

# CGIAR

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## **Mid-Term Meeting 1999 May 24 - 28 Beijing, China**

### **The Third System Review: From Proposals to Practice**

#### **System Review Follow-up: Consultative Council Propositions on Science**

#### **Progress Reports on IPR Matters and Proposal for Review of Plant Breeding:**

- Development of an Institutional Mechanism for Holding Patents, and Update on IPR Audits of Centers**
- TAC Proposal on Terms of Reference for a Systemwide Review of Plant Breeding in the CGIAR**

Attached are two reports prepared by the Center Directors Committee and TAC on IPR matters and a systemwide review of plant breeding respectively. These documents are issued as background to agenda item 3(b)ii – Progress reports on IPR matters and proposal for review of plant breeding.

# Mid-Term Meeting 1999

PROGRESS REPORT  
ON  
ASPECTS OF  
INTEGRATED GENE MANAGEMENT  
CENTERS' RESPONSES

Center Directors' Committee (CDC)

Beijing  
May 1999

## INTEGRATED GENE MANAGEMENT

The Strong Review recommended integrated gene management as one of the major pillars of the Centers' research agenda. This was based on a range of premises:

- patenting processes and new varieties, and entrusting their use under free licensing;
- a legal entity which could hold CGIAR patents;
- the conservation of agrobiodiversity and its sustainable and equitable use;
- research on genomics and molecular breeding for the purpose of supporting NARS to enhance the productivity of major farming systems in an ecologically, economically, and socially sustainable manner;
- strict adherence to the equity and biosafety provisions of the Convention on Biological Diversity and national government regulations;
- a central coordinating and servicing unit for advising both IARCs and appropriate NARS;
- a widened food security basket through inclusion of minor and underused millets, legumes, tubers, and other crops;
- the use of molecular and Mendelian methods of breeding in an integrated manner;
- an effective public information and communication system, with total transparency and accountability in relation to work in the field of biotechnology; and
- a System-wide review of plant breeding efforts, with the aim of freeing up resources for new priorities while accelerating the introduction of modern marker-assisted breeding and bioengineering technologies.

These recommendations can be broadly grouped into two major areas for response – both critical to the future success of the Centers' work with their partners. The first grouping focuses on enhancing science in the Centers through increased research on genomics, molecular breeding and bioengineering technologies, and the integration of these with Mendelian methods of breeding. The second grouping relates to better management of intellectual property in the CGIAR Centers in order to retain freedom to operate and also to enter into new and more diverse partnerships necessary in the new scientific era.

**N.B.** -- *In responding to these two groupings it is however important to emphasize that this progress report is not a definitive statement from the CDC on IGM nor does it describe the extensive -- and continuing -- work in Centers relating to genetic resources, pre-breeding, and genetic improvement using established breeding methodology (referred to by the Strong Review as Medelian methods). This work continues to be a major strength of the system concentrating on traits that are important to resource-poor farmers, and not unusually the focus of the private sector. Such traits include durable disease resistance; drought and heat tolerance in crops; adaptation to stressed environments and enhanced yield and nutritional quality.*

*This report does, however, focus on some real progress by the Centers in response to the Strong Review's comments on IGM and addresses aspects raised by the Consultative Council during their meeting in January 1999. These responses focus on new scientific methodologies and better IP management.*

**N.B.** -- In relation to the recommendations regarding the role of minor and underutilized crops, a CGIAR workshop was held at the M.S. Swaminathan Foundation in March 1999. A separate report on this has been prepared.

## **Genomics, Molecular Breeding and Bioengineering**

The extent to which Centers have embraced these newer technologies varies across the System, but some examples of significant progress are listed below. They are not a complete listing, but are indicative of progress:

- CIAT has requested authorization to field test genetically modified rice and soon cassava germplasm.
- Jointly with EMPRABA, CIAT has filed a patent for the genetic transformation protocol for *Brachiaria*.
- A *Bt* gene provided by Plant Genetic Systems (Belgium) conferring resistance to insects has been successfully transferred to potato. Dramatic increases in resistance to potato tuber moth have been observed and now several varieties, popular in different regions of the world, have been transformed. CIP has freedom to distribute these varieties in 10 developing countries.
- Researchers at IRRI and Kansas State University are collaborating with CIP scientists in locating and screening candidate genes for disease resistance through molecular DNA analysis. Several promising candidates have been chosen and will be used as probes to locate similar genes in wild and cultivated potato germplasm, which can then be transferred to potato varieties for testing.
- CIP scientists are creating genetic maps of cultivated diploid relatives of potato with a focus on identifying sources of resistance to major diseases and insects. Efforts to map quantitative resistance genes in these diploids, especially for late blight resistance, have resulted in identification of several loci that contribute to resistance.
- The genetic engineering strategy for potatoes at CIP focuses on genes that are already present in potato, both cultivated and wild species. Once identified, genes can rapidly be incorporated in cultivated varieties. To date, genes conferring resistance to Potato Virus X and Y have been identified and cloned, in collaboration with Sainsbury Laboratory (UK).
- CIP routinely uses molecular markers for characterizing both its sweetpotato and potato germplasm, as well as searching for genes of interest in the genetic resources collections. The molecular genetics laboratory has just acquired its first automated DNA sequencer, which will enhance the process.
- Sweetpotatoes have been transformed with genes conferring insect resistance, and field-tested. CIP scientists, working in collaboration with Chinese scientists, have just developed an improved regeneration system for sweetpotato plants after transformation.
- New initiatives between IRRI and CIMMYT on genomic studies for drought tolerance in rice, maize and wheat.
- Establishment of high throughput, automated DNA screening at CIMMYT providing capacity for a large scale molecular marker facility; DNA fingerprinting of genetic resources; and EST sequencing. CIMMYT is now a member of the International Triticeae EST Consortium.
- CIMMYT, through non-exclusive agreements with ARIs and the private sector, now has access to DNA 'chip' technology; 'gene machines' (reverse genetics); and high-level scientific expertise.
- CIMMYT has completed the mapping of the genes involved in resistance to insects, viruses and drought resistance in maize and recently completed projects to transfer these genes using molecular markers to susceptible germplasm, resulting in improved varieties; efforts are now focused on incorporating these markers as routine breeding tools.

