring the HACCP-based framework to meet the unique situations in which the CGIAR Centers operate. This level of internal participation has the additional benefit of avoiding the perception that stewardship is just centrally-imposed "red tape" designed by a consultant. Participation in developing the HACCP-based framework will thus help generate Center and researcher commitment to using the resulting stewardship framework.

The sample stewardship framework included in this report is arranged chronologically. Ultimately, the CGIAR will need to develop a series of stewardship implementation modules—one for each stage of work, and one for each stewardship challenge likely to cut across an entire project. These modules should be useful either as stand-alone documents or in conjunction with each other, depending on the specific needs of a particular project. In the initial phases of developing a stewardship framework, however, proceeding chronologically helps ensure that no issues are missed, and makes the cross-cutting nature of some concerns more visible. Input from stakeholders at this point will ensure that key issues are prioritized and that none are missed. After a full chronological stewardship framework is completed, the next step will be to derive implementation modules that can easily be used by Centers and individual researchers. Modules should be organized in outline, or question format, and should be designed with an eye toward facilitating training and implementation. They should offer standardized approaches, and highlight key concerns, but include enough flexibility to be easily adapted to a host of different situations.

Ideally, these standardized stewardship modules will be useful across the CGIAR System as a whole, and will allow the CGIAR System to further its goals in the most efficient manner possible. After an initial investment of time, energy and money to develop the modules, attention can turn to enhancing each Center's capacity for employing these modules to develop appropriate stewardship strategies for each project it undertakes. This framework of System-wide stewardship modules that can be tailored by each Center to meet the particular needs of specific projects both ensures consistency across projects, and minimizes the administrative burdens associated with developing and implementing project-specific stewardship plans. At the same time, such an approach will build transferable, System-wide institutional experience with stewardship, and will ensure that the stewardship plans remain flexible enough to be appropriate in many different countries with a diverse array of capacities to regulate and register the products of these new technologies.

Throughout the lifecycle of a project, the proposed Stewardship framework places an emphasis on data management, material traceability, and containment protocols as essential characteristics of an effective stewardship system. Its successful implementation will require institutional commitment both to the internal investments necessary in order to

implement the approach within the CGIAR System, and to the external investments necessary both to build NARS capacity to share in implementation, and to develop end-user farmer capacity to prudently manage the new technology.

1. Macro-Level Recommendations

Many practices that constitute effective stewardship already occur on an *ad hoc* basis throughout the CGIAR System. This study adopts an explicitly systemic perspective to promote a more structured and predictable approach to stewardship that will promote coherence, efficiency and collaboration across the System as a whole. Among the advantages from institutionalizing stewardship across the CGIAR will be streamlined implementation of consistent governance standards, and the production of compatible stores of information. In turn, a clear institutional governance plan with regard to stewardship will empower the CGIAR in its negotiations with private IP rights holders over stewardship commitments. The CGIAR will be able to come to those negotiations with a credible and rigorous stewardship system already in place, and thus will be better positioned to allay the concerns that might otherwise prompt private IP rights holders to demand stewardship measures that might be incompatible with the CGIAR's IPG focus. At the same time, this stewardship framework will lay the groundwork necessary to shepherd projects through the regulatory approval process, whether by a Center or a partner.

This stewardship system seeks to capitalize on the advantages of systematization while also recognizing the need to retain the flexibility to respond to local contexts, and unique project characteristics. This difficult balancing act can be achieved only if the CGIAR creates a System-wide institutional climate that values stewardship as a practice for sustainable agriculture, and does not send messages that stewardship is a bothersome side-issue, full of time- and resource-wasting transactional work. Developing the necessary level of commitment to stewardship will require investment in training staff at all levels—from the Director General to the field staff support. In short, the CGIAR must commit to creating an overall culture of stewardship. Only with a significant institutional commitment to cultivating stewardship norms and procedures as part of fulfilling the CGIAR poverty alleviation mission will this proposed framework be truly integrated into all levels of System operations.

To achieve this, the CGIAR will have to build System-wide stewardship knowledge management structures that incorporate stakeholders into the decision-making process, and can be operationalized into systems of ongoing evaluation and accountability. System-wide software and common templates will be a critical part of this process. Thus coordination with ongoing CGIAR initiatives to standardize technology platforms is advisable.

System-wide training on stewardship planning and implementation will ensure that the Centers activities are consistent, and will allow the CGIAR to take advantage of economies of scale. It will lay critical groundwork for Center-level, and project-level stewardship activities, and will increase the likelihood that stewardship obligations across various projects are compatible. Moreover, System-wide training and investment will help cultivate the practice of research-to-distribution stewardship planning, a key pre-condition for successful stewardship.¹²² This kind of centralized training and investment will have the

¹²² The prerequisites for successful stewardship include a skilled staff, well-equipped laboratories with proper working conditions, facilities for field testing experimental crops, access to informational networks

added advantage of strengthening the Center's capacity to deal with IP rights and the complex regulatory processes that often surround testing, marketing and growing transgenic and other novel plants. It would also have the benefit of facilitating more effective use of the CGIAR's vast store of knowledge and information, which is as much an IPG as are the seeds delivered to farmers.

Since the CGIAR System currently partners with many developing country institutions in order to facilitate testing and dissemination of information, technologies and policies, (CGIAR Science Council 2006 p. 16) those relationships will have to be accounted for in stewardship planning. Capacity-building and joint implementation with NARS should be part of any CGIAR-wide stewardship planning process. The CGIAR can use these collaborative endeavors as an opportunity to develop a consistent approach to stewardship that furthers development of and access to IPGs. In doing so, the CGIAR not only advances its goal of providing urgently needed agricultural technologies to support food security and sustainable development, but in the process may also play the leading role in laying the groundwork for new public good norms for IP rights licensing and management.

1.1 Overview of HACCP-based Stewardship Approach

1. **Hazard Identification:** Conduct a hazard analysis (at a sufficient level of detail so that the analysis leads to identification of relevant and appropriate control measures).
2. **Control Points:** Identify critical control points. This process will include 1) gathering information; 2) defining barriers and identifying causes; and 3) developing and selecting possible solutions.
3. **Critical Limits:** Establish the appropriate operation parameters for each control point identified above as a response to a hazard.
4. **Monitoring:** Develop and implement a monitoring plan to ensure that control points do not exceed the critical limits, including developing monitoring criteria. To ensure effectiveness, this may involve a combination of self-monitoring and third-party monitoring.
5. **Corrective Action:** Develop and implement a corrective action plan for instances in which control points exceed the designated critical limits. This process will include: 1) identifying the corrective action to be taken when monitoring establishes that a critical control point is not under control; and 2) using feedback from monitoring and corrective action to review and revise the strategy identified in HACCP Principles 2-4 as needed.
6. **Validation:** Establish procedures to verify that the HACCP system is working effectively and develop the criteria for measuring the success of strategy.
7. **Documentation:** Create a streamlined recordkeeping and documentation program.

The point of developing a HACCP-based stewardship process is to ensure that stewardship concerns are included in the initial conception of any project, rather than as an add-on at later stages. It will also be critical to ensure that other CGIAR-sponsored activities do not cut against the stewardship message inculcated by the HACCP-based stewardship process. To that end, as the CGIAR re-examines its activities, particularly those involving the content of its training programs; the guidance and explanatory information it provides to Centers and to NARS; and most particularly the ways that it finances projects, it should do so with stewardship in mind.

and databases, commitment to stewardship at all levels of endeavor, and an adequate extension and training system.

In the process of adapting the HACCP methodology to the public agricultural research context, two broad themes emerge: knowledge management and control over materials.

1.2 *The Need for a Coordinated Stewardship Knowledge Management System.*

Coordinated knowledge management will be essential for successful stewardship across the CGIAR System. On the most basic levels, there is a need to know what data and information exists, and to have a sense of the priority users of this data and their needs. Currently, there is no central repository of information, nor is there a coordinated means to search, retrieve or even identify the relevant information held within the numerous valuable databases scattered throughout the CGIAR. Not only are these databases not currently cross-linked with each other, but they frequently store information in incompatible formats. There is the need to create a plan to ensure identification of, and access to this information, possibly through an integrated, searchable, data management system. This is a long-term goal, one that many in the CGIAR System are already working to achieve. Wikis may be a useful interim tool in this process.

