Generation Challenge Programme

CULTIVATING PLANT DIVERSITY FOR THE RESOURCE POOR

Genetic Resource Policies and the Generation Challenge Programme

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Generation Challenge Programme: An Introduction

Farmers in the developing world face challenges such as drought, pest and disease infestations, and low soil fertility that threaten each season's harvest. Poor farmers' lack of resources keeps much-needed irrigation, pesticides, and fertilizers beyond their reach. These production constraints often represent the difference between healthy and hungry families.

The Generation Challenge Programme (GCP) aims to bridge that gap by using advances in molecular biology to harness the rich global heritage of plant genetic resources and create a new generation of crops that meet the needs of resource-poor farmers. The urban poor also benefit from improved varieties through lower food costs.

The emerging Genomics Revolution has the potential to bring new science to bear on problems encountered by resource-poor farmers bypassed by earlier waves of innovation. Plants specifically designed to overcome the difficult conditions found in smallholders' fields and marginal environments can improve the quality and quantity of these farmers' yields and particularly contribute to yield stability, a key element for sustainable livelihood in rural areas. The fast-moving fields of comparative genomics, molecular breeding, and bioinformatics are increasingly important steps on the path to achieving this worthy goal.

The Generation Challenge Programme brings centres of the Consultative Group on International Agricultural Research (CGIAR) together with advanced research institutes (ARIs) in industrialised and developing countries and National Agricultural Research Systems (NARS) in developing countries to deliver the fruits of the Genomics Revolution to resource-poor farmers. The GCP has five subprogrammes that span the spectrum of research in germplasm, genomics, bioinformatics, and molecular breeding for agricultural development:
Subprogramme 1: Genetic Diversity of Global Genetic Resources
Subprogramme 2: Comparative Genomics for Gene Discovery
Subprogramme 3: Trait Capture for Crop Improvement
Subprogramme 4: Genetic Resources, Genomic, and Crop Information Systems
Subprogramme 5: Capacity Building and Enabling Delivery.

The Importance of Policies and Legislation

Ensuring that the Generation Challenge Programme's products make it from the lab to resource-poor farmers is critical. Therefore, a cornerstone of the Programme is that its outputs can be released to target groups without legal constraints, enabling scientists in developing countries to readily use elite genetic stocks and new marker technologies in their breeding programmes. To extend and enhance our impact, the GCP is creating an "integrated platform" of molecular biology and bioinformatics tools that will be freely available to researchers and breeders the world over. By training NARS to use the most advanced crop research technologies available, we empower developing countries to tackle agricultural challenges—as well as poverty and hunger—within their borders.

The GCP's need to develop products for the poor carries the challenge that all the building blocks of the research may fall within the scope of international and national regulations that create sovereign rights or ownership over genetic resources, products, and processes. The Convention on Biological Diversity assigns national sovereignty over biodiversity. Signatories to the Convention can create access to their resources subject to conditions. The International Treaty on

Plant Genetic Resources for Food and Agriculture creates a facilitated access regime through its multilateral system for most (but not all) crops relevant to the GCP. The Agreement on Trade Related Aspects of Intellectual Property Rights of the World Trade Organisation increased the spread of private rights (IPRs) over products and processes used in genomic research. The high priority that is given to these different international agreements and the ongoing search for implementation and enforcement mechanisms both at the international and national levels create a policy/legal environment for the GCP that is of increasing importance and is continually changing.

This was the reason for the Steering Committee of the GCP in its first meeting in September 2003 to reserve a small portion of its funds for policy issues. The research cluster "Policy Research" in Subprogramme 1 dealt with the key policy issues for the GCP: access & benefit sharing (ABS) and intellectual property rights (IPR). It dealt with these issues both as a "service" and as a "researchable issue". These are issues that are derived from international policies and agreements that are relevant to this Challenge Programme and to the CGIAR (and other development-oriented stakeholders) that require the development of institutional policies and procedures. The word "policies" thus has a dual meaning.

In addition to assisting with the formation of the Consortium Agreement, the cluster "Policy Research" produced a number of "policy briefs" during its first year. The following issues were considered vital to a better understanding of the context in which the GCP operates:

1. Overview of the policy environment
2. Humanitarian licenses and definition of "resource poor"
3. Liability and stewardship
4. Other IP-mechanisms
5. Benefit sharing
6. Access legislation
7. Impact of IPR on the breeding sector.

Consortium members assigned their experts in this field to prepare papers introducing relevant issues to non-specialists. The papers were primarily prepared for the GCP and its members. We hope, however, that the publication of the papers in this volume will contribute to a wider use and to the ongoing discussions in the extensive field of genetic resource policies.

The Policy Environment of the GCP Regarding Rights on Biological Materials, Technologies, and Knowledge: An Overview

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1. INTRODUCTION

1.1 The Generation Challenge Programme

The rich pool of genetic resources that exist in collections held by national agricultural research systems (NARS) and the Future Harvest Centres of the Consultative Group on International Agricultural Research (CGIAR) have not yet been tapped with the use of the modern tools of plant molecular biology in a systematic way.

It is the purpose of the Generation Challenge Programme to build a strong alliance of institutions to apply the powerful tools of genomics to unlock the genetic potential within that crop germplasm with the aim to address the needs of the resource poor. The products will be made available as public goods and will enable technologies and intermediate plant material for crop improvement in NARS and elsewhere.

The main source of genetic resources for the GCP will therefore come from collections formed mostly during a period of 30-35 years prior to entering into the Convention on Biological Diversity in 1992-3.

However, some complementary diversity of the crops under research by the GCP alliance are conserved in germplasm banks maintained by different countries and will need to be accessed according to the rules of many international treaties and conventions under discussion or already approved by member countries. These treaties and conventions deal with aspects of genetic resources, benefit sharing and technology transfer, and the application of intellectual property rights over inventions and products of breeding programmes.

For the development of project proposals, the GCP is giving priority to research solutions for abiotic stresses, mainly drought, working initially with barley, common beans, peanuts, wheat, chickpea, maize, cowpea, sorghum, cassava, rice, potato, millet, and *Musa* (see the Programme brochure available at **www.generationcp.org**). This definition is important for the scope of this paper because it indicates that all the GCP focus crops, with the exception of peanuts, will eventually be treated as part of the facilitated mechanism of the exchange of germplasm covered by the Multilateral System to be created under the FAO International Treaty for Plant Genetic Resources for Food and Agriculture (see Annex IV).

1.2 Genetic Resources in CGIAR Gene Banks and in National Gene Banks

The CGIAR was established in 1971 and seeks to contribute to food security and poverty eradication in developing countries. Currently, there are 15 Future Harvest Centres (IARCs), autonomous institutions that form the "CGIAR system". In 1992, the CGIAR adopted the "CGIAR Working Document on Genetic Resources and Intellectual Property," which stated, *inter alia*, the following:

- Material from the gene banks at the centres will continue to be freely available in accordance with the 1989 CGIAR Policy on Plant Genetic Resources;
- Centres do not seek intellectual property protection unless it is absolutely necessary to ensure access by developing countries to new technologies and products;
- Many IPRs acquired by a Centre are exercised without compromising in any manner whatsoever the fundamental position of the CGIAR regarding the free access by developing countries to knowledge, technology, materials, and plant genetic resources.

In 1994, the IARCs signed agreements with the FAO that placed most of their collections in the International Network of *Ex-situ* Germplasm Collections. These agreements state that the Centre holds the germplasm in trust for the benefit of the international community,[1] and bind the IARCs not to "claim ownership, or seek intellectual property rights over the designated germplasm and related information".[2] The one exception is when the germplasm is repatriated to the country that provided it.[3] A matter of discussion has always been whether CGIAR scientists should think about IPR protection for technologies and materials developed at Centres. The issue of IPRs over germplasm held by the CGIAR system has been controversial and has not been completely resolved yet. (Sampath & Tarasofsky, 2002)

Experience has shown that the actual compliance with the contractual conditions (including those relating to IPRs) has been one of the key concerns relating to the CGIAR collections. The Governing Body of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture is mandated to amend the MTAs currently in place between the IARCs and the FAO for plant genetic resources not listed in Annex I of the Treaty, and that were collected prior to the Treaty's entry into force, *inter alia*, to improve compliance.[4] Therefore any future arrangements for benefit sharing decided by the Steering Committee of the Generation Challenge Programme should take this and other previous experiences into serious consideration.

As indicated, the Steering Committee also needs to be well-acquainted with ongoing progress in the implementation of related clauses in the main international treaties and conventions that influence obligatory changes in national regulations of signatory countries directly involved in the development of the Generation Challenge Programme or that are simply sources of genetic resources. A simplified summary of those is given bellow to highlight possible implications to the Programme.

2. INTERNATIONAL AGREEMENTS AND ORGANISATIONS

2.1 Convention on Biological Diversity (CBD) – 1992

The Convention on Biological Diversity seeks to create a holistic legal regime for the genetic species and ecosystem levels of biodiversity with the following objectives:
"… the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding".[5]

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1 Article 3(a).
2 Article 3(b).
3 Article 10.
4 Article 15(iv).
5 Article 1.

Achieving these objectives has several implications for the use and the conservation of genetic resources. Amongst the most relevant provisions is the general regime on access to genetic resources and benefit sharing.[6] In this regime, a framework for bilateral negotiations between provider and user countries is set forth. The elements include:

- An affirmation of the sovereign rights of States over their genetic resources;
- The obligation to endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Parties;
- Where a Party agrees to allow access to its genetic resources, this access shall be on mutually agreed terms and subject to its prior informed consent (PIC).

There is a provision of the Convention that relates directly to intellectual property rights as stated in Article 16, with the title "Access to and transfer of technology". Article 16 (5) states:

> The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall co-operate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

According to Sampath, P.G. and Tarasofsky, R., the provision itself appears to apply more generally than only to technology. While it suggests that intellectual property rights will not be created by the CBD itself, the provision does appear to emphasise the need for positive action in developing synergies between IPRs and the objectives of the CBD. Another key CBD provision concerns Article 8(j), which relates to traditional knowledge. This provision calls for Parties to:

> Subject to 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 utilisation of such knowledge, innovations and practices.

CBD Article 11 calls for Parties to adopt economically and socially sound measures that act as incentives for conservation and sustainable use of genetic resources.

Some key decisions made by the CBD Conference of the Parties (COP) relating to IPRs and Access and Benefit Sharing (ABS) include:

1. Decision III/17 on Intellectual Property Rights called for case studies to be developed on the impacts of IPRs on achieving the CBD objectives, including the relationship between IPRs and traditional knowledge relevant for the conservation and sustainable use of biological diversity. In particular, these case studies are to consider the development of intellectual property rights, including *sui generis* systems or alternative forms of protection, consistent with international law, that could promote the achievement of the Convention's objectives. Furthermore, the Decision called for further work to develop a common appreciation of the relationship between IPRs, the TRIPS Agreement, and the CBD. This last point was reiterated in COP Decision IV/15.[7]
2. At CBD COP-6, Decision VI/24 on Access and Benefit Sharing as Related to Genetic Resources was adopted. This followed deliberations by an Expert Panel and an Ad Hoc Working Group on the topic. Decision VI/24 includes the Bonn Guidelines on Access to

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6 Article 15.

7 Decision IV/15, UNEP/CBD/COP/4, para. 10.

Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation and a section on the Role of intellectual property rights in the implementation of access and benefit-sharing arrangements.

The Bonn Guidelines include several references to IPRs. According to Paragraph 16(d), Parties should consider taking "measures to encourage the disclosure of the country of origin of the genetic resources and of the origin of traditional knowledge, innovations and practices of indigenous and local communities in applications for intellectual property rights". Paragraph 43(c) stipulates several parameters to form the basis of the contractual arrangements between providers and users. These include: "Provision for the use of intellectual property rights include joint research, obligation to implement rights on inventions obtained, to provide licences by common consent" and the "possibility of joint ownership of intellectual property rights, according to the degree of contribution".

In addition, national monitoring can include applications for IPRs relating to the material sought.[8] The section on the role of intellectual property rights calls for Parties and Governments to encourage the disclosure of the country of origin of genetic resources in applications for intellectual property rights in order to help track compliance with requirements relating to prior informed consent and the mutually agreed terms. It further calls for relevant traditional knowledge to also be disclosed during IPR applications.

2.2 WTO Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS)

The WTO TRIPS Agreement is a global agreement that establishes minimum requirements for IPRs. It is powerful not only because of its substance, but because disputes under it are resolved by the effective WTO dispute settlement body. There have already been some WTO disputes involving the TRIPS Agreement,[9] but so far none of them has related directly to the conservation of biodiversity or genetic resources.

Article 7 lays out the objectives of the Agreement, which are to:
…contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Although this provision does not create any specific rights or obligations, it can be a useful aid to the interpretation and application of the Agreement. Article 8(1) lays out certain priority public interests, including those determined to be priorities at the national level, but clarifies that the TRIPS Agreement is not to be violated by legislating in these areas.[10]

The Agreement establishes several forms of IPRs, including copyright,[11] trademarks,[12] geographic indications,[13] trade secrets,[14] and patents.[15] Of these, patenting is likely to be the

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8 Decision VI/24, UNEP/CBD/COP/6, para. 55(c).

9 E.g. WT/DS50 – India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, 31, WT/DS114 – Canada - Patent Protection of Pharmaceutical Products, etc. A number of consultations pending at time of writing relate to the TRIPS Agreement – e.g. 12. WT/DS233 – Argentina – Measures Affecting the Import of Pharmaceutical Products – although these too do not concern the conservation of genetic resources.

10 "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement".

11 TRIPS, sec. 1.

most relevant to the conservation of genetic resources, although some of the other forms of protecting industrial property, such as trademarks, geographic indications, and trade secrets could also be relevant. These rights are to be enforced by civil penalties and, in some cases, by criminal penalties.

Patents

Patents are exclusive rights granted to inventors that prevent others from making, using, selling, or importing the patented invention for a term of at least 20 years. The criteria for granting patents are novelty, inventiveness, and industrial applicability.

Article 27 establishes what can be patented and the scope for exceptions:

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application.…patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect public order or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
    a. (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

This provision contains several elements. The first is the presumption that patents are to be available for any invention meeting the substantive conditions. Secondly, patent rights are to be enjoyed without discrimination. Thirdly, a general exception to this presumption is provided for inventions whose commercial exploitation would violate *ordre public*, public morality or would seriously prejudice the environment. A key term in that paragraph is “necessary”; GATT/WTO jurisprudence suggests that this may set a high threshold.[16] Fourthly, a set of specific exceptions from patentability is provided: plants, animals, and essentially biological processes. Plant varieties may be protected by patents or “effective” *sui generis* systems. No definition of “effective” is provided, and some commentators have suggested that to meet this threshold, the minimum principles of the TRIPS Agreement must be respected.[17] Finally, the provision stipulates that the WTO was to review Article 27.3(b) in 1999. Many WTO member countries

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12 TRIPS, sec. 2.

13 TRIPS, sec. 3.

14 TRIPS, Article 39.

15 TRIPS, sec. 5.

16 See, e.g. BISD 39S/155 – United States – Restrictions on Imports of Tuna (circulated on 3 September 1991), which applied the "least trade restrictive" test. More recently, the decision WT/DS135 –European Communities-Measures Affecting Asbestos-Containing Products, applied a modified test, based on balancing several criteria. Although these interpretations are instructive, caution is, however, called for, since this term may be interpreted differently in the TRIPS Agreement than in GATT Article XX.

17 E.g., Leskien, D. and Flitner, M., *Intellectual Property Rights and Plant Genetic Resources*, Issues in Genetic Resources No. 6, International Plant Genetic Resources Institute, Rome.

have used the 27.3.b exemption and have developed national laws on Plant Breeder's Rights, many of them in conformity with one of the Conventions of the Union for the Protection of New Varieties of Plants, UPOV.

In addition to Article 27.3(b), the TRIPS Agreement contains two general provisions that may limit patent rights. One is specified in Article 30, which allows the Member to provide limited exceptions to the exclusive rights conferred by patents "provided that such exceptions to do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties". Secondly, Article 31 allows Members to issue "compulsory licenses", whereby use is made of the subject matter of the patent without the authorisation of the rights holder. Several conditions are placed on the use of this instrument, including:

- Such an authorisation should be based on a consideration of individual merits;
- The proposed user will have made efforts over a reasonable period of time to secure a voluntary license on reasonable commercial terms, except in cases of national emergency, extreme urgency or public non-commercial use;
- The right holder will be paid adequate remuneration;
- The legal validity of the license and the remuneration will be subject to judicial or other forms of independent review.

Even though such licenses have recently been granted in the field of pharmaceuticals in developing countries, there is little practice in implementing these limitations for purposes relating to the conservation of genetic resources. It should be emphasised, however, that in conformity with general rules of international law, such limitations and exceptions are to be interpreted narrowly so as not to interfere with the object and purpose of the treaty.

Geographic indications

A further intellectual property right that might eventually be attractive to holders of traditional knowledge are Geographic Indications (GIs). GIs are those which identify a good as originating from a Member, a region, or a locality in the territory of a Member, where a "given quality, reputation, or other characteristic of the good is essentially attributable to its geographic origin".[18] In other words, they do not focus on individual inventions, but rather reward a community adhering to traditional practices. These are considered attractive because the rights are held in perpetuity and the holders of the GI cannot assign the right to non-local producers.[19] However, a major drawback is that the knowledge itself is not protected, and therefore GIs cannot prevent misappropriation. These are currently limited to select products – mainly beverages and foodstuffs – although there is now a debate going on in the WTO about extending the coverage. So far, the positions are wide apart.

Some attention is now being paid to the potential to link the mechanisms for establishing geographic indications, especially appellations of origin, with criteria aimed at enhancing conservation. This is an area where further empirical research is necessary so as to develop proposals on enhancing the potential synergies.

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[18] TRIPS, Article 22.1.

[19] Rangnekar, D. *Geographic Indications: A Review of Proposals at the TRIPS Council (draft),* 2002, at p. 15.

Trademarks

Trademarks are marketing tools, whereby a registered sign is attached to a product, which confirms that the product is authentic or distinctive. Local and indigenous communities that choose to register could potentially use trademarks, but they do not create intellectual property rights in the products themselves. Their attractiveness is based mainly on the ability of the trademark to increase market share. Their lifespan can also be extended indefinitely. Several cases exist of traditional artists establishing trademarks, but none exist yet for products derived from genetic resources. However, this could provide some level of protection when variety protection is not yet available for a particular crop.

Trade secrets

More interesting for indigenous and local communities is the protection provided by the TRIPS Agreement for trade secrets. Article 39.2 provides that this protection applies to information that is secret, has commercial value because it is secret, and has been subjected to reasonable steps to keep it secret. Beyond this, there are no substantive standards that trade secrets are required to meet. Trade secrets also have the advantage of having no time limit – i.e., they do not contain any "novelty" requirements. However, the protection is only for the knowledge held by that entity; it does not extend to others who make the same discovery through independent means, such as reverse engineering.

Further developments in the WTO

The relationship between the TRIPS Agreement and the CBD has also been debated in various WTO fora. The Committee on Trade and Environment has this as a standing item on its agenda, although no resolution has been reached.[20] More meaningful developments have taken place in the context described below:

- Review of Article 27.3(b): This review has begun but, so far, has not produced any specific outcome. The general dynamic has emerged whereby developed countries seek to ensure strong protection of intellectual property, while developing countries seek to broaden the flexibility of the standards.

Other relevant debates in the TRIPS Council

The relationship between the TRIPS Agreement and the CBD has been debated extensively in the TRIPS Council.[21] In this context, several interventions have been made regarding the patentability of genetic materials. Some developing country Members have argued against granting patents over genetic material, out of concern that it might limit access and benefit sharing as called for under the CBD.[22] Others have argued that if the criteria for patentability are rigorously applied, there should be no conflicts with the CBD.[23]

Another issue that has been debated is the introduction of a requirement that patent applications be accompanied by disclosures regarding source of origin, any related traditional knowledge, evidence of PIC of the country of origin, and evidence of fair and equitable benefit sharing. Several developing country Members have sought to introduce this requirement. Some developed

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[20] See, e.g. Report of the CTE to the WTO Ministerial Conference, 1996, para. 206-209.

[21] See WTO, IP/C/W/368. *The Relationship between the TRIPS Agreement and the Convention on Biological Diversity* – Summary of Issues Raised and Points Made, Note by Secretariat, 8 August 2002.

[22] See WTO, IP/C/W/163. Submission by Kenya.

[23] See WTO, IP/C/M/30. Submission by Switzerland.

country Members have argued that if these requirements are conditions for patentability, they violate the TRIPS Agreement in that Article 29 sets forth rules on disclosure, Article 62.1 allows for only "reasonable" procedures, and Article 27.1 provides for non-discrimination in patent availability.[24] Other Members have sought to achieve this requirement by amending the TRIPS Agreement,[25] although not all countries have agreed that these proposals would violate the TRIPS Agreement. Beneath this legal argument lies a deeper policy conflict over whether patent officials should be tasked with this level of examination and whether contractual arrangements are to be preferred to a system of institutionalised PIC.

- Doha Development Agenda: Paragraph 19 of the Doha Ministerial Declaration states: We instruct the Council for TRIPS, in pursuing its work Programme including under the review of Article 27.3(b), … to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and … In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

- "Implementation" Agenda: One of the key themes that dominated the discussions leading up to the Doha Ministerial and subsequently are the set of issues known as "implementation" concerns. These are issues put forward by developing countries to rebalance existing agreements or to address implementation problems with these agreements. These are referred to in Paragraph 12 of the Doha Declaration and are part of the ongoing negotiation process, although the precise negotiation modalities are not yet clear.[26] The Compilation of Outstanding Implementation Issues is not yet a finalised text,[27] and has not formally been adopted. Nonetheless, the Compilation is a useful indicator of developing country positions, and it can be expected that many of these will be put forth in the current WTO negotiations.

Two "Tirets" and one proposal are directly relevant to IPRs and genetic resources. Tiret 88 stipulates that a "clear understanding in the interim that patents inconsistent with Article 15 of the CBD shall not be granted". This suggests that a mechanism to ensure consistency should be established until the completion of the formal reviews of the TRIPS Agreement and other relevant negotiations. In addition, two alternative formulations have been made to amend TRIPS Article 27.3(b) so that it is consistent with the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.[28] Finally, there is a proposal of least-developed countries to

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[24] See WTO, IP/C/M/29. Submission by Japan.

[25] See WTO, IP/C/W/228, IP/C/M/32 and IP/C/M/33.Submission by Brazil; and WTO, IP/C/W/356. Submission by Brazil, China, Cuba, et al.

[26] Vivas Eugui, D.. *Issues Linked to the Convention on Biological Diversity in the WTO Negotiations: Implementing Doha mandates*, CIEL, 2002, available on http://www.ciel.org/Publications/Doha_CBD-10oct02.pdf**.**

[27] See WTO, JOB(01)/152/Rev.1, 27 October 2001.

[28] "...Article 27.3(b) to be amended in light of the provisions of the Convention on Biological Diversity and the FAO Treaty on Plant Genetic Resources for Food and Agriculture. Also, clarify artificial distinctions between biological and microbiological organisms and process; ensure the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest; and prevent anti-competitive practices which will threaten food sovereignty of people in developing countries, as permitted by Article 31 of the TRIPS Agreement".

"...Article 27.3(b) should be amended to take into account the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources. The amendments should clarify and satisfactorily resolve the analytical distinctions between biological and microbiological organisms and processed; that all living organisms and their parts cannot be patented; and those natural processes that produce living organisms should not be patentable. The amendments should ensure the protection of innovations of indigenous and local farming communities; the

establish a review process that clarifies that "all living organisms, including plants, animals and parts of plants and animals, including gene sequences, and biological and other natural processes for the production of plants, animals and their parts, shall not be granted patents".

"TRIPS-Plus" Implementation: Some bilateral trade and investment agreements outside the jurisdiction of WTO and the TRIPs Agreement contain so-called "TRIPS – plus" obligations. These are obligations that go beyond the minimum standards set out in the TRIPS Agreement, including the tightening of the exception provisions in Article 27, and more in particular the patenting of plant varieties.

2.3 UPOV

The International Convention for the Protection of New Varieties of Plants (UPOV Convention) establishes UPOV,[29] which creates a harmonised system for plant breeder's rights (PBRs), is one possible *sui generis* system that would appear to meet the requirements of Article 27.3(b) of the TRIPS Agreement.

The UPOV Convention was developed in 1961, but has been revised several times, most recently in 1978 and 1991. It provides for PBRs over new varieties of plants. Since 1998, when UPOV 1991 entered into force, new parties to the Convention must adhere to the 1991 version, rather than that of 1978.

There are significant differences between UPOV 1978 and UPOV 1991. UPOV 1991 generally creates a higher standard of protection for PBRs. One difference is that under the 1978 Act, a breeder is entitled to protection through being the "discoverer" of the new plant variety, whereas under the 1991 Act, mere discovery is not sufficient. Nonetheless, the criteria for "novelty" appear to emphasise commercial considerations,[30] rather than testing for inventiveness.

Another important development is the rule on "essential derivation" in the 1991 Act. Under the 1978 Act any protected variety could be freely used as a source of initial variation to develop further varieties, so that such further varieties can be protected by the subsequent breeder without any obligation towards the breeder of the initial variety. Under Article 14(5) the 1991 Act, the essentially derived variety, which meets the normal protection criteria, may be the subject of protection, but it cannot be exploited without the authorisation of the breeder of the original variety. Some authors have expressed the concern that the determination of whether the new varieties are essentially derived from an earlier one is likely to be done through agreement between the breeders or litigation, rather than by the examination process. If this is the case, the relative bargaining strength of the breeders may become a factor that is to the disadvantage of developing countries.[31]

Under UPOV 1978, it was possible for farmers to practice the custom of saving and exchanging part of their harvest so as to have seed to plant for the following season, the so-called "farmers

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continuation of traditional farming processes including the right to use, exchange and save seeds, and promote food security".

[29] Union Internationale pour la Protection des Obtentions Végétales or the International Union for the Protection of New Varieties of Plants.

[30] The test for novelty in Article 6(1) is that the "propagating or harvested material of the variety has not been sold or otherwise disposed of to others …"

[31] Dhar, B. and Chaturvedy, S. *Introducing Plant Breeder's Rights in India:A Critical Evaluation of the Proposed Legislation*, Journal of World Intellectual Property, 1(2), 1998; cited in Dutfield, G. , Intellectual Property Rights, Trade and Biodiversity,(1999), at p. 28.

privilege". This is not expressly provided for under UPOV 1978, but its wording did not prohibit it,[32] and this was the practice in many Member countries to the extent that significant "brown bagged" seed could be traded. Under the 1991 Act, governments are expressly provided the discretion to decide whether or not to restrict a breeder's right "in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting...the protected variety".[33] Indeed, some governments have decided to use this provision to enshrine the "farmer's privilege" for all or for a limited number of crops and for all or for certain categories of farmers.[34]

The 1991 Act also provides for exceptions for (a) acts done privately and for non-commercial purposes, (b) acts done for experimental purposes and (c) acts done for the purpose of breeding other varieties, subject to specific conditions. Furthermore, it allows for the restriction of PBRs in the public interest.[35]

Finally, under UPOV 1978, any varieties eligible for PBRs protection could not be patented, whereas UPOV 1991 is silent on this question. As such, the possibility for double protection for plant varieties exists.

2.4 World Intellectual Property Organisation (WIPO)

Under its Programme relating to new intellectual property issues, WIPO has begun looking in depth at the intellectual property aspects of access to genetic resources. As a result of controversies arising from proposals by some developing countries during the negotiations of the WIPO Patent Law Treaty to require certificates of origin for patent applications involving genetic resources, it was agreed to establish a process under WIPO for considering these issues in greater depth. This led to the creation of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore, whose first session was held in 2001.

The Intergovernmental Committee has proven to be a venue for debating key issues, enabling information gathering, and commissioning further analytical work. So far, it has been unable to forge consensus, although it is still at an early stage of its work. Its mandate contains the following elements:

a) With respect to genetic resources:

- Considering the development of "best contractual practices", guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing, taking into account the specific nature and needs of different stakeholders, different genetic resources, and different transfers within different sectors of genetic resources policy;

b) *With respect to traditional knowledge*:

- Determining the scope of "traditional knowledge" in order to discuss the type of protection that can be awarded by intellectual property rights.

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32 UPOV, Article 5(1) sets out what the breeder's authorisation is required for.

33 UPOV, Article 15(2).

34 E.g. See EC Regulation 2100/94, *EU Biotechnology Inventions Directive*, Article 11, on community plant variety rights, which applies to main food crops. Under these rules, small farmers are not required to pay any remuneration to the right holders, whereas other farmers must pay an "equitable" amount; see also Australia's Plant Breeder's Rights Act of 1994, allows famers to save the seeds from a protected variety for next year's crop without paying a royalty to the breeder and UNEP/CBD/COP/3/Inf.20. *Biological Diversity and Intellectual Property Rights: Issues and Considerations*.

35 UPOV, Article 17(1).

- Compiling, comparing, and assessing information on the availability and scope of intellectual property protection for traditional knowledge.
- Considering the revision of existing criteria and developing new criteria, which would allow the effective integration of traditional knowledge documentation into searchable prior art.
- Considering ways of assisting traditional knowledge holders in relation to the enforcement of intellectual property rights, in particular by assisting them to strengthen their capacity to enforce their rights.

Currently, negotiations are also ongoing in WIPO to develop the Substantive Patent Law Treaty (SPLT). Whereas the TRIPS Agreement establishes the minimum required elements of national laws on intellectual property rights, the SPLT will spell out the full substance of these rights in an effort to harmonise them. In its present form, the draft treaty does not allow parties to make any further demands on patent applicants other than those found in the treaty.[36] This would preclude countries from requiring the disclosure of country of origin of genetic materials and proof of prior informed consent in their acquisition as part of the patent process, as these are not included in the current criteria.

A recent meeting of the Intergovernmental Committee (Seventh session) took place in Geneva in November 2004. Regarding the matter of access to genetic resources, the working group that discussed the document on rules for access and benefit sharing prepared by the Secretariat (WIPO/GRTKF/IC/7/9) did not reach a consensus and decided to review the subject at the next session. The discussions interposed by regional groups and by developing countries on the acceptance of an International Regime by Governments, with binding characteristics, for the treatment of access and benefit sharing under the CBD, have taken most of the heat in plenary declarations. It will probably take another long-term battle to find the equilibrium of forces.

2.5 FAO International Treaty on Plant Genetic Resources for Food and Agriculture

After years of negotiation, the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted on 3 November 2001 and entered into force in June 2004. The treaty aims at the conservation and sustainable use of plant genetic resources for food and agriculture, the fair and equitable sharing of benefits arising out of their use, and sustainable agriculture and food security.[37] At the heart of the Treaty is a Multilateral System (MLS) that seeks to facilitate access to a negotiated list of plant genetic resources, annexed to the treaty as "Annex I", as well as the fair and equitable sharing of benefits arising from their use. Genetic resources listed on the MLS are to be circulated "freely". Developing countries are encouraged to place germplasm in the MLS in exchange for benefit sharing in areas of information exchange, technology transfer, and capacity building. *Ex situ* collections that existed prior to the CBD, which are excluded from the application of the CBD,[38] may now be dealt with under this treaty. This will be of great help for the implementation of the Generation Challenge Programme, as most of the crops chosen for the initial phase are listed in Annex I of the IT.

Article 9 of the treaty addresses the contentious issue of "farmers' rights". It places the responsibility for realising these rights on national governments. Article 9 (2) states:

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[36] GRAIN "WIPO moves toward "world" Patent System", available on http://www.grain.org/publications/wipo-patent-2002-en.cfm, 2002.

[37] Article 1.1.

[38] CBD, Article 15(3).

In accordance with their needs and priorities, each Contracting Party should, as appropriate and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:

a. protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
b. the right to equitably participate in sharing of benefits arising from the utilisation of plant genetic resources for food and agriculture; and
c. the right to participate at making decisions, at the national level on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

Article 12.3 (d) stipulates that access to genetic resources from the MLS be provided on the condition that intellectual property or other rights that limit facilitated access to the genetic resources, or their genetic parts or components, "*in the form received from the MLS"* are not to be claimed. As such, it would appear that such genetic material received from the MLS can be claimed for IPRs that have been modified in some way from the form they were received from the MLS.[39] However, a recipient who commercialises a plant genetic resource for food and agriculture that incorporates material from the MLS must pay to a financial mechanism an equitable share of the benefits arising from commercialisation.[40] If the product is such that there is no restriction on the availability to others for research or breeding, such as those protected under the UPOV system (1978), then the recipient is encouraged – but not required – to pay benefits for an initial period of five years, unless the Governing Body comes to another decision by consensus.

