THE WORLD BANK OPERATIONS EVALUATION DEPARTMENT

The CGIAR at 31:An Independent Meta-Evaluation of the Consultative Group on International Agricultural Research

Thematic Working Paper
Review of Biotechnology, Genetic Resource, and Intellectual Property Rights Programs

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Abbreviations and Acronyms

AGM	Annual General Meeting (CGIAR)
AKIS	Agricultural Knowledge and Information Systems (World Bank)
ASARECA	Association for Strengthening Agricultural Research in Eastern and Central Africa
CAS	Country assistance strategy (World Bank)
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIAT	Centro Internacional de Agricultura Tropical (CGIAR)
CIFOR	Center for International Forestry Research (CGIAR)
CIMMYT	Centro Internacional de Mejoramiento de Maïz y Trigo (CGIAR)
CIP	Centro Internacional de la Papa (CGIAR)
CORAF	Conseil Ouest et Centre Africain pour la Recherche et le Développement
DG	Director General
DGF	Development Grant Facility (World Bank)
Embrapa	Brazilian Agricultural Research Corporation
FAO	Food and Agriculture Organization of the United Nations
GPG	Global public good
GPPPs	Global public policies and programs
ICARDA	International Center for Agricultural Research in the Dry Areas (CGIAR)
ICLARM	International Center for Living Aquatic Resources Management (CGIAR)
ICRAF	International Center for Research in Agroforestry (CGIAR)
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics (CGIAR)
ICW	International Centers Week (CGIAR)
ICWG-GR	Inter-Center Working Group on Genetic Resources (CGIAR)
IFPRI	International Food Policy Research Institute (CGIAR)
IITA	International Institute of Tropical Agriculture (CGIAR)
ILCA	International Livestock Center for Africa (CGIAR)
ILRAD	International Laboratory for Research on Animal Diseases (CGIAR)
ILRI	International Livestock Research Institute (CGIAR)
IPGRI	International Plant Genetic Resources Institute (CGIAR)
IPR	Intellectual property right
IRRI	International Rice Research Institute (CGIAR)
ISNAR	International Service for National Agricultural Research (CGIAR)
MTM	Mid-Term Meeting (CGIAR)
NARS	National agricultural research systems
NGO	Nongovernmental organization
OECD	Organization for Economic Cooperation and Development
OED	Operations Evaluation Department (World Bank)
R&D	Research and development
SACCAR	Southern African Centre for Cooperation in Agricultural and Natural Resources Research and Training
SINGER	System-wide Information Network for Genetic Resources (CGIAR)
TAC	Technical Advisory Council (CGIAR)
TSR	Third System Review (CGIAR)
UNEP	United Nations Environment Programme

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Contents

Preface

This is one of five thematic working papers by independent scholars prepared as part of the meta-evaluation of the Consultative Group on International Agricultural Research (CGIAR) conducted by the Operations Evaluation Department (OED) of the World Bank. The report, entitled *The CGIAR at 31: An Independent Meta-Evaluation of the Consultative Group on International Agricultural Research*, is available on OED's external Web site: http://www.worldbank.org/oed/gppp/. The thematic working papers are: C. B. Barrett, "Natural Resources Management Research in the CGIAR: A Meta-Evaluation," C. K. Eicher and M. Rukuni, "The CGIAR in Africa: Past, Present, and Future," B. Gardner, "Global Public Goods from the CGIAR: An Impact Assessment," W. Lesser, "Reviews of Biotechnology, Genetic Resource and Intellectual Property Rights Programs," and D. J. Spielman, "International Agricultural Research and the Role of the Private Sector."

The report on the CGIAR is part of a two-phase independent review by OED of the World Bank's involvement in global programs. The first phase has been published: *The World Bank's Approach to Global Programs: An Independent Evaluation, Phase 1 Report* (OED, Washington, D.C., 2002). The second phase, due in fiscal 2004, involves case studies of 26 programs, of which the CGIAR is one. The inclusion of the CGIAR evaluation in the OED review of the Bank's global programs was requested by the Development Grant Facility (DGF) and Bank Management in June 2001, and endorsed by OED's global program advisory committee.

While the focus of the meta-evaluation is on the Bank and the strategic role it has played and ideally will continue to play in the future in ensuring the CGIAR's development effectiveness, the thematic and country working papers and the country background papers focus on the different components of CGIAR activities that determine impact, including country perspectives. In addition to informing a broader understanding of the policy and technical context of CGIAR implementation, the papers provide a tool for assessing the performance and impact of the whole CGIAR partnership; this, in turn, provides a critical context for gauging the impact and value added of the Bank's participation in the program, the primary objective of the CGIAR meta-evaluation.

All five thematic working papers are based on extensive reviews of CGIAR's own evaluations as well as other related scholarly literature and discussions with relevant stakeholders. Four of the five thematic working papers were extensively peer-reviewed by knowledgeable external experts. A list of working and background papers and peer reviewers for the working papers is provided in Annex 5.

In addition, four country case studies on Brazil, India, Colombia, and Kenya provide developing country perspectives on the CGIAR. Two of the four – a study on India, written by Dr. J. C. Katyal and Dr. Mruthyunjaya, and a study on Brazil, by Jamil Macedo, Marcio C.M. Porto, Elisio Contini, and Antonio F.D. Avila – are issued as country working papers. The other two – C. Ndiritu, "CGIAR-NARS Partnership: The Case of Kenya" and L. Romano, "Colombia Country Paper for the CGIAR Meta-Evaluation"– are available on request.

The CGIAR was the first program providing global public goods to receive grants from the Bank's net income. Although the program has an impressive tradition of self-assessments, System-level evaluations have been few and far between. An exception, the Third System Review (TSR), was carried out in 1998, 17 years after the previous System-level review. OED determined that a meta-evaluation would most effectively assess CGIAR performance and inform OED's overall review of the Bank's involvement in global programs. In brief, the objectives of the meta-evaluation were three-fold:

- Evaluate implementation of recommendations in the 1998 TSR review
- Identify issues confronting the CGIAR from a forward-looking perspective
- Draw lessons for overall Bank strategy on global public policies and programs

The meta-evaluation report is in three volumes. *The Overview Report (Volume 1)* addresses strategic questions regarding the organization, financing, and management of the CGIAR as these have affected research choices, science quality, and the Bank's relationship to the CGIAR. *The Technical Report (Volume 2)* explores the nature, scope, and quality of the System's scientific work, assesses the scope and results of the reviews, and analyzes the governance, finance, and management in the CGIAR. *The Annexes (Volume 3)* provide supporting materials and are available on request.

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Summary

1. This part of the meta-evaluation is based on seven System-wide reviews and reviews of seven Centers identified for particular attention.[1] The main text identifies the principal issues in three focus areas – biotechnology, genetic resources, and intellectual property rights (IPR) – with particular attention to the following

- The key issues the CGIAR and individual Centers face
- The role and effectiveness of the reviews in identifying those issues

2. Each of the three sections of this report ends with specific recommendations. Detailed materials, including synopses and comments on the individual reviews, are contained in annexes.

3. *Inter-relations among the fields*. Biotechnology, genetic resources, and intellectual property rights (IPR) are related in intricate ways. Genetic resources often provide the raw materials to which biotechnological techniques are applied, leading to the production of new products. IPR may be utilized to control access and use of those new products or the genetic resources incorporated into them. Hence, a biotechnology program must operate within the framework of available materials; at the same time, the outputs of such programs will determine the potential applications of IPR.

4. The level of interaction between the three is determined endogenously by the activities of the Centers themselves. For example, more basic biotechnology research has the prospect for requiring access to protected materials and producing developments of potential broad use and value. Hence, the need to accommodate IPR is higher. Conversely, the breeding of next generation varieties for developing country use requires less external sourcing and a lower prospect of broad applications and great commercial value. Under that scenario, IPR are less significant. Recognizing those interdependencies, it is beneficial to evaluate the three areas together, as is done here.

5. This report makes no attempt to carry out an independent evaluation of programs. Rather, prior relevant reviews at the System-wide, Program, and Center levels serve as the principal source of information and evaluation. Interviews with, and questionnaires from, knowledgeable individuals within the outside the CGIAR have been used to clarify and, to a limited extent, update material from those reviews. On occasion, other background documents are used to clarify general practices outside the CGIAR System. Recommendations based in part on information not included in the reviews are so noted.

1. CIAT, CIMMYT, IITA, ILRI, IPGRI, IRRI, and ISNAR.

1. Introduction

1.1 This section of the meta-evaluation reports on three inter-related aspects of the CGIAR programs, biotechnology, genetic resources, and Intellectual property Rights (IPR). Each relates to the production of Global Public Goods (GPG) in distinct ways:

1.2 *Biotechnology*. With the ongoing discussions of biotechnology, it is easy to loose sight of the fact that it is indeed a technology. More correctly it is actually a series of technologies, each with a different function and role. What those technologies have in common, from the perspective of this meta-evaluation, is a mechanism for assisting Centers in producing products which would not be possible without biotechnology, or which can be produced more rapidly or inexpensively with biotechnology than without.

1.3 One of the "products" producible with biotechnology is knowledge. While research always potentially produces new knowledge, the current situation with forms of biotechnology being relatively recent and at the forefront of biological research means that the output of significant discoveries is relatively high with some areas of biotechnology research. Other outputs include new varieties which can be produced more rapidly using molecular markers than when relying exclusively on traditional breeding methods. In still other cases, the resultant new varieties (transgenics) would not have been producible using traditional technologies. In the form of new knowledge, biotechnology is producing GPG directly while in the form of new varieties, GPG production is indirect. In either case, biotechnology is a key element of current biological research, and a component of producing GPG.

1.4 Biotechnology, especially in the form of transgenics, is often controversial. Particular areas of controversy regarding developing countries are whether biotechnology is applicable for resource poor farmers, and whether it is necessary or even feasible to feed growing populations on limited land bases. Some argue for, some against.[2] Here, the purpose is not to attempt to resolve that debate on behalf of the CGIAR – that is better left to a future date when subsequent developments can be appreciated. Rather, it is to take the pragmatic view that biotechnology is an important area of current biological science with, at minimum, great promise for enhancing food quantity and quality, and reducing environmental impacts compared to some current agricultural technologies. Hence, it is an area of scientific pursuit essential for the CGIAR. In McCalla and Brown's (2000) words, "It is a solution not without problems, but one we cannot afford to ignore."

1.5 What remains unresolved for the CGIAR is the particular aspects of biotechnology to invest in, and the level of that investment compared to other activities, such as more traditional breeding and training. Also relevant are decisions on what technologies to develop and which to acquire using licensing and other measures. Implicit is more of an understanding – possibly a policy – on interactions with the private sector.

1.6 *Genetic resources*. Until recently, genetic resources for food and agriculture (GRFA) came close to meeting the definition for pure public goods. They are non-rivalrous in that the information contained in the genome can be used without reduction in access by multiple researchers. The broad distribution of the materials, including in public gene banks with open

2. For a flavor of that literature, see Pinstrup-Anderson and Schioler (2000) (pro) and Anderson (2000) (anti).

access policies, has meant they are non-excludable as well. And because some of the genetic information may be of nearly global utility, GRFA approached being true Global Public Goods (TAC, 2000).

1.7 Recent changes, including practices in response to the Convention on Biological Diversity (CBD), as well as changes in IPR regimes which facilitate the capturing of value for those materials is some cases, among others, have in recent years led to some restrictions on access to GRFA. In response, the CGIAR, working in collaboration with the FAO and CBD, has been striving to implement procedures for maintaining the open access believed necessary to maximize worldwide food production. That goal is particularly important for resource poor farmers who, with limited purchased inputs, depend proportionally more on the productive potential of planting materials.

1.8 *Intellectual property rights*. Intellectual property rights do not in themselves directly contribute to the production of GPG. Rather, they are supportive in nature, allowing, if properly managed, the Centers to fulfill their GPG mandate more efficaciously. Hence, this section is limited to an assessment of IPR management within the CGIAR and its effects on the realization of the CGIAR mandates. The connection between the mandate and production of GPG is left to other parts of this meta-evaluation.

1.9 IPR for plants and animals, and ancillary increases in private sector investment in agricultural research, are relatively recent, and evolving, developments to which the public research sector is still adjusting. Developed country research institutions nonetheless have accommodated IPR to the extent of many U.S. universities and other public sector research institutions establishing offices for managing intellectual property assets.

1.10 The CGIAR remains equivocal regarding the use and roles of IPR. Indeed, seemingly only recently has the System recognized the pertinence of IPR for contemporary biological science research and the need for the Centers to accommodate IPR as part of its overall activities.

2. Biotechnology Research at the CGIAR

Background

2.1 Because "biotechnology" or the "new biotechnology" can be interpreted many ways, a pragmatic approach is taken here to categorizing work into four areas:[3]

- Marker-assisted breeding,
- DNA related work (mapping, etc.),
- Transgenics, and
- Bio-informatics.

3. Details of the evaluation process are included in Annex 1.

Tissue culture, while classified by some as biotechnology, is not included among those technologies for the purposes of this report.

2.2 The material presented here is based on three System-wide reviews, as follows:

- Report of the CGIAR Panel on General Issues in Biotechnology,
- Third System-wide Review of the CGIAR, and
- System-wide Review of Plant Breeding Methodologies in the CGIAR.

This is in addition to the individual Center reviews.

2.3 *Investment*. Currently the private sector worldwide invests approximately 70 percent of the total, particularly for transgenics. As a result, nearly 80 percent of agricultural biotechnology related patents are owned by the private sector. For the developing countries, in contrast, less than 10 percent of funding comes from the private sector. The CGIAR has invested an estimated $25 million in biotechnology research. This represents about 25 percent of the plant breeding budget, but is widely considered to be inadequate. The advent of the Challenge Programs, the first round of which includes two biotechnology applications, can potentially increase the flow of funds to that research area. However, the one approved to date excludes transgenic research for the initial four year funding cycle.

2.4 *Policies*. A Center's position statement on biotechnology was adopted in 1998. Endorsed are recognition of the food-producing and environmental potential of biotechnology and the CGIAR's comparative advantage in providing access. Also that year, the use of genetic use restriction ('terminator') technologies was excluded.

2.5 *Center activities*. All but IPGRI and IFPRI of the focus Centers have biotechnology programs, particularly in marker assisted breeding. CIMMYT with its Applied Biotechnology Center (ABC), presently involved in producing *Bt* corn transgenics and further developing the apomixis technology, has one of the most extensive programs. ISNAR, through its Intermediary Biotechnology Service (IBS), provides advice on integrating policies, education, and infrastructure for more effective programs.

2.6 *Partnerships*. Partnerships with the NARS has been evolving from bilateral into multilateral arrangements through research networks. Training support funding has been in a general decline. Contacts with the private sector by the Centers and the NARS are very limited.

Key Issues for the CGIAR

2.7 *Research focus*. Of over-riding importance is the absence of a broad decision on the focus of research on narrower short term projects vs. broader longer term programs. This distinction is of particular issue for biotechnology for biotech research (with the possible exclusion of marker assisted breeding) is generally longer term, more risky research. A rational can be made for either approach under the general goal of assisting the poor. Attempting to do both, the current de facto approach with funding divisions varying from Center to Center, though risks mediocre outcomes in both. Current funding is presently insufficient to conduct simultaneously world class research in the two diverse areas.

2.8 The CGIAR must also consider carefully what the true comparative advantages are. If, as has been suggested, they relate to an excellent working knowledge of the germplasm collection, then there is reason to question the conducting of more basic research at the Centers. As a case in point, CIMMYT scientists undoubtedly have the expertise to develop the apomixis technology. Major universities and research institutions worldwide, as well as private firms, do as well. No clear rational has been made for apomixis research as the best use of CIMMYT scientists.

2.9 Finally, consideration must be given to how genetically modified crops may be distributed and managed once available. In that regard, Herdt (2000) identified the possible need for a corporate entity to move developed products from discovery to use. Many - and certainly *Bt*-producing crops – require monitoring to delay resistance development and possible gene transfer. There is no evidence the Centers have considered that issue, and their role, systematically.

2.10 *Decision outsourcing*. The CGIAR appears to have operated on the basis of providing internally for all its needs. In biotechnology, where successful transgenic gene constructs in particular are potentially available for licensing, recreating similar technologies seems an inefficient approach. Bio-informatics is a key yet costly aspect of functional genetics. Certainly, the Centers need access to that expertise, but there has been no public discussion of whether to provide it internally or through a partnership or license arrangement. The remaining biotech-related issues, examined below, are essentially subcomponents of the issue of decision outsourcing.

2.11 *Consistency of quality of science*. Success in biotechnology research depends on the quality of the science. Science quality is determined by the skills and motivation of scientists as well as facilities. For cutting-edge research, ongoing connections with the international research community are also essential. While not perfect, most leading institutions have used peer review and competitive grants to advance research quality. This is done to a far lesser extent by the CGIAR, to its possible detriment. The Challenge Program system may introduce more competition and interaction into the CGIAR, at least during the second round of non-targeted pilot programs. At this stage, the limited documentation on the Challenge system does not make it possible to project the longer term effects.

2.12 *NARS relationships*. There is an absence of an underlying policy for biotechnology training with the NARS. Individual Centers appear to operate in a pragmatic way as follows:

- Advanced – collaborate as with any peer institution,
- Mid-level – host scientists for lab projects and training, and
- Weaker – limited interaction at present.

2.13 This seems to make sense in a pragmatic way, yet some reviews urge the Centers not to allow the weaker NARS to fall further behind, while failing to consider just what role in biotechnology those cash-strapped institutions may have. The ISNAR-type research management training seems more appropriate for that group of NARS.

