SCIENCE COUNCIL

CGIAR

Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers

Review Panel: Brian Johnson (Chair)
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MAY 2007

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH

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Correct citation: CGIAR Science Council (2007) Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers. Rome, Italy: Science Council Secretariat.

THIS DOCUMENT CONTAINS:

- Science Council Commentary

- Transmittal letter and Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers

Science Council Commentary
on the Report on Biosafety Policies and Practices

April 2006

The report

1. The Panel Chair, Dr Brian Johnson, and the Scientific Secretary, Dr Gabrielle Persley, presented the Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices (SDR/SC:IAR/04/01). Comments were received from members and observers in plenary. A Science Council Working Group was later convened under the chairmanship of Dr Mike Gale to discuss the report with the Panel Chair and secretary and to review the recommendations.

2. The Panel's report was based on an analysis of a questionnaire and review of case studies on living modified organisms (LMOs) provided by the Centers. The report found that all centers had in place (or were actively putting in place) effective biosafety policies for their LMO research in their host countries. While the policies focused on LMO research, The Panel pointed out that, in general, only after product development was there any consideration of the regulatory issues needed for release of product in partner countries. The report and the recommendations therefore focused on strengthening the development of the Centers' biosafety policies, adding ethical policies where appropriate, and developing a corporate regulatory research capacity through an inter-Center network approach.

3. The Panel's report noted that more could be done to capture the scientific information relevant to risk assessment (RA) and, in particular, the RA dossiers that would be needed to meet regulatory requirements for the eventual deployment of LMOs. It was suggested that consideration be given to undertaking more biosafety research at the CGIAR Centers. The existence of codes of practice would give confidence to civil and political society. Moreover, Center biosafety codes should be developed with reference to appropriate national legislation.

4. The 12 recommendations contained in the report are:

Recommendation 1: Enhance CGIAR Center Biosafety Policies
Recommendation 2: Enhance Capacity Building in National Biosafety Policies and Practices
Recommendation 3: Strengthen Center Capacity in Biosafety Practice and Research through Pro-active Approaches to Biosafety
Recommendation 4: Develop an Integrated Approach to the Practice of Biosafety in the Centers
Recommendation 5: Establish a CGIAR System Biosafety Network
Recommendation 6: Increase Biosafety-related research by the Centers
Recommendation 7: Publish and Communicate Results of Biosafety Research
Recommendation 8: Prepare for Forestry and Fisheries Biosafety Issues
Recommendation 9: Undertake more Risk/benefit Analysis
Recommendation 10: Develop Plans for Preparing Risk Assessment Dossiers for Product Approval
Recommendation 11: Better Address Bioethical Issues

Recommendation 12: Initiate a CGIAR Systemwide Biosafety Workshop to Plan Implementation of the Biosafety Panel's recommendations.

Commentary

5. SC thanked the Chair and his panel for providing an excellent report with very clearly justified recommendations on the important subject of biosafety in the CGIAR. The SC did, however, express its disappointment that the Terms of Reference framed by iSC had limited the Panel to a consideration only of LMOs, which are but one facet of biosafety in the CGIAR. The ToRs did not allow the authors to emphasize that biosafety was not only an LMO issue but that biosafety considerations should be applied to all CGIAR products.

6. SC was keen to point out that products of transgenic breeding presented no different biosafety issues, and should be treated no differently (from the biological stand point of environmental risk or food safety) from products improved through any other breeding methodologies. It is most important that CGIAR policy does not add to the present confusion for consumers by indicating that LMO products present qualitatively different risks to the environment.

7. It was clear, of course, that the regulatory frameworks governing the release of LMOs being put in place around the globe did require a different approach to information gathering for LMOs relative to the products of other breeding technologies.

In general, the SC:

8. Welcomed the proposal to raise awareness of biosafety issues in the CGIAR and to plan and further develop biosafety policies (for all products and not just LMOs).

9. Endorsed the idea that 'business plans' should be developed from the outset for those LMO products destined for release, and that the plans should meet relevant national regulatory frameworks. (The concept of an adequate business plan addresses several of the Recommendations and so the following responses address issues rather than a sequential response to each Recommendation.)

10. Endorsed the organization of Center Biosafety Officers into a CGIAR Biosafety Network to share experiences. SC would like to see this group include NARS representatives. This was important because the stronger NARS were, in many cases, implementing regulatory policies for LMOs independently of the IARCs. Moreover, intergovernmental mechanisms (i.e. ASEAN in Asia) have also been effective in networking regulatory research and guidelines. The SC believes that the nature and extent of any new biosafety research at Centers should be a coordinated product of the new network.

11. Endorsed the implementation of 'ethics committees' at all Centers.

More specifically the SC:

12. Supported the notion (in Recommendation 1) that Centers continue to strengthen biosafety policies for the product of breeding research, including LMOs.

13. Endorsed the need for Centers to consider the regulatory requirements of some LMO products, i.e. those intended for eventual release, at an earlier stage of research. The focus should be on the development of a full business plan outlining all aspects of regulation and pathways for outcomes, including the roles and responsibilities of the Centers and their partners involved in the release of the product. The focus of the regulatory requirements would be on environmental considerations.

14. Supported the concept that the Centers develop an instrument for enhancing biosafety policies and for conducting appropriate regulatory research. The most appropriate instrument should be decided by the Centers, drawing on their corporate experience by developing a "central advisory service" and networking in other endeavors such as in IPR. The mechanism suggested by the Panel is a Biosafety Network (as in Recommendation 5) which would seem appropriate. NARS interest and involvement will go beyond enhancing capacity in this subject (as suggested in Recommendation 2) because, in all cases, NARS will be responsible for the release and deployment of new varieties. They must be involved at the outset, in order to prepare in a timely fashion and play their part in the design and planning of necessary pre-release research (referred to in Recommendation 3).

15. The network should include CGIAR animal and fish germplasm enhancement scientists (Recommendation 8). The network should also include or link to the ISNAR/IFPRI group dealing with developing GMO regulatory capacity in developing countries.

16. Noted that there may be a need for the Network to adopt the role of a "central supplier of information". Because of the increased scrutiny of transgenic breeding, preparation to meet regulatory standards will be a major part of the business. One key activity of the "central supplier of information" should be to ensure that evidence already obtained on particular transgenes and events, especially from industry, is made available to the members of the network so that work is not duplicated. The Centers are best able to identify the appropriate instrument for a "central supplier of information".

17. Noted that it was particularly important to identify a CGIAR scientist, who, modestly funded, would initially coordinate and lead the network. This scientist should explore extra funding or international collaboration that might be available outside the System to augment approaches to biosafety.

18. Supported the idea that transgenic programs designed to produce varieties or other products destined for release (rather than only research application) are associated at the outset with a business plan to meet the regulatory requirements of the NARS. This will include plans and costings for timely (as in Recommendation 3), integrated approaches (as in Recommendation 4), and research (including elements of Recommendation 6). It should also include a cost benefit analysis (along the lines of Recommendation 9) and plans for the development of 'risk assessment dossiers' (Recommendation 10). NARS interested in deploying LMO products should be involved in these plans.

19. The SC supports the concept of "safety first research" for all breeding products destined for release on a case-by-case basis. This may include some special attention to LMOs having a high probability of eventual release, and where the results will be of general value for NARS dealing with local regulatory issues. Further, the SC encourages research on the appropriate regulatory requirements needed for a pro-poor use of the product. Inherent in this concept is

that the regulatory requirements are built on a cost benefit analysis and different emphases may be required to develop regulatory regimes appropriate to market conditions and to the poor.

20. Supported the Recommendation (Recommendation 7) dealing with publication.

21. Agreed that an initial meeting will be necessary to implement the agreed steps addressing biosafety (Recommendation 12). Rather than being prescriptive, the SC expects this meeting to be convened, and the agenda set, by the new network.

22. Agreed that all Centers be encouraged to establish or strengthen consideration of ethical principals in their research (as in Recommendation 11). However SC noted that a separate review of 'Ethics in the CGIAR' was underway and suggests that action should not pre-empt that study due to be completed in 2004.

23. The SC recommends that the Center Directors develop a plan, including the appropriate instruments for Networking and for a "central supplier of information" for biosafety policy development and implementation by the Centers and for appropriate regulatory research for product release.

24. Noted that some funds are available to progress the assembly of the network and implementation of an initial meeting, and these could be made available for the agreed-upon instruments managed by the network leader's Center.

25. Stated that it is the intention of the SC to continue to monitor implementation of biosafety issues in the CGIAR.

The way forward:

- CDC should be asked to identify a biosafety coordinator.
- The coordinator should identify the key CGIAR research staff involved in biosafety policy and representatives of NARS.
- A first meeting with the aims of establishing and harmonizing biosafety regimes over the Centers, identifying appropriate biosafety research and identifying the requirements of NARS, particularly in the eventual deployment of LMO products.
- The meeting could well be held back-to-back with a CGIAR genomics meeting, since many of the same researchers will be involved.
- Producing, from the meeting, a clear commentary on the 'best-practice' approach to biosafety issues in CGIAR Centers.
- Establish a follow-up review in 2010 (after five years) to monitor progress.

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12 February 2004

Dear Professor Pinstrup-Andersen,

Re: Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers

I am pleased to submit to you and your colleagues on the CGIAR Science Council the Report of the Panel on Biosafety Policies and Practices, which was commissioned by the interim Science Council in 2003. The report contains a discussion of the current biosafety policies and practices of the CGIAR Centers, identifies emerging issues, and makes 12 specific recommendations as to future strategy, policy and practices.

The main messages of the Panel's report are threefold:

1. The CGIAR Centers should be more proactive in considering biosafety issues associated with the use of gene technology in food and agriculture earlier in the research phase, rather than treating biosafety considerations primarily as a regulatory issue, to be addressed if and when a promising new technology is progressing towards the development phase. Moving towards such a proactive, research-based approach would also better position the Centers to develop the necessary dossiers for seeking regulatory approval for their most promising new technologies.

2. The CGIAR Centers, through their world-wide network of scientists and research sites, and collections of genetic resources of the world's major food crops, have under-utilized advantages for conducting biosafety-related research. To fulfill this research potential, the Centers will need to expand their skills in some areas, especially those related to ecology and environmental sciences. Such new international biosafety research may best be implemented through an international network of researchers, formed by the CGIAR Centers and their research partners.

3. There are many common interests amongst the CGIAR Centers in relation to biosafety policy and practices, and the Centers' roles in supporting national research systems and regulatory authorities, but few joint activities. The Panel recommends that the Science Council sponsor a workshop to enable the CGIAR Centers and their partners in national research systems and regulatory bodies to discuss the Panel's report and recommendations with the Panel members and other stakeholders, and to develop implementation plans and budgets for the proposed new activities.

./...

Professor Per Pinstrup-Andersen
Chair, CGIAR Science Council
c/o Science Council Secretariat
FAO, Rome, Italy

cc: Dr Vir Chopra
Professor Anne Kapuscinski
Professor Norah Olembo
Dr Gabrielle Persley
Dr Amir Kassam

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I would like to take this opportunity to thank the members of the Biosafety Panel for their dialogue with the Centers, their insights during Panel's discussions and their contributions to the report. The Panel members are Drs Vir Chopra, Anne Kapuscinski and Norah Olembo; Gabrielle Persley served as Scientific Secretary of the Panel. The Panel also thanks Dr Amir Kassam for his many contributions towards facilitating the work of the Panel. The helpful and efficient assistance of the administrative staff of the SC Secretariat in FAO, Rome is also gratefully acknowledged. Several other FAO staff members met with the Panel during our meeting in Rome in May 2003, and we thank them for sharing their knowledge with us.

