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The Status of Public and Proprietary Germplasm and Information:

An Assessment of Recent Developments at FAO

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Contents

Editors' Introduction

Anatole F. Krattiger

ii

The Status of Public and Proprietary Germplasm and Information:

An Assessment of Recent Developments at FAO

1

Cary Fowler

	<i>Executive Summary</i>	1
1. Introduction		3
2. The Legal and Political Status of PGRFA: FAO-CGIAR Agreements		4
3. The Related Issue of "Related Information"		6
4. The International Treaty on Plant Genetic Resources for Food and Agriculture		8
4.1 Background		8
4.2 IPRs and Access Under the Treaty		10
4.3 MTAs Under the Treaty		11
5. Summary Regarding Legal Issues		13
6. Conclusions and Political Considerations		13
References		14

Editors' Introduction

The recently adopted International Treaty for Plant Genetic Resources for Food and Agriculture has brought to conclusion a long negotiation process that stretched over more than a decade but many specific interpretation and implementation questions remain. In this context, a range of flanking agreements are providing some guidance on the precise working whereas others may need to be re-negotiated to be consistent. One such agreement is between the Food and Agriculture Organization of the UN (FAO) and Centers of the Consultative Group on International Agricultural Research (CGIAR) that places certain collections "in trust" for the international community under the auspices of FAO. How will this agreement be affected? And what will be the new obligations of the CGIAR? What precisely is meant by the term "and related information" that has already caused significant confusion?

These and other questions are being clarified in this paper in a comprehensive manner by one of the leading authorities on the matter, Cary Fowler. His connection with the Treaty is very intimate because he served as the CGIAR's representative in the negotiations for the Treaty. Before that, he worked for FAO and headed the FAO Secretariat that developed the Global Plan of Action for Plant Genetic Resources for Food and Agriculture that was adopted by 150 countries in 1996 and he researched and drafted FAO's first report on The State of the World's PGRFA. In 1996, he also served as special advisor to the Secretary-General of the World Food Summit, and had a similar role at the follow-up summit last year. Cary Fowler currently has two positions. One is at the Agricultural University of Norway where he is Professor and Director of Research at the Center for International Environment and Development Studies. The other position is with IPGRI, the International Plant Genetic Resources Institute, one of the Centers of the CGIAR, where he serves as Senior Advisor to the Director General.

Cary Fowler has published widely and written a number of books; arguably, his best book is also the one that is least read, namely *Unnatural Selection: Technology, Politics and Plant Evolution* (published by Gordon and Breach Science Publishers in 1994).

It should be noted that as always, the views expressed in the article are those of Cary Fowler and do not necessarily represent those of his respective employers. Though, in this particular paper, I suspect, they do!

Anatole F Krattiger

The Status of Public and Proprietary Germplasm and Information: An Assessment of Recent Developments at FAO ¹

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Executive Summary

This paper examines two major international agreements that establish the access and benefit sharing rules for plant genetic resources and information related to these genetic resources:

1. The Agreement between the Food and Agriculture Organization of the UN (FAO) and Centers of the Consultative Group on International Agricultural Research (CGIAR) that places certain collections “in trust” for the international community under the auspices of FAO, and
2. The recently adopted International Treaty for Plant Genetic Resources for Food and Agriculture (the “Treaty”).

Together, these two agreements will cover most of the genetic diversity (and much of the information associated with it) of virtually all of the world’s most critical food crops, as well as a number of other important crops and forages. These agreements—the first a group of intergovernmentally-sanctioned contracts; the second, international law—define what shall be available/accessible, what can be done with these genetic resources, and whether and how intellectual property rights (IPRs) can be employed in connection with them. Understanding these agreements is therefore essential to those involved in research, plant breeding, and the conservation and distribution of plant genetic resources for food and agriculture (PGRFA).

Centers of the CGIAR hold some of the most important and most used collections of PGRFA in the world. Since 1994, access to these materials has been governed by an agreement between FAO and the Centers. Centers offer free access to the materials under the terms of a Material Transfer Agreement (MTA), which prohibits recipients from claiming ownership over the materials received and from seeking IPRs over them. The intent is to ensure that these genetic resources remain accessible and available for all to use. Significantly, in the context of aggressive claims of sovereignty over germplasm and charges of biopiracy flying about, the FAO-CGIAR Agreement also recognizes that the CGIAR-held collections have a certain history—that they were “donated or collected on the understanding that... (they) would remain freely available and... conserved and used in research on behalf of the international community...” Through the FAO Commission on Genetic Resources, countries have endorsed the FAO-CGIAR Agreement and thus implicitly recognized the international and public status of the germplasm.

Under the FAO-CGIAR Agreement, information related to specific germplasm accessions is also available automatically. At a minimum, this includes passport and characterization data, assuming the Center has

¹ Fowler, C. 2003. The Status of Public and Proprietary Germplasm and Information: An Assessment of Recent Developments at FAO. *IP Strategy Today* No. 7-2003.

it. "Information" under this Agreement refers to such information/data, not to DNA sequences, which are sometimes referred to as "information." Moreover, the Centers distribute accessions—they are not required or expected to distribute genes, expressed sequence tags, etc. This is important because it affects the interpretation of the prohibition against claims of ownership and IPRs over the material received. When viewed in the context of other elements of the FAO-CGIAR Agreement, this means that recipients can acquire germplasm, use it in breeding programs, and incorporate it into varieties that can be legitimately protected by IPRs. The FAO-CGIAR Agreement does not address the issue of derivatives and the FAO Commission on Genetic Resources has never been able to come to any consensus regarding the extent to which received germplasm must be altered before it can become eligible for protection in a manner consistent with the MTA used by the Centers. As a result, national IPR laws (typically UPOV-consistent) have become the default position. In practice, few obvious cases of abuse have occurred in the more than 700,000 accessions that have been distributed since 1994.