2.14 *Politicization of technologies*. In 1998, the CGIAR made the decision not to use genetic use restriction technologies, even though there are possible valuable applications of

those technologies. Among other possibilities, "terminator"-type technologies could help in preventing the use of saved *Bt* transgenic crops if saved seed led to reduced toxin expression and hence increased risk of resistance development. Moreover, such a step can increase future pressure by the vocal anti-biotechnology community to exclude technologies for political, not scientific, reasons. In general, the Centers should avoid taking absolutist positions on technologies, reserving the opportunity for case-by-case decisions as scientific knowledge and applications evolve.

2.15 *Review process*. The form and scope of reviews at both the System-wide and Center levels typically lack any real detail on what the current research programs actually are. There is no systematic and comparative way to determine the research quality at the Center level. Many annual reports have moved so substantially to a human interest focus as to be uninformative about what Center activities and achievements actually are. And finally, financial reporting uses different categories and combinations of activities so that connecting programs to budgets and making cross-Center comparisons is impossible. Current financial reports can serve as a basis for auditing for fiscal integrity, but are useless for program management purposes. Together, this all means the CGIAR is very opaque for anyone relying on documents to understand and evaluate programs.

Treatment of Key Issues by the Reviews

2.16 *Research focus*. The reviews send a mixed message regarding the relative priority of more basic research. While some refer to the potential of biotechnology to serve CGIAR goals, others emphasize the importance of the poverty elevation goal and support of weaker NARS. Some reviews recommend the acquisition of specific capacities, such as bio-informatics.

2.17 *Decision outsourcing*. This issue is rarely addressed directly. Centers are praised both for internal generation of products and services, as well as for partnerships (which is not synonymous with outsourcing). Overall organizational efficiency is not discussed.

2.18 *Consistency of quality of science*. The reviews, particularly at the Center level, treat the science quality issue very inconsistently. Some make judgments about the quality of the science without describing the basis of the determination. Many (as well as many annual reports) do not contain publication lists, and none describe the laboratory facilities (such as the degree of automation).

2.19 *NARS relationships*. As noted, Centers are praised for establishing extensive partnerships while extolled not to allow the weaker NARS to fall further behind. There is little attention given to what the Centers can practically do nor is much consideration given to the interaction of ISNAR-type research management and scientific training.

2.20 *Politicization of technologies*. This issue is not discussed in the reviews.

2.21 *Review process*. A review of the System-wide review process was conducted in 2000 (CGIAR, 2000(d)). In general, besides asserting that System-wide reviews should be at the level of "operational quality of the organization," the issues identified here have not been addressed.

Recommendations: Biotechnology

(Recommendations in italics use materials drawn from outside the reviews).

2.22 **Recommendation 1 – Policy:** The CGIAR needs a specific policy connecting the general goal of poverty alleviation with the time frame of research – short term, low risk, or longer term, higher risk. From that policy, the degree and areas of biotechnology application can be derived, as well as the relationships with NARS at all proficiency levels.

2.23 **Recommendation 2 – Comparative Advantage:** As part of satisfying Recommendation #1, it will be necessary to identify the key comparative advantage of the Centers. In most cases, this will be a close working knowledge of the extensive germplasm collections. That comparative advantage suggests biotech research should focus on marker assisted breeding and, secondarily, transgenics, as compared to structural and functional genetics.

2.24 **Recommendation 3 – Integration with International Science:** In the absence of a specific policy on biotechnology, a closer connection with international science, including competitive funding and peer review in international journals, will focus research according to international standards. Some Centers are already following this approach; others need to adjust for a quality biotechnology program.

2.25 **Recommendation 4 – Outsourcing:** An incentive system is needed that will encourage outsourcing where efficient. The standard CGIAR practice seems to be the provision of an internal supply, whether the need be expert advice or research. Internal sourcing can be not only inefficient, but limits flexibility in a dynamic research and policy environment.

2.26 **Recommendation 5 – Challenge Programs:** In the term beyond the pilot programs, the Challenge Programs process should be managed in an openly competitive manner embodying Recommendations 3 and 4.

2.27 **Recommendation 6 – Exclusionary Technology Decisions:** The CGIAR should avoid taking absolute policy decisions against use of specific technologies, such as was done with genetic use restriction ("terminator") technology. Many technologies can have useful applications, plus the exclusion of some technologies invariably leads to increased pressure to exclude others.

Recommendations: Partnerships

2.28 **Recommendation 1 – Biotechnology Training:** For NARS, emphasize joint research projects while limiting general training programs when follow-up opportunities are limited.

2.29 **Recommendation 2 – Research Management Training:** Identify research management specialists from outside the CGIAR to conduct the critical research management training programs.

2.30 **Recommendation 3 – Private Sector:** Develop a policy, including a Code of Conduct as appropriate, for collaboration with the private sector. In addition to general considerations (maintaining the focus on benefits to the poor), the policy should provide

guidelines to individual researchers for any needed approval, limits on information sharing, as well as considerations for when to outsource to private firms.

Recommendations: Reviewing and Reporting

2.31 **Recommendation 1 – Financial Reporting:** Budgetary categories and definitions should be established and standardized across the Centers as management tools. For example, categories relating to germplasm conservation should not include chartization or breeding work as well.

2.32 **Recommendation 2 – Annual Reports:** Reports should contain a straightforward factual description of program goals, activities, and achievements, as well as funding sources.

2.33 **Recommendation 3 – Center Reviews:** Reviews require standardization in several dimensions, including (a) program descriptions listing scientist hours, goals, achievements, budgets and funding sources, and (b) measures of the quality of science.

2.34 ***Recommendation 4 – Review Format:*** *revise the review format to rely principally on (a) self evaluation and goals, and (b) external peer review using publications and other products.*

3. Effectiveness of Current Policies and Practices for Conserving and Distributing Genetic Resources for Food and Agriculture

Background

3.1 *Policies*. Since 1994, the CGIAR collections have been placed in trust under the auspices of the FAO.[4] The FAO, late in 2001, successfully negotiated the International Treaty on Plant Genetic Resources, which lays out access requirements and benefit sharing conditions, including for the CGIAR materials. "Designated" materials are to be shared without charge, but a Material Transfer Agreement requires benefit sharing of any resulting profits.

3.2 Within the CGIAR, the System-wide Genetic Resources Program (SGRP) was established to coordinate activities across the CGIAR gene banks. SGRP is also the first System-wide Program. In 1994, SINGER was established to provide a searchable database for the CGIAR collections. The SGRP is presently raising funds to (a) bring facilities up to international standards, and (b) fund conservation activities in perpetuity through an endowment. These activities contain funds for additional characterization as well.

3.3 *Collections*. The CGIAR gene banks contain over one half million *ex situ* accessions, of which 75 percent are traditional varieties, landraces, and wild relatives. Of the 150,000 samples distributed annually, 80 percent go to developing countries vs. 1 to 4 percent to

4. Details of the evaluation process are included in Annex 2.

private firms. The CGIAR collections represent about 10 percent of total accessions worldwide, but 35 percent of all distinct samples. Despite the number of samples distributed, there is little evidence even the working collections are extensively used in breeding programs. This is due in a large measure to the limited chartization of the collected materials. By one estimate, half the samples lack passport or chartization information. Costs of storage vary considerable across species due to storage requirements and regeneration complexity. Corn, for example, costs about 10 times the amount for wheat.

3.4 Collections for crop species contain up to 70 percent of the existing diversity of materials. For livestock and fungi the scope of collections is far smaller.

Key Issues for the CGIAR

3.5 The management of genetic resources by the CGIAR has been undergoing a dramatic transition in the decade since placing the collections in trust with the FAO was first considered. The transformation has been both extensive and rapid, with more promised as endowment funds are secured. The proper management of its genetic resource wealth is critical for the CGIAR as germplasm knowledge and manipulation is a (if not the) key comparative advantage.

3.6 *Use of genetic resources*. The CGIAR collections presently are used sparingly. While conservation is an important goal in its own right, the lack of chartization clearly limits use (and resulting benefits). Highest priority should be given to expanding the chartization, and for a more outward focus to gene bank use.

3.7 *Authority of SGRP*. SGRP has been an effective System-wide Program in part because of the authority to mandate compliance with standardized procedures under FAO auspices. Yet the SGRP (like essentially all System-wide Programs) has no independent authority. At issue is the position of the SGRP when organizational needs emerge outside the scope of the FAO agreement but not supported by all the Centers with gene banks. The Genetic resources Policy Committee has recently been reviewed with the recommendation that it serves a continuing important role. Additional recommendations included more operational-level support, a better balance of needs with member qualifications, and the granting of a small budget CGIAR, 2002).

3.8 *Non-plant genetic resources*. Most of the activities and provisions for plants under the FAO in trust agreement do not apply to non-food plants and other materials. Collections of forages, animals, and fish are far less complete than for crop species, while not accorded any of coordination and procedural approaches under the International Treaty. There is a need to enhance both the scope and management of those collections.

3.9 *Implementation of the International Treaty*. Now that the Treaty has been successfully negotiated, many significant implementation aspects must be adopted, many over the coming two years. These include benefit sharing contributions and restrictions placed on countries not designating materials for the System. The implications for the CGIAR of those decisions will be significant so that the CGIAR must be forcefully and effectively represented at the discussions by the SGRP. A process is needed to (a) identify the CGIAR positions and (b) allow the SGRP sufficient latitude to negotiate effectively.

3.10 *Financial reporting*. Centers are inconsistent in how gene bank costs are reported, some including only conservation and facilities expenses, while others include aspects of breeding activities. The non-standard budgetary categories make cross-Center comparisons impossible.

Treatment of Key Issues by the Reviews

3.11 *Use of genetic resources*. The current fundraising campaign is providing for an increase in chartizations, but strictly speaking, the issue is only indirectly addressed in the reviews through references to make the System more open and outward focused. The current and prior inadequacy of funding was identified frequently.

3.12 *Authority of SGRP*. The need for change was stated forcefully, but only in general terms. Whether the changes to date are sufficient to satisfy the reviewers is not known.

3.13 *Non-plant genetic resources*. The reviews focused almost completely on genetic resources for plants.

3.14 *Implementation of the International Treaty*. The Treaty did not exist when the reviews were completed.

3.15 *Financial reporting*. The need for more standardized cost reporting was not mentioned.

Recommendations

(Recommendations in italics use materials drawn from outside the reviews.)

3.16 **Recommendation 1 – System-wide Authority:** Provide the SGRP with specific System-wide authority**,** and an independent budget, for implementing System-wide Programs and policies. The SGRP has been an effective coordinating mechanism due to the authority indirectly conferred through the FAO and the International Treaty, yet there are additional areas which can benefit from harmonization but lie outside the FAO agreement – for example, non-plant genetic resources.

3.17 **Recommendation 2 – Use of Genetic Resources:** Place a high priority on characterizing the accessions. Use of the extensive genetic resource collections is limited by the paucity of chartization information available. The SGRP needs also to understand better how the large number of accessions distributed to NARS are used. Higher publication levels in international journals would also make the collections more useful to the international community.

3.18 **Recommendation 3 – Non-Food and Agriculture Access:** Develop access mechanisms for non-food use, presently excluded in the facilitated System for designated germplasm. Non-food use would enhance the potential of finding beneficial uses, as well as increasing the benefit-sharing potential.

3.19 ***Recommendation 4 – Benefit Sharing:*** *Work with NARS and national governments on identifying benefit sharing and Farmers' Rights mechanisms. Success of the International*

Treaty depends in no small part on the form and degree of benefit sharing, with which the SGRP can assist.

3.20 ***Recommendation 5 – Financing Contingencies:*** *Develop contingency policies in case the current fund raising campaign is incompletely successful. Consideration should be given to prioritizing collections according to core collections (containing a majority of the genetic variation) or maintenance costs per accession.*

3.21 **Recommendation 6 – Non-plant Genetic Resources and *in situ* Collections:** The non-plant genetic resource collections and management need to be brought up to the level of those for GRFA, and means and mechanisms of *in situ* collections enhanced.

3.22 ***Recommendation 7 – Training:*** *Expand NARS genetic resource policy training to consider broad management practices such as avoiding the cost of holding duplicates (beyond identified backup collections). That is, take leadership in the overall rationalization of the international collections of GRFA.*

4. CGIAR IPR Policies and Practices

Background

4.1 Emphasis here is on Plant Breeders' Rights (PBR) and patents. These two instruments receive the greatest attention regarding research in agriculture and are the most controversial. Recognition though should not be lost of the associated, and often interactive, roles of trademark, copyright and additional protection mechanisms.

4.2 *Roles of IPR.* IPR have become more significant in agriculture over the past decade, due largely to increasing private sector investment. Presently, the private sector is the major investor in agbiotechnology in developed countries. To recover those large investments, firms have been protecting materials and components with various forms of IPR. Public sector institutions have been utilizing those instruments as well to allow control and raise funds for subsequent research. The overall consequences have been greater research funding than otherwise, but with impediments to access/exchange of materials.

4.3 *CGIAR policy*. The CGIAR has only recently been accommodating IPR in its activities. The CGIAR has an IPR policy, as do several Centers. The policies allow for IPR on a case by case basis, but only in exceptional cases when needed for control and when not impeding the mission. A Central Advisory Service (at ISNAR) was established in 1999 to assist Centers in understanding the effects of IPR, developing training for scientists, and establishing policies and procedures; several Centers have subsequently hired their own IPR specialists. ISNAR is presently undergoing a restructuring process so that the eventual form and function of the Center cannot be determined at this time.

Key Issues for the CGIAR

4.4 *Develop a standard policy*. The present practice whereby individual Centers manage IPR under different policies leads to inconsistencies and confusion. There is a need for a detailed standard CGIAR policy based on a conceptualization of when and how IPR can assist in advancing the mission.

4.5 *Implementation approach*. With the uniform policy as a base, a standardized implementation system is needed. This system must accommodate such aspects as in what countries to seek protection, when sole vs. multiple licensees might be beneficial, how to employ patents as 'bargaining chips', and to protect patents from infringement when required.. A centralized entity is needed to undertake those tasks. The CAS has neither the staff nor resources to serve that role.

4.6 *Assist NARS*. The NARS (excluding the few largest) face the same issues regarding IPR, but with even fewer resources than the CGIAR to respond. The CGIAR must raise the capacity of the NARS in the area of IPR as a component of performing its mission.

4.7 *Enhance IPR record keeping*. Managing IPR involves first and foremost improved record keeping on receipts and transfers of materials and conditions. Effective systems, previously lacking at the Centers, will necessitate a single gate keeper at each Center who is informed on all materials entering the leaving the Center.

Treatment of Key Issues by the Reviews

4.8 *Develop a standard policy*. At the time of the reviews, the existing CGIAR and Center policies were being developed, and considered adequate.

4.9 *Implementation approach*. Several reviews (along with Herdt (2000)) recommended the establishment of a central 'foundation' for the management of IPR. The functions of the proposed foundation were not identified in detail.

4.10 *Assist NARS*. The needs of the NARS and the roles of the CGIAR in meeting them were not discussed in the reviews.

4.11 *Enhance IPR record keeping*. The importance of record keeping was recognized, but not emphasized as a key need.

Recommendations

4.12 **Recommendation 1 – CGIAR Policy:** Establish an overall CGIAR IPR policy. The policy can follow the pattern of the individual Centers policies and the GRFA IPR policies. The policy should be as unrestrictive as possible – i.e., not prohibit use of IPR for funding purposes – so as to allow maximum flexibility in the future. The general policy will provide a single system for all the Centers, facilitating access and lessening conflict among Centers. The policy can also describe what if any residual rights the inventor(s) will retain in his/her/their work.

4.13 **Recommendation 2 – CGIAR Strategy:** Using the IPR policy as a base, develop a CGIAR IPR strategy. The strategy should include among other issues:

- The management of IPR as "bargaining chips" (how effective has that approach been for other public sector entities, what kinds of technologies make effective chips, how likely is the CGIAR to produce those kinds of inventions?),
- When in the product development process to license,
- How frequently IPR has been used for blocking product release within the CGIAR and lessons for licensing policies, and
- Considerations for when to use single or multiple licensees.

4.14 **Recommendation 3 – Central Entity:** Establish a System-wide office run by practitioners for managing IPR with the following functions:

- Hold patents, copyrights, trademarks, etc., and pursue infringers and other violators as needed,
- Establish universal MTAs for sharing materials not covered by those for GRFA,
- Recommend acceptable language for MTAs signed by CGIAR researchers,
- Maintain a database of all incoming and outgoing MTAs, and
- Provide training in understanding and working with IPR (in conjunction with CAS).

4.15 Those changes will move the CGIAR to the "single door" access system recommended in some of the reviews. Additionally, the central entity can offer services on a fee basis, so that Centers have the option of where to receive the needed advice. Services could include:

- Determining when and in which countries to file for patents,
- Reviewing and recommending licensing terms, and
- Considering and recommending terms for licenses with private sector entities.

4.16 The NARS should have access to the services for fee on a similar basis as the Centers.

Annex 1: Sources Consulted

Books and Articles

Anderson, L. 2000. *Genetic Engineering, Food and Our Environment.* White River Junction, Vermont: Chelsea Green Pub.

Byerlee, D., G. E. Alex, et al., 1998). "Strengthening National Agricultural Research Systems Policy Issues and Good Practice." Washington, D.C., World Bank.