The relationship between the TRIPS Agreement and the IT has not yet been discussed in detail due to its recent adoption and the lack of "policy making" meetings that should have been proposed during 2003. The adoption of the IT is an important and relevant new development regarding issues related to the patentability of living material. It raises several issues that run in parallel to those raised under TRIPS/CBD.

Its provisions regarding IPRs on plant genetic resources covered by a multilateral system call for mutually supportive interpretation of the IT with the TRIPS Agreement and the CBD. As the objectives of the IT will be attained through its close links with the CBD, the conditions for the relationship between the TRIPS Agreement and the IT are similar to the one between the TRIPS Agreement and the CBD. In its Articles 12.3(f) and 13.2.b(iii) the IT acknowledges that access to genetic resources shall be consistent with the adequate and effective protection of intellectual property rights and relevant international agreements. Comparable ways and means to ensure a mutually supportive implementation, as outlined under point 3, will be sought for the IT in its relation to the TRIPS Agreement and the CBD. Currently, a dialogue on the conditions for ABS is taking place in the context of the IT with an aim to agree on a standard Material Transfer Agreement. (UNEP/CBD/WG-ABS/2/INF/1 – 30 September 2003).

Some directions came to light after the Intergovernmental Expert Group met for the first time in Belgium in October 2004 to consider a draft of the Material Transfer Agreement (MTA) to be used to move crops listed in Annex I of the IT. The questions referred to:

- the level, form, and manner of payments in line with commercial practice;
- levels of payment for different recipients who commercialise products derived from material in the MS;

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[39] Kalpavriksh, and GRAIN. *The International Treaty on Plant Genetic Resources: a challenge for Asia,* 2002.

[40] Article 13(d).

- exemption rules for small farmers in developing countries and countries with economy in transition;
- the definition of terms of commercialisation under Art. 13.2.d(ii);
- what constitutes the incorporation of material accessed from the MS;
- interpretation of when is a product available without restriction for further research and breeding;
- definition of monetary and other benefits for the purposes of the standard MTA;
- ways to ensure application of Art. 12.3; and
- terms to be included in the MTA to ensure that recipients are bound to it on acceptance of material from the MS.

The Expert Group reported to the Second Meeting of the Interim Committee of the Treaty held in November 2004. After approving most of the suggestions, the Committee called for a second meeting to take place in June or July 2005 before the First Meeting of the Governing Body, scheduled to take place in Madrid, Spain, by February 2006. The complicated regional composition of the Delegations for the above-mentioned meeting can be found in the report of the Second Meeting of the Interim Committee of the Treaty on the FAO Home Page.

3. RELEVANCE OF THE INTERNATIONAL AND NATIONAL LEGISLATION RELATED TO IPR AND ABS TO THE GCP

Overview

Having described above the major international treaties, conventions, and related developments that can impact the acquisition of genetic resources and subsequent technology transfer of product derived thereof, it will be necessary to analyse which assets the GCP projects will need in the course of its development. The national Access and Benefit Sharing legislations already implemented or under development by several countries are reviewed in an accompanying paper and have to be considered in any further analysis. Other definitions such as “resource-poor”, “public goods”, and “humanitarian licenses” are being dealt with in other papers of the policy cluster and need to be taken into consideration in the composition of the global scenario in which the Programme is going to be implemented.

Biological material and related information subject to IP may include: seeds (including breeders lines), plant cells, plant varieties (including parent lines), processes to obtain hybrids, processes to genetically modify plants (vectors, bio-ballistics), gene promoters, gene markers, isolated DNA sequences, isolated and purified proteins, proprietary genomic information contained in data bases as related to specific cloning libraries, and ethnobiological information (indigenous/traditional knowledge). The use of these assets should be negotiated in a way that guarantees the final product accessibility by the resource-poor and at the same time a share of benefits from commercial operations.

The freedom of the GCP to operate can involve different strategies:

- Check whether the protection of the materials and technologies are indeed restricted in the countries where the research is being executed and the countries where the products are to be used (IPRs are territorial, and most biotechnological patents are currently not valid in most developing countries).

- Negotiations with the holders of the rights before research starts. This is necessary in countries where the research exemption is very limited (e.g., the USA), or negotiations when there is a sign of an emerging product.
- Alternatively, the GCP may use technologies and let the market decide what kind of negotiations are needed at the end of the line – possibly assuming that many holders of the rights will not sue this public organisation that works for the poor.

Critical questions come to mind and should be answered at the different phases of each component project. For instance, at the initial phase, which kind of agreements do CGIAR Centres enter into in order to access proprietary (or not) genetic material/resources? Does it account for the present CGIAR and/or donors' policies? During development, how much of others' proprietary technology is used at CGIAR Centres/ NARS at present and will be used in the development of the Generation Challenge Programme (IP registrar still not available)? Will the use of such technology affect the development of the final product, to be released for the benefit of the resource-poor? And before the release phase, there should be "technology transfer" planning to maximise the use of Generation Challenge Programme products.

Benefits from the use of natural resources, including agrobiodiversity research agreements, may include monetary compensation in the form of royalties and advance payments. They may also include source country capacity building efforts such as training, equipment, and infrastructure development. Other benefits, less tangible but no less important, may be research on subjects that are important to the host country and the building of collaborative relationships that will endure beyond the scope or duration of a particular project.

Some types of Benefits to Source Country Partners from Research and Development Agreements can be adapted from Rosenthal, 1997 as being:

- Royalties – A percentage of earnings from commercial sales by the licensing partner may be agreed upon in the initial agreement, or the agreement can specify a range and require the parties to negotiate the final rate on a case by case basis. Some issues to consider in royalty structures include: a) relative contribution of partners to invention and development; b) information provided with samples; c) novelty or rarity of sample organisms. The general rule for the Generation Challenge Programme is that the partner who develops the IP owns it. However, the partner should pay attention to indications of the Steering Committee on the issue of commercialisation opportunities.
- Advance payments – Access fees may take the form of lump-sum or milestone payments, per sample fees, payment for re-supply of samples, or in-kind contributions of equipment and training. Advance payments are valuable for establishing trust funds that can provide immediate benefits to stakeholders. While training could be one way to deploy benefit sharing, it is unlikely that there will be advance payments for the acquisition of samples from gene banks situated in different countries.
- Priority research areas – Agreements can require that locally important but understudied problems such as local biotic and abiotic stresses will be investigated by scientific partners. This is an interesting way to enter the avenue of benefit sharing with the final delivery of new cultivars, better adapted to the stress conditions. The Generation Challenge Programme priorities include just that. The paper on non-monetary benefit sharing adds some more options in this direction.

Since the GCP is supposed to provide royalty free access to its inventions and materials for use for/by the poor, there is little reason to believe that monetary benefit sharing will come into play.

However, when the same technologies are commercialised for other target groups, the GCP has to take this issue into account.

The Consortium Agreement has already sorted out a number of responsibilities in this field, but the GCP has to be aware of developments in these international agreements and their translation into a wide range of national laws (see annex).

4. CONCLUSION

The Generation Challenge Programme works in a legal environment that has been changing dramatically over the past few decades. Rights of inventors, countries, and local communities rest on biological materials, technologies, information, and traditional knowledge that the GCP intends to use. In order to make sure that the products of the Generation Challenge Programme will be available for the poor as planned and as expected by the sponsors, we have to make sure that we have a freedom to operate to distribute these products. This calls for GCP policies on how to deal with the concepts and laws derived from these international agreements.

5. REFERENCES AND OTHER SOURCES OF INFORMATION

Internet links:

www.biodiv.org
www.fao.org
www.wipo.net
www.upov.org
www.wto.org
www.cgiar.org
www.embrapa.br

Sampath,P.G. and Tarasofsky, R. 2002. Study on the Inter-Relations between Intellectual Property Rights Regimes and the Conservation of Genetic Resources Ecologic – Institute for International and European Environmental Policy.

Rosenthal, J.P. 1997 Equitable Sharing of Biodiversity benefits: agreements on genetic resources Proceedings of the Cairns Conference, OECD.

Henne, G., Liebig, K., Drews, A. & Plan,T. ,2003. Access and Benefit Sharing : An Instrument for Poverty Alleviation – German Development Institute (GDI), Tulpenfeld 4, Bonn.

6. ANNEXES

I – Table with some countries & laws
II – Table with Generation crops versus centres of origin
III – Table with CG Centres & crops in gene banks
IV – Table with Generation crops & crops in Annex 1 of the FAO IT
V – Generation IP rules

Annex I. Some examples of national legislation of interest.

Country	Conditions for Access/ Benefit sharing	PVPs	Protecting farmers/ land races	Protecting Indigenous knowledge	IT-PGRFA	Patents/WTO TRIPS	Patents Plants/ Animals Possible?
Bangladesh	No regimes yet, but benefit sharing provision part of draft PVP law.	Draft PVP law consistent with UPOV 78 and 91 and Indian PVP law.	Daft Bioidiversity & Community knowledge protection act.	Draft Act " The Biodiversity and Community Knowledge Protection Act".	Signatory.	Member of WTO TRIPS complaints.	No.
Nepal	Legalisation on access and benefit sharing is under development.	Development of a sui generis under discussion.	To be developed.	To be developed.	Signed but not ratified.	WTO observation status.	Under discussion.
Botswana	ABS strategy under development; Anthropological research act.	Sui generisis PVP under development based on UPOV.	To be developed.	To be developed.	To be considered.	Member of WTO. Signatory of TRIPS(?)	No information.
Vietnam	Separate regimes for Research and for exports. Permits given by responsible sector authorities.	Decree of the Government on protection of New Plant Varieties- based on UPOV.	Under Development.	Under Development.	Considered.	No patent law; biological material protected under gov't regulation. Application for WTO membership.	Not in general, but part of US - Vietnam trade agreement.
Cambodia	No regime.	A draft PVP law under development.	Will be protected under new PVP law.	Act/law under development.	No Information.	Patents laws 2002 and 2003. Will be Member of WTO.	No.
Thailand	Addressed in the PVP 1999. Access: the Thailand Biodiversity Centre.	PVP Act 1999. Combination of UPOV 78 and CBD.	Protection under the PVP act.	Protection and Promotions of Traditional Thai Medicinal Intelligence Act.	Signed but not ratified.	Member of WTO TRIPS compliant.	No. Patents on micro-organisms unclear.
Colombia	Access regulated through the Andean decision 391.	UPOV 78. Protection under Andean decision 345.	No specific legal regime.	No specific legal regime. Disclose origin, source and PIC in patent application.	Signed but not ratified.	Member of WTO and signatory of TRIPS.	No, but transgenic plants patentable.
Kyrgyz Republic	Gov't decision July 7, 1995, N269. Copywright Law and Related rights.	"Legal Protection on Breeding achievements (1998)"- UPOV 91.	Not addressed in current legislation.	Not addressed in current legislation.	Signed.	Member of WTO and TRIPS compliant.	Plants and animals can possibly be patented.
Sri Lanka	No regimes yet.	Draft legislation.	To be developed.	To be developed.	No information.	Member of WTO TRIPS compliant patent legislation.	No.

Kenya	No national regime in place. But various legislations touch on the issue.	UOPV member (under 1978 Convention).	Not addressed in current legislation.	Testing patenting through utility model on herbal medicines.	Signed but not ratified.	Patent legislating in TRIPS compliant Member of WTO.	No.
Ethiopia	Draft access legislation developed.	PVP under development based on OAU model law. Not member of UPOV.	Procedures and regulations under development under the PVP and access laws.	No Specific law. Policies under development.	Ratification considered.	Patent law form 1995. Not member of WTO, but membership is under consideration.	No.
Zambia	To be regulated through Farmers and Community Rights Bill (under development).	Plant variety protection bill, 2002, based on UPOV and OAU model law.	Farmers and Community Rights Bill; Gene fund under development.	No information.	Informati on to be gathered.	Revisions of patent law 1995. Member of WTO and signatory of TRIPS.	No.
Rwanda	Draft regulations in place. UNCST handling permits.	Draft PVP based on OAU model law.	No information.	A new act under development.	Ratification discussed.	Member of WTO, TRIPS signatory, Patent bill amended 2000.	No.
Tanzania	No Act and no permit system.	PVP developed 2002 based on UPOV 91.	Not addressees in current legislation.	Not addressed in current legislation.	Ratification discussed.	Member of WTO. TRIPS compliant. Patent bill from 1987.	No.
Malaysia	Access to Genetic Resources and Benefit Sharing Bill.	Draft PVP legislation based on UPOV Model Law.	Not addressees in current legislation?	Addressed in Access to GR and BS Bill..	Considered.	Member of WTO.	No information.
Philippines	Executive order, 247, 1995. ABS-systems in place.	PVP Act 9168, 2002.	Landraces can be protected (through PVP).	Act 7586 (1992) on Protected Areas; Act 8371 (1997) "Indigenous Peoples Rights Act" .	Considered.	Member of WTO TRIPS compliant.	No.
Namibia	Access legislation in place.	No Information.	No Information.	No Information.	No Information.	No modern legislation.	No.

Source: GRIP course, 5-23 May 2003.

Annex II. World centres of diversity of cultivated plants.

Country	Plant
Chinese Centre:	broomcorn millet, Italian millet, Japanese barnyard millet, Koaliang, buckwheat, hull-less barley, **soybean**, Adzuki bean, velvet bean, Chinese yam, radish, Chinese cabbage, onion, cucumber, pear, Chinese apple, peach, apricot, cherry, walnut, litchi, sugar cane, opium poppy, ginseng camphor, and hemp.
Indian Centre:	**rice, chickpea**, **pigeon pea**, urd bean, mung bean, rice bean, **cowpea**, eggplant, cucumber, radish, taro, **yam**, mango, orange, tangerine, citron, tamarind, sugar cane, **coconut palm**, sesame, safflower, tree cotton, oriental cotton, jute, crotalaria, kenaf, hemp, black pepper, gum arabic, sandalwood, indigo, cinnamon tree, croton, and bamboo.
Indo-Malayan Centre:	Job's tears, velvet bean, pummelo, **banana**, breadfruit, mangosteen, candlenut, **coconut palm**, sugarcane, clove, nutmeg, black pepper, and manila hemp.
Central Asiatic Centre:	**common wheat**, club wheat, shot wheat, peas, **lentil**, horse bean, **chickpea**, mung bean, mustard, flax, seasame, hemp, cotton, onion, garlic, spinach, carrot, pistacio, pear, almond, grape, and apple.
Near Eastern Centre:	einkorn wheat, durum wheat, poulard wheat, **common wheat**, oriental wheat, Persian wheat, two-row barley, rye, Mediterranean oats, common oats, **lentil**, lupine, alfalfa, Persian clover, fenugreek, vetch, hairy vetch, fig, pomegranate, apple, pear, quince, cherry, and hawthorn.
Mediterranean Centre:	durum wheat, emmer, Polish wheat, spelt, Mediterranean oats, sand oats, canarygrass, grass pea, pea, lupine, Egyptian clover, white clover, crimson clover, serradella, flax, rape, black mustard, olive, garden beet, cabbage, turnip, lettuce, asparagus, celery, chicory, parsnip, rhubarb, caraway, anise, thyme, peppermint, sage, and hop.
Abyssinian Centre:	Abyssinian hard wheat, poulard wheat, emmer, Polish wheat, **barley**, **grain sorghum**, **pearl millet**, **African millet**, **cowpea**, flax, sesame, castor bean, garden cress, coffee, okra, myrrh, and indigo.
South Mexican and Central American Centre:	**maize (corn), common bean**, lima bean, tepary bean, jack bean, grain amaranth, malabar gourd, winter pumpkin, chayote, upland cotton, bourbon cotton, henequen (sisal), sweetpotato, arrowroot, pepper, papaya, guava, cashew, wild black cherry, chochenial, cherry tomato, and cacao.
South American Centre:	**potato**, starchy maize, lima bean, **common bean**, edible canna, pepino, tomato, ground cherry, pumpkin, pepper, Egyptian cotton, passion flower, guava, heilborn, quinine tree, tobacco, strawberry, **manioc**, **peanut**, rubber tree, pineapple, Brazil nut, cashew, and purple granadilla.

Highlighted crops are the main crops for the CP; all these except for groundnut and soybean, are included in the Annex 1 of the International Treaty.

Annex III. Generation IP rules as in Consortium Agreement (version 10 August 2004).

24 **Challenge Programme IP**

24.1 To the extent permitted under any applicable laws and regulations, ownership of Challenge Programme IP will be retained by the Consortium Members who developed the material in question. The Consortium Members agree to deal with these rights as set out in this Agreement.

24.2 Each Consortium Member has a non-exclusive, royalty-free right to use Challenge Programme IP for the Activities with the aim to provide technology and products to the resource-poor on a royalty-free basis.

24.3 Each Consortium Member must:

a. co-operate with each other Consortium Member and promptly do all things and execute all legal documents necessary to share Challenge Programme IP with the Consortium Members in accordance with clause 24.2;
b. respond to a request from the Challenge Programme Director or any other Consortium Member to provide information in its possession about existing or potential Challenge Programme IP;
c. use its reasonable efforts to ensure that its Personnel (including Seconded Personnel),:
    i. identify Challenge Programme IP generated or developed by them;
    ii. communicate details of Challenge Programme IP to the relevant SubProgramme Leader; and
    iii. do all things and execute all documents necessary to share the Challenge Programme IP with the Consortium Members in accordance with clause 24.2.

24.4 If a SubProgramme Leader or Consortium Member considers that a development arising from the Activities may be protected by a Registered IP Right, the SubProgramme Leader or Consortium Member should communicate details of that development to the Challenge Programme Director. All such communications should be clearly marked as Confidential Information.

25. **IP Management**

25.1 Each Consortium Member will no less than annually submit to the Challenge Programme Director in the form provided in Schedule 4 [IP Management] reports detailing:

a. IP owned or controlled by the Consortium Member, available as Background IP and identified in the Consortium Member's annual agreement pursuant to clause 5.3 [Annual Consortium Member's Agreement];
b. Pre-Existing IP which the Consortium Member intends to use in the course of Activities, and which are subject to restrictions on use, publication, or re-distribution that might impact the publication of Challenge Programme Results or the distribution of Consortium products as global public goods; and
c. Challenge Programme IP generated by the Consortium Member.

25.2 When such reports are required to support the Programme Steering Committee's role as described in Schedule 2 [Role of Programme Steering Committee], the Programme Steering Committee may on a case-by-case basis require any Consortium Member to submit reports in the form provided in Schedule 4 [IP Management] more frequently than annually.

26. **Commercialising Challenge Programme IP**

It is recognised that the Activities will generate predominantly global public goods. However, the Consortium may pursue opportunities to Commercialise IP under the following conditions:

26.1 The Programme Steering Committee will identify opportunities for Commercialising Challenge Programme IP and make recommendations to the Consortium Members about Commercialisation of Challenge Programme IP.

26.2 Each Consortium Member must notify the Programme Steering Committee where it considers an opportunity for Commercialisation exists.

26.3 The Consortium Members agree to abide by the benefit sharing provisions of the International Treaty on Plant Genetic Resources for Food and Agriculture ('International Treaty') when they become effective, in the event that they commercialise Plant Genetic Resources for Food and Agriculture that is derived from the material included in the Multilateral System of Access and Benefit-Sharing of the International Treaty on Plant Genetic Resources for Food and Agriculture.

26.4 The Consortium Member will seriously consider all recommendations by the Programme Steering Committee for the advance and administration of the commercialisation of Challenge Programme IP.

Humanitarian Licences: Making Proprietary Technology Work for the Poor

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1. INTRODUCTION

The Generation Challenge Programme intends to develop technologies and methods that result in products such as drought tolerant varieties for the poor in developing countries. Intellectual Property Rights (IPR) may reside in these final products either by intellectual property assigned by the GCP itself to its inventions or by a reach-through of third party right holders of enabling technologies, equipment, or materials that were used to develop the end product.

Users of protected inventions need to acquire the consent of the holder of the rights. Commonly such consent is provided via a variety of license contracts in which the rules for the use of the invention are spelled out and the (commercial) interests of both the licensor and the licensee are connected. Such license contracts are negotiated by the two (or more) parties concerned. Not-for-profit organisations, especially those working for the resource-poor, generally cannot offer the licensor significant monetary benefits. Major companies may however allow such organisations the free use of their inventions, often based on their responsibilities to society. In the biological sciences such contracts are essential since the products of research are intended to be used, re-used, and often distributed further by smallholder farmers. Such license contracts are called "humanitarian licenses". Humanitarian licenses are thus an important way to create a freedom to operate for researchers and end-users of protected products or processes. This paper discusses experiences in this field and presents a draft humanitarian license for the GCP Consortium Agreement.

Why humanitarian licenses?

Humanitarian licenses can be considered from at least two aspects: that of the provider and that of the subsequent developer(s) who deliver the useable products to clients or customers.

The objective of the developer of products is to get free access to technology that is needed to serve its target groups and, more importantly, to be allowed to transfer the subsequent products to these groups with few restrictions. This is particularly important in breeding research for development since the products of such breeding generally enter local seed systems where the breeder cannot control the further multiplication and spread of the technologies (e.g., genes). The breeder can thus not be held responsible for possible breaches of intellectual property rights in such cases. Furthermore, the breeders that aim at supporting resource-poor farmers generally are funded by public funds, do not derive income from these activities, and cannot be expected to pay large sums in commercial royalties.

Providers may include the following:

1. the private sector, large and small,
2. public institutions in developed and developing countries,
3. international organisations,
4. philanthropic entities,

5. IP management entities, etc.

Providers have and can be expected to entertain the provision of IP under a humanitarian license. In this usage, humanitarian means that the provider will obtain little (or no) payment for providing the IP and will receive no (or "below market rate") remuneration from license fees. This action by the provider is "humanitarian" to it since this means the forgoing of a business opportunity and the assistance of public or not-for-profit efforts. It also entails the recognition that others will profit from the use of the provider's IP, including monetarily. There are a number of such cases and a couple of examples will be examined in detail later: the Monsanto Company broad enabling technology license for cassava to the Donald Danforth Plant Science Centre, and the (now) Syngenta and other companies' provision of licenses to the technologies needed to develop Golden Rice.

Reasons for granting humanitarian licenses

The impetus to convey a humanitarian license may be driven by internal and external considerations for the provider and may include the following:

1. the internal image of the company and its relationship with the employees (employee pride in working for a company that shows a "human face");
2. a public company pledge or policy and an organisation in place charged to find uses for company assets that would not otherwise be used (and this activity may be part of or closely coordinated with the philanthropic foundations of the provider);
3. a public sector entity's stance of cooperation with less fortunate institutions and countries, including the commitment to the development of products and services for such;
4. non-monetary benefits in the contract (e.g., Pioneer-Egypt);
5. reach-through benefits: clauses in a contract can be beneficial for the provider, e.g., that the provider wants to be informed of patents based on provided information or technology (e.g., rice genome programme) so that possible royalty-bearing licenses could be negotiated;
6. access to useful data long before publication has also been a feature of private-public interactions, and the two cases of provision of draft rice genome sequences (Syngenta and Monsanto) were both successful. In these cases there was no requirement for pre-publication clearance, but this is included in the more recent proposed agreement for the use of the Pioneer-DuPont/Ceres/Monsanto maize full-length EST sequences. This complexity probably reflects the relative importance of maize versus rice for these companies and also reflects that such a complex sharing activity is novel to a number of the companies.

A related consideration is for tax benefits, at least in the USA, where the donation of a complete IP estate could lead to such benefits. However, since this requires the abandonment of the rights of the entity to this same IP, it may eliminate from consideration proven, useful IP that has already been shown to lead to products. Such decisions also require that a somewhat costly tax audit be conducted and this may preclude many "small" IP estates from consideration. Such estates may become available when a company may change business focus or abandon a product development stream. The donor also needs to identify a recipient that will satisfy the tax code requirements. The donation by Monsanto of its Precision Agriculture database to the University of Illinois is probably on such example (Box 1.).

Box 1. Donation to Ag Institutions.

Making Precision Ag Database Available to the University of Illinois

A 2002 transfer of information from Monsanto's Precision Agriculture database to the University of Illinois will help researchers understand key agronomic conditions and their interactions.

The Precision Agriculture database, valued at $18 million, was assembled as part of an internal Monsanto corn-research Programme in the late 1990s. That Programme examined linkages among environmental and soil factors, grower inputs, corn yield, and grain quality. It was designed to interpret the vast amount of complex data generated by modern technologies, including remote sensing, yield monitors, and geographic information systems.

The Precision Ag database will be available via the Internet to other US-based ag institutions and their researchers. The Automated Learning Group (ALG) at the National Centre for Supercomputing Applications (NCSA) will mine the database for relationships among temperature, moisture, and growth. Researchers hope to find ways to improve crop yield and grain quality, and to benefit the environment as well, by improving the use of soil nutrients.
http://www.monsanto.com/monsanto/layout/our_pledge/sharing/donating_tech.asp#04.

Finally, a humanitarian license may be granted to make sure that future technology will be widely available. Such licenses are the basis of the open-source movement (see Susan Bragdon in this volume).

2. EXAMPLES

2.1 Enabling technologies for use in cassava

Monsanto has donated important cassava technology to the Donald Danforth Plant Science Centre that allows the latter to more effectively work on this crop, a staple food for millions of people in Latin America, Africa, and Asia (box 2).

Box 2. Monsanto Company to Share Technologies with Donald Danforth Plant Science Centre to Support Global Cassava Research (adapted from Monsanto press release).

ST. LOUIS (April 16, 2002) – Monsanto Company announced today it is supporting a global effort to increase production and quality of cassava by granting the Donald Danforth Plant Science Centre a royalty-free license enabling technologies commonly used in agricultural biotechnology. "By providing this license we hope to accelerate valuable research taking place in public and non-profit research institutions to benefit the developing world".

The Donald Danforth Plant Science Centre is a St. Louis-based not-for-profit, basic research institution devoted to the creation of new knowledge that will lead to the sustainable production of nutritious and abundant food for the peoples of the world. Monsanto's technologies will support efforts already underway at the Danforth Centre to conduct research and further develop a comprehensive global research plan to tackle the most significant challenges facing cassava farmers, including control of disease, post-harvest deterioration, and enhancing the nutritional content of the crop. "By granting this license, Monsanto has enabled researchers at the Danforth Centre, and our collaborators around the world, to continue our important work while now freely using Monsanto technology to even further advance agricultural research on cassava, a crop that hundreds of millions of people will continue to rely upon for food security and economic development in coming decades".

"By sharing our technology and other scientific knowledge, Monsanto hopes to encourage other companies and technology developers to do the same," said Robb Fraley, Chief Technology Officer of Monsanto. Monsanto also is supporting the Danforth Centre's efforts to develop virus-resistant cassava through a multi-year grant from the company's philanthropic organisation, the Monsanto Fund.

Monsanto's contributions to the Danforth Centre are in keeping with the New Monsanto Pledge and its commitment to sharing knowledge and technology with public institutions to benefit people and the environment, particularly in the developing world. **http://www.monsanto.com/monsanto/layout/media/02/04-16-02.asp**

This license, while stressing research, at least anticipates a commercial license as well as a research license, and enables the DDPSC to sub-license to entities in a large number of countries. While the license is restricted to specific trait areas, these are sufficiently broad to encompass many of the current R&D transgenic work in the crop at the DDPSC and within the Cassava Biotechnology Network. In this case it also appears that there is no material transfer anticipated; the effective genes would be developed by the DDPSC and partners and many of the enabling technologies would already be in use by these researchers.

2.2 Golden Rice

The more famous Golden Rice license, involving technology from six multinational companies and that of the inventors at the University of Freiburg and at the ETH, Zurich, brokered by Zeneca (now Syngenta) is presented next. Golden Rice is a genetically modified rice with high levels of beta-carotene and other carotenoids. These are precursors to Vitamin A, which is deficient in the diet of people in highly populated areas of Asia, Africa, and Latin America. This agreement facilitates the delivery of a public health programme aimed at countering deficiency diseases associated with Vitamin A, which accounts for irreversible blindness in 500,000 children each year (Source: FAO). The inventors of "Golden Rice" are Professor Ingo Potrykus of the Institute for Plant Sciences, Swiss Federal Institute of Technology, Zurich, Switzerland, and Dr. Peter Beyer of the Centre for Applied Biosciences, University of Freiburg, Germany.

Box 3.

'GOLDEN RICE' COLLABORATION BRINGS HEALTH BENEFITS NEARER (adapted from a press release by Syngenta)

A collaboration is announced today that will help fight blindness in developing countries through the use of genetically modified rice. The collaboration will help the inventors of 'Golden Rice' to deliver their gift of nutritionally-enhanced rice to the developing nations of the world, bringing closer the health benefits for countries where Vitamin A deficiency is the cause of 500,000 cases of irreversible blindness each year.

The inventors of 'Golden Rice' have reached an agreement with Greenovation and Zeneca, and are working with agencies throughout the world to enable the delivery of this technology free-of-charge for humanitarian purposes in the developing world. This will bring closer the 1982 vision of the Rockefeller Foundation who stimulated and funded this research into rice varieties which might offer global public health benefits.

Dr. Gary Toenniessen of the Rockefeller Foundation endorsed the agreement. "This collaboration will speed the process of conducting all appropriate nutritional and safety testing and obtaining regulatory approvals. The agreement should help assure that 'Golden Rice' reaches those people it can help most as quickly as possible. We look forward to following the progress of this agreement as a possible model for other public-private partnerships designed to benefit poor people in developing countries,"

The inventors of 'Golden Rice', Professor Ingo Potrykus and Dr Peter Beyer, will fulfil their commitment to give this technology to resource-poor farmers in developing countries, and contribute to poverty alleviation by increasing nutritional benefit from crops and income generation. Zeneca will explore commercial opportunities for sales of 'Golden Rice' into the growing market for healthy foods in the developed world. At the same time, Zeneca will provide regulatory, advisory and research expertise to assist in making 'Golden Rice' available in developing countries.

Professor Ingo Potrykus said, "Zeneca has been involved with carotenoid research for a number of years and have demonstrated an awareness and sensitivity to the needs of impoverished people in the developing world. Zeneca will help us to deliver 'Golden Rice' more speedily to those that need it most".

The collaborators anticipate that 'Golden Rice' will not be available for local planting and consumption until 2003 at the earliest.

May 16, 2000

The "Golden Rice" technology was developed with funding from the Rockefeller Foundation (1991-2002), the Swiss Federal Institute of Technology (1993-1996), the European Union under a

European Community Biotech Programme (FAIR CT96 1633)(1996-2000), and the Swiss Federal Office for Education and Science (1996-2000). Greenovation (http://www.greenovation.com) was founded in Freiburg, Germany in September 1999. This university spin-off biotechnology company performs and funds research and development in plant biotechnology for agricultural and phytopharmaceutical applications.

The outcome of the arrangement enabled the inventors to then license the combined technology package and the accompanying materials developed by the inventors to a number of primary licensees. Some of the licensees had rights to sublicense to other public sector entities in a specific country or in a number of countries.

3. HUMANITARIAN LICENSES IN OPERATION

'Only for smallholder farmer' provisions

The Golden Rice case contains a restriction to the royalty-free license for production of the Golden Rice grain to farmers in developing countries who earn less than $10,000 per year from farming. This restriction, among others, served to protect a business opportunity for Syngenta for the product and for the larger, more commercially relevant farmers. Zeneca (now Syngenta) had plans to develop a commercial golden rice market for developed countries and also for the more advanced sector of developing countries. The Humanitarian license did not secure any rights for Syngenta for its planned commercial product: Syngenta would rely on obtaining any such licenses in its normal course of business. The desire of the company to retain a potential customer base for its commercial golden rice in parts of the developing country market led to the restriction of the availability of the technology for humanitarian uses to farmers in these countries earning less than US$10,000 per year. Who would be responsible for monitoring compliance with this? Transaction costs remain to be seen. Syngenta has announced recently that it will no longer develop a commercial Golden Rice product, but that it will continue its support for the humanitarian project **(**http://syngenta.com/en/media/article.aspx?pr=101404&Lang=en, and Paine *et al*.,2005 Improving the nutritional value of Golden Rice through increased pro-vitamin A content. Nat. Biotech. 23, 482 – 487).