The above account of the IPR-related prohibitions and possibilities for germplasm acquired from CGIAR Centers is consistent in all major respects with the treatment of the subject under the new Treaty. The FAO-CGIAR Agreement, in fact, will be terminated, and the Treaty will apply to CGIAR collections as soon as Centers formally agree to accept the provisions of the Treaty. They have already signaled that they intend to do so.

The Treaty establishes a Multilateral System of facilitated access and benefit-sharing for certain genetic resources of specified crops. These genetic resources must be under the management and control of the Contracting Party (a country that has ratified the Treaty) and in the public domain. Materials under development are available only at the discretion of their developer during the period of development. Access to genetic resources is consistent with IPRs, which are expressly recognized in the Treaty.

The Treaty prohibits recipients from claiming any IPR that would "limit facilitated access to plant genetic resources for food and agriculture, or their genetic parts and components, in the form received from the Multilateral System." While the construction of this sentence opens the door for multiple interpretations, this provision must be understood in the context of the entire Treaty. The Treaty's benefit-sharing provision is triggered only when someone accesses material from the Multilateral System, uses it, and protects the resulting product (which must be a PGRFA—not a breakfast cereal, for example) in a manner that restricts further access to and use of the product. In other words, materials accessed from the Multilateral System—genetic resources from countries that ratify the Treaty—can be used in breeding programs and the resulting varieties or lines may be protected by IPRs, though benefit-sharing requirements may apply.

Information about genetic resources within the Multilateral System must also be made available by Parties to the Treaty and by CGIAR Centers. The Treaty, however, provides numerous exemptions from this provision. The information to be provided is only that which is "associated, available, non-confidential, descriptive information." As with the FAO-CGIAR Agreement, information under the Treaty is not interpreted as genetic material but as data and knowledge.

The precise terms of the Treaty's benefit-sharing requirements are yet to be determined. The Governing Body of the Treaty, comprised of countries that have ratified it, will have to agree upon this at its first meeting. The Treaty states, however, that the benefits to be provided will be "in line with commercial practice." The Governing Body will attempt, by consensus, to capture this in the text of a MTA that will accompany all shipments of materials covered by the Treaty. Monetary benefits will be used to support PGRFA-related programs, primarily in developing countries and countries with economies in transition.

The Treaty contains enough built-in problems and ambiguities to trouble anyone working in the field of PGRFA. Scientific, legal, and political perfection was never a realistic option. Nevertheless, the new Treaty is a considerable achievement, for it holds out the prospect that germplasm flows in the future might become more automatic and routine than they are now. Facilitated access and a transparent system for benefit sharing will advance the use of genetic resources which will promote sustainable agriculture and food security. After years of political wrangling, it appears that much of the genetic diversity of major crops will be available to future generations under international law, a gift from past generations and our own to our children and theirs.

1. Introduction

Increasingly, developments in the field of intellectual property rights (IPRs) are affecting the management of plant genetic resources. Conversely, how international institutions and negotiating forums treat genetic resources is affecting the management and application of IPRs.

IPRs have become the focus of debate in intergovernmental forums dealing with the conservation, exchange, and use of plant genetic resources for food and agriculture (PGRFA). To an innocent bystander, it might have appeared that opposition to or support of IPRs was driving discussions instead of concerns about the future of plant genetic resources and food security.

Two very different kinds of agreements are key to understanding how the “international community” wishes to treat IPRs within the context of managing global genetic resources. Namely:

1. Contractual agreements between FAO and the Centers of the Consultative Group on International Agricultural Research (CGIAR) regarding the Centers’ collections of germplasm, and
2. The new International Treaty for Plant Genetic Resources for Food and Agriculture (the “Treaty”), which will replace the former.

For better or worse, the debate concerning whether the international community will sanction the existence and use of IPRs in relation to germplasm (especially that held “in-trust” or contained within a multilateral system) is over. IPRs are explicitly recognized in the new Treaty. Indeed, the Treaty’s benefit-sharing mechanism is tied to them. While vestiges of old debates will doubtless linger, the questions to be debated now are mostly ones of definition and interpretation. This may not make their resolution any easier, however, for the challenge of balancing two important needs remains: the need to protect a globally critical resource and ensure that its use remains available to all, and the need to facilitate the application of modern science and technologies to genetic resources.

This paper does not aspire to cover the entire range of IPR-PGRFA issues within international agreements. Instead, it looks at two key instruments, how particular phrases and constructions in them might be interpreted, and what impact this will have on how genetic resources can and will be used.

In general, when faced with an issue of agreement or Treaty interpretation, one needs to look at:

Precedent: How has the term been used historically, particularly in the relevant forum or negotiations? What is the history of the debate about the term within the negotiations? How has it been operationalized or “understood” thus far?