Charles, D., 2001. "Seeds of Discontent." *Science*, 294: 772-75.

Cohen, J.I., 2001. "Harnessing Biotechnology for the Poor: Challenges Ahead for Capacity, Safety, and Public Investment." *J. Human Dev.,* 2: 239-62.

Cohen, J.I., C. Falconi, J. Komen, and M. Blakeney, 1998. "The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centers." Draft – included in Panel Report.

Echeverría, R. G., E. Trigo, et al., 1996). "Institutional change and effective financing of agricultural research in Latin America: findings of a workshop organized by the Inter-American Development Bank and the World Bank." Washington, D.C., World Bank.

Eisenberg, R.S., 1989. "Patents and the Progress of Science: Exclusive Rights and Experimental Use." *Univ. Chicago Law Review,* 56: 1017-86.

Evenson, R. and B. Wright, 2001. "The Value of Plant Biodiversity for Agriculture." Chap. 10 in Alston, Parley and Taylor (eds.), *Agricultural Science Policy*. Baltimore: Johns Hopkins Press (published for IFPRI).

Falconi, C., 1999. "Agricultural Biotechnology Research Capacity in Four Developing Countries." ISNAR Briefing. 2001.

Fischer, K. and D. Byerlee, 2001. "Public Research Organizations in an Era of Privatization: Managing Intellectual property and Income Generation." World Bank, AKIS Discussion Paper, 23 May.

Fuccillo, D., L. Sears, and P. Stapleton (eds.), 1997. *Biodiversity in Trust.* Cambridge: Cambridge Univ. Press.

Granstrand, O., 1999. *The Economics and Management of Intellectual Property.* Cheltenham, U.K.: Edward Elgar Publishing.

Heller, M.A. and R.S. Eisenberg, 1998. "Can Patents Deter Innovation? The Anticommons in Biomedical Research." *Science*, 280: 698-701.

Herdt, R., 2000. "Thoughts on the CGIAR." Rockefeller Found., Dresden, 24 May (as revised).

Heywood, V.H. (Exec. Ed.), 1995. *Global Diversity Assessment.* Cambridge: Cambridge University Press (published for UNEP).

IPGRI, 2001. *Geneflow 2000-2001.* "Germplasm Flows Shown to Greatly Benefit Developing Countries."

Kreider, R.D., S.P. Kowalski and A.F. Krattiger, 2000. "The Intellectual and Technical Property Components of pro-Vitamin A Rice (*Golden* Rice): A Preliminary Freedom-to-Operate Review." Ithaca, New York: ISAAA, ISAAA Briefs No. 20-2000.

Lesser, W., 1998. *Sustainable User of Genetic Resources under the Convention on Biological Resources: Exploring Access and Benefit Sharing Issues.* Oxon, U.K.: CABI.

McCalla, A. and L. R. Brown, 2000. "Feeding the Developing Worlds in the Next Millennium: A Question of Science?" Pp. 32-36 in G.J. Persley and M.M. Lantin, eds., *Agricultural Biotechnology and the Poor.* Washington., D.C.: CGIAR.

Pardey, P.G., J. Roseboom, and B.J. Craig, 1999. "Agricultural R&D Investments and Impacts." Chap. 3 (pp. 31-68) in Alston, Pardey, and Smith (eds.), *Paying for Agricultural Productivity*. Baltimore: Johns Hopkins Press.

Pardey, P.G., and N.M Beintema, 2001. "Slow Magic: Agricultural R&D a Century After Mendel." IFPRI, Food Policy Report, Oct.

Pinstrup-Anderson, P., and E. Schioler, 2000. *Seeds of Contention.* Baltimore: Johns Hopkins Press.

Salazar, S., C. Falconi, J. Komen, J. Cohen (2000). The Use of Proprietary Biotechnology Research Inputs at Selected Latin American NAROs, ISNAR Briefing 2001.

Sampaio, M.J.A., and E.A.B. Brito da Cunha, 1999. "IPR at Embrapa: A Question of Policy, Management, and Change of Heart." In J.I. Cohen (ed.), *Managing Agricultural Biotechnology: Addressing Research Program Needs and Policy Implications for Developing Countries,* Wallingford, Oxon: CAB International, pp. 240-48.

Shoemaker, et al., 2001. "Economic Issues in Agricultural Biotechnology." USDA, ERS, AIB-762, March.

Thayer, A.M., 2001. "Owning Biotech." *Chemical and Engineering News*, 79 (Sept. 17): 25-32. Available online at www.pubs.acs.org.

Documents Reviewed

CGIAR, 2002. "Review of CGIAR Genetic Resources Policy Committee." August.

CGIAR, 1998(a). "Mobilizing Science for Global Food Security." MTM.

CGIAR, 1998(b). "Shaping the CGIAR's Future." ICW.

CGIAR, 1999(a). "The Third System Review: From Proposals to Practice." MTM.

CGIAR 1999(b), "Reducing Poverty Through Cutting-Edge Science." ICW.

CGIAR, 2000(a). "Charting the CGIAR's Future: A New Vision for 2010." MTM.

CGIAR, 2000(b). "Charting the CGIAR's Future: Reshaping the CGIAR's Organization." ICW.

CGIAR, 2000(c), "System-wide Review of Plant Breeding Methodologies in the CGIAR." SDR/TAC: IAR/00/18.

CGIAR, 2001(d). System-wide Reviews of the CGIAR: Concepts, Options and Recommendations." ICW/00/10, 22 Oct.

CGIAR, 2001 (draft). "Summary Record of Proceedings." 2001 AGM, November.

CIAT, 2001(a). "CIAT in Perspective 2000-2001."

CIAT, 2001(b). "Sustainable Rural Livelihoods: CIAT's Strategic Plan 2001-2010." Oct.

CIMMYT, 2000. "Policy on Intellectual Property." Available at www.cimmyt.cgiar.org. May.

External Review of the CGIAR Gene bank Operations (1996). SGRP.

External Review of the CGIAR Gene bank Operations. Annex: Centers' Responses to the External Review (1997). SGRP.

FAO, 1 996. "Draft Report on the State of the World's Plant Genetic Resources." D/W0986, 1023, 1055, April, Rome.

First External Review of the System-wide Genetic Resources Program (1998). TAC Secretariat and FAO.

Genetic Resource Policy Committee, various reports.

"Genetic Resources in the 21st Century: Exciting New Solutions for Intractable Problems," 2001. Proposal, unpublished.

"Harnessing Agricultural Technology to Improve the Health of the Poor," 2001. Proposal, unpublished.

IITA, 2001. "IITA Annual Report 2000."

IITA, undated. "IITA Strategic Plan 2001-2010."

ILRI, 2001. "Deciphering the code of life to benefit the poor: Annual Report 2000 –2001."

International Treaty on Plant Genetic Resources for food and Agriculture, FAO. Nov. 2001.

IRRI, 1994. "IRRI's Policy on Intellectual Property Rights." Available on www.irri.cgiar.org. Oct.

IRRI, 1999. "IRRI Intellectual Property Management Review (IP Audit)." Official Briefing. IRRI.

IRRI, 2000. "IRRI Intellectual Property Management Review and IP Audit: Phase II." IRRI.

ISNAR, 1998. "Plan of Work for a Central Advisory Service on Proprietary Technology within the CGIAR, 1999-2000." Dec.

ISNAR, 2001(a). "Annual Report 2000."

ISNAR, 2001(b). "Medium Term Plan 2002-2004," April.

Ministry of Foreign Affairs, Danida, 1999. "Analysis of Danish Assistance to the CGIAR Centers." StS.4, Aug.

Report of the CGIAR Panel on Proprietary Science and Technology (1998). CGIAR Secretariat, SDR/TAC:IAR/98/7.1, Mid-Term Meeting, 25-29 May.

SGRP, 1999. "Annual Report, 1998." Available online at www.sgrp.cgiar.org.

SGRP, 2000(a). "Annual Report, 1999." Available online at www.sgrp.cgiar.org.

SGRP, 2000(b). "A Funding Plan to Upgrade CGIAR Center Genebanks." Rome, March.

SGRP, 2001(a). "Annual Report, 2000." Available online at www.sgrp.cgiar.org.

SGRP, 2001(b). "Booklet of CGIAR Center Policy Instruments, Guidelines and Statements on Genetic Resources, Biotechnology and Intellectual Property Rights." Version I, Rome, Sept.

SGRP, undated. "The Strategy of the CGIAR System-wide Genetic Resources Program." Available online at www.sgrp.cgiar.org.

"Stripe Study of Genetic Resources in the CGIAR" (1994). TAC Secretariat and FAO, AGR/TAC:IAR/94/2.1.

"System-wide Review of Plant Breeding Methodologies in the CGIAR" 2000. CGIAR Secretariat, SDR/TAC: IAR/00/18, Oct.

TAC Secretariat, 2001. "Report of the Fifth Program and Management Review of IITA." SDR/TAC:IAR/01/08, May.

TAC Secretariat, 2000. "Fifth External Program and Management Review of CIAT." SDR/TAC:IAR/01/08

TAC Secretariat, 1999. "Report of the First External Review of ILRI." DR/TAC:IAR/00/15, Oct.

TAC Secretariat, 1998(a). "Report of the CGIAR Panel on General Issues in Biotechnology." SDR/TAC:IAR/98/6.1, April.

TAC Secretariat, 1998(b). "Fifth External Program and Management Review of IRRI." Nov.

TAC Secretariat, 1998(c). "Fifth External Program and Management Review of CIMMYT." Nov.

TAC Secretariat, 1998(d). "Fifth External Program and Management Review of IFPRI." SDR/TAC:IAR/98/2, Aug.

TAC Secretariat, 1997(a). "Fourth External Program and Management Review of IPGRI."

TAC Secretariat, 1997(b). "Fourth External Program and Management Review of ISNAR."

Third System Review of the CGIAR, 1998. "The International Research Partnership for Food Security and Sustainable Agriculture." October.

Persons Interviewed or Contacted

Subhash Morzaria, ILRI
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Annex 2. Biotechnology

Investments and Ownership Patterns in Biotechnology Research Worldwide

Pardey, Roseboom and Craig (1999, Table 3.8) report that private funding of agricultural research in the OECD countries rose from 41 percent in 1981 to 49 percent in 1993. Those figures represent total R&D investments, not those exclusively directed to breeding and other life form research. In part, that shift represents an absolute increase in private investments. But imbedded as well is a real decline in public investment; while OECD real increases averaged 2.7 percent for 1971-1981, the level fell to 1.8 percent over the 1981-1993 period (Pardey, Roseboom and Craig, 1999, Table 3.6). Considering only the United States, total private sector agricultural sector R&D expenditures in 1995 were (in 1992 dollars) $3.4 billion, 17 percent higher than the $2.8 billion in public expenditures that year. Moreover, the composition of private sector R&D expenditures has evolved over time; compared to 1960, expenditures on seeds rose by 10 percentage points while machinery fell by over 20 percentage points (Shoemaker, et al., 2001, p. 3).

At the international level, real developing country agricultural expenditures exceeded those of developed countries by 1991, when developing countries provided 54 percent of the total. Spending in Asia and the Pacific (excluding China) grew most rapidly at an annualized average of 6.2 percent over 1981 – 91, compared to 1.7 percent among the developed countries (Pardey, Roseboom and Craig, 1999, Table 3.12). While hard numbers are limited, most of those funds were provided by the public sector. CGIAR investments rose rapidly, 14.5 percent annually for 1972-81 over the first decade following establishment. However, real total funding stagnated following 1991 with annual decreases in real funding of .66 percent from 1990-97. Because additional Centers were added over that period, and the mandate widened, actual declines on a programmatic basis were even greater (Pardey, Roseboom, and Craig, 1999, p. 58).

Cohen (2001) reports that 92 percent of agricultural biotechnology research funding in developing countries in the 1990s came from the public sector vs. only eight percent from private sources. This contrasts with 70 percent private sector support in the U.S. for the same period.

Ownership of R&D products, as represented by the holding of patent rights, has also been dominated by the private sector. Of the 1,386 biotech-classified patents awarded by the US Patent and Trademark Office through 1998, 79 percent are held by the private sector and 71 percent by just five firms (Monsanto, DuPont, Syngenta, Dow Chemical, and Aventis) (Thayer, 2001).

Biotechnology Research in the CGIAR

The CGIAR has invested approximately $25 million overall in biotechnology research in projects ranging from gene mapping to policy studies (Cohen, 2001). In total, 11 of the 16 Centers are reported to be engaged in biotech research. Despite this, it was judged the CGIAR was “under-investing in biotechnology” and “investment in biotechnology research will need to be increased by a significant amount” (TAC, 1998(a)).

More specifically, the nine Centers with biotechnology programs in 1999[1] invested $5.3 m in fingerprinting and marker-related breeding activities and $4.1 m in 'gene splicing' and 'genetic engineering' activities. Capital investment that year for the same nine Centers was $1.3 million. Those figures are estimated to represent about 25 percent of plant breeding budgets (CGIAR, 2000(a)).

At the 1998 MTM, the Chairman identified biotechnology as being an important tool for providing food security, and an area in which the CGIAR has a "clear comparative advantage in ensuring access by the countries of the South." A significant investment will probably be needed. "What we need now is a clear and public statement of this [biotechnology] policy." The Panel on General Issues in Biotechnology similarly saw the CGIAR as a 'catalyst', and, among other actions, "expand international networks for biotechnology research" (CGIAR, 1998(a)). At a 1999 joint CGIAR/US National Academy of Sciences, the CGIAR was seen as a vehicle for providing factual scientific information needed to instill confidence in biotechnology solutions (CGIAR, 1999(b)).

Policy Statements

In 1998, a "Centers' Position Statement on Biotechnology" was adopted. It advocates the "prudent application of a full range of biotechnology tools" with the technologies serving as an "important means for ensuring environmental protection" and transgenics in particular providing "important options." The Centers have a "clear comparative advantage" in ensuring access of biotechnology tools to the South (reproduced in SGRP, 2001), p. 39).

Also in 1998, the CGIAR took the strong position of banning all genetic use restriction ('terminator') technologies. "The International Agricultural Research Centers supported by the Consultative Group on International Agricultural Research [] will not incorporate into their breeding material any genetic systems designed to prevent seed germination." (1998 ICW, reproduced in SGRP, 2001, p. 40).

Programs at Individual Centers

Information on biotechnology programs at individual Centers is not consolidated in a single location. Annual reports differ in the level of detail provided, while some Centers make Strategic Plans readily available and others do not. Reported budgetary figures are at a very general level so that it is not possible to determine what expenditures on 'biotechnology' are at any Center. All this says it is certainly possible to miss some of the key elements of a biotechnology program at a Center when relying on secondary sources. IPGRI is excluded due to the absence of programming specifically directed to biotechnology.

CIMMYT. CIMMYT's biotech research is done through the Applied Biotechnology Center (ABC) with seven scientists (including the Director) on staff in Mexico. Projects include marker-based transfer of abiotic stress and disease resistance, as well as herbicide resistance for maize. Following the recent mapping of crop genomes, CIMMYT has been focusing on functional genetics. CIMMYT has also been a major partner in the developments of apomixis technology (CIMMYT Web site)[1]. No information is readily available on the budget for the ABC or the publication record of the ABC scientists (CIMMYT, 2001; Web site).

IRRI. In 1998-2001, IRRI worked in the following areas:

- Use of molecular markers to enhance diazotrophs and rhzobia response in rice,
- Structural and functional genetics,
- Resistance to biotic and abiotic stresses, and
- Enhancement and extension of development on Golden Rice.

Collaboration and training with NARS is managed largely through the Asian Rice Biotechnology Network (ARBN) (IRRI 1998-2002 Plan of Work; IRRI, 2001; Web site).

CIAT. CIAT's biotechnology programs are largely focused on germplasm use and conservation, including (CIAT, 2001(a), 2001(b); Web site):

- Molecular marker technologies to facilitate plant breeding,
- Techniques for assessing the genetic diversity of crops and wild species
- Agroecological, agronomic, and genomic data at the intra- and interspecific levels
- Characterization of exotic and novel genes and gene combinations, and
- Techniques for interspecies gene transfer.
- Cooperators include public research institutions in the developing and developed worlds.

IITA. IITA lists no specific biotechnology program, but incorporates those techniques in cultivar improvement, particularly marker assisted breeding, functional genomics, and transgenic methods for allele transfer and targeted gene expression. A review of recent publications confirms those are the current areas of biotechnology-related research. The Biotechnology Research Unit was established in 1990, but did not venture into genetics and transformation until 1996. The Strategic Plan refers to possible future use of molecular markers and transgenics when appropriate (IITA, 2001 and undated; TAC, 2001). A $1.5 million biotech lab was in the early planning stages in 2000.

ILRI. ILRI's biotech-related research is in regards to genomics, both structural and functional. Genomics research is applied to livestock improvement and health as well as vaccine development and forage improvement. A review of journal publications confirms that as the thrust of biotechnology research at ILRI (ILRI, 2001; Web page).

ISNAR. ISNAR's objective is assisting developing countries to increase the effectiveness and efficiency of their agricultural research systems, which in aggregate account for over 90 percent of agricultural research spending in developing countries. Of particular relevance to biotechnology is the Intermediary Biotechnology Service (IBS), which provides advice services on the integration of policies, education, and infrastructure for successful utilization of new technologies. Activities listed for 2000 include a series of publications on the use of biotechnology for small farmers, as well as an ongoing 'flagship' management training program. Additional activities include biosafety regulation support, but that area lies outside the focus here. IBS was combined in a single 'managing of new technologies' project with CAS (see IPR section), along with information technologies, due to unexpected funding shortfalls in 2000. The projected 2002 budget is $2.2 million (ISNAR, 2001(a) and (b)).