This exemption is an example of a restriction that might be acceptable to Challenge Programmes and Centres, but the definition of the restriction for Golden Rice requires policing of the use of the IP and materials by the licensee (and sub-licensees). This *de facto* requirement could add large yearly monitoring and accounting costs and also could provide opportunities for the licensees to be in breach of the agreement. This point must be kept in mind, especially for the Generation Challenge Programme. For example, if other entities provide IP and materials for drought product concepts, and where it could be reasonably expected that the use for commercial markets in developed and developing countries would be retained by the licensor for their own direct use or license to a commercial developer, that market segmentation terms do not fall unduly on the licensee to monitor and are not defined in terms that require extensive or annual activities that could be costly or prone to error. One solution would be to accept that all sublicenses would need to be approved by the original licensor.

The Golden Rice license is an important example of how "smallholder" or "resource-poor" can be defined. Other examples are based on area cultivated or tonnage produced. For example, in the European Union, farmers who produce less than 92 tons of grain are exempted from paying royalties to breeders on farm-saved seed. In Colombia, this is the case for farmers cultivating less than 5 ha.

These examples are, however, geared to specific conditions. Almost all farmers in Asia, Africa, and northern South America produce less than 92 tons; some highly commercial (greenhouse) flower producers may farm less than 5 hectares and by no means fall in the resource-poor category.

Additional support

In some cases, the providing entity or its charitable foundation has also provided resources to fund the R&D around the provided technology. This is also true of the two examples above, where in the former case, the Monsanto Fund and Monsanto Company have funded cassava research at the Donald Danforth Plant Science Centre, and the Syngenta Foundation has funded work at the University of Freiburg and the ETH, Zurich, on Golden Rice. The Syngenta Foundation for Sustainable Development has also funded a project on Insect Resistant Maize for Africa that is managed by the Kenya Agricultural Research Institute in Nairobi and the International Maize and Wheat Improvement Centre, headquartered in Mexico. Similar relationships and outcomes can be seen for the virus-resistant sweet potato projects in Africa and the delayed ripening and virus-resistant papaya projects in Malaysia, Thailand, the Philippines, Vietnam, and Indonesia.

Capacity building is also a common type of additional support sometimes included in humanitarian licenses, especially training on the responsible use of the technology. The use of (confidential) biosafety data could also be a valuable asset for recipient institutions.

Co-development on the basis of a granted technology

Another example includes the co-development of commercially important IP and materials: new maize promoters to express Bt genes and maize plants containing these new expression cassettes by a large multinational company (Pioneer/Dupont) and a developing country partner (Agricultural Genetic Engineering Research Institute, Egypt). From the available information on the web, we understand that Pioneer grants a humanitarian license to jointly develop derived technologies that will be patented by the donor. The recipient obtains an automatic royalty-free license in the home country and the donor gets the rights elsewhere. A similar example was mentioned in the deals of KARI in Kenya on maize where the recipient institute would also get a free license for use in Kenya plus an undisclosed percentage of the royalties on that worldwide use. These examples show a thin line between humanitarian licenses and collaborative agreements aimed at mutual commercial benefits.

Alternative mechanisms

Another very simple access mechanism would be statements by IP holders that they would not assert their IP rights for certain uses, crops, countries, etc. The option for non-assert licenses are probably highest when no material – physical or informational – is transferred between the parties.

Alternatively, one could think of a broadly accepted system whereby humanitarian licenses do not need to be negotiated, but are automatic when technologies are to be used for the poor (from humanitarian licenses to humanitarian rights). However, these options do not seem to be preferred by the private sector technology providers since this may not sufficiently contribute to the objectives above (e.g., the public image objective and that of engaging partners in understanding the value and the management of IP) and may not provide enough securities in terms of stewardship by the recipient (and associated indemnification of liabilities). They may prefer

actual license agreements for the value of the relationship/interaction between the entities or to instil the value of IP recognition in public sector/non-traditional partners.

Mechanisms

Humanitarian licenses may be negotiated between individual technology users and providers (e.g., Pioneer–Egypt). They may also be negotiated by two parties on behalf of all (potential) users (e.g., Golden Rice). The high transaction costs of such negotiations have led to a number of initiatives that intend to facilitate access to IP for development:

1. The evolution of The Public-Sector Intellectual Property Resource for Agriculture (PIPRA) may provide an opportunity to access IP that might otherwise be licensed away exclusively to commercial users. This represents an aspiration on the part of a large number of US universities and research centres to retain certain rights when licensing new inventions to commercial entities, so as to be able to grant humanitarian or public sector licenses in the future. No license has been reported yet under PIPRA. This initiative also involves the development of a database to pool the IP assets of the participants (patents and licenses) to aid in the development of public sector products. Another encouraging aspect of this initiative is the likely development of a related EU policy as a result of the activities of the European Action on Global Life Sciences. While this effort would likely increase the range and access to technologies and IP, it is not expected to be in place before mid-2006.

2. The ISAAA and, more recently, AATF have been established to provide a broker role between technology users and providers. ISAAA has concluded a number of such licenses since the late 1990s while also negotiating with development agencies development costs and training in the recipient country. These initiatives have not led to one generally accepted format for humanitarian licenses that could be used as a standard for all cases.

3. Finally, a consortium of research institutions may develop a clause in the consortium agreement that automatically grants a humanitarian license to all users of a certain category similar to the "Golden Rice" contract, but more widely applicable. The Generation Challenge Programme is currently developing such an agreement.

4. CHALLENGES FOR THE GENERATION CHALLENGE PROGRAMME

The GCP uses a wide diversity of materials (plants, cells, DNA) and needs access to a wide range of technologies in order to reach its goal in providing breakthrough technologies to the resource-poor. Licenses for the use of protected technologies are thus essential for the GCP. Such licenses must be humanitarian in character for the GCP to deliver on its goals.

What makes a license a humanitarian license for the GCP?

The license will be considered humanitarian by the licensee and its subsequent sub-licensees if there are no financial obligations on the part of the licensees to the licensor and, as in the case of GCP, if the license enables the licensed GCP-partner(s) to serve their mandate crops targeting the resource-poor farmers in developing countries through national partners. One of the most important considerations is that the terms of the license will have a great effect on the subsequent sub-licenses. For this reason, research-only licenses may entail a significant down-side as the terms for use by the Centres' customers and clients is neither assured nor defined. From a Centre's or the GCP's point of view, investing public funds in an approach with no clear path or given success would need to be carefully evaluated. That said, it is also possible that a research-

only license might be acceptable for technology that is not yet well understood by the licensor and where the likelihood of utility will be more uncertain. In such cases, a commitment to negotiate in good faith for a subsequent license and with as many of the expected terms specified in the primary agreement would also be relevant considerations. As discussed above, the terms in research and commercial licenses should also be the minimum acceptable for monitoring and reporting back to the licensor. The licensee would also need to transfer at least these same requirements to its sub-licensees.

Box 4.

Proposed Amendments to GCP Consortium Agreement to include Humanitarian License Grants.

Definition:

"Subsistence Use" in relation to Challenge Programme IP means:

- direct personal or family consumption; or
- barter (exchange) for personal or family food, shelter, fuel, or clothing; or
- use in trade or business resulting in monetary income of less than E10,000 per year per business entity.

24.5 Humanitarian License Grants. To the extent it has the right to do so, each Consortium Member hereby grants to each person throughout the world the following irrevocable, perpetual, non-exclusive, freely-transferable, worldwide, paid-up, royalty free rights and licenses in Challenge Programme IP, solely for Subsistence Use and for no other use or purpose.

(a) a license under any patent or patent application claiming Challenge Programme IP, with the rights to make, have made, use, import, offer for sale, sell and otherwise transfer products, and to perform all methods, and to authorize others to do any or all of the foregoing.

(b) a license under plant breeders' rights included in Challenge Programme IP, with the rights to produce or reproduce, condition for the purpose of propagation, offer for sale, sell or otherwise market, export, import and stock plants for any of the foregoing purposes.

(c) a license under all worldwide copyrights, moral rights, contract rights, and other proprietary rights pertaining to works of authorship (excluding trademarks and trade names) included in Challenge Programme IP with the rights to reproduce, display, perform, modify, prepare and have prepared derivative works based upon, and to distribute and sublicense the Challenge Programme IP provided under such license and derivatives thereof.

24.6 Each Consortium Member hereby agrees that:

(a) the resource poor of the world are the intended third party beneficiaries of the license grants of clause 24.5 Humanitarian License Grants

(b) any license granting rights for the Commercialisation of Challenge Programme IP shall acknowledge in writing the license grants defined in clause 24.5 Humanitarian License Grants, and

(c) no royalties shall be due or owed to said Consortium Member or its sublicensees for the delivery of any products or services to or by any person for Subsistence Use.

24.7 Nothing in the license grants of clause 24.5 Humanitarian License Grants shall be interpreted as:

(a) an obligation by any Consortium Member to register any Challenge Programme IP; or

(b) a warranty or representation by any Consortium Member as to the validity or scope of any of the Consortium Member's rights in Challenge Programme IP; or

(c) a warranty or representation that anything made, used, sold, transferred or otherwise disposed of under said license grants is or will be free from infringement of intellectual property or proprietary rights of third parties; or

(d) an obligation to bring suit against a third party for intellectual property infringement; or

(e) conferring by implication or otherwise any license or rights under any Intellectual Property of a Consortium Member other than Challenge Programme IP as defined in this Agreement, regardless of whether such Intellectual Property is dominant or subordinate to Challenge Programme IP; or

(f) an obligation by the Consortium Member to furnish any additional know-how or improvements.

An initiative by the GCP

The partners of the Generation Challenge Programme are bound to its consortium agreement, which regulates the sharing of technologies and information among the member institutions which may be international (under the CGIAR) or national (in developing and industrialised countries). This may complicate the issue since some of these institutions may be considered competitors of a commercial technology provider. However, the Agreement does not cover all the research in these institutions and the free access within the GCP is restricted to research under the Programme and directed at the resource-poor. The GCP still has to sort out a mechanism on obtaining humanitarian licenses from outside the consortium and the roles of the individual institutions and the Programme management in starting, executing, and concluding such negotiations.

The consortium agreement itself is intended to serve as a humanitarian license provider for technologies and information developed by the consortium members themselves.

The above is different from the humanitarian licenses granted in so far that this will not involve bilateral contracts between technology provider(s) and recipient, but only if the recipient uses the technologies for the resource-poor. The latter is defined widely to avoid monitoring problems in most developing countries, where farmers earning more than 10,000 Euro can be easily identified from the vast majority of resource-poor farmers in least developed countries. Examples of the latter are for example large wheat farms in Kenya and horticultural enterprises in Ecuador (flowers) and Ethiopia (vegetables).

The potential advantage of the inclusion of a humanitarian license clause in a consortium agreement is that transaction costs are likely to be very low when bilateral negotiations and the drafting of bilateral contracts are not required anymore. A potential disadvantage is the fact that the technology provider does not have direct links with the users anymore, making the management of liability issues more difficult (see Sullivan in this volume). When a phrasing can be found that satisfies not only the consortium members of GCP but also the major private technology providers, we may achieve a greatly facilitated technology transfer for helping solve the needs of the poor.

5. APPENDIX I. DRAFT LICENSE AGREEMENT

The following template agreement (adapted from various sources) provides an example of a DRAFT license and would be used at the start of a negotiation. Points for the negotiators to consider include keeping the license simple to administer, such as requiring only notification of the provider when a research sub-license has been granted, rather than requiring prior consent. Other points include the lack of any financial considerations, the cost of administration, and keeping opportunities for the licensee to be in breach of the agreement low. Very important factors that can contribute to a simplification and lowered transaction costs in managing licensed technology is the degree of inherent trust between the parties or a past record of responsible management by the licensee of previous licenses or other legal obligations. Inherent trust can also be derived from the nature or stature of the entity requesting the license.

The likely receipt of a commercial license is strongly mooted. In some cases, hesitation to grant an up-front commercial license may be due to an inability of the parties to describe the likely subsequent partners and product developers in sufficient detail at the early stages.

DRAFT LICENCE AGREEMENT

THIS IS AN AGREEMENT effective the _____day of _____, 200x, by and between COMPANY and INSTITUTE.
Whereas a shared objective of each of the INSTITUE and COMPANY (the "Parties") is to further scientific research and education and to facilitate technology transfer and the non-commercial and commercial development of products in the life sciences.
And whereas each of the INSTITUTE and COMPANY is interested in facilitating research, education and technology development to benefit the peoples of the developing nations.
And whereas the INSTITUTE has made a significant commitment to addressing the food and agriculture needs of the world's poor in developing countries through specific research initiatives and to facilitate development and utilisation of improved crop species to improve the health and nutrition of the malnourished peoples of the developing world.
Whereas the INSTITUTE has made a significant commitment to the development of improved – varieties for the developing world farmers,

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, the parties agree as follows:

Grant of License
COMPANY grants a royalty-free, non-exclusive, worldwide, research-only license to the INSTITUTE under any COMPANY patents or patent applications pertaining to the – xxx technology ('COMPANY Technology'), solely for use in CROP for the following traits: control of – Diseases, and Enhanced Nutritional Content, with the right to sublicense according to the sublicense provision below, and for no other use or purpose. Licenses of COMPANY Technology for additional traits must be specifically requested of and approved by COMPANY.

Sublicense provision
INSTITUTE has the right to grant research-only sublicenses to the COMPANY Technology solely for use in CROP under this Agreement, and will notify COMPANY quarterly as to the granting of such sub-licenses. Any sub-license granted under this license must be consistent with the terms and conditions of this License Agreement.

Commercialisation
COMPANY will not unreasonably withhold the grant of a commercial license to INSTITUTE for the purpose of granting commercial sub-licenses, upon request for such commercial license and demonstration by INSTITUTE that such a commercial sub-license is necessary to support the advanced development of improved CROP varieties, with regard to the traits listed in "Grant of License", above.

Express exclusion of Biological Material Transfer
COMPANY IS PROVIDING NO BIOLOGICAL MATERIAL UNDER THIS AGREEMENT, only the rights to COMPANY Technology, described in the License and Sublicense provisions of this Agreement.

Term of Agreement
Initial term of 10 years with the option for renewal every 3 years upon request by INSTITUTE.

Limitation of Liability for Technology and Derived Products

It is expressly understood, however, that in making the conveyances and grants under this Agreement COMPANY MAKES NO REPRESENTATIONS, EXTENDS NO WARRANTIES, EITHER EXPRESS OR IMPLIED, AND ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO: THE UTILITY, PERFORMANCE, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF ANY TECHNOLOGY PROVIDED OR ANY PRODUCTS DERIVED FROM THE USE OF THE TECHNOLOGY; THE SUITABILITY, COMPLETENESS OR ACCURACY OF INFORMATION OR OTHER DATA PROVIDED IN CONNECTION WITH THIS AGREEMENT; OR ANY USE OF THE TECHNOLOGY OR PRODUCTS DERIVED FROM THE USE OF THE TECHNOLGY BEING FREE FROM INFRINGEMENT OF ANY THIRD-PARTY PATENT RIGHTS.

Licensee stewardship and regulatory obligations

INSTITUTE agrees to exercise diligent project and product stewardship and to take all necessary and appropriate action to properly prevent gene flow and/or development of resistance for all traits used in combination with COMPANY technology. INSTITUTE must obtain all necessary approvals in accordance with all applicable governmental statutes, rules and regulations in effect for genetically transformed plant material and related research and/or development field trials from all appropriate and relevant biotechnology regulatory bodies. INSTITUTE shall seek and obtain all necessary regulatory approvals and follow all applicable national and international regulatory guidelines (including those governing import and export of such materials) in each country. INSTITUTE shall require the same of all sub-licensees.

Indemnification of COMPANY

INSTITUTE agrees to assume all responsibility and liability for use of COMPANY technologies by the INSTITUTE and its sublicensees, as described in the terms and conditions to be set forth in this Agreement. INSTITUTE agrees to defend and indemnify COMPANY, and hold COMPANY harmless from all product and other liability claims alleged or arising from the use of COMPANY Technology by INSTITUTE and/or its sublicensees.

Confidentiality

During the term of this Agreement certain confidential information, data and materials may be sent to the INSTITUTE and placed in the INSTITUTE's custody by COMPANY personnel or be developed pursuant to this Agreement and maintained in the INSTITUTE's custody. The INSTITUTE agrees that such materials, information and data, except that which is or becomes public knowledge through the INSTITUTE's authorised disclosure, constitute the property of COMPANY and that the INSTITUTE will not use or disclose any such information, data or materials during or after the term of the Agreement without the prior written consent of COMPANY. All such materials, information and data in the INSTITUTE's custody shall be promptly delivered to COMPANY upon termination of this Agreement. When the INSTITUTE is required by law to disclose any such materials, information or data to an authorised government agency or to any other party, the INSTITUTE shall promptly notify COMPANY of the request prior to any disclosure.

It is further agreed and understood that specific information disclosed shall not be deemed to be available to the public or in either party's prior possession merely because it is embraced by more general information available to the public or in the other party's possession.

Cooperation of the Parties for Public Announcements and Releases

The Parties agree to consult with each other prior to either Party issuing press releases or making public announcements regarding COMPANY’s contribution to this Project.

Termination

Either party may terminate this Agreement upon at least sixty (60) days written notice to the other party should the other party commit a material breach of its obligations or be in default under any of the provisions of this Agreement, provided that the other party has failed to cure the breach or default (or, if such breach or default cannot be cured within the sixty (60) day period, the other party has not taken reasonable steps to cure the breach or default) within the same sixty (60) day notice period.

Termination Obligations

The termination of the Agreement shall not relieve either party of its obligations to the other in respect of

(i) maintaining the confidentiality of information, and

(ii) indemnification.

Assignability

The rights acquired herein by the INSTITUTE may not be assigned, transferred or sublicensed in whole or in part to any third party. Any attempted assignment, transfer or sublicense shall be void and shall terminate all rights of the INSTITUTE under this Agreement.

Notice

All notices required or permitted to be given under this Agreement shall be in writing and shall be delivered personally, given by prepaid telegram or mailed postage prepaid to the person named and addresses set forth below.

If to COMPANY: COMPANY

Attention: with a copy to: COMPANY
Attention: Intellectual Property Counsel

If to the INSTITUTE:

Attention:

Relationship of the Parties

In connection with this Agreement, each party is an independent contractor and as such will not have any authority to bind or commit the other. Nothing herein shall be deemed or construed to create a joint venture, partnership, fiduciary or agency relationship between the parties for any purpose.

Entire Agreement

This Agreement merges and supersedes all previous agreements respecting its subject matter.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered as of the date first shown above.

THE COMPANY

By _____
Name: _____
Title: _____

THE INSTITUTE

By _____
Name: _____
Title: _____

The Evolving International Regime of Liability and Redress Relating to the Use of Genetically Modified Organisms: A Preliminary Report

Shawn N. Sullivan
CIMMYT, Mexico

EXECUTIVE SUMMARY

Potential liability risks relating to the development, production, and marketing of agricultural products have existed for generations. However, the increasing use of genetic engineering and genetically modified (GM) crops introduces new liability issues.

Concerns for human health, conservation, and sustainable use of biological diversity and possible economic injuries have led to public opposition to, and strict regulation of, genetically modified organisms (GMOs) in many countries. Whether or not GM crops can cause physical harm, the perception that GM products may be unsafe or undesirable creates certain economic risks. These risks arise in part from the fact that opposition to GM products has closed some national markets to products containing GM materials. An example is the recent US litigation over Starlink maize, in which the unintentional commingling of GM maize – which was unapproved for human consumption – with conventional maize, exposed Aventis CropScience to millions of dollars in liabilities.

Most countries traditionally have dealt with agricultural risks within the general system of liability and redress that prevails under national law. Laws relating to breach of warranty, negligence, trespass, and nuisance are potential sources of liability in connection with the use of GM products. In addition, some countries have adopted new liability regimes that are specifically tailored to deal with GMOs.

Cartagena Protocol article 27 calls upon the parties to that agreement to investigate the "elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements" of GMOs. The process of considering such international rules is now under way. Among the issues being considered in this context are questions such as: Is a binding international law regime of liability and redress for GMOs the only possible outcome of the investigation called for by Cartagena Protocol article 27? If an international law regime is deemed necessary, is a generally applicable liability system sufficient or should there be a system specifically designed to deal with GMO-related injuries? What kinds of damages should be compensable under a liability and redress system? Who should bear responsibility for GMO-related losses? To what kinds of activities should a liability and redress system apply? To what kinds of GMOs should such rules apply? What should be the standard for proving that a person's actions caused damage? Should liability be imposed without regard to fault? What defences should be available to a potentially responsible party? What kinds of financial security mechanisms can facilitate redress of GMO-related injuries?

Public agricultural research institutes should acquaint themselves with liability and redress matters, as these issues have the potential to become significant obstacles in institutes' attempts to provide products to poor people in developing countries. To date, the public sector has been underrepresented in international discussions on liability and redress. However, there is still time

for the public sector to become more fully engaged in the debate. In addition, many donors are willing to help public sector research institutes to understand and develop capacity to deal with liability and redress matters. To facilitate the collection of relevant questions, comments and observations regarding liability and redress issues, a questionnaire at the end of this report solicits the views of public sector institutes.

1. INTRODUCTION

The prospect of incurring liability in connection with the production and marketing of agricultural and food-related products is nothing new. Since early in the 20th century, and in some cases even before then, developed country producers of food products that caused harm to consumers could expect to be haled into court or before other government bodies and required to make good the damage caused by a deleterious product. Likewise, as plant breeding became a more truly scientific enterprise and companies began producing seed of "elite" plant varieties, these companies sometimes found themselves having to pay farmers for lost yields due to inferior germination rates,[41] unexpected susceptibility to biotic or abiotic stresses,[42] and in general to the failure of the seed to live up to what was promised when it was sold.[43]

The risks of liability in the food and seed industries were not dramatically different from those in other fields such as the manufacture of machinery or pharmaceuticals. Consequently, it was possible for producers of food and agricultural products to factor these risks into the costs of their operation, and the insurance industry met the needs of significant producers by offering product liability insurance to mitigate the impact of these risks.

What is new in the context of liability risks posed in 21st century agriculture arises from the biotechnology revolution of the last three decades and the varying social, cultural, and legal reactions around the world to that revolution. The work of Werner Arber, Hamilton Smith, Daniel Nathans, Paul Berg, and other pioneers with restriction enzymes and DNA ligase made possible advances in recombinant DNA technology, exemplified by the first chimeric plasmids constructed by Stanley Cohen and Herbert Boyer.[44] These developments changed the world and the way many people think about life itself.

Genetic engineering moved from the realm of science fiction to everyday reality. Agricultural researchers began exploring the potential of genetic engineering to enable them to surpass the yield, nutritional, and productivity ceilings that seemed to be imposed by nature in conventional plant breeding. Multinational agribusiness companies began investing in genetically modified (GM) crops and, in some cases, had huge commercial successes.[45] In the US alone, by the year 2003, farmers planted 42.8 million hectares of GM crops.[46] In the public sector, too, genetic

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[41] See, e.g., Vaughn's Seed Store v. Stringfellow, 56 Fla. 708, 48 So. 410 (1908)(Florida Supreme Court affirmed breach of warranty judgment against seed vendor whose product failed to germinate).

[42] See, e.g., Jacob Hartz Seed Co., Inc. v. Simrall, 807 So. 2d 1271 (Miss. Ct. App. 2001)(Mississippi Court of Appeals upheld finding breach of warranty with regard to soybean seeds publicized as being disease resistant but which were infected by soybean mosaic virus); Latimer v. William Mueller & Son, Inc., 149 Mich.App. 620, 386 N.W.2d 618 (1986) (Michigan Court of Appeals upheld verdicts for breach of express and implied warranties with regard to bean seeds infected with halo blight).

[43] Helena Chemical Co. v. Wilkins, 47 S.W.3d 486, 44 Tex. Sup. Ct. J. 675 (Tex. 2001)(Texas Supreme Court affirmed breach of warranty verdict based on representation that sorghum seed was particularly suited for dry land farming).

[44] See generally I. Edward Alcamo, DNA TECHNOLOGY – THE AWESOME SKILL 69-84 (2d ed. 2001)(concisely summarizing history of development of modern biotechnology).

[45] See generally Daniel Charles, LORDS OF THE HARVEST – BIOTECH, BIG MONEY AND THE FUTURE OF FOOD (2001)(relating the story of the rise of the agricultural biotechnology industry).

[46] See Clive James, Preview: Global Status of Commercial Transgenic Crops: 2003, http://www.isaaa.org/kc/CBTNews/press_release/briefs30/es_b30.pdf.

engineering showed promise as a new tool for developing useful agricultural products for poor people in developing countries.

The acceptance of genetically modified organisms (GMOs), however, has been far from universal. Particularly in Europe but also in many other countries, the environmentalist movement perceived in this novel technology a new threat to the environment. With the advent of GM crops, environmental activists, some scientists, organic farmers, and others warned of a variety of potential harms to human health, to other species of plants and animals, and to entire ecosystems. In response, some countries imposed moratoria on the introduction of new GM crops.

Concerns about GMOs relate to several different types of alleged dangers. For example, there is concern that humans could be injured as a result of allergic reactions to antigens introduced via genetic engineering to a formerly benign food crop from other species.[47]

Some fear that antibiotic resistance genes, often used as selectable markers in genetic engineering, could migrate to microbes and create uncontrollable pathogens that might threaten human and animal health.[48]

With regard to the herbicide resistance traits that have successfully been incorporated into the genomes of certain crops such as cotton, soybean, and corn, concerns have been expressed that the resistance traits could be transferred to weedy relatives of the crops and create "super weeds" that could not be controlled.[49]

In the context of insect-resistant genes such as the *Bacillus thuringiensis* (B.t) genes, which express proteins that are toxic to certain insects, many fear that it will be difficult or impossible to prevent the emergence of huge insect populations that are no longer susceptible to Bt, which, in addition to its GM form, is a widely-used, naturally-occurring, topically-applied insecticide.[50]

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[47] Paul F. Lurquin, HIGH TECH HARVEST – UNDERSTANDING GENETICALLY MODIFIED FOOD PLANTS 148-49 (2002). The most widely-publicized instance underlying this contention is the series of experiments that the American company Pioneer Hi-Bred International, Inc. once conducted with soybeans that had been engineered to express proteins normally found in Brazil nuts. See LORDS OF THE HARVEST (cited in note 5) at 223-24. Many people have severe allergic reactions to allergens contained in Brazil nuts. A scientific study – which involved human test subjects as well as electrophoresis – of the experimental soybeans confirmed the presence of the allergen. See Julie A. Nordlee, Steve L. Taylor, Jeffrey A. Townsend, Laurie A. Thomas & Robert K. Bush, Identification of a Brazil-Nut Allergen in Transgenic Soybeans, N.E. J. OF MEDICINE, Vol. 334, No. 11, pp. 688-692 (March 14, 1996). Although Pioneer abandoned its research into this project and never brought it to market, the Brazil nut allergen episode fueled the controversy over GMO food crops. In a 1999 interim report on genetically modified foods, the British Medical Association (BMA), citing among other things the Pioneer example, called for an indefinite moratorium on transgenic agriculture pending further research on the spread of antibiotic resistance and new allergies. This BMA report was cited as a principal reason for the rejection by Zambia in 2002 of GMO food aid in the midst of a famine. See Andy Coghlan, Zambia's GM food fear traced to UK, http://www.newscientist.com/news/news.jsp?id=ns99993317 (Jan. 29, 2003). In March 2004 – after five years with no reported cases of GMO-induced allergies – the BMA issued a new report in whose tone was more moderate than its predecessor. It stated: "While we are not aware of any evidence that existing GM foods cause allergic reactions, it remains possible that any new food products could elicit new allergies…. The BMA shares the view that that there is no robust evidence to prove that GM foods are unsafe but we endorse the call for further research and surveillance to provide convincing evidence of safety and benefit". See BMA, Genetically modified foods and health: a second interim statement. http://www.bma.org.uk/ap.nsf/Content/GMFoods/$file/GM.pdf.

[48] Maarten J. Chrispeels & David E. Sadava, PLANTS, GENES AND CROP BIOTECHNOLOGY 536 (2d ed. 2003). Although evidence suggests that this possibility is remote, "[s]cientists have largely accepted that the risk of [antibiotic resistance] gene being passed on, however small, is too great to accept, and are phasing out [their] use". See Mark Henderson, Threat that never was, THE TIMES (London) Dec. 14, 2000.

[49] See Roger Dobson, Mutant weeds raise fear of disaster for farmers, THE TIMES (London) May 26, 1996.

[50] PLANTS, GENES AND CROP BIOTECHNOLOGY (cited in note 8) at 549-50.

Another contention is that the use of insecticidal transgenes could upset ecosystems by killing non-target, beneficial insects such as certain butterflies, bees, and wasps, which assist in pollination, and lacewig, which control certain plant pests.[51]

Some GMO opponents further argue that the traits resulting from genetic modification could give transgenic varieties an unnatural advantage, allowing them to outperform conventional varieties and displace or lead to the extinction of wild species.

The many uncertainties about GMOs, together with the "hysteria"[52] that surrounds their introduction into the human food supply in some countries, led Robert Hartwig, the chief economist for the New York-based Insurance Information Institute, to remark last year that "Genetically modified foods are among the riskiest of all possible insurance exposures that we have today".[53]

Researchers who are comfortable with the idea of GMO crops may be tempted to dismiss potential liabilities associated with those crops. Indeed, many of the fears cited above have been discounted by a significant body of scientists as unscientific, overstated, or within the realm of manageable risks.[54] However, it would be a grave error to assume that developers of GMOs cannot incur liability if any given concern proved to be unfounded. It is not the place of this report either to rebut or confirm GMO-related fears because, whether or not they are valid, they have led many European and other governments to impose strict controls on the introduction of new GMO crops. The fact that there is significant regulation of and public opposition to GMO products in many countries presents a real risk of liability because of the prospect of market rejection of crops and commodities containing GM materials. Acknowledging that social acceptance or disapproval of GMOs has a tremendous impact on potential risks in using this

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[51] See Testimony of Janet L. Andersen, Ph.D, Director, Biopesticides and Pollution Prevention Division Office of Pesticide Programmes Office of Prevention, Pesticides, and Toxic Substances US Environmental Protection Agency Before the Committee on Science Subcommittee on Basic Research, US House of Representatives (Oct. 19, 1999)("For ecological effects, EPA examines the exposure and toxicity of the plant-pesticide to non-target organisms, such as wildlife and beneficial insects"), http://www.epa.gov/ocir/hearings/testimony/ 101999ja.htm.

[52] Oxford University evolutionary biologist Richard Dawkins characterized the situation in this manner in 1998. See Charles Arthur & Steve Connor, Scientists worried by modified food risks, The Independent (Aug. 19, 1998). Of course, not all concerns about GMOs are hysterical. But while there are valid concerns about GMOs, a great deal of misinformation – as well as a disproportionate emphasis on the potential risks of GMOs in comparison with other, less-politicised risks – has often frustrated attempts at rational public debate and policy-making in this arena. Compare Modified food-aid fears slammed, BUSINESS DAY (Johannesburg, S.A.), March 6, 2003 ("[S]cientists complained that humanitarian groups … had frightened African government s into rejecting food aid. They said the groups had also alarmed starving populations. 'Some groups have told people that genetically modified products are dangerous and could cause cancer,' said the executive director of industry body Africabio, Prof. Jocelyn Webster") with 400 Bags of Bad Maize Destroyed On Court Orders, THE NATION (Nairobi, Kenya) Sept. 9, 2004 (reporting that more than 100 Kenyans "have in recent months died" as a result of eating maize contaminated with the naturally-occurring but "deadly aflatoxin mould").

[53] See Food biotech is risky business, WIRED NEWS (Dec. 1, 2003), http://www.wired.com/news/medtech/0,1286,61096,00.html.