Context: In what context is the term used? It is essential to note that individual phrases or paragraphs in a treaty are not “stand alone” constructions. They exist within a context and must be interpreted in a way that is logical and consistent with the entire text—this approach is a basic tenet of international law.

Practice: What is the experience to date? What does this tell us about how the broader community uses and interprets the language, and how the law has treated it, if at all?

Process: What process exists for resolving ambiguities? In the case of the new Treaty, there are both future negotiations concerning a Material Transfer Agreement (MTA) and a formal dispute settlement provision in the Treaty.

2. The Legal and Political Status of PGRFA: FAO-CGIAR Agreements

Struggles over plants and planting materials are ancient, certainly dating back hundreds if not thousands of years. The first proposals for applying IPRs to plants are also relatively old, occurring in the 19th century prior to the rediscovery of Mendel's laws of heredity (White 1975).

In the 20th century, a number of institutions began to assemble large collections of PGRFA, first in an effort to tap them for breeding programs,² and later for more conservation-oriented purposes. During most of this period, PGRFA were considered the "common heritage" of humankind (Hawtin & Reeves 1998). Landraces were freely provided by countries and freely exchanged by scientists. There were few if any efforts to "privatize" them as genetic resources. Among the many reasons it was considered beneficial to place them in the "public domain," one key consideration was that virtually all countries heavily depend on crops and genetic resources from other regions (Palacios 1998).

Spurred by the establishment of the International Board for Plant Genetic Resources (IBPGR; now the International Plant Genetic Resources Institute or IPGRI), collecting by national programs and Centers of the CGIAR took off in the 1970s and 1980s. Collections that numbered in the hundreds of thousands globally at the beginning of this period ballooned into the millions by the 1990s (FAO 1998). Typically, collecting expeditions sponsored by IBPGR/IPGRI or other CGIAR centers were organized in collaboration with national programs. The samples were split between a center and the national program for their conservation/use (NRC 1993).

During the 1970s and 1980s, CGIAR centers did not consider themselves the "owners" of these collected genetic resources, nor did they manage the materials in such a way that they appeared to be the owners. The materials remained freely available, and centers supplied genetic resources regularly and in large quantities to scientists, breeders, and national programs (Fowler Smale & Gaiji 2001) No one was turned away.

During its International Centers' Week in 1988, the CGIAR adopted a policy statement on genetic resources that formalized the existing understanding. This statement asserted that the centers were trustees, not owners, of the materials they had collected and were storing. Specifically, the policy stated the following:

The CGIAR regards the preservation of variability in plant germplasm as vital for research in subjects related to crop improvement. It is the CGIAR policy that collections assembled as a result of international collaboration should not become the property of any single nation, but should be held in trust for the use of present and future generations of research workers in all countries throughout the world (IPBGR 1989).³

The CGIAR position was perfectly consistent with that expressed by the international community in the FAO Undertaking on Plant Genetic Resources (the "Undertaking"). Article I of the Undertaking, which sets out its objectives, states that:

² As Krull & Borlaug (1970) put it: "Although plant collecting is extremely useful in elucidating the taxonomic and evolutionary relationships between different species and varieties, its principal justification is to obtain natural variability that can be useful in broadening germ plasm pools for plant improvement." For a brief account of early collecting efforts, see Ford-Lloyd & Jackson (1986).

³ Interestingly, the Statement contains no reference to IPRs. By 1992, however, a CGIAR "Working Paper" on genetic resources and IPRs stated that the CGIAR recognized both Plant Breeders' Rights and the concept of Farmers Rights, in accordance with the agreed interpretation of the FAO International Undertaking. See Hawtin & Reeves (1998). FAO Conference resolutions 4/89 and 5/89 provided this "agreed interpretation" and in the process tacitly approved the use of the genetic resource "heritage" (noted in Article 1) in breeding programs resulting in varieties protected by Plant Breeders' Rights.

This Undertaking is based on the universally accepted principle that plant genetic resources are the heritage of mankind and consequently should be available without restriction (FAO 1983).

In 1994, amidst concerns that either Centers (through IPRs⁴) or host countries (by legal or physical means) might somehow appropriate this heritage, those Centers of the CGIAR holding *ex situ* collections of plant genetic resources entered into agreements with FAO that brought the collections under the auspices of FAO.⁵ This Agreement was considered an interim one, pending completion of negotiations for a binding international treaty on PGRFA that had just begun at FAO in Rome. As the CGIAR was exercising trusteeship rather than ownership over the plant genetic resources it held, the CGIAR assumed that once international law was in place the status and handling of the PGRFA would fall under the dictates of the law (i.e., the future International Treaty on Plant Genetic Resources for Food and Agriculture).

The 1994 Agreement between FAO and the CGIAR Centers formally acknowledges that the Centers are custodians of the PGRFA—that they hold the material “in trust” for the international community. In its Preamble, the Agreement also makes a politically significant statement about the history of the germplasm held by the Centers, how they came to acquire it, and their understanding of how the materials would be treated:

...the germplasm accessions have been donated or collected on the understanding that these accessions will remain freely available and that they will be conserved and used in research on behalf of the international community, in particular the developing countries.

In the Agreement, Centers agree not to “claim legal ownership over the designated germplasm” or seek any IPRs over “that germplasm or related information.” Furthermore, they agree to ensure that when materials are transferred to another person or institution they are bound by the conditions regarding ownership and IPRs.⁶ In a Joint Statement issued by FAO and the Centers at the time of the signing of the Agreement in 1994, the Parties stated that the requirement for binding germplasm recipients to the conditions of the Agreement would be “satisfied by arrangements, such as MTAs...”