As the CGIAR explores opportunities for bringing together its diverse databases, it will be important to include an awareness of stewardship needs and obligations from the beginning. Creating structures to simplify and routinize management and communication of stewardship information should be a priority. To achieve this, as the CGIAR's separate databases are integrated, data should be standardized and linked with the relevant stewardship obligations. This level of knowledge integration may pose significant challenges for the CGIAR. Personnel may suddenly be asked to manage information in ways that seem alien or unnecessary. Clear communication about the relationship between effective knowledge management and successful stewardship will help minimize resistance, as will a widely participatory process for developing the stewardship framework in the first instance.

Coordinating stewardship knowledge management will offer many advantages. First, and perhaps most importantly, it allows the kinds of standardization that make data and information useful in multiple contexts. Standardization may also be a valuable technique for reducing the administrative burdens on researchers and individual CGIAR Centers associated with implementing the stewardship framework. By including stewardship information in the process of data generation, storage and retrieval, the CGIAR can, in a very simple manner, substantially improve awareness of regulatory requirements, as well as the rules, norms and practices that shape stewardship obligations in agricultural research and development. A widely-participatory process for developing the stewardship framework and modules will ensure that there is general agreement about the kinds of stewardship concerns that fall within the purview of central or local decisionmaking. That agreement will, in turn, ensure consistency of implementation across Centers and projects. This is particularly important because effective knowledge management will be key to successful interactions with IP rights holders, particularly those in the private sector. Starting from a System-wide stewardship management modules will free individual Centers from having to invest time and resources creating their own plans. Instead, individual Centers can focus their attention on tailoring stewardship strategies to account for practical application and implementation concerns.

Traceability is another essential characteristic of an effective stewardship system that hinges on the kind of knowledge management described above. Awareness of stewardship obligations must be integrated with data or information, and must travel with that information, as well as with the seeds themselves, throughout CGIAR and its NARS partners. This kind of cross-cutting stewardship concern requires integrated information coordination across the CGIAR System.

The micro-level recommendations below offer suggestions on how to integrate appropriate data management into stewardship modules at every stage of the crop development process. Only through effective information management and communication can CGIAR's drive to make its research more accessible to small-holder, under-resourced farmers, be harmonized with the stewardship commitments the System may make in order to access privately held technologies and information. By coordinating stewardship and information management, the CGIAR System can achieve both goals at the same time. Coordination will ensure that CGIAR entities do not take on IP stewardship obligations that make IPG information inaccessible to the System's partners. It will also assist the System to develop and implement stewardship modules in a fashion that nurtures collaborative action, improves knowledge sharing, and strengthens infrastructure within the CGIAR System. Effective information sharing and management can thus enrich IPGs while at the same time setting the ground for effective stewardship.

Doing this properly requires strengthened lines of communication between researchers, CGIAR institutions and NARS partners. While successful stewardship cannot be a top-down process, it will require System-wide coordination to ensure that knowledge sharing and IP stewardship commitments do not work at cross purposes. Stewardship concerns must be systematically incorporated as the CGIAR System, and individual centers formulate priorities and research strategies. Under these circumstances, making a commitment to develop coordinated data management and knowledge sharing plans may enable synergies from previously isolated activities across the CGIAR System and within NARS, while also preventing needless duplication.

Successful coordination of on-farm practices with stewardship commitments will require a participatory process to develop community-based management plans adapted to local conditions. As part of this process, CGIAR will have to work closely with NARS leaders to strengthen local organizations and other information intermediaries, and to reinforce, in some cases to develop, effective knowledge sharing channels. Farmer-focused initiatives will be needed to assist CGIAR and its NARS partners develop their capacity to create, manage and share stewardship information both vertically and horizontally. That means going beyond the CGIAR's traditional role of providing research expertise to help build the skills and systems necessary in order for NARS partners and end-user farmers to take ownership of the stewardship process. Many past and ongoing CGIAR projects provide useful models for how to do this.

Including stewardship concerns in the planning and management stages of a project, rather than as an add-on during implementation will make for better planning, and improved potential for effective implementation. The CGIAR will be able to take advantage of the enhanced awareness of implementation at the agreement stage that comes from involving end users in the planning stages. That means that from the inception, a project will include consideration of the data needed to obtain regulatory approvals later on in the process, and will ensure that data needed for ensuring good stewardship is generated at every stage of the product development process. And, the NARS partners who will be responsible for implementing many of the stewardship commitments contained in a license will be able to weigh in on practicality under real world circumstances.

Finally, an important advantage of knowledge coordination across the CGIAR System will be the possibility of standardizing many of the legal documents associated with managing transgenic and other novel crops and other proprietary intellectual property. By developing what lawyers call a "form file," a repository of exemplars including sample documents and specially-drafted contract provisions, the CGIAR can create a tremendous resource that will empower individual Centers in their negotiations with private entities.

The Centers will be able to access pre-prepared documents that already contain pro-poor language. Starting from this existing language will help Centers streamline their negotiations with private entities, and will minimize legal costs incurred on a project by project basis. By standardizing the core of license negotiations, while leaving room for case-by-case consideration of specifics, this aspect of the stewardship plan should vastly improve the experience of CGIAR researchers and staff entering into these kinds of agreements. Other documents likely to be needed on a semi-regular basis, including: confidentiality agreements, sample applications for permits and approvals, and materials distribution agreements, would also be appropriate candidates for inclusion in the repository. Having access to an array of pre-prepared forms that can be tailored to individual project will greatly reduce the burden that stewardship planning and implementation might otherwise impose on Centers. It will also turn each license negotiation into an opportunity for institutional learning that will help the CGIAR develop further its capacity to negotiate IPG-compatible agreements with private partners.

In particular, the scope of confidentiality agreements might be something that the CGIAR want to invest some time in considering. Industry confidentiality agreements tend to be overbroad, and to resolve all ambiguities in favor of secrecy. Given the CGIAR's IPG mission, this default position will probably not be appropriate. Having access to previously prepared language about confidentiality that has been specifically tailored to the needs of the CGIAR Centers, particularly with regard to publication, would help the CGIAR ensure that its agreements with private partners do not compromise on the System's core values. Such language is also an opportunity to clarify the uses that the CGIAR can make of information developed within a project to benefit other projects, both within the Center and across the System.

Having the document repository or "form file" described above would also allow the CGIAR Centers to make more efficient use of the services of IP brokers like the African Agricultural Technology Foundation (AATF) or the Public Intellectual Property Resource for Agriculture (PIPRA) (See Annex II). These organizations can be very helpful for leveraging the CGIAR's resources, particularly in the context of patent landscaping and ultimately licensing CGIAR-developed technologies to NARS and SMEs. But relying on these services to develop forms and documents in the first instance would not be the best choice for a number of reasons. First, in-house development of these forms allows for the efficiencies of scale that come with centralization. Second, even though the Centers will have very different needs that flow from the diversity of projects they undertake, there are likely to be core commonalities that could benefit from standardization. By creating one repository that contains CGIAR-approved exemplars that can be adapted to specific situations, the System can ensure some consistency across projects with regard to stewardship obligations, while still respecting the different needs associated with different projects. Third, in-house development of these templates would both build new internal expertise and capitalize on existing internal CGIAR expertise to guide the drafting language. At the very least, developing and using a set of in-house documents will prevent the CGIAR Centers from assuming incompatible or contradictory obligations. A baseline of consistency and compatibility in stewardship obligations will, in turn, facilitate implementation of the proposed System-wide stewardship framework, thus making possible the efficiencies and economies of scale attendant that accompany such an approach.

1.3 Control over Materials

Control over materials, including transgenic and other novel materials, is a vital part of any stewardship plan. First, many transgenic or otherwise novel crops have been modified to

add an endogenous herbicidal or insecticidal capacity. Proper control over this technology, including containment of plants, seeds and other biological materials is a critical part of stewardship efforts directed at staving off or slowing the development of resistance among the target population. *Bt*-maize and StrigAway (imazapyr-resistant) maize seeds are two examples of the kinds of crops that raise this concern: the former has a novel trait as a result of transgenic technology, while the latter has a novel trait that derives from the more conventional technique of EMS mutagenesis.

The undesirable consequences of gene flow raise a host of other stewardship related concerns. Control over materials can minimize the possibility that gene flow will result in the creation of “super-weeds”, the introgression of novel traits into wild relatives or conventional crops, or the undesired adventitious presence of the novel trait in crops destined for markets in which the novel trait is not approved. These concerns matter not only from a general environmental or biosafety perspective, but also because they raise the possibility of IP-based or tort-based liability. Thus, responsible control over materials, including crop containment, furthers environmental as well as biosafety and IP-protection goals.