- In partnership with IRD scientists based at CIMMYT, large populations of maize and maize-Tripsacum have been developed containing the transposable element Mutator, for use in tagging useful genes and for reverse-genetic analysis of isolated gene sequences.
- IITA has on-going activities on the use of molecular markers (microsatellites, RAPD, AFLP, and RFLP) for characterization and assessment of genetic resources of yams, cowpea, cassava, maize, and plantain/banana in collaboration with institutions in the USA, Canada, and the UK.
- There are new initiatives between IITA and CIMMYT on genomic studies for *Striga* resistance in maize, and between IITA and CIAT for resistance to cassava mosaic diseases.
- IITA is collaborating with the Institute of Plant Science, Zurich, and Royal Veterinary and Agricultural University, Denmark, to develop a low cytogenetic cassava, through genetic transformation.
- There is collaborative work on bioengineering cowpea for insect and virus resistance by IITA with institutes in Belgium and the UK.
- Three chromosomal regions (QTLs) have been identified in cattle by ILRI that correlate with tolerance to the disease trypanosomiasis.
- Establishment at ILRI of an F12 advanced intercross population of mice for high resolution mapping of QTLs relating to genetically heritable disease traits of livestock and man.
- Collaborative work between Trinity College, Dublin, and ILRI to sequence mitochondrial DNA of cattle has identified a new centre of domestication in Africa, with a pool of potentially valuable adaptive traits for the introgression into higher productive cattle breeds.
- Collaboration between ILRI and The Institute for Genomic Research (TIGR) to sequence the genome of *Theileria parva*, and rumen bacteria with unique biochemical pathways for plant fiber digestion.
- Collaboration between ILRI and the Kenya Agricultural Research Institute (KARI) utilizing DNA fingerprinting to characterize smut-resistant Napier grass.
- Development of collaborative programmes by IPGRI on the extent and distribution of diversity using molecular techniques (RAPDs, AFLPs and SSRs) and GIS techniques.
- Optimizing particle bombardment and electroporation transformation techniques in *Musa* by the INIBAP programme of IPGRI and developing transformation techniques to introduce fungal-resistance into *Musa*.
- Characterization of the complete genebank collection of lettuce using molecular techniques involving a partnership between IPGRI, the CGN genebank (Netherlands), and biotechnology companies. Also, collaboration with partners on molecular characterization of the IPGRI/INIBAP *Musa* collection.
- Selective PCR of internal transcribed spacer (ITS) sequences for sequence comparison between different *Stylosanthes guianensis* types in Mexico, to correlate diversity of hosts-pathogens.
- Collaboration of IPGRI and national programmes to establish the use of molecular techniques for monitoring and management of diversity of useful forestry species subject to disturbance, overharvesting, etc.
- IRRI has reached the halfway point in establishing a bank of 40,000 deletion mutants of IR64 to facilitate gene discovery through forward and reverse genetics.
- Through the Asian Rice Biotechnology Network, IRRI has transferred to China, India, Philippines, and Vietnam the capacity for molecular pyramiding of genes for pest and disease resistance.

- IRRI is coordinating an international Molecular Breeding Program that aims to produce near-isogenic introgression lines for use both in rice improvement and rice genomics.
- IRRI has initiated field testing of rice engineered in-house for enhanced resistance to pests and diseases.
- IRRI has established a DNA sequencing facility for constructing physical maps of important regions of the rice genome, for gene isolation and analysis, for generating stress-related EST libraries, for generating constructs for bioengineering and for fingerprinting genetic resources.
- IRRI is coordinating a project under the System-wide Genetic Resources Program to exploit advances in genomics research for the management and use of *ex-situ* germplasm collection.
- WARDA has developed its capacity in molecular marker breeding and the Molecular Biology Laboratory is now fully operational.
- Activities that would lead to gene tagging and development of marker-assisted selection for weed competitiveness, blast and RYMV resistance, and drought and acidity tolerance have been initiated.
- Breeding populations have been developed and are being utilized with collaborators in Cornell University, IRD (ORSTOM), and IRRI.
- WARDA continues to develop new fertile and stable interspecific progenies from *O. sativa* and *O. glaberrima* crosses using embryo rescue and doubled haploid breeding.

In addition to the above, Centers are organizing major workshops on specific issues. For instance, an international workshop under the auspices of SGRP has been organized on Genebanks and Comparative Genetics, to be held at ISNAR in August 1999. The meeting will develop a collaborative research agenda on the use of comparative genetics to support the improved utilization of the *ex-situ* collections held in trust by the CGIAR. Another significant example is a workshop supported by the Rockefeller Foundation to take place at CIMMYT on drought tolerance in major cereals from June 21-25 1999. The main objective of the workshop is to develop a strategy for improving drought tolerance in farmers' fields, based on current information, approaches and germplasm, and emerging technologies, especially in biotechnology.

Lastly, in response to the Strong Review's recommendation, a System-wide review of breeding efforts is being coordinated by TAC in order to provide guidance and future directions for accelerating the introduction of modern marker-assisted breeding and bioengineering technologies. Centers have been consulted on the ToR for this review and have provided inputs to TAC.

## Better IP Management in the CGIAR

The second grouping of recommendations relating to IGM concerns better IP management in the CGIAR.

- Background

As early as MTM92, the CGIAR agreed on a set of working principles on genetic resources and intellectual property. Significant changes have occurred since then that affect both the exchange and use of genetic resources, and the management of intellectual property.

In relation to genetic resources:

- The CBD came into force on 29 December 1993.
- Centers signed agreements with FAO on 26 October 1994, bringing their germplasm collections under the auspices of FAO as part of the International Network of *Ex-Situ* Collections. Materials covered in these agreements referred to as designated germplasm<sup>1</sup>, are listed in the appendices to the agreements.
- The Multilateral Trade Agreement that came into force 1 January 1995 embodies provisions on TRIPS. As a result, many countries are now developing and enacting IPR legislation, including plant variety protection.

