Expert Panels on Biotechnology Issues

Biotechnology (general issues)

Chair: Richard B. Flavell (U.K.)

Members:

Peter Quail	(Australia)
Robert Goodman	(USA)
Hirofumi Uchimiya	(Japan)
Jozef Schell	(Belgium)
Josef-Franz Seitzer	(Germany)
Michael Hansen	(USA)
Sam Dryden	(USA)
Gary Toenniessen	(USA)
Qifa Zhang	(China)
Govindarajan Padmanaban	(India)

Resource Person:

David Hoisington (USA)

Panel Secretary:

Michael H. Arnold (UK)

Proprietary S&T

Chair: Timothy Roberts (U.K.)

Members:

Stephen Crespi	(U.K.)
June Blalock	(USA)
Robert Horsch	(USA)
Silvia Salazar	(Costa Rica)
Sam Dryden	(USA)
Gary Toenniessen	(USA)
Brian Wright	(Australia)
Camila Montecinos	(Chile)
Marcio de Miranda Santos	(Brazil)
Bernard Le Buanec	(France)

Resource Person:

Carry Fowler (USA)

Panel Secretary:

Don Plucknett (USA)

..... see over for contact info

/ap - Oct. 97

Contact information for Panel on Proprietary Science and Technology

* designates location, not necessarily nationality

Name	E-mail	Fax	Telephone
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Crespi (UK) (c/o)	scoleman@btgplc.com	(44-171) 403 7586	(44 171)403 6666
Sam Dryden (US/Colo*)	bigston1@ix.netcom.com	(303) 449-9699	(303)449-9696
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Miranda Santos (Brazil)	marcio@sede.embrapa.br	(55-61) 347 2061	(55-61) 340 5518
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Salazar-Fallas (Costa Rica)	silvias@cariari.ucr.ac.cr	(506) 244 24 27	(506) 244 32 40
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Resource Person:

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Panel Secretary:

Donald L. Plucknett (US)	donpluckn@aol.com	(1-703) 3545423	(1-703) 9411936

15/09/97

PANEL ON PROPRIETARY SCIENCE AND TECHNOLOGY

Mailing/courier addresses

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*must use phone # for courier: (506) 244 32 40

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Berkeley, CA 94720-3310

Expert Panel: General Issues in Biotechnology

The Panel will:

1. Identify issues of major concern to the CGIAR that will facilitate positioning the CGIAR in the global agricultural research system.

2. Provide advice and guidelines on immediate or long-term needs with respect to:

   - comparative advantage analysis
   - risk management
   - strategic alliances
   - strategy and resources

3. Prepare a draft strategy on biotechnology for the CGIAR, taking into consideration needs of the centers and the stakeholders, identifying options for the strategic involvement of the CGIAR in the use of biotechnological approaches to solving problems relevant to its mission.

4. Prepare a report and recommendations to be presented to TAC for commentary and for consideration of the Group at ICW97.

Expert Panel: Proprietary Science and Technology

The Panel will:

1. Identify and examine issues of major concerns to the CGIAR in the area of proprietary science and technology and in the context of ongoing deliberations in the Convention on Biological Diversity, the FAO Commission on Genetic Resources for Food and Agriculture, and World Trade Organization (with respect to Trade-Related Intellectual Property System or TRIPS).

2. Provide advice and recommendations on immediate and/or long-term needs with respect to such issues as:

   - further refinement/resolution of CGIAR Guidelines for IPR
   - a central legal capability within the CGIAR for advising centers on proprietary matters
   - documenting and studying existing center or inter-center experiences in proprietary matters
   - tracking proprietary negotiations within the CGIAR for assessing future implications.

3. Prepare a draft strategy for addressing proprietary issues in the CGIAR in the short, medium, and long-term and suggest a framework within which future proprietary negotiations should occur consistent with accepted CGIAR policy and mandate

4. Prepare a report and recommendations to be presented to TAC for commentary and for subsequent consideration by the Group at ICW97.

Taking Biotechnology Forward in the CGIAR

The CGIAR intends to address major issues in biotechnology to assist the system to develop both a strategy for the medium and long term and an overarching policy framework. The strategy and the framework should provide a flexible environment for the centers of the CGIAR to manage biotechnology within their programs. A number of key issues have already been identified and include:

- interaction and collaboration with the private sector
- intellectual property
- harmonization with global agreements
- protection and promotion of international public goods
- flow of products to beneficiaries in developing countries
- biosafety
- ethics
- benefit sharing
- public awareness and perception.

The following process is suggested for the Group's consideration:

> Establishment of two ad hoc expert panels to define and address the issues according to the attached Terms of Reference. One expert panel will address general issues of biotechnology; the second panel will address issues specifically related to proprietary science and technology.
>
> The expert panels will work under the auspices of TAC and will consult widely with CGIAR stakeholders and existing committees.
>
> The expert panels shall include in their membership external, highly qualified individuals and representatives of existing CGIAR committees.
>
> The expert panels will present reports to TAC for commentary. The reports and commentary will be tabled at ICW97 for consideration by the Group as to further action.

<u>Conditions of Operation</u>

- Panels should take as a starting point the existing situation in the CGIAR
- Panels will draw on the expertise of existing CGIAR committees in areas where efforts are ongoing (e.g. GRPC for ethics issues, benefit-sharing, etc.)
- Panels should include members who are familiar with the CGIAR and are conversant with the external environment in which it operates (e.g. the convention on Biological Diversity for proprietary issues, the position and problems of NARS, etc.)
- Panel members should be appointed (approved) by the Group.

Panels on Biotechnology Issues

List of Documents

1. Intellectual Property Rights and Access to Genetic Resources in the Consultative Group on International Agricultural Research (CGIAR). Paper by G. Hawtin and T. Reeves, presented to the workshop Intellectural Property Rights III - Global Genetic Resources: Access and Property Rights. 4-6 June, 1997, Washington, D.C., U.S.A.

2. Strengthening CGIAR-Private Sector Partnerships in Biotechnology: A Private Sector Committee Perspective on Compelling Issues. Paper presented at CGIAR Mid-Term Meeting 1997. 26-30 May, 1997, Cairo, Egypt. (Doc. No. MTM/97/10).

3. The CGIAR and Biotechnology: Can the Renewal Keep the Promise of a Research Agenda for the Rural Poor? Paper by the NGO Committee Chair on biotechnology in the CGIAR, presented at CGIAR Mid-Term Meeting 1997. 26-30 May, 1997, Cairo, Egypt. (Doc. No. MTM/97/15).

4. The Role of Biotechnology in the CGIAR: A Report on the Highlights of a Stakeholders Consultation. Paper presented at the CGIAR Mid-Term Meeting 1997. 26-30 May, 1997, Cairo, Egypt. (Doc. No. MTM/97/17)

5. Bioengineering of Crops. Report of the World Bank Panel on Transgenic Crops (**Draft**).

TAC Secretariat
16/09/97

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH
TECHNICAL ADVISORY COMMITTEE
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Via delle Terme di Caracalla, 00100 Rome, Italy
Cables: FOODAGRI ROME - Telex: 610181 FAO I
Telephone: 57052458 - Facsimile: 57053298
E-Mail: Shellemiah.Keya@fao.org

Our ref : PR 3/11.1 Biotech (PS&T) DATE: 3 October 1997

Dear Dr. Plucknett,

On behalf of the Chair of the Technical Advisory Committee (TAC), I hereby confirm your appointment as Scientific Secretary of the Expert Panel which will examine Proprietary Science and Technology. This appointment will span the period from now until MTM '98 (i.e., late May 1998).

I refer you to the E-mail of 4 September 1997 from the TAC Chair, wherein the scope of the task and terms of reference for the assignment of the Panel Members are made explicit (Annex I). For ease of reference, I am also attaching the general terms of reference for 'Taking Biotechnology Forward in the CGIAR' (Annex II) and the specific terms of reference for the Expert Panel on Proprietary Science and Technology (TORs: Annex III).

You will note that much of the work will be done via E-mail and correspondence. It is anticipated that, among other things, you will monitor, synthesize, collate, and distribute the information so generated, and will meet with the Panel, and/or its Chair from time-to-time. Other meetings with TAC and CGIAR Members are tentatively specified below:

(i)	1997	Meeting of the Expert Panel prior to ICW '97 (October 1997);
(ii)	1998	Meeting of the Expert Panel prior to late May
(iii)		Any other meeting engagement as may be specified and negotiated with the TAC Chair.

As you are aware, the Expert Panel for Proprietary Science and Technology will consist of about eleven persons. Each Panel member will participate solely in a personal capacity. The administrative and logistical aspects will be managed by the TAC Secretariat. You will keep track of the time involved and direct expenses incurred.

./...

Dr. Donald L. Plucknett
Agricultural Research and Development
International
7127 Little River Turnpike
Suite 205 A
Annandale, Virginia 22003
U.S.A.

A number of background documents have already been forwarded to the Panel Members by the CGIAR and TAC Secretariats. Other documents will be sent to them as and when the need arises, usually at your request.

For your participation in the work of this Panel you will receive an honorarium at US$ 300 per day. Payment will be made upon completion of your assignment and receipt of a statement from you giving details of the number of working days spent on the task and any other authorised expenses you may have incurred. Please note that any travel inside or outside your home base in connection with the Study would need to be authorised in advance. When travelling for the purpose of the Study, you will also receive non-accountable per diem of US$ 250 per day to cover expenses, as well as business class air tickets when travelling by air.