The Center Directors Committee (CDC), and its 2003 Chair, Dr Adel El-Beltagy, were especially helpful in facilitating the Panel's interactions with the Centers, for which we are most grateful. I would also like to thank the Director Generals and staff of all the CGIAR Centers for their prompt responses to the Panel's initial questionnaire in May 2003, and for their comments and suggestions on the draft report that was circulated later in 2003. Several other stakeholders in the CGIAR system commented on the Panel's draft report and we thank them for their suggestions towards improving the report.

I am pleased to have the opportunity to Chair the Biosafety Panel and I look forward to discussing its findings and recommendations with you and your colleagues on the CGIAR Science Council in the near future.

Yours sincerely,



Brian Johnson
Chair
CGIAR Biosafety Panel

CONSULTATIVE GROUP ON INTERNATIONAL AGRICULTURAL RESEARCH
SCIENCE COUNCIL AND CGIAR SECRETARIAT

Report of the Biosafety Panel to the CGIAR Science Council on Biosafety Policy and Practices of the CGIAR Centers

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SCIENCE COUNCIL SECRETARIAT
MAY 2007

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SUMMARY AND RECOMMENDATIONS

This study was commissioned by the CGIAR interim Science Council as a strategic study of biosafety across the CGIAR system, in order to shed light on current policies, procedures and practices and to make recommendations on future biosafety policies and practices for the CGIAR system.

The main body of information that formed the basis for the analysis was gained from a questionnaire developed by the panel, to guide consultations with the CGIAR Centers and other stakeholders. An excellent response was received from the Centers, with almost all Centers returning their completed questionnaires and supporting documentation within a short time frame. This greatly facilitated the work of the Panel, and is an indication of how seriously the Centers regard the issue of biosafety.

The report contains a discussion of the current biosafety policies and practices of the CGIAR Centers, identifies emerging issues, and makes 12 specific recommendations as to future strategy, policy and practices.

Living Modified Organisms (LMOs) Currently under Development by CGIAR Centers and Their Partners

Gene technology has been used by the Centers over the past decade or more to introduce potentially useful traits into those crops for which they have designated responsibility within the CGIAR system. Molecular techniques are also being used for the development of new vaccines for the control of East Coast fever in livestock in Africa.

The Centers and their partners are investigating a wide variety of species/trait combinations, using living modified organisms (LMOs), in at least 15 different crop species. These genetically modified crops are intended for use in various geographic areas, and are being developed under the regulatory systems in operation in these countries. All are currently in the research phase and have yet to be taken through the process of regulatory approval for possible commercial release.

The Panel makes several recommendations as to the future development of biosafety policies and practices by the CGIAR Centers and across the system; the role of the Centers in capacity building within the Centers themselves and with their host and partner countries; the future needs for biosafety-related research that may take a more pro-active approach in designing beneficial and safe LMOs; on the need for risk/benefit analysis, comparing LMOs with other technology options; the need to mobilize additional scientific and financial resources for the development of dossiers required by regulatory authorities before taking any promising products through to practical use; and finally on ethical considerations in the use of new gene technology in sustainable agriculture.

The main messages of the Panel's report are threefold:

1. The CGIAR Centers should be more proactive in considering biosafety issues associated with the use of gene technology in food and agriculture earlier in the research phase, rather than treating biosafety considerations primarily as regulatory issues, to be addressed if and when a promising new technology is progressing towards the development phase. Moving towards such a proactive, research-based approach would also better position the Centers to develop

the necessary dossiers for seeking regulatory approval for their most promising new technologies.

2. The CGIAR Centers, through their world-wide network of scientists and research sites, and collections of genetic resources of the world's major food crops, have under-utilized advantages for conducting biosafety-related research. To fulfill this research potential, the Centers will need to expand their skills in some areas, especially those related to ecology and environmental sciences. Such new international biosafety research may best be implemented through an international network of researchers, formed by the CGIAR Centers and their research partners.
3. There are many common interests amongst the CGIAR Centers in relation to biosafety policy and practices, and in the Centers' roles in supporting national research systems and regulatory authorities, but few joint activities. The Panel recommends that the Science Council sponsor a workshop to enable the CGIAR Centers and their partners in national research systems and regulatory bodies to discuss the Panel's report and recommendations with the Panel members and other stakeholders, and to develop implementation plans and budgets for the proposed new activities.

A list of 12 specific recommendations follows that elaborates on these main messages.

LIST OF RECOMMENDATIONS

Recommendation 1 - Enhance CGIAR Center Biosafety Policies

The Panel recommends that the CGIAR Centers continue to develop biosafety policies, governing research, technical analysis and transparent, participatory deliberations on the biosafety of their research and proposed releases of living modified organisms (LMOs), aimed at achieving scientifically reliable and publicly trusted decisions about whether a given LMO developed or tested by the Center is sufficiently safe and beneficial to release.

Recommendation 2 - Enhance Capacity Building in National Biosafety Policies and Practices

The Panel recommends that the Centers continue to support their partner countries in developing scientifically sound and publicly credible biosafety policies and in building national capacity for framing regulations, implementing and monitoring them; and in fostering the skills required for the preparation of the dossiers of information on individual LMOs, which form the basis for decisions by regulatory authorities. The Centers activities in capacity building should be better coordinated with other bilateral and international programs, such as those being implemented by the UN agencies in response to the Cartagena Protocol on Biosafety.

Recommendation 3 - Strengthen Center Capacity in Biosafety Practice and Research through Pro-active Approaches to Biosafety

The Centers need to take a more pro-active approach to biosafety, both for their own biosafety practices and for their roles in helping to build national biosafety capacity. In order to achieve this, they will need to mobilize additional resources and a broader range of expertise, including that which has developed in the public research sector and in the private sector over the past decade.

Recommendation 4 - Develop an Integrated Approach to the Practice of Biosafety in the Centers

The Centers' practice of biosafety science needs to develop a more comprehensive approach that integrates biosafety research, risk analysis, post release monitoring, and feedback to inform future decisions about the use of LMOs in different situations.

Recommendation 5 - Establish a CGIAR System Biosafety Network

A systemwide biosafety network should be established, so as to share experiences, expertise and scientific and financial resources for biosafety across the CG system. This network may need to access additional expertise in the areas of: (1) system safety science and management; (2) evolution and ecology of population, community, and landscape structure and processes; (3) facilitation of transparent, representative group deliberations; and, if the Center intends to address food safety, (4) public health, toxicology, immunology (to address allergenicity questions), food sciences, and related fields.

Recommendation 6 - Increase Biosafety-related Research by the Centers

The Centers should establish and implement a forward-looking and systematic biosafety research program, which may be co-ordinated by the biosafety network. This would involve a transparent and participatory process for developing key biosafety objectives, identifying key gaps in information needed to meet these objectives and pursuing biosafety-related research to fill these information gaps.

The biosafety research program should develop scientific methods and generate scientific data on safety design of the LMO itself; safety testing and verification; safety management practices, and safety monitoring.

Recommendation 7 - Publish and Communicate Results of Biosafety Research

Centers should place a high priority on publishing results of their biosafety research in peer-reviewed, scientific journals. They should also make their biosafety assessments and biosafety research results more accessible to civil society, by putting in place communications policies and practices designed to facilitate the dissemination of biosafety information in a publicly accessible form.

Recommendation 8 - Prepare for Forestry and Fisheries Biosafety Issues

Although the World Agroforesty Center (ICRAF), CIFOR (forestry) and the World Fish Center (WFC) do not presently work on LMOs, groups that they work with are likely to seek their help with biosafety issues in the future. These Canters should prepare themselves for this eventuality through active participation in a systemwide biosafety network and in biosafety training of staff members.

Recommendation 9 - Undertake more Risk/benefit Analysis

The Panel recommends that the Centers develop the capacity and seek additional resources for undertaking risk/benefit analyses of all LMOs under development. Specifically, ***the Panel recommends*** that Centers:

- Develop and adopt formal methods for risk/benefit analysis of LMOs intended for commercial use. These should be based on credible research data, aimed primarily for use within the Center as part of their research prioritization and justification program, but which can also be used more widely.
- Seek partners within target countries with the aim of developing risk/benefit analyses for the use of particular LMOs within specific territories.
- Identify sufficient resources, within the Center and in partnership with target country institutes and industry, to carry out risk/benefit analysis at the earliest possible stage in the development of an LMO.
- Identify sources and repositories for socio-economic, agronomic, ecological and human health data and expertise needed for risk/benefit analysis and support capacity building in this area.
- Incorporate comparisons, based on reliable research, including socio-economic research of the benefits and safety of an LMO relative to alternative methods of addressing the particular agricultural or food security problem.

Recommendation 10 - Develop Plans for Preparing Risk Assessment Dossiers for Product Approval

The Panel recommends that, in relation to the LMOs presently under development by the CGIAR Centers and their partners, the Centers need to assess the feasibility of some or all of these becoming new products. Plans for preparing risk assessment dossiers should be put in place at the earliest opportunity and should include realistic estimates of the scientific and financial resources that will be required to develop the dossiers, on which regulatory authorities will base their decisions about product approval.

Recommendation 11 - Better Address Bioethical Issues

The Panel recommends that:

- Centers share their experiences and develop a unified approach to the production and maintenance of ethical codes covering research and development of LMOs.
- Centers identify key stakeholders both in their host countries, target countries and among donors and promote their involvement in developing and maintaining ethical codes.
- Each Center maintains a standing Ethics Committee advising the Biosafety Committee. We recommend that the role of the Ethics Committee should be both to maintain ethical standards and codes used by the Center, and to consider and address the ethical dimensions both of the Center research program as a whole, and individual research projects. We recommend that the Committee has at least half of its members drawn from stakeholder bodies outside the Center, and reports directly to the Center Director General.
- Centers and CGIAR as a whole publicize their development and use of ethical codes aiming to increase public confidence in their research.

Recommendation 12 - Initiate a CGIAR Systemwide Biosafety Workshop to Plan Implementation of the Biosafety Panel's Recommendations

The Panel recommends that, in order to ensure that the results of the CGIAR investments in gene technology are able to be used with safety and confidence, the Biosafety Panel report and its recommendations be discussed at a workshop involving members of the CGIAR Science Council,

the Biosafety Panel, representatives of the CGIAR Centers, their R&D partners and other stakeholders, including national regulators, policy makers, civil society, farmers and consumers.

The purpose of the workshop would be to develop an implementation plan for a proactive approach to biosafety by the Centers and their partners.

1 INTRODUCTION

During the last decade the CGIAR Centers have initiated and / or intensified efforts to harness the advantages of modern biology (biotechnologies) for genetic enhancement of a range of traits, generating materials and products for upgrading the efficiency of agricultural enterprise. The major traits targeted in plant species are improved productivity, resistance to pests and diseases, tolerance to abiotic stresses and enhancement of nutritional quality. In the product development area, attention is being given to applications such as vaccines for animal health care and diagnostics for pest surveillance and biodiversity monitoring and conservation.

Across the CGIAR system as a whole, the Group has affirmed its view of the value and relevance of biotechnologies in furthering the missions and mandates of its Centers. The Group has emphasized that efforts made in developing and deploying new biotechnologies will be directed to generating public goods. The Centers involved in activities in gene technology are developing biosafety policies and practices to safeguard the well-being of staff undertaking research activities and to ensure as far as possible that any potential products are benign to human and animal health and the environment.

This study was commissioned by the CGIAR interim Science Council in 2002 as a strategic study of biosafety across the CGIAR system, in order to shed light on current policies, procedures and practices and to make recommendations on future biosafety policies and practices across the CGIAR system. The Terms of Reference for the Study are attached (Annex A).