Both in its draft and final forms, the Agreement was seen and formally endorsed by the FAO Commission on Genetic Resources. This is a point worth emphasizing because the Agreement states how and on what basis the Centers acquired materials from countries. It also acknowledges that the approach of placing *collections* under the auspices of FAO and designating accessions—points that are critically important for establishing and understanding the status of the collections and for determining how they should be managed—were seen and endorsed on more than one occasion by the countries from whom the materials were obtained through the FAO Commission on Genetic Resources. Subsequent assertions by certain groups and individuals that countries had not somehow approved of the materials being treated as part of the public domain, or that the “in trust” status was of questionable legitimacy, are quite unfounded (see e.g. GRAIN 2002). Materials were collected with the consent of both the farmers and the countries at the time of collection, and the status of the materials as being held “in trust,” not for the providing country but for the “international community,” was acknowledged and endorsed by the

⁴ No center at that time had sought or received any grant of IPRs for plant material held “in trust” or derived from such material.

⁵ Centers associated with the CGIAR are legally autonomous, each with its own board of trustees, articles of incorporation, etc. Typically, they cooperate and coordinate on matters concerning PGRFA and related policy issues. In this instance, all Centers having PGRFA collections signed separate but identical agreements with FAO. For convenience, I refer to these agreements in the singular.

⁶ Centers are obliged to ensure that recipients are “bound” by these conditions; the Agreement does not oblige the Centers to ensure that these conditions are met. A separate “Joint Statement” issued by FAO and the CGIAR Centers addresses the issue of enforcement and outlines the steps that Centers will take when violations of the conditions are believed to have taken place.

countries themselves, repeatedly.⁷ These endorsements were, it might be added, the act of sovereign countries.⁸

3. The Related Issue of “Related Information”

The FAO-CGIAR Agreement and the new Treaty deal not only with germplasm but also with information associated with it. As noted above, Article 3(b) of the Agreement with FAO states that the Center does not “claim ownership over the designated germplasm, nor shall it seek any IPRs over that germplasm or related information.” This phrase is repeated in the MTA (MTA) currently used when providing access to designated germplasm.⁹

What does “related information” mean in this Agreement? The question is not trivial, particularly since “information” can be proprietary and because DNA sequences and other genetic materials are increasingly referred to as “information.”

Upon the occasion of the signing of the Agreement in 1994, FAO and the Centers issued a “Joint Statement” (previously referred to above) which addressed certain operational issues. This first statement contains a paragraph dealing with the question of “related information” directly:

Article 3(b): The words “related information” at the end of Article 3(b) refer to information which has been compiled with respect to individual accessions. Such information includes passport and characterization data and, when available in the databases of the respective genebanks, evaluation data and information on indigenous knowledge.

This explanation is quite specific, and leaves little room for an interpretation broad enough to argue that information equals genetic material. In simple terms, the information is *related* to germplasm; it is not itself germplasm. Though the wording is not as “tight” as it could have been, Article 3(b) gives no support to those who might argue that the agreement mandates the provision of proprietary information by the Center, or subsequently, by recipients of germplasm that are bound by the terms of the MTA. Article 3(b) speaks not of all information, but of information when it is “available” in the databases of the respective genebanks.

⁷ Likewise, the claim that each and every gene is “designated” and that the MTAs prohibit as much as a single gene contained in the collections from being used in a variety protected by IPRs is also spurious. Some non-governmental organizations (NGOs)—angry that the Centers were not legally challenging plant breeders’ rights certifications for varieties containing designated germplasm in the parentage—charged the Centers with unilaterally interpreting (and violating) the Agreement and not conforming with the wishes of either the countries or the FAO. Regardless of one’s views of the IPR system, it is clear that the Centers were acting properly and that the alternative interpretation of what could and could not be done with germplasm acquired from the Centers, was incorrect. Accessions, not genes, are designated. Collections, not genes, are placed under the auspices of FAO. And, more importantly, the intent of countries to allow the accessions/collections to be used to create new varieties that can legitimately be protected by IPRs is made clear by the new International Treaty, which bases its benefit-sharing mechanism on the premise that materials will be used to produce IPR-protected varieties. Groups that oppose the IPR system are aware that a prohibition against using any gene found in the 500,000 designated accessions held by the CGIAR would effectively render the UPOV system unusable, which is their goal. Neither the FAO-CGIAR Agreement nor the subsequent actions of countries, however, confirm such an interpretation.

⁸ Even though the Convention on Biological Diversity is inapplicable for the majority of CGIAR-held materials (because they were acquired prior to the Convention), the Convention’s basic requirements for access—that it be on the basis of prior informed consent and mutually agreed terms—were met by the Centers and confirmed by the countries through the FAO-CGIAR Agreement.

⁹ Significantly, the Centers have historically designated *accessions* to FAO, providing it with a list of accessions covered by the agreement, on a regular basis. For practical purposes, and in the context of the agreement, “designated germplasm” can be viewed as synonymous with accessions. This, as I have argued, is consistent with the language in and intent of the agreement and confirmed by negotiations for the Treaty.