I attach herewith a note on Administration/Financial Matters Related to TAC Missions for your information (Annex IV). I am also enclosing a Designation of Beneficiary Form which should be completed and returned to us at your earliest convenience.

If other information is desired, please do not hesitate to contact me.

We look forward to working with you.

With kind regards.

Yours sincerely,

Shellemiah O. Keya
Executive Secretary, TAC

Enclosures:

Annex I	E-mail from TAC Chair of 4 September 1997
Annex II -	TORs: Taking Biotechnology Forward in the CGIAR
Annex III -	TORs: Proprietary Science & Technology
and	Profiles for Panel on Proprietary Science & Technology
Annex IV -	Administrative/Financial Matters Related to TAC Missions

SAME SENT TO OTHER P.M.S

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH
TECHNICAL ADVISORY COMMITTEE
FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
Via delle Terme di Caracalla, 00100 Rome, Italy
Cables: FOODAGRI ROME - Telex: 610181 FAO I
Telephone: 57052458 - Facsimile: 57053298
E-Mail: Shellemiah.Keya@fao.org

BY EXPRESS AIRMAIL

PR 3/11.1 Biotech (PS&T) 19 September 1997

Dear Dr. Blalock,

On behalf of the Chair of the Technical Advisory Committee (TAC), I hereby confirm your appointment as a member of the Expert Panel which will examine Proprietary Science and Technology. The Panel will be chaired by Mr. Timothy Roberts (UK) and your appointment will span the period from now until the CGIAR's Mid-Term Meeting in late May 1998.

I would like to refer to the E-mail of 4 September 1997 from the TAC Chair, wherein the scope of your task and terms of reference for your assignment are made explicit. For ease of reference, I am also attaching the general terms of reference for `Taking Biotechnology Forward in the CGIAR' (Annex I) and the specific terms of reference for the Expert Panel on Proprietary Science and Technology (Annex II).

Whereas much of your work will be done via E-mail and correspondence, it is anticipated that you will need to meet with the Panel, TAC and CGIAR Members as tentatively specified below:

(i)	1997	Meeting of the Expert Panel prior to ICW'97 (late October 1997);
(ii)	1998	Meeting of the Expert Panel prior to late May '98;
(iv)		Any other meeting engagement as may be specified and negotiated with the TAC Chair.

.../2

Dr. June Blalock
Coordinator, Licensing Program, Off.of Tech. Transfer
Agricultural Research Service, USDA
Room 415, Bldg. 005, BARC-W
Beltsville, MD 20705-2350
USA.

For Information (without enclosures):

Mr. Timothy Roberts, Panel Chair
Dr. Donald L. Winkelmann, TAC Chair
Mr. Alexander von der Osten, Executive Secretary, CGIAR

As you are aware, the Expert Panel for Proprietary Science and Technology will consist of eleven persons Each Panel member will participate in a personal capacity. The logistical aspects will be managed by the TAC Secretariat. Your panel will be supported by a scribe/secretary with professional background in the issues of concern.

A number of background documents have already been forwarded to you by the CGIAR and TAC Secretariats. Other documents will be sent to you, as and when the need arises, usually on the request of the Panel Chair.

For your participation in the work of this Panel you will receive an honorarium at US$ 300 per day. Payment will be made upon completion of your appointment and receipt of a statement from you giving details of the number of working days spent on the task and any other authorized expenses you may have incurred. Please note that any travel inside or outside your home base in connection with the assignment should to be authorized in advance. When travelling for the purpose of the work of the Panel, you will also receive non-accountable per diem of US$ 250 per day to cover expenses, as well as business class air tickets when travelling by air.

I attach herewith a note on Administration/Financial Matters Related to TAC Missions for your information (Annex III). I am also enclosing a Designation of Beneficiary Form which should be completed and returned to us at your earliest convenience.

We look forward to working with you.

With kind regards.

Yours sincerely,

Shellemiah O. Keya
Executive Secretary

Enclosures:

Annex I	-	TORs: for Taking Biotechnology Forward in the CGIAR
Annex II	-	TORs: for the Expert Panel on Proprietary Science and Technology
Annex III	-	Administrative/Financial Matters Related to TAC Missions

Garrioch, Jane (SDRC)

From: Garrioch, Jane (SDRC)
To: Blalock, June; Crespi, Stephen; de Miranda Santos, Marcio; Dryden, Sam; Flavell, Richard; Goodman, Robert; Hansen, Michael; Horsch, Robert; Le Baunec, Bernard; Montecinos, Camila; Padmanaban, G.; Quail, Peter; Roberts, Timothy; Salazar-Fallas, Silvia; Schell, Jozef; Seitzer, Josef-Franz; Toenniessen, Gary; Uchimiya, Hirofumi; Wright, Brian; Zhang, Qifa
Cc: Serageldin, Ismail; von der Osten, Alexander; 'Riley, Sir Ralph'; tacwink; Keya, Shellemiah (SDRC); Gryseels, Guido (SDRC); Kassam, Amir (SDRC)
Subject: Message from Donald Winkelmann
Date: 4 September 1997 10:01AM

From earlier exchanges you will know that the CGIAR is aware that it must make serious choices about the role of biotechnology in the work of its centers and is seeking counsel as it weighs the surrounding issues. You have generously agreed to support this effort and the panel to which you have been appointed is indicated in the lists hereunder. As well, what follows expands a bit on the terms of reference for the panels, contains some administrative detail, and provides information on panel members and addresses.

A copy of the initial terms of reference is being sent to you along with a late August letter that amplifies the terms, provides a general timetable (note that it envisions two reports, not one as in the initial terms of reference), and makes some observations about the process. As background, it is affirmed that the CGIAR engages in research and related activities. Its goals are centered on poor people and feature the alleviation of poverty and protection of natural resources for sustainable food security, largely, but not exclusively, through improved technologies which increase productivity while conserving biodiversity, land, and water.

Reaffirming some of the points made in earlier correspondence, the CGIAR wants a strategy and a policy framework to guide its centers in managing biotechnology. Thus, the panels will want to identify issues that should be of concern as a strategy and policy framework are developed. The Group is looking for policy options, is aware that those will be shaped by science, law, and economics as well as by beliefs and perceptions, and wants a sense of the implications of different options along with counsel on those most consistent with its goals.

How all of that is achieved is left to the panels. The Group expects two reports from each panel, the first emphasizing the identification of issues that should be treated and a process for doing so (due in early October) and the second emphasizing analysis and counsel pertaining to the issues (due in mid-April 1998). As the late August note says, it seems likely that a combination of meetings and electronic exchange will emerge as the modus operandi for interaction. (Indeed it seems likely that many of you, busy as you are, are counting on an electronic format.)

Consultation with CG members and centers is perceived as an integral part of the effort. As well, it is hoped that the panels will take into account work going on elsewhere, especially that of the CGIAR's Genetic Resources Policy Committee which is now preparing a report focused on ethical issues as they relate to proprietary science. Finally, panels will want to be familiar with the evolution of the CGIAR's view on intellectual property as expressed in "Intellectual Property Rights and Access to Genetic Resources in the CGIAR" by Hawtin and Reeves (June 1997).

The panels will operate under the auspices of TAC's Sub-Committee on Reviews, chaird by Sir Ralph Riley. TAC will provide logistical support and support persons to aid each panel, e.g., with note taking and report writing. As well, TAC will cover costs associated with participation in the panels along with a daily honorarium of $300 and, while on travel status, a non-accountable expense allowance of $250 per day. In due course, the TAC Secretariat will provide information pertinent to administrative issues.

Membership of each panel is in the list that follows. A brief biographical sketch, fax and e-mail numbers of each member are contained in a note that will reach you within the next few days.

PANEL ON GENERAL BIOTECHNOLOGY SCIENCE

Dryden, Sam
Flavell, Richard
Goodman, Robert
Hansen, Michael
Padmanaban, Govindarajan
Quail, Peter
Schell, Jozef

Seitzer, Josef-Franz
Toenniessen, Gary
Uchimiya, Hirofumi
Zhang, Qifa

PANEL ON PROPRIETARY SCIENCE

Blalock, June
Crespi, Stephen
Dryden, Sam
Horsch, Robert
Le Baunec, Bernard
de Mirando Santos, Marcio
Montecinos, Camila
Roberts, Timothy
Salazar-Fallas, Silvia
Toenniessen, Gary
Wright, Brian

On behalf of TAC and the CGIAR I want to thank you for your willingness to help us in this critically important endeavor. All of us wish you well in your efforts.

Sincerely yours,

Donald L. Winkelmann
TAC Chair

---

cc: Ismail Serageldin
Sir Ralph Riley
Alexander von der Osten
TAC Secretariat

Panels on Biotechnology Issues

List of Documents

1. Intellectual Property Rights and Access to Genetic Resources in the Consultative Group on International Agricultural Research (CGIAR). Paper by G. Hawtin and T. Reeves, presented to the workshop Intellectural Property Rights III - Global Genetic Resources: Access and Property Rights. 4-6 June, 1997, Washington, D.C., U.S.A.

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5. Bioengineering of Crops. Report of the World Bank Panel on Transgenic Crops (**Draft**).