[54] See, e.g., Nicola Cabibbo, "Study Document on the Use of 'Genetically Modified Food Plants' to Combat Hunger in the World", Science and the Future of Mankind: Science for Man and Man for Science, Pontifical Academy of Sciences (2001), http://www.vatican.va/roman_curia/pontifical_academies/acdscien/documents/sv%2099(5of5).pdf; Norman E. Borlaug, Ending world hunger. The promise of biotechnology and the threat of antiscience zealotry (2000), PLANT PHYSIOL. 124: 487-490.American Medical Association Council on Scientific Affairs, *Genetically Modified Crops and Foods* (2000), http://www.ama-assn.org/ama/pub/article/2036-4030.html. Of course, one cannot interpret such general support for GMOs as an indication that no concerns regarding GMOs are valid. Even the countries that have most unreservedly embraced GM crops acknowledge the risks potentially presented by this fledgling technology and have adopted elaborate biosafety regulations requiring pre-release toxicology and allergenicity testing of GMOs as well as other protective measures. Thus the issue is not whether there are risks – all fields of endeavor involve risks – but whether those risks can be managed in a reasonable and responsible manner.

technology, the global reinsurance company Swiss Re explained recently, "When assessing the future risk profile, the decisive element is not whether modern biotechnology is dangerous, but how dangerous it is perceived to be".[55]

As Swiss Re notes, public perceptions – whether or not they are accurate – can result in claims for economic damage to growers of non-GM crops. For example, if transgenes from genetically modified crops migrate in the cross-pollination of non-transgenic crops,[56] or if post-harvest GM produce becomes commingled with non-GM produce, producers of the GM crops could be exposed to liability if the non-transgenic crops lose market value (such as by loss of export markets or loss of organic certification) as a result of GM "contamination".[57]

Claims for economic losses of this nature have already been made against certain developers of GM crops. For example, in the US, Aventis CropScience became embroiled in massive litigation and agreed to pay millions of dollars to settle economic and alleged personal injury claims after its Starlink maize hybrid – which expressed the insecticidal protein Cry9C and was approved in the US for use as animal feed but not for human consumption – appeared in human food products.[58] In a provincial court of Saskatchewan, Canada, a class of organic farmers has brought claims against Monsanto Company and Aventis seeking compensation for, among other things, the ongoing costs of removing genetically engineered canola from certified organic farmers fields' and seed supplies.[59] In 2000, Advanta Seeds UK agreed to pay claims by British farmers who had to destroy crops of oilseed rape because the seed they purchased from Advanta contained GM materials due to "cross-pollination of [Advanta's] conventional crop seed by GM material on the Canadian plains".[60] The total payout by Advanta was expected to reach several million British pounds.[61]

2. SOURCES OF POTENTIAL LIABILITY UNDER EXISTING NATIONAL LAWS

As noted, the general issue of liability has been present in agriculture for generations. Over the years, most countries have managed to fit agricultural risks within their existing legal systems without the need to create specially-tailored legal regimes. This section of the report briefly

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[55] See Genetic engineering and liability insurance – The power of public perception, http://www.swissre.com/INTERNET/pwsfilpr.nsf/vwFilebyIDKEYLu/WWIN-4VFDC7/$FILE/genetic_eng.Paras.0003.File.pdf

[56] See Richard A. Repp, Biotech Pollution: Assessing Liability for Genetically Modified Crop Production and Genetic Drift, 36 IDAHO L. REV. 585 (2000).

[57] See, e.g., Charles Clover, The moral maze over GM crops – Concerns: could cross-contamination bring health risks?, THE DAILY TELEGRAPH (London, UK) March 10, 2004 ("Organic farmers, who stand to lose their certification if their crops are shown to be contaminated, are theoretically most at risk from contamination by GM maize in Britain"); Breaking new ground – Harmful or not, genetically engineered food could lead to knotty claims, VIEWPOINT, Vo.. 26, No. 2 (Fall 2001)("growers and producers of conventionally raised crops will suffer a loss if their produce is inadvertently mixed with genetically modified crops, even if there is no evidence of physical harm to humans, livestock or property").

[58] An extensive analysis of the regulatory steps followed in the Starlink matter is found in D. L. Uchtmann, Starlink™ - A Case Study of Agricultural Biotechnology Regulation, 7 DRAKE J. AGRIC. L. 159 (2000), http://www.farmdoc.uiuc.edu/legal/pdfs/DrakeStarLink.pdf. For the decision of the US District Court for the Northern District of Illinois in the consolidated Starlink litigation, which explains the bases on which liability was pursued against Aventis, see In re Starlink Corn Products Liability Litigation, 212 F. Supp. 2d 828 (N.D. Ill. 2002), http://www.ilnd.uscourts.gov/racerimg/5054547_50.pdf

[59] See Revised Statement of Claim, http://www.saskorganic.com/oapf/pdf/amended-claim.pdf

[60] James Meikle, Payout for farmers in GM seeds blunder, THE GUARDIAN (Manchester, UK) June 3, 2000.

[61] Steve Connor, GM mix-up firm will pay British farmers millions in compensation, The Independent (London, UK) June 3, 2000.

reviews some of the existing legal doctrines under national laws of some countries that could be relevant in assessing and planning for liability risks relating to GMOs.

Contractual claims

As a starting point, contractual liability is an obvious possibility for anyone who has promised that goods or services will conform to certain criteria. An example is a farmer who has contracted with a purchaser to provide GM-free produce but whose crops have been cross-pollinated with GM materials. Even if the farmer is entirely innocent and ignorant of the presence of GM materials in his produce, he can be held liable to the purchaser for failure to deliver what was promised.

Even if a merchant or producer has not openly made any promises about the quality or performance of his product, the applicable law may provide that the seller is deemed to have made a warranty that the product will conform to certain standards and/or be free of certain defects. Article 1645 of the French Civil Code requires a seller of defective goods to compensate the buyer for harm resulting from the defect if the seller knew of the existence of the defect. French case law, however, holds that one who sells defective goods in the course of his business is treated as if he knew of the defect.[62] In the US, the Uniform Commercial Code recognizes warranties of merchantability and fitness of for a particular purpose in covered sales of goods. Similar provisions appear in the UK Sale of Goods Act 1979[63] and the laws of many other countries.[64] "Thus, for example, where crops are sold for the purpose of manufacturing GM-free product, there may be an implied condition that the crops are suitable for this purpose".[65] And while liability to consumers in the first instance may be imposed on the immediate seller, that seller can often sue "up the chain" of distribution, so that liability may ultimately reach the manufacturer or developer of the product.[66]

All laws of this nature hold the potential for those involved with GMOs to incur contractual liability.

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[62] K. Zweigert & H. Kötz, AN INTRODUCTION TO COMPARATIVE LAW 676 (3d ed. 1998).

[63] See Paul Mitchell, The Development of Quality Obligations in Sale of Goods, 2001 L. Q. REV. 645.

[64] See, e.g., Artículo 44(b), Decreto Ejecutivo 25234-MEIC. Reglamento Ley Promoción Competencia y Defensa Efectiva Consumidor (Costa Rica), http://www.meic.go.cr/esp/informacion/reglapromo.html; Artículo 8, Decreto Legislativo Nº 716 (Peru).

[65] David Dalton, Liability Issues Associated with GM Crops in Australia, Science and Economic Policy Branch, Australian Government Department of Agriculture, Fisheries and Forestry (Sept. 2003) at 12**,** http://www.affa.gov.au/corporate_docs/publications/pdf/innovation/liability_issues_paper_final.pdf

[66] See, e.g., Ter Neuzen v. Korn, [1995] 3 S.C.R (Canadian Supreme Court)("liability is imposed for implied warranties of fitness for defective products supplied under contracts for work and materials as well as under contracts for sale. The purchaser has a remedy against the business seller, even absent negligence. The seller can always recover, up the chain of production, from the manufacturer"); Antonieski v. Graphic Enterprises Inc**.,** 22 Phila.Co.Rptr. 623 (1991)("Liability moves transactionally up the chain of distribution until the manufacturer pays for the breach of implied warranty of merchantability to the distributor who initially sold the goods"). One commentator has characterized this scenario as "the domino effect of warranty litigation up the chain". See Jane Stapleton, Duty of Care and Economic Loss: A Wider Agenda, 107 L. Q. REV. 249 (1991). Notably, the European Union's Product Liability Directive – which is not based on a warranty theory – anticipated "the dangers of indiscriminately targeting all parties down the chain of supply … and effectively avoided [those dangers] by the creation of a two-tier system of liability, whereby the mere supplier could escape liability if it could identify a party higher up the chain". See Jane Stapleton, Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective, 39 Washburn L. J. 363 (2000).

Tort claims

Another major source of liability that could apply to GMO-related activities lies with the branch of law known variously as tort, *responsabilité délictuelle*, *acto ilícito civil*, *unerlaubte Handlung,* etc.[67] All of these terms refer to a private or civil wrong or injury (other than breach of contract) for which a court may provide a remedy through a lawsuit for compensation.

Tort laws generally impose liability for negligent acts and omissions. Negligence means the failure to exercise that degree of care which a reasonable and prudent person would have exercised under the same or similar circumstances. Where a person has a duty to another to exercise such care and his failure to do so results in damage to the other person, then, subject to certain conditions and exceptions, tort laws impose liability on the negligent person for the injuries sustained.

In contrast to liability for negligent acts and omissions, in some circumstances, tort laws apply "strict liability". Strict liability means that a person who develops a product or engages in an activity that causes injury to others may be legally responsible even in the absence of actual knowledge of the hazard and even if that person exercised reasonable care under the circumstances. A celebrated English judicial decision to which many participants in discussions on GMO-related liabilities look for guidance[68] is *Rylands v. Fletcher*,[69] which held that, "the person who for his own purposes brings onto his land and keeps there anything likely to do mischief if it escapes must keep it at his peril". *Rylands v. Fletcher* has been applied in a number of countries in a variety of circumstances, specifically including cases of environmental contamination.[70] In addition, various legal systems have developed special rules imposing strict liability in connection with the marketing of defective products.[71]

Tort laws also recognize the right of a landowner to be free from unreasonable interference by others with the landowner's ability to enjoy possession of the land. Violations of this right are known by terms such as trespass, *entrada illegal*, *unbefugtes Betreten,* and other expressions, and give rise to responsibility for damage caused by the unlawful intrusion. Trespass laws have been applied in cases of the drift of aerially-applied agricultural chemicals that cause damage to neighbouring lands.[72] Many commentators consider these cases analogous to anticipated cases of GM pollen drift and resulting adventitious presence of GMOs in previously non-GM fields.

Another potentially applicable legal doctrine is known as the law of "nuisance". In English law, courts first recognized "private" nuisances, and by the sixteenth century, began to recognize "public" nuisances. These types of tort liability exist in the UK, the US, and other "common law" jurisdictions whose basic legal concepts are derived from the English system. One is subject to liability for a private nuisance (i) if one's conduct is the legal cause of an invasion of another's interest and (ii) if the invasion is either (a) "intentional and unreasonable" or (b) "unintentional

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[67] See generally A.J. Waldron, Transgenic Torts, 1999 J. BUS. L. 395 (discussing tort law options under English law).
[68] See, e.g., Daniel Lawrence, James Kennedy & Elizabeth Hattan, New Controls on the Deliberate Release of GMOs, EUR. ENVT'L L. REV. 51, 55 (Feb. 2002); Memorandum submitted by the Department of the Environment, Transport and the Regions and the Ministry of Agriculture, Fisheries and Food to the UK Parliament, April 1999, http://www.publications.parliament.uk/pa/cm199899/cmselect/cmenvaud/384/9042902.htm.
[69] (1865) 3 H & C 774; 159 ER 737 (Court of Exchequer); (1866) LR 1 Ex. 265 (Court of Exchequer Chamber); (1866) LR 3 HL 330 (House of Lords).
[70] See Simon Deakin, Angus Johnston & Basil Markesinis, MARKESINIS AND DEAKIN'S TORT LAW 498 (5th ed. 2003).
[71] See Dan B. Dobbs, THE LAW OF TORTS 977-1020 (2000)(surveying US product liability doctrines such as those embodied in the Restatement of Products Liability and section 402A of the Restatement (Second) of Torts).
[72] See, e.g., Schronk v. Gilliam, 380 S.W. 2d 743 (Tex. Civ. App. 1964); Cross v. Harris, 230 Or. 398, 370 P. 2d 703 (1962).

and otherwise actionable under the rules controlling liability for negligent or reckless conduct, or for abnormally dangerous conditions or activities".[73] The civil law[74] counterparts to nuisance – found in continental European legal systems and those derived from them – are known by various names such as annoyance, abuse of right,[75] i*mmissionsschutz,*[76] or *troubles de voisinage*.[77] These doctrines are used frequently in cases of environmental damage[78] and might be applied in cases of GMO-related injuries.

Liability for intellectual property infringement

Most individuals, companies, and institutes that create new GMOs seek patent protection over their inventions in the countries where they see the greatest likelihood of commercial success. However, the reach of patent protection is territorial; a patent issued on a product, for example, in the US, does not apply to activities that occur outside that country. For this reason, public agricultural research institutes located in developing countries are sometimes able to take advantage of the fact that certain biotechnology innovations are not patented where they conduct their work. In such a situation, it is possible lawfully to use the technology without obtaining the consent of one who holds a patent over it in another country. But if produce containing GM materials were exported from a developing country to one where those materials were patented, then there is at least the possibility that the importer could incur liability for patent infringement.

Another concern relating to the patenting of GMOs – in countries where the GM technology *is* patented – is that farmers whose non-GM crops cross-pollinate with GM plants in neighbouring fields might be held liable for patent infringement when they make use of progeny containing patented genes. In *Monsanto Canada, Inc. v. Schmeiser*,[79] the Canadian Supreme Court upheld a patent infringement judgment against a canola farmer who claimed that Monsanto's patented herbicide resistance gene appeared in his crops as a result of cross-pollination and wind-blown seed that produced "volunteer" plants. While the full implications of the Schmeiser decision remain to be seen, the case is cited by many observers as yet another scenario in which the deployment of GMOs can give rise to liability.

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[73] Cox v. City of Dallas, 256 F.3d 281 (5th Cir. 2001).

[74] The term "civil law" can be confusing because it has different meanings in different contexts. In comparative studies of different legal systems, the term "civil law" is used "to distinguish a system of law based upon the Roman legal tradition from a system based on the English common law". See N. Stephan Kinsella, A Civil Law to Common Law Dictionary, 54 LA. L. REV. 1265 (1994). However, the expression "civil law" or "civil responsibility" is often used in "common law" countries to distinguish obligations owed to a private person or entity from those held toward public authority under criminal law. Unless otherwise indicated from the context, as used in this report, "civil law" refers to legal systems derived from the Roman law.

[75] A. N. Yiannopoulos, Abuse of the Right of Ownership, 4 LA. CIV. L. TREATISE, PREDIAL SERVITUDES § 41 (2d ed.).

[76] See James Gordley, Immissionsschutz, Nuisance and Troubles de Voisinage in Comparative and Historical Perspective, ZEITSCHRIFT FÜR EUROPÄISCHES PRIVATRECHT 9 (1998).

[77] One French legal expert states that *troubles anormal du voisinage*, or "abnormal vicinity nuisance" is "the most traditional and the most used legal basis … in instances of industrial or agricultural pollution". See Pierrick B. Le Goff, The French Approach to Corporate Liability for Damage to the Environment, 12 TUL. EURO. CIV. LF 39 (1997)(quoting Geneviève Viney, Les principaux aspects de la responsabilité civile des entreprises pour atteinte à l'environnement en droit français, La Semaine Juridique (JCP), Edition Générale, Doctrine, 39 (1996)).

[78] See, e.g., Barrette v. Ciment du Saint-Laurent Inc., No. 200-06-000004-930 (Quebec Super. Ct. 2003)(applying article 976 of the *Code civil du Québec* to a case involving cement dust and particulate emissions, noise, and odors from a cement plant), http://www.jugements.qc.ca/php/decision.php?liste=4623828&doc=5F0741420B551700.

[79] 2004 SCC 34, http://www.lexum.umontreal.ca/csc-scc/en/rec/html/2004scc034.wpd.html.

Special liability regimes for GMO-related damage

Some countries and sub-national governments have passed or are considering legislation that establishes liability specifically for GMO-related injuries. In some cases, these laws create special regimes applicable only to GMOs, while in others GMO-related issues are explicitly incorporated into a general environmental liability system. An example of the latter approach is the European Union's new Directive on Environmental Liability.[80] An EU institutions press release, issued prior to the adoption of the directive, described this aspect as follows:

The [directive] covers both contained use and release into the environment of GMOs. GMOs would cause environmental damage when they cause damage to biodiversity, water, and/or soil (in this latter case, the soil contamination should create a potential or actual serious harm to human health). When the release of the GMO has been specifically authorised or when it was not possible to foresee the damaging effect of the GMO on the basis of the best science, there would be no strict liability. In case of negligence (for example, when the operator does not follow the instructions given by the manufacturer on how to use the GMO), the operator would still be liable. It should be noted that traditional damage, i.e. to the crop of an organic farmer, is covered by the civil liability systems of the Member States, and not by this [directive].[81]

This is a largely unharmonised movement, and the result is a maze of potentially or demonstrably inconsistent liability systems. Space does not permit individual consideration of each of these systems in this report. However, examples of these laws are cited in subsequent sections of this report in order to illustrate some approaches that have been proposed in the context of an international liability system.

Criminal sanctions

In addition to imposing liability for damages and the obligation to remediate losses, some national laws now also impose criminal responsibility for serious infractions. These criminal sanctions add the prospect of fines and possible incarceration to the already daunting possibility of civil liability. Both natural persons and juridical entities such as corporations and other organisations can incur criminal responsibility. And while it is impossible to incarcerate a corporation – which, after all, is only a "fiction created by law"[82] – the consequences of criminal liability at the level of a corporation or organisation can be devastating. In addition to the possibility of fines, a juridical entity that has been convicted of a crime can be debarred from entering into or bidding on public contracts in many jurisdictions.[83]

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[80] Directive 2004/35/CE of the European Parliament and the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage.

[81] EU Institutions, **"**Frequently asked questions on the Commission's proposal on Environmental Liability**",** Press Release (January 24, 2002), http://europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=MEMO/02/10%7C0%7CRAPID&lg=EN.

[82] See Klein v. Board of Supervisors, 282 US 19 (1930).

[83] For example, the US Federal Acquisition Regulation provides that contractors may be debarred from entering into contracts with the federal government, or into subcontracts funded by the federal government, if they have committed an "offense indicating a lack of business integrity or business honesty that seriously and directly affects the present responsibility of a Government contractor or subcontractor". See 48 C.F.R. § 9.406.2(5). Debarment is not an automatic consequence of conviction but a discretionary act on the part of the head of a government agency. See 48 C.F.R. § 9.406-1 (a) ("The existence of a cause for debarment … does not necessarily require that the contract be debarred; the seriousness of the contractor's acts or omissions and any remedial measures or mitigating factors should be considered in making any debarment decision").

Criminal laws specifically relating to GMOs are a new phenomenon, and most countries have not yet adopted them. Examples of some that have are the following:

- In 2002, section 420 of Mexico amended its federal penal law[84] to impose a prison sentence of up to 9 years and a substantial fine upon anyone who, in contravention of applicable norms, introduces into the country, sells, transports, uses as feed, or releases to the environment, "any genetically modified organism that alters or could alter negatively the components, structure, or functioning of natural ecosystems".

- Section 3(7) of the Slovenian Management of Genetically Modified Organisms Act provides that, "A legal or natural person who performs work with GMOs in a contained use, deliberately releases GMOs into the environment, or places products on the market, is criminally liable and liable for damages in compliance with the law in the event of damage resulting from their GMO management (liability principle)".[85]

Criminal sanctions can be very effective deterrents to unlawful behaviour. However, "[the] blunt determination of criminal law – guilty or innocent – may discourage socially beneficial activities".[86] This seems almost certain to occur in the case of criminal laws that are uniquely-targeted against certain uses of GMOs, unless such laws are very clear and specific and require the presence of criminal intent (*mens rea*) as a prerequisite to criminal liability.

Even in those countries that have not specifically criminalised conduct relating to GMOs, developers of GMOs should be aware that they are nonetheless subject to the general criminal laws. These include general prohibitions against making false statements to government agencies – a criminal law provision that can become relevant in virtually any type of regulatory proceedings.

3. INTERNATIONAL ENVIRONMENTAL LAW RELATING TO BIOLOGICAL RESOURCES

The doctrines explained in the previous section are matters of national law. Normally, the reach of those laws extends only throughout the territory of the country that enacted them.[87] In addition to these national law measures, for more than a decade, there have been efforts underway at an international level to persuade nations to agree to deal with GMOs in a globally consistent manner. As noted below, in recent years these efforts have focused specifically on the establishment of an international regime of liability and redress.

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[84] http://www.cibiogem.gob.mx/normatividad/delitos_bioseguridad/codigo_penal_federal.html

[85] Unofficial English translation provided by courtesy of Mag. Julijana Lebez Lozej, Ministry of the Environment, Spatial Planning and Energy, Republic of Slovenia.

[86] See Geraldine Szott Moohr, Federal Criminal Fraud and the Development of Intangible Property Rights in Information, 2000 U. ILL. L. REV. 683.

[87] This is the so-called "territoriality" principle of jurisdiction. See Mark W. Janis, AN INTRODUCTION TO INTERNATIONAL LAW 322 (2d ed. 1993). As explained by US Supreme Court Justice Oliver Wendell Holmes, territorial jurisdiction is a "general and almost universal rule" holding "that the character of an act as lawful or unlawful must be determined wholly by the law of the country where the act is done…. For another jurisdiction, if it should happen to lay hold of the actor, to treat him according to its own notions rather than those of the place where he did the acts, not only would be unjust, but would be an interference with the authority of another sovereign, contrary to the comity of nations, which the other state concerned justly might resent". American Banana Co. v. United Fruit Co., 213 US 347 (1909). There are, however, exceptional situations when a state will exercise extraterritorial jurisdiction over one of its nationals, over acts in a foreign country which produce effects within national territory, over acts in a foreign state committed against one of its citizens, over pirates and hijackers, and over those who commit gross abuses of human rights. See AN INTRODUCTION TO INTERNATIONAL LAW at 324-30.

The Convention on Biological Diversity

The first widely-ratified international agreement to deal explicitly with GMOs is the Convention on Biological Diversity (CBD). The CBD was produced in 1992 in Rio de Janeiro, at the United Nations Environment Programme's "Earth Summit". The Earth Summit also produced a statement of principles known as the Rio Declaration on Environment and Development.[88] Principle 15 of the Rio Declaration states the following "precautionary principle", which has become important in discussions regarding the safety of GMOs:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The CBD aims primarily to encourage conservation and sustainable use of biological diversity and fair and equitable sharing of the benefits of genetic resources. Biological diversity is defined as: "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems".

The CBD entered into force in 1993 and there are now 188 parties, a notable exception being the US. The CBD is implemented through a Conference of the Parties (COP), a meeting of representatives of the states-parties that have ratified the Convention.

CBD article 14(2) deals specifically with "living modified organisms," or "LMOs",[89] and calls on the COP to "examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter". The CBD secretariat began organising workshops and holding consultations regarding liability and redress in the mid-1990s.[90]

The Cartagena Protocol on Biosafety

At the second COP of the CBD in November 1995, the COP established an Open-Ended Ad Hoc Working Group on Biosafety to draft a proposed protocol on biosafety. Negotiations, which began in June of 1996, were suspended in February 1999 due to the inability to reach agreement on several key issues among the major negotiating blocs: the European Union; the Like-Minded Group of developing countries; the Miami Group of major agricultural exporters (Argentina, Australia, Canada, Chile, US,[91] and Uruguay); and the Compromise Group (Japan, Korea, Mexico, Norway, and Switzerland).

The negotiations later resumed, and in January 2000, the COP adopted the draft protocol proposed by the Working Group. This protocol, known as the Cartagena Protocol on Biosafety, has been signed and ratified by 107 countries. It entered into force on September 11, 2003.

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[88] http://www.unep.org/Documents/Default.asp?DocumentID=78&ArticleID=1163.

[89] "LMO" has essentially "the same meaning as" the term "GMO". See Helmut Gaugitsch, Biosafety in the International Context – The Cartagena Protocol, ENVIRON SCI. & POLLUT. RES. 9 (2) 2002. Given the wider familiarity of the public with the term GMO, this report uses the term GMO in the place of LMO, except where the term LMO appears in official texts.

[90] See, e.g., UNEP/CBD/BS/WS-L&R/1/3.

[91] Because the US is a non-signatory to the CBD, it participated in these discussions only as an observer.

The goal of the Cartagena Protocol is, in accordance with the "precautionary principle" stated in Principle 15 of the Rio Declaration, to provide protection against adverse effects on the conservation and use of biological diversity as a result of the transfer, handling, and use of living modified organisms that are produced by the application of modern biotechnology.

The Cartagena Protocol provides countries the opportunity to obtain information before new GMO organisms are imported. It acknowledges each nation's right to regulate genetically engineered organisms, subject to existing international obligations. It establishes a "Biosafety Clearing-House" to help countries exchange scientific, technical, environmental, and legal information about GMOs.

The Cartagena Protocol creates an advance informed agreement (AIA) procedure that in effect requires exporters to seek consent from an importing country before the first shipment of a GMO intended to be introduced into the environment, such as seeds for planting or microorganisms for bioremediation.

The Cartagena Protocol requires shipments of GMO commodities that are intended for direct use as food, feed, or for processing to be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment". It also establishes a process for considering more detailed identification and documentation of GMO commodities in international trade.

With regard to liability and redress, article 27 of the Protocol provides that,

the Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.

This article set in motion a new process – separate from the one already under way in the context of CBD article 14(2) – for the creation of a liability and redress regime.[92]

Like the CBD, the Cartagena Protocol is implemented through a Conference of the Parties. The first COP, acting as a Meeting of the Parties, under the Cartagena Protocol was held in Kuala Lumpur, Malaysia, in February 2004. The prominence with which the issue of liability and redress was treated in this first meeting signals the importance that Cartagena Protocol article 27 is likely to assume in the near future.

4. SOME OF THE KEY ISSUES TO BE DETERMINED IN LIABILITY & REDRESS NEGOTIATIONS AT THE INTERNATIONAL LEVEL

The objective of Article 27 of the Cartagena Protocol

As is true of all texts that represent a compromise among groups with different objectives, identifying one clear purpose underlying Cartagena Protocol article 27 is not feasible. However, it can safely be said that this article reflects the concerns of many nations that some international

[92] UNEP/CBD/COP/6/12/Add. 1 at 8. The CBD Secretariat has acknowledged that the processes under CBD article 14(2) and Cartagena Protocol article 27 should be coordinated.

standards must exist to govern the imposition of liability for damages due to the use of GMOs and to ensure that such damage will actually be remedied. The article's instruction that the COP should take "due account of the ongoing processes in international law in these matters" is an acknowledgement that a number of international instruments already exist for the purpose of allocating legal responsibility in certain cases of environmental damage.[93]

Liability regimes typically serve one or more of the following three functions: (i) addressing a violation of law after the violation has occurred; (ii) deterring or otherwise preventing damage before it can happen; and (iii) repairing damage after it has occurred.[94] Various participants in discussions regarding Cartagena Protocol article 27 have emphasised different rationales for proposed liability and redress rules. Predictably, governments of chief GMO-exporting countries tend to favour the compensatory rationale of liability laws. Governments of countries that see themselves as likely net importers of GMOs, on the other hand, tend to argue for a stricter, more preventative regime. And some GM opponents seem to see strict biosafety regulation – including the establishment of tough liability rules – as a convenient substitute for outright bans on GMOs in their strategy to inhibit the introduction of GM crops. For example, the June 28, 2004, edition of *The Scientist* reported on the reaction of Henning Strodthoff, a "gene technology expert at Greenpeace", to a new German law that, among other things, "increases liability for planters of GM crops".[95] According to *The Scientist*, Strodhoff praised this as "progress", and remarked: "If GM crops are allowed, then we need strong regulations". When asked what Greenpeace would prefer in a GM planting law, he said: "Our goal is to stop GM planting. We want GM planting to be forbidden".[96]

The highly polarised views of GMOs that currently prevail are unlikely to be reconciled in the near future. Thus, it is unrealistic to expect universal agreement on a clearly-defined set of objectives underlying a Cartagena Protocol liability and redress system. However, from the perspective of public sector developers of GM crops, it is certainly desirable that both the rationale and the rules of any such system be clear and specific, because uncertainty in any liability system tends to curtail legitimate and beneficial activities as well as those which may be harmful.[97] Moreover, the deterrent effect of such a system on beneficial activities is likely to be most acute in the case of public institutions, which do not market patented products for profit. This is because the GMO developer in these cases has less ability than would a for-profit

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[93] Among these conventions are the 1979 Convention on Long-range Transboundary Air Pollution; the 1985 Vienna Convention for the Protection of the Ozone Layer; the 1989 Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal; and the 1992 United Nations Framework Convention on Climate Change. See UNEP/CBD/ICCP/2/3 and UNEP/CBD/WS-L&R/2.

[94] THE CARTAGENA PROTOCOL ON BIOSAFETY: A RECORD OF THE NEGOTIATIONS 82 (CBD Secretariat 2003).

[95] Ned Stafford, Law may stifle German science, The Scientist (June 28, 2004), http://www.biomedcentral.com/news/20040628/02/.

[96] Id.

[97] Cf. Katherine A. Davis, An International Drug Administration: Curing Uncertainty in International Pharmaceutical Product Liability, 18 NW. J. INT'L L. & BUS. 685 (1998)("The reality in the pharmaceutical market is that, with no way to accurately anticipate a product's liability risks, and with the only weighable consequence being the potential for extremely large liability exposure, the safest course of action for pharmaceutical companies is to keep a product off the market or increase prices to such a level that pharmaceutical companies can cover the costs that result from uncertain liability risks. This reality has created distortions in the international pharmaceutical market, increased both manufacturing and consumer costs, and chilled research and development of new pharmaceutical products"). See also Westman Comm'n Co. v. Hobart Int'l, Inc., 796 F.2d 1216 (10th Cir. 1986)("if the antitrust laws applicable to vertical dealings are uncertain or inefficient, they are likely to have a chilling effect on beneficial, procompetitive market interaction").

enterprise to cover its risks by allocating a portion of profits to a reserve fund for contingent liabilities.[98]

Does Article 27 require the establishment of an international regime?

A threshold question in deliberations under Cartagena Protocol article 27 is whether a liability and redress system carrying the force of binding international law is necessary or desirable. The Australian government has taken the position that, "Article 27 of the Protocol does not *require* the establishment of a liability regime – it requires a process to be established to appropriately elaborate international rules and procedures in the field of liability and redress for damage resulting from transboundary movement of LMOs".[99] Other participants in the debate are adamant that a liability system must be established under international law, while some discussions acknowledge that a non-binding international agreement – perhaps along the lines of the International Undertaking on Plant Genetic Resources – is a more realistic objective in the light of the four-year timeline established by article 27. A recent commentary on this issue observes:

The differences in national regimes demonstrate the need for substantive international standards on liability for LMOs, especially if the regime is to serve a deterrent function. But even if the parties negotiate and ratify a binding international instrument there are potential problems due to the lack of participation by significant LMO exporting countries.[100]

A generally applicable or sectoral liability and redress regime?

Another fundamental issue on which opinions seem to be deeply divided is the specificity of the article 27 regime. Some observers claim that GMOs should be subject to a uniquely-applicable, tailor-made system of liability and redress. One advocate of such a so-called "sectoral" liability system acknowledges that, "[t]his may not be the most ideal situation" and that "[i]n a perfect world, environmental liability rules would be common to all areas of international environmental law".[101] However, he contends that "in the real world", the "existing liability rules do not provide sufficient guidance", and that the development of an international GMO liability and redress system should not be delayed pending the creation of a comprehensive international environmental regime whose negotiation might not be concluded for many more years.[102]

Critics of the "sectoral" approach note that,

Scientifically speaking, the mere use of biotechnology does not create a technology-*specific* environmental risk. Rather, environmental safety of biotechnology products and activities is determined by the same parameters as those applicable to other products and activities. The risk an organism or related activity may pose to the environment depends on the organism's properties

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[98] The situation of not-for-profit developers of GMOs is somewhat analogous to that of manufacturers of generic pharmaceuticals, who can be disproportionately affected by expansive liability rules due to those manufacturers' lower price margins. See Payton v. Abbott Labs, 386 Mass. 540, 574, 437 N.E.2d 171, 189-90 (1982)("Imposition of such broad liability could have a deleterious effect on the development … of new drugs, especially those marketed generically").