NARS

National agricultural research systems (NARS) in developing countries currently face a host of challenges. While from 1981-1991 the annual rate of growth in research expenditures for developing countries (3.8 percent) continued to exceed that of developed countries (1.7 percent), by the late 1980s the rapid expansion of NARS was ending as a substantial slow-down of funding was experienced worldwide (Byerlee, Alex et al., 1998). Especially hard hit were the NARS of Latin America and sub-Saharan Africa (Echeverría, Trigo et al., 1996). Despite this funding slow-down, in general NARS have dramatically increased the number of researchers and the level of training of their staff, so that total expenditure per researcher has fallen substantially (Komen, 2000).

The biotechnological expertise of developing country NARS varies widely. Mexico, which established its first tissue culture laboratory in 1970, is one of the most advanced in biotechnology (Falconi, 1999). Indonesia began biotech research a little later, followed by Kenya and finally Zimbabwe. The techniques used at these NARS also vary widely. For most NARS agricultural biotechnology is used primarily for genetic markers and tissue cultures and far less frequently for genetic engineering of crops (Salazar, et al., 2000)[1].

Partnerships between public NARS and private entities in developing countries seem to be limited. More specifically, as NARS has accessed proprietary biotechnology tools they have used partnerships occasionally, but not extensively. MTAs and licensing are more commonly used, but there is a general lack of knowledge concerning the intellectual property aspects of agricultural biotechnology research in developing country NARS (Salazar, et al., 2000).

Partnerships

CIMMYT:

- The Asian Maize Biotechnology Network (AMBIONET) is a partnership between national agricultural research systems in China, India, Indonesia, the Philippines and Thailand, and the International Maize and Wheat Improvement Center (CIMMYT). AMBIONET emphasizes the use of biotechnology tools for maize improvement through capacity building and collaborative research.
- The Insect Resistant Maize for Africa (IRMA) project was launched in 1999 by the International Maize and Wheat Improvement Center (CIMMYT) and the Kenya Agricultural Research Institute (KARI). The project is aimed at producing maize that is adapted to various Kenyan agroecological zones and is also resistant to key insect pests, primarily stem borers. Both conventional and biotechnology-based sources of resistance will be examined for their effectiveness against the borers.
- A partnership was begun recently with Pioneer Hi-bred seeking genes and pathways associated with drought tolerance in maize. Additionally, ABC lists five adjunct scientists, in France, Mexico, and Japan.

IRRI:

- IRRI uses a “consortium” approach in working with NARS as well as advanced international research institutions. Under the management of the Council for Rice

Research in Asia, relations with advanced institutes are maintained through "shuttle" scientists spending a year at another institution. Relations with NARS are determined by the stature as peers or clients. IRRI was praised for the "impressive range" of its partnerships.

CIAT:

- CIAT's collaboration with NARS has evolved from bilateral arrangements to multilateral ones managed through joint research networks like PROFRIJOL, LAC, and the Cassava Biotechnology Network. CIAT is considered the most connected within the CGIAR, as well as having extensive arrangements with international organizations. Training activities, with the unit reduced to three employees, have been largely devolved to other institutions and most programming contracted out.

IITA:

- IITA has responsibility for the System-wide IPM program. Associations with the NARS is largely through sub-regional research organizations like CORAF/WECARD, ASARECA, and SACCAR. Consistently declining national support for NARS has made collaboration increasingly difficult, and the "future looks bleak indeed." Collaborations with NGOs and farmers groups have been increasing, but both have limitations; the effectiveness of NGO collaborations has never been assessed, while farmer group calls for product development assistance are incompletely met due to supply-chain infrastructure limitations. Private sector collaborations are limited to informal arrangements with the Nigerian seed sector.

ILRI:

- ILRI has long been recognized for its training support of NARS. Recent funding cuts have led to shifting the organization from open programs to project-based activities, typically through research networks like SADC, ASARECA, and CORAF. Concerns were expressed by the Review Panel that one network had few research ties with ILRI, but the focus on targeted training was recommended even in the event of funding improvements. Funding constraints of a number of NARS is limiting research collaborations. For livestock research, NARS provide essential connections for farm-level surveys and assessments.
- ILRI is the lead Center for the System-wide livestock program, as well as being in charge of farm animal genetic resources. A significant amount of research is outsourced to advanced research Centers when ILRI lacks the specific expertise.

IPGRI:

- Unlike the preceding Centers, IPGRI has only a small genetic resource collection under its direct control and no breeding activities. Its support and coordinating activities are conducted largely through networks and collaborations, of which there are multiple. Of particular relevance are the regional groups, which are highly divergent in focus and scope. Further linkages have been formed with NGOs and farmer groups. Principal training requests, now largely transferred to regional groups,

remain in the technical area of gene bank operations. Increasing areas of requests are for genetic resource policy and support of farmer groups responsible for local conservation activities.

Challenge Programs

There is no written statement of the objectives and functioning of Challenge Program. Verbal statements suggest it is to involve focused program areas which will function collaboratively with a network of cooperating institutions in both the developed and developing worlds. At some stage, the Programs may be awarded competitively, but for the present, targeted cooperators seem likely. Current plans call for the development of pre-proposals for the 10 candidate pilot Programs, with the endorsed Programs to have full proposals developed beginning in mid-February, 2002. The 'regular' Challenge Program process involves a January 15th deadline for the submission of concepts, followed in June by a selection of a subset for pre-proposal development and further winnowing by October when final proposals are requested (CGIAR, 2001). Two of the 10 pilot Programs have a biotechnology link:

- Harnessing Agricultural Technology to Improve Health of the Poor (including possible transgenic-based biofortified crops), and
- Global Genetic Resources (including a range of technologies from gene mapping to transgenics for enhancing genetic resource use).

As of mid-2003, the second proposal has been approved for the initial four years of operation. That stage is not to include work involving genetic transformations. Both proposed Programs have a major genetic resource utilization base, with significant aspects of partial mapping, functional genetics, and informatics, with gene transfer a longer term possibility. Of the two, the former is the narrower in scope as only dietary attributes are sought, while the latter will potentially consider a broad range of attributes like salinity tolerance, with a significant characterization process required at the start. In terms of Program organization, both will involve a range of Centers and outside contributors. The former Program will be managed by technical peer review and an outside committee of experts, with 44 percent of the funding directed to non-CGIAR participants. Similar information is not available for the latter program (Genetic Resources, 2001; Harnessing, 2001).

System-wide Reviews

Three relevant System-wide reviews of CGIAR biotechnology-related programs and policies exist:

- Report of the CGIAR Panel on General Issues in Biotechnology (TAC, 1998(a)),
- Third System-wide Review of the CGIAR (1998), and
- System-wide Review of Plant Breeding Methodologies in the CGIAR (CGIAR, 2000(a)).

Report of the CGIAR Panel on General Issues in Biotechnology (TAC, 1998(a)). The Panel was established in response to prior expressed concerns that the CGIAR was under investing in biotechnology research, and that a new strategy was needed. Emphasis was placed on the

uses of biotechnology for germplasm improvement. The Report discussed the need for a 'code-of-conduct' on biotechnology research, and the need for greater investment, particularly in bioinformatics. Achieving those goals will require broader and stronger partnerships. Recommendations included:

- Development of a new strategy involving both external networks and internal organization.
- Establishment of a new fund (with a Steering Committee and Secretariat) for enhancing networking.
- Review of internal expertise, particularly in bioinformatics.
- Establishment of a CGIAR Biotechnology Service Unit to comment on all proposed Center projects with a biotechnology component, and provide supportive, professional advice.

Third System-wide Review of the CGIAR (1998). The Strong review made five recommendations related to biotechnology and ancillary research relationships:

- *Recommendation 2:* The International Centers should serve as a "bridge" and "resource Center" bringing advanced science to focus on the needs of the poor. CGIAR research should be primarily "upstream" as the System "cannot afford to focus on the newest basic research" (p. 45).
- *Recommendation 4:* Gene management should focus on "genomics and molecular breeding," and the accelerated introduction of "modern marker-assisted breeding and bioengineering techniques."
- *Recommendation 8:* As regards NARS, the CGIAR should continue to emphasize capacity building and the strengthening of partnerships. Capacity building is seen as a major focus of the CGIAR. Weak NARS "cannot be allowed to fall further behind" while the stronger NARS can be enhanced through "meaningful collaborative research" (p. 74).
- *Recommendation 11:* Partnerships should be broadened. This activity should include both advanced institutions and universities, as well as the "vital and growing" private sector, including in developing countries (pp. 86-88).
- *Recommendation 27:* The overall policy for CGIAR collaboration with the for-profit sector should "be developed at the System level."

System-wide Review of Plant Breeding Methodologies in the CGIAR (CGIAR, 2000(a)). The Review Panel recognized that in the short term, the inclusion of biotechnology in Centers programs would increase costs, in part due to the need to explore more fields. In the longer term, effective costs are likely to decline, except for equipment. That point raises the issue of the effectiveness of Center-specific labs compared to centralizing some activities. In the case of marker-assisted breeding, no conclusion was reached. Overall, a need for a "large improvement in synergies between Centers" was identified. Centers were found to vary widely in the effectiveness of implementing biotechnology research. Most though operated on a pragmatic "needs basis." This is in part due to a donor emphasis on short term projects, when some reviewers felt the Centers should be evolving to longer term, high risk research. Strategies for transgenics were found lacking at all Centers. NARS are constantly seeking

enhancement in biotechnology-related skills, even though not all have the capabilities to apply the acquired knowledge. Key recommendations include:

- Recommendation 4: Develop a System-wide program in bioinformatics.
- Recommendation 5: Develop a System-wide program, or plan of action, in genomics, particularly functional genomics.
- Recommendation 7: Centers should coordinate research and combine data.
- Recommendation 8: Elaborate a policy of collaborative research with for-profit organizations.
- Recommendation 19: Develop budget presentation with goal of facilitating comparisons.
- Recommendation 22: Perform *ex ante* cost/benefit analysis before initiating expensive new projects.

Responses to System-wide Reviews

Report of the CGIAR Panel on General Issues in Biotechnology (TAC, 1998(a)). The TAC took the position that biotechnology is becoming increasingly important as a tool for genetic improvement, and that the Centers "need to have in-house capabilities." Biotechnology and molecular genetics "should be integrated with [germplasm conservation and improvement] programs"

Third System-wide Review of the CGIAR (1998). A number of initiatives were generated in response to the System-wide Review (CGIAR, 1999(a)):

- Agreed the Centers should serve as a global resource Center and enhance external partnerships.
- Establish a TAC review of plant breeding techniques and expenditures on biotechnology.
- "… maintain [CGIAR's] emphasis on capacity building without creating a new mechanism for its work."
- Broaden partnerships, including the establishment of a Science Partnership Committee the designation of an analytical review of "Partnerships and Research: Lessons for the CGIAR."
- "System-wide initiatives be given a central place" while noting the initiative structure and transaction costs are a problematic, and that System-wide Programs are most effective when involving a limited number (3- 4) of Centers and NARS.

The review Panel's recommendation for the broadening of CGIAR partnerships was endorsed (CGIAR, 1998(b)). A policy statement on biotechnology was subsequently adopted (see section B preceding).

System-wide Review of Plant Breeding Methodologies in the CGIAR. The TAC noted than any use of plant breeding tools must be related to the poverty alleviation focus of the CGIAR. Marker-assisted breeding was recognized as potentially speeding up the breeding process, while there is a need to raise the capacity of bioinformatics to 'adequate levels'. Recognizing the need to be poised to adopt new technologies as opportunities occur, the

TAC emphasized the need to maintain expertise in the Centers (CGIAR, 2000(a)). The overall report was endorsed at the ICW (CGIAR, 2000(c)).

Center Reviews

Of the eight Centers of focus in this meta-review, six are reported on below. The remaining two, IPGRI and IFPRI, had no specific biotechnology-related activities and are excluded.

IRRI (TAC, 1998(b)). IRRI was commended for a rapid entry into biotechnology, and marker technology in particular. The Panel suggested IRRI become the preferred collaborator for functional genomics. A specific recommendation (# 3) was the careful evaluation of developments in bioinformatics. The biotechnology group introduced marker-assisted breeding techniques, subsequently providing a well equipped lab for breeders to use for their own molecular screening. The review Panel saw some delays in movement to automated screening, considered necessary for effective use of the breeding technology.

CIMMYT (TAC, 1998(c)). The Applied Biotechnology Center (ABC), established only in 1996, was lauded for "an impressive list of achievements," including:

- New, non-radioactive marker technology,
- Mapping of a number of maize traits,
- Transfer of corn borer genes,
- Transformation of both maize and wheat, and
- Acquisition of a *Bt* maize technology.

Concern was expressed about the lack of apparent integration of the biotechnology and traditional maize and wheat improvement programs. Two related recommendations (#7 and 9) involved the development of clear joint programs including the incorporation into the breeding programs. The apomixis project, then involving 6 or 18 percent of ABC scientists, was identified as 'extremely important' and continuation encouraged with "all available resources." As regards the balance of effort, 75 percent then was devoted to gene mapping and marker-assisted breeding, with the remainder going to genetic engineering. The Panel suggested "genetic engineering should remain a priority area of research." CIMMYT is held in high esteem by the NARS.

ILRI (TAC, 1999). Overall, the Review Panel judged the quality of science at ILRI in need of improvement. Some general decline in research productivity was detected. That assessment however was not applied to animal genetics and disease resistance, "where ILRI is becoming a world leader." Significant advances are also being made in diagnostics. One relevant recommendation (# 6) was to merge livestock genetic research with the production of disease resistant lines.

CIAT (TAC, 2000). Biotechnology research at CIAT is described as "impressive," "relevant and productive, taking a problem solving approach." Through partnerships, CIAT is taking a regional role in developing biotechnology. Recommendation 11 calls on CIAT to review its varied partnership experiences with the goal of identifying key indicators of success for both its own and other Center use.

IITA (TAC, 2001). The Panel concluded research quality is enhanced by the use of new technologies, but there is a need for "a clear strategy for the use of biotechnologies in crop improvement." Publication output and quality overall are considered good.

Recommendations included:

- Recommendation 4: Initiate a regional scientists' forum on the development and use of genetically modified crops.
- Recommendation 5: Develop clear priorities for crop improvement research.

ISNAR (TAC, 1997(b)). The relevance of the most recent ISNAR review must be considered carefully due both to its relative age (1996 data collection) and appearance at the change of the Director General. The Reviewers also noted the difficulty of the ISNAR task given the ongoing financial problems of many NARS, and ISNAR's own substantial financial constraints. The IBS was also relatively new in 1996 so does not have much of a record to review. That said, the Panel noted several limitations in ISNAR performance, including a relative lack of staff trained in management and the detachment of priority setting from resource considerations, leading to few verifiable changes in programming and resource allocations. Recommendations included moving to more researched-based service provision, and streamlining the number and diversity of projects. Specific to biotechnology, IBS in its initial 21/2 years was described as "highly regarded" in terms of both activities and outputs, having "successfully established its visibility."

Responses to Center Reviews

IRRI. Both the TAC and IRRI endorsed all the Review recommendations, and indicated an intent to strengthen capacity in bioinformatics. Bioinformatics is presented by the IRRI Board as a linkage between traditional and genomic data sets, and hence an important IRRI functional area (TAC, 1998(b)).

CIMMYT. The two recommendations for integrating the ABC work into the breeding programs were endorsed by CIMMYT (TAC, 1998(c)).

ILRI (TAC, 1999). The general weaknesses were acknowledged by both TAC and the ILRI Board, and the recommendation to merge livestock genetics and breeding was accepted.

CIAT (TAC, 2000). TAC raises the issue of how the Panel measured the quality of science at CIAT. CIAR accepted the recommendation for a partnership review.

IITA (TAC, 2001). Recommendation 4 was accepted, number 5 acknowledged with the comment that prioritization of crops had previously occurred, based on the relative economic importance of the crops. Prioritization will be further refined, "particularly for selecting the most appropriate biotech approaches."

ISNAR (TAC, 1997(b)). All recommendations were endorsed.

Assessment of Reviews and Responses

Despite all the promise, the near term payoff for agbiotech in all applications worldwide has been modest. This is a critical point brought out in the System-wide Review (CGIAR, 2000(a)) for it relates directly to the CGIAR mission. If that mission is indeed focused on low risk, near term research directed to the truly poor, then the investment in biotechnology should be modest. Conversely, if the mission is higher risk, longer term research, then biotechnology should be a major focus. Since the matter of mission is not resolved, least between and among some donors, it is not possible for the CGIAR to establish a rational biotechnology policy – despite multiple calls for one. A great risk is attempting to follow simultaneously both the short term, low risk and long term, high risk strategies which, with funding limitations, will diminish both efforts.

This external assessment of biotechnology programs is complicated by the limited attention given in the Center reviews to the kinds of research being conducted at the Centers and the quality of the science. Is it really applied and localized, or connected to the international scientific research community in a dynamic environment? Is the support directed internally, or is the project funding based on international competitive grants? These would say much about the kind of science and forms of collaboration. The general impression given though is most research is quite applied, and hence regionally as opposed to internationally focused. To the extent that is true, frontier research will be difficult to sustain at the Centers. Conversely, those who rely on grant funding are clearly linked to the international scientific community.