In **practice**, no one requesting germplasm to my knowledge has demanded genes, expressed sequence tags (EST's), etc., and cited the FAO-CGIAR Agreement as evidence that Centers are obliged to supply such. As noted earlier, Centers placed "collections" under the auspices of FAO and routinely designate "accessions" as falling under the terms of the Agreement. They do not, for example, designate or undertake to provide specific genes, ESTs, etc.

The language of the Treaty is, if anything, even more explicit about what information must be provided (and what information can be withheld) in relation to materials in its Multilateral System. The Treaty substantively addresses this subject in two different Articles. In Article 12.3(c), the Treaty states that:

All available passport data and, subject to applicable law, any other associated, available, non-confidential, descriptive information, shall be made available with the plant genetic resources for food and agriculture provided;

This paragraph clearly puts proprietary information beyond the reach of a recipient. Note also that the information is to be made *available*—it is not necessarily provided in each instance. In many cases the recipient of germplasm will not choose to avail him/herself of the availability of the information.

Article 13.2(a) of the Treaty gives further detail about what is meant by "information."

The Contracting Parties agree to make available information which shall, inter alia, encompass catalogues and inventories, information on technologies, results of technical, scientific and socio-economic research, including characterization, evaluation and utilization, regarding those plant genetic resources for food and agriculture under the Multilateral System. Such information shall be made available, where non-confidential, subject to applicable law and in accordance with national capabilities....

Since the FAO-CGIAR Agreement was made, Centers have distributed more than 700,000 "in-trust" accessions. While certain questions have arisen regarding both the Centers' handling of these accessions and actions subsequently taken by recipients, I am not aware of any issues or "controversies" that remain outstanding. By any measure, the abuse rate of the MTAs is extraordinarily low.¹⁰ More importantly, FAO has consistently expressed its confidence in the Agreement and in the Centers' implementation of it.

No disputes or controversies have arisen regarding the provision of "related information." CGIAR Centers are well appreciated for supplying extensive, high quality information about accessions, both from Center databases and through the System-Wide Information Network for Genetic Resources (SINGER; <http://www.singer.cgiar.org>).

To be sure, the FAO-CGIAR Agreement and associated MTA beg the question of "derivatives," but in practice the Centers' approach to this matter has been quite consistent with the approach of the newly adopted Treaty (see below). "In trust" materials are allowed for use in breeding programs aimed at producing varieties protected by plant breeders' rights.

Much of the foregoing has implicitly considered how the FAO-CGIAR Agreement and the Treaty might be interpreted while observing how the Agreement has actually been implemented. Of course, as with any "static" agreement in a changing world, questions and new demands arise that were unforeseeable at the time the agreement was made.

Under the FAO-CGIAR Agreement, occasionally "unreasonable demands" were made that cited the language of the Agreement as justification (e.g., when a request was made for the entire collection of a Center, and for diseased materials, in violation of quarantine regulations). Such instances triggered a **process** (see Article 13 of the Agreement): IPGRI, in consultation with and on behalf of the other

¹⁰ See Fowler, Smale & Gaiji (2001), for an analysis of trends in the flows of germplasm into and out of Center collections and for estimates of the magnitude of "abuse" of MTAs.

CGIAR Centers, would discuss the matter with FAO. The Centers and FAO have typically resolved such matters quickly and amicably. In 1998 they issued a "Second Joint Statement" detailing their understanding of a variety of issues and how they should be handled. In one case—that concerning derivatives—the issue was too controversial or complicated for the FAO Secretariat to comfortably move forward. Considerable differences of opinion about this case existed amongst the members of FAO. In the absence of specific guidance from the FAO Commission, the CGIAR had no real alternative other than to be guided by national law and practice and its own best judgement about the intent of the agreement. It might be noted that Article 13 of the Agreement does contain a dispute resolution mechanism involving formal arbitration. On no occasion in the past eight years, however, has this even been mentioned in discussions with FAO, much less used.

In addition to the question of "related information," a second relevant issue exists as to what CGIAR Centers are obliged to make available, and, by extension, what might be considered "public." What materials are actually designated under the Agreement with FAO?

CGIAR Centers use the "Guidelines for the Designation of Accessions Under the FAO Agreements" for determining what materials to treat as being held "in trust." These Guidelines state that:

Centres now designate material if it is eligible for designation (i.e., not acquired with restrictions preventing a Centre from managing it in accordance with the FAO Agreements), and, as noted below, if the Centre is prepared to manage it in accordance with the Agreements.

As the Guidelines make clear, this means that Centers must be able to commit to (a) long-term conservation, and (b) unrestricted availability. If they are unwilling to commit to the first for some technical or scientific reason, or unable to commit to the second, then they do not designate. According to the Guidelines, when deciding whether to designate an accession Centers are not to consider the value or potential usefulness of the material, nor are they to make value judgments about whether the material should or should not be publicly available.

In conclusion, it should be borne in mind that the FAO-CGIAR Agreement seeks to ensure that the material remains available and used. Interpretations of the Agreement that would limit use must be suspect. Were conditions to change (new technology/new law), then a new "Joint Statement" might be warranted. All of the CGIAR's experience to date indicates that FAO would be a good and sympathetic partner in drafting a statement consistent with past practice and the goals of the Agreement.