Private partners will want assurances that the materials they entrust to the CGIAR can be properly handled. Currently, it seems that biosafety processes, other than those involving advanced informed consent under the Cartagena Protocol, are left to the individual researchers in the various CGIAR Centers. That means that the processes for ensuring control over regulated materials may vary from Center to Center and project to project. While that approach might be adequate in the short-term, it places a significant burden on individual researchers. Even though researchers have experience with the kinds of containment measures necessary for controlled breeding, without standard operating procedures and proper training they may not fully appreciate the different level of care necessary for activities involving transgenics and other novel varieties. Moreover, when stewardship is an individual affair, the institution loses a portion of its stewardship knowledge every time a researcher leaves. In the absence of an overarching stewardship plan, the departure of a researcher can create a stewardship crisis within a project.

In addition to these disadvantages to the CGIAR itself, an *ad hoc* approach to biosafety is unlikely to satisfy private partners who have both reputation and business concerns that hinge on successful containment of these crops. These partners will instead want to see official biosafety processes that have been formally adopted and institutionalized. Finally, the lack of an integrated and formalized process for ensuring crop containment might expose the CGIAR Centers to unwanted publicity and even liability in the event of an inadvertent escape.

So, a critical aspect of implementing a stewardship plan will be attention to control over materials throughout the crop development process.¹²³ That means developing an appreciation of the need for, and methods to accomplish containment from laboratory-to-farm and beyond. Thus, containment might be a good candidate for a cross-cutting stewardship module in addition to being a component of the stewardship modules prepared for various stages of a project.

Successful control over materials is intimately entwined with the challenges of knowledge management. Identifying control over materials as both a cross-cutting stewardship concern, as well as a concern at each stage of a project, helps bring the connection between

¹²³ As noted earlier, these same concerns apply to IP-protected and confidential information. Thus, stewardship involves containment of information as well as of materials.

knowledge management and control over materials into focus. For example, such an approach surfaces the need to institute a standardized process for recordkeeping that enables a clear chain of custody for all transgenic and novel varieties. This chain of custody can then be used to track movement of transgenic and novel products. The ability to track these products is a critical first step for effective insect resistance management, for preventing cross-breeding with landraces where applicable, and for preventing persistence in the environment more generally.

A clear chain of custody will also be necessary in order to implement many of the commitments Centers are likely to make to IP-holders in the process of negotiating a license to use the IP. These commitments will likely relate to containment both for biosafety and for identity preservation and IP protection reasons. Thus, IP-holders might want to see handling and transfer protocols, segregation, security and labeling protocols and clear plans for monitoring and oversight. The CGIAR should begin developing these protocols independent of IP-holder pressure. They will streamline and simplify the work at the various CGIAR Centers, and will provide useful information and feedback about the success of stewardship choices currently being made across the CGIAR. As a final reason for CGIAR engagement with this issue on a System-wide level, all of these issues are also likely to arise in the context of discussions with regulators. Having a pre-existing set of protocols will reduce the expense and effort necessary to obtain regulatory approvals and to establish regulatory compliance.

2 Tentative Details of Micro-Level Recommendations

This framework is intended to provide structure and guidance, but with the proviso that a new HACCP-based stewardship analysis must be conducted for each project keyed to the unique aspects of that project. The appropriate stewardship analysis will identify key decision points, and therefore stewardship control points, in the agricultural crop research and development process. Among the candidates for critical control points will be: laboratory research, contained plant development, field trials, seed production, seed distribution, on-farm uses, post-harvest sale or use. For each critical control point, this report offers sample stewardship concerns, methods to address those concerns, oversight techniques to monitor effectiveness of those stewardship methods, as well as knowledge management techniques to ensure continuous institutional learning (Shambu Prasad, Laxmi & Wani 2006). The details included in this framework are for illustrative purposes only. Input from internal CGIAR stakeholders will be necessary to transform this sample into a stewardship framework within which the CGIAR to can address stewardship issues systematically and consistently. Once a stewardship framework is fleshed out, the next step will be to derive implementation modules that can easily be used by Centers and individual researchers. Modules should be organized in outline, or question format, and should be designed with an eye toward facilitating training and implementation. They should offer standardized approaches, and highlight key concerns, but include enough flexibility to be easily adapted to a host of different situations.

A summary of the recommendation outlined below is that the CGIAR System develop a stewardship framework that targets, at a minimum, five different stages of new crop development: 1) decision to initiate a project; 2) laboratory science for crop development; 3) field testing of novel varieties; 4) seed production and delivery; and 5) on-farm practices, including harvest and transport to market. Once stewardship modules keyed to work stages within a project are developed, these modules can be used to generate a set of derivative modules focused on cross-cutting stewardship issues that are likely to recur at multiple stage of work. At a minimum, such modules will be needed for biosafety, confidentiality, and deployment of IP-protected materials through private partners.

The modules should fit together as a seamless, compatible system that ensures stewardship continuity throughout the lifecycle of product development, delivery and use. Each module should include verification processes based on clearly identifiable indicators. Since the Centers themselves are not always actively involved in the production and distribution of seeds, or in the actual farming itself, developing and implementing some stewardship modules will necessitate early and active involvement by NARS, SMEs and farmers themselves. Below is a (non-exhaustive) outline of the kinds of issues to be considered at each critical stage of new crop development.

One note of particular emphasis: Stewardship planning at the project initiation stage is critical, as is reducing to writing any agreements with private partners. Without a clear written agreement the System is vulnerable to personnel changes and the attendant loss of institutional memory. Any negotiations for the right to use IPR-protected technologies should occur before the System invested resources in product development. And, attention should be paid to negotiating System-wide rights of use, rather than project-by-project rights. Negotiating for after-the-fact permission to use materials or processes covered by IPRs wastes time, energy and resources that could otherwise be devoted to fulfilling CGIAR's mission.

Stewardship Concerns

- Technology that will be useful and appropriate in the System's work
- Proper deployment of technology
- Freedom to operate
- Capacity to implement stewardship
- Confidentiality and IP management

Methodology and Response

- Suitability of a project for a particular location
- Institutionalized plans for technology
 - Identify appropriate technology in the public domain
 - Establish industry willingness to provide proprietary materials
- Coordinated Negotiations
 - Consult the System-wide form file for sample contract language
 - Negotiate an appropriate written agreement that details stewardship obligations
- Coordinated stewardship knowledge management
- Best practices for managing information and materials
 - Identify proper level of confidentiality
 - Confirm capacity to employ appropriate stewardship techniques
- Data management and recordkeeping

Oversight

- Training across the CGIAR System
- Stewardship knowledge management plan
- Formal biosafety and IP management plan
- Stewardship as an agenda item at board meetings
- Identified stewardship officer at each Center
- Annual reporting
- Clear lines of responsibility for stewardship
- Stewardship included in job descriptions

Laboratory Research and Contained Plant Development

Stewardship Concerns

- Compliance with Cartagena Protocol and domestic notification and clearance requirements for imported material
- Safety within the laboratory
- Regulatory requirements
- Misidentification of seeds, plants or other materials
- Containment failure during transfer
- Inadvertent mixing through failure to properly store materials
- Accidental release into the environment
- Confidentiality and IP management

Methodology and Response

- Advanced informed consent (where necessary)
- Best practices for laboratory research
 - Establish appropriate biosafety level for intended work
 - Confirm construct prior to transformation
 - Confirm host materials prior to transformation
- Labeling, tracking and disposition of plant material as part of an inventory management system
- Lab protocols
- Transfer protocols including packaging requirements
- Data management and recordkeeping

Oversight

- Training—possibly a certificate program with regular continuing education
- Confirm material identity before transfer
- Accidental Release Plan
- Crisis management plan
- Regular review of standard operating procedures
- Annual reporting requirement
- Clear lines of responsibility for stewardship

Field Trials

Stewardship Concerns

- Compliance with Cartagena Protocol and domestic notification and clearance requirements for imported material
- Misidentification of seeds, plants or other materials
- Compliance with regulatory requirements (especially for transgenics)
- Allocation of responsibility between CGIAR, NARS and other partners
- Reproductive isolation to prevent out-crossing
 - Dissemination of new transgenes
 - Persistence in the environment

- Introduction into the food and feed pathways
- Insect resistance management
- Pesticide management
- Containment failure during transfer
- Inadvertent mixing through failure to properly store materials
- Accidental release into the environment
- Incomplete clean out of equipment or field
- Volunteer plants on the site
- Confidentiality and IP management

Methodology and Response

- Advanced informed consent where necessary
- Labeling, tracking and disposition of plant material as part of an inventory management system
- Transfer and storage protocols
- Confinement protocols that detail methods and controls to maintain reproductive isolation including:
 - Removal or bagging of flowers and tassels
 - Termination of field trial prior to flowering
 - Spatial or physical isolation
 - Border rows to act as pollen/insect traps
 - Temporal isolation
- Plan to prevent unlawful harvest from field-site
- Institute a Field Trial Audit Program
- Post-harvest field “cleaning” and use restrictions
- Protocol for disposing of residual or excess plant material from the site during and after the field trial
- Data management and recordkeeping