Nor are the reviews revealing on how efficient the research is – for example, the degree of automation used in marker assisted breeding. Also lacking is much consideration of the organization of research – should, for example, marker assisted breeding screening be done by the individual scientists, or should a centralized service be made available? If the service is centralized, should it be free, or on a fee basis? Many public sector programs have previously experimented with a range of alternatives, providing a rich source of comparative information. The CGIAR most assuredly does not need to develop all its own systems.

From the CGIAR and Centers perspective, there has been little evident follow through on the existing System-wide and Center reviews. Recommendations were typically rather general and numerous, endorsement modest, and follow through extremely limited. That is not a very productive process.

More generally, there remains a need for a definitive statement on biotechnology research by the CGIAR, as has been called for in several reviews. The current policy, while conceptually endorsing biotechnology, establishes only self-evident positions, such as providing options. While this statement might serve a public relations purpose – certainly an important role – it provides no internal direction for the Centers or the TAC. Nor are the difficult issues addressed – what specifically is the CGIAR's "clear comparative advantage in assuring access"? Do the Centers indeed have a critical mass of researchers, what are the real needs of the NARS in biotechnology, and what other entities are also able to contribute? Answering those and other questions will lead to the development of a real policy, not merely a public relations statement.

Absent a real strategy, in the short term, most Centers are presently involved in marker-assisted breeding activities, which are well within the scope of many researchers and have a

reasonable promise of practical shorter term results. Marker-assisted breeding also connects with a clear Center comparative advantage, the knowledge and use of the germplasm collections. Genomics, both structural and functional, have less clear benefits and research can perhaps be conducted more efficiently elsewhere. The same can be said of bioinformatics beyond a very minimal level of competency needed at some of the Centers. At least for the present, bioinformatics specialists are in very short supply and will be very costly and difficult for the Centers to attract and retain. Transgenics work in many cases can also be devolved to other institutions. Cases where that general policy may not apply are for exotics of limited interest outside the CGIAR (cassava) or crops which are easy to transform and difficult to breed conventionally (potato).

Beyond those cases, a major investment in biotechnology seems better managed by a few of the larger Centers with the resources and minimum capacity required. Indeed, that is the current situation with IRRI, CIMMYT, and CIAT, among those of particular focus of this meta-evaluation, having taken leadership in biotechnology. For those (or other) Centers to serve effectively as resource Centers, more formal System-wide arrangement than currently exists will be required.

For the longer term, it is not feasible to project the relative importance of areas of research emphasis. Hence, an approach is to establish a research organization process for directing future resources. The organization will require some form of competition as the resource allocation mechanism. Presently, the international research community uses the competitive research and refereed publishing venues for determining future research focus. Those mechanisms are not without their limitations – they are expensive in terms of grant preparation time, can be directed into unproductive areas, and do not function as well with applied work of regional focus. The relatively high level of overhead of many Centers is also a competitive disadvantage. Yet that is what is available and overall probably operates better than internal allocation. Indeed, some CGIAR programs like ABC have already moved far in that direction. Competition also implies outsourcing when more efficient, which can also be accommodated on a competitive basis. The LabX program used by Embrapa in Brazil is a model of how outsourcing can be operated. CAMBIA, along with many major universities, are examples of entities which are possible sources of contract or partner research. Those institutions operate with greater autonomy than the Centers with their poverty alleviation mandate and can better accommodate the risk of basic research.

Conceivably, the Challenge Programs approach is a mechanism for achieving that kind of integration and competition, particularly if the Programs are open to grant proposals from outside the System. At this stage though, too little information is available about the operationalization of the process to predict if it represents a real departure, or simply another organizational tweak.

A final accommodation that will be needed is one with the private sector. Presently, the Centers have little contact with the private sector, but as biotechnology research is dominated by that sector, a basis for more collaboration needs to be found. As one example, CIMMYT should reconsider the appropriate level of scientific effort to go into the refinement of the apomixis technology. In many cases, the public sector can provide the creative input for initial new product discovery, but is not efficient at the slow, detailed process of refinement.

That can often be done better by the private sector, given suitable care in establishing the licensing arrangements.

The CGIAR also needs to be careful not to exclude technologies for political reasons. The reference here is to the genetic use restriction ('terminator') technology. The CGIAR has pledged not to use it, in recognition of the potential harm to seed-saving small farmers. Yet there are potential benefits to using that technology, such as preventing the reuse of *Bt*-producing plant seeds, where the expression of the toxin may decline over generations, hastening resistance development. Moreover, the private sector can still use related technologies, or F1 hybrids for that matter, F1s often being used as a costly means of preventing seed saving.

Capacity building for the NARS appears to have been substantially affected by revenue shortfalls at both the Center and national levels. As has been noted elsewhere, training is one of the first areas to be cut when finances decline. While that appears to apply to biotechnology training as well, other factors are involved as well. General capacity building programs in that area are of questionable value for those scientists lacking the facilities to apply the newly-acquired skills. The Centers are cajoled not to allow weak NARS to fall further behind, but as a practical matter lack the resources to do otherwise, particularly in the more esoteric aspects of biotechnology. As a consequence, capacity building seems to have evolved more toward cooperative research activities, and especially the exchange of scientists. That approach worked well for the Rockefeller rice research program, and is an effective mechanism for advancing the Centers research programs. Yet the approach has limitations as well:

- Principal focus on a narrow spectrum of mid-capacity NARS. Weaker NARS lack the capacity, while the stronger ones are more on par than clients of the Centers, and
- CGIAR research priorities are effectively imposed on the NARS, which may or may not meet national needs.

If the CGIAR is not to evolve exclusively into an upstream research institution, renewed attention is needed overall on the appropriate forms of training. For biotechnology training in particular, however, an emphasis on training through doing, while limiting general training sessions, seems appropriate. The more open and competitive research environment identified above is a mechanism for enhancing exchanges of scientists if made a requirement for research grants.

Often, as ISNAR has discovered, the real training requirements are in general research management, a need ISNAR has attempted to fill. Organization and constrained resources though have made those efforts less than successful. The IBS program is now focused on establishing the necessary infrastructure and policies for an effective biotechnology program. There is certainly a large gap to be filled with few entities providing that kind of assistance. Yet again the resources are so limited that a broad impact is precluded. The resource scarcity is further exacerbated by an apparent attempt to serve a broad clientele group slightly rather than assisting the intermediate level NARS in depth. Apparently, little thought is given to outsourcing for skills not internally available, which leads to neither the best available programming, nor efficient organization.

A Final Observation

No research group, public or private, is clear at this stage on the appropriate allocation of resources to and within agricultural biotechnology. The uncertainties are just too great. For the present, the greatest emphasis on marker assisted breeding with less on transgenics is roughly in accordance with resources and opportunities. Future resource allocation will need to be more carefully coordinated. Needed are (a) detailed policy on goals, (b) more complete integration with the international scientific community, which through grants and peer review can help determine future directions, (c) procedures for determining when to outsource and when to conduct research internally, and (d) clearer directions and guidelines for collaborating with the private sector.

Annex 3: Genetic Resources

Policies

International Policies

Currently most genetic resources for food and agriculture (GRFA) are held *ex situ* in gene banks controlled at the international, national and local (including private ownership) levels. Current estimates indicate approximately 4.5 million accessions held worldwide (including duplicates) (see Section IV.B). Of those, about 10 percent are held at the CGIAR Centers, with particularly large collections of rice, maize, potato, and wheat materials, including wild relatives, landraces, and improved varieties.

The Convention on Biological Diversity (CBD) in Article 15(1) recognized the "sovereign right of states over their natural resources" such that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation." However, as the vast bulk of the accessions in the CG gene banks were collected prior to the CBD going into force in 1994, the CBD strictly speaking does not apply to them. Moreover, in subsequent years, only a handful of nations have adopted access legislation so that in most instances there are no general prohibitions to the collection of GRFA (see Lesser, 1998, Chap. 3). Hence, the legal status of many of the CGIAR accessions was ambiguous. More recently, more than 50 countries have established legislation restricting the exports of plants, seeds, and other biological material (Charles, 2001; Fischer and Byerlee, 2001).

To rectify that ambiguity, most of the CG collections were in 1994 placed under the auspices of the FAO International Undertaking on Plant Genetic Resources to constitute part of the international network of base collections. System needs and procedures were identified in the Global Plan of Action (from Leipzig Conference of 1996) (see Lesser, 1998, Chap. 6). Material held 'in trust' at the Center collections is known as 'designated' germplasm. The International Undertaking was renamed the International Treaty upon adoption in November, 2001. It will go into force following the deposit of the 40th ratification.

The International Treaty, which, among other activities, controls access and benefit sharing for the network collections, has been revised several times. The Treaty incorporates the concept of a Multilateral System to which access is provided on specified terms ('facilitated access'), including benefit-sharing requirements (Article 12). Proposed crops include the major staples of rice, maize, wheat, and potatoes, among others (but not soybeans) (Annex I). Access is conditional on the acceptance of a standard Material Transfer Agreement (MTA) to incorporate benefit sharing requirements (Articles 12.4 and 13.2(d)). Benefit sharing requires a recipient commercializing a plant genetic resource-related product "that incorporates material accessed from the Multilateral System" pay "an equitable share of the benefits." The share, form, and manner of the payment are to be established by the Governing Body at its first meeting (Article 13.2(d)). The applicable MTA is to be adopted by the Governing Body.

The facilitated access to GRFA provided under the Multilateral System is recognized as a major benefit (Article 13.1). Materials are to be provided free or at most at cost, and are to include passport and other non-confidential information (Article 13.3(c) and (d)). Materials are provided for research, breeding and training purposes, but must "not include chemical,

pharmaceutical, and/or other non-food/feed industrial uses." (Article 12.3(a)). Following two years of the entry into force of the Treaty, the Governing Body shall consider limiting access for those entities which have not included their GRFA in the Multilateral System (Article 11.4). The option of seeking IPR on materials, "their genetic parts or components" "in the form received from the Multilateral System" is restricted (Article 12.3(d)).

Article 15 applies specifically to the CGIAR *ex situ* collections. Materials are placed into three categories, as follows:

- Materials identified in Annex I shall be treated identically to other materials covered by the Treaty (Article 15.1(a)).
- Materials collected prior to the Treaty going into force but not included in Annex I "shall be made available in accordance with the provisions of the MTA currently in use," but must subsequently be amended, particularly regarding access and benefit sharing (Article 15.1(b)).
- Any materials received subsequently to the Treaty coming into effect and not included in Annex I will be made available on terms mutually agreeable to CGIAR and the supplying country which has rightful ownership to the materials (Article 15.3).

CGIAR Policy Process

With the adoption of the CBD in 1992, the CGIAR recognized that more than two decades of experience in conserving and utilizing GRFA placed it in a powerful position to assist in the implementation of the CBD, but that the realization of that potential would "require serious stocktaking and a careful rationalization of its genetic resources activities." (Strategy)

The 1992 TAC Review of CGIAR Priorities and Strategies confirmed the need for a System-wide strategy and Program on genetic resources, leading to the commissioning of the Stripe Study. The 1994 Stripe review (see below) identified a need to "leap from its paradigm of individual voices at autonomous Centers to a fully coordinated policy on genetic resources management across the System." This was met that same year with the creation at the Mid-Term Meeting of the System-wide Genetic Resources Program (SGRP) with the responsibilities to (CGIAR Mid-Term Meeting, 1994):

- Ensure that appropriate policies and strategies are formulated for genetic resources,
- Perform a representation role in international forums,
- Coordinate and, as needed, centralize documentation and information services,
- Be the principal genetic resources fund raiser for the System, and
- Provide a permanent Secretariat for the pre-existing Inter-Center Working Group on Genetic Resources.

"The SGRP joins the genetic resources programs and activities of all CGIAR Centers in a partnership whose goal is to maximize collaboration, particularly in five thematic areas. The five areas are (Strategy):

- Policy,
- Public awareness,
- Information,

- Knowledge and technology, and
- Capacity-building.

The SGRP is the first System-wide Program established in the CGIAR. It is guided by a Steering Committee – the Inter-Center Working Group on Genetic Resources (ICWG-GR) – with representation from each Center and FAO. SGRP is supported by a small Secretariat, hosted by IPGRI, whose Director General is the Program Leader (Strategy).

The initial proposed budget for SGRP was US $1 million annually through 1998, raised to US $1.6 million in 1996. However, actual appropriations have left SGRP under funded by 30 to 50 percent of that amount through 1998.

Material Transfer Agreement

In 1998, the SGRP conducted a review of the MTA which must be accepted for the distribution of GRFA according to the terms of the FAO agreement. The standard terminology was developed by IPGRI and subsequently approved by both FAO and CGIAR in 1999. The agreed language requires that the recipient of designated germplasm does not "claim ownership over the germplasm to be received, nor to seek IPR over that germplasm or related information."[1] The materials may be distributed directly to third parties provided those parties accept the same conditions. Acceptance of the materials "constitutes acceptance of the terms of the agreement." (MTA). A closely related MTA for non-plant genetic resources was approved in 2000.

The SGRP and individual Centers have invested time in probing alleged violations of MTAs. While enforcement is generally beyond the scope and means of the CGIAR and individual Centers, a jointly agreed CGIAR/FAO statement establishes the actions to be taken by a Center when a MTA was believed to have been violated (Second Joint Statement (1998), reproduced in SGRP, 2001(b), p. 10).

SINGER

SINGER (CGIAR System-wide Information Network for Genetic Resources), established in 1994, links the genetic resource systems of individual Centers, allowing them to be searched collectively. SINGER entered its second phase in 1998 with key identified objectives including the expansion to incorporate the full range of available data, including databases on forest, aquatic and livestock resources. Another objective was to link databases from outside the CGIAR. Highest priority is to be given to an increase in the quantity and quality of data available. Currently, SINGER contains data on the identity, source, characteristics, and exchange of over one half million accessions.

In 1999, the user-interface was totally remodeled, and in 2000 the server was upgraded. That latter year also marked the introduction of a new version of the "Tool Kit" through which users can query the database through the Web. The search may be done either for taxonomic characteristics or geographic descriptors. Currently, GPS data are being appended, which will enrich the passport data by linking to appropriate environmental information. Presently, emphasis is being placed on data quality and scope (breeders may now display a variety's pedigree on the Web) (SGRP, 1999, 2000(a), 2001(a); SINGER Web site).

In conjunction with ISNAR, a training needs assessment was conducted in 1999. Identified priorities were GR policy, research management, and technical needs. Technical training, an ongoing need due to staff turnover, and is being managed through the training of regional trainers. Policy has emerged recently as a major training interest.

Genetic Resource Collections

International Collections

The CGIAR collections contain over one half million *ex situ* accessions, of which 75 percent are traditional varieties, landraces, wild species, and weedy relatives (SGRP 2000(a), p. 5)[1]. Of those, over 90 percent are 'designated' (SINGER Web site).

In total, the CGIAR gene banks distribute about 150,000 samples annually (SGRP, 2000(a)). Of those, about 80 percent go to developing countries and the remaining 20 percent to developed ones. Principal recipients in developing countries are NARS and universities. The private sector has receive only between one and four percent, with the bulk of those going to developing countries as well. (IPGRI, 2001, p. 3 and External Review, 1996).

Regional and National Collections

With the CGIAR gene banks holding an estimated 10 percent of the total accessions, national collections contain the vast majority of that remaining. However, with the CGIAR collections corresponding to 35 percent of all distinct samples, the regional and national facilities contain many duplicates, some intentional, some not. Estimates of coverage of wild species ranges from a high of 70 percent for tomatoes to 1 percent for cowpeas. Given the inadequate facilities and poor management of many developing country *ex situ* collections, it is believed a high percentage of the accessions held there have lost their viability. Collections of agricultural livestock are very limited while, for fungi, it is estimated (1990) only 17 percent of those known to exist are in collections and less than 1 percent of those believed to occur. (Data in Heywood, 1995, Table 3.1-6 and Chap. 8, pp. 582 and 1002).

Private Sector Collections

The private sector holds only an estimated 1.25 percent of accessions (FAO, 1996). Private breeding firms nonetheless rely primarily on their own collections in producing new materials for sale. This is because the characteristics of the accessions are well understood, with undesirable traits largely removed.

Issues

Very little of the material held *ex situ* is used in breeding programs. Indeed, little in the working collections is extensively used. This is due in part to the lack of characterization of gene bank materials – by one estimate nearly one half of all accessions worldwide lack passport or characterization information. As a result, using those accessions is a slow and expensive process. Conversely, there is little evidence improved varieties, even if based on less than 10 percent of available germplasm, are more vulnerable than traditional landraces (Evenson and Wright, 2001).

A cost study for maintaining and bringing all CGIAR gene banks up to International standards was commissioned of IFPRI in 1996. The report indicated annual recurrent costs (in 1999 US dollars) of $7.539 million. An additional $20.8 million would be required over a five year program to bring the gene banks up to International standards. Of the $18.8 million required (excluding 'indirect costs') for the five year plan, 21 percent is for storage costs and 20 percent for additional chartization. (SGRP, 2000(b), Tables 5 and 6). Individual Center financial reports proved insufficient for documenting costs for the costs attributed to the gene bank operations varied across Centers. Some counted only direct costs, others included depreciation, while yet others counted related breeding activities.

Costs of storage and regeneration vary considerably due to the characteristics of the crop. Comparing only regeneration and introduction costs for corn and wheat, they are estimated to be $123.59 vs. $2.04 and 16.69 vs. 2.06 respectively. Differences are due to the variations in cross pollination potential and growth habits. As a result of these cost differences, the estimated lifetime costs for a corn accession is $230 – 500 vs. only $25 – 75 for wheat. Non-seed propagated crops are far more costly. Due to the cost differences a need was noted to establish conservation policies "to determine what types of genetic resources ought to be added or retained in the collection." (SGRP, 1999, p. 28).