TAC Secretariat
16/09/97

International Centers' Week

Biotechnology in the CGIAR

Reflections for Consideration

Presented by the German Delegation

Washington D.C., 27 - 31 October 1997

Biotechnology in the CGIAR - Reflections for Consideration

At the Mid-term Meeting of the CGIAR in Cairo CGIAR Chairman Ismail Serageldin initiated a discussion to clarify the CG's role in biotechnology and to strengthen the application and profile of biotechnology at the Centers. This proposal was most welcome in view of the unprecedented challenges the world community is facing: the need to double accessible food in the coming 30 years while at the same time securing the natural resource base.

The CGIAR needs to critically assess the state of the art and the options available to enhance technology development, transfer and adoption, including biotechnology, to make its research strategy more effective. While biotechnology could provide significant contributions to food security and poverty alleviation of the CGIAR's beneficiaries, it raises some issues that require attention: These are partly related to technology development and technology transfer *per se*, and partly specific to biotechnology and its unique characteristics.

No doubt several Centers successfully apply conventional biotechnology. However, present discussions focus on genetic engineering, whether and to what extent the CGIAR should engage in this area. Following the initial discussion at the MTM, CG members recognized the need for further clarification, and it was decided to set up two panels with specific mandates to review biotechnology and intellectual property rights issues.

To elaborate on relevant experiences and perspectives in Germany, BMZ convened a working group[1]. The preliminary outcome of the discussions of this working group is summarized in the following.

Comments on the TAC Biotechnology Panels

1 Terms of Reference and Process: The following points need to be stressed:

1.1 It has to be ensured that advice from the two panels in collaboration with TAC covers the entire range of aspects relevant for policy making in the CGIAR at the system level; the specific panels cover only part of the TORs.

1.2 The Group needs to be clear about TAC's role in this process; for the MTM 1998, the Group should aim for a consolidated, coherent policy paper that covers the results of both panels, TAC's recommendations to the Consultative Group as well as the state of the discussions of the Genetic Resources Policy Committee.

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1 Composition of working group: Alonso Rodriguez, BMZ; Fischbeck, Emeritus, Techn. University of Munich (conventional&molecular breeding); Jacobsen, Hannover University (molecular genetics); Kürschner, ATSAF (CGIAR resource person) Leskien, Consultant Hamburg (academic lawyer, specialised on IPR for DCs); Schiemann, Federal Biol. Res. Centre Braunschweig (biosafety); Schilde, Tübingen University (molecular tissues&cell culture); Seitzer, KWS Einbeck (private sector breeder); Stegemann, EcoAgriDev/Forum Environment&Development-WG Agric.&Food (NGO representative and genetic resources specialist); Stoll, Max-Planck-Institute Heidelberg (foreign public& international law), von Urff, Techn. University of Munich (agric. policy& economics, socioeconomic implications of biotechnology), Weiskopf, GTZ (CGIAR resource person); Wolpers, GTZ (biotechnology programme)

1.3 The composition of both TAC panels requires further balancing with regard to the expertise required:

- In both panels imbalances are evident regarding representation from the South (less than 20%) and from the regions (over 40% from North America).

- Panel on "General Issues in Biotechnology": requires expertise in socioeconomics; yet members are largely biologists and molecular geneticists with limited knowledge on institutional aspects and on the CG's target groups

- Panel on "Proprietary Science and Technology": over-representation of natural sciences (7 out of 11) and of the private sector, insufficient legal expertise; legal expertise present is biased towards the private sector perspective.

Specific Issues to be addressed

2 Contribution to the CGIAR goals?

2.1 How to assess the potential of biotechnologies relevant to the CGIAR goals?

- A thorough problem analysis and a cost-benefit analysis are required to identify and to justify potential areas of biotechnology research for the CG, considering that:

  - biotechnology is a tool, although of increasing importance, and that we have to reevaluate the priorities given to the ongoing agenda programmes;

  - biotechnology is expected to provide added value, e.g. to conventional breeding in terms of efficiency and adaptation to developing countries.

  - fundamental know-how and methods of gene technology are provided by AROs and the private sector, whereas huge investments would be required to build up capacities at the Centers;

2.2 How to design problem- and demand-oriented programmes, which include biotechnology as an integral part and contribute effectively to the CGIAR goals?

- Activities of Centers should cover the entire range of activities, including awareness and capacity building in NARS, the facilitation of technology transfer, policy analysis and advice as well as training.

- The CG has to take a rather differential view on genetic engineering for each Center and topic. The respective potential and the state of the art differ greatly between crops, fields of application and the problems to be addressed.

- A biotechnology-driven approach to agricultural research for development is not desirable, because an *a priori* budget target for investments in biotechnology could divert Centers from the actual needs of the target groups.

- Continuous appraisal of research is required regarding ecological, health, cultural and socioeconomic risks and to ensure that biotechnology contributes to improve the standard of living, in particular of poor people. One concern is also the reduced time lap between basic research and field application.

3 Role of CGIAR Centers in biotechnology and focus of activities

3.1 Centers have a particular role as bridge builders between frontier science and small scale farmers in providing biotechnology applications, policy analysis, and capacity building, as well as training for NARS. This role is

- guided by research priorities which have been well defined and which represent
- the specific needs of the NARS partners and the target groups, especially resource poor farmers, in the respective mandate regions.

3.2 Capacity building and training require, in our understanding, that Centers invest in hard-core biotechnology research by

- focussing on well-selected and well-focused problems only (e.g. to address yield stability and variance under different growth conditions, in particular in less favoured areas).
- taking into account the already existing research capacities of AROs and the private sector; a broad-based investment of Centers in basic biotechnology research does not seem to be justified.

3.3 Centers have a comparative advantage in research areas and crops that are not addressed by the private sector or by AROs (e.g. research on improved tolerance to biotic and abiotic stresses, identification of genes or gene sequences in the most important food crops; research on under-utilized crops e.g. Cassava, Yam, Millets).

4 Collaboration with NARS Partners

4.1 Training and capacity building of NARS are particularly important where alternative capacities are non-existant, e.g. for biotechnology applications in food crops of regional importance or in under-utilized crops, focussed in particular on problems of the poor. Centers should strengthen collaboration with NARS considering that

- minimum requirements of physical and staff capacities at the Centers have to be determined for providing effective services to NARS and to enhance technology transfer, e.g. by developing constructs and transformation systems;

- an awareness and advisory function of Centers towards NARS is required on policy issues such as biosafety (e.g. by the Intermediate Biotechnology Service); and that

- networks provide an effective means for continued support and backstopping for NARS. In the case of Cassava Biotechnology, Centers have successfully demonstrated their catalytic role by mobilizing additional research capacities (development of a transformation and regeneration system).

4.2 The CGIAR should develop a strategy for enhancing technology transfer and to strengthen developing countries' access to technologies, by increased cooperation with efforts in the private sector and by AROs:

- Centers could take a more active role in the acquisition of know-how and technologies (as a broker) to improve access of NARS to technologies and products in well defined areas.

- Existing experience in private sector-ARO-NARS-cooperation (e.g. within the framework of ISAAA) should be analysed and utilized to the benefit of developing country target groups.

5 Implications Regarding Intellectual Property Rights

5.1 The basic working principle of the CGIAR to produce International Public Good needs to be reaffirmed in view of the increasing cooperation with the private sector:

- The access of developing countries to technologies and to scientific knowledge developed by the CGIAR within the framework of the present working principles on IPR should not be restricted (e.g. through comprehensive patent claims including genes, procedures and their applications).

- Careful monitoring is required to counteract actions that restrict the access of developing countries, in particular of resource poor farmers, to technologies and to clarify circumstances that require an alternative CGIAR strategy regarding co-operations and agreements, in particular with the private sector and AROs .

5.2 Present developments of increased privatisation and application of patent rights in international agriculture require consequent follow-up by the CGIAR:

- Policy advice for Centers needs to consider the different IPR frameworks (in particular North America and Europe). Are the present IPR working guidelines being overtaken by patenting agreements of Centers with partners? This should be addressed by the TAC panel.

- An economic appraisal of eventual transaction costs is required to forecast implications of changes in patenting policies; clarification is also needed for policy requirements in the CGIAR regarding the use of patents by Centers and the access of developing countries to patents.

- There is an urgent need to identify respective legal capacity that can assist the CGIAR-System and the Centers to facilitate appropriate patenting steps to ensure royalty free access for developing countries to technologies.

6 Access to Genetic Resources, Biodiversity and Biosafety

6.1 Access to genetic resources in the Center genebanks has to be ensured both for Centers themselves as well as for developing countries; extensive patenting of germplasm may create problems for Centers and the countries of origin to have access to germplasm from their own breeding programmes or genebanks (e.g. private sector initiative to patent a maize genepool):

- There is a need to clarify to which extent biotechnology cooperations are covered by the existing Material Transfer Agreements (MTAs cover only the material supplied).

- There is an urgent need to analyze the implications of private sector actions on international germplasm exchange (are the FAO agreements affected, and if so, how?)

- The Centers are encouraged to act as an adviser and advocate, and to alert developing countries to respective developments.

- Regarding biosafety, Centers should assist their host countries and countries in their mandate area to introduce functional biosafety regulatory frameworks as well as means to avoid potential risks. The exchange of genetically modified organisms (GMOs) with third parties should conditioned to the approval of the receiving country (prior informed consent).

6.2 Biodiversity Management in the CGIAR has to follow the principles and regulations agreed to and laid down in the legally binding Biodiversity Convention.

- Maintaining diversity and free access for developing countries has to remain the overriding principle of the CGIAR strategy.