Oversight

- Training of personnel with regular updates and refreshers
- Confirm material identity before transfer
- Accidental release plan
- Crisis management plan
- Monitor field trial site to confirm that containment practices are implemented in accordance with regulatory and System requirements
- Monitor field trial site to confirm that containment practices are successful
- Inspection and verification of post-harvest measures
- Stewardship written into job descriptions
- Periodic reporting
- Clear lines of responsibility for stewardship

Seed Production

Stewardship Concerns

- Insufficient isolation of breeding stock
- Pesticide management
- Misidentification of seeds, plants or other material

- Inadvertent mixing of plant material through failure to clear field
- Incomplete clean-out of equipment
- Allocation of responsibility between CGIAR and NARS
- Confidentiality and IP management

Methodology/Response

- Advanced informed consent where necessary
- Labeling, tracking and disposition of plant material as part of an inventory management system
- Transfer protocols
- Data management and recordkeeping
- Confinement protocols that detail methods and controls to maintain reproductive isolation including:
 - Removal or bagging of flowers and tassels
 - Spatial or physical isolation
 - Border rows to act as pollen/insect traps
 - Temporal isolation
- Plan to prevent unlawful harvest from field-site
- Institute an Audit Program when needed
- Post-harvest field “cleaning” and use restrictions when appropriate
- Protocol for disposing of residual or excess plant material from the site during and after seed production

Oversight

- Training of personnel
- Confirm plant identity before transfer
- Monitor field plantings to confirm that management practices are in place to meet regulatory, CGIAR and any other requirements
- Plan to prevent unlawful harvest from field-site
- Institute a post-harvest field audit program
- Post-harvest field “cleaning” and use restrictions
- Periodic reporting
- Clear lines of responsibility for stewardship

Seed Distribution

Stewardship Concerns

- Compliance with IP commitments
- Compliance with regulatory requirements
- Allocation of responsibility between CGIAR, NARS, and SMEs.
- Inadvertent mixing of seeds

Methodology and Response

- Collaborative planning to coordinate responsibilities
- Written agreements specifying stewardship obligations
- Data management and recordkeeping

Oversight

- Seed distribution records available for review by CGIAR Center
- Training SME and NARS partners to address issues unique to transgenic and novel seeds
- Clear lines of responsibility for stewardship
- Periodic reporting

On-farm Practices

Stewardship Concerns

- Biosafety
 - planting
 - pest management protocols
 - pesticide management
 - insect resistance management
 - worker safety
 - other, including resource inputs and sustainability
- Harvest
 - containment of transgenic and novel materials
 - contamination
 - animal foraging
- Compliance with IP commitments
 - proper destruction of organic remains
 - proper channeling of products into designated markets

Methodology and Response

- Labeling, tracking and disposition of plant material as part of an inventory management system
- Data management and recordkeeping
- Transfer protocols

Oversight

- Training SME and NARS partners to address unique issues
- Plan to prevent unlawful harvest from field-site
- Institute a post-harvest field audit program
- Post-harvest field “cleaning” and use restrictions
- Clear responsibility for stewardship
- Periodic report

Post-harvest Sale

Stewardship Concerns

- Market segmentation commitments
- Import restrictions

- Use limitations

Additional NARS and SME Issues

- educational outreach
 - need to create a culture of stewardship
 - Create capacity to implement stewardship plans
 - Involve end-users in developing a culture of stewardship.
- mentoring and support
 - feedback to individual CGIAR centers
 - feedback to CGIAR System
- oversight

F CONCLUSION

This paper offers guidance to help the CGIAR System develop the stewardship programs it will need as part of a broader strategy for responding to the global shift towards private ownership of the fruits of agricultural research. The proposed stewardship framework identifies a common institution-wide set of stewardship commitments that can form the basis of such a program. At the same time, the framework proposed in this paper is intended to ensure that individual CGIAR Centers retain enough 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.

Table II-1. International Law Obligations for Countries in which the CGIAR System has a Presence

Country	CGIAR Centers	WTO Status		UPOV Membership	Cartagena Protocol Membership
Afghanistan	CIMMYT ICARDA	in progress	LDC		
Algeria	Bioversity ICARDA	in progress			Yes
Angola	CIAT	Yes			
Argentina	ICARDA	Yes		Yes	
Australia	Bioversity	Yes		Yes	
Bahrain	ICARDA	Yes			
Bangladesh	CIMMYT IRRI Worldfish	Yes	LDC		Yes
Belgium	Bioversity	Yes			Yes
Benin	Bioversity IITA WARDA	Yes	LDC		Yes
Bhutan	CIAT		LDC		
Bolivia	Bioversity			Yes	Yes

	CIAT ICARDA CIFOR				
Brazil	Bioversity CIAT CIFOR ICARDA	Yes	LDC	Yes	Yes
Burkina Faso	Bioversity CIAT CIFOR IWRI WARDA				Yes
Burundi	CIAT ICRAF	Yes	LDC		Yes
Cambodia	CIAT IRRI IWRI Worldfish	Yes	LDC		Yes
Cameroon	Bioversity CIAT CIFOR IITA WARDA Worldfish	Yes			Yes
Central African Rep.	WARDA		LDC		Yes
Chad	WARDA	Yes	LDC		Yes
Chile	Bioversity ICARDA	Yes		Yes	
China	Bioversity CIAT CIMMYT CIP ICRAF IFRI ILRI IRRI	Yes		Yes	Yes
Columbia	CIAT CIMMYT ICARDA ILRI	Yes		Yes	Yes
Congo D.R	Bioversity IITA WARDA Worldfish	Yes	LDC		Yes
Costa Rica	Bioversity	Yes		Yes	Yes
Cote d'Ivoire	Bioversity CIAT	Yes			

	WARDA				
Cuba	Bioversity	Yes			Yes
Cyprus	Bioversity ICARDA	Yes			Yes
Czech Republic	Bioversity	Yes		Yes	Yes
Denmark	Bioversity	Yes		Yes	Yes
East Timor	CIAT	LDC			
Ecuador	Bioversity CIP ICARDA	Yes		Yes	Yes
Egypt	Bioversity ICARDA WARDA	Yes			Yes
Eritrea	ICARDA ICRAF		LDC		Yes
Ethiopia	Bioversity CIAT CIFOR CIMMYT ICARDA CIRAF IFPRI ILRI IWRI	in progress	LDC		Yes
Fiji	Worldfish	Yes			Yes
Georgia	CIMMYT	Yes		Yes	Yes
Ghana	Bioversity CIAT IFPRI IITA IWRI WARDA	Yes			Yes
Greece	Bioversity	Yes			Yes
Guinea	Bioversity CIFOR WARDA	Yes	LDC		Yes
Guinea Bissau	WARDA	Yes	LDC		
Hungary	Bioversity	Yes		Yes	Yes
India	Bioversity CIAT CIMMYT CIP ICRISAT IFPRI ILRI	Yes			Yes

	IWRI				
Indonesia	Bioversity CIAT CIFOR CIP ICRAF ILRI IRRI	Yes			Yes
Iran	Bioversity CIMMYT ICARDA	in progress			Yes
Iraq	ICARDA	in progress			
Israel	Bioversity	Yes		Yes	
Italy	Bioversity IFPRI	Yes		Yes	Yes
Jordan	Bioversity ICARDA	Yes		Yes	Yes
Kazakhstan	CIMMYT IWRI	in progress			Yes
Kenya	Bioversity CIAT CIP ICRAF ICRISAT IITA ILRI	Yes		Yes	Yes
Kuwait	ICARDA	Yes			
Kyrgyzstan	IWRI	Yes		Yes	Yes
Lao	CIAT CIFOR ICRAF IRRI IWRI Worldfish	in progress	LDC		Yes
Lebanon	ICARDA	in progress			
Lesotho	CIAT	Yes	LDC		Yes
Liberia	WARDA	in progress			Yes
Libya	ICARDA	in progress			
Madagascar	CIAT	Yes	LDC		Yes