[99] UNEP/CBD/BS/TEG-L&R/1/INF/1 at 3.

[100] Elizabeth Duvall, A Liability and Redress Regime for Genetically Modified Organisms under the Cartagena Protocol, 36 GEO. WASH. INT'L L. REV. 173 (2004).

[101] Philippe Cullett, Liability and Redress in Biotechnology: Towards the Development of Rules at the National and International Levels (International Environmental Law Research Centre Feb. 2004) at 9, http://www.ielrc.org/Content/WP04011P.pdf.

[102] Id.

and resulting interaction with the environment. This is the case regardless of whether those properties are the result of breeding technologies – either traditional techniques, or biotechnology – or "natural" evolution.[103]

In a national law context, treating damage from the use of GMOs as one among many different forms of environmental damage is the approach taken in the *Ley de Bioseguridad de Organismos Genéticamente Modificados*, which was approved by the Mexican federal Senate on April 24, 2003, but has yet to be approved by the Chamber of Deputies, as is required in order for the law to enter into force. In a report accompanying the legislation,[104] the combined Senate commissions that produced the legislation explained that:

Liability for damage to the environment and to human health caused by activities involving GMOs was another theme that arose in the Consultative Forum on the initiative. In this regard, it was felt that this subject does not relate exclusively to the biosafety of GMOs, but belongs to the field of environmental and health matters…. The [biosafety] initiative governs administrative responsibility that derives from noncompliance or violation of its provisions, specifies infringements, and establishes their respective sanctions in the administrative arena, all of which are imposed without prejudice to [sanctions] which arise by virtue of criminal responsibility, in terms of the applicable penal provisions, or by virtue of civil or environmental liability, which is dealt with expressly in article 203 of the *Ley General del Equilibrio Ecológico y la Protección al Ambiente*.[105]

Scope of activities to which the regime should apply

By its terms, Cartagena Protocol article 27 applies only to "damage resulting from transboundary movements" of GMOs, and not to activities or events which take place entirely within the territory of a single state. In the light of this provision, the Australian government – along with some other nations – has taken the position that it, "is not necessary to develop a regime under the Protocol that goes beyond that transboundary movement", and "[n]ational legislation should be adequate to deal with national impacts and should be better placed to deal with the environmental and legal means of redress within such jurisdictions".[106] Not surprisingly, other participants in the debate have argued the opposite – that the international regime should be as broad as possible. Moreover, many observers have insisted that any international system of liability should be without prejudice to any remedies that may exist under national laws.[107]

The reality is likely to be that liability and redress initiatives will be proposed, debated, and enacted at many different levels in the domestic legislation of any given country at the same time that negotiations regarding Cartagena Protocol article 27 are under way. As a practical matter, this means that producers of GMOs may be subject to overlapping liability regimes and that they may have to concern themselves with liability issues at all stages in the development, production,

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[103] Stanley H. Abramson & Laura M. Reifschneider, Model Act – Proposed Provisions for a Transparent, Effective and Workable Biosafety Regulatory Framework (Dec. 2002), http://www.arentfox.com/modelbiosafetyact.pdf.
[104] http://www.senado.gob.mx/gaceta.php?&lk=152/Dictamen_Bioseguridad_Final_22ABR03.html.
[105] The concept of regulating new kinds of organisms on the basis of their characteristics, rather than the specific process by which they were produced, is the method employed by the Canadian government for approval of plants with novel traits (PNTs). See Phil Macdonand, Regulation of Plants with Novel Traits (PNTs) in Canada, in Proceedings, Public Awareness and Risk Assessment in Agricultural Biotechnology, August-September 1999, http://www.agbiotechnet.com/proceedings/May%202000/8_macdonald.pdf.
[106] Australian Government, Department of Foreign Affairs and Trade, Cartagena Protocol on Biosafety - Correspondence with Secretariat of the Convention on Biological Diversity, http://www.dfat.gov.au/environment/bsp/bio_sub/sep2003_questionaire.html.
[107] UNEP/CBD/BS/COP-MOP/1/9/Add.1 at 6.

and delivery of GMOs. This is because, irrespective of how broad any international regime may ultimately be, it is unlikely that national policymakers will intentionally leave gaps in the law where GM crops would be entirely free of liability considerations.

Who should bear legal responsibility for GMO-related losses?

Public international law, as exemplified by treaties, is largely a matter of the rights and obligations of nation-states. With notable exceptions relating to human rights, international law traditionally has had little to say about the responsibilities of non-state actors. There is, however, a framework of state responsibility that recognises the obligations of states to each other in environmental matters. One of the best-known cases of state responsibility under international environmental law is the Trail Smelter arbitration, which involved damage to farms in the US state of Washington produced by the aerial drift of pollutants from a privately-owned factory in British Columbia, Canada. In a statement that has come to represent a basic principle of state responsibility, the arbitration tribunal held that, "[n]o State has the right to use or permit the use of its territory in such a manner as to cause injury…in or to the territory of another, when the case is of serious consequence and the injury is established by clear and convincing evidence".[108] Thus, under the Trail Smelter standard, a state is responsible for the environmental consequences of activities in its own territory when it causes actual injury in a neighbouring state's territory.

Because international law is primarily concerned with the rights and responsibilities of states, the liability and redress regime contemplated by Cartagena Protocol article 27 may focus initially on the rights and obligations of nations that import and export GMOs. There already is, however, substantial pressure to ensure that responsibility for GMO-related losses reaches beyond the nations involved and is imposed on private companies and individuals involved in import and export, as well as on producers, manufacturers, transporters, and others significantly involved in production and distribution of GMOs.

Some national liability regimes have adopted a broad view of who may be held liable. The Nigeria Biosafety Guidelines, for example, provide that liability can be imposed on "any person who carries out any activity in relation to LMOs/GMO(s) or products thereof", which directly or indirectly causes harm.[109] Those guidelines go on to state that, "Liability shall attach to the applicant, the person responsible for the activity, which results in the damage, injury or loss, as well as to the provider, supplier or developer of the LMOs/GMO(s) or products thereof".

In a report on possibilities for coexistence of GM and non-GM crops, the UK's Agricultural Biotechnology Commission stated that all its members agreed that there "should be access to compensation for farmers who suffer financial loss as a result of their produce exceeding statutory thresholds through no fault of their own".[110] The Commission suggested that, in the absence of insurance coverage, parties responsible for providing compensation could include: "Government; agricultural biotechnology companies holding GM consents; consent-holders and other parts of the agricultural supply industry, or a combination of Government and industry; or all farmers through a small levy on harvested crops".[111]

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[108] Trail Smelter Arbitration, US-Can., 3 UNR.I.A.A. 1905 (1974), 35 AM. J. INT'L L. 684 (1941). This principle is restated in Principle 2 of the Rio Declaration on Environment and Development.
[109] http://bch.biodiv.org/doc/leg/nigeria_biosafety_guidelines_2001.pdf.
[110] See Martha Grekos, GM Coexistence and Liability Report Published, [2004] J. PLANNING & ENVT. L. 582.
[111] Id.

Some observers have suggested that liability for GMO-related harm should be imposed directly on the holders of patents that cover a GMO.[112] Such arguments are driven in part by the possibility that patent holders could hold farmers liable for using the patented GMOs, even when they appear in the farmer's field through cross-pollination or wind-blown seed. There is a strongly-felt belief in many circles that if patent holders can hold farmers liable in this situation, then the patent holders must in turn bear responsibility for losses incurred by the farmer as a result of the adventitious presence of GMOs.[113]

Arguments to impose liability on intellectual property holders have influenced legislation and regulation in a number of jurisdictions. For example, Senate Bill No. 2304,[114] introduced earlier this year in the legislature of the US state of North Dakota, provided that, "A producer has a claim for relief against the patent holder of a transgenic wheat seed for damages sustained" under certain circumstances.

In the context of public sector agriculture for the benefit of developing countries, imposing liability on patent holders could produce unintended consequences. First, since there is no such thing as a global patent – patents are issued by national governments or regional organisations such as the *Organisation africaine de la propriété intellectuelle* – it is possible for different persons to hold patents on the same technology in different countries. Moreover, because many developing countries did not allow the patenting of GM products until recently, many technologies that are likely to be used for humanitarian purposes in developing countries are not patented in those countries. Further, one can imagine the disincentives for private enterprises to donate GM technology for humanitarian uses that would arise from a rule imposing liability on patent holders and developers of GMOs in all cases. While a company may be happy for its technology to be used on a royalty-free basis, for humanitarian purposes, in a given developing country, it may look at the matter differently if its generosity could expose it to significant liabilities.

What kinds of GMOs should be covered by the regime?

GMOs can be developed for a diverse array of purposes, and not all of them would present all of the risks that have been most widely publicised. For example, at least some elements in the standard list of GMO-related risks would not be relevant in the case of cereal plants that have been engineered to express higher than normal levels of micronutrients, and that do not use antibiotic markers or possess herbicide- or insect-resistant traits.

Recognising that GMOs are not all alike, in the course of negotiations over the text of the Cartagena Protocol, the European Community proposed to include an annex to the protocol, which would have listed GMOs that "are not likely to have adverse effects".[115] However, the Like-Minded Group insisted that the Protocol must apply to all GMOs, and the proposed annex was deleted.[116]

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[112] See, e.g., Liability and Redress in Biotechnology (cited in note 61) at 6; UNEP/CBD/BS/TEG-L&R/1/2 at 5.
[113] Liability and Redress in Biotechnology (cited in note 61) at 6. Cf. Maria Lee & Robert Burrell, Liability for the Escape of GM Seeds: Pursuing the "Victim"?, 65 MODERN L. REV. 517 (2002)("If patent law sees contaminated farmers as malefactors, and regulation concentrates on environmental and health issues, an alternative form of control may be available in the civil liability provisions of the common law").
[114] See S.B. 2304, A Bill for an Act to create and enact a new chapter to title 4 of the North Dakota Century Code, relating to damages for cross-pollination with transgenic wheat; and to provide for a legislative study council, http://www.state.nd.us/lr/assembly/58-2003/bill-text/DAGR0400.pdf.
[115] THE CARTAGENA PROTOCOL ON BIOSAFETY: A RECORD OF THE NEGOTIATIONS 118 (CBD Secretariat 2003).
[116] Id. at 25.

Although the idea of such an annex did not prevail in the negotiations, the logic of not treating all GMOs as if they were identical remains attractive to many participants in the ongoing liability debate. For example, the Australian government has made the point that,

When looking at existing international liability regimes, it is important to recall that the Protocol does not regard all LMOs as dangerous. The Protocol specifically leaves that decision to governments to determine, on the basis of risk assessments and in accordance with their national environmental circumstances. International liability regimes that treat the transboundary movement of a good as inherently dangerous are therefore not readily applicable.[117]

Defining damage or loss in the liability regime

Among the most critical issues in the liability and redress debate are those which relate to the definition of damage. What kinds of losses will be compensable under the liability regime? How will the amount of loss be quantified? Should there be a minimum threshold of damage, and if so, what should it be?

Neither CBD article 14(2) nor Cartagena Protocol article 27 specifies what is meant by damage, although the CBD article is specifically concerned with "damage to biological diversity". Some participants thus have suggested that the definition of damage in the evolving international liability regime should be restricted to damage to matters affecting human health and the conservation and sustainable use of biological diversity.[118] Others argue for an expansive definition that would include the complete array of losses that could be attributable to the presence of GMOs, including economic, bodily, and environmental injuries.[119]

Valuation of losses is a related issue. In general, legal compensation systems are intended as much as possible to restore an injury or loss scenario to the *status quo ante*. In the case of bodily injuries, this normally means that the responsible party will be obligated to pay for at least the costs of medical treatment (in some cases including a period of continuous health monitoring as well as surgical interventions), plus lost wages, diminished earning capacity and the like. In cases of environmental injury, valuation of the loss often means determining the amount of money necessary to restore the environment to the condition it occupied prior to the injury. Environmental liability systems generally adopt the "polluter pays" principle, according to which an operator causing environmental damage or creating an imminent threat of such damage should bear the cost of necessary preventative and remedial measures.[120] If public authorities undertake such measures, they will seek to recover those costs from the responsible party.

In the Cartagena Protocol discussions, a similar approach has been proposed in cases of damage to biological diversity.[121] In a document released by the CBD Secretariat on September 9, 2004, regarding the assessment of damage under Cartagena Protocol article 27, it was observed that,

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[117] Australian Government, Department of Foreign Affairs and Trade, Cartagena Protocol on Biosafety - Correspondence with Secretariat of the Convention on Biological Diversity, http://www.dfat.gov.au/environment/bsp/bio_sub/sep2003_questionaire.html.
[118] UNEP/CBD/BS/TEG-L&R/1/2 at 4.
[119] Id.; UNEP/CBD/BS/COP-MOP/1/9/Add.1 at 3.
[120] See, e.g., Directive 2004/35/CE of the European Parliament and the Council (cited in note 40).
[121] Valuation of damage requires that there be some knowledge regarding the injured persons or things as they existed prior to the injury. In the context of damage to biological diversity, the point has been made that most developing countries do not have comprehensive catalogues of the flora and fauna that exist within their territories.

For the situation where it is possible to restore the loss of the conservation and sustainable use of biological diversity to the status that existed before the damage occurred, the possible approach employed could include restoration by replacing the same components at the same place, or in a condition which leads to a status that is deemed to be equivalent or superior to the baseline condition. Measures could be taken such as replanting of cultivated or wild plants, by release of fish or by building up a stock of wild animals. For the situation that is not possible for restoration, reinstatement by equivalent, or complementary remediation could be used to restore a loss to the conservation and sustainable use of biological diversity. It was also noted that the valuation of damage to the conservation and sustainable use of biological diversity in monetary terms only becomes an issue if there is no requirement to repair damage by means of measures of reinstatement.[122]

The idea of requiring a minimum threshold of damage in order for an injury to be compensable does not, in itself, seem to be highly controversial. CBD article 14(1)(a) indicates that, at least for purposes of that convention, not every theoretical "injury" to biodiversity is of concern, but only those events which can have "significant adverse effects on biological diversity". And, as emphasised by the International Law Commission, the need for injury to rise above a *de minimis* level before it can be compensable is also a basic principle of international law:

The harm must lead to a real detrimental effect…. Such detrimental effects must be susceptible of being measured by factual and objective standards.... In carrying out lawful activities within their own territories, States have impacts on each other. These mutual impacts, so long as they have not reached the level of "significant", are considered tolerable. [T]he threshold of intolerance of harm cannot be placed below "significant".[123]

Any controversy over damage thresholds almost certainly will revolve around what is "significant" harm. This will depend in part on the nature of the injury in question. For example, what if the minute adventitious presence of transgenes due to a tortuous act were to cause an organic farmer hundreds of thousands of dollars in damages? In such a case, the fact that only a tiny quantity of GM materials is present might not have much bearing on whether the damage is compensable, provided that the responsible party acted in an unlawful manner. In cases where the alleged damage takes the form of genetic erosion or variation within originally non-transgenic species, however, there seems to be much more room for debate about the point at which a compensable injury occurs.

Fault-based or strict liability?

A fundamental issue in liability and redress systems is whether legal responsibility will be imposed only when a party is at fault or whether fault is irrelevant. A significant body of opinion holds that liability for damage caused by the use of GMOs should be strict. For example, H.B. No. 2176, a bill introduced in the legislature of the US state of Hawaii earlier this year, would impose strict liability – defined as "absolute liability for any damages that result from the use of genetically engineered organisms without respect to intention or negligence" – on "any person who genetically engineers organisms for their use as food".[124]

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[122] UNEP/CBD/BS/TEG-L&R/1/2

[123] International Law Commission, Draft Articles on International Liability for Injurious Consequences Arising out of Acts not prohibited by International Law (1996), Commentary to Draft Article 2, paragraphs 4, 5.

[124] See A bill for an act relating to liability for genetically engineered food, H.B. No. 2176, http://www.capitol.hawaii.gov/sessioncurrent/bills/HB2176_.htm.

Proof of causation

Traditionally legal systems have not imposed liability for harm unless there is some reasonable assurance that the accused party's conduct or product actually caused the injury in question. In environmental matters, the requirement of proof of causation as a prerequisite to the imposition of liability has sometimes been a difficult hurdle for plaintiffs seeking damages or other relief. Many observers believe that the causation requirement would be similarly hard to prove in cases of GMO-related damage, among other things, because, "[d]amage to biodiversity would be most likely from diffuse [factors, a] cumulative impact from a number of sources rather than from a clearly identifiable single source".[125]

Among the proposals put forward in the context of liability and redress for GMO-related damage is the suggestion that legal systems should employ a rebuttable presumption. Rebuttable presumptions are not uncommon in environmental legislation.[126] An example of an existing law that uses this procedural device is the Austrian Law on Genetic Engineering, which provides that:

If depending on the case the LMO subject to the contained use or a deliberate release may cause damage, it is presumed that the damage is due to the characteristics of the LMO resulting from the genetic modification. To rebut the presumption, the notifier demonstrates the likelihood that the damage is not due to the characteristics of the LMO resulting from the genetic modification (or in combination with other hazardous characteristics of the LMO).[127]

Standing/right to bring claims

In the event of damage related to the use of GMOs, who should have the right to sue or otherwise bring a claim? Normally a party who suffers "direct" injury is entitled to make a claim. However, often public authorities also have the ability to sue. In some cases, parties who purport to represent the interests of injured persons, who lack the resources to sue, may be given the right to make a claim. In general, the broader the class of persons who are entitled to sue, the more likely a potentially responsible party is to be sued.

Defences available to the potentially responsible party

In instances where harm has occurred, there may still be reasons why liability should not be imposed on an otherwise responsible party. For example, other legal regimes recognise defences to liability (i) in cases of so-called "acts of God" or force majeure (occurrences entirely beyond the control of the party); (ii) where a party has done all that is possible under the existing state of knowledge and technology (state of the art) to prevent harm; (iii) where a party has complied with all regulatory requirements; (iv) where a third party's actions caused the injury; and (v) where the injured party voluntarily and knowingly consented to the action before it was taken.[128]

Most legal regimes impose statutes of limitations, prescriptive periods, or other doctrines whose effect is to foreclose the possibility of liability after the passage of a certain amount of time. One example highlighted in a report on a liability and redress workshop in the context of the

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125 UK Agriculture and Environment Biotechnology Commission, Liability Sub-Group, Draft Paper on Issues for Discussion, Feb. 2002, http://www.aebc.gov.uk/aebc/about/papers/aebc0207.htm.

126 For example, under the US Resource Conservation and Recovery Act, used oils that contain more than 1,000 ppm halogens are considered to be hazardous waste because they are presumed to have been mixed with halogenated hazardous waste. See 40 C.F.R. § 261.3.

127 See UNEP/CBD/ICCP/3/3 at 6.

128 MARKESINIS AND DEAKIN'S TORT LAW (cited in note 30) at 540, 759.

Cartagena Protocol is the Swiss law on genetic engineering.[129] It provides that a claim must be brought within three years after the claimant has knowledge of the damage and, in any event, no more than 30 years after the injury occurred.[130]

Financial security mechanisms

Frequently, in cases involving environmental remediation, the party determined to be responsible for contamination is insolvent and cannot pay the costs of remediation. Recognising that similar situations are likely to arise under the Cartagena Protocol system of liability and redress, in February 2004, the Cartagena Protocol COP acknowledged the need to encourage the development of financial security mechanisms that would pay for remediation when the responsible party cannot.[131] The most frequently-mentioned mechanisms for ensuring that redress and remediation will occur are (i) a requirement that potentially responsible parties carry liability insurance that would cover the risk; (ii) a requirement that they post a bond or other security with an appropriate public authority; and/or (iii) the establishment of a victims' compensation fund. Any of these mechanisms could impose significant additional costs on public sector producers of GMOs. And in many cases none of these options may be within reach of the public sector.

In the first instance, it may be very difficult to obtain insurance coverage for GMO-related losses. For a great many years, most liability insurance policies have expressly excluded coverage for contamination or pollution unless it arises from a sudden and accidental event.[132] Depending on how courts apply seemingly arcane rules of insurance policy interpretation, such an exclusion might or might not apply to an event of GMO-related "contamination". However, in the 1980s, many companies in the international insurance industry began using a more comprehensive, "absolute" pollution exclusion, which excludes coverage for all pollution-related losses, regardless of how they happen.[133] Not surprisingly, given their incentive to reduce their companies' potential exposure under liability policies, some insurance industry representatives take the position that "any substance in the wrong place at the wrong time" – including GM components – constitutes "pollution" that is excluded by such policy provisions.[134]

Despite the standard liability policy exclusions mentioned above, a New Zealand commission wrote in 2002 that "[e]xisting liability policies are likely to provide cover" for genetic engineering applications.[135] Nevertheless, the commission quickly added that, "the position may change quite soon".[136] Indeed, there has been an increasing trend, among companies that insure farming risks, toward specifically excluding all types of damages that might be associated with GMO crops, including even losses due to arson or vandalism by GMO opponents.[137] For example, in 2003, the UK-based company NFU Mutual stated that it would exclude the following GMO-related losses from coverage under its policies:

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[129] UNEP/CBD/BS/WS-L&R/1/3 at 5.
[130] Id.
[131] UNEP/CBD/BS/COP-MOP/1/9/Add.1 at 13.
[132] See David A. Gaudioso, A Matter of Interpretation: The Judicial Quagmire Concerning the Sudden and Accidental Exception to the Pollution Exclusion Clause, 2 VILL. ENVTL. L.J. 373 (1991).
[133] See Limited and Absolute Pollution Exclusions Defeat Insurer's Duty to Defend Environmental Cleanup Action, 25 No. 9 INS. LITIG. REP. 328 (2003).
[134] See Breaking new ground (cited in note 17).
[135] See Report of Royal Commission on Genetic Modification 321 (July 27, 2001), http://www.gmcommission.govt.nz/RCGM/index.html
[136] Id.
[137] See, e.g., Paul Brown, Insurers refuse to cover GM farmers: Leading companies liken risk to thalidomide and terrorism, THE GUARDIAN (Manchester, UK), Oct. 8, 2003.

NFU Mutual will not indemnify the insured in respect of any liability arising from the production, supply of, or presence on the premises of any genetically modified crop, where liability may be attributed directly or indirectly to the genetic characteristics of the crop.

In particular, no indemnity will be provided in respect of liability arising from the spread or the threat of spread of genetically modified organism characteristics into the environment or any change to the environment arising from research into, testing of, or production of genetically modified organisms.[138]

Some insurers have stated that they place GMO-related risks in the same risk category as losses due to asbestos exposure,[139] war, nuclear accidents,[140] and terrorism,[141] and one company has been quoted as saying that, "The worry is that GM could be like Thalidomide [a morning sickness medication that caused serious birth defects in humans in the 1960s, and] only after some time would the full extent of the problems be seen".[142] Because insurance companies will not underwrite risks whose magnitude and likelihood of occurrence cannot be actuarially predicted, the insurance industry is unlikely to voluntarily begin offering express coverage for GMO-related risks until the current uncertainty produced by social, political, and economic pressures has subsided.

An alternative to insurance would be a requirement that persons who introduce GMOs to the environment must post a bond or other security to guarantee fulfilment of regulatory requirements and to serve as a compensation fund in the event of injuries to third parties.[143] In this context, a bond is a promise to pay a sum of money which is secured by an insurance policy or assets which have been pledged to support the obligation. In the event that the promisor fails to comply with the requirements, the insurance company becomes liable on its bond to pay the promised sum, or in the case that property has been pledged as security, the property may be forfeited.

The problem with insurance bonds is that, as noted above, there is much doubt about whether insurance companies will be willing to underwrite risks relating to GMOs. If such insurance were available, the premiums would constitute an additional cost that public research institutions may not have factored into their strategy and budget for distributing GMO-related products for humanitarian purposes.

In the absence of insurance bonds, a requirement that companies or institutes pledge assets – such as cash, land, equipment, etc. – to secure their performance would present additional potential obstacles to humanitarian projects involving GMOs. Few universities, institutes, or their national agricultural research system partners have unencumbered assets available to use for such security, and even fewer have the inclination to use them for such purposes.

The third alternative that is frequently mentioned is a government-established compensation fund, which would be composed of contributions by various users of GMOs and would compensate

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[138] Id.
[139] See Liability insurance may be too risky for GM industry, THE WORLD TODAY (June 21, 2000), http://www.abc.net.au/worldtoday/stories/s142446.htm
[140] Rob Edwards, Farmers told GM crops are too dangerous to insure, THE SUNDAY HERALD (Glasgow, UK), March 10, 2002.
[141] Sean Poulter, Is GM the new Thalidomide?, DAILY MAIL (London) Oct. 8, 2003).
[142] Id.
[143] See Royal Commission Report (cited in note 95) at 323.

farmers who incur GMO-related losses.[144] For example, a recent Danish proposal placed before the European Parliament provided that,

[G]rowers of GM crops are responsible for maintaining the proper distances vis-à-vis conventional or organic producers. Producers of conventional or organic crops who believe their production has been damaged by genetic drift from a GM field may apply to the government for compensation, provided they have a minimum loss of DKK 5,000 (about 690 Euros…Compensation will be financed by a fund, partly based on taxes paid by farmers and partly by a tax of DKK 60 (about 8 Euros) per hectare on GM crop plantings. [145]

Placing financial responsibility on growers of GM crops is not likely to be a viable option in most developing countries, among other reasons because resource-poor farmers generally will not have the financial means to make such contributions. Accordingly, many proposals suggest that compensation funds should be funded by biotechnology companies and other developers of the GMOs instead of by farmers. [146]

Considerations of developing countries & institutions working for them

Developing countries and nongovernmental organisations that are interested in them have already been involved in the Cartagena Protocol liability and redress discussions. According to a recent "synthesis of views" that were submitted to the CBD Secretariat,

Several submissions expressed concern that developing countries, because of a lack of appropriate technology and capacity, are particularly vulnerable to the potential damage to the environment and human health that may be caused by introduction of LMOs into their territories.[147]

Another submission focused on the need of developing countries that receive food aid to know the nature of the food that is being offered sufficiently in advance for the recipient country to decide whether to accept the aid.[148]

To date, it appears that the voices of public agricultural research institutions, and of collaborative efforts to bring biotechnology innovations to developing countries for humanitarian purposes, have either been underrepresented in discussions regarding liability and redress or have not been heard at all. As one knowledgeable observer recently remarked,

The negotiations for a Liability & Redress regime in the Protocol entirely ignore the scenario in which the technology developer is, say, a Consultative Group on International Agricultural Research (CGIAR) centre or a national university or a government agency from a developing country. The negotiations are likely to use scenarios about the seed sector and the food chain similar to the private sector for crops such as hybrid corn, and from there to extrapolate towards a

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[144] A similar mechanism exists in the US in the context of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, which established the "Superfund" trust.
[145] See Hasse Kristensen, Denmark – Biotechnology – Proposed Danish Legislation for GM Co-Existence, USD.A. FOREIGN AGRICULTURAL SERVICE GAIN REPORT (March 8, 2004), http://www.fas.usda.gov/gainfiles/200403/146105616.pdf .
[146] For an example of an English proposal along these lines, see No protection for GM-free farmers, SCUNTHORPE EVENING TELEGRAPH (Scunthorpe, UK), Feb. 23, 2000.
[147] UNEP/CBD/BS/TEG-L&R/1/2 at 2.
[148] Id. at 3.

general requirement of containment and segregation of GM and non-GM crops that is simply not achievable for most subsistence crops in centres of genetic diversity.[149]

As discussed in greater detail in the following section of this report, public agricultural research institutions must begin to study this issue and lend their experience and perspective to the debate.

5. WHAT DOES THE EVOLVING LIABILITY & REDRESS REGIME MEAN FOR THE PUBLIC SECTOR?

Whether one likes it or not, the global movement to establish liability and redress rules relating to the use of GMOs is not simply going to disappear, nor should it. It is appropriate for government authorities to enact such rules that are responsible, measured and grounded in the relevant scientific, economic, and cultural realities. What should be avoided, though, is the possibility that liability rules could be made so intimidating and drastic that humanitarian research, development, and delivery projects could be rendered impractical or unworkable and thus have to be abandoned.

From now on, all public agricultural research institutions that hope to use GMOs in making an actual impact on the lives of poor people in developing countries should take account of liability and redress issues. This is not primarily because public institutions could find themselves with huge liabilities (although this is also at least a possibility). The real potential "danger" is that the application of unsound or ill-considered liability rules could thwart the humanitarian goals for which many public agricultural research institutions are working.

It is possible that public institutions could produce potentially life-saving technologies, only to find it impossible to distribute those products to their intended beneficiaries. Even if the institution were willing to take the risk of liability, draconian liability rules could dissuade partners, who assistance may be critical to the success of a humanitarian project, from providing needed inputs. Anecdotal accounts suggest that fear of potential liability has already caused some public institutions to experience difficulty in persuading donors of genetic technologies to remove "research only" restrictions contained in material transfer agreements that accompanied the genes in question.

Continued uncertainty and concerns about potentially crippling liability could also discourage NARS partners, funding agencies, and local distribution agents and dealers from cooperating with public institutes in the development and delivery of GMO products. Alternatively, fear of liability could lead important collaborators to demand that the public institution indemnify them against any potential liability. Because many public institutions are prohibited by their charter from entering into such indemnification agreements, and because research institutes can hardly be expected to underwrite risks that insurance companies will not touch, demands of this nature could quickly lead to the total breakdown of many worthwhile collaborations.

Liability and redress regimes also can impose additional costs in the distribution of GM products, which should be factored in the budgets of public sector humanitarian projects. In addition, some important donors, notably including the UK's Department for International Development, have begun to require plans for risk management in the projects that they fund, and potential liabilities obviously should be considered in such plans. Liability issues are thus one among many extra-scientific items – also including intellectual property rights, public relations, and biosafety

[149] Willy De Greef, Commentary: The Cartagena Protocol and the future of agbiotech, NATURE BIOTECHNOLOGY 22:7 at 811 (July 2004).

regulation – that must play a role in a well-defined strategy for distributing public goods to needy persons.

If what has been said so far seems to paint an unwelcome picture of the future for publicly funded agricultural research, there is also good news. The level of awareness of liability issues is rising among public institutes and their donors, and some donors have expressed a willingness and even eagerness to help research institutes to build capacity to deal with these issues. These donors may be inclined to see an institute's forthright attempts to confront the liability issue as welcome evidence of forward-looking, realistic thinking.

In addition, experts have developed and are continuing to develop "stewardship" measures, which are designed to minimise potential adverse impacts on health, the environment, and economic conditions by GM products.[150] The public sector should familiarise itself with stewardship standards and incorporate them into its standard mode of operation.

Liability and redress rules that specifically affect the activities of public agricultural research are in their infancy. An exotic patchwork of laws, rules, and regulations in national legislatures has begun to take shape. However, current proposals for an international liability system in accordance with article 27 of the Cartagena Protocol are still embryonic and very wide-ranging. There is still time for public institutions to bring their unique perspective to the ongoing international conversation.

Frequently legislative and regulatory proposals – including those relating to liability – are publicised and comments from the public are invited prior to their being made final. Such "notice and comment" procedures present excellent opportunities for public agricultural research institutes to tell their story and explain what is often an underemphasised aspect in international negotiations on liability and redress.

Public institutions with a real stake in the outcome of these debates should coordinate their efforts to understand and help shape the liability and redress debate. They should study carefully developments within the Secretariat of the Convention on Biological Diversity and activities conducted in the context of the Cartagena Protocol, as well as local developments in the countries, provinces, and states where they anticipate distributing products for humanitarian purposes. Research collaborations such as the Generation Challenge Programme may, in fact, provide an ideal context for public institutions to engage in the coordinated assessment of and response to liability developments.

[150] See, e.g., Thomas P. Redick, Stewardship for Biotech Crops: Strategies for Improving Global Consumer Confidence, 44 JURIMETRICS J. 5 (2003).