Panel Members

A study panel was established in January 2003. Dr Brian Johnson (English Nature UK) was appointed Panel Chair, with Professors Vir Chopra (National Academy of Agricultural Sciences, India), Anne Kapuscinski (University of Minnesota, USA) and Norah Olembo (University of Nairobi, Kenya) as Panel Members; Dr Gabrielle Persley (the Doyle Foundation) is the Scientific Secretary of the Panel. Dr Amir Kassam is the Resource Person from the CGIAR Science Council Secretariat. Contact details for the Panel Members are given in Annex B.

2 SCOPE OF THE STUDY

The CGIAR Centers and their partners are developing a range of new technologies to improve the livelihoods of poor people in developing countries. These technologies may include new plant varieties developed with the aid of breeding techniques such as embryo rescue, wide crosses and/or marker-assisted selection. Some applications of gene technology may result in new molecular diagnostics for plant and animal diseases, improved biocontrol agents and new vaccines for the control of livestock diseases. Other applications of gene technology may lead to the development of living modified organisms (LMOs). All new technologies for agriculture (e.g. new plant varieties, diagnostics, biocontrol agents and animal vaccines) require an appropriate regulatory framework, and biosafety assessment as to their risks and benefits in particular environments. However, the scope of this study is limited to the biosafety issues associated with the use of living modified organisms (LMOs).

Living modified organism (LMO) means any living organism that possesses a novel combination of genetic material obtained through the use of transgenic technology. LMO is a synonym of genetically modified organism (GMO).
Biosafety refers to policy and practices used to ensure the safe use of living modified organisms in research and in food, agriculture and the environment.

The CGIAR Centers have the potential to develop LMOs in a wide range of species of crops, micro-organisms, trees, fish and livestock. However, only LMOs in crops and micro-organisms are currently under investigation by some of the Centers.

The Centers are also directly concerned with policy and management aspects of biosafety, both in designing and implementing their own internal biosafety policy and practices and in advising their host and partner countries on establishing and managing effective national biosafety systems. In regard to capacity building in national programs, ISNAR and IFPRI are the managing agents for a major new USAID-supported Program for Biosafety Systems (PBS) in developing countries. This program also involves several other CGIAR Centers amongst its collaborators. Further details on the program are available at www.agbios.com

There are ethical as well as scientific and economic issues associated with the safe use of LMOs in food, agriculture and the environment. The panel considered the extent to which the Centers were addressing ethical issues, and the appropriate means by which they could address these complex issues.

3 STUDY METHODOLOGY

The main body of information that formed the basis for the analysis in this study was gained from a questionnaire developed by the panel, to guide consultations with the CGIAR Centers and other stakeholders. A copy of the panel's questionnaire, and the covering letter sent to the Center Directors in May 2003 are attached (Annex D). An excellent response was received from the Centers, with almost all Centers returning their completed questionnaires and supporting documentation within a short time frame. This greatly facilitated the work of the Panel, and is an indication of how seriously the Centers regard the issue of biosafety.

The Panel gained additional information from documentation, meetings with personnel from other organizations, and from personal contact with the Centers by Panel members. The Panel also met with key staff within FAO when the Panel met in Rome in May 2003. An earlier draft of this report was circulated to the Centers and other stakeholders in October 2003, and their comments are reflected in this document.

4 FINDINGS AND RECOMMENDATIONS

4.1 Living Modified Organisms (LMOs) under Development by the CGIAR Centers and Their Partners

The Centers and their partners are investigating a wide variety of species/trait combinations, using living modified organisms (LMOs), in at least 15 different crop species. These genetically modified crops are intended for use in various geographic areas, and are being developed under the regulatory systems in operation in these countries. All are currently in the research phase and have yet to be taken through the process of regulatory approval for possible commercial release.

Gene technology has been used by the Centers over the past decade or more to introduce potentially useful traits into those crops for which the individual Center has designated responsibility within the CGIAR system. Some examples are listed in Table 4.1. Molecular techniques are also being used of the development of new vaccines for the control of East Coast fever in livestock in Africa.

Several Centers have initiated programs in gene technology as an aid for crop improvement, targeting mainly transgenic resistance to biotic stresses in crops. Research involving *Bacillus thuringiensis (Bt)* genes is being conducted to address insect resistance in rice, maize, pigeon pea, chickpea, sorghum and cowpea. Other Center efforts are directed towards developing LMOs resistant to bacterial, fungal and viral diseases in rice, pigeon pea, and groundnuts respectively.

These LMOs are intended for use in various geographic areas. They are being developed under national regulatory systems in operation in the countries concerned. All LMOs are currently in the research phase and have yet to be taken through the process of regulatory approval for commercial release.

The Centers are not yet developing transgenic lines of fish or trees. However, gene technology is being used in the Centers with responsibilities for trees (CIFOR) and agroforestry (ICRAF) for the characterization of biodiversity, and for the development of marker assisted selection for traits such as rapid growth and pest and disease resistance in trees and other agro-forestry species.

4.2 Synopsis of Case Studies

Several Centers provided details to the Panel of the development of some of the selected LMOs, in the form of case studies. Both the Centers and their partners are addressing biosafety issues during the research phase. The case studies examined by the Panel are summarized in Table 4.2. They include the following applications of gene technology in the development of living modified organisms:

- *Maize* with Bt genes for insect resistance
- *Rice* with Xa21 gene for bacterial blight resistance
- *Rice* with Bt genes for insect pest resistance
- *West African rice* cultivars with resistance to rice yellow mottle virus and to nematodes
- *Rice* resistant to rice hoja blanca virus
- *Beans* with drought tolerance
- *Cassava* with resistance to stem borer

- *Cowpea* with transgenes for resistance to Maruca vitrata
- *Groundnuts* with transgenes for resistance to the Indian Peanut Clump Virus
- *Potato* with Bt resistance to potato tuber moth
- Recombinant vaccines against East Coast Fever in cattle in Africa.

Table 4.1 Living Modified Organisms (LMOS) under Development by CGIAR Centers and their Partners

CGIAR CENTER	LMOs UNDER DEVELOPMENT
CIMMYT, Mexico	**Maize:** Bt maize (Mexico and Kenya)
IRRI, Philippines	**Rice:** Xa 21 for bacterial blight Chitinase/NPRI genes for sheath blight Bt genes for stem borer, leaf folder Crt1, psy, lcy genes for pro vitamin A (golden rice) Ferritin gene for enhanced iron
ICRISAT, India	**Groundnut** resistant to Groundnut Rosette Disease (GRD) and Peanut Clump Virus (IPCV) **Pigeon pea** resistant to pod borer and fungal pathogens, (*Phytophthera* and *Fusarium* blight) and to *Helicoverpa armigera* insects **Sorghum**: Bt sorghum **Chick pea:** Bt chick pea
CIAT, Colombia	**Beans:** Drought tolerance **Cassava:** Bt for resistance to stem borer **Rice:** Resistant to Rice Hoja Blanca Virus (RHBV)
IITA, Nigeria	**Cowpea**: Bt cowpea **Plantain:** with anti fungal genes; **Cassava:** low cyanide content; African cassava mosaic virus resistance
CIP, Peru	**Potato**: Bt potato
ILRI, Kenya	**Livestock vaccines:** P67 vaccine for East Coast Fever (ECF); Schizont vaccine for ECF
WARDA, West Africa	**Rice**: Resistant rice to Rice Yellow Mottle Virus (RYMV)
IPGRI	**Banana**, with disease resistance (being developed through a joint program with the Government of Uganda, INIBAP, IITA, KUL-Belgium, CIRAD- France on improving East African bananas in Uganda
ICARDA	**Chickpea** with disease and abiotic stress resistance Lentil with disease and abiotic stress resistance, Barley and wheat with abiotic stress resistance (with AGERI, Egypt)

Table 4.2 - Summary of Case Studies of Living Modified Organisms (LMOs) under Development by the CGIAR Centers and their Partners

	CENTER	
1.	CIMMYT Mexico	- *Bt maize in Mexico 1991 – 1999:* ▪ Research conducted to identify useful Bt genes and gain expertise for field testing. Ten trials approved and carried out. ▪ Biosafety measures: detasseling, containment, isolation, destruction of field sites. ▪ Applications for import of transgenic seed and field trials approved by CIMMYT's Biosafety and Bioethics Committee (BBC), Director General and Mexican National Biosafety Committee, CNBA. ▪ Limited risk assessment carried out. ▪ Field testing of Bt Maize in Mexico stopped by moratorium in 1999, but development and evaluation continued in CIMMYT'S biosafety greenhouse.
	Kenya	- *Bt. Maize in Kenya 1999 to-date:* ▪ Research with Kenya Agricultural Research Institute (KARI) to develop and deploy Bt. Maize for resource poor farmers under project "Insect Resistant Maize for Africa (IRMA), targeting stem borers. ▪ Two imports of Bt maize leaves approved by Kenya National Biosafety Committee and KARI Institutional Biosafety Committee. ▪ Lab experiments carried out to determine which Bt genes target which stem borer. ▪ Green house testing of Bt seeds being considered and quarantine field site for field trials established. Experiments on gene flow and other environmental factors carried out. ▪ Insect species on farmers' fields and soil biodata collected to monitor environmental impacts.
2a.	IRRI Philippines	- Several transgenic rices with useful genes for resistance to diseases and insects developed. *Case study on transgenic rice with Xa21 gene for bacterial blight resistance*: ▪ Xa21 inserted in rice cultivar IR 72 through transformation. ▪ Applications for LMO approved by Institute of Biosafety Committee (IBC) and final by National Committee on Biosafety of the Philippines (NCBP). ▪ Evaluation of IR 72 under greenhouse alongside susceptible check and found highly resistant to bacterial blight. Three IR 72 transgenic lines evaluated under field conditions found to be resistant. Biosafety measures: containment, bagging of panicles, autoclaving of soils before disposal, transgenic seeds stored under strict conditions, regular monitoring, burning of vegetative plant parts, burying of stubbles, restricted entry to sites. Experiments regularly monitored by Institute Biosafety Committee. IRRI policy on GMOs in place. Risk assessment by independent agencies and developer of LMO, National Agricultural Research Extension Systems.

2b	IRRI, with NARS in China and India, 1996-2003	Case study on transgenic rice with several Bt genes (cryIAb/cryIAc) driven by tissue-specific and constitutive promoters: Applications for LMO approved by Institute of Biosafety Committee (IBC) and final by National Committee on Biosafety of the Philippines (NCBP); similar applications were submitted and duly approved by the National Biosafety Committees of China and India before importing Bt rice seeds from IRRI, Philippines. Evaluation of MH63, Azucena, IR72, Mot Bui, IR68899B, Tulasi, Vaidehi, Basmati 370, Dinorado etc. under greenhouse alongside with control check and found highly resistant to stem borer. All bioassay data and molecular data were systematically recorded and correlated with phenotypic data and the best lines were selected based on all positive results. MH63 and IR72 were field evaluated against several insect pests in China and India; Bioassay data and non-targeted insects' pests were also monitored and showed excellent results with good agronomic performance. MH63, a CMS line was also crossed with a Restorer line to develop the Hybrid Bt rice, Shan You 63 which also showed excellent plant protection and yield advantage. All these studies have been published in referred journals. Marker free Bt rice (with stable homozygous for Bt gene) has also been identified which is now being used as a donor material for breeding work. Preliminary Data on Toxicological study showed no difference in between control and transgenic Bt rice. Several homozygous Bt rice lines in different background are now ready for detailed food-safety study and may be deployed in Experimental field for further monitoring of risk assessment and cost/benefit studies.
3.	CIAT Colombia	- Research focus on genetic transformation work for plant breeding for beans, *Brachiaria*, cassava and rice, using bombardment and *Agrobacterium.* • *Case studies: transgenic hybrids for drought tolerance in beans, introduction of resistance to stem borer in cassava, generation of rice plants resistant to Rice Hoja Blanca Virus.* • Applications for LMOs made to CIAT Biosafety Committee then to Colombian National Biosafety Council for field trial approval. • Biosafety Studies: gene flow analysis from transgenic to wild/weedy relatives, effects of Bt. cotton on soil micro biota diversity. • Biosafety under containment: biosafety greenhouse, restricted entry, seed stored under restricted conditions, bagging of panicles, autoclaving soil before use and disposal, strict phytosanitary conditions, organic disposal incinerated. Rice field trials under controlled conditions, screens used to prevent contact with birds, plant residues incinerated isolation of fields, field rotation, gene flow analysis. Experiments monitored by the Colombian National Biosafety Council.