Prior System-wide Reviews

Three relevant reviews of the CGIAR GRFA and related matters have been conducted:

- Stripe Study of Genetic Resources in the CGIAR (1994)
- External Review of the CGIAR Gene bank Operations with Annex (1996), and
- First External Review of the System-wide Genetic Resources Program (1998).

Stripe Study of Genetic Resources in the CGIAR (1994). The general objectives of the Stripe Study were to study ways in which the CGIAR discharges its responsibilities for genetic resource conservation, and to recommend to TAC options for changes in CGIAR strategies. Of the five recommendations made, the first two related to placing the CGIAR collections in trust, while not seeking financial benefit. Those recommendations were implemented in conjunction with FAO soon thereafter (see III.A). The remaining recommendations are as follows. These recommendations, while limited in number, are very far reaching.

- Create a standardized system of information management "to enable databases to be integrated throughout the System" (5.5.1)
- Place all CGIAR programs on the conservation of genetic resources into a single System-wide Program with coordinated policies (6.2.5).
- The reformulation of IPGRI as the Agricultural Genetic Resources Institute responsible for the proposed System-wide Program (6.2.5)
- Establish a Genetic Resources Fund with support from existing and new donors (7.7)

In addition to the recommended new governance form, two alternatives were identified:

- Use an existing Center genetic resources unit head as the cross-Center coordinator and spokesperson, and as Chair of the ICWG-GR, or

- Establish a new Central Director with a new Genetic Resources Board. The Director would be responsible for policy while administration would continue to reside with the individual Centers.

The Review identified difficulties in understanding the true costs of the genetic resource programs in the CGIAR due to differences across Centers in what is included in the released figures.

External Review of the CGIAR Gene bank Operations (1996). One of the first acts of the SGRP was to commission an external review of the CGIAR gene bank operations, to include a technical assessment of the constraints and opportunities of Center operations in scientific and financial terms. The review consisted of individual studies of the 11 Centers with gene bank operations plus one International Network. The general report consists of a compendium of the cross-cutting issues from the individual Center reviews; responses to the individual Center reviews are included in the review Annex. The review panel in general found the gene banks "well managed though under funded." Inconsistencies were found across Center gene bank operations, including the administrative designation of the gene bank (whether a division or department) as well as the level of chartization and evaluation at several Centers. Research was similarly found to be spotty, particularly as regards publication in international scientific journals. SINGER was found to need to make a number of improvements to simplify communications. Training programs were found to be extensive, but often suffered first with funding shortfalls.

Major recommendations out of 27 included:

- Recommendation 9: Centers should consider establishing an Advisory Committee on Genetic Resources.
- Recommendation 10: Quantify costs of running gene banks at different Centers.
- Recommendation 18: Place a high priority on regeneration of materials not meeting International Standards.
- Recommendation 19: Produce as soon as possible a set of International Gene bank Standards.
- Recommendation 20: Further refine designated 'core' collections.
- Recommendation 22: Place greater emphasis on published research.
- Recommendation 23: Need for a System-wide approach for identifying research needs
- Recommendation 27: Cost the resources needed to overcome the problems and bottlenecks identified by the review panel, leading to the preparation of a System-wide strategic plan.

First External Review of the System-wide Genetic Resources Program (1998). With a review panel drawn from universities and research institutes (Wageningen, Scottish Crop Research Institute, Indian Agricultural research Institute), as well as the World Bank, this more conceptual review aimed to answer two key questions:

- What role the CGIAR System of genetic conservation programs has and should play in the global context [FAO global plans and strategies], as well as its effectiveness?
- How to provide security of funding on a long-term basis?

The Panel identified three principal accomplishments during the early years of the SGRP (Chapter 4.7):

- Assistance to Centers in reaching agreement on common policies on genetic resources through improved coordination and discussion. Inter-Center collaboration has improved.
- Development of SINGER has permitted an increased information flow within the CGIAR, has improved access to information, and has stimulated the upgrading of documentation of Centers' collections.
- SGRP publications and public awareness efforts that have highlighted scientific output and improved public awareness.

The Panel made 18 specific recommendations along with a number of more general observations/proposals. Of the 18 recommendations, 8 can be considered the widest reaching and hence important for the future of SGRP:

- Recommendation 1: SGRP and the Centers clarify realistically, on a per-crop basis, the aims and objectives of their genetic resources conservation programs, indicating attempted coverage of targeted gene pools.
- Recommendation 4: SGRP and each crop-commodity Center should give high priority to: objectively quantifying costs of maintenance of accessions of different crops; guaranteeing the long-term security of Centers gene banks; adhering to appropriate standards; and identifying sources for sustainable funding.
- Recommendation 6: SGRP give high priority to the implementation of a proposed project "Development of a Scientifically Sound and Financially Stable Global Gene bank System."
- Recommendation 7: CGIAR should give high priority to making resources available to enable the Centers to implement fully, and in a more timely fashion, the recommendations made by the Gene bank Operations Review.
- Recommendation 8: SGRP prepare a strategic plan with prioritized objectives and areas of research/activity.
- Recommendation 9: A new SGRP structure be developed for achieving greater functional effectiveness and efficiency in System-wide cooperation in GR activities in the CGIAR.
- Recommendation 13: SINGER be made more user-friendly and user-responsive to a wide range of stakeholders.
- Recommendation 16: SGRP devote more of its resources to fund activities in the areas of genetic resources policy research and capacity strengthening.

General recommendations were also provided in such areas as the reorganization of the SGRP (Chapter 5.6, emphasis added):

- "Despite the achievements of the last few years, the panel believes that the existing [SPGR] *needs to be changed.* While there are several options from an organizational standpoint, the Panel believes that *the status quo is not one of them*.
- "To be effective the SGRP needs [] a higher profile, a clearer vision, strategy and direction, *more focused priorities and a more outward looking approach*."

- Regarding funding, the Panel noted the persistent under funding, while noting the 'significant' overhead charges (Chapter 4.6). Funding problems were attributed to donor focus on Center core funding, while individual Centers get little recognition for System-wide gene bank operations compared to their individual programs and priority crops.

Additionally, the roles and contributions of the genetic Resource Policy Committee were reviewed in 2002 (CGIAR, 2002). The review identified a number of important contributions made by that Committee and noted the needs would continue into the future. Recommendations included the provision of more operational assistance, better matching of the skills of the members with Center needs, and the allocation of a small budget (the Committee presently operates on a voluntary basis).

Responses to Reviews

Stripe Study of Genetic Resources in the CGIAR (1994)

Written responses. The TAC (also 1994 MTM) endorsed the concept of a System-wide program on genetic resources, while proposing a fourth governance alternative. That option would involve stipulating one Center as the lead Center with the responsibility to formulate approved policies and strategies, as well as being the principal fund raiser. Finally, the designated Center would provide the permanent Secretariat for the ICWG-GR. IPGRI was proposed as the lead Center. The remaining recommendations were accepted, particularly enthusiastically that of improving and standardizing information management.

Actions taken:

- The CGIAR collections were placed in trust in the hands of FAO.
- IPRGI was subsequently designated as the host Secretariat of SGRP.
- SINGER was established for managing data.

External Review of the CGIAR Gene bank Operations (1996)

Written responses. The ICWG-GR concurred with all recommendations, with the proviso in several cases that related activities to those recommended were already underway. More particularly, note was made that IFPRI was commissioned to study the costing of gene bank operations, and a "clear strategy" for SGRP was being developed. Recommendations to the individual Centers with gene banks tended toward the technical, such as suggestions for enhanced funding, better management of core collections, and, in a few cases, improvements in facilities. Generally, the recommendations were accepted, within the scope of financial feasibility.

Actions taken:

- A cost survey was completed differentiating the costs of regeneration and storing different kinds of accessions
- A plan was developed for raising additional funds, including an endowment, for adequately supporting the gene banks.

- SINGER was revamped and a searchable database placed on the Web.

First External Review of the System-wide Genetic Resources Program (1998)

Written responses. The ICWG-GR and IPGRI endorsed the Panel's recommendations in general, noting however the number of activities currently underway related to Recommendation 16. Disappointment in the Review was expressed as a failure to distinguish between the role of SGRP "broadly defined, which includes all the GCIAR activities on genetic resources, and the SGRP narrowly defined, which includes only those elements principally concerned with System-wide and inter-Center coordination, collaboration, representation, and information." As a result, "clear authority rests with no one." The proposed remedy is to maintain the current SGRP structure and activities for the technical components, while a 'higher body' is identified for the overall policy making and coordinating role. A second area of identified inadequacy involved the inadequate attention given to genetic resource management for aquatic, livestock, forest, and microbial resources.

The TAC reply identified recommendations 3, 8, 9, and 13 as critical to the major functions of SGRP. Five urgent tasks were identified: policy, representation, information, public awareness, and training. At the 2000 MTM, the working group on genetic resources saw a need for uniform GRFA policies at the System level, as well as suggesting the establishment of an endowment fund for gene banks. The Genetic Resource Policy Committee, reporting at the 2000 ICW, questioned calls for the combining of gene banks under a single 'management entity', in favor of systems which promoted conservation and breeding. A study of the feasibility of raising endowment funds for enhancing gene bank operations was commissioned.

Actions taken:

- A standardized MTA for plant genetic resources was developed and adopted (see Section IV.A[c] (Annual Report, 1999).
- TAC's 'urgent tasks' have been adopted as the six Thematic Areas of SGRP (Strategy; see Section IV.A.b).
- Decided governance of SGRP resides with the Board of Trustees of IPGRI (SGRP, 2000(a)).
- Decision to include the full range of available data as well as CGIAR databases on non-plant genetic resources.
- Link to non-CGIAR databases added.
- SINGER developed a "tool kit" allowing Centers to place databases on the Web (Annual Report 1998).
- SINGER user interface was totally remodeled in 1999, enhancing access by a wide range of users (SGRP, 2000(a)).
- Greater focus in training, led by ISNAR, was directed to policy and institutional issues (SGRP, 1999 and 2000(a)).

A study of costs of maintaining accessions done by IFPRI revealed major lifetime cost differences based on both growth habits and storage requirements. This suggests that "conservation priorities should be set to determine what types of genetic resources ought to be added to or retained in the collection." (SGRP, 1999).

Center Reviews

No mention of GRFA is made in the IFPRI (TAC, 1998(c)) and ISNAR (TAC, 1997(b)) reviews so that they are excluded from consideration here.

IITA Review. Major recommendations included the issuance of all agreements (MTAs and the like) through a single office, and the use of the CGIAR-FAO agreed MTA for accessing all future germplasm (TAC, 2001, Recommendation 12).

CIAT Review. CIAT has an international mandate for the preservation of cassava, common beans, and tropical forage germplasm. Cassava, lacking at present a secure cryopreservation technology, is particularly costly to maintain. Responsibilities include service activities as well as research. In 1996, the former Genetic Resources Unit metamorphosed into a program with little change in operations or objectives. The Panel judged the staff to be competent, motivated and hardworking, but lacking sufficient resources to complete the necessary tasks. Research is most constrained, and new mandated crops (tropical fruits) threaten to exacerbate the existing over-extension of the staff. Recommendations included the securing of the necessary funding, and development of a cryopreservation technique for cassava (TAC, 2000).

IRRI holds the world's largest collection of rice germplasm, with the collection still expanding. As of 1998, genetic conservation and related research is being carried out by a separate Genetics Research Program. The staff was judged to be professional and effective, including being well published in international journals. The Panel's sole comment was to register a concern the Program status would lead to isolation, and suggested a divisional status is preferable to program (TAC, 1998(a)).

CIMMYT Review. The formally separate maize and wheat germplasm programs were, in 1998, combined as Global Project 1. Previously, the separate programs had been making good progress in conservation and regeneration, but much remains to be done. The Panel questioned CIMMYT's full commitment to the establishment of a truly integrated institution-wide program as a "unified and cohesive scientific entity." Additional exciting scientific opportunities were identified, with the Panel suggesting CIMMYT pursue them (TAC, 1998(b)).

ILRI Review. ILRI manages a gene bank for forages, as well as livestock. An enhancement of the forage collection, including germination tests, to take up to five years, is underway. A recommendation was made to merge the animal genetics and genomics programs into a single activity. A Domestic Animal Genetic Resources Information Database has been developed and is to be linked with SINGER. The Panel suggested ILRI develop a policy statement regarding the conservation of livestock genetic resources, and the ILRI role in those efforts (TAC, 1999).

IPGRI Review. Genetic resources are of course very significant for IPGRI's programs, so that the review treated them in considerable detail. However, the review predates many of IPGRI's more significant recent activities. For example, the review noted that the genetic resources program lacked "coherence and direction," and hence did not project "weight in the global scene." Both matters, many observes would agree, have been addressed. No attempt is

made here to examine the detailed recommendations regarding the programs for coconut and bananas/plantains. The review particularly praised the following activities:

- Quality of research, particularly regarding an understanding of genetic diversity,
- Developing the core collection concept, and
- Enhancing farmer participation in crop conservation and improvement.

Identified areas needing improvement included:

- The agenda was seen as overly donor-driven,
- Need to prioritize agenda for appropriate conservation,
- Lack of a systematic means for identifying researchers for outsourced publications,
- Need to develop in house expertise on genetic resource policy analysis,
- Private sector relationships limited,
- Overall policy environment within and outside the CGIAR very complex and unlikely to "contribute effectively to the necessary clarity in both the decision process and System representation."

Collection missions, over 100 of which were conducted with IPGRI participation during the review period, are no longer mentioned (TAC, 1997(a))

Responses to Center Reviews

Only the following five reviews contain replies related to genetic resources:

- *IITA Review*. IITA accepted all the components of Recommendation 12 (TAC, 2001). The recommendations were similarly endorsed at the 2001 AGM.
- *CIAT Review*. CIAT management acknowledged the need for further funding, and pledged a higher priority for fundraising, as well as cooperation on the SGRP funding program. A reliable cryopreservation technique for cassava has been proposed as a System-wide effort (TAC, 2000).
- *ILRI Review*. The recommendation for the merger of the animal genetics and genomics programs was accepted. No mention is made of the suggestion for developing a policy for animal genetic resources (TAC, 1999).
- *IPGRI Review*. The conclusion of undue donor influence over the agenda is questioned. The recommendations for further articulation of linkages between institutional, thematic, and regional strategies were accepted, and the need for greater peer review of project plans and research contracts acknowledged (TAC, 1997(a))

Assessments of Reviews and Responses

Within a decade, rapid progress by any standard, the Centers have made enormous transitions in the management of their genetic resources. The GRFA Program clearly fits a definition of Global Public Good, providing a major public benefit as well as a comparative advantage for Center activities. Faced early last decade with the recognition that the previous ambiguity over the ownership and control of the extensive genetic resource collections were no longer viable in the post-Biodiversity Convention era, the System identified a resolution through

FAO and mover rapidly to implement it. That decision appears to be well accepted worldwide, clarifying what could have been a major point of contention of the 11 Centers with a germplasm collection. The recent adoption of the International Treaty further clarified the responsibilities and access to those materials on a broadly acceptable basis. The International Treaty has established a basis for managing non-designated materials and those recently collected under the terms of the Biodiversity Convention.

Implementing those steps required significant institutional changes at the CGIAR, including the institution of the first System-wide Program, the SGRP. In general, the several recent System and program reviews identified the key issues needing change, and the System, most notably IPGRI, acted rapidly and appropriately in addressing the changes. For example, the two System reviews identified a need for better data access, and SINGER modified its system accordingly. The recent Financial Plan and endowment campaign are putting in place both the surety of long term funding and levels of funding needed to meet the real requirements of the genetic resource program. These are critical steps, and were accomplished through a smooth combination of identification of need through reviews and quick, positive responses.

The System reviews are virtually silent on the conservation of non-GRFA materials and on *in situ* conservation as well. Forest, livestock, and fish genetic resources can be as significant in serving the needs of the poor are as are GRFA so that those materials must be given more attention in the future.

Where responses have not been as rapid and complete are in the broader management and strategic areas, particularly as identified in the External Review (1996). In particular, the Panel noted, "To be effective the SGRP needs [] a higher profile, a clearer vision, strategy and direction, *more focused priorities and a more outward looking approach*." Little documentation exists that such a sweeping assessment and priority setting has been completed, nor that the recommended policy and practice research and publication has been undertaken. The current approach appears to be more inward than outward looking. Limited research published in major journals, a means of coordination with international science, is another indication of an insular attitude.

The organization of SGRP has been modified, but it is unclear if the change is sufficient to meet the needs identified by the Panel. Of considerable importance is the issue of the authority of the SGRP. Certainly the SPGR has the appearance of authority as the FAO 'in trust' mandates has harmonized many aspects of gene bank management. Moreover, convergence of opinion is easily accomplished in cases like raising an endowment where the benefits are clear and the effort required of individual Centers limited. However, should the SGRP need to make a less popular demand on individual Centers, its authority to mandate anything, and consequences for not complying, are not at all clear. For a truly System-wide Program to function, the matter of authority needs to be clarified. Even in its present form, while effective, the SGRP is not a good model for other CGIAR System-wide Programs, for the in trust agreement with FAO gives the SGRP a more harmonizing and authoritative aspect than is typically possible in the autonomous minded CGIAR.