6. GLOSSARY

Biodiversity – the term used in the Convention on Biological Diversity to refer to the variability among living organisms from all sources, including, inter alia, terrestrial, marine, and other aquatic ecosystems and the ecological complexes of which they are part: this includes diversity within species, between species, and of ecosystems.
Bond – a promise to pay a sum of money in the event that the promisor fails to comply with statutory or other requirements. Such a bond is usually secured by an insurance policy or other assets, which are forfeit if the promisor fails to comply with the requirements.
Cartegena Protocol on Biosafety – a legally binding international agreement that is designed to provide a framework for the safe trans-boundary movement of living modified organisms. The Protocol entered into force on September 11, 2003.
Civil law – a system of law based upon the Roman legal tradition.
Common law – a system of law based upon the English legal tradition.
Compromise Group – in negotiations over the Cartagena Protocol, a bloc of countries comprised of Japan, Korea, Mexico, Norway, and Switzerland.
Convention on Biological Diversity (CBD) - a legally binding international agreement opened for signature at the Earth Summit in Rio de Janeiro in 1992. There are now 188 parties to the CBD. The CBD's objectives are: the conservation of biological diversity (biodiversity); the sustainable use of biodiversity's components; and the equitable sharing of benefits derived from genetic resources.
Express warranty- an affirmation of fact or promise made by a seller to a buyer which relates to the goods or services sold and becomes part of the basis of the parties' bargain.
Genetic engineering – the genetic modification of organisms by recombinant DNA techniques.
Implied warranty – a promise regarding the quality of goods or services which the law deems to be implied in a contract.
Indemnification – an arrangement in which one party legally exempts another from liability for damages or loss or assumes such liability for another.
Liability – legal responsibility, either civil or criminal, as determined by a court, other public authority, or private tribunal such as an arbitration panel.
Like-Minded Group – in negotiations over the Cartagena Protocol, a large bloc of developing countries that sought strict controls on the use of GMOs.
Living modified organism – the term used by the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to refer to any biological entity that possesses a novel combination of genetic material obtained through the use of *modern biotechnology*, which in turn is defined as the application of: a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b. Fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.
Miami Group – in negotiations over the Cartagena Protocol, a bloc of major agricultural exporting countries (Argentina, Australia, Canada, Chile, United States, and Uruguay) that are significant producers and exporters of GM products.
Negligence - failure to exercise that degree of care which a reasonable and prudent person would have exercised under the same or similar circumstances. Where a person has a duty to another to exercise such care and his failure to do so results in damage to the other person, tort laws impose liability on the negligent person for the injuries sustained.
Nuisance - A private nuisance is a nontrespassory invasion of another's interest in the private use and enjoyment of land. A public nuisance, on the other hand, involves an unreasonable interference with a right common to the general public
Potentially responsible party – a person or entity that is or may be liable for environmental or other damage or loss.

Precautionary principle – an approach that governments sometimes apply to deal with risks, especially environmental and health risks, arising from new technology or new products. Article 11.8 of the Cartagena Protocol on Biosafety adopts the following statement of the precautionary principle: "Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects … shall not prevent that Party from taking a decision … in order to avoid or minimise such potential adverse effects".
Rebuttable presumption – an assumption of fact that is accepted by a court or tribunal as true until disproved.
Responsabilité délictuelle – the French civil law equivalent to common law torts.
Statute of limitations – a legislative act providing that civil claims for damage shall be barred after a certain period of time.
Stewardship – a wide range of actions aimed at minimising environmental impacts throughout a product's life cycle.
Strict liability - liability imposed without regard to the defendant's negligence or intent to harm.
Tort – in the common law, a private or civil wrong or injury (other than breach of contract) for which a court may provide a remedy through a lawsuit for compensation.
Trespass – a common law tort defined as an entry on another person's property without lawful authority and doing some damage, however inconsiderable, to that property. A person may commit a trespass by physically entering upon another's land or by causing a thing or third person to enter the land.
Troubles de voisinage – a civil law concept, similar to nuisance in the common law, which permits one to recover damages for abnormal neighbourhood annoyances.

Open Source Mechanisms: The Example of BIOS

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1. BIOTECHNOLOGY AND AGRICULTURE

The polarised debate

Millions of farmers worldwide try to grow food and maintain adequate livelihoods under poor and risky growing conditions while suffering from poverty, hunger, and poor health. Around the world, more than 800 million people go to bed hungry. Some 5 million die every year from nutrition-related illnesses. More than 70% of the world's population lives in rural areas in developing countries and depend on agriculture to provide income and food security. For most people in developing countries, a better standard of living depends on increasing productivity in agriculture. Agricultural biotechnology has the potential to help farmers in developing counties produce more by developing new crop varieties that are drought-tolerant, resistant to insects and weeds, and able to capture nitrogen from the air. In addition, biotechnology has the potential to make the foods farmers produce more nutritious.

Nevertheless, the role of modern biotechnology in agriculture and food security is the subject of increasing debate and controversy. The real heat in the debate stems back to the late 1980s, when rapid scientific and technological advances added new dimensions to the discussions. Industry consolidation, the increasing commercialisation of genetically modified foods, the expansion of proprietary research and products, the growth in activities and influence of environmental activists, and the increasing food security in the world, particularly in Africa, has made for a difficult environment for assessment of the potential role of biotechnology in addressing food security. The ability to discuss the potential of biotechnology, how, and under what circumstances it might address problems facing millions of poor farmers, becomes hamstrung between two extreme poles. At one end are those who tout biotechnology as a panacea, a box that if checked off will solve the problems of world hunger without other efforts and without real risk. At the other end are those who associate all biotechnology with genetically modified organisms (GMOs), link biotechnology with nothing but danger and risk and see no potential benefits whatsoever. They believe that the development, commercialisation, and application of the technology should be stopped.

The confusion created by the resulting polarised debate makes it difficult for developing countries to derive benefits from the technology while minimising the associated risks. While not a panacea, biotechnology as it could apply to agriculture and human nutrition has the potential to help address problems that affect billions of lives.

The Generation Challenge Programme and IP mechanisms

The CGIAR's Generation Challenge Programme (GCP) reflects the belief that biotechnology research, together with appropriate policies, better infrastructure, and traditional research methods, can bring benefits to millions of poor farmers and consumers. The GCP was created to use advances in molecular biology to harness the rich global heritage of plant genetic resources

and create a new generation of crops that meet the needs of resource-poor people. The majority of biotechnology research is done by a few private corporations that focus on the agricultural sectors of industrial countries, where they expect the highest rate of return on their investment. Driven by the private sector, the trend in industrialised countries has been toward the expansion of the scope and/or applications of patents and plant breeders' rights to biomaterials. These trends are replicated (through bilateral and multilateral pressures) in the legal systems of developing countries. If ensuring that the GCP's products make it from the lab to resource-poor farmers is integral to its work, the GCP will have to grapple with the mechanisms by which it – and its partners – will relate to and/or manage intellectual property rights.

Fortunately, the GCP is not alone in its concerns or need to find new ways of "doing business". Traditionally, secrecy and protection were considered two of the main pillars of the biotechnology industry and were seen as essential to generate innovation and economic yield. But today, researchers from both the private and public sectors are concerned that instead of promoting innovation, IP systems have manacled scientific knowledge production and generated transaction costs. The explosion of patenting has created a thicket of rights that is contrary to the dissemination and fluid exchange of research tools that typically characterise agricultural research. Scientists face restricted access to some crucial enabling technologies and general uncertainty as to whether they will find themselves on the wrong side of infringement litigation. If industry innovation is hampered by how the current system functions, the stifling effect of proprietary ownership of basic research tools for the development and use of biotechnology to improve human well-being on a global scale should come as no surprise.

One of the most interesting approaches for researchers and institutions eager to exploit the promise of biotechnology is based on the open source paradigm of the software movement. This paper will begin by briefly reviewing the philosophy and practice associated with open source software and in particular its copyleft licenses. Next the paper will explore the similarities and differences presented by biotechnology, in particular how copyright law (the most relevant area of IP for software) and patent law (the most relevant area of IP for biotechnology) may present different issues. Finally, the paper concludes with a summary of the main features of some of the current efforts in this field of particular relevance to the GCP.

2. OPEN SOURCE APPROACHES

Open source software

The term "open source" stems from the technical characteristics of most software and from a resistance to the commercial practices arising from these characteristics. Software is created using programming language – the source code – that humans can understand. To be executed by the computer, source code must be translated by the machine into a machine-readable format called the "object code". Unlike source code, object code is difficult for humans to understand. Commercial software is distributed primarily only in machine-readable or object code format. In the initial stages of software development, computer programmers freely exchanged code amongst themselves. In the 1970s, however, private companies began to exploit the difference between source and object codes and to use intellectual property rights to protect software developments that formerly would have been freely exchanged. Distributing software without the source code makes it difficult for competitors to reverse engineer or learn from software distributed. The act of withholding it is used by commercial software firms to maintain proprietary control over their products.

The open source movement believes that source code should be freely accessible and available. In open source projects, source code is distributed with the object code so that it can be studied, improved, and modified by other programmers. A description of the variations among projects and philosophies in the movement is beyond the scope of this paper,[151] but the primary consideration underpinning most of the projects is that software should be available without restraints upon modification, examination, or redistribution. Norms of sharing combine with the utilitarian justification that open source is a better means of producing software when compared with the products of the traditional hierarchical firm model. The open and collaborative nature of the projects lead to higher quality products developed in a shorter time and at less cost.[152]

Studies of innovation show that the most successful researcher-developed technologies are those that the key stakeholders – the people who built, bought, or used the technology – modified the most.[153] The evolution of optimal solutions to challenges is best-served by a process coined "learning selection" whereby the key stakeholders – software engineers, computer hackers, or farmers, as the case may be – are motivated to interact with each other and share knowledge. Through a decentralised and democratic process where key stakeholders interact in improving a technology and in making those improvements available, knowledge is embedded in the technology. While some argue that the open source software movement is a model for decentralised, democratic decision-making and ownership, this characterisation ignores some important details. Examination of the most prominent open source software projects shows that they are actually tightly controlled by a small number of project leaders who direct the development of the project. In fact, the role of reputation and normative constraints in open source software development is very similar to the traditional culture of science where work was traditionally published and accessible with quality ensured through peer-review.

The open source software movement is also not necessarily anti-business as the success of businesses like Red-Hat[154] and the support of big businesses such as IBM in open source software development demonstrate. Services associated with software have proven to have commercial value without undermining the primary tenets of the open source movement. In addition, proprietary products are not prohibited long as the primary software remains available without restraints upon modification, examination, or re-distribution.

The open source software projects have developed a set of novel legal mechanisms aimed to ensure that communally produced code remains freely available and is not captured into closed, proprietary forms. The concerns are addressed through licenses that accompany the distributed source code. A variety of licenses have been developed which display a range of terms and conditions intended to address different concerns over capture[155] but they all require that the recipient of the software must be provided the source code.

The most prominent versions of such licenses are those that require further licensees who improve or modify the software to make such modifications available on the same terms as the initial software as licensed. The license also precludes the addition of any legal terms besides

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[151] Dibona, Chris, et.al., *Open Source: Voices from the Open Source Revolution.* O'Reilly Open Source. 1999.
[152] See, for example, Raymond, Eric, *The Cathedral and the Bazaar*, O'Reilly, 1999.
[153] Douthwaite, Boru,, *Enabling Innovation: A Practical Guide to Understanding and Fostering Technological Change*, Zed Books, 2002.
[154] See, www.redhat.com
[155] For example, some OS licenses impose restrictions on the modifications of the licensed software, others do not. Some forbid commercialization of the licensed software while others permit or require fees for use of the code.

those initially found in the license.[156] The licenses are commonly referred to as "copyleft" to demonstrate their differences between the objective of this approach – continued accessibility of creative works – and what many felt was the growing trend in copyright law in terms of accessibility.

It is important to understand that copyleft is not "anti-intellectual property", but is in fact a use of intellectual property, in this case copyright. Copyleft licenses use the property rights arising from copyright to ensure adherence to the terms of the license. Essentially, the activity of the licensee in copying, distributing or modifying the source code is a facial violation of the copyright holder's exclusive rights, but the copyright holder agrees not to assert those rights as long as the licensee's activity is conducted under the conditions set out in the license. In the case of open source, the conditions include redistributing the code under the same conditions by which it was obtained. Hence, the underlying copyright provides the property right basis for the license, but it is enforced only if additional property rights accrue.

Biotechnology: parallels to open source software

Because of many analogous factors, including the need for innovation to be affordable and more decentralised in order to be meaningful, the open source movement in software development presents an interesting model in distributive technological development for agricultural innovation. Thus far, biotechnology is being developed largely with a view towards simple and immediately profitable so-called solutions to complex ecological problems. Some authors argue that what has happened in the seed industry is directly comparable to computer software in the 1970s and hence some version of open source may also have direct relevance to agricultural research and development.[157] These authors note that like computer programmers who traditionally shared code freely among themselves, for millennia farmers exchanged seed and allowed others to grow and reproduce it. Then, in both software and agriculture, private companies sought to appropriate for themselves that which previously would have been shared. They sought to replace a public property regime with a private one. As noted above, in software, an innovative legal mechanism called copyleft was developed to ensure that no one could take someone else's copyleft protected programme, change it, and then prevent others from copying and changing it too.[158] An open source initiative in agriculture would be based on the inclusive, relatively decentralised,[159] and democratic model of open source inviting all innovators to participate if they abide by the rules of making their innovations available for further research and improvement. The idea is based also on the logic that farmers are both users and innovators of technology. The model could be applied for the development of plant varieties, for agro-machinery, for biotechnologies, and for the sharing of information and knowledge.

Biotechnology: divergences from open source software

An open source initiative in agriculture will not just happen. It will need to be catalysed and will need to have champions. The relevance and, more importantly, the limits of the analogy will need to be pushed and understood not so the effort is abandoned but so the differences can be addressed. The capital barrier to entry for a computer hacker, for example, is much lower than that for an innovator in agricultural research and development. Issues of regulatory costs and

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[156] These licenses are sometimes said to have a "viral" quality because the terms of the initial license attach to any subsequent products incorporating the original code.
[157] See, Douthwaite, supra; and Ravi *The Case for Biolinuxes* (the South Centre).
[158] Stallman, Richard and Lawrence Lessig *Free Software, Free Society: Selected Essays of Richard Stallman.* Free Software Foundation, 2002.
[159] In the cathedral versus the bazaar sense explored by Eric Raymond.

needs, liabilities, and profit margins all need to be explored and analysed. Getting the incentives right will also be important, as well as establishing the appropriate legal enforcement mechanisms. It will also be important to see where we are chronologically in the technology development in agriculture compared to where software was when the open source initiative was launched in that field. The concerns of the private sector agricultural interests with regard to the effects of patents and other intellectual property rights compared to those of the software giants may also give insight into the means of launching an open source initiative in agriculture.

One critical legal difference is that software largely deals with copyright and in biotechnology the intellectual property of most relevance is patent law. An essential function of patent law is disclosure and, at least in theory, it is meant to keep the characteristics of the invention publicly accessible. A patent application must provide sufficient information to allow one of ordinary skill in the art to make and use the invention or it should not be granted. But, as noted above, the underpinnings of open source software are about access, improvement, and production; source code disclosure largely achieves these aims. One of the essential functions of patent law, the intellectual property law of most relevance to biotechnology, is disclosure. Yet this is not sufficient to achieve the aims of access, improvement, and production in this field. Indeed, with the trends of industry consolidation and the expansion of intellectual property in the biosciences, the patents themselves may block public use. To reflect the ideals of the software open source movement, the focus of "open source" biotechnology must therefore be on the accessibility of biological discoveries and the ability to innovate rather than on disclosure.

As noted above, norms of the open source software movement to keep information and discoveries communal and accessible is similar to the traditional practice of science. Nevertheless, publication or dedication to the public domain – the traditional approach of scientific researchers and research institutions – does not necessarily make an invention publicly available.[160] This is because biological technologies are increasingly not self-contained, but rather are interdependent technologies that require several key components to function. Technologies can be seen as 'wheels' requiring a number of 'spokes' to function. The ability to transfer a gene to a crop plant, for example, may require dozens of individually protected, discrete technologies. Denial of access to any one of these can deny the use of the technology by potential users, and worse, prevents the iterative and cooperative shaping and improvement of the technology to meet diverse users' needs. Unfortunately, the placing of one or more key components into the public domain allows no leverage to bring other components into a collective whole with broad access. The potential and limits of licensing in an open source patent context – as opposed to publication or dedication to the public domain – is therefore of interest to encouraging innovation in the field of biological technologies.[161]

Open source licensing in the software context has developed around the rights granted by copyright. Copyright protects the fixed and original expression of software in the form of symbols or indications of computer code. Copyright arises automatically when the copyrighted work is fixed in a tangible medium. No formal institutional process, publication, or distribution is needed to perfect the rights. Copyright confers exclusive rights only against unauthorised copying

[160] Rebecca Eisenberg notes that prompt disclosure in the public domain can be potentially treacherous if one's ultimate goal is to keep information freely available. Eisenberg uses the following hypothetical to illustrate: Two rivals, Public University and Private Company each sequence a different portion of the same gene. The patent system in their jurisdiction offers more generous protection for full-length genes than for gene fragments. If Public University freely discloses the portion in a public domain database, Private Company might add that information to its partial sequence, complete the sequence and file a patent application it would not have been in a position to file without the Public University disclosure. The need, therefore, for coherence, for "buy-in" into domain enhancement becomes clear.

[161] Rosen, Lawrence, *Open Source Licensing: Software Freedom and Intellectual Property Law*. Prentice Hall, 2004.

or against other violations of the specifically enumerated rights of the copyright holder. The exclusive rights of the copyright holder extend only to those arising out of contact with the copyrighted work. Independent creation of a work is a defence to claims of copyright infringement even if the work is similar or identical to the protected work. Copyleft-type licensing takes advantage of this by creating a contractual relationship between the creator and user of the software. In copyright, whenever there has been access, there is an opportunity to condition such access on agreement to particular terms for access. In copyleft, the copyright owner agrees not to assert her exclusive rights so long as the agreed terms of the license are followed. The exclusive rights associated with patents are different from those associated with copyright and open source patent licenses will need to develop with those differences fully explored. For example, patents prohibit the making, using, selling, sale, or importation of the claimed invention or information provided by the patent holder even if the invention is independently created. Patents may therefore exist where the alleged infringer is neither aware of the patent nor the terms of by which the patent owner would authorise the activity.

Shrink-wrap licenses and material transfer agreements have been used in ways that are analogous to the label licensing approach taken under open source copyright. For example, patented seeds may be provided in a "seedwrap" license containing terms restricting the commercialisation of any improvements. The point of access is the point where a license can be imposed. But in the case of patents, an independent developer of a patented invention has not been in the position to invoke a license and so remains prohibited from all uses of the invention. It is not clear under US patent law whether a patent holder can make the claimed invention available under binding, generally announced terms of use as opposed to a license between parties. Another option would be for the patent holder to not sue for infringement when the invention is used. What is not clear, however, is if a failure to enforce will ensure accessibility or have the same practical effect as a failure to patent in the first place, and neither is the risk of the invention being captured in proprietary improvements.

The major differences between the letter and practice of patent and copyright law[162] will need to be analysed to understand the potential and limitations of open source patenting[163]. It is clear that an open source approach is promising to resolve the tension amongst the communality of science, the broad ability to innovate, and the economic incentive of patent law. From open source software we have seen new business models emerge that demonstrate that money can be made without controlling or restricting access to the tools of innovation. In biological technologies, these tools – enabling technologies – may be considered pre-competitive for high-margin applications, but are crucially lacking for low-margin applications. Free access to such tools is critical for their continued evolution in all contexts but it is also important to be able to address the challenges of low margins and the market failures associated with the needs of those people for whom the GCP was established to serve: the resource poor.

3. CURRENT EFFORTS

A number of organisations are exploring the issue of the application of open source beyond the arena of software.[164] In the area of biological innovation, probably the most prominent and relevant example to the GCP, is the BIOS Initiative of Cambia.[165] BIOS – Biological Innovation for an Open Society – is developing, promoting, and validating a new model for the innovation and delivery of biological technologies. BIOS will first apply this democratisation of innovation

[162] E.g., the existence of improvement patents.
[163] See, Feldman, Robin, *The Open Source Biotechnology Movement: Is it Patent Misuse?* 2004.
[164] See Wired Article Open Source Everywhere
[165] www.bios.net and www.cambia.org

to problems of biology, ranging from food nutrition and agriculture, though its paradigm should extend to challenges in environment, medicine, and public health. BIOS will do so by catalysing a large community of innovators to produce high quality and relevant technologies and secure them in a protected, universally-accessible commons.

The private sector has addressed the access problem by creating large IP portfolios and negotiating cross-licensing arrangements to obtain full platforms of enabling technologies. This bars entry in even the private sector to all but a few big players. The public sector, with its fractured portfolio and its eagerness to license out publicly-developed technology, is at a grave disadvantage. This was one of the impetuses to the creation of the GCP in the first place. Without a mechanism – like the protected, limited commons envisioned in the BIOS Initiative – the critical work of the GCP could be for naught. This is why the founding institutions of the GCP placed the issue of product delivery and its relationship to infrastructure, policy, and legal mechanisms as a high priority.

By promoting new thinking, new institutional mechanisms, new technologies, and a new business model, BIOS will allow complete re-thinks about empowering 3rd-world (and indeed 1st world) innovators to address local, small-margin, small market innovations in food, agriculture, public health, industry, and environment. BIOS's structure provides a new method for innovation and the ability to secure the resulting technologies in a commons, accessible to all.

BIOS is an international initiative, catalysed by CAMBIA in the early stages. Core activities involve the construction and curator ship of portfolios of biological enabling technologies and the development of a suite of open access license templates, applying aspects of the open source licensing found in software to patented technologies. Portfolios will be seeded with CAMBIA technology and will grow through contributions of existing technology (either by assignment or licensing) and the commission of future technologies. Open access licensing will prevent the technologies from being privately appropriated and enable cost-free public access, predicated on the sharing of improvements and on collective defence and sharing of regulatory information. BIOS will also play a leading role as an international coordinator and advocate for the identification of key areas in the technology and/or intellectual property landscape where targeted innovation is needed to democratise problem solving. This will involve stimulation and sponsorship of targeted innovations as well as interventions with salient policy initiatives to increase fairness in access to the tools of innovation.

While all BIOS technologies will be freely available, contributions to BIOS will be received in exchange for support services and direct access to a portfolio manager who is a leading expert in the chosen specific technology and its intellectual property landscape. Contributors will be notified of advances and improvements in the field, in the form of knowledge or more formal intellectual property, have facilitated direct access to others in the field, have the ability to target problems for solving on a web-based incentive structure, and more.

Now in its initial phases, BIOS is focusing on developing the core structures necessary to enable the application of an open innovation, collaborative production model to biology. A suite of open access licenses are being developed, with the first to be concluded before the end of 2004. Two publicly-accessible, technology-specific portfolios will be established with accompanying services and the IT facility to analyse IP and technology landscapes. In order to harness the creative efforts of a large community, BIOS has begun the design of an IT infrastructure to facilitate communication between innovators and the exchange of knowledge. BIOS's IT capabilities and its choice of skilled staff are designed to enable the identification of policy interventions relevant to biological innovations in trade, public health, environment, agriculture,

and food security. Collaborations are in process with existing firms (e.g. InnoCentive, Inc.) to allow for web-based technology commissioning. Relationships with participants will be established (whether contributors, licensees, innovators, or collaborating firms) through international workshops and the promotion of BIOS's underpinning rationale, philosophy, and business plan.

A new project called the "Science Commons" will be officially launched in the winter of 2005. Started by the founders of the Creative Commons and with advice from the Centre for the Public Domain at Duke Law School, the project will encourage universities to voluntarily forgo some of the protections of patent and trade secret laws in order to make scientific research more accessible to other universities, researchers, and the public through an alternative licensing regime. John T. Wilbanks, who has worked on the Semantic Web in the life sciences for the World Wide Web Consortium, will head the Science Commons beginning in November. The Science Commons will cooperate with the World Wide Web Consortium on the development of the Semantic Web to allow more sophisticated searches related to the life sciences. Its proponents say the Semantic Web holds great promise for scientific research because it could help scientists easily find and use data related to their fields of study. Science Commons developers also want to encourage efforts to find cures for rare diseases. It is considering setting up a patent pool where scientists studying rare diseases could deposit research that a health foundation or public agency could aggregate and eventually help commercialise through negotiations with drug companies.

4. CONCLUSION

The existing innovation system in biology encourages the private appropriation of enabling technologies. Researchers, institutions, and initiatives like the GCP, with an interest in exploring the promise of biological technologies for addressing the problems of the four billion people at the bottom of the economic pyramid, have trouble accessing the tools that govern the conversion of information into processes or products because of intellectual property, capital, regulatory, trade, and, other barriers. The GCP recognises that a cornerstone of its programme is that its outputs are released as "public goods", that they are accessible and, that they enable scientists in developing countries to engage in an innovation process that is relevant and addresses their own problems. One promising mechanism is the application of the open source approach. The GCP should consider collaborating with ongoing initiatives in this area. The open source approach is inclusive, supports the innovation process without being anti-business, and can proceed without a needed modification of current IP system. The GCP, like open source patenting in the biological sciences, is breaking new ground.

Benefit-Sharing: Implications for the Generation Challenge Programme

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1. INTRODUCTION

The Generation Challenge Programme (GCP) is embarking on a programme to more effectively use collections of genetic resources for the resource-poor using a range of genomic technologies. It will have to secure access to genetic resources and technologies as well as a freedom to operate the products, at least for final use, for the resource-poor in developing countries.

This study is part of a number conducted by the GCP on the implications of international and national policies and regulations on the Programme. This paper focuses on the issues of the sharing of benefits arising out of the use of genetic resources, as expressed in the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture (further referred to as the Treaty).

The paper is developed in parallel with a study performed at the request of the Commission for Genetic Resources for Food and Agriculture (CGRFA) of the UN Food and Agriculture Organisation (FAO).

2. INTERNATIONAL AGREEMENTS

The Convention on Biological Diversity has introduced the concept of national sovereignty over genetic resources in a world that implicitly (and since 1983 explicitly) considered genetic resources as a heritage of mankind, with the exception in mainly industrialised countries of new plant varieties that may be protected by intellectual property rights. The task of national governments to regulate access and promote sustainable use of genetic resources opened the way for explicit benefit sharing arrangements between countries and with provider communities. The latter has been included as part of Farmers' Rights in the Treaty.

However, neither the Treaty, nor in the Convention on Biological Diversity, specified equitable benefit sharing. CBD document UNEP/CBD/COP/3/Inf.53 states that "What constitutes a 'benefit' that can be shared is limited only by the imagination and ingenuity of the partners involved". The Common Policy Guidelines of the Botanic Gardens define benefit-sharing as the sharing of benefits arising from the use, whether commercial or not, of genetic resources and their derivatives, and may include monetary and non-monetary returns.

The poverty-alleviating effect of ABS arrangements depends on (1) the volume of benefits transferred, (2) the types of benefit, and (3) the beneficiaries (Henne et al., 2003). Benefit-sharing should be fair and equitable. Equity is a relative term and can be determined only by the participants in the process. It means not only equitable compensation, but equal standing among participants in making decisions about what form benefits should take (Moran, 2000).

Monetary benefit sharing can involve upfront payment, one-time payments when products are in the pipeline or formulated as a share of the value once products are marketed (e.g. as a share of royalty earnings). A key issue in these arrangements is the definition of the contractual partners and the role of the actual providers (farmers/communities) therein.

The application of the concept of national sovereignty to genetic resources implies the need to establish bilateral agreements between the provider country and the prospective user. Such bilateral contracts have been based so far on independent negotiations and have led to a wide variety of outcomes, mainly for use in the pharmaceutical sector. The exchange of germplasm for agricultural uses is however much more intense, greatly facilitated by the existence of collections in national and international genebanks. Specifically for this sector, the high transaction costs of the large number of potential bilateral negotiations has led to the Treaty that provides through its multilateral system a facilitated access to genetic resources of a number of listed species for food and agriculture among all signatory states.

Since the CBD came into force, the exchange of plant genetic resources for food and agriculture has become more difficult, especially in countries that were in the process of developing their national legislation in this field and that had not assigned responsibilities well. Countries that have an operational national system can demand conditions that the users are not used to, as illustrated by the Brazilian cassava case, presented in the document by Sampaio in this series.

In the field of genetic resources in agriculture, monetary arrangements are uncommon. We therefore concentrate on non-monetary benefits (NMBS). The difference may however not be very clear. Many (although not all) non-monetary benefits entail costs for those parties seeking access. What may be monetary at the international, global level (transferring money to a fund), might become non-monetary at the national or local level, and provide for goods and services.

References to defined elements of non-monetary benefits in major representative sources are compiled and arranged according to the three categories distinguished in the IT in Table 1.

3. BENEFIT SHARING UNDER THE CBD

National regulations with non-monetary benefit sharing clauses

Although many countries have established some form of ABS regulations, explicit references to NMBS arrangements were found in the legislation of only seven countries:

- Argentina (Law on Access to Genetic Resources: Art. 18),
- Bangladesh (Biodiversity and Community Knowledge Act (Art 13, 14,16),
- Bolivia (Supreme Decree No. 24676: Art. 40a-d),
- Brazil (Provisional measure No. 2.186-16: Art. 25),
- Costa Rica (Decree No. 31514-MINAE: Art. 6m),
- India (The Biological Diversity Bill: Art 21:2b-f), and
- The Philippines (Executive Order No. 247: Section 5).

In contrast to the monetary benefit-sharing clauses, most references to NMBS remain relatively unspecified. Brazil and Bolivia mention “technology access and transfer”, “unrestricted licensing”, and “training of human resources” without further specifications. Bangladesh’s and Costa Rica’s focus on NMBS is broader including economic, environmental, scientific-technological, social, or cultural benefits as options.

Most specific is the Executive Order of The Philippines, demanding collectors to sign either an Academic Research Agreement or a Commercial Research Agreement. As such, the Philippine legislation well exceeds the average national ABS regulation in providing for highly detailed NMBS clauses (Sections 5h,i,l). However, representatives of the pharmaceutical industry and many academic researchers found the Executive Order and Implementing Rules and Regulations

to be overly bureaucratic and costly in practice, and companies criticised a requirement to license technology to the Philippines. In response, the government is redesigning administrative and other elements of the regulation to ensure it does not act as a direct disincentive to research (Laird 2001).

None of the investigated national NMBS regulations refer to agricultural practice *per se* but do not exclude it either.

Bilateral framework agreements containing NMBS clauses

Obviously, bilateral "framework agreements" are more detailed than national regulations. Of 13 agreements investigated, three cases regard research and development for agricultural use:

a) Companies that test plant extracts from the University of Peradeniya (Sri Lanka) agree to grant the University a fellowship for a period of three years, valued at US$15.000.

b) The research agreement on the discovery of (unspecified) natural products from micro-organisms between Syngenta Crop Protection AG (Basel, Switzerland) and the Hubei Academy of Agricultural Science (China) stipulates that the user should care for "intellectual property-related training, technology transfer, exchange of results, funding of strain collections, fermentation, and pre-screening activities in China".

c) The ABS Agreement between the Lebanese Agricultural Research Institute (LARI, Lebanon), and the Kew Royal Botanic Gardens (United Kingdom) contains detailed NMBS clauses, including "acknowledgement of LARI as source of the material in research publications, joint authorship of the publications, copies of research results, and encouragement of study and training and/or study of both LARI and Kew personnel".

The limited number of cases on agricultural use contrasts with the large number regarding the pharmaceutical sector that may also be more comprehensive in their description. The 1991 Merck-INBio agreement stands out as one of the most detailed, transparent, and pro-active agreement in terms of NMBS. That the cash income obtained from bio-prospecting by Costa Rica is approximately USD 5 million, whereas in addition a significant non-monetary contribution was realised in the form of technology transfer, training, provision of equipment, contributions to the System of Conservation Areas, and the creation of national capacities, including negotiating capacities.

However, most framework agreements in this category contain relatively unspecified NMBS clauses on the "exchange of research results", the "supply of training and trainers", and other forms of support that help to strengthen the collaboration between the parties involved.