The past decade has also seen marked changes in the management of intellectual property related to agricultural research products. In the early part of the decade this was exemplified by a greater emphasis in the public sector (particularly universities) on commercialization of research products, especially plant varieties. Whilst this has continued to be a significant feature, undoubtedly the 1990s will be remembered as the decade of the seed/biotech companies in the private sector. A revolution has occurred, and is still underway, involving massive company mergers, huge investments in biotechnology and unprecedented emphasis on the acquisition and protection of intellectual property. This is not only occurring at the product level (e.g., herbicide resistant crops) but also at the fundamental and basic levels of plant and animal genomes, biochemical pathways, genes and associated promoters, etc. Never has agriculture – or indeed other areas of science – witnessed such dramatic and far-reaching changes. Against this background, no research organization can afford to remain static; it is necessary to respond, and respond in such a way that perceived threats are minimized and new opportunities maximized. The challenge for the CGIAR Centers to effectively respond to this changed and changing situation is, perhaps arguably, the biggest issue before us. A correct response will see the effectiveness of the Centers enhanced, whilst no action, or an incorrect response could markedly reduce the Centers' capacities to be the best and most effective partners for our colleagues in the south.

- Centers' Response

It is against this background that responses to the Review's recommendations have been made. For example, the CBC stated "*CBC is comfortable with most scientific aspects of the IPR recommendations as drafted in the report. CBC does not, however, accept the idea of a central legal body or board that would speak for individual centers or hold patents for them. All Chairs believe that resolving IPR questions in a prudent yet rapid fashion is crucial for many of the centers and for the system as a whole. The Chairs are aware that solutions to IPR problems are being sought in many international forums. At the end of the day, the CGIAR will clearly need to be in compliance with those internationally agreed upon conventions. But Centers are faced with operational*

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<sup>1</sup> The majority of materials currently held in Center genebanks has already been designated as coming under the agreement with FAO. Further material is being designated (as stocks are cleaned and multiplied) with the result that only those materials carrying special conditions imposed by the supplier would remain undesignated. (In 1996, such material accounts for less than 5 percent of the total holdings.)

*problems NOW, and there must also be some internal attempts to resolve these problems.”*  
There have been many reinforcements of this statement in ensuing months.

From the Centers’ perspective there are two major challenges – one internal, and one external to the system – but both directly impinge on the future effectiveness of the Centers as ‘leading edge’ international research institutions working for the resource-poor. There is a danger, already being realized to some extent, that Centers’ freedom to operate in terms of delivering needed products to our partners will be curtailed significantly in the coming weeks, months, and years, unless Centers more effectively manage their own IP (the internal challenge) and the IP of others, including the private sector, NARSs, ARIs and farmers (the external challenge). A further consideration in respect of IP management will be ensuring compliance (and if necessary, enforcement) of IPR.

Freedom to research is also becoming more complex, as Centers increasingly use the intellectual property of others. Agreements are required, and failure to gain such agreements not only restrains research activities but could culminate in costly breaches of patents if the products of such research are inadvertently released by Centers or their partners.

However, the major concern for Centers is constrained freedom to operate, in the sense of developing and releasing products based on the proprietary technology of others. This is exacerbated daily as other parties protect more and more IP. Given the common belief of many, that disclosure alone is no longer an effective strategy to keep Centers’ IP in the public arena, access to useful, cutting-edge technology and products will be increasingly uncertain. This situation would greatly reduce the effectiveness of the Centers and their partnerships, as they seek to overcome the enormous challenge of food security, poverty and environment.

It is therefore of the utmost importance that the prime reason for any change in Centers’ IP management must be based on efficiency, effectiveness and freedom to operate. In this regard, a more forward-looking approach to IP protection by Centers has a potential twofold benefit; firstly, if Centers protect their own IP they can ensure it remains in the public arena; secondly, it provides Centers with ‘bargaining chips’ to access the technology of others on more favourable terms. There are, as always, potential downsides to such actions, but if properly managed these can be minimized, if not eliminated. In this regard, it is interesting to note the comments of Ambassador Bob Blake (on behalf of the Agriculture Sustainability Committee) to the Strong Review:

*We commend the centers’ active leadership in patenting germplasm developments in ways that will assure their availability to farmers and plant breeders in all countries.*

Against this background the Centers have made significant progress towards better IP management in the CGIAR.

## Progress Report on IP Management Initiatives at Centers

Since ICW98 significant progress has been made relating to IP Management, some of this at individual Centers and some on a Center-wide basis. For example, a number of Centers now have Board-approved IP policies; IP Committees; and clear statements on IP management and related issues. Summaries of the System-wide aspects are provided below:

- Centers' Statements on Genetic Resources, Biotechnology and Intellectual Property Rights

At MTM98, the Centers tabled a series of papers relating to a 'Position Statement on Genetic Resources, Intellectual Property Rights and Biotechnology.' There was subsequent revision of two of the documents contained therein and a third was added at ICW98.

These statements have now been incorporated into a single publication available here at MTM99. It is expected that further updates will be provided at ICW99.

- Guiding Principles for the Consultative Group on International Agricultural Research Centers on Intellectual Property and Genetic Resources

At ICW98 it was reported that the Centers were revising the Guiding Principles. Accordingly, the CDC Committee on IP is currently working on:

- revising the language to make the Principles less tentative,
- developing more precise definitions of the terms "germplasm" and "related information" as contained in the agreements signed with FAO, and
- defining what constitutes a derivative – i.e. establishing the minimum that has to be done to designated germplasm before being able to claim intellectual property protection.

The output of the work of the CDC Sub-committee will be brought to the attention of the GRPC for its consideration and endorsement. FAO is also being consulted in the process, and the endorsement of the FAO Commission (CGRFA) will eventually be required.

In relation to 'derivative' it is considered that this issue is fundamental to the appropriate management of IP related to genetic resources in the CGIAR.

