

The International Regime, as it Applies to Plant Genetic Resources for Food and Agriculture (PGRFA)

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The International Regime

The World Summit on Sustainable Development mandates countries *to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing...to effectively implement the [access and benefit sharing provisions] of the Convention [on Biological Diversity]*. Those provisions spawned fundamental change in the realm of genetic resources.¹ Prior to the Convention on Biological Diversity (CBD), many regarded such resources as part of the common heritage of all mankind. And prior to the CBD there were discussions within the fora of the FAO and elsewhere about the global distribution, use, and benefit sharing from the use of plant genetic resources for food and agriculture. The CBD, however, confirmed that states have sovereign rights over their natural resources.

To a significant degree, the genetic resource provisions of the CBD were prompted by emerging applications of biotechnology in the pharmaceuticals industry. Those provisions are writ large, however, and encompass a broad range of application of genetic resources from drug development to industrial manufacturing to consumer products to agriculture. In each such context, CBD mandates have been superimposed upon conventional practices under which applications and uses of genetic resources have evolved. These practices vary among applications, as do their history and global breadth.

This variation has very significant implications for the nature and content of any "International Regime." Nowhere is this more evident than in the realm of plant genetic resources for food and agriculture (PGRFA), where deliberate use and modification of genetic resources has been under way for thousands of years; and where an elaborate array of institutions and protocols have evolved to encourage and facilitate both the development of such uses and the global sharing of benefits derived from these developments. The following paper uses the specific example of PGRFA to illustrate both unique aspects of these applications of genetic resources, and a range of considerations more generally applicable to any "international regime".

The Critical Importance of PGRFA and the Goals of an International Regime

Field trials growing old and new (1930s to the present) US Pioneer brand maize hybrids show that newer hybrids outperform older hybrids no matter the weather. In a drought year, yields using 1990s hybrids are 10 tonnes per hectare compared to 5 tonnes per hectare using 1930s hybrids. In ideal growing conditions, 1990s hybrids yield around 13 tonnes per hectare; nearly

¹ Under the Convention, "genetic resources" has a broad interpretation that includes "any material of plant, animal, microbial or other origin containing functional units of heredity" that is of "actual or potential value" (Article 2).

double the yield of 1930's hybrids. Improved yields are due to plant breeders assembling new combinations of genetic diversity from among a broader pool of genetic diversity. The continued development of new varieties that are improved by virtue of their genetic make-up is essential:

- to meet human needs for food, health and economic security;
- to reduce pressures on the environment from ploughing wild and fragile lands;
- to allow adaptation to changing weather (drought, salinity) and ever evolving pests and diseases; and
- to help reduce chemical inputs and thus contribute to a cleaner environment.

It is therefore essential to further enhance the processes of accessing and improving plant genetic resources for food and agriculture. Diversity that cannot be accessed represents potential lost opportunities for farmers and for consumers. Access to plant genetic resources goes beyond legalities and includes biological parameters. Genetic resource diversity may be inaccessible because its potential is unknown, or it is too risky and time-consuming to incorporate into an adapted variety, or because there are legal uncertainties relating to access and benefit sharing. Plant genetic resources for food and agriculture only become useful when they are grown on farms and contribute to agricultural productivity. The goals of an International Regime must therefore be to facilitate access and benefit sharing from the use of genetic resources. Ideally a regime would address both the legal and biological issues that affect access, use and benefits.

Access and Benefit-sharing for PGRFA: Features and Limitations Imposed by History, Biology and Laws.

Who are the beneficiaries? Benefit-sharing is usually discussed in the context of benefits that flow back to providers of genetic resources. However, benefit-sharing in respect of PGRFA should be understood in a much larger context; one that is global and multi-generational. By far the greatest number of beneficiaries are downstream of where PGRFA are accessed, further developed and then used in agriculture. Each of us as consumers of food is a beneficiary. Future generations will be beneficiaries provided mechanisms are established that encourage sustainable development, stewardship and use of genetic resources that will continue to improve agricultural productivity whilst protecting the environment. These mechanisms must encourage the more effective use of PGRFA on farms. It is in the more effective use of PGRFA that benefit-sharing in its more usually understood and narrower context comes into focus. It is important to identify the activities and the actors who contribute to the use of PGRFA, and it is also critical to consider the nature of PGRFA in respect of their global distribution and use.