Local communities or farmer groups are not mentioned, except in the Benefit Sharing Plan of the International Co-operative Biodiversity Group (a consortium of 18 US and West African organisations, notably from Nigeria). The Plan states that ICBG revenues are to be used *inter alia* for "the economic well being of rural communities" and that the African members of the ICBG are involved in "all stages and in all the aspects of the drug development process". It is unknown to what extent these provisions have resulted in concrete benefits for local communities. (Iwu and Laird, 1998)

Plant specific agreements with NMBS clauses

Most detailed are the NMBS clauses in agreements that are based on one specific type of source material (mainly pharmaceutical uses again). All seven cases investigated contain explicit provisions.

a) An agreement between UC Davis (USA), the University of Mali, and the Bela community (Mali) on the access to and benefits from the wild rice gene *Xa21* derived from *O.longistaminata* in 1997 founded a Genetic Resources Recognition Fund to finance fellowships at UC Davis for students from source countries, giving priority to Mali. Farmers in developing countries would also be able to acquire seeds of UC Davis's transgenic lines at the same cost as traditional parental lines.

b) The Memorandum of Understanding (1998) between USDA, the Paraguayan National University of Asunción, the Ministry of Agriculture and Livestock, the Instituto Agronómico Nacional (IAN), and IPGRI describes the terms under which the USDA can access Chilli pepper *(Capsicum)* germplasm in Paraguay. The source country is offered a security backup of the collection in Paraguay at the USDA National Storage Laboratory, training to IAN scientists, an inventory of wild crop relatives native to Paraguay, and an analysis of *in situ* preservation of *Capsicum.*

An interesting case in terms of its focus on local development is the 1995 agreement between the Tropical Botanical Garden and Research Institute (TBGRI, Kerala State, India) with Arya Vaiya Pharmacy Ltd. (India) and the Nutriscience Innovations (USA) on a plant-based anti-fatigue drug which provide employment of approx. 700 people. The agreement between the South Africa-based Council for Scientific and Industrial Research (CSIR) and the *San* (Kalahari bushmen, Angola, Namibia) on a plant based appetite-suppressant has led to the construction of an extraction facility and the establishment of a Botanical Supplies Unit, each the first of its kind in the world.[166]

4. BENEFIT SHARING UNDER THE TREATY

Scope and beneficiaries

Whereas the Treaty defines Farmers' Rights as to include the right to equitably participate in sharing benefits (Art. 9b), and refers to the need that farmers should benefit from the implementation of agreed plans and programmes under the funding strategy (see Art. 18.5), such a reference is absent from the text in Art. 13, detailing non-monetary benefit sharing. Article 13 focuses specifically on exchange of information, access to and transfer of technology, and capacity building. Emphasis seems to lie on strengthening the public and private sectors and not farmers directly even though it does not exclude them. Some benefit types, listed in Table 1 and taken from major literature sources, do not easily fit the three categories distinguished in Article 13.2 of the Treaty. These types include food and livelihood security benefits, social recognition, contributions to the local economy, creation of employment, and investments in institutions.

Mechanisms

Article 10.2 specifies that the Multilateral System for Access and Benefit-sharing (MLS) should be efficient, effective and transparent. Article 13 describes the areas of benefit sharing and proposes some mechanisms for non-monetary benefit-sharing that are detailed below. The issue

[166] Idem.

of how the financial resources for this be raised is not addressed more than that the Treaty calls on all relevant stakeholders to contribute to the implementation of the MLS.

The Global Information System, to be developed in conjunction with the Clearinghouse Mechanism of the CBD is mentioned as a mechanism for the proposed exchange of information (Art 17), but the process is not specified:

"(T)he establishment and maintenance of, and participation in, crop-based thematic groups on utilisation of PGRFA; all types of partnerships in research and development and in commercial joint ventures, human resource development and effective access to research facilities" should cover the transfer of technology. Apart from an emphasis given to the role of networks (Art 16), mechanisms have to be developed.

Strengthening training programmes and facilities and carrying out research in or with the provider countries should cover capacity building aspects of benefit sharing.

In summary, some of the benefit sharing arrangements will have to be developed and effectuated by the Parties themselves, some by the users and providers that have sought and provided access to germplasm under the MLS. Benefit-sharing arrangements between other parties than the States themselves should be regulated and facilitated by contracting States. Farmers are recognised as a major category of beneficiaries.

Given the complete lack of harmonisation of national legislation under the CBD, and the fact that most of the GCP crops fall under the Treaty which came into force this year, it is now most interesting to review the Treaty.

The Multilateral system basically disassociates benefit-sharing from access. Hence the flow of benefits from users to providers will be predominantly indirect.

5. STAKEHOLDER PERSPECTIVES

The Treaty calls for a fair and equitable sharing of benefits arising out of the use of genetic resources. However, the Treaty provides little guidance about the mechanisms to realise this objective among the various stakeholders involved in conservation and sustainable use of genetic resources.

Parties to the Treaty – States

States form the Contracting Parties to the Treaty. Governments are required to implement the provisions of the Treaty. Provider countries and user countries may be distinguished, but it should be realised that the overall interdependence in genetic resources means that all countries are users, and many are also providers. Therefore, the terms user and provider countries may apply to the same country depending on the case.

Actual conservation and sustainable use of genetic resources and the other tasks assigned by the Treaty have to be implemented by various stakeholders under the jurisdiction of the State. In benefit-sharing we may distinguish between the actual providers of PGRFA (e.g. local communities that contribute to the development and maintenance of genetic resources in particular in centres of diversity, or genebanks that maintain local stocks), and the actual users, (e.g. the public and private plant breeders and researchers in all member countries and the farmers

that depend on genebank stocks for restoration). Considering that NMBS is often closely linked to broader development goals, Parties may consider integrating NMBS in their bilateral and multilateral international cooperation programmes.

Farmers as providers

Although the Treaty mentions under the funding strategy (see Art. 18.5) that farmers should benefit from the implementation of agreed plans and programmes, a specific reference to farmers is absent in Art 13.2 on non-monetary benefit sharing. The Treaty is thus not specific about the mechanisms through which farmers are to share in the benefits. In particular, no specific guidance is provided to national governments regarding the involvement of the various stakeholder groups in planning and decision making regarding ABS. Nevertheless, the implication of the Multilateral System is that benefit-sharing should be generic and regard any farmer rather than those specific farmers who provided valuable germplasm.

Breeders and researchers as users

The primary users of PGRFA are breeders and researchers in universities, international, national, or local research institutions, and private research laboratories and seed companies. Whereas users will have to sign the standard MTA, this MTA will probably not be instrumental in establishing benefit sharing in detail. Many users will agree with providers on various forms of benefit sharing, such as establishing scientific partnerships involving transfer of technologies, knowledge,e and information. Benefit sharing with other stakeholders such as local government and farmer communities is likely to remain indirect e.g. through access to better varieties.
The Centres of the CGIAR have played an important role in this since their inception through their involvement in conservation as well as in research (often in collaboration with national research systems and other stakeholders). Benefits thus have been provided in the past through the provision of new varieties to NARS and the distribution of accessions and improved material (along with related technology and information), and the training of national scientists (Fowler, 2003). In participatory plant breeding programmes, the role of provider and user often comes together in a single team.

The need for intermediaries

A major challenge of Contracting Parties is to effectively reach the above stakeholders and to motivate and allow them to actively participate in the (non-monetary) sharing of benefits. Whereas governments in provider countries have to make sure that farmers share in the benefits (Art. 9) but may lack the channels for effectuating this (Dávalos et al., 2003). The formalisation and regulation of Farmers' Rights and activities geared at local development may assist in reaching this goal. Governments in user countries have to stimulate users (breeders) to contribute to benefit sharing mechanisms realising that they often do not exert direct control over them. This is true for the private sector, but even for the formerly public sector institutions that have been given a high level of autonomy from the Government in many countries. The development of implementation mechanisms for benefit sharing may need a mixture of legally binding and voluntary measures. Non-monetary benefit-sharing is likely to rely on the latter. This may call for a careful analysis of current and potential intermediaries.

National Agricultural Research and Extension Services (NARES) are meant to reach farmers with information and plant varieties. Their effectiveness varies among countries and among client groups within countries, with smallholder farmers being poorly addressed in many countries.

Additional channels for reaching farmers in ecologically diverse conditions where the need for support (and the link to conservation) is strongest may be provided by NGOs.

Business (seed) and academic associations may be instrumental in stimulating benefit sharing by their members (e.g. the Common policy Guidelines for Botanic Gardens, 2000). Also genebanks may play a role when they can extend their role as brokers in genetic resources, to a brokerage function towards benefit- sharing arrangements. Moreover, genebanks have a direct function in information exchange on genetic resources.

The strong multilateral character of the relation between providers and users of PGRFA of the Treaty provides a strong argument for a role of international institutions in the implementation of some of the functions associated with the Treaty, including benefit-sharing arrangements. This particularly applies to information exchange through FAO and the CBD, capacity building through the Capacity Development Initiative of GEF, and a combination of technology transfer, capacity building, and information exchange through the CGIAR.

CGIAR is both a user and an important provider of shared non-monetary benefits.

6. POTENTIAL IMPACT ON THE GENERATION CHALLENGE PROGRAMME

The GCP is a user of a wide range of genetic resources. It has already experienced limitations to access and was required by a provider country to share some non-monetary benefits (in that analyses have to be done in the country of origin).

Such problems are likely to decrease significantly when countries ratify the International Treaty and design effective national laws to deal with the provisions of this Treaty at a national scale. Almost all crops in the GCP (with the exception of groundnut) fall under the Treaty and will be shared under its multilateral system.

The effects of benefit sharing on the GCP depend first on the diffusion and cooperation strategies of the GCP itself. Where its products will be patented and commercialised, a call for monetary benefit sharing is likely to be heard. If, on the other hand, products will be freely available (property-free or royalty-free) the situation will be different. In the latter case, the GCP itself can then be considered a mechanism for benefit sharing through its role in capacity building, technology transfer, and information exchange. As such, it may assume a position as an intermediary and benefit from bilateral and multilateral agreements under the CBD and the Treaty respectively.

A position, where IP that is generated in the GCP will be commercialised in commercial markets and provided royalty-free for use for the poor, does not create a clear position in the benefit sharing discussion. It may require a thorough analysis and possibly negotiations with those responsible for the multilateral system.

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Table 1. Benefits by type.

Exchange of information	Information on collaborative efforts Sharing of research and development results Access to databases General sharing of information relevant for conservation and use Access to scientific information relevant to conservation and use of biodiversity Improved knowledge of biodiversity Improved knowledge of natural environment
Access to and transfer of technology	Access to materials Access to collections Access to products Access to commercially released varieties for further research and breeding Access to relevant technologies Transfer of knowledge and technology Transfer of equipment, software, know-how Joint ventures for the creation of technological foundations Participation in product development Participation in planning and decision-making Undertaking commercial production, processing or manufacture Creation of alternative industries or crops Partnership in the economic exploitation of processes and products Sharing of rights Joint ownership or sole ownership of intellectual property rights Free licensing for the utilisation of patented processes and products
Capacity building	Cooperation in scientific research and development programmes Facilitation of research partnerships Formation of collaborative agreements with local institutions Co-operative scientific research and technological development Consolidation of scientific research infrastructure Providing country conducting field trials Research directed to priority needs, such as health and food security Participation of source country scientists in research Cooperation in conservation efforts In-kind support for conservation (e.g. genebank facilities) Benefits in kind e.g. augmentation of national collections in the country of origin Increased opportunities for developing joint strategies for conservation and use Voucher specimens to be left in national institutions Control over samples in provider countries Cooperation in education and training Training in bio-prospecting methods, etc. Training in science, in situ and ex situ conservation and management, information technology and management/administration of ABS Institutional capacity building Increased scientific capacity Strengthening capacities for technology transfer Investment in research and development infrastructure Investment in the capacity of local industry Undertaking commercial production, processing or manufacture Resources for the implementation of access regulations Institutional and professional relationships Exchange of staff
Local development	Food and livelihood security benefits Social recognition Contributions to the local economy Creation of employment Support for community development activities; Investment in local institutions

Issues on Access to Genetic Resources
Under the auspices of the CBD *vis* à *vis* under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture

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1. INTRODUCTION

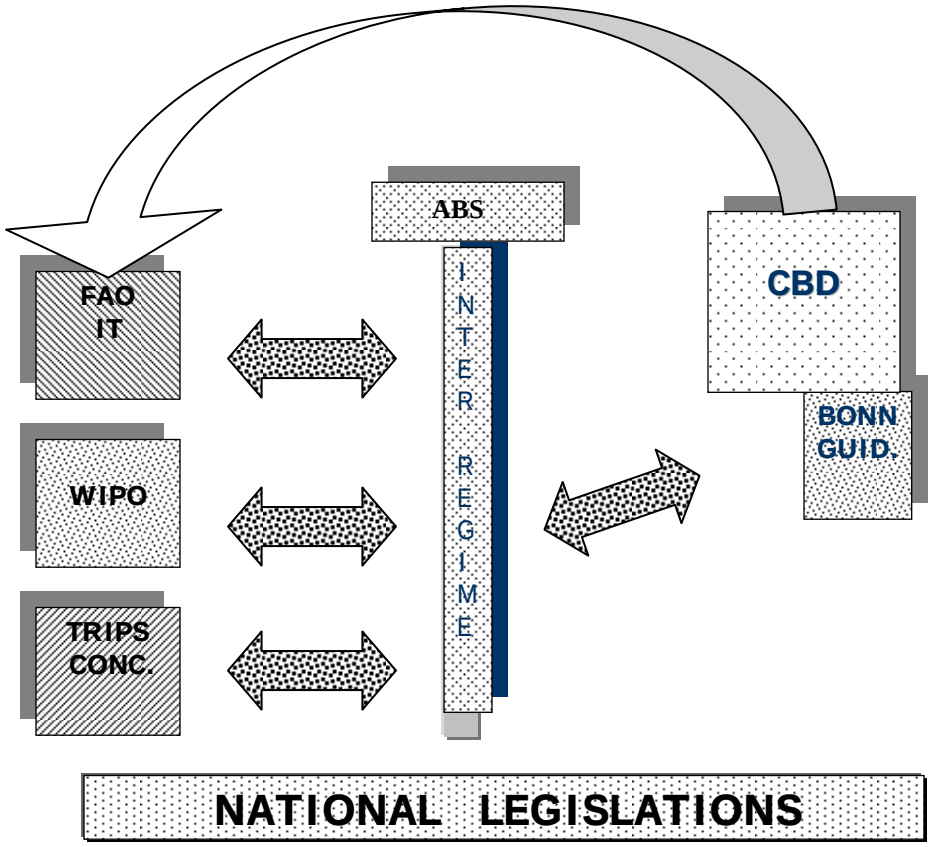
The issue of access to genetic resources continues to be part of an important, ongoing discussion on international, regional, and national policy-making agendas. The efforts made by countries to control and benefit equitably from the flow of commercial exploitation of genetic resources have paved the way for the emergence of a series of policies and legal instruments.

Conflicting interests and misunderstandings among industrialised countries, "like-minded megadiverse countries",[167] research institutions, and indigenous peoples have influenced, to a greater or lesser extent, these policies and legislative processes and initiatives (Muller, 2003).

The Convention on Biological Diversity (CBD), the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (FAO IT), and Decision 391 of the Andean Community of Nations[168] on a Common Regime on Access to Genetic Resources, are a sample of international or regional advances in policy and legislation (see also Scheme 1).

Many international fora are discussing related matters trying to find a compromised harmonisation between the two major lines of thought driven by WTO (TRIPS) and the CBD. Examples are the TRIPS Council - Review of Article 27.3(b) (meeting regularly since 2003 on this issue), the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore coordinated by WIPO (meeting since 2001 and which held its seventh meeting in Nov.,2004), the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing of the CBD, with its fourth meeting scheduled for March 2006 and which is set to develop an International Regime on Access and Benefit Sharing. (see also the first paper in this volume – *The Policy Environment of the Generation Challenge Programme regarding rights on biological materials, technologies and knowledge – an overview*).[169]

[167] Bolivia, Brazil, China, Colombia, Congo, Costa Rica, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, South Africa and Venezuela.
[168] Bolivia, Colombia, Ecuador, Peru, and Venezuela.
[169] Paper by Maria Jose Sampaio, submitted in 2004 as part of the Generation Challenge Programme policy grant to Embrapa.



Scheme 1. Interacting forces in the design and implementation of benefit sharing rules.

Additionally, according to information found in the Clearing House Mechanism of the CBD,[170] more than 30 countries around the world have approved policies and regulations on access to genetic resources and benefit sharing (ABS) (see Table1). Draft Laws and regulations are also listed for Bangladesh (1998), Pakistan (2004), Pacific Forum (2001), and Thailand (1996) by the GRAIN database.[171]

These instruments, laws, and regulatory frameworks concerned with access to and use of genetic resources, determine rules and procedures that govern how genetic resources can be accessed and used.

This paper analyses the developments of these different international regimes and their translation in national legislation with regard to the regulation of access to genetic resources. We realise that this analysis is time-bound given the continuous developments in this field. This paper was prepared in March 2005.

[170] (**www.biodiv.org**) – updated Feb.2005.
[171] www.grain.org

Table 1. Laws and Regulations on Access to Biological and Genetic Resources and Benefit Sharing, on Bioprospecting of biological and chemical substances and on the Environment as it interfaces with biodiversity use and conservation (Database on ABS Measures – www.biodiv.org).

Country /Region	Instrument	Status
African Union	African Model Legislation for the Protection of the Rights of Communities, Farmers, Breeders, and for the Regulation of Genetic Resources	Adopted - 1998
Andean Pact	Decision 391: Common Regime on Access to Genetic Resources	Entered into Force - 1996
Central American Countries	Central American Regime on Access to Genetic Resources and Biochemical and Traditional Knowledge	Draft
Argentina	Resolution 91/03 – National Strategy on Biological Diversity	Adopted – 2003
Australia	Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources	Adopted – 2002
	Queensland's biodiscovery Act 2004	Adopted - 2004
Bolivia	Supreme Decree 24676	Entered into Force – 1997
Brazil	Provisional Measure 2.186-16	Entered into Force - 2001
Bulgaria	Biological Diversity Act 2002	Entered into Force - 2002
Cameroon	Law 96/12	Entered into Force - 1996
Colombia	Decree 309	Entered into Force - 2000
Costa Rica	Biodiversity Law 7788	Entered into Force - 1998
Cuba	Environmental Law 81	Entered into Force - 1997
Ecuador	Special Law for the Conservation and Sustainable Use of Biodiversity	Draft – 2002
El Salvador	Environmental Law	Entered into Force - 1998
Ethiopia	Proclamation to provide for the establishment of the Institute of Biodiversity Conservation and Research	Entered into Force - 1998
Gambia	National Environmental Management Act	Entered into Force - 1994
Guinea-Bissau	Biodiversity Law and Hand Craft	Draft - 2005
Guyana	Environmental Protection (Bio-prospecting) Regulation	Entered into Force - 2001
India	The Biological Diversity Act, no. 18	Entered into Force – 2003
	Biological Diversity Rules	Entered into Force - 2004

Kenya	Environmental Management and Co-ordination Act	Entered into Force - 2000
Malawi	Environmental Management Act no. 23	Entered into Force - 1996
	Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi	Adopted - 1996
Mexico	General Law of Ecological Balance and Environmental Protection	Entered into Force - 1998
	General Law for Sustainable Forest Development	Entered into Force - 2003
Nicaragua	General Law for Environment and Natural Resources	Entered into Force - 1996
Panama	General Law for Environment no. 41	Entered into Force - 1998
Peru	Law no. 26839 on the Conservation and Sustainable Use of Biological Diversity	Entered into Force - 1997
	Law no. 28216 on the Protection of the Peruvian Biological Diversity and Collective Knowledge of the Peruvian People	Entered into Force - 2002
Philippines	Executive Order 247 Guidelines for Bioprospecting	Entered into Force - 1995
	Implementing Rules and Regulations of Republic Act no. 9147 – Wildlife Resources Conservation and Protection Act	Entered into Force - 2004
	Guidelines for bioprospecting activities in the Philippines	Draft - 2004
Portugal	Decree-Law no. 118	Adopted – 2002
South Africa	National Environmental Management Biodiversity Act 2004	Adopted – 2004 Entered into Force - 2006
Switzerland	National Plan of Action for the Protection and Sustainable Use of PGRFA	Adopted – 1999
Uganda	National Environmental Statute	Adopted – 1995
Vanuatu	Environmental Management and Conservation Act no. 12	Entered into Force - 2003
Venezuela	Biological Diversity Law	Entered into Force - 2000

2. THE EVOLVING GLOBAL DISPUTE ON ACCESS TO GENETIC RESOURCES

Although historically genetic resources were exchanged freely under the universally accepted idea that they were part of the common heritage of humanity, in reality it was factual power and force that determined who would have control over them. For centuries – from the time of the Egyptian Pharaohs – plants and seeds have been transported from one place to another. After 1492 and the meeting of the Europeans and the Americans, colonies were systematically stripped not only of gold and mineral wealth but also of "exotic" (to Europe) new plants and genetic resources. It is also true that as a result of this meeting of cultures and the contact with other continents and regions, many new genetic resources and crops, animals, and technologies arrived in America.

Gradually, with the intensification of agriculture, especially during the XVIII and XIX centuries, the flow of genetic resources not only implied the movement of seeds and new crops between Europe and America, Asia, and Africa (Harlan, 1971; Hobhouse, 1992), but gave way to the development of new varieties that would incorporate the genetic characteristics of diverse geographical origins. This is important, as the CBD has placed considerable emphasis on, and hope in, the concept of the "countries of origin" of a determined species or genetic resource, to materialise and make effective the fair and equitable sharing of the benefits derived from access to these resources. At present, the so called "megadiverse countries" of these continents continue to concentrate the greatest part of the biological diversity of the planet and, at the same time, to be centres of origin and crop diversity.

In the case of wild and endemic species with the potential for pharmaceutical and biochemical uses, the concept of "country of origin" may have a much more determinant role; this is less so in the case of cultivated species. In the latter case, the idea of *interdependence* has become especially important. No country is independent in terms of plant genetic resources for food and agriculture (Muller, 2003).

The overwhelming majority of countries depend considerably on genetic resources that did not originate in their territories or even in their regions. In the genealogy of many crops, there is material that has been obtained from various sources and from different countries. Thus, it is possible to infer:

a) that considerable amounts of plant genetic resources used by national agricultural programmes originate from different sources and are provided by different countries,
b) that assigning an economic value to each resource could, in practice, be very difficult, and
c) that the benefits generated from these materials would be realised as improved varieties of crops and are generated because of their adaptation to different areas, heights, stresses, and other characteristics.

The determination of the origin, *vis-à-vis* centre of diversity, also poses some difficulties. This situation results in the bilateral negotiations concerning these genetic resources being, at best, very complicated and with high transaction costs. This fact led to the idea of promoting the development of a *multilateral type system* that would allow the continuous and fluent exchange of material vital to agriculture and food, with due recognition being given to the general principal of sovereignty.

A second important element that should be considered is the fact that, when the CBD was adopted in 1992, Resolution 3 (known as the *Interrelationship between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture*) was also approved. Resolution 3 addressed the need for Contracting Parties to resolve pending issues, including that of access to *ex situ* collections of genetic resources that had not been acquired in accordance with the access principles of the CBD.

In November 1993 (before the CBD came into force), the FAO Conference adopted Resolution 7/93, in which the member countries request that the FAO General Director initiate a process to adapt the International Undertaking to the new rules and principles established by the CBD on access to genetic resource and benefit sharing (ten Kate and Lasen-Diaz,1997). This was the genesis of the negotiation process of the new FAO International Treaty, which entered into force in June, 2004.

As seen in Table 1, most of the Laws and regulations on ABS where developed before or at the same time that the FAO Treaty was being finalised (1998 – 2002), but in totally different fora and with different Government representatives for most developing countries. Most of the delegations present at the Treaty discussions were composed of FAO diplomats or Ministry of Agriculture representatives while most of the discussions under the CBD are dominated by representatives of Ministries of Environment or similar agencies. It is not surprising, therefore, that their approach would differ. It remains to be seen how the implementation rules (MTAs) of the Treaty will be developed in a way to promote and facilitate the use of genetic resources and at the same time provide for the CBD's objectives of benefit sharing. It would be better and easier if member countries of both Treaty and Convention could interpret the terminology of "benefit sharing" in a somewhat broader way than just the financial benefit arising from the commercial use of new plant varieties or other commercial applications of biodiversity derivatives.

In addition, for the implementation of a Challenge Programme such as the GCP, which deals with many of the crops listed in the Annex 1 of the FAO Treaty and is therefore included in the Multilateral System, and with the bulk of the germplasm accessions deposited at the *ex situ* collections of the CGIAR Centres, the critical question remains how countries will internalise the Treaty's decision with regards to access to new germplasm accessions found *in situ* conditions if and when they become Parties to the Treaty in case they already have an adopted ABS legislation (e.g. see current situation of the "Like-Minded Megadiverse" countries in Table 2).

Table 2 . Current status of the "Like-Minded Megadiverse Countries" and/or countries with CGIAR Centres* in relation to different Genetic Resources national and international instruments.(source: CBD and FAO web sites visited March 22,05).

Country	Status CBD	Status FAO IT	Status National ABS legislation /regulation
Bolivia	Ratification - 1994	-	Entered into force - 1997
Brazil	Ratification - 1994	Signature - 2002	Entered into force - 2001
China	Ratification - 1993	-	-
Colombia*	Ratification - 1994	Signature - 2002	Entered into force - 2000
Congo	Ratification - 1996	Accession - 2004	-
Costa Rica	Ratification - 1994	Signature - 2002	Entered into force - 1998
Ecuador	Ratification - 1993	-	Draft - 2002
India*	Ratification - 1994	Ratification - 2002	Entered into force - 2003
Indonesia*	Ratification - 1994	-	-
Kenya*	Ratification - 1994	Accession - 2003	Entered into force - 2000
Madagascar	Ratification - 1996	Signature - 2002	-
Malaysia*	Ratification - 1994	Accession - 2003	-
Mexico*	Ratification - 1993	-	Entered into force - 1998
Peru*	Ratification - 1993	Ratification - 2003	Entered into force - 1997
Philippines*	Ratification - 1993	-	Entered into force - 1995
South Africa	Ratification - 1995	-	Enter into force - 2006
Venezuela	Ratification - 1994	Signature - 2002	Entered into force - 2000
Cote d'Ivoire*	Ratification - 1994	Ratification - 2003	-
Nigeria*	Ratification - 1994	Signature - 2002	-
Sri Lanka*	Ratification - 1994	-	-
Syrian Arab.Rep*.	Ratification - 1996	Ratification - 2003	-
Italy*	Ratification - 1994	Ratification - 2004	-
USA*	Signed – 1993	Signature - 2002	-

3. STILL UNEVEN PATHS

A comparison of some of the national legislations can bring an insight of the possible dilemmas that researchers and administrators of the GCP may encounter in the future when accessing new material held in national gene banks or *in situ*, depending on whether the crop is listed in Annex 1 of the FAO IT or not.

Decision power

The access legislations in countries of Latin America are characterised by the concentration of power in the hands of the State. To deliver that the legislation indicates the need for the installation of governmental only or open- ended committees with mixed composition, such as in India, to analyse research processes and bio-prospecting contracts. In the Philippines and in Colombia, control is exerted by the government only via different agencies. Australia has chosen a non-centralised model with more emphasis on local communities. It is clear that the CBD has influenced the decision process as it highlights the power of the State in the decision making regarding the conservation and use of genetic resources.

Participation of local communities

In Costa Rica, the Philippines, and Colombia, the government has the final decision on matters related to access to genetic resources. However, the previous informed consent (PIC) by local communities is obligatory. The Costa Rican legislation goes further, giving the local community the right to express "cultural objection" to the PIC for cultural, spiritual, social, or economic reasons. In Colombia, the legislation provides for different ruling if the access involves traditional knowledge or not and if the community is indigenous or black. There are also differences if the interested institution is public or private. The latter trend is also followed by the Philippines's regulations. In Brazil, communities have a final saying at some specific state level legislation, while the final decision is taken by the government at federal level. However, in all cases, PIC is suggested as an obligatory component, in accordance with the CBD requirements.

Benefit sharing

To devise the best mode of benefit sharing among communities and other beneficiaries is an obligation of national legislations. According to Hayashi (2004), financial benefits can be accrued in short, medium, and long terms, as seen already in some legislations. In the Philippines, a short term example is given by the need to pay fees and licenses for each accession; or fixed up front payments as in the case of Costa Rica. Medium term benefits could be accrued in the form of research funds and/or laboratory equipment and infrastructure and long term benefits being paid in the form of royalties over the commercial applications of products derived from the genetic resources and/or associated traditional knowledge. The division and transfer of monetary benefits to local communities when traditional knowledge is involved seems to always be the complicated phase and is not yet resolved in most of the legislations. According with Article 16 of the CBD, the Directive in the Philippines and the Law in Brazil provide for the obligatory transfer of technology as one of the forms of medium and long term non-monetary benefit sharing. The Colombian Law goes further by giving the Government the right to access the technology developed with the use of its genetic resources. In India, the law directs the benefits to the local communities when they can be duly identified, and if not, the monetary benefit has to be paid into a local Biodiversity Fund and used to conserve local biodiversity. The Australian legislation allows for contracting parties to decide on the benefit sharing mode and examples can be found where they have taken the format of fees, royalties, capacity building, and technology transfer.

Private land owners

Both in Brazil and in Australia, the private land owner is considered an essential party in the contract, necessary when genetic resources are found in the private land. Considering that in Australia there are several different land ownership regimes, different benefit sharing contracts will be observed according to the real ownership rights. Costa Rica makes a difference for public domain assets and private assets of public environmental interest. The first set comprises the continental, marine, and insular fauna and the nation's resources as well as the biochemical and genetic properties of local biodiversity. The second set comprises resources found in private property. In the Philippines, the private owner should be informed of the objectives, duration, and methodology to be used during the bio-prospecting exercise but it does not specify how the owner will share part of the benefits accrued from the eventual commercial exploitation of valuable products. In the Indian legislation there is mention of the participation of local communities, but is it does not specifically mention the participation of the private owner. In Colombia, the private owner participates as part of the contract with the State, the company, the research institute, and the local communities if they are also involved. The legislation does not mention the private owner in particular but refers to "other natural or juridical persons recognised as providers".

Control of the process

Bio-piracy is a problem everywhere in biodiversity-rich developing countries and exerting control over the collection and use of the products of biodiversity is therefore a very serious and costly task for source countries. Some of these are relying on national researchers themselves and on negotiations to be developed in good faith. In the Philippines, the regulations demand that national researchers are part of every commercial contract with the objective of involving universities and research centres in the transfer and acquisition of technology. The obligatory Philippine citizenship works as a kind of control mechanism. The Colombian legislation obliges for the same number of nationals from Colombia and foreigners in the bio-prospecting contract. The Brazilian legislation goes further, indicating that access by foreigners can only be provided in conjunction with a national public research institution, made responsible for the activities previously approved by a national Council. India and Costa Rica only provide for punitive action against unauthorised access and Australia does not specify a particular control system.

Control of the research and commercial contracts

Controlling contracts and research processes is of vital importance to secure that the species to be collected and the localities under bio-prospecting correspond to the initial agreement. The system differs with different legislations but it seems to receive much less attention than the requirements of each negotiation. India and Colombia impose sanctions in the cases of negligence with the agreed clauses of the contract and the Colombian regulations provides for the actual cancellation of the contract. In Brazil, licenses from different agencies are required when the process involves local communities or foreigners before the national Council gives its approval. The national partner is responsible for the development of activities and must report annually to the Council, who can cancel the license when noticing any wrong doings. In the Philippines, the Inter-Agency Committee on Biological and Genetic Resources deals with the implementation and monitors all the research contracts. The Australian regulations express strong care for the potential environmental damage of related activities but do not specify forms of control. It seems clear that most developing countries underestimate the size and cost of a system to exert the real control needed to guarantee the fair and equitable benefit sharing clauses of any contract. Controlling the acquisition of materials, development, scale-up, pre-market testing, and eventually the commercial phase is an enormous task that can only be built if a robust infrastructure of information sharing exists. However, it is also important to remember that science needs to be developed within a certain speed and that overwhelming control runs counter to this feature most of the time.