- There is an urgent need to assess the effects of biotechnology on the future conservation and utilization of agrobiodiversity. This includes potential risks of biotechnology regarding genetic erosion, e.g. by the selective research on genotypes that are easy to transform or by a broad adoption of a single genotype (such as the “green revolution variety" IR8).

- Efforts should be supported to use the vast opportunities of the new techniques for a more reliable characterization of genetic diversity within cultivated crop species and their preservation in situ, ex situ or in vitro. Strategies to improve the competitive value of land races through biotechnology should be developed.

7 Concluding Remark

In summing up, biotechnology represents an important domain which provides new methodologies and opportunities for the Centers which should be integrated into the agenda of the CGIAR and the programmes of the individual Centers. As the CGIAR Chairman pointed out at the MTM in Cairo "biotechnology is a tool, to be used in conjunction with other tools, not as an end to itself". In that sense, we hope that the above reflections will provide a contribution to move the discussion forward leading to the necessary actions by the Consultative Group and the Centers.

SOK

JANUARY 1997

Global Concerns and Issues

in Biotechnology

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Introduction

Biotechnology consists of a gradient of technologies, ranging from the long-established and widely used techniques of traditional biotechnology through to the novel techniques of modern biotechnology which enable the genetic manipulation of living organisms, provide modern immunology with a basis for new diagnostics and vaccines, and allow new cell and tissue culture techniques for the production of biological products.

Biotechnology is not an industry in itself, but a set of enabling technologies, arising from modern biology, that are being applied to research and product development in several existing industries, notably in pharmaceuticals and agriculture, and in the conservation of the environment.

The impact of modern biotechnology is becoming increasingly evident, as the substantial investments over the past two decades in research and development in modern biotechnology are now resulting in a wide range of new products, processes and services, which contribute to improvements in human health, agricultural production and environmental conservation. This is evidenced by the fact that total sales of new biotechnology products in the USA alone in 1995 were approximately US$10 billion. These are estimated to grow at 12% annually over the next decade (Ernst and Young, 1996).

The **global concerns** which need to be addressed by the applications of modern biology are:

1. the need to substantially increase world food production;
2. the need to increase the incomes of the urban and rural poor;
3. the need to control infectious diseases in humans and animals, and
4. the need to conserve the environment

Modern biotechnology can contribute to the resolution of the global issues of hunger, poverty, disease and environmental degradation, but several key issues will affect its successful applications to these problems over the next decade. These key issues are:

1. **New technology development** to address specific problems
2. **Intellectual Property Management** to enable access to technology
3. **Regulatory procedures** to enable the safe use of biotechnology

Global Concerns

There are four key global concerns which need to be addressed by the applications of modern biotechnology.

1. **Food Production**. The World Food Summit in Rome in November 1996 highlighted the need for substantially increased food production, especially in developing countries. The Summit's Action Plan agreed the intention of the global community to halve the number of people who are undernourished over the next decade, from 800 million to 400 million. This will require a two-pronged approach based on both the need to continually increase food production just to keep pace with population growth, and the need to increase the incomes of the urban and rural poor so that they are able to purchase food and fuel for their families.

2. **Poverty Reduction**: A dynamic agricultural sector is the engine of growth for many countries. This is based on the sale of surplus food by farm families and by the sale of commodities for export. The increasing importance of high-value export commodities offers new opportunities for developing countries. For example, the expanding exports of high value horticultural crops, such as vegetables, fruits and flowers has significantly increased the incomes of many smallholder cooperatives in Kenya. Chile and Colombia have also benefited from similar high-value horticultural exports.

3. **Disease Control:** There is increasing global concern as to the need to control infectious diseases affecting both humans and animals. Some are long-standing but seemingly intractable problems, such as sleeping sickness, measles and malaria. Others, such as AIDS and Ebola virus, are newly discovered threats.

4. **Environmental Conservation:** There is global concern on the need for environmentally sustainable development. This is based on the concept that it should be possible to increase the standard of living of the world's population without unnecessarily depleting the world's finite natural resources and further degrading the environment. This requires increasing productivity from existing agricultural land, so as to avoid bringing more wilderness areas into farming. These areas are a rich source of biodiversity, and often only marginally suitable for agriculture. Yet pressure for new land for farming is a continuing threat to environmental conservation.

Issues in Biotechnology

Three issues will affect the successful applications of modern biotechnology to these global issues. These are firstly:

1. **New Technology Development:**

After several years of skepticism, modern biotechnology is starting to have significant economic impact on agricultural productivity through improved productivity, enhanced products and reduced input costs. There are at least 15 novel ag-biotech products on the market with initial sales of US$380 million in 1996 and an expected market growth of 20% annually over the next decade. The products are mainly genetically engineered crop varieties with novel traits, new diagnostics for plant and animal diseases, and several new biopesticides. Novel vaccines against major animal diseases, are in late stages of development (Ernst & Young, 1996).

In 1997, it is estimated that there will be approximately 1.5 million acres of transgenic crop varieties grown in the United States. These crops include maize, cotton and potatoes with insect resistance, soybeans with herbicide resistance, and tomatoes with extended shelf-life. Other novel products which are close to market are: canola able to produce lauric oils, which would make it a direct competitor with coconut and palm kernel oils; and several biopesticides able to attack fungal diseases and insect pests.

Most of these novel products in agriculture are coming from new biotechnology firms in the USA, and/or multinational seed and chemical companies. There has been significant consolidation in the ag-biotechnology business over the past few years, as many of the new biotechnology firms with commercially viable technologies have either merged, been acquired, or entered into strategic alliances with major firms, to enable the development and distribution of the new technologies. The products of the new technologies in agriculture will be distributed mainly through the seed of new crop varieties. Hence the alliances established between new biotechnology firms and seed companies, often with their own plant breeding programs, are starting to have commercial returns.

Thus modern biotechnology is well on the way to having a significant impact on agriculture, especially in North America, and increasingly in other OECD countries, especially the major agricultural exporting countries. The R&D programs of the past decade are showing that it is possible to develop new transgenic crop varieties with improved pest and disease resistance which require less pesticide use; fruits and vegetables with extended shelf life; and oil crops with specified oil content. Genetic mapping techniques are being used routinely in some cereal breeding programs to substantially reduce the time and cost of developing a new crop variety.

The emerging technologies which will become increasingly important are the greater use of genome mapping in plant and livestock breeding, especially to identify specific genes which convey desirable characteristics; improved transgenic plants with more specific promoters to enable improved control of genes inserted in target plants; the combination of biotechnology with information technology to develop decision support systems for farmers, applicable to practices such as integrated pest management; and novel vaccines against human and animal diseases.

In the pharmaceutical industry, progress has been even more rapid. There are 34 biotechnology therapeutics/vaccines approved by the Food and Drug Administration in the USA. Product sales in 1995 were valued at US$7 billion. There are also 284 potential new pharmaceuticals in clinical trials in the USA, 40% of which are for cancer treatments, and 10% for AIDS/HIV treatment. Biotechnology is now an integral part of new drug development, and it is estimated that 85% of all new pharmaceuticals will be produced using biotechnology by the year 2000 (Ernst and Young, 1996).

The size of the markets now being captured by biotechnology-based products reflects the substantial R&D investments, especially by the private sector. In 1995 the annual R&D expenditure in biotechnology in the USA alone was approximately US$10 billion, of which 80% was for human health care and 20% for agriculture. To give an indication of the scale of R&D investments, a new biotechnology firm such as Chiran invested US$166m on R&D in 1995, while a major pharmaceutical company such as Merck had an R&D budget of US$1.231 billion in 1995 (Ernst and Young, 1996).

The **global challenge** is that the early commercial applications of biotechnology are almost all emerging in North America, and there is relatively little R&D investment addressing the problems of food production, human and animal health, and environmental conservation throughout the developing world.

For example, at the meeting of the Consultative Group on International Agricultural Research (CGIAR) in Washington D.C. in October 1996, it was stated that the CGIAR centers presently invest approximately US$22 million annually in biotechnology. This includes about US$10 million invested by the International Livestock Research Institute (ILRI) in animal biotechnology, and approximately US$12 million spent over the several other international agricultural research centers dealing with biotechnology applications to the major tropical food crops (CGIAR, 1996).

There is significant under-investment by the international development community in the potential of agricultural biotechnology in developing countries. Indeed the CGIAR's total biotechnology investments are less than those of a small biotechnology firm in the USA. There is an urgent need for much more creative partnerships amongst national governments of all countries, the national and multinational private sector and the international development community, if the necessary level of investment is to be made in biotechnology to address the urgent needs of food production, human and animal health, and environmental conservation on a global scale.

2. Intellectual Property Management:

The significant investments in modern biotechnology by the private sector are being driven by the fact that many of the new products and processes are protectable by patents and other forms of intellectual property. Thus a company is able to capture many of the benefits of its investments in biotechnology, in contrast to previous public good research

in biology, from which an individual company could not benefit directly from the intellectual property involved. This means that the powerful new discoveries in modern biology and genetics are able to be developed into products for commercial purposes.

The second significant development is that in the negotiations of the Uruguay Round of the General Agreement of Tariffs and Trade (GATT), the signatories agreed to set minimum standards for trade-related intellectual property (TRIPs). Thus all nations who are signatories to the GATT agreement have agreed to instigate an internationally accepted form of intellectual property management over the next decade.

