

Workshop
on
Biosafety Regulations for Transgenic Crops
and the Need for Harmonizing them
in the Asia-Pacific Region

31 July – 2 August 2006



HIGHLIGHTS AND RECOMMENDATIONS



Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB)

C/o ICRISAT, NASC Complex, Dev Prakash Shastri Marg, Pusa Campus
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International Crop Research Institute for the Semi-Arid Tropics

ICRISAT, Patancheru 502 324, Andhra Pradesh, INDIA

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Organized by

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New Delhi-110 012, INDIA

International Crop Research Institute for the Semi-Arid Tropics
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Foreword

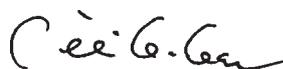
The Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB) was established in 2003 under the umbrella of the Asia-Pacific Association of Agricultural Research Institutions (APAARI), an apolitical regional forum that promotes and strengthens activities of the national agricultural research systems (NARS) in research and development in partnership with several regional and international organizations. APCoAB, one of the regional programs of APAARI, has the mission “to harness the benefits of agricultural biotechnology for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific region”.

In keeping with the need for the safe application of biotechnology, several countries in the Asia-Pacific region have evolved biosafety regulations and guidelines for research, development and transboundary movement of genetically modified (GM) crops and their products. Harmonizing regulations at the regional level and building capacities that are critical for their coordinated implementation are vital for transferring the benefits of biotechnology to farmers and consumers in the region.

In this context, a workshop on “Biosafety Regulations for Transgenic Crops and the Need for Harmonizing them in the Asia-Pacific Region” was organized by APCoAB in collaboration with the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) from 31 July to 2 August 2006 at ICRISAT, Patancheru, India, involving 30 participants and observers from 12 countries of the region. This publication is an outcome of the discussions held during the workshop, where important recommendations on priority areas for harmonization, capability building and future strategies were made.

We are thankful to the participants and resource persons whose contributions ensured the workshop’s success. We appreciate the support provided by Dr. Kiran Sharma, Principal Scientist, ICRISAT, Dr. Ravi Khetarpal, Head, Plant Quarantine Division, National Bureau of Plant Genetic Resources (NBPGR), New Delhi and Dr. T.V. Ramanaiah, Director, Department of Biotechnology, Government of India, (DBT), in organizing the program and conducting the proceedings. We hope that the recommendations of the workshop will be useful for policymakers, research managers,

researchers and the industry in developing appropriate policies and programs that synergize regional cooperation for enhanced crop productivity, greater food security and poverty alleviation, while addressing the concerns of biosafety and environmental protection.



William D. Dar
Director General,
ICRISAT



Raj Paroda
Executive Secretary,
APAARI

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Acronyms

APAARI	Asia-Pacific Association of Agricultural Research Institutions
APCoAB	Asia-Pacific Consortium on Agricultural Biotechnology
CBD	Convention on Biological Diversity
COP-MOP	Conference of the Parties serving as Meeting of the Parties
CPB	Cartagena Protocol on Biosafety
CSO	civil society organization
DBT	Department of Biotechnology, Government of India
GM	genetically modified
GMO	genetically modified organism
ICRISAT	International Crop Research Institute for the Semi-Arid Tropics
IPR	intellectual property rights
ISAAA	International Service for the Acquisition of Agri-biotech Applications
LMO	living modified organism
NARS	national agricultural research systems
NBPGR	National Bureau of Plant Genetic Resources
NNP	National Nodal Point
WTO	World Trade Organization

Biosafety Regulations for Transgenic Crops and the Need for Harmonizing them in the Asia-Pacific Region

Introduction

Biotechnology offers exceptional opportunities to meet the growing needs of food and feed security by enhancing productivity, profitability and environmental sustainability of farming systems. The rapidly increasing area being covered by genetically modified (GM) crops in China, India, Iran and the Philippines signifies that such opportunities are being realized even in the developing countries of Asia-Pacific. Along with, it is also being recognized that the application of genetic modification technology and the use of GM products must be accompanied by systematic assessment of their potential impact on food and feed safety and safety of environment. Accordingly, adoption of appropriate biosafety measures, including development and implementation of biosafety regulations, has been a high priority for countries applying biotechnology for agricultural research and development.