4. The International Treaty on Plant Genetic Resources for Food and Agriculture (the "Treaty")

4.1 Background

First, some background and a few observations:

- The access and benefit-sharing provisions of the Treaty apply only to specifically identified crops/species—approximately 35 crops or crop complexes, plus a modest number of tropical forages. The Treaty does not regulate access to other crops/species, except in the case of CGIAR holdings of such materials. The Treaty will legally bind only the countries that formally ratify or accept

it¹¹; however, the Treaty's standard MTA might be used in the transfer of materials to non-Parties to the Treaty.

- The Treaty does not contain the phrase, "related information," and thus avoids any ambiguity or uncertainty that might have existed previously about that term.
- The Article concerning the CGIAR (Article 15) does not mention the word "information," although the Centers will effectively be bound to articles in the Treaty that mention it.
- The Treaty refers to international cooperation to promote access and exchange of "appropriate information" in conformity with Part IV of the Treaty (which explicitly recognizes intellectual and other property rights).
- Finally, Article 17 is devoted to the "Global Information System," but contains nothing that would support a definition of information that would encompass genetic material, or encroach upon proprietary information.

I have dealt above in some detail with how the Treaty and the FAO-CGIAR Agreement treat "related information," and with the question of whether "related information" could be construed in any way as to mean germplasm, genes, ESTs, etc. I wish to briefly consider now what is actually in the Treaty's Multilateral System and what can be done with it. In particular, does the Treaty establish IPR-related rules for accessed germplasm that are substantially different from those of the Agreement?

Article 12 of the Treaty deals with the question of access. It enjoins recipients from claiming any IPR or other right that would "limit facilitated access to plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System." The operative (and controversial) phrase here is "in the form received." This is because in Article 13 the financial benefit-sharing mechanism of the Treaty is triggered precisely when a recipient uses material obtained from the Multilateral System to make and commercialize a PGRFA product that "incorporates" the Multilateral System material and then protects this product in such a way as to restrict further research and breeding with the product. The use of the term, "incorporates" in this context indicates that the Treaty foresees that breeders will take material from the System, use it, and protect their new PGRFA products in such a way as to limit its use in research and breeding. In exchange for this privilege, benefit sharing is required. This provision therefore serves to clarify somewhat the Article 12 prohibition against IPRs on material "in the form received."

There is, however, still disagreement among delegates as to the impact of the phrase "in the form received" in regard to the "parts and components" of genetic resources accessed from the Multilateral System. Article 13 presumes that material received will be incorporated, and that IPRs will protect the new product containing the incorporated material. Article 12's "prohibition," therefore, could be interpreted as prohibiting something that most IPR law already prohibits, namely the protection of pre-existing material.

Can someone obtain an accession from the Multilateral System and subsequently patent a gene contained therein, under U.S. law for example, without violating the Treaty? This was the subject of much corridor discussion during the Treaty negotiations. The U.S. Patent and Trademark Office has expressly prohibited the patenting of naturally-occurring genes and has distinguished between these and the "isolated and purified" form of the DNA molecule that can be patented under U.S. law (US Department of Commerce 2001). Many countries are not convinced by this distinction and will probably be prepared to argue that such patenting opens the door to Treaty violations. Nevertheless, at a minimum it is clear that even in such cases the material received from the Multilateral System (e.g., in the form of seed), will remain available for use in *that* form even if the "isolated and purified" form has been patented.

¹¹ This raises an additional problem. Unless the Treaty is widely adopted, it could become international law with major geographic gaps in coverage. (Falcon & Fowler 2002)

If (a) national IPR laws are respected (as the Treaty mandates), and (b) if any clarification or conflicting interpretation would effectively require all Contracting Parties to agree, then it would appear that the Treaty may even allow U.S. style patent protection for “parts and components.” One can only speculate. Use of such protection, if allowable, may kick in the benefit-sharing provisions of the Treaty, but that is a matter beyond the scope of this paper. It is interesting that the U.S., which was extremely concerned about these IPR-related provisions of the Treaty, has recently signed the Treaty, stating that it has had a “change of heart” regarding the matters that were previously of concern. One might read into this that they no longer see a big problem or major contradiction with their IPR system.

4.2 IPRs and Access Under the Treaty

Article 12 deals with access and naturally focuses on access to PGRFA itself. Article 12 explicitly states that access to PGRFA “*under development... shall be at the discretion of its developer, during the period of its development.*” This, of course, would circumscribe the kinds of demands that might be placed on certain CGIAR materials or those held under the “management and control” of the Contracting Parties to the Treaty, and would thus be available from the Treaty’s Multilateral System.¹²

Previously, I argued that the Treaty’s treatment of “related information” is substantially similar to and consistent with the approach of the FAO-CGIAR Agreement. But what about sequence information? As one can see from the text of Article 12, quoted above, wide latitude is given to the holder of the information. The information to be provided is only “associated, available, non-confidential, descriptive information.” This combination of limiting adjectives did not find its way into the Treaty by accident. Needless to say, many countries, including all OECD countries as well as a number of developing countries, were extremely interested in protecting the research and intellectual property of their biotechnology companies, among others. Sequence information—not to mention genes and ESTs (even if they were to be interpreted, incorrectly I think, as “information”)—could fall under any of the excludable categories. It could be unavailable (due to practical or IPR circumstances, or even the fact that it was “under development”); it could be confidential, etc. Acting in good faith with the spirit of the Treaty, and in keeping with the CGIAR’s mission, Centers might want to make certain information and materials available. Some might claim that the Centers were not obliged to release such items, but the Treaty gives (and was designed to give) reasonable discretion to the provider of information.