What are the activities? Activities that are essential to further improve varieties are: conservation of PGRFA, evaluation of exotic germplasm, pre-breeding or germplasm enhancement programs, breeding of improved varieties, production of crops, and continued scientific research. Farmers have traditionally played the roles of conservator, varietal improver, and producer of food. Farmers who cultivate landraces today continue to play these three roles. In most of the industrialized world, and increasingly in the rest of the world, however, specialist roles have emerged. In these specialist roles conservators are usually funded publicly; pre-breeding or germplasm enhancement is largely funded by public

funds, plant breeders can be funded either by public funds, which may be national or international programs or through private, commercial funding, and farmers rely upon sales of their harvested crop for income. Conservators, pre-breeders, breeders and farmers can each be viewed as engines of activity. Each is essential to create a continuum starting with the conservation of PGRFA, access to PGRFA through the further improvement of crop varieties, to the growing of crops on farms and their harvests so that benefits ultimately accrue to consumers. " Without sufficient diversity, we play a waiting game, waiting for the pests and diseases to get the upper hand and assign a crop to extinction and the history books" (Cary Fowler).

Features of PGRFA that must be addressed by an International Regime

Diversity and inter-relationships: The diversity of actors, multi-national dependencies for genetic resources, and the long-term public benefits from conserving a broad base of genetic resources mean that a workable international regime for PGRFA must accommodate and encourage the need for both public and private investments. Shortfalls of capacity in one country have negative spillovers for other countries and therefore need to be redressed. Needs of farmers for improved varieties that are insufficiently provided for should be addressed. Multinational dependencies mean that shortfalls or a lack of capacity in one country undermine opportunities for all. And recognition needs to be provided for farmers' contributions to the development of crop diversity.

The nature of PGRFA: Varieties grown today in farmer's fields have pedigrees that cross countries and which often span continents. Pedigrees of varieties bred in plant breeding programs can usually be traced back to founder varieties used when those programs commenced during the 1930's-1960's. Farmer landraces trace back 8-10,000 years to sites of original domestication from wild relatives. For example, maize was originally domesticated in Oaxaca, Mexico. Varieties known as landraces were then developed by farmers as seeds were carried north and south and selection occurred in different environments. Maize landraces were present in the southwest of the territory now known as the US by at least 3,500 BC and they were also grown by indigenous people in the region that is now known as New England by at least 1000 AD. By 1600 maize had spread across Europe, Asia and Africa.

Examination of pedigree backgrounds of maize hybrids developed by Pioneer Hi-Bred that were widely used on farms in the United States, France and Mexico during the 1990s shows that pedigrees track to several founder varieties or populations. Some pedigree backgrounds are common in hybrids grown in different regions of the world (e.g. US landraces Leaming and Reid Yellow Dent, developed 1840-1860). In contrast, other germplasm backgrounds are restricted in the country of deployment. For example, Mexican landraces Tuxpeno and Zapalote Chico are present in Pioneer hybrids grown in Mexico, but not in hybrids grown in the US or France. In contrast, several examples of pedigrees that cross countries and continents are also evident. For example, FSOP was developed in the US but is used in hybrids grown in Mexico; Argentinean Maiz Amargo had its origins in Argentina and now appears in pedigrees of hybrids grown in both the US and in France; P54 a hybrid once grown in Cuba appears in the pedigrees of hybrids grown in Mexico.