4.	IITA Nigeria	- *Development of transgenic cowpea for resistance to Maruca vitrata.* • Biosafety studies: gene flow studies between non transgenic cowpea and wild cowpea lines. Gene exchange does occur at very low frequency. Results to determine isolation distance. Studies on longevity of hybrid seed in field and effects of insecticidal genes on non target organisms e.g. parasitoids of *Maruca vitrata*. Risk assessment by developer of LMO and independent assessment. • Applications: Nigeria biosafety guidelines are operational although not yet legally binding. Consent to be obtained from National Biosafety Committee.
5.	ICRISAT India	- *Research on transgenic groundnuts for resistance to the Indian Peanut Clump Virus and pigeon pea.* • Gene flow in pigeon pea using non transgenic germplasm. No gene flow was detected from cultivated to wild species. Information was gained on possible deployment of GM pigeon pea. • Application for approval made to Institutional Biosafety Committee (IBSC) approved by the Indian Department of Biotechnology (DBT). • Biosafety measures taken: Biosafety guidelines available. Research activities under lab and glasshouse have P2 level, safe storage, sterilization before disposal, autoclaving of instruments, incineration, monitoring of containment facilities, field trials under controlled conditions.
6.	CIP Peru	- *Proposed biosafety Case Study on Bt potato in developing countries.* *Field trials of Bt potato with resistance to Potato tuber moth (PTM) conducted in Peru. Trials in Asia and Africa awaited.* • CIP Biosafety Committee present. Final decisions by CONAM a government advising body on environment. In Peru law on biosafety and regulations published. • Bt potatoes have passed first stage of proof-of-utility. Biosafety measures: confined experiments, flower removal, sterile varieties used, No gene flow experiments conducted.
7.	WARDA Cote d'Ivoire	• No work on LMO's at center but collaborative work on transgenic rice. • Undertook collaboration with institutions e.g. John lnnes center, UK to create resistant rice cultivars to Rice Yellow Mottle virus and to nematodes. No field-testing done due to absence of biosafety regulations in most West African Countries. • Internal Biosafety Committee Established. Draft framework for guidelines on GMO's developed. • National policy for implementation of biosafety regulations being prepared. Confinement facilities nearly complete.

8.	ILRI Kenya	- Research on East Coast Fever (ECF) • Diagnostic process for LMO's being developed P67 vaccine produced using transformed bacteria • Schizont vaccine candidates produced using transformed E.coli and pox viruses. • Biosafety Measures: Work with vaccinia and Salmorella conducted under containment. Work with pox viruses carried out under BL2 containment. No field trials yet with LMO's. • Institute Biosafety Committee and National Biosafety Committee to approve release of LMO's.

4.3 Biosafety Policies and Practices at the CGIAR Centers

Cohen *et al.* (1999) have identified the following four major elements for developing and implementing biosafety policies and practices:

1. Written guidelines – to clearly define the structure of the biosafety system, the roles and responsibilities of those involved and the review process;
2. Regulatory authorities – comprising well trained individuals in the host country, who are confident about their decision-making ability and to ensure the support of their institutions;
3. An information system – enabling the biosafety evaluation process to be based on up-to-date and relevant scientific information and the concerns of the community; and to ensure that biosafety data and procedures are recorded and archived;
4. A feedback mechanism – for incorporating new information and revising the regulatory system.

The written guidelines may include the Terms of Reference (TORs) of biosafety committees and biosafety officers. They may also include specific text or documents on aspects of biosafety, including safety regulations in the laboratories, in the field, and in transit. Regulatory authorities may include both national and institutional committees or bodies who are involved in approving research. Information systems include public and institutional awareness materials as well as records and databases. A policy statement may also be included. The feedback mechanism should include the establishment of a responsible body and procedures to report on, monitor and adjust current research, events or regulatory systems.

Criteria for Assessing Effectiveness of the Centers' Biosafety Policies and Organizational Structures

The panel used the following general criteria to develop the part of the questionnaire designed to assess effectiveness of the current biosafety systems in operation at the CGIAR Centers:

- Availability of a specific biosafety policy framework and documented guidelines for procedures and practices, developed by a wide range of stakeholders;
- Existence of an effective and transparent biosafety committee structure in both the Centers and host countries;
- Adequate coordination between Center and host country biosafety and regulatory systems;
- Science-based identification of biosafety issues concerning genes/gene sources, regulatory sequences, selectable markers, target environments for release and purpose of deployment of the LMOs for food, feed, and industrial uses;
- Timely, objective and transparent clearance and approval procedures;
- Effective biosafety monitoring mechanisms;
- Availability of legal frameworks for biosafety in the host and partner countries with whom the Centers collaborate.

Current Biosafety Systems in Operation at the CGIAR Centers

Implementation of a biosafety regulatory process requires a functional structure and an operational plan. These two elements are required both at the institutional and national levels for overseeing and ensuring that experiments in laboratories and green houses and trials under containment and open field conditions are undertaken with adequate safeguards. In the context of applications of biotechnologies by the CGIAR Centers, these responsibilities are discharged by

designated committees at Center and host country levels and with small variations of nomenclature are termed Institutional Biosafety Committees (IBCs) and National Biosafety Committees, respectively.

Biosafety Committee Composition
The expertise represented on the bodies/committees entrusted with developing regulatory frameworks is widely variable both in the case of Centers and the Host Counties. The Centers rely on their staff scientific expertise (biological and social sciences) with added representation from Host Country authorities on their Institutional Biosafety Committees.

National Biosafety Committees
The National Biosafety Committee in the Host Country (the nomenclature is variable) is the responsible body to frame, regulate and monitor biosafety aspects of biotechnological research, field evaluations, release into the open environment and commercialization of biotechnology-based products. In some countries, laws have been passed and in others they are at various stages of enactment to give legal status to these Committees.

The composition of National Biosafety Committees in different Countries is variable. They tend to have a high representation of administrators from Government departments. Consumer groups and members of the civil society are under represented on most national committees. Center staff representation on these Committees is infrequent.

Findings

1. Most of the Centers using gene technologies have formally constituted Institutional Biosafety Committees whose duties and responsibilities (though they vary from Center to Center) have been defined. Some Centers have appointed specific Biosafety Officers while in others a Principal Investigator acts as the nodal, coordinating person.

2. As criteria for action, most Centers have prepared Institutional Biosafety Guidelines, primarily developed by Center staff, in accordance with the requirements of their respective host country national regulatory authorities.

3. The Institutional Biosafety Committees are charged with implementing good laboratory practices for biotechnology-related research in laboratories and greenhouses and the required biosafety regulations in trials of LMOs under containment.

4. These Institutional Biosafety Committees also oversee the preparation of risk assessments reports.

5. Recommendations of the Center's institutional biosafety committee are advisory, with final decisions entrusted to the Center Director General, with approval of the National Biosafety Committee.

6. Applications for approval of biotechnology-related research involving the use of LMOs generally follow the route of: Investigator/Developer of LMO, to Institutional Biosafety Committee, to National Biosafety authority for clearance and approval to proceed with laboratory, greenhouse, and /or field evaluations of LMOs.

Recommendation 1 - Enhance CGIAR Centers' Biosafety Policies

The Panel recommends that the CGIAR Centers continue to develop biosafety policies, governing research, technical analysis and transparent, participatory deliberations on the biosafety of their research and proposed releases of LMOs, aimed at achieving scientifically reliable and publicly trusted decisions about whether a given LMO developed or tested by the Center is sufficiently safe and beneficial to release.

Recommendation 2 - Enhance Capacity Building in National Biosafety Policies and Practices

The Panel recommends that the Centers continue to support their partner countries in developing scientifically sound and publicly credible biosafety policies; in building national capacity for framing regulations, implementing and monitoring them; and in fostering the skills required for the preparation of the dossiers of information on individual LMOs, which form the basis for decisions by regulatory authorities. The Centers activities in capacity building should be better coordinated with other bilateral and international programs, such as those being implemented by the UN agencies in response to the Cartagena Protocol on Biosafety.

4.4 Biosafety Practice: Science, Research, and Capacity Building

This discussion assumes that the main goal of CGIAR Center involvements in gene technology is to develop and release beneficial and safe LMOs that enjoy broad acceptance and wide adoption. The Centers are pursuing this goal at a time when the social contract between science and society is undergoing a major transformation. Instead of expecting science to produce 'reliable' knowledge and then communicate its findings to society, this new social contract expects science and its technological applications to be 'scientifically reliable' and 'socially robust', as well as open and transparent, in order to gain broad acceptance (Gibbons 1999). Decisions and actions regarding the biosafety of specific LMOs therefore require greater integration of science with participatory processes and policy than in the past.

What does it take for the Centers to achieve scientifically reliable and publicly trusted biosafety practices for LMOs on the ground? They obviously need to operate and be seen to operate within appropriate legislative and policy frameworks of the countries where the LMO activities occur, and in a manner consistent with the Center's own biosafety policy and practices. Legislation and policy alone, however, cannot achieve beneficial and safe uses of LMOs. Also needed are complementary, on-the-ground biosafety practices starting as far ahead of LMO releases as possible.

The practice of biosafety is a learned, material practice that should focus on accident prevention and learning from mistakes via scientific and participatory processes, starting at the earliest stage of LMO design through research, development and final use of particular LMOs. This is the central wisdom gained from over 100 years of safety movements and safety work on other complex technologies that offered benefits while posing potential risks and that led to the professions of system safety science and management (Aldrich 1997, McIntyre 2000, Kirwan 2001).

In recent successful cases of taking such a 'safety first' approach to uses of technology (Kapuscinski et al. 2003), "an analytic-deliberative process has evolved whereby potentially affected parties in the private and public sectors collectively identify key safety issues to be

addressed, which in turn has produced knowledge and agreements about safety that met and moved beyond scientific 'reliability' to 'socially robust' and publicly credible arrangements (Gibbons 1999)".

Parties involved in developing, regulating or analyzing LMOs have yet to explicitly and fully adapt the principles and methods of system safety science and management to the biosafety of LMOs (Baram 2002). There is tremendous potential to build upon the biosafety practices already in place in certain countries, companies and CGIAR Centers. This will require a conscious shift away from the prevailing and conflict-prone, risk-focused approach and towards a more forward-looking, 'safety first' approach that is better equipped to reach scientifically based and widely trusted conclusions about whether an LMO is sufficiently beneficial and safe to release. Indeed, the CGIAR Centers are ideally situated to lead this shift in a manner that fits the needs and situations of developing countries.

The prevailing risk approach typically involves over 10-15 years of research and development before carrying out major work on risk assessment and management (Figure 4.1). Quite far downstream in terms of the LMO developmental time, and at the point of seeking regulatory approval for field tests, developers conduct risk assessments and develop measures (such as isolation) to try to manage risks. The field tests themselves focus on gathering data on agricultural traits and rarely build on research designed to test or verify the assessment of environmental safety of the LMO. Risk assessment and management then get central attention at the far end of the process, when private companies or public institutions seek approval for commercial releases and export/import of an LMO. Waiting until this late stage puts all parties - from LMO developers and regulators to potential users and concerned citizens - into a reactive mode that tends to fuel controversy and conflict. This can lead to inordinate delay or even rejection of the LMO, wasting invested resources.