The third significant development is the fact that public sector R&D institutions, especially those in industrial countries are also addressing the requirement to best manage the intellectual property they develop. This reflects government policies to ensure that there is a return on investments of public funds in R&D, in that intellectual property generated from inventions can be used to negotiate access to other proprietary technologies, for continuing product development and availability to the community.

Much of the intellectual property, patents, and knowledge and investment in the effective use of agricultural biotechnology, at present lie with a small number of firms worldwide. Successful access to these core technologies by other parties in order to evaluate their applicability to orphan commodities and global concerns will require critical negotiations, and knowledge of the available resources, including genetic resources and intellectual property.

3. Regulatory Systems:

The third issue which will affect the successful application of biotechnology to address global concerns is the development of safe and effective regulatory systems to guide the applications of biotechnology.

In the pharmaceutical industry, the regulatory procedures for pharmaceuticals developed using recombinant DNA technology are essentially the same as those used for chemical drug development and conventional vaccines. These procedures, although often lengthy, and expensive, are based essentially on the product developed, and its behaviour in clinical trials, and not on the process by which it was developed. There are now several hundred novel products in clinical trials worldwide as potential treatments for various human health problems.

In agriculture, the development of acceptable regulatory arrangements has been more controversial, largely due to the perceived threats to the environment from genetically modified organisms. The approaches taken by various countries differ. For example, the USA, Australia and Japan have developed regulatory systems largely based on assessing the familiarity of the product and its characteristics, and using existing legislation to the greatest extent possible.

The regulatory systems developed within the European Union place more emphasis on the process by which the product was created, and are backed by legislation in individual countries, largely to address the concerns of the environmental community.

There has been a great deal of work done by many countries throughout Asia, Africa, Latin America and the Middle East in order to assess the regulatory approaches taken in the OECD countries, and to develop internationally acceptable regulatory systems suitable to the social and economic needs of particular countries. Various bilateral and international agencies, including ISNAR, OECD, the Rockefeller Foundation, the United Nations Agencies (FAO, UNEP and UNIDO) and the World Bank have been active in this field. Several developing countries now have in places or are developing regulatory systems suited to their needs and enabling them to address their problems in food production.

There has been a protracted international debate to develop an harmonized regulatory system for agricultural biotechnology. Some of these discussions are taking place under the auspices of the Convention on Biological Diversity. In view of the over-arching use of biotechnology, the Commission on Sustainable Development is also well placed to set the issue of safe use of biotechnology in the context of sustainable development in its widest sense.

The key points in the development of a regulatory system to enable the safe use of biotechnology are that it should be based on scientific principles; it should take account of community concerns as to the risks perceived in any new technologies; and it should be sufficiently flexible to adapt and learn from new knowledge as it accumulates.

Conclusion:

In summary, after a decade of discussing the **promise** of modern biotechnology, its effectiveness in delivering new pharmaceuticals to treat human and animal diseases, and new agricultural technologies to increase food production has been proven. Modern biotechnology will be the main source of new technologies for human health care and the improvement in food production, and the conservation of the environment over the next decade. However, the present applications in agriculture are mainly limited to the major temperate export commodities and the high-value horticultural crops. There is significant under-investment by developing countries and by the international development community in biotechnology. Indeed the CGIAR's total biotechnology investments of US$22 million per year are less than those of a small biotechnology company in the USA. There is an urgent need that national governments, development agencies and the private sector invest in the development and applications of modern biotechnology to meet the global concerns of hunger, disease, poverty and environmental degradation. This will require many more creative partnerships and a greater sharing of knowledge and concerns amongst public R&D agencies, national and multinational companies, and the

international development community, if the necessary levels of scientific and financial investment are to be made to address the urgent needs of food production, human and animal health and environmental conservation on a global scale.

These new partnerships in biotechnology will require:

1. Clear identification of problems which could be addressed by the application of modern biotechnology,
2. Scientific capability,
3. National and international financial resources,
4. Management of intellectual property, and
5. Internationally acceptable regulatory systems which are suitable to the social and economic needs of particular countries.

It is instructive to recall that there has been little public outcry in industrial countries when new biotechnology-based treatments for cancer or AIDS are evaluated through clinical trials, given that the patients consider that the prospect of a possible successful cure outweighs any perceived risk inherent in a new technology. One might imagine that there are also people living in other countries in hunger, sickness and poverty, who, if given the option, may similarly weigh the benefits and risks associated with new biotechnologies, if it offered them the glimpse of a better life, free of hunger, disease and poverty. This is the challenge of modern biotechnology.

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GJP/JJD/PG 17 January 1997

SoK
5/22/97

The Role of Biotechnology in the CGIAR: Points to Consider from USAID's Office of Agriculture and Food Security

DISUCSSION PAPER - DRAFT

I. INTRODUCTION

The following comments are offered by a team of technical specialists located within USAID's Office of Agriculture and Food Security in response to document MTM/97/17 prepared by the CGIAR Secretariat for the Mid-Term Meeting 1997. The document in question is titled *The Role of Biotechnology in the CGIAR: A Report on the Highlights of the Stakeholders Consultation.* Specialists providing input include those with expertise in biotechnology, germplasm and natural resource conservation and the International Agricultural Research system. The comments are intended to provide a platform for provocative discussion and do not necessarily represent the specific policy of the U.S. Agency for International Development. The team welcomes critical commentary on the points provided herein and hopes that others will share their views.

II. HISTORICAL PERSPECTIVE

The U.S. Agency for International Development (USAID) has a long history of engagement in the Consultative Group on International Agricultural Research (CGIAR or "Centers") and the IARCs have been viewed as major players in advancing our agricultural development goals. USAID recognizes, in particular, the critical role that the Center's have played in the international agricultural research community and the specific contribution of this technology-intensive system to the Green Revolution. Research efforts on crop and livestock breeding, agricultural systems, germplasm preservation and agricultural policy have been at the foundation of the Center's activities and remain a cornerstone to achieve global food security. However, recent achievements spawned by the "biotechnology" revolution in agriculture, and the changing institutional paradigms accompanying this revolution mandate a critical review of the Center's comparative advantages in this area. While the debate regarding the Center's role with respect to biotechnology has been ongoing, recent progress in agricultural biotechnology within the last year, as evidenced by the appearance of several bio-engineered agricultural products in the international marketplace, has revitalized the discussion.

The Agency recognizes the importance of biotechnology as a powerful tool to address issues related to food security, market advantage and natural resource conservation. USAID has been supporting a number of bilateral initiatives in agricultural biotechnology (crop and livestock) since the mid-1980's. As a result, USAID has direct experience with the technical and policy issues surrounding deployment of this technology in a development context. Agency programs have attempted to draw on a range of institutional expertise, linking developing country, academic and industry partners. While USAID has found a variety of innovative relationships to be helpful, the Agency has also found that the technical and policy issues surrounding these efforts require substantial attention. USAID believes that it would be useful to share some of our experiences and conclusions, in the hope that these could help further the CGIAR's

exploration of the opportunities and challenges that lie in this important area.

The Agency remains willing to provide technical assistance, as needed. USAID recognizes that the current budgetary allocation for biotechnology-related research activities within the CGIAR centers is probably not adequate to address the multitude of agricultural needs and opportunities in developing countries. USAID also appreciates the broader concern that the Centers remain technologically relevant. However, the Agency believes that additional expenditures of the magnitude being considered should be approached with caution in light of the complex political, institutional and legal issues surrounding this technology. The following comments and observations might usefully be considered as the system explores further the role of biotechnology in its programs and in achieving its objectives.

III. KEY CHALLENGES

A. Financial Resources

USAID believes that it may not be prudent to focus already strained financial resources to increase in-house capacity, at large, given that key ares of comparative advantage to conduct this type of research have not yet been clearly identified. This must be done in the context of an increasingly globalized research system that includes many research institutions with a much larger capacity for employing biotechnology and where major investments are continuing. Nor is it a question solely of funding availability as many such institutions benefit from stronger positions with respect to proprietary protection giving them a competitive edge. Even if additional resources representing some multiple of the current level are provided to augment in-house capacity, these may not be adequate when divided among the number of competing interests, crops and constraints and the number of centers.

Once a general sense of the Center's objectives and potential comparative advantages have been achieved, a rigorous priority setting exercise will need to accompany additional resources. Even if a multiple of the current level of funding were obtained, it would still need to be highly focussed to be effective; this would likely mean that investments in some centers might be much larger than investment in others. Priorities should capitalize on the Center's strengths and avoid duplication of effort with advanced laboratories outside the system. To this end, USAID concurs with the observation noted in the "stakeholders consultation" that additional capacity should not be established at the expense of those research activities which are the core strengths of the CGIAR system.

B. Human and Institutional Resource Capacity (Centers and NARS)

Given the current disparity in funding between the CGIAR centers and advanced institutions (public and private) in the developed world, an expanded capacity to conduct in-house research will require substantial increases in the human resource capacity of the Centers at a time when private industry represents a highly competitive "draw" for such expertise. This is particularly true for the area of genomics and accompanying expertise in bioinformatics. This situation may also be encountered by NARs seeking to upgrade their research ability in a highly competitive marketplace for research talent.