PGRFA do not fit the pharmaceutical model: Access and benefit-sharing regimes are often considered using a pharmaceutical type model. In this model, a unique genetic resource is envisioned that has great monetary worth because access can be controlled and the product

it is used in is in high demand and can command a high price due to a lack of substitutes. However, the model for the vast majority of plant genetic resources used for food and agriculture presents a different set of realities. The global spread of varieties over millennia means that it will be unusual to find a unique genetic resource in one location. And alternate choices are usually available, for example chemical control can be used in place of a gene for pest or disease resistance. Most usually, then, specific PGRFA are neither rare, nor can they command a high price. In addition, local efforts are usually needed to identify useful PGRFA and to develop new crop varieties. In contrast, many drugs can be effective regardless of the country in which they are developed or where they are used. The historical transfer of crop varieties around the globe also means that it is usually impossible to track a variety grown today back in its pedigree to its origin thousands of years ago.

The main challenge: Promoting more access and use of PGRFA: It is the historic and continued transfer and improvement of plant genetic resources, a process that has evolved over millennia, which provides the basis for developing more productive varieties. Access to genetic resources is necessary to allow development of improved varieties that can be used on farms. Yet PGRFA for the most part do not fit a bilateral pharmaceutical type model. The solution has been to develop an internationally agreed multilateral framework where access to PGRFA is assured: assured access is itself the major benefit that removes the need for countries to undertake the laborious task of developing potentially hundreds or thousands of bilateral agreements. Access and benefit-sharing for PGRFA has therefore trodden two complimentary paths. One is a multilateral approach for specifically listed crops that was directed to the Food and Agriculture Organisation (FAO) of the United Nations under the auspices of the Convention on Biological Diversity (CBD). The second is a bilateral approach that is being developed by the CBD itself. The bilateral approach deals with access to varieties (listed and unlisted) that are currently extant in farmer's fields, that are not listed species, or any species for which use is non-agricultural.

The Multilateral Approach: The International Treaty

The Multilateral System (MS) was adopted in November 2001 by over 100 nations. It came into force as the FAO International Treaty on June 29th, 2004.

The objectives of the Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security. Through the Treaty, countries agree to establish an efficient, effective and transparent Multilateral System (MS) to facilitate access to PGRFA, and to share the benefits in a fair and equitable way. The MS applies to over 64 major crops and forages. The major gene bank collections currently held under the auspices of the FAO in CGIAR genebanks are expected to be part of the MS. The Governing Body of the Treaty, composed of countries that ratify the Treaty, will set out detailed conditions for access and benefit-sharing in an Material Transfer Agreement (MTA). This standardized MTA may well prove to be an important model for other genetic resource areas under the International Regime.

Conditions for access: PGRFA may be obtained from the MS for utilization and conservation in research, breeding and training. When a commercial product is developed using these resources, the Treaty provides for payment of an equitable share of the resulting monetary benefits, if this product is restricted from use by others for further research and breeding. If others may freely use the newly developed variety in their breeding programs, then payment into the MS is voluntary. Privately funded plant breeding organizations rely upon effective

intellectual property (IP) on the varieties they create to underwrite continued investments in research and product development. The international treaty therefore respects and accommodates the need for organisations to obtain IP. Principle donors to the multilateral system will be governments.

Benefit Sharing: The Treaty provides for sharing of the benefits of using PGRFA through information exchange, access to and the transfer of technology, and capacity building. It also forseees a funding strategy for activities that benefit small farmers in developing countries. Benefits of the International Treaty flow to:

- farmers and their communities by recognizing the contributions of farmers and communities to the conservation and development of PGRFA and giving governments the responsibility for implementing those rights;
- consumers, because of a greater variety of foods, agricultural products, and increased food security;
- the scientific community, through access to plant genetic resources crucial for research and plant breeding;
- international agricultural centres, whose collections the Treaty puts on a safe and long-term legal footing;
- both public and private sectors, which are assured access to a wide range of genetic diversity for agricultural development; and
- the environment, and future generations, because the Treaty will help conserve genetic diversity to face unpredictable environmental changes, and future human needs.