In contrast, the goal of the preventative safety first approach is to anticipate and prevent biosafety problems as far upstream of LMO release as possible (Figure 4.2). The main elements of the safety first approach include:

- Initial *safety criteria setting* through preventative risk assessment, safety design (of the LMO itself) and planning to reduce and control identified risks;
- *Safety verification* testing of the LMO through appropriate lab and field tests;
- *Safety follow-up* (monitoring) to promptly detect unforeseen problems and take corrective action; and
- *Safety leadership* via training and independent certification of biosafety professionals, a safety-oriented management style in public and private institutions involved with LMOs, and a framework for managing the application of cross-institutional safety standards.

By making safety a primary consideration throughout the process of developing, producing and using an LMO, the safety first approach avoids the pitfalls of the prevailing risk approach while directing resources towards the development, release and adoption of LMOs credibly shown to be sufficiently beneficial and safe.

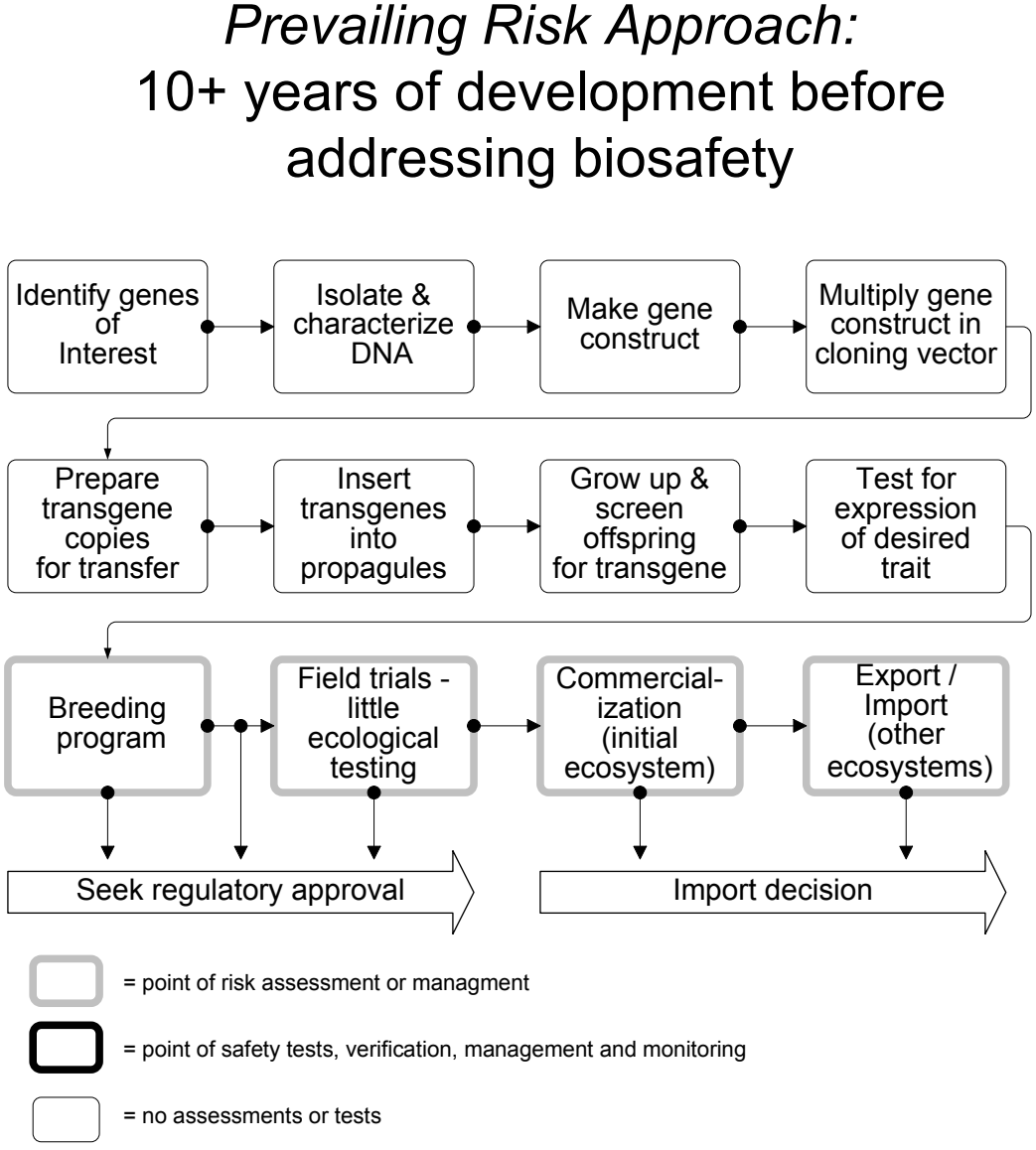


Figure 4.1 Prevailing Risk Approach to Biosafety

Note to Figure 4.1: The prevailing risk-focused approach to biosafety of LMOs applies major work on risk assessment and risk management quite late in the lengthy process of research, development, and regulatory decision-making (depicted by grey borders around the later steps). Field tests conducted as part of seeking regulatory approval rarely include empirical tests to estimate the ecological risk or safety of the LMO in the range of environments where it might be produced commercially; environmental risk/safety information collected for the conditions of one country may not be adequate for assessing risk/safety under the environmental conditions of a country of import.
Source: Kapuscinski (2003).

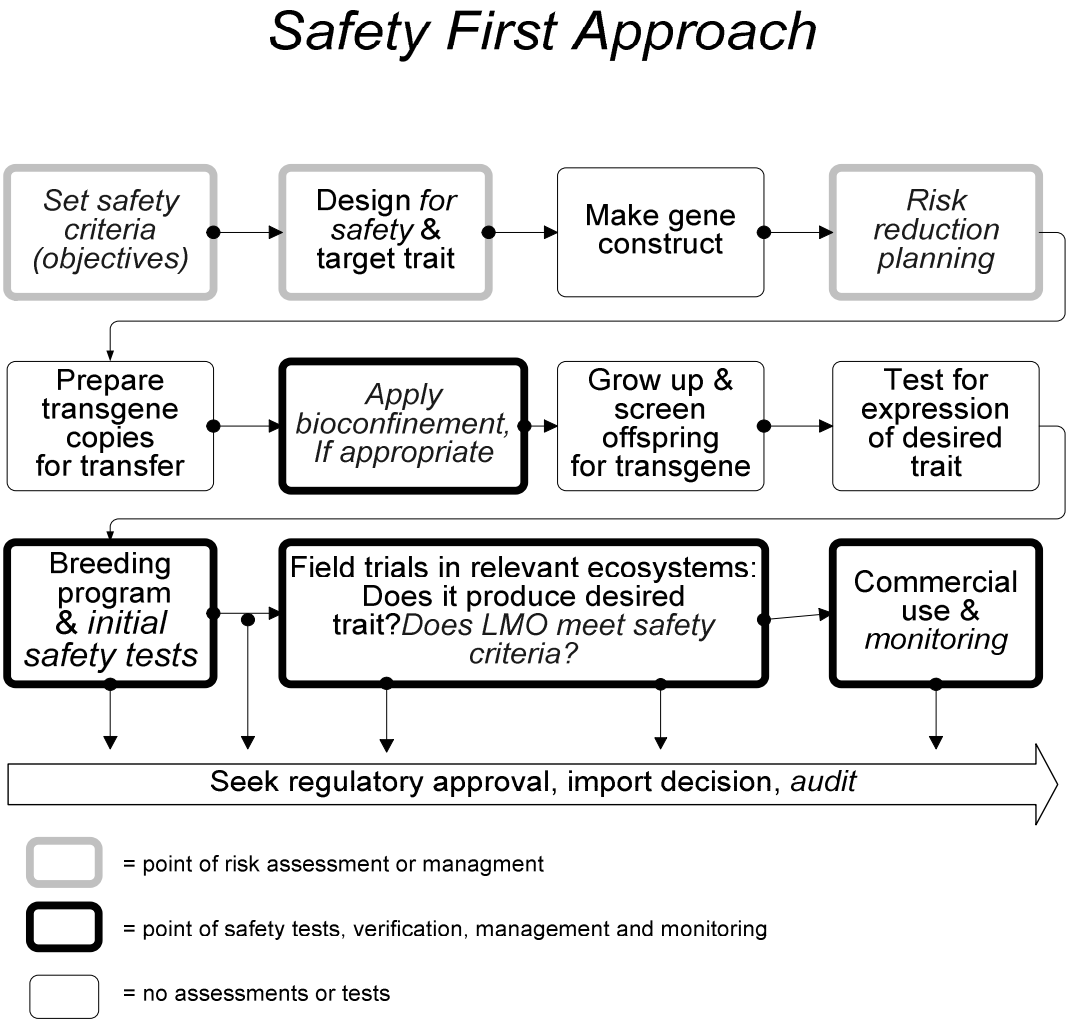


Figure 4.2 Safety-first Approach to Biosafety

Note to Figure 4.2: The pro-active, safety-first approach is designed to anticipate and prevent biosafety problems as far upstream of LMO release as possible. It stresses risk assessment and management early on (depicted by grey borders around early steps) and adds explicit steps pre- and post-commercialization to verify and monitor safety (depicted by black borders around middle and later steps). Safety criteria are negotiated at the outset through transparent and representative deliberations, informed by the best available scientific information. The safety criteria set the objectives for the subsequent processes of safety design, risk reduction planning, the building in of bioconfinement or other safety measures, initial and field safety verification tests, and post-commercialization monitoring. Source: Kapuscinski (2003).

Findings on Biosafety Practices at the Centers

The Panel reviewed the Center responses to the questionnaire, and analyzed the case studies to arrive at summary findings and recommendations regarding biosafety practice in terms of biosafety science, research and capacity building. The main findings and recommendations are summarized below:

1. All Centers meet or exceed the capacity and requirements of their host country to govern the biosafety of LMOs. Some host countries are still developing their biosafety governance

frameworks. In a few cases, the lack of adequate host country regulatory capacity is constraining further research by the Center.

2. Most of the Centers are actively helping their host country to develop its biosafety governance frameworks and most identified multiple biosafety capacity needs for the host country and other countries they work in.

3. The Centers are currently focused on containing and confining LMOs within projects underway in labs, glass/screen houses or field tests, using apparently adequate containment and confinement practices. The main objectives of the current research projects are to develop LMOs and measure their agriculturally important traits. These projects generally involve little or no specific biosafety related research objectives. In some instances, the Centers are able to draw on biosafety-related work conducted elsewhere (e.g. resistance management in relation to Bt genes). However, in other cases, environmental impact assessments are being initiated by some Centers to assess risks associated with LMOs in particular environments.

4. Some Centers have plans for, or are conducting, biosafety research projects and/or risk/benefit analyses on LMOs. The current biosafety research of the Centers focuses on two main issues: gene flow and marker genes, including the avoidance of antibiotic and herbicide resistance markers in gene constructs.

   The submitted descriptions of current biosafety field research projects by some Centers indicate intelligent study designs that facilitate gathering important baseline information - for instance, on patterns and levels of gene flow from crop varieties to wild or weedy relatives - without requiring environmental release of the LMO.

5. In relation to gene flow, the Centers have a particular responsibility and a research advantage since they are located in the Centers of diversity of the world's major food crops and their wild and weedy relatives.

6. In relation to marker genes, CIP has undertaken research on identifying non-antibiotic, selectable marker genes for use in potato and sweet potato. CIAT is moving its safety design of genetic constructs to "precision genetic engineering" involving tissue-specific expression. This is an example of good safety design because it should reduce variability in transgene expression, which should reduce variability in overall LMO behavior and, in turn, improve the predictability of biosafety tests. IRRI has developed marker-free Bt and Golden indica rice that may have added value and public acceptance of LMOs.