Malawi	CIAT ICRISAT IITA Worldfish	Yes	LDC		
Malaysia	Bioversity IWRI Worldfish	Yes			Yes
Mali	Bioversity CIAT ICRAF ICRISAT ILRI WARDA	Yes	LDC		Yes
Mauritania	Bioversity ICARDA WARDA	Yes	LDC		Yes
Mauritius	Bioversity	Yes			Yes
Mexico	CIMMYT ICARDA	Yes		Yes	Yes
Morocco	Bioversity ICARDA	Yes		Yes	
Mozambique	CIAT CIFOR ICRISAT ICRAF IITA ILRI IRRI	Yes	LDC		Yes
Myanmar	IRRI Worldfish	Yes	LDC		Yes
Nepal	CIAT CIMMYT IRRI IWRI	Yes	LDC		
Nicaragua	CIAT ILRI	Yes		Yes	Yes
Niger	CIAT ICRISAT ILRI WARDA	Yes	LDC		Yes
Nigeria	CIAT	Yes			Yes

	IITA ILRI IPFRI IRRI WARDA				
Norway	Bioversity	Yes		Yes	Yes
Oman	Bioversity ICARDA	Yes			Yes
Pakistan	Bioversity ICARDA IWRI	Yes			
Palestine	ICARDA				
Panama	Bioversity			Yes	Yes
Peru	Bioversity CIP ICARDA ICRAF	Yes			Yes
Philippines	CIAT CIP IRRI ICRAF Worldfish	Yes			Yes
Poland	Bioversity	Yes		Yes	Yes
Portugal	Bioversity	Yes		Yes	Yes
Qatar	Bioversity ICARDA	Yes			Yes
Russia	Bioversity	in progress		Yes	
Rwanda	CIAT ICRAF IWRI	Yes	LDC		Yes
Saudi Arabia	ICARDA	Yes			Yes
Senegal	Bioversity CIAT IFPRI WARDA	Yes	LDC		Yes
Sierra Leone	WARDA	Yes	LDC		
Slovakia	Bioversity	Yes		Yes	Yes
Solomon Islands	Worldfish	Yes	LDC		Yes
Somalia	ICRAF		LDC		
South Africa	CIAT CIFOR IWRI	Yes		Yes	Yes
Sri Lanka	IWRI	Yes			Yes

Sudan	Bioversity CIAT ICARDA ICRAF	in progress	LDC		Yes
Swaziland	CIAT	Yes			Yes
Switzerland	Bioversity	Yes		Yes	Yes
Syria	Bioversity				Yes
Tajikistan	IWRI	in progress			Yes
Tanzania	CIAT ICRAF IITA IWRI	Yes	LDC		Yes
Thailand	CIAT ICRAF ILRI IRRI Worldfish	Yes			Yes
The Gambia	Worldfish WARDA	Yes	LDC		Yes
Togo	CIAT WARDA	Yes			Yes
Tunisia	Bioversity ICARDA	Yes		Yes	Yes
Turkey	Bioversity ICARDA	Yes		Yes	Yes
Turkmenistan	IWRI				Yes
UAE	ICARDA	Yes			
Uganda	Bioversity CIAT CIP ICRAF IFPRI IITA IWRI WARDA	Yes	LDC		Yes
Ukraine	Bioversity	Yes		Yes	
USA	CIAT IFPRI	Yes		Yes	
Uzbekistan	IWRI	in progress		Yes	
Vietnam	CIAT CIFOR CIP ICRAF ILRI IRRI	Yes		Yes	Yes

	IWRI Worldfish				
Yemen	ICARDA	in progress			Yes
Zambia	CIAT CIFOR Worldfish	Yes	LDC		Yes
Zimbabwe	CIAT CIFOR ICRISAT	Yes			Yes

Annex 1

Case Studies of CGIAR Centers' involvement in product stewardship

CASE STUDY 1: SUCCESS STORY OF *Bt* COTTON IN INDIA AND ITS REGULATIONS

The approval for commercial release of first transgenic crop in India was granted in 2002 for three cotton hybrids to Mahyco, a leading national seed company. The insect resistance in these hybrids was introgressed from *Bt* cotton cocker-312 (event MON 531) developed by Monsanto Company into the parental lines of Mahyco proprietary hybrids.

The core transgenic research that culminated in the development insect-resistant cotton was designed and conducted by Monsanto. The research involved the isolation of gene from *Bacillus thuringiensis* (*Bt*) and the further development to ensure effective level of expression. The technology was thus developed and fully owned by Monsanto. In 1996, Mahyco imported 100g of Cocker-312 seeds containing *cry1Ac* gene and crossed with Indian cotton breeding lines to introgressed *cry1Ac* gene, converting forty elite parental lines for the *Bt* trait. During 1996-98 limited field trials were conducted at one location and risk assessment studies (escape study, aggressiveness and persistent studies, biochemical analysis, toxicological studies and allergenicity studies) were initiated. During 1998-99, multi-locational field trials were conducted at 40 locations in 9 states to assess agronomic benefits and biosafety. In 2000, the Indian Genetic Engineering Approval Committee (GEAC) operating under the Indian Ministry of Environment and Forests gave approval for conducting large scale field trial on 85 hectares and seed production trials on 150 hectares. In 2001, field trials were extended to 100 hectares including those under the All Indian coordinated improvement project of Indian Council of Agricultural Research (ICAR). In 2002, GEAC approved commercial cultivation of these hybrids in few states.

It is amply clear that Monsanto owns the technology, while the risk assessment studies for the Indian cultivars have been undertaken by the licensee, Mahyco. The liability for the technology performance is therefore with Monsanto while those associated with the field lies with Mahyco. Further to safeguard the interests of Indian farmers, GEAC stipulates certain conditions in giving the sanction for commercial release:

- i) The period of validity of approval is three years from April 2002 – March 2005.
- ii) Every field where *Bt* cotton is planted shall be fully surrounded by a belt of land called 'refuge' in which the same non-*Bt* cotton variety shall be sown. The size of the refuge belt should be such as to take at least five rows of non-*Bt* cotton or shall be 20% of total sown area whichever is more.
- iii) To facilitate this, each packet of seeds of the approved varieties should also contain a separate packet of the seeds of the same non-*Bt* cotton variety, which is sufficient for planting in the refuge defined above.
- iv) Each packet should be appropriately labeled indicating the contents and the description of the *Bt* hybrid including the name of the transgene, the GEAC approval reference, physical and genetic purity of the seeds. The packet should also contain detailed directions for use including sowing pattern, pest management, suitability of agro-climatic conditions etc., in vernacular language.
- v) Mahyco will enter into agreements with their dealers/agents, that will specify the requirements from dealers/agents to provide details about the sale of seeds, acreage cultivated, and state/regions where *Bt* cotton is sown.

- vi) Mahyco will prepare annual reports by 31 March each year on the use of Bt cotton hybrid varieties by dealers, acreage, locality (state and region) and submit the same in electronic form to GEAC, if asked for by the GEAC.
- vii) Mahyco will develop plans for Bt based Integrated Pest Management and include this information in the seed packet.
- viii) Mahyco will monitor annually the susceptibility of bollworms to Bt gene vis-à-vis baseline susceptibility data and submit data relating to resistance development, if any, to GEAC.
- ix) Monitoring of susceptibility of bollworms to the Bt gene will also be undertaken by an agency identified by the Ministry of Environment and Forests at applicant's cost. The Ministry has entrusted Central Institute for Cotton research (CICR), Nagpur to carry out the above monitoring.
- x) Mahyco will undertake an awareness and education program, inter alia through development and distribution of educational material on Bt cotton, for farmers, dealers and others.
- xi) Mahyco will also continue to undertake studies on possible impacts on non-target insects and crops, and report back to GEAC annually.
- xii) The label on each packet of seeds, and the instruction manual inside the packet should contain all relevant information.
- xiii) Mahyco will deposit 100 g seed each of approved hybrids as well as their parental lines with the National Bureau of Plant Genetic Resources (NBPGR).
- xiv) Mahyco will develop and deposit with the NBPGR, the DNA fingerprints of the approved varieties.
- xv) Mahyco will also provide to NBPGR, the testing procedures for identifying transgenic traits in the approved varieties by DNA and protein methods.

According to Dr. Raju Barwale, Managing Director, Mahyco, it was clear that private sector owns the responsibility of any failure in the field. This also includes food safety, environmental safety, and unintended effects, which might be on soil microorganisms. Crop failure due to such factors as drought and flooding are not included under the private sector's responsibility. However, he suggested that the government establish certain timeframe (e.g., five years), beyond which the seed companies should not be liable. He further mentioned that, if the private sector is making a profit, such as in the case of Bt cotton, it should be able to deal with any liability-related litigation and accept the terms and conditions laid down by GEAC. Meanwhile, Dr. Barwale felt that the national governments should own the responsibility for genes/traits that are shared on humanitarian grounds.