The bilateral approach: The CBD per se

Bilateral agreements providing access to and use of plant genetic resources under the guidelines of the CBD (Prior informed consent and benefit sharing) are still important for PGRFA because they include varieties that are grown in situ, wild species and non food or feed uses. No market can exist without both the supply and demand for PGRFA, and it is important to re-iterate that access to PGRFA is dependent upon biological and legal factors. PGRFA that could be useful in agriculture will languish and be under-utilised, failing to produce additional benefits to consumers or to would be germplasm providers, unless there are programs in place to explore the utility of those genetic resources. Opportunities to identify PGRFA that may be useful in another country are very dependent upon in-country pre-breeding and breeding programs. The multi-national pedigrees of Pioneer maize hybrids, for example, demonstrate that a breeding program in Iowa is in effect also a pre-breeding program for France. Countries cannot expect to experience a demand from breeders in other countries for use of their in situ germplasm unless there are in country breeding programs to uncover potentially useful germplasm. Consequently, the goals of the CBD to encourage sustainable use of genetic resources cannot be met if only the legalities of ABS are worked out. The biological challenges of identifying and encouraging the use of exotic genetic resources must also be resolved.

A contractual approach: A contractual model could be envisioned with full up-front disclosure and transparency. Benefit sharing terms would be agreed between parties so that accessors would know ahead of investing in research and product development their commercial

liabilities. Sanctions for non-compliance would need to be in place to provide an essential basis of trust between parties. Policing via patents has often been mentioned. It is important to note, however, that placing additional demands on patents not only serves to weaken investors willingness to invest in research, it is also an inefficient option for the genetic resource provider. Most developments of PGRFA do not end up in the form of a patent, and even when they do it is not usually the patent that creates the monetary flow; the monetary flow commences with the sale of the product that contains the genetic resource. Other means to track genetic resource use or to validate compliance might include certificates of origin or source and codes of conduct. Annual reports documenting use of the genetic resources might be envisioned, possibly with their party audits. Civil penalties for companies that bio-prospect without an ABS agreement could be appropriate including suspension of rights in the country, withdrawal of visas and/or monetary penalties. International arbitration tribunals may be needed for dispute resolution. However, it will be important to keep costs low. Developed countries should provide capacity building to assist developing countries to effectively negotiate with companies.

The CBD obligates members to facilitate access to genetic resources. Referencing owners of genetic resources or providing a registry of agreements could be useful. County focal points that can clearly identify parties that have authority to negotiate access and benefit sharing terms are critical needs. And it is essential to emphasise once again that plant breeding programs are required to identify potentially useful germplasm. There are few prospects of requests for access to exotic germplasm without the evaluation of those resources that can occur within an in country breeding program.

Conclusions

Continued access to and use of PGRFA is critical for human health, economies and the environment. The greatest value of PGRFA is realized in farmers' fields, in the agricultural production system. It is important to encourage yet more effective access to and use of PGRFA. Both public and private sector activities are required. Effective IP is an essential prerequisite to encourage innovation and risk taking in the use of PGRFA by commercial breeders. The FAO-IT and CBD together provide two complementary paths forward to facilitate access, benefit creation, and the sharing of benefits. Both accommodate needs of commercial breeders to obtain IP on derived varieties. It is important that the needs of both the providers and the users of genetic resources are met. Otherwise, there will be breaks in the continuum linking PGRFA that flow ultimately through farmers to consumers. Breaks in the linkage between PGRFA and consumers mean that agricultural productivity declines and additional pressures are then put on current and future generations to maintain food, health and environmental security.

Plant breeders have grown accustomed to licensing important traits and technologies. Building trust is an important component to effective access and benefit sharing. Experiences of commercial companies, who are often both providers and accessors of germplasm or technologies in license type agreements, may be useful to help countries gain experience and confidence in developing bilateral agreements. It is also crucial to focus resources to meet the biological constraints in identifying and using exotic genetic resources. An international regime with legal certitude will remain non-functional unless additional resources are applied in field breeding programs to identify potentially useful exotic germplasm.