7. The Centers have impressive strengths in the kinds of agricultural sciences needed for biosafety science and decision-making. They generally lack essential and complementary expertise in system safety science and management; evolution and ecology of population, community, and landscape structure and processes; and, if the Center intends to address human health safety aspects, public health, toxicology, immunology (to address allergenicity), food sciences, and related fields. The Panel is unsure to what extent their staffs include professional facilitators/social scientists skilled in managing multi-stakeholder deliberative and participatory processes on highly technical and controversial issues.

8. Centers differ on whether they should address the food safety aspects of LMOs. Several prefer to direct such work to existing national institutions that they believe have the

appropriate capacity. Others expressed a desire to undertake LMO food safety research and analysis within the Center in the future.

9. There appears to be no empirical research underway to directly compare the benefits and safety of an LMO to alternative methods of addressing the particular agricultural problem at issue. The questionnaire did not specifically request such information so it is possible that certain Centers are planning or conducting such comparative research. Several Centers did identify socio-economic effects as an area of future biosafety research, something that could be addressed through appropriately designed comparative research.

10. There is a general congruence of thinking among Centers regarding future biosafety - related research needs. The priority areas are:

- Safety of new GM-derived foods and feed for human and animal consumption;
- Effects of LMOs on non-target organisms;
- Gene flow and environmental safety;
- Resistance management, especially in relation to the deployment of Bt genes for insect resistance, a common trait being explored for several crops;
- Socio-economic aspects of deploying GM crops; and
- Effective models for public awareness.

Other important areas in safety design research are on better control of the number of transgene copies and integration sites in the LMO genome; and biological confinement methods such as inducible expression of transgenes and blocking of reproductive traits. Safety verification research would have to expand from studying pathways of LMO and transgene movement (e.g. gene flow) to include research on possible environmental and human health consequences (i.e. negative, neutral or positive) of transgene movements.

Recommendations for Strengthening Biosafety Practice and Biosafety Research by the CGIAR Centers

Recommendation 3 - Strengthen Center Capacity in Biosafety Practice and Research through Pro-active Approaches to Biosafety

The Centers need to take a more pro-active approach to biosafety, both for their own biosafety practices and for their roles in helping to build national biosafety capacity. In order to achieve this, they will need to mobilize additional resources and a broader range of expertise, including that which has developed in the public research sector and in the private sector over the past decade.

Recommendation 4 - Develop an Integrated Approach to the Practice of Biosafety in the Centers

The Centers' practice of biosafety science needs to develop a more comprehensive approach that integrates biosafety research, risk analysis, post release monitoring, and feedback to inform future decisions about the use of LMOs in different situations.

Recommendation 5 - Establish a CGIAR System Biosafety Network

A systemwide biosafety network should be established, so as to share experiences, expertise and scientific and financial resources for biosafety across the CG system. This network may need to access additional expertise in the areas of: (1) system safety science and management; (2) evolution and ecology of population, community, and landscape structure and processes; (3) facilitation of transparent, representative group deliberations; and, if the Center intends to address food safety, (4) public health, toxicology, immunology (to address allergenicity questions), food sciences, and related fields.

Recommendation 6 - Increase Biosafety Related Research by the Centers

The Centers should establish and implement a forward-looking and systematic biosafety research program, which may be co-ordinated by the biosafety network. This would involve a transparent and participatory process for developing key biosafety objectives, identifying key gaps in information needed to meet these objectives and pursuing biosafety-related research to fill these information gaps.

The biosafety research program should develop scientific methods and generate scientific data on safety design of the LMO itself; safety testing and verification; safety management practices, and safety monitoring.

Recommendation 7 - Publish and Communicate the Results of Biosafety Research

Centers should place a high priority on publishing results of their biosafety research in peer-reviewed, scientific journals. They should also make their biosafety assessments and biosafety research results more accessible to civil society, by putting in place communications policies and practices designed to facilitate the dissemination of biosafety information in publicly accessible ways.

Recommendation 8 - Prepare for Forestry and Fisheries Biosafety Issues

Although the World Agroforesty Center (ICRAF), CIFOR (forestry) and the World Fish Center (WFC) do not presently work on LMOs, groups that they work with are likely to seek their help with biosafety issues in the future. These Canters should prepare themselves for this eventuality through active participation in a systemwide biosafety network and in biosafety training of staff members.

4.5 Risk/benefit Analysis of Potential LMO Products

Risk analysis and assessment of impacts on human and environmental health and safety is the overall method by which the biosafety of LMOs is evaluated. Under the prevailing risk approach, this has constituted a major 'first hurdle' that an LMO product must pass--quite far downstream in its development--before it can be considered for general release within a specific territory. Under the more forward-looking and preventative, safety first approach (Figure 4.2), risk analysis is iterative, starting at the earliest stage of LMO design and research through field testing and finally in applications for commercial approval, each time with more depth and drawing on

lessons learned at the earlier stage. The advantage of the safety first approach to risk analysis is that it offers a better chance of resolving major concerns in a scientifically and publicly credible manner by the time a product reaches the last iteration of risk analysis in an application for commercial approval.

In some countries, biosafety has an even wider meaning that extends into additional dimensions of sustainability, where the socio-economic and agronomic impacts of both the LMO and the systems within which it would be used are considered.

For example Directive 2001/18 of the European Union requires that member states assess the wider, indirect effects of releasing an LMO, and some member states are interpreting this as assessment of factors such as potential extension of range of a crop, changes in agrochemical loads on the environment, and impacts on crop rotations. Assessments of these factors inevitably lead to the identification of potential benefits or disadvantages associated with the use of the LMO. Although regulatory committees do not carry out a formal risk/benefit analysis, the trend in Europe is towards the provision of information that could be used as part of the wider decision-making process of giving consent for release, helping politicians to be better able to balance risks against probable benefits.

Thus, under the prevailing risk approach, risk/benefit analysis occurs very far downstream in the research and development process and has become a 'second hurdle' that an LMO (or product derived from it) must overcome. Because of public concern, this hurdle is in some cases the main determinant of whether technology transfer is achieved. The questions are not only 'is this product demonstrably safe?' but also 'is it wise to use this product in our country and will its use lead to more sustainable agricultural systems?' A risk/benefit analysis is often carried out at the political level, but is often ill informed and partisan, with commercial interests trying to promote their product on the one hand and anti-GM organizations trying to argue that the risks outweigh the benefits. Controversy is further fuelled by the fact that the risk/benefit analysis occurs so late in the development process. Such conflict could be greatly reduced by taking a safety first approach, in which risk/benefit analysis would start as early as possible in research and development of an LMO by integrating it in, and parallel to, laboratory and field tests, rather than waiting until the point of applying for commercial approval.

The Panel considered that it would be worthwhile asking the Centers whether there was a formal framework for risk/benefit analysis in existence within the Center. This was because they wanted to know how much of the expertise on ecological, human health, socio-economic and agronomic impacts that is needed to carry out such analyses resides within Centers and the wider networking that typifies the way Center staff work.

The responses to the questionnaire show that one Center appears to have a formal framework in place for carrying out risk/benefit analysis. A number of Centers do not have a formal framework, but make the point that 'informal' risk/benefit analysis is carried out as part of the Centers' process for determining research priorities. Other Centers may be developing formal methods for risk/benefit analysis, but do not yet have them in place. The costs of deployment of GE varieties have not been considered in such an analysis because they are to a great extent unknown.

Centers largely agree that their staff has the knowledge and skills to be able to carry out risk/benefit analyses, especially if sufficient funds were available and they collaborated with

partner institutes. While they clearly have impressive expertise in agricultural sciences, they may lack other necessary expertise in evolutionary and ecological sciences, human health related fields (if the Center intends to address human health risks/benefits), and facilitation of multi-stakeholder, deliberative processes. All Centers agreed that risk/benefit analyses would be worthwhile, with several making the point that a risk/benefit analysis would provide sound information to the public and politicians. Centers made the important point that risk/benefit analysis would help to convince both the Center itself and potential investors of the value of, and need for the LMO. Some Centers pointed out that such analyses should be made by comparing the impacts of the LMO with current crops and practices. Some Centers expressed the opinion that risk/benefit analyses would be worthwhile but should be made by the 'target' country, using information and expertise from Centers and NARS. Other Centers noted that given their situation in developing countries, little reliable data exist on some of the factors necessary for risk/benefit analysis, but as Centers and countries accumulate more experience and better capacity, more meaningful analyses can be conducted.

It should be noted that the development of some LMOs is for research purposes only. Many of the transgenics that are being worked on now by the Centers will never make it to a "commercial" product. There are many examples where LMOs are being developed in order to advance the science, to develop an efficient transformation system for that species, to test the efficacy of a certain gene and so on. That might explain why many Centers do not yet have formal methods for risk/benefit analysis for potential commercial LMO-based products.

Centers involved in developing LMOs should consider conducting research that compares the benefits and safety of an LMO to alternative methods of addressing the particular agricultural or food security problem. It would be important to involve an adequately interdisciplinary team of scientists in designing such research. Comparative research would provide a direct way of impartially testing the asserted benefits and of risks that arise in biosafety debates.

Recommendation 9 - Undertake more Risk/benefit Analysis of Gene Technologies

The Panel recommends that the Centers develop the capacity and seek additional resources for undertaking risk/benefit analyses of all LMOs under development. Specifically,

the Panel recommends that Centers:

- Develop and adopt formal methods for risk/benefit analysis of LMOs intended for commercial use. These should be based on credible research data, aimed primarily for use within the Center as part of their research prioritization and justification program, but which can also be used more widely.
- Seek partners within target countries with the aim of developing risk/benefit analyses for the use of particular LMOs within specific territories.
- Identify sufficient resources, within the Center and in partnership with target country institutes and industry, to carry out risk/benefit analysis at the earliest possible stage in the development of an LMO.
- Identify sources and repositories for socio-economic, agronomic, ecological and human health data and expertise needed for risk/benefit analysis and support capacity building in this area.

- Incorporate comparisons, based on reliable research, including socio-economic research, of the benefits and safety of an LMO relative to alternative methods of addressing the particular agricultural or food security problem.

4.6 Moving from Research to Product Development

There are many LMOs currently at various stages of laboratory and field testing by the Centers and their partners. These potential products have primarily been developed for their promise as "international public goods", able to address constraints and commodities that are not likely to be a priority for private companies (e.g. drought tolerance in African maize, disease resistance in cassava).

The currently estimated cost of taking a LMO (e.g. a new crop variety) through the regulatory approval processes in North America is in the order of US$8-15M (as estimated by the US Biotechnology industry organization). These costs include substantial experimental work involved in the preparation of the data and dossiers required by regulatory authorities on which to base their decisions. Costs may vary depending on the demands of national regulatory systems and the novelty of the transformation, but they are likely to remain high, especially for first risk assessments of novel LMO products. The cost of deployment of an LMO in developing countries is very difficult to estimate.

It is not clear how the Centers intend to mobilize the human and financial resources necessary to move the present list of experimental LMOs into potential product development, and indeed which of the current transgenics under development are likely to pass the rigorous regulatory and technical hurdles and be released as promising new technologies that will help improve food security and create wealth in developing countries.

Recommendation 10 - Develop Plans for Preparing Risk Assessment Dossiers for Product Approval

The Panel recommends that, in relation to the LMOs presently under development by the CGIAR Centers and their partners, the Centers need to assess the feasibility of some or all of these becoming new products. Plans for preparing risk assessment dossiers should be put in place at the earliest opportunity and should include realistic estimates of the scientific and financial resources that will be required to develop the dossiers, on which regulatory authorities will base their decisions about future product approval.