4. FAO IT MATERIAL TRANSFER AGREEMENTS – Casting the Future of the Multilateral System

As mentioned before, the access and benefit-sharing provisions of the Multilateral System are applicable to resources of the Annex 1 List. It is important to highlight that the IT is not limited to a Multilateral System and, therefore, does not only address plant genetic resources in the List. The provisions made for conservation standards, sustainable use, international cooperation, and Farmer's Rights, among others, go beyond the resources given in the List, but are always limited to plant genetic resources for *food and agriculture*.

The IT explicitly states that the provisions made in the Multilateral System will also be applicable to collections of plant genetic resources held in *International Agricultural Research Centres* of the CGIAR (Article 15: *Ex situ* Collections of Plant Genetic Resources for Food and Agriculture

held by the International Agricultural Research Centres of the CGIAR and other International Institutions).

As a basic principle, the IT relies on a multilateral regime, where access to genetic resources is materialised through standardised MTAs which are approved by its Contracting Parties (including access to collections from International Centres). Under this system, the possibilities for direct bilateral negotiations with regard to genetic resources are limited, and are replaced by decisions adopted at the Governing Body level, based on the decisions made by the Parties to the Treaty. The Governing Body will define the material content of the instrument or tool (the MTA) which will define access conditions and obligations. Thus, the relationship between the country of origin and the access applicant is governed by the MTA and a multilateral negotiation process in a certain way, limiting the discretional capacity of the State (Muller, 2003).

With regard to benefit sharing, the IT proposes a different formula from most of the ABS legislations and regulations. Article 13.1 of the Treaty recognises that access as such is already a substantial benefit generated by the Multilateral System. In Article 13.2, it provides four mechanisms through which the benefits arising from access to plant genetic resources that are part of the List and are a part of the Multilateral System shall be shared fairly and equitably. These include:

a) *the exchange of information* (through a Global Information System on Plant Genetic Resources for Food and Agriculture (Article 17)), which will include those catalogues, inventories, results from research, and technologies, amongst others, that are not deemed confidential;
b) *access to and transfer of technologies*, in accordance with applicable intellectual property rights, under fair and most favourable terms;
c) *capacity-building* to establish programmes for scientific and technical education, and the carrying out of joint research activities (in developing countries and countries with economies in transition), among others;
d) *the sharing of monetary and other benefits*, which will materialise through contracts or corresponding model agreements on material transfer (developed by the Governing Body) and which will be directed towards Trust Accounts (Article 19.3(f)). The latter point is dependent upon the benefits being derived from materials that are either not available to third parties or are available with restrictions.

In the case of products available without restrictions for research and breeding, the Governing Body can determine the payment made as a result of periodic evaluations (Article 13.2(d)(ii)). In the case of economic benefits, the Governing Body shall also determine the level, form, and manner of payment made into the Trust Account, taking into account commercial practices (Article 13.2.(d)(ii)).

Although the IT provides for the use of MTAs, there is no direct relationship between the provider or the country of origin and the recipient of plant genetic resources. The equitable and fair distribution of benefits is influenced and conditioned by the Multilateral System.

Some of the elements listed during the Second Meeting of the Steering Committee were:
1. Preamble;
2. Parties to the Agreement;
3. Definitions – in this case there are four proposals for the meaning of "commercialisation", three options for "product", and four options for "incorporation of genetic material";
4. Subject matter of the MTA/material to be transferred;

5. General Provisions;
6. Rights and obligations of the provider (taken from the Treaty);
7. Rights and obligations of the recipient (taken from the Treaty) – there are six options to define when a product would be available without restriction;
8. Interpretation;
9. Dispute resolution/settlement – there are three options for dispute settlement and two major options for dispute resolution;
10. Additional terms such as Warranty, Duration of the Agreement, Entire agreement, Guarantor;
11. Signature/Acceptance – three options;

Given the importance of the MTA for the implementation of the IT and given the importance of the IT for the easier management of samples needed for the development of the GCP, some of the features were discussed by a small group of country experts with regional representation and later approved during the Second Meeting of the Steering Committee (2004) and will become part of the final MTA may require help from scientists working directly with genetic resources. If researchers such as those involved with the GCP do not help to shape the ideas and the requirements set forth in the MTA, it might come up as a very complicated instrument to deal with. A critical meeting to prepare a first draft of the MTA will take place in Tunis, in June 2005. The results will be submitted to the First Meeting of the Governing Body scheduled to take place around February 2006 in Spain.

For the GCP, it will be important to pay attention in the years to come to how ABS legislations will interface with the internalisation of the IT rules under national regimes. To the author's knowledge, the Brazilian ABS legislation is the only specific legislation to give an option for the immediate implementation of the FAO Treaty as soon as it is ratified.

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6. ANNEX 1 .CASE STUDY – ACCESS TO CASSAVA GERMPLASM FOR USE BY THE GENERATION CONSORTIUM

For many years, CIAT has been collecting cassava germplasm samples in many countries as part of its mandate to acquire and conserve the maximum variability possible of Manihot esculenta and other related species, including wild relatives. However, Brazil is said to be the centre of origin for *Manihot esculenta* and therefore Embrapa and other research institutions have also been maintaining an extensive collection of materials which have been characterised and improved over the last 25 - 30 years.

The Cassava Project proposal is part of the Generation Challenge Programme proposal to screen around 1,000 accessions for drought tolerance characteristics using SSRs. Researchers have chosen to use 500 accessions collected in the Northeast Region of Brazil, a very dry region. However, most of these accessions are not yet duplicated at the CIAT germplasm bank as they were collected after the outcomes of the Convention of Biological Diversity, a landmark for the fee exchange of plant material around the world.

The scientists took for granted that the needed DNA samples were going to be made available for screening in a matter of months and further distributed among the participant institutions in different countries for further analysis and characterisation.

However, that is not the case because Brazil has a Genetic Resources Access Legislation in force since 2001 that obliges Embrapa to submit a complex documentation to a National Council which will decide, after some months, if the material can be made available and under which conditions. Most probably a contract or a complex MTA will have to be signed between Embrapa and the Federal Government represented by the Council (and maybe other partners in the project) aiming to guarantee the due benefit sharing of future outcomes of the project.

Apart from the uncertainty and the time that will be consumed to deal with the negotiations, there is nothing wrong with the concept of benefit sharing. However, it would be easier to deal with research needs in the area of agriculture if the FAO International Treaty were already operational. Cassava, for instance, is one of the crops listed in Annex I of the Treaty and therefore subject to the simplified rules of the Multilateral System. Because the Treaty that entered into force in February 2004 has no rules as yet for the MTA, cassava and other materials listed in Annex I will continue to be subject to national Access legislations. This is also the case because Brazil has not yet ratified the Treaty.

Fortunately, to avoid further delays, the Director of the programme has approved a review of the initial proposal to allow for samples to be analysed in Brazil first, while the needed licenses to move samples to other countries and partners are obtained by Embrapa. That will, of course, require an increased operational cost because the appropriate laboratories are in different locations in Brazil.

Screening experiments were developed in both sites, CIAT and Embrapa, as required. After that, scientists from CIAT and Embrapa prepared a list of accessions that need to be sent to CIAT and to other partners of the programme. Detailed descriptions and complete passport data were gathered, obliging the two institutions to review their data banks. A special proposal was initially submitted to the National Council for discussion and potential approval in April 2005. As the engagement of environmental non-governmental organisations with the matter of access to genetic resources and traditional knowledge increases in Brazil, the dialogue with the Council is

becoming more difficult. What should be a straightforward interpretation of the Access Legislation is becoming more complex and difficult to comply with because many questions, such as the definition of beneficiaries of the benefit coming from the potential exploitation of cassava genetic resources contained in *ex situ* germplasm banks held by public institutions (such as Embrapa) prior to the legislation entering into force (2001), are yet to be defined by the implementing body.

It remains to be seen how the Generation Challenge Programme's goals will be interpreted by the national authority. The lack of clear immediate or medium term results, peculiar to this type of research, may create more difficulties for approval.

Also, it is a matter of time before Embrapa obtains the license. If it delays for too long, the consequence will be the probable cancellation of the project. Who stands to benefit?

Further details of the process will be added to this report as they become available to serve as a baseline for the procedure that will probably be applicable to most of the countries with access legislation and that keep samples of plant material not yet duplicated in any of the Future Harvest Centres gene banks.

7. SCHEME 1: Possible paths in multilateral and bilateral negotiations – examples of crops from the Annex 1 (cassava) and non-annex 1 (groundnut) considering the case of Brazil as centre of origin, the characteristics of the ABS legislation in place and the fact that this legislation already recognises the possible exception for crops that are to be accessed with the rules of the FAO IT Multilateral System, after Brazil ratifies the Treaty

EXAMPLE 1

CASSAVA
FAO IT ANNEX 1

MTAs
to be implemented

EXAMPLE 2

GROUNDNUT
FAO IT NON-ANNEX 1

BRAZIL IS THE CENTRE OF ORIGIN
BRAZIL HAS AN ACCESS LAW SINCE 2000
LEGISLATION MAKES AN EXCEPTION FOR FAO IT ANNEX I CROPS

MATERIAL COLLECTED BEFORE 2000

MATERIAL IN NAT. GENEBANKS – IT MTA

MATERIAL SENT TO CIAT/ IITA – IT MTA

MATERIAL IN NAT.GENE BANKS – NATIONAL LAW MTA OR CONTRACT TO BE NEGOTIATED CASE BY CASE

MATERIAL SENT TO CIAT/ ICRISAT – IT NON-ANNEX I MTA

MATERIAL COLLECTED AFTER 2000

MATERIAL IN NAT. GENE BANKS – IT MTA

IN SITU MATERIAL TO BE SEND TO CIAT AND IITA – NAT.LEG. MTA (TO BE NEGOTIATED ON A CASE BY CASE (for material in private and community area) or
IT MTA according to Art. 12.h of the IT (for mat. found *in situ* – Federal area)

MATERIAL NAT.GENE BANK – NAT. LEG. MTA TO BE NEGOTIATED CASE BY CASE

MATERIAL TO BE SEND TO CIAT AND ICRISAT – NAT. LEG. MTA TO BE NEGOTIATED CASE BY CASE

Impacts of Strengthened Intellectual Property Rights Regimes on the Plant Breeding Industry in Developing Countries

A synthesis of five case studies[172]

Niels Louwaars, Rob Tripp, Derek Eaton, Victoria Henson-Apollonio, Rufa Hu, Maria Mendoza, Fred Muhhuku, Suresh Pal, Joseph Wekundah[173]

1. EXECUTIVE SUMMARY

The study

In the past few decades the subject of intellectual property rights (IPRs) has occupied the centre stage in debates about globalisation, economic development, and poverty elimination. This study concerns the strengthening of IPRs in the plant breeding industry and its effect on agriculture in developing countries. This strengthening is reflected in the growth in the number of countries that grant such rights, an expansion of the types of inventions that can be protected, and a broadening of the scope of protection offered by extant IPR systems. Central to the spread of IPR systems is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs 1993) of the World Trade Organisation (WTO) requiring all WTO members to introduce a minimum level of protection for intellectual property in their national laws as well as subsequent bilateral or multilateral trade agreements that call for further strengthening of IPR regimes in developing countries.

The principal objective of this study is to describe and evaluate initial experiences with strengthened IPRs in developing country agriculture, focusing on five case studies. Such an assessment is a prerequisite for the formulation of policy guidelines and "good practice" lessons for implementing IPRs in ways that enhance their impacts on productivity and equity. The preliminary nature of developing countries' experience with IPRs in agriculture precludes most possibilities for quantitative evaluation of impacts; in many cases possible effects of IPRs are confounded with other developments (such as domestic policy changes and the liberalisation of international trade). The study thus concentrates on qualitative evaluation of initial experiences and analyses the efficiency with which IPRs are implemented at the institutional level (including interactions with other regulatory mechanisms), the effectiveness of the new IPR regimes in providing added incentives for the breeding and seed sectors (both public and private), and the equity of outcomes for producers (with particular attention to smallholders).

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[172] A study, commissioned by the World Bank; full report available at http://www.cgn.wageningen-ur.nl/pgr/images/IPRinbreedingindustry.zip . The results of the study were offered to the GCP as a contribution by Wageningen UR.

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The wide variation in plant breeding capacities and seed industries among developing countries demands a case study approach for this research. The range of types of IPRs in force or contemplated, as well as the great variation in local institutions and farming systems, adds to the justification for a careful examination of a relatively few cases in terms of countries and crops. The choice of examples is constrained, however, by the fact that many countries have yet to establish an IPR regime for plant varieties. China, Colombia, India, Kenya, and Uganda were chosen to represent a wide range of situations. The study focused on three types of crops: export crops, crops (for market or subsistence) with good commercial seed potential, and crops that attract little commercial seed interest.

The study concentrated on patents, plant breeders' rights systems, and trademarks. The protection of plant varieties with patents is fairly uncommon; the principal examples are found in the US, where certain vegetatively propagated species have been eligible for patent protection since 1930 and more recently utility patents have been accepted for varieties of any type of crop. The most common system of IPRs for plant varieties is known as plant variety protection (PVP), related to several conventions of the Union for the Protection of New Varieties of Plants (UPOV). Patent protection is more common in biotechnology, where many of the genes, tools, and processes are protected by patents, although there are considerable differences among countries regarding eligibility and coverage. The plant breeding industry also relies on other mechanisms to protect its varieties and limit their use. Perhaps the most common is hybridisation, which encourages farmers to buy fresh seed each season and prohibits competitors from multiplying a variety. Other mechanisms include the use of seed laws, contract law, brands, and trademarks.

The study assumes that the primary justification for the establishment of IPRs is to increase welfare in society. By offering a type of monopoly for the commercial exploitation of an innovation, IPRs are intended to provide an incentive for creative endeavours by inventors and authors. The monopoly may, however, disadvantage particular stakeholders. The establishment of an IPR, which is based on national law, thus requires careful consideration of the different seed systems in the country and of the balance of economic interests of different stakeholders in society. Such analysis at the national level also needs to be balanced against potential benefits from international harmonisation at the legal and/or implementation levels. The analysis of IPRs also must take account of existing systems that regulate seed production and marketing, set biosafety standards; and enable the operation of contract law.

The case study countries

Although three of the four case study countries with PVP laws are members of UPOV under the 1978 convention, there are significant differences between them in the details of their legislation and in the actual performance of PVP. Aside from TRIPS, a major pressure for the initiation of PVP came from the foreign horticultural industry in Colombia and Kenya. In China this was part of a wider policy to promote the development of the domestic seed industry and to establish a framework for interaction with foreign agricultural technology. The establishment of PVP in India had its major impetus from a well-developed private seed industry leading to an extensive public debate about the nature of PVP; the result is legislation whose eligibility for inclusion in a UPOV convention has yet to be tested. In Uganda, which has yet to establish PVP, the debate is currently restricted to a small committee of professionals dealing with breeding and genetic resources.

Plant varieties are not eligible for patent protection in the case study countries. Trademarks are commonly used in all case study countries to protect seed company names and marks, but not for official variety names. None of the case study countries have particular exemptions in their patent

laws that compare with those usually available in PVP for other breeders or farmers. The establishment of PVP in the case study countries was often marked by controversy regarding the level and extent of protection for extant varieties.

The experience of the case study countries indicates that the ease of implementing PVP seems to be overestimated. In all cases, the effectiveness of PVP is still being tested and refined, and the cases illustrate that establishing a PVP law and putting it into practice are two separate challenges.

There is not yet sufficient experience on levels of participation to draw conclusions about the local resources required to manage PVP. In Colombia and Kenya, most applications for protection concern horticultural crops, for which the testing is largely managed externally. In China, on the other hand, there is a considerable demand for PVP, largely to protect publicly-developed varieties. In large countries with extensive seed markets, investment in PVP will be easy to justify; for smaller markets and niche varieties the justification will be more difficult. It is worth noting that protection, testing, and maintenance fees are currently uniform in each of the case study countries, without regard to type of crop or seed market.

Early experience indicates that sanctions for violations are often not well defined and that the courts are not well prepared to enforce the rights. In all cases, private and public plant breeders are learning that the major responsibility for identifying violations and pursuing cases rests with them, implying additional investments of staff and resources.

There is very little experience in the case study countries with the implementation of patents for plant breeding or biotechnology, with the exception of China. There is little or no case law in the case study countries relevant to the enforcement of such patents.

2. IPRs AND THE EVOLUTION OF THE PRIVATE SEED SECTOR

The emergence of the private seed sector in the case study countries owes relatively little to national IP regimes. By far the most dynamic private seed sector in the sample (India) has grown and diversified without the benefit of any IPRs but in the context of quite liberal seed laws and in many cases through the use of hybrids as a means of appropriation. While not necessary for initial private seed sector development, PVP may contribute to further growth and diversification. The nature and extent of this contribution will depend on the characteristics of the national seed system. Seed companies tend to take advantage of PVP and patents when it helps protect them against competitors gaining access to their materials. In Colombia and Kenya, protection is commonly not sought for hybrids. On the other hand, where hybrids are used in a competitive seed sector, such as India and China, they attract the majority of interest for PVP.

IPR systems can also limit farmers' seed saving and hence provide additional incentives for private seed provision; although there are no instances of this as yet in the case study countries, both Kenya and Colombia are considering modifications in their laws that could limit seed saving. Authorities admit that it would be difficult (as well as politically sensitive) to enforce such requirements with smallholders. In the flower industry, breeding firms' control of export markets is a very effective deterrent to on-farm multiplication of planting materials.

The question of whether IPRs will create a shake-out in the industry at the cost of the smaller companies cannot yet be answered in the case study countries. Such increasing concentration in the industry could be a result of the costs associated with protection, particularly for smaller companies. The situation in India, with many small seed companies in operation, deserves

particular attention. In addition, restricted access to technology might become a bottleneck for smaller companies.

3. IPRs AND THE PUBLIC RESEARCH SECTOR

The establishment of PVP regimes comes at a time when national agricultural research institutes (NARIs) are being asked to take much more responsibility for revenue generation. Research administrators see the possibility of earning income by licensing public varieties and other inventions but the degree to which such royalties can fulfill that promise depends on farmer demand for public varieties and on the ability of the institutions to manage and enforce their rights. In the case study countries there is little evidence so far of actual revenue generation from public breeding through IPRs, with the exception of institutions in China. The expectations of NARI management are however quite high. Potential limitations, such as competition with the emerging private sector for human resources and lack of freedom to operate with third-party IPR are rarely taken into account in NARIs' IP strategies.

A major problem with revenue generation from PVP is that the potential opportunities are patchy. There is a danger that this heterogeneity may be translated into inequitable and questionable public research resource allocations, further reducing research on orphan crops and a smallholder farmer focus in favour of breeding objectives and methodologies directed at large-scale commercial production. Mechanisms to share income with the individual researchers and research groups are under development in some institutions. NARI's capacity to market their own IP and to negotiate access to third party IP is currently very limited.

International Agricultural Research Centres (IARCs) have policies on IP that permit IP protection of inventions and materials if this will ensure that the subject materials and technologies will be available to its target groups. Several IARCs have some staff with legal backgrounds assigned to IP, plus access to a central advisory service. However, resources are limited and the increasing pressure to show impact at the local level will stretch current capabilities.

The IP issue is central in the balancing of relationships between private seed companies and public research. As IARCs focus on poverty alleviation and smallholder farmers, and NARIs place increased emphasis on earning royalties from their germplasm with commercial potential, IARCs have to rethink their relationships with NARIs. When IARCs can earn royalties on their materials from domestic seed producers, they find themselves in the same position as NARIs with regard to possibilities that opportunities for revenue generation may affect priorities.

The growth of the private seed industry would seem to provide a more effective link between public plant breeding and farmers' fields. However, many public varieties do not attract the interest of commercial seed enterprises, and this encourages many NARIs to organise their own seed production and marketing. In addition, many NARIs still find themselves with obligations to public seed production efforts. The establishment of IPR systems does little to resolve these challenges for public plant breeding.

4. IPRs AND SEED USERS

Farmers' seed systems are the main source of seed and new varieties for most crops in the case study countries. IPRs may reduce the effectiveness of these systems by limiting the saving, exchanging, and selling of farmer-produced seed of protected varieties. There are no instances to date of such restrictions in case study countries, but proposals for the strengthening of some national PVP regulations introduce these issues.

In some countries the choice of varieties is currently expanding through the opening of the seed sector, backed by economic policies and changes in seed regulations, and these trends may be further supported by IPRs. When the commercial seed market expansion is very rapid, IPRs can help control rogue traders (e.g. in India and China). However, restrictions on small seed enterprises and semi-commercial operations may jeopardise the provision of seed of some local varieties supplied commercially. In addition, the breeding of niche varieties and their delivery by small seed companies may be threatened.

IPRs help flower growers secure access to a wide range of varieties in the case study countries, but only when the establishment of IPRs contributes to a trustworthy business environment. These IPRs are not necessarily operational in the production countries, and their main point of application is in the main wholesale markets. Non-specific IPRs like trademark protection are an additional tool for the flower breeders.

It is likely that NARIs focus on revenue generation, supported by the introduction of IPRs, may divert their attention from the needs of marginal farmers. This may also affect the conduct of participatory methods in breeding and variety selection.

5. LESSONS

General

Many of the principal IPR strategies have only been in place a few years (or are still in the final stages of approval). Because the incentives provided by any IPR regime usually interact with various other factors (such as the liberalisation of domestic agricultural markets, increased globalisation, and a reduction of public expenditure for agricultural research and seed production) it is difficult to identify unambiguous conclusions regarding the possible contributions and concerns that IPR regimes might present for plant breeding in developing countries. However, the difficulty in identifying clear causality at this early stage does not mean that IPRs are unimportant. On the contrary, IPR regimes may lead to significant changes in plant breeding and seed production, and the subject warrants careful future study and monitoring. Despite the preliminary nature of the report's conclusions, the analysis points to a number of significant lessons that need to be presented and disseminated to different stakeholder groups.

There are several priorities for monitoring. These include assessing the extent to which IPR regimes (and other policy changes) in particular countries influence the priorities and products of public plant breeding, affect the structure and concentration of the domestic seed industry, and determine the options available to smallholders. On a global level, it is particularly important to monitor how IPRs are treated in multilateral and bilateral negotiations, and how IPRs influence the role of MNCs in technology transfer in developing countries.

Political realities, limitations in administrative resources, and varied economic incentives in most developing countries indicate that it is unrealistic to expect rapid establishment and effective enforcement of the type of IPR regimes that are found in some industrialised countries. In any case, IPR regimes should be part of developing countries' development pathways and consistent with their own priorities and capacities instead of being externally imposed. Donors and others hoping to support these processes must be prepared for a long-term and individualised development of national agricultural institutions.

IPR regimes must be developed at the national level, and much donor effort should support individual processes of multi-stakeholder debate, design, and implementation. Support for specifically-tailored IPR regimes is possible because of the range of options that are available for providing appropriate incentives. On the other hand, respecting individual country priorities and circumstances in the design of IPR regimes does not imply that opportunities for harmonisation and cooperation should be forgone. Mechanisms such as UPOV and PCT facilitate the implementation of IPRs and reduce transaction costs, but the object of harmonisation is to provide economic benefits rather than to promote coalitions whose standards are dictated by their strictest partners.

There should be particular attention in these discussions to issues related to international public goods, in particular, the conduct of international agricultural research with regard to IPRs in plant breeding and its relation with national research systems. A further issue that requires attention at the international level is access to some of the basic tools and processes of biotechnology. These may be protected in the North but the possible legal implications for the new varieties and agricultural products derived from such technology are often uncertain for the Southern scientists who use them.

The design of IPR instruments

Policymakers need to realise that IPRs are important not because countries may be required to accede to the conditions of an international agreement but rather because they offer possible mechanisms for stimulating research, enabling access to technology, and promoting enterprise growth, all for the good of society. As such, they are merely one tool in a range of policies that may be applied in specific contexts to further agricultural development (e.g. for supporting public agricultural research, regulating seed production and marketing, providing an enabling environment for agribusiness development, and empowering smallholders).

In most countries, the design and implementation of an IPR regime for plant breeding should be seen as a long-term process, subject to monitoring and adjustment. The establishment of PVP systems or patent offices is not necessarily sufficient to initiate widespread changes within the seed industry. It often takes considerable time for the infrastructure to be established, for plant breeders to become conversant with the system, and for the courts to be able to handle complaints.

Not only do IPRs in plant breeding have to be seen in the context of a wider range of agricultural policies, but IPR regimes themselves must be carefully tailored to specific situations. It is important that countries recognise that they have choices in designing legislation consistent with the TRIPs Agreement and that there are still opportunities for debating and interpreting the Agreement itself. The UPOV Conventions offer some important advantages for fulfilling the requirements for a *sui generis* system but they do not exhaust the possibilities. Similarly, there are several options with respect to tailoring national patent regimes for agricultural biotechnology. The key elements in IPR systems that can be adapted to the specific conditions of individual national seed sectors include the specific terms of the farmers' privilege and the breeder's exemption, the relationship between different IPRs (patents, PVP, trademarks, trade secrets), the exhaustion of these different types of IPRs, and possible differential treatment of particular crops.

Policy makers need to consider the resources required for the establishment or strengthening of IPR systems. Institutional capacity to deal with the processing of applications and the granting of rights is quite variable among countries. Cooperation and harmonisation at the implementation level can lower some of these costs. Fee rates that make an office self-supporting should be

welcome, but care must be taken to avoid unfairly taxing or discouraging applicants, and especially smaller players.

The introduction of transgenic varieties to developing countries presents special challenges, but does not necessarily imply the adoption of overly rigid IPR regimes. Limited experience to date has shown that in the absence of IPRs for GM plant varieties and biotechnological inventions, multinational companies have sometimes resorted to biosafety regulations in an attempt to protect their technology. Biosafety organisations are however not appropriate for such purposes, and policymakers need to create a clear division of responsibilities among various agencies for regulating the use of GM varieties. In many cases, the enforcement of existing seed laws can offer an appreciable improvement in limiting unauthorised sale of GM seed. Further research is needed on the extent of IP protection necessary for stimulating the development of GM varieties (where desired).

The implementation of IPR regimes

Policymakers must consider the institutional arrangements for PVP. A PVP authority may be included as part of an existing seed regulatory agency or established as a separate organisation; the expense of setting up a separate entity must be balanced against possible concentration of power or conflict of interest. In addition, there must be confidence that the PVP authority is independent from the interests of (public) plant breeding organisations.

The challenges of adequate enforcement for IPRs in plant breeding should not be underestimated. There is very little legal capacity in most countries to support IPR regimes for plant breeding. Implementation of IPR regimes must include attention to strengthening the court system's knowledge of IPRs in plant breeding, and the ambitions and scope of any IPR system must be consistent with the capacities of the legal system, including contract enforcement.

For the establishment of PVP, there are a number of important parameters that require careful consideration. These include: the designation of which species are to be covered; fee structures (and possible subsidies or differentiation by crop); the nature of the breeder's exemption for use of protected varieties; and the implications for farmers' abilities to save, exchange, and sell seed in accordance with local custom. For patents the choices are similar: which processes and products are patentable and the scope of protection. For trademarks, the key question is whether a variety name can be protected.

Because the establishment of IPR regimes is a gradual process, careful monitoring is required. Policymakers need to assess whether particular IPR regimes are actually providing incentives for seed system development consistent with national agricultural goals. This includes analysing if farmers have equitable access to an increasing diversity of crop varieties and if the structure of the commercial seed market provides confidence for participants while at the same time encouraging new entrants.

IPRs in international negotiations

IPRs for plant breeding are not a magic bullet that automatically stimulates or redirects agricultural growth, but they can be an important part of a comprehensive agricultural development strategy by helping support competitiveness and diversity in plant breeding and seed supply. Given the value of well designed IPRs for agricultural development, policy makers should not treat IPRs as a negotiable bargaining chip in trade negotiations or other international discussions.

IPRs need to be considered in international agreements that tackle related issues, in particular biodiversity and trade. National policies towards international agreements on biodiversity, negotiated by representatives with environment (CBD) or agriculture (IT/PGRFA) background need to be in line with the choices made in the field of IPR, which are primarily derived from economic and trade policies. Countries must be clear about how IPRs relate to national sovereignty over plant genetic resources and rights of indigenous communities (CBD), as well as Farmers' Rights (IT/PGRFA) in order to avoid conflicts of interpretation. This requires a capacity in IPR issues with a much wider group of stakeholders than commonly envisaged. Article 9 of the IT/PGRFA encourages open and informed national debates on issues related to genetic resources, including IPRs.

For many countries, the possibility of being required to establish particularly restrictive IPRs for plant breeding is more likely to be a product of bilateral trade agreements than to derive from TRIPs obligations. National policymakers need to be prepared to enter such negotiations with a full understanding of the implications of such "TRIPs-plus" agreements for their national plant breeding and seed systems. This requires close cooperation between national policy makers with trade, agriculture, and environment backgrounds to analyse the room for manoeuvres in interpreting and modifying any such requirements imposed by potential trading partners.

In the only case study country with legislation that includes Farmers' Rights (India), there is not enough experience to assess the degree to which this offers useful incentives for the development or promotion of farmer varieties. Further monitoring is required.

Agricultural policies

This study emphasises that IPR regimes in plant breeding should provide incentives for diversifying and strengthening plant breeding and seed production. This implies that policymakers cannot consider IPR regimes in isolation from wider issues of national agricultural policy.

The role of NARIs is a subject of considerable debate in light of generally declining national budgets and the growth of the private sector. Many NARIs are uncertain of whether to complement or compete with the private sector and hence are confused about how to take advantage of IPRs. Policymakers need to set clear guidelines in this area. NARIs need to distinguish between using IPRs in order to facilitate the use and delivery of their varieties, and seeing IPRs as a contributor to institute budgets through royalty income. Most NARIs seem to have little knowledge about the costs of obtaining and enforcing IPRs, and there is little realistic assessment within the NARI's of their capacity to compete with the private sector in producing commercially viable products (or in rewarding and maintaining staff for this task).

Most NARIs are too poorly organised to acquire access to complementary technology on equitable terms or to assess their "freedom to operate" with protected techniques and tools. NARIs are no match for the legal and negotiation skills or resources of major technology firms. NARIs need assistance to formulate IP policies and strengthen their legal and negotiation capacities.

The strategies that NARIs adopt for using IPRs will depend on answers to fundamental questions about the role of public sector agricultural research. For instance, different approaches to relations with the private sector must be taken into account. In addition, the way that NARIs manage IPRs has a significant bearing on the extent to which germplasm resources are shared more widely.

Policymakers must recognise that systems of international germplasm exchange are being threatened by an almost exclusive focus on the possible financial advantages accruing to the control of germplasm, without appreciating the importance of facilitated access.

Policymakers also need to ensure the development of the private domestic breeding sector. With few exceptions, domestic firms do not have the resources to invest in high technology and must depend on MNCs and advanced research institutions that protect their inventions. There are a few examples of incipient consortia of local seed companies formed to negotiate access to biotechnology, and national policy should support such efforts.

There are still serious challenges with respect to delivering useful varieties, particularly of non-hybrids and so-called "orphan crops", to smallholders. The combination of limited and isolated markets with widespread seed saving means that even fairly strong IPR regimes are unlikely to elicit commercial interest in the near future. Policymakers must find ways of combining (largely) public plant breeding, appropriate formal seed delivery (most likely private or cooperative), and support to local seed diffusion mechanisms, to serve the farmers dependent on these crops.

There are no indications in the case study countries to date that PVP unduly contributes to a concentration in the seed sector. Early experiences in biotechnology patents in the case study countries are insufficient to establish any evidence for concentration, despite the fact that most transgenics currently have one commercial source. However, it is important to support a critical assessment of developments in the coming years. This is an area in which industrialised countries could provide some useful guidance given their longer experience in monitoring and regulating anti-competitive practices.

Finally, it is worth reiterating that the purpose of IPR regimes in agriculture is to provide appropriate incentives for science and commerce to better serve the nation's farmers. National policies need to ensure that farmers are conversant with, and participate in, debates regarding possible IPR regimes; that they are well-informed consumers who understand their rights in agricultural input markets; and that their interests and priorities are reflected in the work of public agricultural research.

Generation

Cultivating Plant Diversity for the Resource Poor

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