Perhaps the External Review itself – or, if not the Panel, then the System review – was also somewhat deficient in making such broad and vague recommendations about the 'need for

change'. With the number of immediate tasks, the SGRP and its board are hard placed to develop simultaneously a new vision for the genetic resource program. The Program is also limited by being largely a CGIAR institution, long known for its internal and separate focus, with an inherent lack of familiarity with other institutional approaches needed for the new era. Review panels can reasonably be expected to provide more guidance than the identification of a need for change – something typically evident even on more casual observation.

At the individual Center review level, genetic resources receive little attention. In part, that might be due to date of several key reviews (CIMMYT and IRRI, 1998, IPGRI, 1997), which was early in the major transition process. Nonetheless, the CIAT review (TAC, 2000) actual included a far broader discussion of the role and handling of the germplasm collection than the CIMMYT and IRRI reviews, whose holdings are far vaster and of greater international significance. Future Center reviews need to give further attention to the important genetic resource issue.

Technical training has been evolving down to the regional level, which is appropriate. IPGRI has been maintaining strong contacts with the regional institutions, which serve as the natural base of conservation efforts. Training needs in genetic resource policy has been increasing. IPGRI expertise in that regard seems narrower than perhaps is ideal, while, as a major participant in the international debate with a major stake in one approach, it must recognize the requirement for extra care to present a balanced analysis of options.

That said, there remain a number of second round issues that have not yet been noted, much less addressed, by the review process. Several pending issues are identified below and serve as an indication of the kinds of far-reaching factors which may impact the CGIAR in the future.

Control Over Genetic Resources

Placing the CGIAR collections in the 'in trust' agreement with FAO resolved many practical and control issues, but simultaneously created control matters which may need to be dealt with in the future. One is recognizing the sequential MTA approved by FAO is of dubious legal standing, meaning enforcement is heavily reliant on moral suasion. Neither the FAO nor CGIAR is well positioned to monitor use so that practical 'enforcement' falls to NGOs like RAFI. The System will at some point have to contend with the reality that its and RAFI's objectives may be different, yet the System has ceded most of its control authority. RAFI for example may publicize examples (such as for materials transferred before the MTA came into use) which are not actual violations, but can nonetheless provide much damning publicity. The Second Joint Statement also calls on the Centers to "request and urge" no IPR be sought on materials distributed prior to the MTA coming into use. While an understandable policy, it places the Centers in an ambiguous position of placing *ex* post limitations. This could discourage use of CGIAR materials, which is exactly counter to the intent of the entire arrangement.

External Use of Genetic Resources

For the Benefit Sharing aspects of the International Treaty to meet the likely expectations of many supplier nations, some revenues will need to be generated through commercial use. The amount of voluntary contributions has to remain in doubt. Yet the use data show that only

some 1 percent of materials are transferred to private firms where the likelihood of revenue generation is greatest. The prohibition on the use of CGIAR GRFA for pharmaceutical and commercial uses is another limitation on the generation of funds for Benefit Sharing. Indeed, overall, the collections, with the large amounts of uncharacterized materials, seem better designed for conservation than use. Conservation is of course a critical need, but perhaps not a sufficient one to justify the $7.5 million annual real costs in perpetuity. If the current endowment campaign is successful (as everyone hopes and expects), difficult decisions on selecting the crops to preserve can be delayed for a time. But the high cost and limited usability of much of the material will at some time necessitate a deeper consideration of the purposes of the collections, particularly considering the wide variability in national collections. This is clearly a large issue which exceeds the scope and control of the CGIAR itself, yet the highly visible position the CGIAR has taken in GRFA management means it must also take responsibility for the success of the entire approach, not merely the viability of its own 11 collections. These issues are not even identified in reviews of the System.

Sensibly, the International Treaty and the MTAs in use leave undefined just what data, beyond passport data, must be provided with accession. This absence of definition allows the use of flexibility in the future, if for example some information is based on traditional knowledge, or other is known to have commercial value. That information can presently be managed separately, even sold, to provide a greater level of control.

Financial Management

A careful consideration of the Centers' comparative advantage indicates that close access to and knowledge of the germplasm collections are among them (see also section on biotechnology). This is a major justification for leaving gene bank location and daily management with the individual Centers. Some Centers emphasize the connection between management and use by merging the budgets of the two functions. While there may be some intra-Center justification for that approach, it makes cost and budget comparisons impossible, limiting the opportunity for cost savings. A revised and standardized cost accounting system would assist with System-wide control. Periodic cost tabulations are insufficient for that purpose.

The System also seems to lack a process for finding (or even considering) cost efficient approaches, such as for information management. The External Review and System-wide Review both recommended the enhancement of and access to data, a request SINGER was able to satisfy within a reasonable period. But also at issue is cost – could another entity have provided the same result at a lower cost? That prospect seems not to have been considered, nor is it clear the current organization has a process for outsourcing. Compared to private businesses, the CGIAR operates on an old (and likely inefficient) model of internal sourcing.

Overall, the several programs contributing to GRFA are a model of both the provision of GPG by the CGIAR, and how the CGIAR can accommodate external change and respond appropriately in a relatively brief period. The associated SGRP similarly indicates the benefits of a System-wide approach, although the authority for harmonization granted through the FAO in trust arrangement means it can not serve as a model for other CGIAR System-wide Programs. The SGRP has implemented recommendations from the System-wide reviews effectively, most recently in the financial planning. The reviews themselves identified

effectively external issues, but where less guiding in directing internal CGIAR organizational changes. At the individual Center level, reviews addressed little attention to the significant GRFA matters. A series of ancillary GRFA issues are now likely to emerge and will require carefully considered responses. The authority of SGPR in establishing uniformity across the 11 Centers with germplasm collections may need to be considered as part of those responses.

Annex 4. Intellectual Property Rights

Role of IPR

Both patents and PBR provide limited, partial monopoly control over the identified inventions. The limit is temporal, typically 20 years from the date of first application. The monopoly control is partial because it applies only to the "scope" of the invention; any invention lying outside that scope is not covered. Moreover, ownership does not give the right to practice the invention – that may be limited by the need for regulatory approval or by the existence of another partially overlapping patent. For those reasons, patents and PBR are sometimes said to provide only "negative rights," that is, the right to prevent unauthorized use. Any profits come from the sale/licensing of the invention is in the marketplace.

In exchange, the public benefits from an increase in expenditures and investments on R&D. Moreover, inventions are made public, contributing to a storehouse of knowledge and helping to assure that substitutes will be available following the expiration of protection. However, because monopoly restrictions reduce dissemination, public benefits are not as great as they would be for unprotected materials (see e.g., Granstrand, 1999, Chap. 3).

IPRs are national in character; that is, rights do not apply except in countries where rights have been sought and awarded. The owner of a variety protected in say Chile cannot prevent its use in Kenya if no protection is held there, but can prevent importation into Chile or any third country where protection is held.

Patents

Patents are awarded for inventions which are novel, and display utility and an inventive step (nonobviousness). Novelty assures the invention is indeed new, while nonobviousness prevents the granting of a patent for a trivial extension. Utility requires the invention have an identified use, but not necessarily that the use is practical or efficient. Patents may be granted for products, products-by-process, and processes. Patent offices have some latitude in interpreting novelty and inventive step so that there is some difference between countries in the 'scope' of patents granted. For example, the U.S. Patent and Trademark Office approves about two-thirds of applications, while Germany's rate is closer to 50 percent. Some developing countries have issued patents based on the grant in a developed country.

In the area of life forms, few developing countries allow patents for plants or animals. Some countries do allow the protection of gene constructs. But as laws typically make no explicit mention of genes, it often cannot be determined if such patents will be allowed or not until a grant has been made. The patenting status of genes is particularly critical for agricultural biotechnology as PBR does not prohibit the transfer of genes from one variety to another. That is, the absence of both plant and gene patents in a country means essentially no IPR protection for agbiotech (see Lesser, 1998).

The legality of using a patented invention in research is knows as the research exemption. But since that exemption is not statutory (written) in patent law, its extent must be inferred from case law. Here, the distinction is made between working **with** a patented invention and working **on** one. Working with a patented lab instrument for example would clearly be

illegal, but working on a prior invention for the purpose of improvement is ambiguous. Eisenberg (1989) considered a number of theories of innovation and scenarios of science and relationship between researchers and rights owners. The results of her analysis are not unambiguously in support of free research access. "But as the line between basic and applied research becomes blurred in certain fields, patent protection increasingly threatens to encroach on the domain of research science, making it necessary to work out an accommodation …" (Eisenberg, 1989, p. 1086).

Biotechnology is one of those areas where applied/basic research boundaries are blurred. Heller and Eisenberg (1998) write of biomedical research where both a 'proliferation of patents on individual fragments held by different owners' and 'stacked' license fees "may lead paradoxically to fewer useful products." In agbiotech, a frequently cited example is Golden Rice, where between 0 and 44 separately protected components, with 30-40 typically applying to a group of developing countries, have been identified, with the actual number depending on which country is being considered (Kryder, Kowalski and Krattiger, 2000).

Some distinction should be made between these concerns and the research exemption *per se.* Research access itself is rarely of concern – what is problematic is securing rights *ex post* to commercializing products of that research as a classic hold up case ensues. The negotiation of commercialization terms *ex ante* would reduce the holdup component, but has the practical problem of imposing large transaction costs for many projects which will never materialize. Negotiations are seen as particularly burdensome for public sector researchers due to smaller staff resources with the needed expertise and a less commercial outlook overall. Hence, while a statutory research exemption in patent law would help to clarify rights and facilitate access in some cases, the issue of securing rights to commercialize products developed under a research exemption is a distinct and separate one.

Plant Breeders' Rights

PBR is a specialized (or *sui generis*) form of IPR applied only to plant varieties. National legislation can vary to some degree, but most current laws are patterned after the UPOV acts. While similar in function and form to patents, PBR is distinct in several key aspects:

- Protection requirements are novelty, uniformity, homogeneity, and distinctness (DUS). While novelty and distinctness (for nonobviousness) are similar to patent requirements, uniformity and homogeneity are particular to PBR. They serve the purpose of assuring the variety replicates itself sufficiently uniformly across individuals and time as to be identifiable. (Marker technology might be used for this purpose in the future, but not at present).
- Breeders Rights: grants breeders rights to use a protected variety in a breeding program without the permission of the variety owner (equivalent to the research exemption for patents). Under the 1991 Act of UPOV (Article 14.5), the resultant variety may be considered to be 'essentially derived' from a source variety, in which case the new variety cannot be used without the permission of the owner of the source ('initial') variety. This is similar in concept to a dependent patent.
- Farmers' Privilege: The right of a farmer to retain part of the crop for use as a seed source on their own lands in subsequent seasons. The UPOV 1991 Act (unlike the prior ones) makes the Farmers' Privilege a national option, but to date most signatory

countries have opted to allow it. In no case does UPOV allow farmers to sell protected varieties of seed[1].

Because of these differences, PBR are generally considered to provide less protection for the owner than do patents.

Material Transfer Agreements

MTAs are technically a form of contract law, and hence not regarded as intellectual property. Indeed, a MTA may be used as a substitute for a patent or PBR. Because contract law varies from location to location (and particularly country to country), the applicable legal jurisdiction is of importance. For that reason, the MTA will often specify where a dispute is to be litigated (or may require binding arbitration where allowed).

A typical MTA will grant research use, but to the second party only; a third party generally must secure a separate MTA from the first party. More significantly, the standard MTA requires a separate agreement for commercialization, leading to the holdup problem often described (see Section IV.A(b)). The proper management of MTA requires at minimum a good record-keeping system. A 1977 ISNAR survey of the CGIAR Centers determined that while some 75 acquired materials are covered by a MTA, almost 40 percent of materials have unknown or no written use agreement (Cohen et. al., 1998, Fig. 2 and Table 3). The potential ramification of MTA violations due to poor records has been a matter of increasing concern to the CGIAR System.

A subsequent (1998) review of selected Latin American NARS found similar issues and potential problems as encountered by the Centers (Salazar et. al, 2000). Some 53 percent of proprietary materials used were found not to be covered by a written agreement, while on the output side 74 percent or products are slated for protection, either by patents or PBR. Recommendations included providing “legal, scientific, and technical guidance” to help NARS address IPR issues. Note is made of the different needs of programs charged with producing products that can be commercialized and programs with more research/academic responsibilities. Fischer and Byerlee (2001) note that, for germplasm, free flow is threatened “not only by [PBR], but by national restrictions on export of local germplasm.” Yet, overall, research access for staple crops “is currently not the main issue.” So that time remains to accommodate policies (Pardey and Beintema, 2001).

Mention is made that, at the time of the survey, no NARS had an in-house IPR management program. That is no longer true, at least for some of the larger programs. Embrapa (Brazil) for example manages training and property rights through a centralized office (Sampao and Brito da Cunha 1999).

Current CGIAR Policies and Practices

Policies

IRRI. IRRI was early among the Centers with the 1994 adoption of an IPR policy. The policy has three components of relevance here (IRRI Web site):

- For products of conventional breeding: no IPR will be sought (Protocol II),
- Biotechnology based: IPR may be sought if specifically judged necessary, and then only to the extent necessary and for a limited period, to ensure availability to developing countries. A good faith effort will be made to notify and consult with the source countries for the materials (Protocol III), and
- For agricultural equipment: IPR will continue to be sought (Protocol IV).

CGIAR. The CGIAR adopted at the ICW in 1996 as an "interim working paper" certain guiding principals on intellectual property and genetic resources (available in SGRP 2001, pp. 31-33). Aspects relevant to IPR include:

- Products of breeding genetic materials supplied by the Centers may be protected by a PBR-type system so long as breeding access is not restricted,
- Centers may protect research results, either products or processes, "in rare cases" when "needed to facilitate technology transfer or otherwise protect the interests of developing nations."
- IPR protection will not be sought as a mechanism for securing financial returns, and
- Centers may enter into agreements with owners of protected materials provided any use restrictions are "consistent with the goals and objectives of the CGIAR."
- In a subsequent policy adopted at ICW 2000, Centers will notify recipients of protected materials of the existence of the protection, "and that it might not apply in their jurisdiction." (in SGRP 2001, pp. 35-36).

CIMMYT. CIMMYT in 2000 adopted an IPR policy applicable to both genetic resource and other materials and processes. The detailed policy has several main components, as follows (CIMMYT Web site):

- Decisions will be made by CIMMYT on a case-by-case basis,
- Any choice to protect research products with IPR will be guided by the commitment to serve the resource poor,
- If revenues are generated through the use of IPR, they will be used to support genetic resources Global Plan of Action,
- Enter into contracts in situations like supporting partnerships, assuring access, avoid blocking, and technology transfer,
- Seek IPR and grant licenses for research products if their absence could restrict the ability of a CIMMYT or NARS to pursue research, and
- Identify restraints to use delivering when possible research products free of use limitations.

IPGRI. IPGRI has a detailed IPR policy since April, 2000 (IPGRI Web site). The policy follows, in a somewhat more detailed and explicit way, the CGIAR guidelines for PGRFA. In particular, protection decisions will be made on a case by case basis, and only if the terms and uses justify the benefits.

Other Centers. Other Centers, including ILRI and IITA, are reported to have Board-approved IPR policies, but they are not readily available for review.

Practices

The establishment of a Central Advisory Service located at ISNAR was approved for an initial two year period by the Committee of Centers Directors in October 1998. The mission is to serve Centers' needs regarding intellectual property by providing and facilitating expert advice and enhancing the exchange of knowledge and experience. Specific tasks include (ISNAR 1998):

- Consult on implications for managing proprietary property,
- Serve as a liaison for managing intellectual property, and
- Establish mechanisms for distributing materials and experiences among the Centers and the global agricultural research community.

CAS has recently been approved for an additional two-year period with the TOR yet to be made public.

IRRI, CIMMYT, and ICARDA (half time) have each appointed an IPR specialist. The responsibilities of those employees have not been described in a publicly available location, but they are said to include training of scientists and advising on protecting materials and use of externally acquired protected materials.

ILRI holds one patent on a vaccine against theileria infection in the United States (1992) and Kenya (1994). To date, the vaccine has not been licensed to a private firm. ILRI also has a Board-approved IPR policy and, in 2000, established an IP Management Unit.

Prior System-wide Reviews

Three relevant reviews of the CGIAR IPR policies and practices have been conducted:

- Report of the CGIAR Panel on Proprietary Science and Technology (1998)
- Third System Review of the CGIAR (1998)
- System-wide Review of Plant Breeding Methodologies in the CGIAR (2000(c))

Report of the CGIAR Panel on Proprietary Science and Technology (1998)

The Terms of Reference for the Panel required it to identify and examine issues of major concern regarding proprietary science, and provide advice and recommendations, including a draft long term strategy. The diverse Panel had strong differences of opinion regarding both IPR and biotechnology so was able to agree only on some practical steps. Matters of concern and agreement included:

- Access to materials covered by IPR,
- The high costs of a properly managed IPR system, which could deflect funds from the main Center missions, and
- Centers should not pursue products expressly with the expectation of monetary returns, and anyway the costs of an IPR protection system would outweigh revenues, at least for a long initial period.

Other areas proved more difficult for reaching a consensus for a minority of the Panel felt Center developments with significant monitory potential should be protected. On that point there was some possible discordance with the Danida position (1999, Sec. 2.6.1) that the Centers "cannot, and should not, rely on patenting their new varieties for income generating purposes."