4.7 Ethical Issues

Development of new biotechnologies in clinical medicine and human genetics has for a long time taken place within well-developed and continuously evolving ethical frameworks. Not only do these frameworks reflect the constantly changing morals and ethical standards of societies in different parts of the world, but they also have the practical value that, if developments conform to existing ethical codes, they are much more likely to be acceptable to both politicians and the public. Technology transfer is much more likely, investment can be recovered and new research and development is more likely to be funded. Biosafety is inherent in ethical codes in this area, with a well-informed precautionary approach being taken in developments such as virus-mediated vaccination, embryology and transplantation surgery. Ethical codes in these areas can provide a fundamental framework for biosafety, showing researchers where research and

development is currently permissible and where it may be undesirable, whilst at the same time providing sufficient freedom for scientific curiosity to be satisfied, and progress to be made.

Biotechnology in agriculture, forestry and aquaculture has no such history of development of ethical codes, although there has been increasing interest in the ethics of these technologies over the past two decades. Much of this debate has been concerned with the perceived morality of transgenic technology, but only recently has the issue been taken forward into practical ethics. For example, in 2001 the UK Advisory Committee on Releases into the Environment (ACRE) published guidance for researchers that recommended best practice in the construction of transgenic crops. This was in effect an attempt at developing an ethical code for the early stages in the development of an LMO and made some important recommendations on the selection of plants to be transformed, use of markers and gene restriction technologies. Although the guidelines were not mandatory, they laid down some limits of acceptability and therefore influenced biosafety. The UK guidelines are available at www.defra.gov.uk/environment/acre/bestprac/guidance/index.htm.

The CGIAR Centers have also produced guiding principles for research on GMOs that covers best practice in laboratories and for field trials, and has the elements of an ethical approach.

Because of the link between biosafety and ethics, the Panel asked the Centers questions about whether the Center and host country had developed ethical codes, and whether they believed such codes would be beneficial.

The responses to Section 6 of the questionnaire show that most Centers are aware of the need for ethical codes, but at the time of the survey there was a wide range of guidelines being used. Some Centers are actively using either CGIAR guidelines or "working principles" derived from them. Some Centers have formally adopted "Guiding principles on development and deployment of genetically engineered organisms" and others have developed their own "Biopolicy" or codes of best practice. Some have no codes, either because they have not yet developed them or they are not yet using gene technology to produce LMOs.

All Centers that responded to the questionnaire agreed that ethical codes were desirable "to avoid problems and gain public confidence", "…. to promote its mission whilst also ensuring the trust and confidence of the public" and "…. ethical guidelines would, if well conceived, be beneficial to the research process, ensuring that research is conducted in a responsible manner and the concerns/interests of all stakeholders are considered and addressed….". One view was that although ethical codes would be valuable, there was a risk that they could impede progress.

Recommendation 11 - Better Address Bioethical Issues

The Panel recommends that:

- Centers share their experiences and develop a unified approach to the production and maintenance of ethical codes covering research and development of LMOs.
- Centers identify key stakeholders both in their host countries, target countries and among donors and promote their involvement in developing and maintaining ethical codes.
- Each Center maintains a standing Ethics Committee advising the Biosafety Committee. We recommend that role of the Ethics Committee should be both to maintain ethical standards and codes used by the Center and to consider and address the ethical dimensions both of the

Center research program as a whole, and individual research projects. We recommend that the Committee has at least half of its members drawn from stakeholder bodies outside the Center, and reports directly to the Center Director General.

- Centers and CGIAR as a whole publicize their development and use of ethical codes aiming to increase public confidence in their research.

4.8 Implementation Plan

Several of the Centers and other stakeholders who commented on the Panel's draft report noted the desirability of the Centers and others involved in biosafety with the Centers and their research partners to come together to discuss the implications of the Panel's recommendations and how these may be implemented.

There may be an opportunity to conduct the workshop in association with the new Program on Biosafety Systems, which is being managed by ISNAR and IFPRI, and in which several other Centers are also participating. Other Centers may also be interested in hosting the workshop in 2004.

Recommendation 12 - Initiate a CGIAR System Biosafety Workshop to Plan a more Proactive, Research-based Approach to Biosafety by the CGIAR Centers

The Panel recommends that, in order to ensure that the results of the CGIAR investments in gene technology are able to be used with safety and confidence, the Biosafety Panel report and its recommendations be discussed at a workshop involving members of the CGIAR Science Council, the Biosafety Panel, representatives of the CGIAR Centers, their R&D partners and other stakeholders, including national regulators, policy makers, civil society, farmers and consumers. The purpose of the workshop would be to develop an implementation plan for a proactive, research based approach to biosafety by the CGIAR Centers and their partners.

ANNEX A

BIOSAFETY PANEL TERMS OF REFERENCE

CGIAR iSC Biosafety Study Panel on the Safe Use of Gene Technology and its Products

Summary Terms of Reference

The Panel, commissioned by the CGIAR interim Science Council (iSC), will undertake a study of biosafety policies and practices in the CGIAR System and make recommendations to the interim Science Council on future CGIAR policies and practices and the future CGIAR research agenda in relation to these issues. Specifically, the Biosafety Study Panel will assess and make recommendations in the following areas:

1. **Present Biosafety Policy and Practices:** Assess the present CGIAR policies and the policies and practices of the CGIAR Centers in regard to the safe use of gene technology and its products.
2. **Risk/benefit Analysis of Potential Products**: Identify potential near term products of gene technology developed by the CGIAR Centers and their research partners that are ready for evaluation and assess the plans of the Centers for undertaking such evaluations in partnership with their host countries and other collaborators.
3. **Case Studies:** Develop a suite of case studies that would serve as illustrations of the range of biosafety-related issues facing the CGIAR Centers and their partners in developing countries, and identify how these issues may be resolved. The case studies may include biosafety issues affecting the conservation of biodiversity, the development of new plant varieties to address biotic and abiotic stresses, the applications of gene technology to fish improvement and the development of new vaccines for the control of livestock diseases.
4. **Future CGIAR Research Agenda:** Make recommendations on the possible future research agenda and research strategies for the CGIAR Centers on biosafety related issues, whereby the Centers could contribute data to illuminate the biosafety debate, based on the comparative advantages of the Centers.
5. **Future CGIAR Policies and Practices:** Make recommendation to the Science Council on the possible future CGIAR policies and practices in biosafety to guide the Centers and their partners in the safe use of gene technology and its products. This will include advice on how the CGIAR System can continue to monitor developments in this fast changing field and have in place mechanisms (including the necessary institutional strengths) to ensure that the principles and practices of the Centers reflect current best practices and timely responses to emerging issues.

ANNEX B

BIOSAFETY PANEL MEMBERS CONTACT DETAILS

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ANNEX C

BIBLIOGRAPHY

Aldrich, M. (1997). Safety First: Technology, Labour and Business in the Building of American Worker Safety 1870-1939. The John Hopkins University Press, Baltimore, MD.

Baram, M. (2002). Biotechnology and Social Control. In Changing Regulation: Controlling Risks in Society. Kirwan, B., Hale, A. and A. Hopkins (Eds). Pergamon Press, pp.217-232.

Gibbons, M. (1999). Science's New Social Contract with Society. Nature 402 SUPP 2 December 1999: C81-C84.

ICSU 2003. New Genetics, Food and Agriculture: Scientific Discoveries-Societal Dilemmas. International Council for Science, Paris. www.icsu.org

Kapuscinski, A.R., R. M. Goodman, S.D. Hann, L.R. Jacobs, E.E. Pullins, C.S. Johnson, J.D. Kinsey, R. L. Kall, A. G.M. La Viña, M. Mellon and V.W. Ruttan. (2003). Making 'Safety First' a Reality for Biotechnology Products. Nature Biotechnology 21(6): 599-501.

Kapuscinski, A.R. (2003). From Reactive to Pro-active Biosafety: Science, Technology and Capacity Needs in Proceedings of the Norway/UN Conference on Technology Transfer and Capacity Building, June 23-27, 2003, Trondheim. P. Schei, O. Hokstad, F. Katerås and A. Lindgaard, (Eds). Norwegian Directorate for Nature Management and Norwegian Institute for Nature Research, in press.

Kirwan, B. (2001). Coping with accelerating socio-technical systems. Safety Science 37:77- 101.

McIntyre, G. R. (2000). Patterns of Safety Thinking. Ashgate Publishing, UK.

Scientists' Working Group on Biosafety. 1998. A Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms. Edmonds Institute, Edmonds, WA. 200 pp. + appendices. Downloadable at:
www.edmonds-institute.org/manual

Stern, P.C. and H.V. Fineberg, (Eds). (1997). Understanding Risk. National Research Council, National Academy Press, Washington, D.C.

ANNEX D

BIOSAFETY PANEL QUESTIONNAIRE TO CGIAR CENTERS

CGIAR iSC Secretariat, Rome
13 May 2003

Memo to CGIAR Director Generals

Re: CGIAR iScience Council Biosafety Study

Dear Colleague,

Over the past decade developments in biotechnology, particularly applications of gene technology, have shown promise for improving agricultural productivity and animal health. Most CGIAR Centers have adopted the use of gene technology not only in their research but also in the transfer of technologies to address biotic and abiotic stresses in their respective geographic regions.

In handling gene technology and its products, it has become important that biosafety issues are considered. Biosafety has emerged as one of the key issues in the transfer of research and development of transgenic organisms to beneficial use. It is in this respect that the CGIAR has requested the interim Science Council to carry out a study on current biosafety policies and practices of the CGIAR Centers and future needs. The interim Science Council has therefore appointed a Panel to conduct out this strategic study. The Panel is meeting this week in Rome. A list of Panel members is attached.

It is very much in the interests of all CGIAR Centers to participate in this study, which aims to make recommendations for identifying and sharing best practice in biosafety across the Centers. Based on the information obtained during the study, the Panel may also make recommendations for future biosafety-related research and further development of policies, procedures and practices. At this stage the study is only concerned with the biosafety of transgenic organisms (those defined as living modified organisms-LMOs-in the Biosafety Protocol of the Convention on Biological Diversity).

To facilitate this study the Panel has prepared the attached questionnaire for data collection from Centers, which in addition to case studies and other relevant documentation will form the basis upon which the Panel's recommendations will be made.

The participation of you and your colleagues in completing the questionnaire and providing any other relevant information on biosafety policies and practices in your Center would be greatly appreciated. We would prefer that all information is submitted to the Panel in electronic form.

Please answer those parts of the questionnaire that are relevant to activities within your Center or within joint projects involving your Center.

Information submitted to the Panel will be treated carefully and any confidentiality identified by Centers will be respected. The study Panel will be preparing a draft report for the iSC, an early draft of which will be sent to Centers for comment.

This study will be a consultative process between the Panel and Centers. To facilitate this process, we would like you to identify a key contact within your Center, and advise the Panel's Scientific Secretary, Gabrielle Persley, of their name and contact details. Gabrielle can be contacted at g.persley@doylefoundation.org and by Tel/fax at 44 141 9423331.

It would be very much appreciated if your completed questionnaire could be sent electronically to the Panel by June 6, at the latest. Please send the reply to Gabrielle Persley with a copy to Amir Kassam at the iSC Secretariat (amir.kassam@fao.org) and the contact Panel member for your Center, who will be in contact with you in the near future.

Should you have any immediate queries please contact either myself or Gabrielle.

The Panel looks forward to working with you in this important area, and thanks you in anticipation of your cooperation.