Treatment of IPRs in the Treaty is quite consistent: IPRs are respected. Everything granted under the Treaty is provided while respecting applicable IPRs. The relevant paragraph from Article 12 of the Treaty states:

Access to plant genetic resources for food and agriculture protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws;

This, of course, also speaks to the question of derivatives. Consider:

- The Treaty provides for access.
- Accessed materials can be incorporated into new products and protected by IPRs (this is part of the basis for the benefit-sharing formula in the Treaty).
- Access to materials under development is at the discretion of the developer.
- Access to an end product is circumscribed (as per Article 12. 2(f) quoted above) by relevant agreements and national laws concerning IPRs.

¹² The PGRFA to which Contracting Parties agree to provide facilitated access is only that which is “under the management and control of the Contracting Parties and in the public domain.” (Article 11.2)

This last provision makes no sense unless the recipient is allowed under the Treaty to take out IPRs. In doing so, the recipient is obliged to deal with the question of essential derivation. Rather than tackling that issue itself (which Treaty negotiators felt was more properly the job of other forums), the Treaty recognizes national law.

4.3 MTAs Under the Treaty

At least five MTAs may ultimately come to be associated with the Treaty and its implementation. Thankfully, not all will be used simultaneously. The five include:

- a. the current (February 2003) MTA used by the CGIAR Centers to distribute designated germplasm;
- b. the draft interim MTA approved by FAO Commission in October and intended for use by the CGIAR on an interim basis until a standard MTA is adopted by the Governing Body of the Treaty for general use;
- c. the yet-to-be agreed-upon standard MTA for the Treaty;
- d. the MTA to be used by Centers for "in trust" materials of crops/species that are not part of the Multilateral System (this MTA might be the same as the standard MTA (b) but theoretically it could be different); and
- e. MTAs used by the CGIAR Centers and others for the transfer of improved germplasm that may incorporate materials from but not itself be part of the germplasm covered by the Multilateral System.

I shall focus below on the interim MTA that will soon come into use and on the standard MTA that will ultimately replace it.

In October 2002, the FAO Commission on Genetic Resources recommended that the CGIAR Centers begin using an "interim MTA" prior to the coming into force of the Treaty and the adoption of the Treaty's standard MTA. The Commission negotiated and endorsed the text for this interim MTA. It still contains the phrase "related information" because although it is transitional, this MTA nevertheless has to be consistent with the existing FAO-CGIAR Agreement.

Because the existing MTA used by the Centers and the interim MTA (scheduled for Centers to begin using in mid-2003) are so similar, it is fair to argue that the strengths and deficiencies of one are those of the other. It is no secret that the CGIAR has, in fact, noted certain deficiencies in the past, including the use of ambiguous terms. These ambiguities, however, have not caused great problems for the Centers. In fact, one might argue that they have been something of a blessing. Indeed, one might also say that without some ambiguities, there would probably be no Treaty. Instead of "facilitated access," we would be facing the prospect and necessity of concluding thousands of bilateral agreements under the Convention on Biological Diversity in order to obtain access to the quantities of resources that should become routinely available under the Treaty (Cooper, Engels & Frison 1994; Fowler 2001; Fowler, Smale & Gaiji 2001; Fowler 2002) Both scientists and lawyers might wish for perfect clarity. But, as the ancient Chinese adage cautions, we should be careful what we wish for.

The yet-to-be-agreed-upon standard MTA for the Treaty could address the questions of information and derivatives. I suspect it will not, however—at least not in ways that are either (a) inconsistent with the Treaty, or (b) inconsistent with prevailing national IPR legislation. Why? Because in the case of (a), countries will preserve ambiguities unless there is full consensus on an interpretation—doing otherwise requires delegates to reopen negotiations on the Treaty, and they will not want to do this. In the case of (b), delegates will not want to take on the business of other forums (WIPO, UPOV, etc.) and will certainly not wish to write or establish IPR law inconsistent with existing law. Any other course of action at FAO is almost inconceivable. Thus, if one is happy with how derivatives are treated now by existing law, then one will continue to be happy under the Treaty. Anyone who is not happy will remain unhappy!

While the text of the Treaty may in some places be ambiguous, and while this may cause uneasiness in some quarters, it is important to note that all future decisions of the Governing Body will be made by consensus *without recourse to voting*, unless it decides otherwise by consensus. In any case, the Governing Body can *never* choose to decide anything concerning amendments to the Treaty or changes to the Annexes by anything other than consensus. This mitigates against radical approaches to certain issues or strange interpretations. Unfortunately, it may also impede the Treaty's natural evolution.

One must realize that the Treaty's standard MTA will become a key tool for translating the language of the Treaty into contractual obligations for recipients of materials from the Multilateral System. Under the terms of the Treaty, the Governing Body will approve the text of the MTA *by consensus*.¹³ According to explicit language in the Treaty, the standard MTA *shall* be approved at the first meeting of the Governing Body. Given the likely composition of the Governing Body (with both developed and developing countries), it is unlikely that extreme positions—or anything other than compromises—will find their way into the text.