In order to provide guidance to this important work, a special study was commissioned by IPGRI from Dr. Melinda Smale of CIMMYT. In this study, she outlines the potential impacts of differing definitions of 'essentially derived germplasm and related information', as follows:

- Under the **most narrow definition** some would hypothesize that all breeders would have an incentive to use the material; a counter-hypothesis might be that only breeders with the greatest financial, legal, and technical resources would be able to use it because of high enforcement costs relative to other sources.
- Under the **broadest definition** there are also counter-hypotheses. Economists usually argue that in general IPR encourages innovation by regulating the use of resources held in common and/or providing temporary monopoly rights; others have argued that stacking of claims and heterogeneous interests in patenting DNA may lead instead to inertia and under-use of the resource. IPR will undoubtedly also be distributed very unequally among breeders in the developed and developing world, reflecting differences in financial, legal, and technical resources.
- In some **intermediate definition**, we might hypothesize the existence of "optimal use" (relative to a stated policy objective and constrained by the technology for and costs of enforcement). Could this be achieved through differential restrictions on use for developed vs. developing countries, exporters vs. importers, or strong vs. weak NARS? It is generally believed that regulation favoring one social group over another leads them to engage in non-productive behavior to ensure their own access. To complicate the problem, we might

hypothesize that the optimum for access may not be the same as the optimum for innovation.

“At present it is at least clear that the wording in Article 14 of the UPOV convention is intractable and therefore remains the subject of discussion by GATT and the seed industry. The efficacy of any CG-specific definition will be affected by outcomes of this discussion. ASSINSEL is now proposing “thresholds” of essential derivation on “a scale of genomic conformity” which are identified using criteria of combining ability, phenotypic and molecular characteristics, but acknowledges that breeders have so far been unable to agree on threshold levels for any species. It is also clear the enforcement costs may vary widely by definition.”

On the basis of these preliminary conclusions consideration is being given to a more comprehensive study on this important topic. IPGRI is integrally involved in this work.

**Another important consideration in the Guiding Principles relates to the level of protection the CGIAR should allow on its germplasm-related IP.** Currently, we state that with agreement from the Centers, "...cells, organelles, genes or molecular constructs may be protected by recipients...". There are, however, increasing calls to limit protection to the whole plant (or animal) and with no greater restrictions than that imposed by, for example, Plant Breeders' Rights, thereby allowing the breeders' exemption important to continuing use of genetic resources. Of course, the ability to enforce any new position would be an important consideration in any proposed change.

Work is continuing on these revisions and a new draft will be tabled at ICW99.

- Central Advisory Service Progress Report from ISNAR on the Central Advisory Service for Proprietary Science.

Following decisions taken by the Committee of Center Directors in late January, the Central Advisory Service for Proprietary Science (CAS) has taken its first steps towards implementation at ISNAR. The CAS has been approved for an initial two-year period during which it will develop fully the work plan submitted as part of ISNAR's final proposal.

This progress report reviews the management and implementation steps that are now underway and of greatest importance for the first year of operation. Each of these actions is facilitated through a series of contacts to be designated at each CGIAR center in the area of intellectual property management. This contact list will ensure that consultations are held with the relevant individuals at each center, and that a true system-wide perspective is gained.

Second, ISNAR is establishing the external Advisory Council for the CAS. Nominations are requested, and letters of invitation will be sent to individuals representing the legal profession, global IPR organizations, developing and developed country officials, and representatives from the international research community. At least two members will also be from the IARCs.

Third, a registry of legal expertise, including technology transfer and acquisition is being developed. This is taking shape through inquiries and consultations with leading experts in the field at universities and with private technology developers. These include those having responsibility for identifying, developing, protecting and managing technologies secured from a wide range of suppliers. A consultation will be held on these opportunities as more complete understandings are gained from these developers and the type of services required by the CGIAR. This registry would include individuals able to travel to centers for a 2-3 day consultation on potential disclosures and other related items.

Fourth, the terms and conditions of the feasibility study for a “wholly-owned subsidiary” for intellectual property to be held and managed for the CGIAR is being developed. This study will be undertaken with independent legal professionals and its proposed terms of reference will be reviewed at the first meeting of the external Advisory Council.

Fifth, advice is being gathered on the most appropriate individual for recruitment to ISNAR to work as the system's primary contact with regard to the CAS. This individual should have proven technology transfer and licensing skills, as well as an excellent working knowledge of the practical implications of the use and application of the various forms of intellectual property protection.

The first meeting of the Advisory Council will also form the basis for conducting a needs analysis among centers. This will build on requests that have already come to ISNAR. One other item for discussion will be the development of a standardized "disclosure" form that can be used by centers as the first step in securing specific IP advice on center-developed technologies and/or materials. This first meeting will be held at ISNAR prior to International Centers Week. It will be followed by an ISNAR-sponsored luncheon at ICW.

Finally, CAS will keep abreast of CIMMYT's work on behalf of the CDC IP Committee regarding center audits for intellectual property used and developed by the IARCs. These audits will follow the terms of reference prepared by CIMMYT in consultation with the other centers. Findings from these audits, as they become available, will provide important information with regard to the type of studies to be commissioned by CAS in the coming year. Thus, a close inter-relation between the work coordinated through CIMMYT and that of the CAS is anticipated. In addition, it will be important for CAS and CIMMYT to work together regarding the registry of expertise to ensure that the best list of legal providers is built, taking advantage of positive experiences among centers, and to avoid duplication of listings.

- IP Audits

Draft Terms of Reference for IP Audits were prepared by CIMMYT and following significant inputs from a number of other Centers, particularly IPGRI, a final document was circulated to all Centers on 11 March 1999. Based on these ToR (see Att. A), six Centers have now identified consultants and drawn up provisional workplans. These have been forwarded to the CG Secretariat, TAC and the Finance Committee in order to secure the release of funds for the consultancies. Several Centers are using a common consultant to carry out this work, whilst others are using consultants with whom they have previously worked.

It is expected that the audits of these first Centers would be completed in time for a report to ICW99.

- Wholly Owned Subsidiary

As noted earlier, the Strong Review recommended the establishment of a separate legal entity at the System level to hold patents for Centers and act on their behalf on all issues of IP.

In responding to this recommendation the CBC expressed the view cited earlier, and the CDC considered a discussion paper (see Att. B) on this topic at their retreat in Den Haag, February 1999.