USAID is generally supportive of the need to focus the valuable advancements of biotechnology on developing country agriculture and the CGIAR system, by virtue of its development mandate and its extensive research network, represents an obvious institutional point for intervention. However, USAID believes that the development of sustainable national programs with in-house capacity should also be an equally important goal as the technology can address a multitude of agricultural problems and opportunities which may be external to the direct mandates of the CGIAR system. USAID would support a CGIAR-led initiative that includes substantial human and institutional capacity building within the NARs and local private sector.

C. Rapid Change and the Ability to Respond

The field of biotechnology is extremely dynamic, with new technical developments occurring on an almost daily basis. Recently developed techniques and approaches may quickly become passe' and inefficient in the face of better technology. This dynamism is, in part, driven by the aggressive R&D investments of the private sector and by a volatile patent situation which may be stimulating innovation around existing technologies. To be truly competitive, the Centers will need flexibility to gain access to state-of-the-art techniques or expertise and a sustainable source of funding which will allow for rapid changes in approach or requirements.

D. Intellectual Property Rights and Biosafety

Issues surrounding ancillary policy areas, such as biosafety and IPR, can become a serious draw on resources. These issues have been a driving force in biotechnology, as compared to more traditional approaches, since the costs of this research are high and the likelihood for success has been marginal, at least in the early stages of the technology's development. This is particularly true for agricultural biotechnology endeavors, which operate on tight profit margins. As a result, many small entrepreneurial companies in the U.S. (most of which have been targeting substantially more resources for biotechnology R&D than what is likely to be proposed for the Centers) have been effectively "bankrupted" as a result of hostile regulatory climates or protracted litigation related to IPR claims. Dealing with these issues is complex enough when the focus is national or when limited "partners" are involved. However, in the case of the Centers, stakeholders, donors and collaborators are numerous. IPR and biosafety issues become increasingly more complex at the multinational level, given that donors do not currently have agreement on many controversial points related to these two areas (i.e. patenting of life, release of Genetically Modified Organisms [GMOs], labelling).

Biosafety: While the Center's have multiple clients and beneficiaries, the biosafety debate is likely to be affected by the policy of the local governments where IARC institutions are located. Some Center's may be readily able to field test GMO's while others may be severely restricted by local requirements. Centers may also be restricted by a lack of national guidelines, in which case they have opted to completely refrain from the use of recombinant DNA technologies. This regulatory environment will vary from Center to Center thereby affecting the impact and ultimate adoption of technologies developed. The concerns regarding biosafety may be further complicated by dialogue on liability which is likely to be discussed in the context of the proposed Biosafety Protocol under the Convention on Biodiversity. Will the Centers, by virtue of an expanded and more visible role in the biotechnology debate, be prepared to deal with scenarios

where a discussion of liability may become part of the dialogue? And, from a governance standpoint, what kinds of new legal and policy challenges would liability concerns present to the Trustees of the Centers?

IPR: Since private sector and, increasingly, public sector technologies in the industrialized countries are likely to be proprietary in nature, the CGIAR system needs to re-examine its patent policy to insure that the policy will not continue to serve as a disincentive to private sector involvement. There is a misconception that IPR equates to "lack of access" and high prices. In fact, a rationalized system of IPR sets the parameters for access and the latitude under such systems can be expansive. Similarly, maintenance of a strident "free release" policy, while advantageous from a number of political perspectives, may actually be counterproductive if it does not enable the Centers to access the best technology to meet its research mandate. The Center's beneficiaries.... resource poor farmers....may ultimately be better served via enhanced access to proprietary technologies which are accessed by the CGIAR system. Latitude provided by any number of licensing options should enable the Center's to obtain these technologies and products in a cost effective and equitable manner but one which maintains private sector interest in the Center's as a possible partner. A very thoughtful analysis of the scientific and policy trade-offs will ultimately be needed. To the extent that it is feasible, the system may wish to allow for case by case judgements within the context of a growing body of experience.

It may be very difficult for the CGIAR to steer a course that pleases all stakeholders. Ultimately, some choices will have to be made by the system, while other choices will occur at the Center level. This approach would continue what has basically become established CGIAR practice, but in the context of a much larger system-wide initiative, the juxtaposition of system and center-level decisions may take on greater visibility.

As if the challenges alone were not complex enough, a great deal of incomplete and misinformation clouds what is already a complex set of legal, ethical and political issues. In this respect, USAID concurs with the Stakeholder's Consultation that effective information and public awareness activities will be important requirements of any CGIAR effort to expand the contributions of biotechnological approaches in its programs.

Currently, the Centers do not have the legal and regulatory expertise to address these policy areas and that additional human and financial capital will be required to effectively deal with these sometimes contentious areas. The amount of resources required to effectively deal with these issues, at least in the short term, while the various debates are "raging", may quickly approach the increase proposed to augment R&D capacity. The U.S., as a result of the 1986 Federal Technology Transfer Act, has developed a strong tradition of technology transfer between the public and private sectors and could provide its legacy of experience to the CGIAR system in this area, as desired.

E. Issues of Germplasm Access/Ownership

The CGIAR occupies a pivotal, but sometimes uncomfortable, position, having a technology generation mandate side by side with a trusteeship role for genetic resources. In the system's earlier days, activities within these mandate areas went together, with the second arising, in

many ways, from the first. The advent of biotechnology and associated IPR mechanisms has appeared to introduce a sometimes discordant note between these two fundamental objectives. There is a real irony in this sometimes tense relationship, since biotechnology is rapidly increasing the relevance and utility of the international crop genetic resource collections. Substantial gains are being made in understanding the degree of diversity in the collections; at the same time, breeding programs are able to employ genetic resources more effectively using biotechnological tools. However, as technologies advance and associated IPR mechanisms multiply, the equilibrium between furthering technology generation goals and discharging germplasm trusteeship responsibilities will likely remain fluid, requiring close attention and a flexible response.

Fortunately, the CGIAR is not alone in grappling with germplasm access and ownership issues. International bodies, such as the FAO Commission on Plant Genetic Resources for Food and Agriculture, are moving forward, albeit slowly, to seek an international consensus on germplasm access and utilization in a post - CBD environment. In a positive sense, these negotiations are done in a setting emphasizing food security and environmental sustainability; economic growth considerations receive less notice. On the other hand, the pace of the negotiations are slow and there are extremely diverse views among the participants, as a natural tension exists between those who wish to defend sovereign rights for national and intellectual resources and those in the research communities and the resource poor farmers who have enjoyed the benefits of a free exchange of genetic materials.

Many CGIAR member countries are facing similar challenges in responding to an increasingly blurry division between public and private domains. And while the CGIAR has a clear mandate with respect to hunger, the environment and poverty, how it can most effectively address those goals will likely remain the subject of a continuing and fruitful debate. Future deliberations on the Center's priorities and strategies will increasingly need to take into account biotechnology, germplasm and ownership issues.

The fact that the issues, and sometimes the CGIAR's own position, are being dealt with in other fora does not lessen the CGIAR's own responsibility. The CGIAR has adopted a prudent strategy of wide consultation, combined with flexibility and a gradual, needs-based approach. Rather than seek a comprehensive policy dealing with all potential questions, Centers have sought advice and made decisions in the context of a set of overall principles. For example, given that most accessions in the Center's collections pre-date the CBD, the Center's free release policy for native materials in the collections represents a rational approach to the debate given the difficulty in assigning sovereign ownership. However, Centers have exhibited flexibility and have made important distinctions between native materials in the collections and those which have been improved through human intervention, particularly when improvements are proprietary in nature. The latter may be protected by some form of IPR. IRRI's Policy on Intellectual Property Rights is based a recognition of the distinction between property rights and patent or intellectual property rights and makes allowances for both within the context of a free release policy. In point of fact, policies akin to that articulated by IRRI, which represent a compromise to the CGIAR "free release" policy may be feasible for recent or future acquisitions, and may be highly desirable for essentially derived germplasm with proprietary modifications. It is likely, that in some cases, a flexible policy approach will insure continued

dialogue with the private sector research community and could potentially enhance the overall quality of the Center's germplasm collections. Farmers will ultimately benefit from the availability of an expanded pipeline of new varieties which are better yielding, disease resistant or have enhanced quality traits. In addition, a strengthening of the CGIAR - private sector collaboration may actually reduce the development costs of proprietary products (given the contribution of public funding) and expand farmer access to proprietary materials which might otherwise be prohibitively expensive.

Continued flexibility insures that changes in policy can evolve as new opportunities open up and new consensus is reached, with perhaps unanticipated benefits accruing. Ultimately, an environment which favors the maintenance of strong connections between conservation and utilization on the one hand, and between research and innovation and service objectives on the other, is what will be needed.

IV. NEXT STEPS/RECOMMENDATIONS

USAID is considering the establishment of a "blue ribbon panel" under the direction of its Board for International Food and Agricultural Development (BIFAD) to provide advice on changing institutional dynamics, particularly in relation to biotechnology and intellectual property rights. The Agency envisions that the panel will focus appropriate interest on the CGIAR system in this analysis, given the importance of the system in the global food security agenda.

Similarly, USAID strongly supports an extensive analysis of these issues under the auspices of the system-wide review which is currently being conducted by the CGIAR system.

USAID could support the establishment of a granting mechanism which could effectively engage advanced laboratories (especially those in the private sector) with the CGIAR system and national program research institutions. The proposed additional funding could be used as "seed" financing to establish competitively awarded, collaborative research ventures, for example, between biotechnology companies and the IARCs.