There was even a lack of agreement on the overall significance of IPR for Center activities. One group sees IPR as a minor matter, and, for public relations reasons, believes the Centers are unlikely to be sued in the worst case scenario. The opposing group saw the need for the Centers to act in an exemplary manner regarding property rights, whatever they might be, even if that required going beyond the letter of the law.

In part, those differing positions reflect a broader difference in perspective on the importance and role of biotechnology for CGIAR programs. The group on the Panel which sees biotech as central to future Center activities places a heavy reliance on an extensive IPR system, for both technology access and 'bargaining chip' reasons. The opposing group sees the Centers as heavily involved in the adaptation of local knowledge through participatory research. Biotech and hence IPR are not counter to that role, but neither are they central. Indeed, as the focus should be on poor farmers of little interest to the private sector, proprietary science will be of little use, and IPR becomes more of a barrier than a benefit.

An intermediate group, while recognizing the potential of biotechnology and a concordant need to remain flexible on IPR matters, saw little need to shift the central emphasis to proprietary science. Hence, IPR will be of peripheral significance. The three recommendations are:

- The needs will depend on the delineation of the CGIAR mission, but proprietary work should never be undertaken simply to generate cash or create bargaining chips,
- Expertise must be acquired quickly to deal confidently with technology transfer and IPR, minimally involving a centralized office, and
- The existing Guiding Principals on IP should be revised, formalized, and enforced. Any policy on seeking IP protection should be based on clear mission-based rules.

Third System Review of the CGIAR, 1998

This overall review of the CGIAR System by necessity of its broad scope touches only tangentially on IPR issues, yet the terms used indicate clearly the expectation of the future relevance of IPR to the CGIAR mission, and the need for enhanced policies and mechanisms.

The gene revolution is identified as creating "fundamental shifts" in the production of and access to food. Since the investment has originated largely from the private sector which is using IPR to recover that investment, "The CGIAR's challenge is to create a new form of public-private partnership that will protect intellectual property while bringing the benefits [] to the poorest nations." Applying IPR to CGIAR-developed technologies is proposed as a mechanism for assuring control (p.9).

A priority recommendation is the creation of a 'legal entity' to hold patents and lead the development of the "rules of engagement" (p. 10). The legal entity is subsequently described

as a "central coordinating and servicing unit" with multiple roles beyond IPR management to include such facets as biosafety and bioethics. IPGRI (with its proximity to FAO) is suggested as the location (p. 55). Alternatively, a "CGIAR-linked foundation" "could hold intellectual property rights on behalf of the CGIAR" as well as "manage funds generated from intellectual property rights." (p. 125).

The single relevant numbered recommendation (# 4) calls for an approach including in part:

- Patenting processes and new varieties, and entrusting their use under free licensing;
- A legal entity which could hold CGIAR patents;
- The text (p. 53) clarifies further the call for patenting, noting the recommended patenting is of a "defensive nature" to compete with the possible concentration of patents in the hands of a few private firms. Patenting can also create a "valuable asset" for the CGIAR, but the high costs of managing patents require the Centers have enough financial resources to fulfill the requirements.

System-wide Review of Plant Breeding Methodologies in the CGIAR, 2000(c)

The focus on IPR issues in this review was incidental, and largely focused on GRFA matters. General points from reviews of CIAT, CIP, and IRRI include the need for common principles on managing IP guidelines, despite the wariness exhibited at some Centers of consolidating IP activities. Better use of CAS was also recommended.

Responses to System-wide Reviews

Report of the CGIAR Panel on Proprietary Science and Technology (1998)

The TAC supported the three Panel recommendations, with extensions. In the case of the first recommendation, the TAC sees IPR as having an ever stronger effect on the CGIAR, particularly recognizing systems that are likely to arise from the CBD and other international agreements. Decisions on protection should be made on a case-by-case basis when seen as furthering CGIAR goals. Decisions should be decentralized to Centers, which should be strongly supported by legal and negotiating council.

In endorsing the second recommendation, emphasis is placed on the "urgency of the matter." The third recommendation is endorsed as well, with again a tone of urgency; "to perform effectively for the poor will require great sensitivity to the issues and opportunities emerging from intellectual property."

Third System Review of the CGIAR, 1998

Written responses. At the 1999 MTM, the Consultative Council's recommendation not to create a System-wide legal entity for holding patents was endorsed. The Centers were also encouraged to complete IPR audits rapidly for the six identified Centers, and the CAS is to conduct a feasibility study of a wholly owned subsidiary for managing IPR (CGIAR 1999(a)). At the 2000 MTM, the IPR and Private Sector Working Group endorsed the concept of defensive patenting for maintaining access to international public goods as well as developing

bargaining chips (CGIAR 2000(a)). The ICW later that year proposed expanding the guiding principals on IP to include all IP, not genetic resources exclusively (CGIAR 2000(b)).

Actions taken

- The recommendation for the creation of a centralized legal entity led to the establishment of the Central Advisory Service for IPR at ISNAR in 1999.
- IP audits for three Centers were completed by late 1999 indicating IP was used "appropriately" with the three remaining Centers expected to complete the process in the near future (CGIAR 1999(b)).

IRRI's two-stage review recommended "single door" IP management under the new office of partnerships. Additional recommendations were made on equipment patenting, copyright, maintaining IP databases, a trademark policy, and the use of standard MTAs for IRRI biological materials (as distinct from designated germplasm) (IRRI 1999). The Phase II audit raised questions regarding the limitations of a policy of defensive registration and publishing, while recognizing IRRI inventions might be assets for the entire CGIAR (IRRI 2000).

System-wide Review of Plant Breeding Methodologies in the CGIAR (2000(c))

TAC in a commentary accompanying the review report fully agreed with the "urgency of establishing coherent System-wide guidelines in intellectual property."

Center Reviews

The Centers listed below are a particular focus of this meta-evaluation and were reviewed in the 1998-2001 period. The ISNAR review predated the creation of the CAS and hence is not relevant to IPR issues, while the IPGRI review, somewhat surprisingly, does not directly address IPR matters.

IITA Review. Drawing on a 2000 IP audit, the Panel acknowledged the work since the first IPR policy statement in 1992. Recommendations included (TAC 2001):

- All MTAs issued through one office,
- Clarify 'freedom to operate' for all accessed materials, and
- Establish an IP committee.

The recently revised IPR policy statement is not readily available for public review.

CIAT Review. General quality of science was judged high, although substantiation of that appraisal is limited. IPR management is identified as growing more prevalent, presenting a "major challenge for CIAT" (TAC 2000).

ILRI Review. The panel was somewhat critical of ILRI's progress in terms of vision, quality of science, accommodation of System-wide management practices, and the need for more rational goals for the vaccine program. ILRI has provisionally adopted an IPR policy (1999). The Panel recommended IPR agreements be assessed on a case-by-case rather than blanket policy basis (TAC 1999).

IRRI Review. The Panel noted the 1994 IRRI IPR policy made the present position clear. The same conclusion was reached regarding the Policy on Partnerships with the Private Sector. Recommended was that both policies be re-examined in light of the changing world situation, particularly the efforts by public sector institutions in developed countries to patent their inventions. Similarly, the private sector partnership policy should be structured to allow access to the best available technologies (TAC 1998(a)).

CIMMYT Review. The Panel noted that IPR is "potentially one of the most important issues to be addressed within the CGIAR in the foreseeable future," and commended CIMMYT on the adoption of a detailed IPR policy (in 1995). No specific recommendations were made on IPR management; rather, confidence was expressed in CIMMYT's contributions in the field (TAC 1998(b)).

IFPRI Review. In addition to high praise for the quality and relevance of IFPRI's policy research, the panel noted that IFPRI could play an important role in IPR research (TAC 1998(c)).

Responses to Center Review

IITA Review. All the IPR recommendations were accepted, including an intent to establish a database of IP-protected materials in use at IITA (TAC 2001).

CIAT Review. CIAT management acknowledged the widening role of IPR and pledged to keep abreast of the issue so that CIAT materials are "fully accessible to the disadvantaged" (TAC 2000).

ILRI Review. There was no response to the specific recommendations regarding IPR management (TAC 1999).

IRRI Review. IRRI agreed to reformulate both policies, a position commended by TAC (TAC 1998(a)). IRRI has subsequently:

- Revised its IPR policy,
- Conducted an IPR audit, and
- Hired an IPR specialist.

CIMMYT Review. TAC commended CIMMYT for "strong leadership in the area of management of intellectual property rights." (TAC 1998(b)). CIMMYT has subsequently:

- Revised its IPR policy,
- Conducted an IPR audit, and
- Hired an IPR specialist.

IFPRI Review. There was no specific response to the mention of IPR-related research. IFPRI staff, most notably Pardey, has contributed a number of related edited works.

Assessments of Reviews and Responses

The CGIAR as an entity as well as the individual Centers has come relatively late to an acknowledgment that IPR management is an inherent component of contemporary science, including agricultural sciences. While public sector research institutions in developed countries were (often reluctantly) adjusting policy in the 1980s or earlier, the CGIAR System did not adopt its first Center-specific policy until the 1990s. Since that point, though, the System has accommodated IPR relatively rapidly. Indeed, the changes have been so rapid that the Third System-wide Review was essentially out of date when released – note how far beyond the specific recommendations the TAC went in its response to the review.

A major contributing factor to the CGIAR Panel on Proprietary Science and Technology was the fundamental disagreements among the Panel members on the role and importance of IPR. The simple answer to such a future impasse is in the narrower selection of Panel members, but that sidesteps the fundamental issue of the need for development of a general opinion on the roles of IPR within the CGIAR. Another approach would be greater involvement of the Private Sector Committee, which did not have a visible role in the several IPR reviews summarized here.

While an overall understanding and acceptance of IPR management is beneficial, the System has appropriately recognized the importance of managing IPR decisions on a case-by-case basis, which in part means Center-specific approaches. Decisions on what to protect, what to access, and how to use what is owned must be made by those closest to and most knowledgeable about the products or processes – that is, the individual Centers. That said, there is both a need of and a benefit to certain centralized functions, if only advisory support and coordination. The CGIAR came late to that approach as well, establishing the CAS only in 1999, and then for but two years (it was recently extended for two more). Little public comment is available on the accomplishments to date of CAS, but from an organizational base, the resources allowed, essentially a single staff person, are completely inadequate for responding to many of the service needs identified. CAS may not be the optimal arrangement, but any modification/substitute requires far more resources than available presently.

The CAS-type response is also completely lacking in authority, relying entirely on voluntary motivation and compliance by the individual Centers. To be sure, a command structure in this new and volatile environment is not optimal either, but a completely voluntary system will require a considerable period before a standardized approach, where desirable, emerges. Yet, with its long lead time reaching this stage, the CGIAR lacks a substantial future grace period in adopting a policy which satisfies national governments and donors on one hand, while allowing researchers to participate in the world scientific community on the other.

The CGIAR approach to IPR can be contrasted with that for GRFA. In the latter case, the agreement with the FAO made it possible in a short time to establish a standardized vision of the roles and rights/responsibilities to GRFA, and implement it through a MTA standard to all Centers. Users have the benefit of understanding the position of all the Centers, and recognizing access is on equal terms across the Centers. Such uniformity is not possible for IPR in general, but a broader agreement on the roles of IPR is needed and must come from some System-wide approach, but just which one is not clear. Several reviews refer to the development of such a standard policy, but none has been forthcoming to date. General

agreement also needs to be established with the bilateral donors lest broad donor opposition to IPR impede the pursuance of world class science at the Centers.

Any policy discussion should consider the consequences of not taking actions. For example, the CGIAR "Guiding Principals" on IPR reject the concept of patenting as a revenue source. Yet that means multinationals may get CGIAR inventions free, which does not make much sense, as the IRRI review points out by example (TAC 1998(a), p. 79). With the no revenue policy, many inventions will not be developed to the point of being useful to anyone. Many public sector researchers – and this is a point not appreciated by many – 'invent' only to the initial stage of indicating the prospect of a useful product. Typically, developments at that stage are patentable, but are not nearly ready for commercialization. Often, the heaviest investment goes into the subsequent development stage, something often beyond the means of the public sector. The obvious solution is a license with the private sector (often an exclusive license is needed to provide the necessary incentive), which then develops the invention further. This licensing approach is not appropriate in all cases, and can be modified by say reserving use rights for the CGIAR, but the general point is the reality of use issues needs to be considered along with the ideological. What is the goal of the CGIAR with its inventions, and how best is that goal achieved?

Once a general policy is enunciated, further development is needed on the establishment of implementation approaches. For example, if the decision is to patent, choices must be made on what to patent where, and how the patents are to be managed. The Strong (Third System-wide) Review proposed a System-wide foundation, but the details and alternatives have never been debated in detail after that proposal was seemingly rejected at the 1999 MTM. That is, to what degree do IPR really interfere with the pursuance of science and use in the CGIAR? Do the publicized examples represent the totality, or are they mere examples of a larger and developing problem? In that context, how would holding patents as "bargaining chips" really work within CGIAR? What are the true costs of an extensive IP system, considering both protecting and defending patents as needed? The Third System Review mentions the need to maintain equity reserves to meet those needs – but how large are those needs? Experience with technology offices in U.S. universities suggests a large negative cash flow for at least a decade. Is that compatible with the CGIAR's current financial position?

Estimates of per-patent costs in the United States range from $10,000 – 30,000, primarily for legal expenses, but can be substantially higher for complex inventions. European Union national patents typically run at twice that amount, due to the need for official translations. A patent for all major countries worldwide can rum to $500,000. In practice, when considering the costs of enforcement of rights, the total can be far higher. For that reason, public research institutions typically make patenting beyond the initial one the responsibility of a licensee. U.S. university patenting offices will employ between one and three practitioners (not necessarily lawyers), relying heavily on specialists to conduct market studies and write patents in each specific subject area.

Below the System-wide level, individual Centers have been making good progress on managing IPR. The carrying out of the IP audits seems to have been an effective initial step in the policy building process. It was recommended on review; the current completion of several Centers cannot be readily determined. The several reviews have particularly identified the leadership of CIMMTY and IRRI, as is appropriate given their leading research

roles. Those Centers, as has been noted, can serve as models for the others, with accommodations to different products and scope of course.

The Centers seemingly are themselves struggling with the IPR issue, leaving little resources or advice for the NARS. Indeed, one of the few times the NARS are specifically mentioned was in the CGIAR Guiding Principals where NARS were to be advised of the IPR status and applicability of transferred materials. Yet, the CGIAR cannot achieve its mission without strong NARS so that strengthening NARS in the area of IPR policy is essential. The need is great but resources and available entities limited so that further CGIAR involvement seems inevitable. This needs to be planned for.

Internally, Centers need to keep better records on IP agreements. This is likely to happen only when (a) agreements are made at the Center and not individual scientist level, and (b) agreements are databased, as recommended in the CIAT and IITA reviews (TAC 2000 and 2001). A centralized database, if agreed on, could follow the model of SINGER.

Overall, an IPR management process is an integral part of contemporary science, and indirectly of providing GPG. The CGIAR has lagged in the development of an appropriate overall policy and approach, beyond the general concept of proscribing steps counter to 'helping the poor'. To the extent the issue is identified in recent reviews, the recommendations, while helpful, have fallen far short of what is needed for a timely policy development. The CGIAR, while in recent years attracting more IPR expertise, still must look outside the System for all the know-how needed. Many IPR issues have general as well as Center-specific components, so that additional consideration (and resources) need to be directed to the appropriate centralized functions, possibly including a single entity to hold patents or, minimally, catalog outstanding IP agreements.

Annex 5: List of Working and Background Papers, Authors, and Peer Reviewers

Working Papers

Barrett, Christopher B. 2002. *Natural Resources Management Research in the CGIAR: A Meta-Evaluation.*

> Peer Reviewers: Jock Anderson, Derek Byerlee, Dana Dalrymple, Hans Gregersen, Ted Henzell, John Lynam, Vernon Ruttan, Meredith Soule, Joachim von Braun, Usha Barwale Zehr

Eicher, Carl K. and Mandivamba Rukuni 2002. *The CGIAR in Africa: Past, Present, and Future*.

> Peer Reviewers: Malcolm Blackie, Dana Dalrymple, Bob Herdt, Alain de Janvry, Romano Kiome, John Lynam, Eric Tollens, Geoffrey Mrema, Wilfred Mwangi, Cyrus Ndiritu, Emmy Simmons, Moctar Touré

Gardner, Bruce 2002. *Global Public Goods from the CGIAR: Impact Assessment.*

> Peer Reviewers: Jock Anderson, Dana Dalrymple, Osvaldo Feinstein, Paul William Glewwe, Hans Gregersen, George Norton, Scott Rozelle, Vernon Ruttan, Sara Scherr, Sudhir Wanmali

Lesser, William 2002. *Reviews of Biotechnology, Genetic Resource and Intellectual Property Rights Programs.*

> Peer Reviewers: Ronnie Coffman, John Dodds, Robert Evenson, Brian Ford Lloyd, Anatole Krattiger, Steve Kresovich

Spielman, David 2002. *International Agricultural Research and the Role of the Private Sector.*

Macedo, Jamil, Marcio C. M. Porto, Elisio Contini, and Antonio F. D. Avila 2002. *Brazil Country Paper for the CGIAR Meta-Evaluation.*

Katyal, J.C. and Mruthyunjaya 2002. *CGIAR Effectiveness — A NARS Perspective from India.*

Background Papers (Available upon request)

Ndiritu, Cyrus 2002. *CGIAR-NARS Partnership: The Case of Kenya.*

Romano, Luis 2002. *Colombia Country Paper for the CGIAR Meta-Evaluation.*