Since the CGIAR Centers are responsible for delivering public goods for the poor, one might negotiate FAO/national governments to take the liability on them. The CGIAR's main role should be to do due diligence of any technology that they can receive from other research organizations, private sector or public sector, and put them in the crops of regional importance. While the CGIAR Centers are endorsing the technology, through well-conducted studies it is being done in good faith and thus liability related to the technology may be owned by National Governments. However, if there are any problems related to field management that may rest with the seed company. The national governments, however, may review insurance policy as today agriculture is become resource intensive and our farmers risk taking capacity is very low.

CASE STUDY 2: GOLDEN RICE

Golden rice has enormous potential to fight malnutrition. Often, it is the economically disadvantaged section of society that suffers from nutrient deficiency. This vulnerable section of society has low purchasing power and thus, to be effective, a nutritionally improved product must be made available to them at the current price, if not cheaper. Golden Rice is an example of nutritional enhancement of a product for economically disadvantaged sections of the society.

Rice is the staple food for billions of people especially in Asia. Rice needs to be polished for storage and polished rice lacks Vitamin A and Iron. Most of the poor suffer from Vitamin A deficiency (VAD) as they cannot afford a balanced diet consisting of adequate quantities of fruits and vegetables, leading to anemia (due to iron deficiency) and night blindness, impaired mental development and reduce disease immunity leading to death in severe cases.

Governments in various countries, including India, have introduced a Vitamin A supplementation program, whereby Vitamin A is added to products like milk and oils. Doses are adjusted according to RDA (Recommended Daily Allowance) and dietary habits. Supplementation programs incur expenses year after year. Further, programs of this nature fail to reach all the targeted population, as the rural population largely depends on crops that are grown on their farm and have practically no access to packed food supplemented with Vitamins. Golden Rice, modified to express transgenes for provitamin A (β -carotene) synthesis in the endosperm, thus is expected to effectively complement traditional interventions in the fight against VAD in developing countries.

The development of Golden Rice led to a significant change in the relationships between the public sector and intellectual property. The Rockefeller Foundation commissioned a study to review freedom to operate (FTO) for pro-Vitamin A containing Golden Rice.¹²⁴ The review indicated that 70 patents were applicable to the improvement of rice, provided all patents irrespective of country of origin of application as well as patents relating to commercially available technological tools legitimately used for research, were taken into consideration. The patents range from gene to the research tool. The published analysis showed however that in practice only a few patents and materials transfer agreements were applicable.¹²⁵

Obtaining “Freedom to Operate” Licenses: Golden Rice¹²⁶

Having identified both the potential of the technology and the perceived constraints for commercialization, the Freedom to Operate issues were resolved within few months in 2000 by a straightforward IP management strategy, comprising of following goals:

- a) Identification of major IP components (the FTO review) associated with the technology
- b) Interpretation by Zeneca¹²⁷ of the relevance of the FTO review to the proposed humanitarian use in developing countries

¹²⁴ Kryer R.D., Kowalski S.P., and Krattiger, A.F. 2000 The Intellectual and Technical Property Components of pro-Vitamin A Rice (GoldenRice™): A Preliminary Freedom-To-Operate Review. ISAAA Brief Number 20. The International Service for the Acquisition of Agri-biotech Applications (ISAAA), Ithaca, New York.

¹²⁵ Analysis by Zeneca showed that in practice only a handful of patents were potentially applicable in the target developing countries, together with a few material transfer agreements.

¹²⁶ Krattiger A and Potrykus 2007 Golden Rice: A product Development Partnership in Agriculture Biotechnology and Humanitarian Licensing in Executive Guide to Intellectual Property Management in Health and Agricultural Innovation. A Handbook of Best Practices (Krattiger A, RT Mahoney (Nelsen et al) MIHR (Oxford, UK) PIPRA (Davis, USA), Oswaldo Cruz Foundation (Fiocruz, Rio de Janeiro, Brazil) and bio Developments-International Institute (Ithaca, USA). Available online at www.ipHandbook.org

¹²⁷ Later became Syngenta after a merger with Novartis

- c) In licensing for the clearly defined humanitarian use, led by Zeneca, for IP component it did not already own or control
- d) Licensing by Zeneca/Syngenta, to and via the inventors of the assembled IP to public sector institutions in developing countries that could use the rights for the benefit of resource poor farmers

The patent holders for possibly enforceable and relevant patents were: Potrykus and Beyer (inventors for the use of specific biosynthetic pathways), Zeneca Ltd. (plant biotechnology related patent), along with Bayer AG Monsanto Company, Novartis AG, Orynova BV, and Zeneca Morgen BV. All of these companies provided access to their technology, free of charge for defined humanitarian research and use of golden rice in developing countries. It is important to note that the licensing process was aided through the involvement of commercially experienced professionals able to comprehend the sensitivities inherent in commercial activities and make them compatible with the needs of the humanitarian project.

Following Zeneca's analysis of the situation and arrangement of the possibly necessary licenses, Zeneca was able to put in place licenses with the inventors to support the latter's intentions of making the technology available free of charge to those who needed it. Within a short time, sixteen licenses, including a license with the right to sub-license, were issued by one of the inventors as planned. These benefited national programs in Bangladesh, China, India, Indonesia, Philippines, and Vietnam to use this technology, for their local rice varieties.¹²⁸

It is worth studying the terms of the Golden Rice licenses that were agreed between Dr. A.C. Dubock for Zeneca and the inventors Potrykus and Beyer:¹²⁹

- Syngenta retains commercial rights, although it has no current plans to commercialize Golden Rice.
- Humanitarian use, and research leading to it, is allowed.
- Humanitarian use is defined as use in developing countries by resource-poor farmers (earning less than US\$ 10,000 per year from farming).
- The technology must be introduced into public seed varieties, as a way to optimize public sector benefit and use.
- Sale of Golden Rice is authorized by farmers, also as a way to reach urban poor, however, there is no charge for the trait itself.
- Farmers are allowed to reuse harvested seeds for sowing.
- Golden Rice may not be released in a country that lacks biosafety regulations and where official government review has not been made to ensure health and environmental safety.
- No 'stacking' in the same crop product, of the Golden Rice trait genes is allowed with proprietary trait genes not controlled by the public sector.
- Export of Golden Rice is not permitted, except to other licensees for humanitarian research and subsequent use (Export of crops is a commercial activity). The purpose of the humanitarian project is to assist resource-poor people in overcoming Vitamin A deficiency.
- With regard to improvements to the Golden Rice technology:

¹²⁸ South Africa also obtained the license, although not for use in rice.

¹²⁹ Subsequent to the execution of the licenses with the inventors, Golden Rice Humanitarian Board was established following the suggestion of the Zeneca Ltd representative, Dr Adrian Dubock. The Board is comprised of various experienced and independent experts, and provides a forum for discussion of strategic and technical issues relating to the humanitarian project.

- a) Humanitarian use of any improvements to Golden Rice is guaranteed under the same terms as the original agreement (and thus any improvements to the technology will serve the humanitarian purpose). Syngenta has acted on this by donating to the humanitarian project new improved transformation events^{130,131} including intellectual property and molecular analytical data.
 - b) Commercial rights to improvements of the technology are granted back to Syngenta.
- No warranties or indemnities are given by the licensor or licensors (as is common for licenses), and each party is responsible for that which it controls.

Key Lessons Learned:

The rapid resolution of the perceived IP constraints surrounding Golden Rice demonstrated, first of all, how an effective IP management, coupled with strong collaborations between the public and private sectors, can help achieve global access to new technologies and products for humanitarian goals. The potential IP constraints identified by Kryder and colleagues¹ did not delay the development of the product, but their clarification and resolution required only managerial and negotiation skills found in the private sector and the resulting goodwill of private sector IP owners.¹³²

More specifically, three specific lessons have been learned:

1. An intelligent IP analysis would have taken into account the intended uses and territories of use, and not caused undue alarm. Publication of the analysis by ISAAA¹ without this consideration, brought intellectual property rights into disrepute, to the disadvantage of an intellectual property system important to encourage publication of useful research, including research for the benefit of the poor.
2. Intellectual property and patents did not delay the development and introduction of Golden Rice. Notwithstanding this, the resolution of the potential IP constraints could not be ignored. Indeed, it was the need for this resolution which caused the inventors to seek collaboration with the private sector.
3. Other constraints are much more critical to the introduction of Golden Rice, in particular, and to potentially life-saving food biotechnology applications, in general. These constraints include:
 - The necessity of governments to establish a sustained and positive policy priority for the adoption of all relevant, including novel, technologies in agriculture.
 - The importance of the establishment of affordable, workable, and science-based regulatory systems designed to comply with international obligations and to address local needs and concerns.
 - The need for the capacity and funding of national agricultural rice research institutions to keep segregated different versions of genetically modified crops, including conducting field trials with them.
 - The anticipated need to develop effective seed distribution systems for reaching farmers in remote areas, including the presence of private sector entities willing to invest in seed distribution systems (However, a major aim is also to have farmers pass

¹³⁰ Paine JA, Shipton CA, Chaggar S, Howells RM, Kennedy MJ, Vernon G, Wright SY, Hinchliffe E, Adams JL, Silverstone AL, Drake R. 2005. Improving the nutritional value of *Golden Rice* through increased pro-vitamin A content. *Nature Biotechnology* 23:482-487.