USAID could also support a system where funding is used to support sabbaticals for CGIAR and national program scientists (the latter perhaps under the direct tutelage of the Center's, where necessary) at advanced laboratories conducting research of interest. Actual variety development could be done at these laboratories by CGIAR scientists, thereby avoiding a duplication of equipment and capital which may not be sustainable if donor interest declines. Sabbaticals could be arranged with the public and private sectors.

Additional funding could also be used to expand the training capacity of the Center's for the benefit of scientists in the NARs, provided that appropriate resources are in place to maintain these linkages and the continuity of research upon completion of training.

V. CONCLUSION

Clearly, the CGIAR's re-examination of biotechnology as part of its entire program seems very appropriate from many points of view. It represents an area of vested interest for members,

Centers and the TAC and should be weighed against long-term goals and short-term operational requirements in the context of an increasingly more complex and innovative international agricultural environment. USAID applauds the efforts undertaken to date and remains willing to assist the debate, as appropriate.

SDC

Consultative Group on International Agricultural Research (CGIAR)

TECHNICAL ADVISORY COMMITTEE (TAC)
Donald Winkelmann, Chairman

Added Information on Expenditures in Biotechnology in 1997

Prepared by the TAC Chairman for discussions on Biotechnology at ICW97, 28 October

Update on 1997 Expenditures in Biotechnology

The following tables report on the amounts being spent by centers in 1997 on various classes of biotechnology. In May 1997, centers engaged in such work were asked by TAC to report estimated expenditures, exclusive of center overheads. In September 1997, the centers were asked to review their earlier estimates and report any changes. The September estimates are the basis for the tables.

Table 1 contains the amounts reported to TAC. In Table 2, the dollar amounts have been converted to percentages.

- Category 8b, Other, contains several different activities. Some of the responses labeled "Other" by centers, e.g., $500t in equipment and infrastructure by IRRI, were distributed across Activities 1-8a.
- While most centers do some amount of training in conjunction with their work, only three centers (CIAT, CIMMYT, and IRRI) explicitly reported training and networks; therefore, category 8a includes only those three.
- Finally, it appears that little of the activity included in "Other" deals directly with genetic transformations.

General conclusions:

- Exclusive of center overhead charges, the centers are spending about $24m on biotechnology. Of that amount, about 27% is related directly to livestock (most of it on animal health).
- Roughly 15% of the total expenditure goes to genetic transformations, with nine centers participating--and some 60% of the total in the three centers with the largest commitments.
- Said another way, about 85% of the expenditures are in small scale biotechnology, where gene mapping is the largest single activity.
- Some 27% of the total is in "Other," with ILRI making up two-thirds of that (via genotyping $1.0m, production of biologicals $1.0m, and pre-biotechnology and testing/delivery $2.1m). Without ILRI, the remaining amounts in "Other" are about 10% of the remaining total.

Table 1: Estimated 1997 Expenditures by Centers in various Biotechnology Activities ($000s)

Centers/ Activities	CIAT	CIMMYT (a)	CIP (b)	ICARDA (c)	ICLARM	ICRAF	ICRISAT	IITA	ILRI	IPGRI	IRRI (d)	WARDA	Total*
1. Tissue Culture	200		400	60		10	300	195	250	920	170	110	2,615
2.Embryo Rescue	50	440		25			130	100	100	110	350	30	1,335
3. ELISA	80	40	500	30			65	25	250	630	100		1,720
4.Marker-Assisted Selection	300	420	275	40			130	40	30		340	210	1,785
5. Gene Mapping	350	990	275	320			220	550	1,000		630		4,335
6. Gene Sequenc-ing	250	200	345	120		20	130	20	200		270		1,555
7.Genetic Transfor-mation	300	935	345	90			260	265	500	260	640		3,595
8a. Networks/ Training	300	100									410		810
8b. Other	100	145		160	310	180	65	580	4,330	230	375		6,475
Total*	1,930	3,270	2,140	850	310	210	1,300	1,780	6,660	2,150	3,285	350	$24,200

(a) CIMMYT reported economics and capital ($175t) under Other; the amount was allocated across Activities 1-8a.

(b) CIP reported Activities 4 and 5 together; half of the total was assigned to each. Activities 6 and 7 were similarly reported and handled.

(c) Reported by ICARDA inclusive of center overheads and adjusted to exclude overheads.

(d) IRRI reported expenditures on construction and equipment, and for management ($525t) under Other; the amount was distributed proportionately across Activities 1-8a.

*Totals may not exactly equal sums, as many numbers have been rounded.

Table 2: Estimated[a] 1997 percentages[b] expended per center and in total on various Biotechnology Activities

Centers/ Activities	CIAT	CIMMYT	CIP	ICARDA	ICLARM	ICRAF	ICRISAT	IITA	ILRI	IPGRI	IRRI	WARDA	**Total[c]**
1. Tissue Culture	10		19	7		5	23	11	4	43	5	31	11
2.Embryo Rescue	3	14		3			10	6	2	5	11	9	6
3. ELISA	4	1	23	4			5	1	4	29	3		7
4.Marker-Assisted Selection	16	13	13	5			10	2			10	60	7
5. Gene Mapping	18	30	13	38			17	31	15		19		18
6. Gene Sequenc-ing	13	6	16	14		10	10	1	3		8		6
7.Genetic Transfor-mation	16	29	16	11			20	15	7	12	20		15
8a. Networks/ Training	16	3									13		3
8b. Other	5	4		19	100	86	5	33	65	11	11		27

[a] See notes for Table 1.

[b] Columns sum to 100%, except for rounding errors.

[c] Represents percentage of grand total for all centers.

MINUTES OF THE MEETING ON

BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS

HELD ON TUESDAY 7 JULY 1997 IN AG MEETING ROOM

Participants:

M. Zehni, Director, AGPD
J. Esquinas-Alcazar, CGRFA, AGPS
G. Moore, Legal Counsel, LEGD
L. Bombin, LEGA
N. Scialabba, SDRN
V. Timon, SDRR
S. Keya, Chief, SDRC (TAC Secretariat)
A. Kassam, SRDC
J. Groenewold, SDRC (rapporteur)

Purpose of the meeting:

The meeting was called by Dr. Zehni to bring together some people in FAO actively involved on matters regarding biotechnology and intellectual property rights (IPR) and to brief thereby the TAC Secretariat on the capacities and documents available in-house.

Itself, TAC Secretariat was asked at the recent Mid Term Meeting of the CGIAR at Cairo in May 1997 to be instrumental for the work of two specialist panels to be formed within the CGIAR, which will review biotechnology issues, and deal comprehensively with intellectual property rights issues, respectively.

This request stems from the rapidly changing framework of biotechnology research and application. For instance, in the US the sector is burgeoning with an approximate yearly budget of 5 billion dollars, while in the EU it is somehow trapped by concerns of politicians, scientists, and consumers as well. The promising research tool biotechnology includes controversial issues regarding ethics, equity, biosafety, and proprietary science and technology. On these issues the System urgently seeks expert advice and will start the discussion at the forthcoming Centres Week in October 1997. Actually the CGIAR is spending about 25 million dollars on biotechnology and the path into the future will be laid down by the two expert panels. TAC Secretariat has particular interest in this meeting in the actual phase of forming the panels and of gathering information.

FAO's involvement in biotechnology and IPR:

The former AGR division published in the early 1990s documents on policy issues and the state of the art of biotechnology in developing countries. Dr. Zehni delivered two issues of these reports during the meeting to inform TAC Secretariat and to provide background material on FAO positions for the expert panels.

On the other side, already in 1983 FAO created the **Commission on Plant Genetic Resources**. The commission was FAO's spearhead to be actively involved in the development of international framework for the conservation, sustainable use and access to plant genetic resources. FAO adopted both the **International Undertaking on Plant Genetic Resources** (1989) as well as the **Convention on Biological Diversity** (1992).

The commission dealt since inception extensively with issues regarding biotechnology and IPR. One of the first tasks in the early 1990s of this commission was to analyze the ethical issues of biotechnology to prepare a **Code of Conduct** on biotechnology "as it affect conservation and use of plant genetic resources".

One of the first inputs for the code of conduct was the survey (more than 400 questionnaires) of international experts in plant genetics. Four are the main areas which were distinguished in the replies: i) ethical issues (biological safety); ii) intellectual property rights; iii) the substitution of traditional crops; iv) appropriate technologies for developing countries. The code of conduct (still in draft form) is prepared to enhance the positive impacts of biotechnology while buffering the negative impacts.

A further document released by the commission in 1994 is the **International Code of Conduct for Plant Germplasm Collecting and Transfer**. This aims at promoting the rational collection and sustainable use of genetic resources, to prevent genetic erosion, and to protecting the interests of both donors and collectors of germplasm.

The issue IPR was analyzed in-depth recently by the commission. A report "**Sovereign and property rights over plant genetic resources**" prepared by Mr. C. Correa, University of Buenos Aires is providing a theoretical and academic background to economic, technical and legal issues to the revision of the above mentioned International Undertaking on Plant Genetic Resources. This paper analyzes also the international developments regarding IPR and the differing legal trends followed by countries to cover with patent rights, or breeder's rights, or a combination of the two intellectual property of differing nature. Important conventions to be named are the **TRIPs** (Trade-related aspects of intellectual property rights) adopted as a component of the Final Agreement of the Uruguay Round (GATT), and the **UPOV** (International Union for the Protection of New Varieties of Plants) based within WIPO.