The CDC decided that a feasibility study on a Wholly Owned Subsidiary would be carried out by the CAS as its first task. The study would be overseen by the CDC IP Committee. However, both the CBC and CDC consider that a subsidiary acting for all the Centers is unlikely to be feasible. Two or three Centers with common interests, acting in concert, is seen as a more likely scenario.

Prof. T.G. Reeves  
Chair, CDC IP Committee

**[CENTER] Intellectual Property Management Review**  
*Terms of Reference*

**March 1999**

In industrialized and developing countries, policies relating to the ownership, control, and use of intellectual property (IP) are evolving almost daily. Given the rapidly changing legal environment in which scientific research takes place, [CENTER] must be careful to protect its ability to distribute freely the products and services emanating from its research programs. For [CENTER], issues relating to the ownership, control, and use of IP are extremely important, because [CENTER] researchers use many proprietary products, technologies, and services that are owned by third parties. Third-party IP frequently is accessed via research contracts that restrict [CENTER's] ability to distribute any products and services generated with the help of this IP. For this reason, if mutually agreeable distribution arrangements cannot be reached, the products of [CENTER's] research activities may not always be available to partners and/or clients.

These concerns highlight the urgent need to understand the role of IP in [CENTER's] activities. It is essential to document the extent to which IP material is created from the CENTER's efforts or obtained through external sources; how IP material is currently used and may be used by the Center in the future; the importance of IP in achieving the CENTER's objectives; and the CENTER's ability to use, protect (if appropriate), and develop IP material.

To strengthen the internal IP management function and to devise a strategy that will safeguard the rights of IP produced by [CENTER] and the [CENTER's] ability to access, use and/or distribute IP in accordance with its research mandate, [CENTER] has decided to commission a comprehensive review of IP management issues. The IP management review will consist of three separate activities: (1) conducting a comprehensive IP audit, (2) identifying a strategy for regulating third-party IP currently used by [CENTER] researchers, and (3) developing long-term IP management guidelines.

## Activity 1: Conducting a Comprehensive IP Audit

A critical first step in managing IP at [CENTER] will be to conduct a comprehensive IP audit.

The investigative phase of the audit will have six objectives, which will constitute a general methodology or framework for the audit. The range of information obtained during this phase may be broadened, but the following six objectives must be adopted as the minimum level of inquiry:

1. *To identify all IP used or handled by [CENTER], whether the IP is formal or informal*  
Purpose: To clarify the terms under which this IP is being accessed and to determine whether the terms of access impose restrictions on [CENTER's] ability to distribute products and services produced with the help of this IP.
2. *To identify who owns the IP and/or was responsible for its creation.*  
Purpose: To clarify ownership of or responsibility for developing the IP.
3. *To identify the source of the IP.*  
Purpose: To specify where the IP came from and how it came to be used by the Center.
4. *To identify any restraints over the use, protection, or development of the IP that may affect [CENTER's] ability to access, use, or distribute its own IP or third-party IP.*  
Purpose: To identify all agreements between [CENTER] and third parties (including all contracts, licenses, collaboration agreements, memoranda of understanding, collaborative work plans, employment contracts, other legal arrangements, and other formal or informal arrangements) in order to identify areas in which IP access and ownership issues may have to be re-examined to ensure compliance with [CENTER's] current IP policy.
5. *To assess the importance of the IP to [CENTER's] activities.*  
Purpose: To distinguish essential from less essential IP and provide information for setting priorities with respect to IP.
6. *To identify all new IP being developed at [CENTER] (specifically, the IP opportunities perceived by the Center, for its own and third-party IP).*  
Purpose: To determine whether steps should be taken to safeguard [CENTER's] ability to use and/or distribute this IP in accordance with its mandate.

The IP audit will be carried out by one or more consultants contracted by [CENTER]. In selecting the consultant(s)/auditor(s), it will be necessary to ensure not only comprehensive knowledge of the science involved but also expertise in the areas of intellectual property management and legal aspects of agriculture-related IP.

The audit will consist of three parts that address the objectives described above.

### ***Part 1. Compile an Inventory of all third-party IP being used by [CENTER]***

The auditor(s) will compile a database containing information about all third-party IP currently used by [CENTER], which may be covered by one or more IP rights (e.g., patents, designs, trade marks, plant variety protection, copyrights, confidential information, an/or common law trade marks and trade dress). The database should be in the form of a table (either in Access or Excel) in which information is recorded under the following headings. These headings constitute the minimum information that is required, although additional information may be included as considered relevant. The manner in which the information is to be recorded is indicated in square brackets.

#### **IP type**

[patent/PVP/confidential information/design/copyright/trade mark/trade dress]

#### **Status**

[registered/unregistered/pending]

**IP details**

[describe the IP materials in detail]

*Note:* This material will include (but not be limited to) the following: germplasm held "in trust" by [CENTER]; proprietary germplasm and/or genetic material used by [CENTER] researchers (e.g., enzymes, molecular markers, promoters); proprietary machinery used by [CENTER] researchers (e.g., laboratory equipment); proprietary techniques or procedures used by [CENTER] researchers (e.g., laboratory procedures); proprietary computer software used by [CENTER] researchers; proprietary information databases used by [CENTER] researchers; and any other IP that may be restricted in its use or distribution.

**Owner**

[name]

**Source**

[identify the source of the IP and the circumstances/agreement/arrangement under which the IP was obtained or used by [CENTER], such as a material transfer agreement, germplasm acquisition agreement, confidentiality agreement, research agreement, or some other arrangement]

**Restraints**

[identify any restrictions, conditions, restraints]

**Importance**

[high/medium/low]

In addition to the information recorded in the table, some provision will be made for obtaining information on important issues such as "restraints" and "source" -- for example, by incorporating cross-references to reports.

The inquiry should also extend to material that is not formally registered or protected but which may potentially be covered by such rights.

This information will be obtained via written questionnaires and personal interviews with selected [CENTER] staff. It is estimated that approximately four months will be needed to compile the database containing information on third-party IP.