¹³¹ Editorial. 2005. Reburnishing Golden Rice. *Nature Biotechnology* 23:395.

¹³² Potrykus I. 2001. Golden Rice and Beyond. *Plant Physiology* 125:1157-1161

the seed on to neighboring farmers to reach “infrastructure remote” areas often associated with VAD).

4. Recognizing that universities are not set up to develop products, Syngenta was instrumental in converting the proof-of-concept results generated at ETH Zurich and University of Freiburg¹³³ into improvements^{3,4} expected to lead to useful products through the application of commercial product development thinking¹³⁴. Although Syngenta retained commercial exclusivity for the technology, the company decided not to develop a commercial product of Golden Rice for markets in developed countries. Syngenta’s sustained support of the project with advice and scientific know-how through to the end of 2007 has proven absolutely essential for the success of the product-development partnership.¹¹

The FTO review of golden rice¹, before commercial analysis, served as a wake up call to the public sector to pay more attention to IP management as a powerful tool for meeting public sector boards. Concerns about potential IP constraints on public sector research on innovation in agricultural public sector interests in IP lead to the establishment of organizations such as Public Intellectual Property Resource for Agriculture (PIPRA)¹³⁵ and the African Agricultural Technology Foundation (AATF)¹³⁶.

While the commercial product is not yet released, it is expected that adoption of Golden Rice on a large scale in different parts of the world will begin probably in 2012 with the Philippines. It is expected to provide an excellent example of how public and private sector innovations can be put to work to help the poor through proper IP management.¹³⁷ By far the largest challenge on public goods development involving transgenic plants are the regulatory requirements and the related socioeconomic concerns; which, in the case of Golden Rice, have delayed research and product development by ten years.

CASE STUDY 3: THE STRIGA TECHNOLOGY

Striga, which is also known as witchweed, is a parasitic weed that attaches to the root of maize and other cereal crops such as millet, sorghum, upland rice and Napier grass throughout Sub-Saharan Africa. It retards the plant growth, thus resulting in stunted plants affecting the yields and in extreme cases causing death of the plant. Striga control measures have been researched in Africa for over 50 years and have focused on agronomic practices, host plant resistance and herbicide application. While many of these are effective, none of these methods has been widely adopted by farmers for several reasons:

- i) The benefits are seen only in the medium to long term since effects built slowly over seasons;
- ii) They require an understanding of Striga life cycle which farmers usually lack;
- iii) They require rotating land out of maize when population pressure and economic consideration of the farmer requires intensification of land use for food production;
- iv) While host plant resistance exists, the gains are inadequate and ineffective under high level of infestation.

¹³³ Ye X, Al-Babili S, Kloti A, Zhang J, Lucca P, Beyer P, Potrykus I. 2000. Engineering the provitamin A (beta-carotene) biosynthetic pathway into (carotenoid-free) rice endosperm. *Science* 287:303-305.

¹³⁴ Enserink, M. Tough Lessons from Golden Rice. 2008, *Science*, 320, 468-471

¹³⁵ <http://www.pipra.org>

¹³⁶ <http://www.aatf-africa.org/>

¹³⁷ Golden Rice is not the only example of this: the excellence shown by the private sector and public sectors in the development of Bt-eggplant products for India, Bangladesh, and the Philippines is another model to guide innovation.

The International Maize and Wheat Improvement Center (CIMMYT), along with BASF (the chemical company) and Weizmann Institute of science in Israel and in collaboration with the Kenya Agricultural Research Institute (KARI), has developed a unique technology, imazapyr¹³⁸-resistant (IR) maize commercialized under the product name StrigAway® for Striga control in maize. The research was funded by the Rockefeller Foundation. The technology combines low dose application of imazapyr seed coating applied to IR maize seed that leaves a field virtually clear of emerging Striga plants. The technology is affordable to resource poor farmer as a very small amount of herbicide is applied to the seed. On-farm experiments at research stations have shown a yield increase in maize productivity of up to three-fold. Commercialization of this technology in true sense is a successful public-private partnerships model.

Sixty late and 20 early maturing open pollinated varieties for mid altitude, 10 open pollinated varieties for low lands, 30 new inbreds and 12 CMS fully converted to herbicide resistance adopted to Striga infested agro ecologies in Sub-Saharan Africa have been developed and are being evaluated in Kenya, Uganda, Tanzania, Malawi, Zimbabwe, Ethiopia, Nigeria, Ghana, Benin, Senegal, Cameroon.. Local seed companies have been given the parental material to bulk up the seeds. The herbicide resistance trait has been derived from naturally occurring genes in maize originally marketed by Pioneer International and made available to CIMMYT on royalty free basis for breeding purposes. The maize germplasm was originally developed by a small laboratory in the USA and was sold to American Cyanamid, which was subsequently acquired by BASF. Together with adapted IR-maize germplasm, CIMMYT and BASF have developed the herbicide seed coating technology and have standardized appropriate dosages for various agro-climatic zones of Africa. AATF helped to launch this product by sponsoring demonstrations on farmer fields. This public private partnership is helping technology to reach resource-poor farmers. To assure proper handling of the technology, BASF further provides broad range of stewardship programs. They range from testing of StrigAway maize hybrids ensuring their tolerance to seed treatment; StrigAway seed treatment protocol, post seed treatments, quality assurance protocol, farmer seed handling stewardship protocol for storage and transportation of treated seeds, stockist seed handling stewardship protocol etc.

CASE STUDY 4: INSECT RESISTANT MAIZE FOR AFRICA (IRMA)

The IRMA Project is aimed at producing stem borer resistant and locally adapted maize for various Kenyan Agro Ecological Zone using conventional and biotechnology mediated method, namely Bt Technology.

The International Maize and Wheat Improvement Center (CIMMYT) and the University of Ottawa signed a research-only agreement in the early 1990's for the transformation of CIMMYT maize inbred lines with publicly developed Bt gene construct with components tracing back to private company developers. A similar agreement was signed between CIMMYT and the French Agricultural Research Center for International Development (CIRAD). CIMMYT Maize line 216 (CML216) was transformed and several events of Bt *Cry1Ab* and *cry1Ba* genes developed and tested in Mexico in late 1990's. This work was transferred to Kenya for further experimentation in early 2000's when IRMA Project was started. More Bt maize genetically modified with *cry1Ab* and *cry1Ba* genes were developed through trait integration by backcrossing.¹³⁹

¹³⁸ Imizapyr is a broad-spectrum acetolactate synthase (ALS)-inhibiting herbicide in the *imidazolinone* family.

¹³⁹ S Mugo, H De Groote*, D Bergvinson, M Mulaa, J Songa, and S Gichuki. 2005. Developing Bt maize for resource-poor farmers – Recent advances in the IRMA project. African Journal of Biotechnology Vol. 4 (13), pp. 1490-1504, December 2005.

An IRMA project partnership between CIMMYT and Kenyan Agricultural Research Institute (KARI) formed a bilateral agreement for further development and testing of lines developed through crossing of CML216 with local maize inbred lines. Selected lines have shown resistance to four of the five major stem borer species (*Chilo partellus*, *Chilo oricalhociliellus*, *Sesamia calamistis*, and *Eldana saccharina*) in greenhouse and confined field trials. However, the technology was not effective in controlling the African stalk borer (*Busseola fusca*).¹⁴⁰ Kenya has a Biosafety Policy but the Biosafety law passed by parliament late 2008 is still awaiting presidential assent.

While the University of Ottawa was willing to give permission for commercialization, they set a condition to do so if no private sector developer would oppose the request. A request sent out to the private sector providers is still pending. It can either be that the private sector providers are not interested in getting involved in an activity that neither helps them nor brings financial revenue. Another possibility is that since private sector have advanced and more effective events, commercialization of product based on these constructs (not wholly belonging to them) may not be suitable to their business. Following this CIMMYT and other CGIAR centers resolved in 2006 to not accept transgenic projects under “research only” agreement.