Yours sincerely

Brian Johnson

Chair
CGIAR iSC Biosafety Panel

May 13 2003
CGIAR interim Science Council Biosafety Study 2003

Biosafety Panel Questionnaire for CGIAR Centers

1. Biosafety Case Studies

In order to illustrate some practical examples of how biosafety is conducted within the CGIAR Centers and their host countries the Panel would like to present some 'biosafety case studies' in the report to the CGIAR Science Council. Please choose at least one and no more than three recent examples appropriate to the Center from the list below and attach a summary of the biosafety procedures, protocols and practices to which the LMO has been subjected during its development. The case studies should be no more than 10 pages. The full risk assessment may be included as an annex.

The following details should be included in the case history:

- Details of biosafety measures applied both in containment and in the field; and how they were/are audited and monitored;
- Dates of applications and consents issued;
- Identification of committees and regulatory laws/statutes involved;
- Summary of the risk assessment conducted:

a) Identified hazards and methods/information sources used to identify them;
b) Assessed risk of each identified hazard and methods/information sources used to assess them;
c) Final risk decision;
d) Summary of monitoring plan for post-release (if there is one), including what it is designed to monitor and methods;
e) Experience to date with implementation of monitoring.

- Future stages in the development and monitoring program for the LMO in question and probable timescales.

Other Issues to be Addressed in Case Studies

The issues to be addressed in biosafety risk assessments are described further in Annexes 1 and 2 attached to this questionnaire. Annex 1 deals with issues during the developmental stages of living modified organisms (LMOs). Annex 2 deals with issues associated with risk assessment of LMOs at the commercial release application stage. It would assist the Panel's understanding of biosafety policies and practices at the CGIAR centers by consideration of how the relevant issues are addressed in specific cases.

Possible Topics for Illustrative Biosafety Case Studies

- Transgenic crops for release in centers of origin and sexually compatible crop biodiversity. (Please include assessment of potential impacts on the CGIAR gene banks)
- Bt maize
- Herbicide tolerant rice for release in Asia and/or the Americas

- Salt and drought tolerant plants (e.g. cereals, forage crops and grasses)
- New vaccines (e.g. for East Coast Fever in cattle in Africa).
- Transgenic fish for release in Asia and/or Africa
- Vegetatively propagated crops such as banana, cassava, potato or sweet potato with pest or disease resistance

If no appropriate case study appears on the above list, please include a recent example selected from the experience of the Center.

2. Biosafety Policy and Practices

2.1. Does your Center have a specific framework for biosafety policy and practices? Please attach a copy of the present policy and associated biosafety guidelines in use at the Center.

2.2. Who developed the framework?

- Center staff alone?
- Center staff in consultation with CGIAR secretariat?
- Center staff in consultation with host country regulators?
- Other – please specify

2.3. Briefly describe the fields of expertise in science and policy that were represented by the entire group who developed the policy.

2.4. Does your host country have a framework for biosafety policy/regulation?

If not, what is the present status of development of such a framework.

2.5. Does the host country have a framework for biosafety practices, such as for conducting scientific biosafety research and assessments? If not, what is the present status of development of such a framework.

2.6. In your view do your biosafety policy and practices meet/fall short of/exceed the biosafety requirements of the host country? Please explain.

2.7. Do your biosafety policies and practices meet/fall short of/exceed the host country's capacity for developing or implementing biosafety policy and practices? Please explain.

2.8. Have you encountered any problems in dealing with host country policies and practices?

2.9. Please give brief details of any current biosafety-related research conducted by the Center, or in partnership with others.

2.10. What do you see as your future biosafety-related research needs?

3. Host Country and Center Biosafety Committees

3.1. Describe whether applications for LMO use for release into the environment (that involve your CGIAR Center) go through a review or approval process by host country and Center safety committees. What is/are the committee(s) called and where is/are it/they situated?

3.2. Are risk assessments submitted to a Committee(s) within your center prior to submission to the host country regulatory system? If not, please describe the system in place.

3.3. Who does risk assessment studies? The developer of LMOs/An independent agency identified by the Committee/ Any other (specify)?

3.4. Are these findings open to public scrutiny? If so how is this done?

3.5. Is legal consent from the committee(s) needed for laboratory containment or experimental (confined) field trials to take place, or is it an advisory committee(s)?

3.6. Please attach a list of the institutions and fields of scientific, technical, and policy expertise represented on the host country safety committee(s). Please indicate the proportion of the committee that is made up of people employed by or associated with your Center? Include reference to:

- Center staff
- Independent members
- Host country regulators
- Civil society representatives/NGOs

3.7. What proportion of the current biosafety committee(s) has direct or indirect commercial interests in biotechnology companies?

3.8. Does the committee(s); (a) review applications for, and (b) inspect or audit approved projects for biosafety in containment situations such as Center laboratories?

3.9. Does the committee(s) (a) review applications for and (b) inspect or audit approved projects in confinement situations, such as field trials involving work supported by the CGIAR Center?

4. Effectiveness of the risk assessment framework

4.1. Is a formal risk assessment prepared for all potentially useful LMOs before field trials/ commercial release? If not please explain why.

4.2. Is a monitoring plan to verify conclusions from the risk assessment and identify unforeseen problems put in place before the release takes place?

What entities are responsible for carrying out the monitoring plan? How is the monitoring paid for?

5. Risk/benefit Analysis of Potential Products:

5.1. Is there a formal framework for risk/benefit analysis of LMOs in place at your Center?

5.2. If yes, please describe the approach of your risk/benefit analysis framework, such as how risk and benefit components are identified, methodologies used. If possible please supply documentation used in your Center.

5.3. Is a formal risk/benefit analysis undertaken for each potentially useful LMO?

5.4. If not, in your view would your Center be able to conduct such an analysis?

5.5. In your view would such analyses be worthwhile? Why?

6. Code of Ethics

6.1. Is there a code of ethics that covers development of LMOs within the Center (and/or host country)?

6.2. If so, please attach a copy of the code or summarize what topics the code covers.

6.3. If not, does your Center believe that such a code might be either beneficial or detrimental to progress and why?

7. Future developments

7.1. Please list the near term products of gene technology at your Center that will be ready for safety evaluation for field trials within the next five years, including those that have already been evaluated for safety but have not yet gone to field trials.

7.2. Please attach one or two summary examples of the proposed safety assessments for these products, if available.

7.3. In your experience how long does it take to prepare a safety assessment for experimental field release (including collecting and evaluating biosafety data)?

- Between one and six months
- More than six months
- More than one year

7.4. What are the constraints for the Center in addressing biosafety issues and conducting risk assessments for LMOs?

7.5. Is there any other information you consider may be relevant to our understanding of biosafety and risk assessment within your Center and host country?

Attachment
Annex 1 - Biosafety Case Studies: Issues to be Addressed
Risk Assessment and Monitoring Issues in Developmental Stages of an LMO

1. Development of LMOs in Laboratories

1.1. **Within laboratories of your Center,** are there formal biosafety guidelines for the construction of LMOs intended for commercial use? If so, please attach a copy.

1.2. To what extent do these guidelines cover:

- Selection of organisms to be transformed
- Choice of marker genes
- Choice of promoters
- Characterization of transformation (e.g. copy numbers, insertion site(s), flanking sequences, integrity of insertions, stability of insertions)
- Preparation and supply of diagnostic primers (to identify the transformation)
- Genetic isolation/restriction technologies for biosafety purposes
- Other strategies for biological confinement of the LMOs where applicable, (e.g. sterilizing fish via changes in ploidy number).

1.3. Are diagnostic primers for LMOs made available to host country regulators and published worldwide? Please list a few examples of print and/or electronic (Internet) publishing of primers.

1.4. Is there a formal system of bio-containment (for labs) operating within the Center? If yes, briefly describe the system in relation to this case study and describe how bio-containment was monitored.

2. Field Trials for LMOs

Small-scale experimental trials (e.g. less than 50 ha total for annual crops; confined fish tanks or ponds at a research station)

2.1. Where are experimental field trials held?

- At the Center
- On land controlled by the Center
- On land controlled by private farmers
- Other

2.2. Is a register of field trials maintained?

2.3. What data/information are recorded within the register? Please list the categories.

2.4. How are data held (electronically, paper)?

2.5. Where are data held (Center, host country regulatory authorities)?

2.6. Is there a biosafety protocol (i.e. a set of bio-confinement measures plus the chain of responsibility for achieving the measures) in place for field trials?

2.7. Does the protocol cover:

- Measures of physical, mechanical or biological confinement of the LMO from non-LMO crops and wild or weedy relatives (e.g. planting separation distances from conventional crops; screens and other mechanical barriers to prevent escape of fish LMO from testing tanks.)
- Emergency procedures for natural and human-caused breakdowns in confinement measures
- Post-harvest monitoring

2.8. How, if at all, is gene flow monitored during small-scale field trials? Does this include gene flow to conventional crops, wild relatives, weedy relatives?

2.9. How, if at all, are impacts of the LMO on biodiversity of flora and fauna in the field trial area (farm field, fish pond area) and readily accessible ecosystems monitored?

2.10. Are these data available for public scrutiny and if so how is this achieved?

3. Extended (Commercial-scale) Trials

3.1. How is the decision made to move from experimental trials to 'commercial-scale' field trials?

- By a committee within the Center?
- By a host country independent committee?
- Joint decision by the Centers and the host country
- Other

3.2. Where are extended field trials held?

- On production-scale facilities (e.g. farm fields, fish ponds) owned and managed by private farmers
- On production-scale facilities managed by the state
- On experimental fields of Agricultural Universities/research organizations
- All of the above
- Other – please specify

3.3. What is monitored and evaluated during extended trials? For example:

- Agronomic characteristics (yield, disease resistance, growth etc)
- Gene flow (pollen, seeds, whole organisms)
- Impacts on biodiversity (where, how?)
- Impacts on non-biotic environment (water, soils)
- Potential socio-economic impacts
- Other factors, including those listed in Annex 2 – please specify

3.4. What (if any) **post-harvest monitoring** is done after commercial-scale trials?

Annex 2 - Identification of Hazards and Exposure Associated with LMOs at Commercial Release Developmental Stage

How does the Center biosafety framework identify the relevant potential **direct and indirect hazards** to address in a **risk assessment** for commercial release in your specific LMO case(s)? How does it assess the risk of each identified hazard? In responding to this question, consider the following examples of issues, recognizing that this list is not comprehensive nor appropriate to each case, but rather to help you develop a response to Question 1 on case studies.

1. Direct Risks from LMOs

1.1. **Gene flow** from pollen or other propagules (seed, whole organisms, fragments of organisms) from crop to crop and to wild relatives (including fish to fish, tree to tree etc).

- Assessment of potential **rates** of gene flow under different environmental conditions in which the LMO is to be deployed (prior to release into the environment
- Assessment of potential **impacts** of gene flow (e.g. weediness and potential impacts on fitness).
- Assessment of potential **inadvertent gene stacking** (due to gene flow from two or more lines of LMO).
- Assessment of potential interactions of new-release LMO with LMOs that have already been released.

1.2. Assessment of Toxicity/Allergenicity/Nutritional value of the LMO and its derivative foods to humans.

- Hazard of altered biochemical content of the LMO that could harm humans or wildlife. Could include assessment of potential toxicity to wildlife likely to be in contact/ feeding on the LMO
- Methodologies and types of data used to make these assessments (e.g. by animal feeding trials/ molecular characterization etc).

2. Indirect Risks from LMOs

- Assessment of potential **changes in management** of the LMO: how the LMO might change crop/organism management (e.g. pesticide use, fertilizer use, cultivation methods and timing, pollution load from fish farm effluent).
- Assessment of potential **changes in range/substitution.** How introduction of the LMO might change the geographic range of cropping or how introduction of the LMO might substitute for existing crops (or fish/trees etc).
- Assessment of the potential **impacts on abiotic resources (e.g. water, soils)** within the intended release area.
- Assessment of potential **socio-economic changes.** Likely socio-economic impacts of the introduction of the LMO.