***Part 2. Compile an inventory of all new IP developed at [CENTER]***

The auditor(s) will compile a similar database containing information about all new IP being developed at [CENTER]. Information to be included in the database will include (but will not be limited to) the following:

**IP type**

[patent/PVP/confidential information/design/copyright/trade mark/trade dress]

**Status**

[registered/unregistered/pending]

**IP details**

[describe the IP materials in detail]

*Note:* This material will include (but not be limited to) the following: new germplasm developed or improved by [CENTER] researchers; genetic material developed, isolated, or identified by [CENTER]

researchers; research materials developed by [CENTER] researchers (e.g., enzymes, molecular markers, promoters); technology developed by [CENTER] staff (e.g., laboratory equipment, field machinery); research techniques developed by [CENTER] staff (e.g., laboratory procedures); proprietary computer software developed by [CENTER] employees; proprietary information databases developed by [CENTER] employees; and any other IP developed by [CENTER] employees.

**Owner**

[name]

**Source**

[identify the source of the IP and the circumstances/agreement/arrangement under which the IP was obtained or used by [CENTER], such as a material transfer agreement, germplasm acquisition agreement, confidentiality agreement, research agreement, or some other arrangement]

**Restraints**

[identify any restrictions, conditions, restraints]

**Importance**

[high/medium/low]

In addition to the information recorded in the table, some provision will be made for obtaining information on important issues such as "restraints" and "source" --for example, by incorporating cross-references to reports.

The inquiry should also extend to material that is not formally registered or protected but which may potentially be covered by such rights.

The information will be obtained via written questionnaires and personal interviews with selected [CENTER] staff. It is estimated that approximately four months will be needed to complete the database containing information on new IP developed at [CENTER].

***Part 3. Identify all contracts, licenses, collaboration agreements, and other legal arrangements that may affect [CENTER's] ability to access, use or distribute its won IP and/or third-party IP.***

The types of contracts, licenses, collaboration agreements and other legal arrangements to be identified shall include (but will not be limited to) the following:

- Formal and informal research collaboration agreements (including memoranda of understanding, work plans for collaborative projects, collaboration agreements, etc.)
- Individual employment contracts (for all categories of staff, e.g., internationally recruited staff, nationally recruited staff, Visiting Scientists, Pre-Doctoral fellows, Research Assistants, Affiliate Scientists, Trainees)
- Material transfer agreements (MTAs) governing the use of germplasm
- Agreements governing the use of third-party research materials
- Agreements governing the use of third-party research equipment or machinery
- Agreements governing the use of third-party research techniques or processes
- Agreements governing the use of third-party software
- Agreements governing the use of third-party information and/or databases

In addition, the auditor(s) will identify:

- Confidentiality agreements to which [CENTER] is a signatory
- Patents owned by [CENTER]

It may be possible to extract some of this information from other databases created through the audit, but this information can also be obtained via written questionnaires and personal interviews with selected *[CENTER]* staff, both scientists and administrators. It is estimated that approximately four months will be needed to identify all contracts, licenses, collaboration agreements, and other legal arrangements that may affect *[CENTER's]* ability to access, use, or distribute its won IP and/or third-party IP.

## **Activity 2: Identifying a Strategy for Regularizing Third-Party IP Currently in Use**

Based on the information compiled during Activity (1), the auditor(s) will identify steps that should be taken to ensure that all third-party IP currently used by [CENTER] researchers is being used legally. When the terms under which [CENTER] researchers make use of third-party IP are considered overly restrictive or simply unclear, the following specific issues will need to be addressed:

- Do alternative products or technologies exist that could be used instead?
- If [CENTER] wants to continue to use the IP, what would be the best strategy for negotiating an agreement that could provide sufficient freedom to operate?
- If an agreement is to be negotiated, should it be negotiated only for [CENTER], for several CGIAR centers, or for the entire CGIAR?
- What are the ramifications of continuing to use the IP without negotiating a formal agreement with the owner?

## **Activity 3: Developing Long-Term IP Management Guidelines**

Finally, the auditor(s) will analyze the information obtained through Activities (1) and (2) to draw up guidelines for IP management at [CENTER] to assure the optimum and appropriate use, access, and protection of existing and future IP. In developing these guidelines, the auditor(s) will address the following issues:

- Management of information about third-party IP used by [CENTER]
- Actions required to assure proper access to and use of third-party IP (e.g., where and how action is required to obtain freedom-to-operate licenses)
- Management of information about new IP developed by [CENTER]
- Strategy for identifying and evaluating potentially valuable IP developed by [CENTER]
- Strategy for seeking protection for new IP developed by [CENTER] when protection is deemed necessary/desirable
- Policies regarding disclosure by [CENTER] staff of research in progress (questions that will need to be answered include: What information can be published or presented in scientific meetings? When? Where? By whom? Subject to what sort of review?)
- Personnel required to implement an effective IP management function (including possible reporting structures)
- Relationship between [CENTER's] internal IP management function and the proposed CGIAR Central Advisory Service

*Note about confidentiality:* Given the potentially sensitive nature of the subject matter, the auditor(s) will treat as confidential all information collected during the course of the IP audit. The results of the audit will be disclosed only to the Director General of [CENTER]. Following review by the Director General and the Research Coordinating Committee (RCC), information considered non-confidential will be made available for more general distribution to the CGIAR Secretariat, to other CGIAR Centers, and/or to the general public.

*Last revised: 11 Mar 99*

## Some Thoughts on the Development of a Wholly Owned Subsidiary (W.O.S.) for CGIAR Intellectual Property

This paper draws significantly on inputs from IPGRI (Geoff Hawtin's email of 1 December 1998), Bob Herdt (his letter of 16 November 1998) and John Barton (advice commissioned by CIMMYT 11 January 1999). In addition, our own recent and current experiences at CIMMYT provide a useful 'reality check' on this section.