Simultaneously, CIMMYT under phase II “Delivering Product to Farmers” developed and released non-transgenic insect resistant maize using conventional breeding methods. This project is a collaborative effort among CIMMYT, KARI and Syngenta Foundation for Sustainable Agriculture (SFSA). Scientists are working on identifying conventional sources of resistance to stem borers and incorporate them into maize varieties that are well adopted to Kenya’s various agro-ecological zones and well accepted by farmers and the consumers.¹⁴¹ The group is exploring possibilities with private sector for commercialization of the Bt maize products.

Lesson Learned: Negotiations for commercialization must be undertaken during initial stages of product development.

¹⁴⁰ S. Mugo, S.T. Gichuki, D. Hoisington, C. Taracha, A. Pellegrineschi, and M. Murenga. 2008a. Development, introduction, and testing of public and private sector Bt maize events in Kenya. Pp IN: Mugo S., J. Gethi, J.O. Ouma, S. Ajanga, J. Beyene, G.M. Murenga, M. Mulaa, P. Likhayo, S. Gichuki, V. Kega, H. De Groote, and A. Chavangi. (Editors). 2008. Book of abstract of the “Consolidating Experiences from IRMA I and II: Achievements, Lessons and Prospects”, IRMA Project End-of-Phase II Conference, 28-30 Oct 2008, Nairobi, Kenya: IRMA Document No. 35: KARI and CIMMYT.

¹⁴¹ S. Mugo, J. Gethi, J. Shuma, C. Mutinda, O. Odongo, S. Ajanga and J. Songa. 2008b. Introduction, development, testing and dissemination of conventional stem borer resistant maize germplasm for mid-altitude ecologies of Kenya. Pp IN: Mugo S., J. Gethi, J.O. Ouma, S. Ajanga, J. Beyene, G.M. Murenga, M. Mulaa, P. Likhayo, S. Gichuki, V. Kega, H. De Groote, and A. Chavangi. (Editors). 2008. Book of abstract of the “Consolidating Experiences from IRMA I and II: Achievements, Lessons and Prospects”, IRMA Project End-of-Phase II Conference, 28-30 Oct 2008, Nairobi, Kenya: IRMA Document No. 35: KARI and CIMMYT.

Annex 2

Experience on product stewardship by various stakeholders

Role of African Agriculture Technology Foundation (AATF) in technology transfer

AATF is a not-for-profit organization designed to facilitate and promote public private partnership for the access and delivery of appropriate proprietary agricultural technologies for use by resource poor small holder farmers in Sub-Saharan Africa.

The Foundation provides expertise in know-how that facilitates the identification, access, development, delivery and utilization of proprietary agricultural technologies. The AATF structure and operations draw upon the best practices and resources of both public and private sector. It also contributes to capacity building in Africa by engaging Africa institutions in the execution of tasks depending on their expertise.

The model of AATF was developed through consultations with several Africa, North American and European stakeholders by the Rockefeller Foundation and the Meridian Institute. The consultations were held to determine the major principles and an operational model for an institution that would negotiate and facilitate access to proprietary technologies that hold great potential to improve the agricultural productivity of African small holder farmers. Stakeholder involvement was ensured through a design advisory committee, comprising representatives from major stakeholder groups, i.e., African National Agricultural Research Services, CGIAR centers, the UK Department for International Development (DFID), seed and biotech companies, organization for cooperation and development, donor organizations and crop science corporations. AATF is funded by the Rockefeller Foundation, USAID, DFID, the Bill & Melinda Gates Foundation and the Howard Buffet Foundation.

The specific activities undertaken by AATF include:

- i) technology licensing and managing regulatory compliance
- ii) freedom-to-operate assessment
- iii) liability protection
- iv) facilitating product development and testing
- v) facilitating product deployment
- vi) facilitating commercialization
- vii) ensuring product stewardship
- viii) partnership management
- ix) facilitating communication and public awareness

The projects under implementation are:

- Striga control in small holder maize fields in Sub-Saharan Africa
- Developing high quality insect resistant cowpea varieties for use by small-holder farmers Sub-Saharan Africa
- Improvement of Banana for resistance to banana bacterial wilt diseases in Africa
- Development of drought tolerant maize varieties

The procedures set up by this institute are of very high standards and perhaps should be propagated further in other developing countries, including those in Asia. The CGIAR could play a role in this by ensuring that technologies developed by CGIAR institutions are managed

through organizations similar to AATF. However, there should be an organization with a global mandate as most crops are grown globally and can be equally important to different continents.

In discussions with professionals at AATF, it became clear that the organization functions as an honest-broker for access and delivery of proprietary technologies. Through their careful evaluation of the technology and judging its suitability to an already identified problem in a neutral way, they ensure that the interests of all parties involved: small farmers, technology developers and donors are adequately taken care of. The technology is then commercialized through the most sustainable system which depending on the circumstances could involve the use of local seed companies. Under these arrangements the parties ensure that liability rests with the partner(s), best placed and able to address a particular potential risk. The allocation of risk is achieved through carefully drafted agreements. AATF also implements product stewardship mechanisms including the conduct of risk analyses to aid in formulating and implementing risk mitigation plans.

Role of Private Sector in Seed Commercialization in India

In a number of developing countries such as India, the seed sector has developed and contributed to the overall growth of Agriculture.

“INDIA : AN EXAMPLE OF SUCCESS”¹⁴²

Only four decades ago, India and famine were synonymous, but the situation today is very different. In 1963, the government established the National Seed Corporation (NSC) and, in 1969, the State Farm Corporation of India. These national operations are complemented by 13 State Seed Corporations (SSCs) that support the production and handling of seeds at the state level.

By the late 1980's the government recognized that the country's seed policies needed to change to favor the growth of the private over the public sector. Beginning in the early 1990s, small-sized private seed firms began bulking up publicly bred varieties and distributing this seed through their own network of private dealers. By 2005 there were over 150 private seed companies operating in India. These include both multi-nationals, several medium-sized firms and a large number of small companies.

The NSC and SSCs now mainly focus on the production of higher volume and lower value seeds such as higher-yielding open-pollinated varieties of cereals, pulses and cotton, while the private-sector concentrates on hybrids. However, joint ventures and partnerships have proliferated between public and private agencies as well as between national and international companies.

Currently the private sector accounts for 70 percent of the seed market in terms of market turnover whereas the public sector has the greater share in terms of volume sales. While the public sector continues to dominate the production and distribution of food crop seeds such as rice and wheat, the private seed companies enjoy a significant share of commercial crops such as cotton, maize, sunflower and vegetables.

Many in Africa have observed this success in India. Structural adjustment and market liberalization policies have led to the privatization of public seed companies. Multi-nationals have entered the market and small-sized private seed firms are establishing, but there are few joint ventures or partnerships between public and private agencies, or between national and international companies. While there has been an increase in the production and marketing of hybrid maize by the private sector, the availability of open pollinated crops has largely been ignored.

¹⁴² Harvesting Ambition – published by Eastern and Southern Africa Seed Alliance (esasa@cgiar.org)

Agricultural production in Africa is largely rain-fed, and farmers strive to achieve food and nutritional security by growing a number of different crops to mitigate production risks. Market opportunities also exist for crops that do not directly compete with the industrialized products offered by low-cost producers in the developed world. Africa can benefit from India's experiences. There is no reason why the African seed sector should not achieve a similar level of success".

Eastern and Southern African Seed Alliance (ESASA)

ESASA is a partnership of research centers, non-profit organizations, investors and corporations with expertise in agriculture development in Africa. It has been championed by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), CNFA Inc., the African Seed Trade Association (AFSTA), and Seed Science Center of Iowa State University (SSC-ISU), and more partners are expected to join the initiative. ESASA's mission is to reduce poverty and instability in the region through the development of strong, sustainable seed industry.

Seeds are the heart of agriculture and its quality improvement will have cascading positive effect for achieving food and nutritional security; employment generation etc., thus providing social and economic stability to the region. Successful examples from any part of the globe, through minor modifications must be adopted. Seed industry must develop further and seed replacement rates improved. Instead of bringing in solutions from outside, local institutions should be established that relies on the local ingenuity of regions' own entrepreneurs. This empowerment will bring about the ultimate change in societies that is sustainable. CGIAR should further encourage such initiatives.

Annex 3

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CGIAR

Independent Science & Partnership Council
c/o FAO
Viale delle Terme di Caracalla snc
00153 Rome, Italy

Tel : 39 06 57056782
Fax : +39 06 57053298
E-mail : sc-secretariat@fao.org