In preparation for the first meeting of the Treaty's Governing Body, which will be convened within a year of the 40th country ratifying or formally accepting the Treaty, FAO is establishing a Panel of Experts to examine the issues involved with the MTA and present recommendations and options. The intergovernmentally-adopted terms of reference for this Panel include the following questions concerning the content/provisions of the future standard MTA:

- What should be the level, form and manner of payments in line with commercial practice?
- Whether different levels of payment should be established for various categories of recipients who commercialise such products or for different sectors and, if so, what those levels, various categories of recipients, and sectors should be?
- Whether to exempt small farmers in developing countries and in countries with economies in transition from the payments, and if so, who qualifies as a small farmer?
- What constitutes commercialisation in terms of Article 13.2d(ii) of the Treaty?¹⁴
- What constitutes incorporation of material access from the Multilateral System?
- When would a product be considered to be available without restriction to others for further research and breeding? (Such a product would be exempt from the Treaty's benefit-sharing provision.)
- How will monetary and other benefits be defined for the purposes of the standard MTA?
- By what means will the MTA ensure the application of Article 12.3? (This Article spells out the conditions under which access to materials and information is to be granted.)
- What terms should be included in the MTA so that recipients are bound by it on acceptance of the material from the Multilateral System? (FAO 2002)

With the exception of the comments made in parenthesis, the above bullet points are verbatim quotations from the Panel's terms of reference. Underscoring the difficulty of the task, virtually all of the terminology contained in these bullet points comes straight from the Treaty.

In addition to the question of the MTA, the first meeting of the Governing Body is also slated to consider and approve procedures and mechanisms to promote compliance with the provisions of the Treaty. It is also expected to consider draft agreements with the CGIAR Centers.

¹³ See Article 19.

¹⁴ This refers to the paragraph laying out the conditions which, when met, trigger the benefit-sharing requirement. One of the conditions is that the recipient commercialise material accessed from the Multilateral System and incorporated into a product which is a PGRFA.

5. Summary Regarding Legal Issues

At the beginning of this paper, I argued that we should evaluate questions about germplasm and related information in the light of Precedent, Context, Practice, and Process. In doing that, I believe I have demonstrated that:

1. No **precedent** exists—either in the FAO-CGIAR Agreements or in the Treaty—for interpreting “related information” to mean genes, ESTs, sequence information, etc.
2. The text of both the Agreements and the Treaty seems to rule out such interpretations (or at least make the case very hard to argue). This is certainly so if one considers the entire *context* of the Treaty—its treatment of access, of IPRs, of the rights of developers, etc.—as well as its text concerning information. Note also that “related information” is not a term the Treaty employs, and so it probably will not pop up in the standard MTA. Finally, expansive interpretations of “information” and “access” to information were not put forth by delegates negotiating the Treaty. Thus, there is reason to question whether countries would now accept broad and reaching interpretations.
3. In **practice**, CGIAR Centers have not experienced cases under the FAO-CGIAR Agreement in which people have made demands based on such interpretations.
4. The **process** for adopting the future standard MTA and for making future amendments to the Treaty ensures that every single Contracting Party will have to agree. In many respects, this is both the good news and the bad news about the Treaty. It surely means, however, that the Treaty will evolve and be interpreted in a moderate fashion in line with existing norms.

6. Conclusions and Political Considerations

The Treaty negotiation process contained a number of potential dangers for the CGIAR and for all who believe that it is important to ensure real facilitated access to materials that can be used in research and breeding programs and ultimately deployed. The Treaty successfully dodged a number of bullets. The international community ended up with a Treaty that apparently has broad support. When the FAO Conference adopted it in November 2001, only Japan and the U.S. abstained out of 183 countries, and the U.S. has since signed the Treaty. As of March 2003, 16 countries (including such politically diverse countries as Canada and India) had ratified and an additional 67 plus the European Union had signed the Treaty.

The CGIAR Centers hold some of the largest, most useful, and most used PGRFA collections in the world (FAO 1998). The fate of these collections is everyone’s concern. Their continued availability for access and use—free from legal or political entanglements—was uppermost in the minds of many, if not most, governments during the negotiation process for the new International Treaty. Consequently, and because of the Centers’ vast experience in handling “international” collections, the views and policy positions of the Centers were of more than trivial interest to delegates, non-governmental organizations (NGOs), scientists and the media. The Centers have formally welcomed the Treaty and indicated their intention to associate themselves with it formally. Politically, the CGIAR System has neither the desire nor the incentive to pursue any other course.

During the course of the Treaty negotiations a number of proposals were made which would have threatened the availability of materials held by the CGIAR Centers. These proposals came in a number of guises—from calls for repatriation of all germplasm in the name of national sovereignty to calls for farmers to take ownership in the name of Farmers and Community Rights. Throughout these negotiations the CGIAR Centers maintained their strongly held view, as expressed in the FAO-CGIAR Agree-

ment and endorsed by the FAO Commission, that the germplasm they held “had been donated or collected on the understanding” that it would “remain freely available...conserved and used in research on behalf of the international community, particularly developing countries.” Attempts to rewrite this history or to cast doubts on the legitimacy of these arrangements failed.

The Treaty ensures that CGIAR-held collections will continue to remain available for use by the world’s plant breeders, scientists, and farmers. One might hope that facilitated access and benefit-sharing will soon become routine and that we can now work out how to conserve our rich heritage of genetic diversity for future generations and how to use it to achieve food security and end hunger.

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