The *ex situ* germplasm collections of the CGIAR have been placed under the auspices of FAO. The CG centres hold the collections as "trustees" for the benefit of the international community, and hence do not own it like other assets and, furthermore, does not imply transfer of legal ownership rights or sovereignty. The prevailing CG policy on IPR quoted from the paper of Mr. Correa mentioned above is recommending that patents should never be sought by the Centres for "naturally occurring genes".

Received documents:

Correa, Carlos (1994) *Sovereign and property rights over plant genetic resources*. Background study No.2, November 1994 for the CPGR (Commission on Plant Genetic Resources).

Esquinas Alcazar, J., and Marina Zanchi (1991) *Survey identifies biotechnology issues.* In: Ceres, 127, January-February 1991.

FAO (1994) *International Code of Conduct for Plant Germplasm Collecting and Transfer*

FAO/AGR (1993) *Biotechnology in agriculture, forestry and fisheries*

FAO/AGR (1995) *Agricultural biotechnology in the developing world*

FAO/CPGR (1989) *Implications of new biotechnologies for the international Undertaking*

FAO/CPGR (1991) *Biotechnology and plant genetic resources and Elements of a Code of Conduct for biotechnology*

FAO/CPGR (1993) *Towards an International Code of Conduct for plant biotechnology as it affects the conservation and utilization of plant genetic resources*

FAO/CPGR (1995) *Recent international developments of relevance to the draft Code of Conduct for plant biotechnology*

FAO/PPAB (1997) *Trade related Aspects of Intellectual Property Rights.* PPAB 97/2 Item 2

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH
TECHNICAL ADVISORY COMMITTEE
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BY COURIER DHL

PR 3/11.1 Biotech (GBI) 17 October 1997

Dear Dr. Arnold,

On behalf of the Chair of the Technical Advisory Committee (TAC), I hereby confirm your appointment as Secretary of the Expert Panel which will examine General Issues in Biotechnology. This appointment will span the period from now until MTM'98 (i.e. late May 1998).

I would like to refer you to the E-mail of 4 September 1997 from the TAC Chair, wherein the scope of the task and terms of reference for the assignment of the Panel Members are made explicit (Annex I). For ease of reference, I am also attaching the general terms of reference for 'Taking Biotechnology Forward in the CGIAR', as well as the specific terms of reference for the Expert Panel on General Issues in Biotechnology (Annex II).

You will note that much of the work will be done via e-mail and correspondence. It is anticipated that, among other things, you will monitor, synthesize, collate, and distribute the information so generated, and will meet with the Panel, and/or its Chair from time to time. Other meetings with TAC and CGIAR Members are tentatively specified below:

(i)	1997	-	Meeting of the Expert Panel prior to ICW'97 (October 1997);
(ii)	1998	-	Meeting of the Expert Panel prior to late May;
(iii)			Any other meeting engagement as may be specified and negotiated with the TAC Chair.

Dr. Michael H. Arnold
"Hamlec"
4, Shelford Road
Whittlesford
Cambridge CB2 4PG
United Kingdom

Information copies (without encl.):

- *Prof. Richard B. Flavell, Panel Chair*
- *Dr. Donald L. Winkelmann, TAC Chair*
- *Mr. A. Von der Osten, Executive Sec., CGIAR Secretariat*

As you are aware, the Expert Panel for the General Issues in Biotechnology will consist of about eleven persons. Each Panel member will participate solely in a personal capacity. The administrative and logistical aspects will be managed by the TAC Secretariat. You will keep track of the time involved and direct expenses incurred.

For ease of reference, please find herewith the list of Panel Members with their contact address and profiles (Annex III).

A number of background documents have already been sent to the Panel Members by the CGIAR and TAC Secretariats (Annex IV). Other documents will be sent to them as and when the need arises, usually at your request.

For your participation in the work of this Panel you will receive an honorarium at US$ 300 per day. Payment will be made upon completion of your assignment and receipt of a statement from you giving details of the number of working days spent on the task and any other authorised expenses you may have incurred. Please note that any travel inside or outside your home base in connection with the Study would need to be authorised in advance. When travelling for the purpose of the Study you will also receive non-accountable per diem (NAE) of US$ 250 per day to cover expenses, as well as business class air tickets when travelling by air.

I attach herewith a note on Administration/Financial Matters Related to TAC Missions for your information (Annex V). I am also enclosing a Designation of Beneficiary Form which should be completed and returned to us at your earliest convenience.

We look forward to working with you.

With kind regards.

Yours sincerely,

Shellemiah O. Keya
Executive Secretary

Enclosures:

Annex I - E-mail from TAC Chair of 4 September 1997
Annex II - Taking Biotechnology Forward in the CGIAR and Terms of Reference of the Panel on General Issues in Biotechnology
Annex III - List of Panel Members, contact addresses, and profiles
Annex IV - List of Documents (enclosed with this letter)
Annex V - Administrative/Financial Matters Related to TAC Missions

Garrioch, Jane (SDRC)

From: Garrioch, Jane (SDRC)
To: Blalock, June; Crespi, Stephen; de Miranda Santos, Marcio; Dryden, Sam; Flavell, Richard; Goodman, Robert; Hansen, Michael; Horsch, Robert; Le Baunec, Bernard; Montecinos, Camila; Padmanaban, G.; Quail, Peter; Roberts, Timothy; Salazar-Fallas, Silvia; Schell, Jozef; Seitzer, Josef-Franz; Toenniessen, Gary; Uchimiya, Hirofumi; Wright, Brian; Zhang, Qifa
Cc: Serageldin, Ismail; von der Osten, Alexander; 'Riley, Sir Ralph'; tacwink; Keya, Shellemiah (SDRC); Gryseels, Guido (SDRC); Kassam, Amir (SDRC)
Subject: Message from Donald Winkelmann
Date: 4 September 1997 10:01AM

From earlier exchanges you will know that the CGIAR is aware that it must make serious choices about the role of biotechnology in the work of its centers and is seeking counsel as it weighs the surrounding issues. You have generously agreed to support this effort and the panel to which you have been appointed is indicated in the lists hereunder. As well, what follows expands a bit on the terms of reference for the panels, contains some administrative detail, and provides information on panel members and addresses.

A copy of the initial terms of reference is being sent to you along with a late August letter that amplifies the terms, provides a general timetable (note that it envisions two reports, not one as in the initial terms of reference), and makes some observations about the process. As background, it is affirmed that the CGIAR engages in research and related activities. Its goals are centered on poor people and feature the alleviation of poverty and protection of natural resources for sustainable food security, largely, but not exclusively, through improved technologies which increase productivity while conserving biodiversity, land, and water.

Reaffirming some of the points made in earlier correspondence, the CGIAR wants a strategy and a policy framework to guide its centers in managing biotechnology. Thus, the panels will want to identify issues that should be of concern as a strategy and policy framework are developed. The Group is looking for policy options, is aware that those will be shaped by science, law, and economics as well as by beliefs and perceptions, and wants a sense of the implications of different options along with counsel on those most consistent with its goals.

How all of that is achieved is left to the panels. The Group expects two reports from each panel, the first emphasizing the identification of issues that should be treated and a process for doing so (due in early October) and the second emphasizing analysis and counsel pertaining to the issues (due in mid-April 1998). As the late August note says, it seems likely that a combination of meetings and electronic exchange will emerge as the modus operandi for interaction. (Indeed it seems likely that many of you, busy as you are, are counting on an electronic format.)

Consultation with CG members and centers is perceived as an integral part of the effort. As well, it is hoped that the panels will take into account work going on elsewhere, especially that of the CGIAR's Genetic Resources Policy Committee which is now preparing a report focused on ethical issues as they relate to proprietary science. Finally, panels will want to be familiar with the evolution of the CGIAR's view on intellectual property as expressed in "Intellectual Property Rights and Access to Genetic Resources in the CGIAR" by Hawtin and Reeves (June 1997).

The panels will operate under the auspices of TAC's Sub-Committee on Reviews, chaird by Sir Ralph Riley. TAC will provide logistical support and support persons to aid each panel, e.g., with note taking and report writing. As well, TAC will cover costs associated with participation in the panels along with a daily honorarium of $300 and, while on travel status, a non-accountable expense allowance of $250 per day. In due course, the TAC Secretariat will provide information pertinent to administrative issues.

Membership of each panel is in the list that follows. A brief biographical sketch, fax and e-mail numbers of each member are contained in a note that will reach you within the next few days.

PANEL ON GENERAL BIOTECHNOLOGY SCIENCE

Dryden, Sam
Flavell, Richard
Goodman, Robert
Hansen, Michael
Padmanaban, Govindarajan
Quail, Peter
Schell, Jozef

Seitzer, Josef-Franz
Toenniessen, Gary
Uchimiya, Hirofumi
Zhang, Qifa

PANEL ON PROPRIETARY SCIENCE

Blalock, June
Crespi, Stephen
Dryden, Sam
Horsch, Robert
Le Baunec, Bernard
de Mirando Santos, Marcio
Montecinos, Camila
Roberts, Timothy
Salazar-Fallas, Silvia
Toenniessen, Gary
Wright, Brian

On behalf of TAC and the CGIAR I want to thank you for your willingness to help us in this critically important endeavor. All of us wish you well in your efforts.

Sincerely yours,

Donald L. Winkelmann
TAC Chair

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cc: Ismail Serageldin
Sir Ralph Riley
Alexander von der Osten
TAC Secretariat