- Exploring our needs (system level)  
In other words, to what extent is the scenario outlined in the preceding section true - for the System as a whole? For individual Centers? IPGRI addresses this as follows:

I. *Is there a need for an entity that deals in some way with Centers' Intellectual Property?*

*Before considering the issues specific to actually establishing an entity (such as staff size, location, governance, etc.), the concerns that such an entity is being established to address must be clarified, verified and understood.*

*The study must, therefore, explore and confirm the assumptions underlying the call for an entity, including, inter alia:*

- 1) *Do the intellectual property rights of those outside the CGIAR impede Centers' freedom of operation in pursuit of their missions? Does this have a significant impact on CGIAR clients? (Answering this question requires looking at questions such as: how much of the technology needed by Centers is proprietary or is likely to be so in the future?; which and how many of the CGIAR clients have a need for the Center products resulting from the use of this technology and would not get them if the Center did not product them?; how does this vary across crops?, etc.)*
- 2) *Who holds the relevant IPRs? (e.g., private sector - and if only a few within this then identify; universities, etc.)*
- 3) *What IPR resources do the Centers have or have the potential to have? (This would have to build on the IP audits underway at individual Centers.)*
- 4) *Is there potential for Center IPRs to be used collectively effectively? (This question should examine generally if such collective use is possible. A more specific look at options for how it could be done effectively follows an analysis of the various answers to the question II of these Terms of Reference.*
- 5) *What advantages would be gained by establishing an entity dealing with Center IPR collectively? In light of the answers to I.2-4 above, would such an entity enhance the bargaining position for access to proprietary technology? (Like in questions I.4, these questions are pitched quite generally, with the question of how the entity might do so reserved for a more explicit examination of an entity's possible modes of operation.)*

- **Possible needs at the Center level.**  
To organize the Center's routine operations in a way appropriate to the new IP world, e.g.,  
 Provide background information to scientists and staff,  
 Develop appropriate employee agreements (including both rights and IP and respect for confidentiality obligations),  
 Develop appropriate documentation procedures; e.g., lab notebooks  
To organize new forms of cooperation with the private sector, e.g.,  
 Develop general policies for the goals of such cooperation,  
 Develop specific policies governing such issues as IP rights in genetic material and access to research results  
 Provide appropriate legal assistance in negotiation of cooperative agreements  
To assist in managing the intellectual property developed at the Center, e.g.,  
 To decide when to seek intellectual property protection  
 To file for and prosecute patent applications,  
 To negotiate commercialization arrangements (in the manner of a university technology licensing office).  
To provide freedom of action and decrease risk of infringement actions against Center, e.g.,  
 To audit Center research from an IP perspective,  
 To alert Centers to new relevant patents,  
 To participate in defense of infringement actions/threats against the Centers and to participate in negotiations utilizing Center/CGIARIP to maintain freedom of action.  
To ensure that Center research can actually benefit developing nations, e.g.,  
 To ensure that Center technology can be transferred "free and clear" to national agricultural research systems (including obtaining legal opinions if necessary)  
 To cooperate with developing nation NARS that are seeking to apply the technology and to protect their freedom to use it in nations in which there is commercial interest.  
To participate in policy debates surrounding national and international IP issues.  
To provide public information and responses on controversial issues.

- **Factors for and against centralization of a W.O.S.**  
 John Barton had these comments:

*The primary reason for a Center to obtain intellectual property is to ensure freedom of action for it and the developing nation entities for whom it is developing technology. The mesh of privately-held IP rights is now so substantial that it will become difficult to apply new technologies without infringing IP rights. The mesh is clearly most solid in the United States; it is spreading into a growing number of larger and middle-income developing nations. Hence, the Centers will need either to cooperate with the private sector in marketing (as well as in research) or to maintain bargaining chips in order to have freedom of action.*

*The best bargaining chips are patents in the developed world on technology that is useful in the developed world, because these are the rights that the private sector most needs. There may be financial returns from these patents, but the financial returns are unlikely to be great - and should certainly not be sought at the expense of freedom to apply Center technologies. This means that the patent management function is not like that of a university technology licensing office, which seeks to maximize financial return through exclusive or non-exclusive licenses; it is rather that of being able to negotiate a cross license or protect against an infringement suit threat against a Center or NARS, by licensing or using the possibility of a counter suit based on CGIAR IP rights that are needed by the private sector. Centralization of this function is useful in order to allow the IP developed in one Center to be used to give another Center freedom of action.*

*In general, centralization is likely to be valuable when it can achieve economies of scale or when the data activities involved are most centralized. Thus, the prosecution of patent applications and the maintenance of a watching brief over IP issues and new patents are certainly best done in Washington or Europe. Similarly, the*

*preparation of educational materials and the organization of programs intended to reach a large number of NARS are probably best done in a centralized way. And centralization is useful as well for global policy debates. In contrast, activity at the Center level is most appropriate when the Center's action and concerns are unique. Because of national law, and because patents are territorial, the drafting of employment agreements and the conduct of efforts to avoid infringement in research are best done at the Center level. The more balanced issues are those involving a specific global industry. CIMMYT, for example, know more about the commercial maize industry and its patents structure than will a centralized entity. Similarly, CIMMYT may better understand the licensing opportunities for a patent in maize than will a centralized office. And, the way that maize intellectual property developments will affect application of CIMMYT varieties in specific nations is better understood by CIMMYT than by a centralized entity. At the same time, a central entity may be able to remain in close contact with some of the private sector, and may be able to help alert CIMMYT to IP issues in important maize nations other than Mexico. Moreover, it may be able to work with NARS in those nations for which it is important to be able to export products into nations in which patents affect the marketing of end products. (This would be important, for example, for Thailand and rice.)*

Other factors against centralization could include the W.O.S. trading off one Center's IP to help another; the key role of individual scientists in drafting patents; and distance from 'the action.'

- **Possible Roles for W.O.S. in relation to Centers.**

The sections above all refer directly or indirectly to the roles on an enhanced IP management system, whatever that may be. However, some of these are set-up tasks (e.g., employee agreements at Centers) and there is a need to consider possible ongoing/longer-term roles for a W.O.S. or similar.

*The centralized institution could be responsible for:*

- β Working with a Center to decide whether to pursue a patent application*
- β Prosecuting the patent application in all appropriate nations*
- β Working with a Center to develop a licensing strategy or to negotiate a specific license at the Center's option*
- β Assisting in negotiations with IP holders to protect the Centers' freedom of action*
- β Maintaining an information basis on new patents and IP developments of importance to the Centers and to NARS and assisting the Centers and NARS to obtain this information. (This is becoming an Internet issue.)*
- β Devising an educational program for all the Centers.*
- β Organizing informational and policy development workshops with the Centers and with NARS*

*The Centers would be responsible for:*

- β Developing their strategies for collaboration with the private sector and for effective application of the Center's technology in developing nations.*
- β Managing employee arrangements.*
- β Ensuring that they avoid IP infringement and that the technology they provide is available to developing nations without infringing patent rights.*
- β Negotiating cooperative agreements with the private sector.*

*The centralized program could be operated under the supervision of a council for representatives of those Centers to which IP issues are most important. The Center representatives would receive training and briefing from the centralized programs as well as participate in the centralized program's management. There needs to be an allocation of the costs of the centralized program and of patent prosecution and of*

*the financial returns from licensing any patents (even though such returns should not be the goal of the operation).*

Prof. T.G. Reeves  
Chair, CDC IP Committee  
January 1999

## **Integrated Gene Management (System Review Recommendation 4)**

### **Terms of Reference for Systemwide Review of Plant Breeding in the CGIAR**

#### **I. Background and rationale**

In dealing with System Review Panel Recommendation 4, pertaining to Integrated Gene Management (IGM), the Consultative Council endorsed the use of an IGM approach at CGIAR Centres. Recommendation 4 also advocated that TAC review the efficiency of Centre plant breeding, focusing on the extent to which appropriate biotechnology and bioengineering techniques are being practiced as effective support to more conventional breeding practices. The aim was to assess the possibility of freeing up resources, implicitly by reducing the resources involved with conventional practices, so that applications of new techniques could be expanded as appropriate. In this context, the Council endorsed such a review, assigned the task to TAC with collaboration from Centres, and asked that TAC present Terms of Reference for the review at MTM99.

#### **II. Broad Issues to be addressed by the review**

Plant breeding has been one of the basic strengths of the CGIAR and its products continue to be of great relevance to the constituencies the CGIAR serves. A full review of its dimensions would encompass a broad range of themes. In framing the review, TAC has opted to focus on those elements that are central to the SRP's concerns. In doing so, the Committee has, in effect, assumed that work on the conservation of germplasm is being done effectively, that plant breeding projects underway are consistent with the priorities of the CGIAR, and that the current investment in plant breeding relative to investment in other undertakings is roughly consistent with CGIAR goals at the System and Centre levels. Each of those assumptions will be reviewed in the course of the next few years in conjunction with the development of a revised strategic plan and priority framework for the CGIAR. What is being emphasized in the current review, then, is the balance of instruments and procedures employed in plant breeding projects and programs currently operated by the Centres, along with the possibility that costs could be reduced were some activities further centralized or out-sourced.

There was discussion about the extent to which such a review should incorporate the many interactions between Centres and NARS. Again, these relationships will be an important part of the more extended review in conjunction with a revised priority framework and strategic plan. Even so, some part of the possibilities is reflected in the question dealing with outsourcing in the questions that immediately follow.

What will be the featured elements in such a review? What questions or issues will guide and orient the effort? At this time there are thought to be five principal considerations. For each of the Centres:

1. What techniques and tools are being used in plant breeding for each relevant crop?
2. For plant breeding and for each crop, what are total expenditures and what are the expenditures on biotechnology for that crop? how much total professional time (including post doctorals and deputed staff) is devoted to that crop and how much of that is from professionals in biotechnology?
3. What opportunities are there for achieving cost reductions through:
  - a. the substitution of new applications (including bioinformatics) for those of conventional techniques?
  - b. improving on the applications of conventional techniques?

4. What opportunities for efficiencies are there through concentrating applications currently found in several Centres or through further out-sourcing to NARIs, advanced institutions, or the private sector?
5. What are the likely gains to be achieved through the implementation of different methods and what would be the estimated capital costs for doing so?

While TAC has contacted Centres and a few experts about the issues, the list might well change as the review unfolds. As well, of course, the issues pursued in visits must be individually tailored to fit the specialized opportunities of each situation. Finally, while pinpoint accuracy would be quite costly, e.g., for the second issue, something less will be sufficient to indicate significant opportunities.

### **III. Modus operandi**

For now the intent is to deal with the first two issues with desk studies through the TAC Secretariat. This effort will clearly involve interaction with the individual Centres on a crop-by-crop basis.

For the remaining issues TAC intends to form a panel of experts with experience in well known plant breeding institutions. Suggestions for potential members will be sought from Centres and a variety of non-Centre sources. The panel will include enough members that constraints on available time should not be a major problem in attracting the desired people, but small enough that there will be overlaps in the membership of the various sub-panels. Each sub-panel will consist of two to three persons. In most cases it is believed that sub-panels can be so formed that each could effectively cover the plant breeding in a single Centre. To fix ideas, panel members might participate in the review of as many as two or three Centres. Given the SRP's interest in assessing the potential for reducing the investment in conventional breeding, it will be necessary to visit Centres and work directly with relevant staff. To date the evidence suggests that a visit will take around four days per commodity, more with larger programmes (e.g., rice), fewer with smaller programmes (e.g., cowpeas). The fifth issue can probably be based on the reports dealing with the other four issues and effectively treated by a specially selected sub-panel.

While a considerable amount of travel will be involved, it seems necessary to visit only the main station or stations for each Centre. Costs of the review will be on the order of \$250,000. TAC aims to have the review completed by ICW99, but notes that this depends heavily on the availability of experts and the seasonality of the breeding work in the various Centres.

### **IV. Conclusions**

TAC believes that the approach described is an efficient way to get at the issues raised by the SRP in a timely fashion. TAC notes that current EPMRs include a significant segment on the applications of biotechnology to plant breeding with acknowledged experts engaged to make such assessments (witness the recent reviews of CIMMYT, ICRISAT, IRRI). In this way and in the course of a few years, many of the issues of concern to the SRP will be covered. However, to the extent that the Group is concerned with more immediate insights into all relevant Centres and with observations about the advantages of centralizing some of the functions currently undertaken by several Centres (but note the counsel of the Biotechnology Panels), TAC commends this Terms of Reference to the Group and recommends its endorsement.