Dr. Raj Paroda, Executive Secretary, APAARI and Dr. Rex Navarro, Director of Communications, ICRISAT conducting a session of the workshop

Recognizing the significance of biosafety regulations for harnessing the benefits of biotechnology, Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), under the umbrella of Asia-Pacific Association of Agricultural Research Institutions (APAARI), has initiated efforts towards harmonization of biosafety regulations and capacity building among the developing countries in the region. As a first step, APCoAB organized a three day regional workshop on “Biosafety regulations for transgenic crops and the need for harmonizing them in the Asia-Pacific region”, in collaboration with International Crop Research Institute for the Semi-Arid Tropics (ICRISAT) in Patancheru, Andhra Pradesh from 31 July to 2 August, 2006. The objective of the workshop was to familiarize the national stakeholders of Asia-Pacific countries with the developments on biosafety regulations in the region and to jointly identify areas of future cooperation, especially in the context of harmonization of biosafety regulations for the facilitated exchange and trade of transgenic crops.

Thirty participants and observers including crop biotechnology experts and representatives of Convention on Biological Diversity (CBD) National Focal Points on Biosafety from 12 countries: Bangladesh, China, India, Indonesia, Iran, Nepal, Malaysia, Papua New Guinea, the Philippines, Sri Lanka, Thailand and Vietnam attended the workshop. The workshop was organized in the following five sessions:

- I. Inaugural session
- II. Keynote lectures
- III. Country reports on biosafety regulations and guidelines
- IV. Group discussions on harmonization of biosafety regulations
- V. Plenary session

Detailed program and list of participants are given in Annexures I-III.

Inaugural Session

In his welcome address, Dr. J. L. Karihaloo, Coordinator, APCoAB gave a brief introduction of APAARI and the genesis of APCoAB. He highlighted that application of recombinant DNA technology and the use GM products must be accompanied by systematic assessment of potential impacts on food and feed safety and safety of environment. He mentioned that some countries of Asia-Pacific, viz. China, India, Iran and the Philippines, are in the forefront of adoption of genetic modification technology at commercial scale. There is, however, a need to harness regional capabilities for developing comprehensive national capacity to comply with the Cartagena Protocol on Biosafety (CPB). In keeping with these needs, the workshop was being organized to review the status of biosafety regulations and framework in

the Asia-Pacific region, identify priority areas for addressing biosafety issues at the regional level, and to develop operational modalities for regional cooperation.



Inaugural session in progress



Dr. William Dar, Director General, ICRISAT delivering the inaugural address

Dr. William Dar, Director General, ICRISAT in his inaugural address mentioned that countries in Asia and the Pacific have made great strides at reducing poverty, ensuring food security and improving human development. Despite the substantial progress, many countries still remain mired in poverty. The potential contribution of biotechnology to sustainable agriculture is truly great, but the introduction of new transgenic varieties, like any new variety, in an ecosystem deserves careful oversight and monitoring. Countries in Asia and the Pacific must continue to develop and perfect existing regulatory instruments on par with related international agreements in order to prevent or minimize possible risks arising from the use and handling of transgenic products. There is great need to inform, coordinate training and research, and respond to regional opportunities for interactions. Harmonizing biosafety regulations in the Asia-Pacific region could enhance collaboration between the countries on common problems in the region, thus improving the problem-solving capacity at the institutional, national and regional levels.

Technical Session I: Keynote Lectures

The session was chaired by Dr. David Hoisington, Global Theme Leader, GT Biotechnology, ICRISAT. Three lectures were delivered in this session.

Dr. Kiran Sharma, Principal Scientist, ICRISAT in his lecture “Transgenic crops: Application and status of commercialization” gave a detailed account of transgenic technology for crop improvement, global status of transgenic crops, current status of transgenic research and development at ICRISAT, biosafety issues and the need for developing partnerships for addressing these issues. He mentioned that by 2025, with the anticipated global population of 8 billion, world food requirement would double. Future breakthroughs will depend on creating additional variability and introduction of desirable genes from related or unrelated species through biotechnological

interventions. Rapid advances in genetic modification technology have resulted in incorporation of a diverse range of desirable genes in 57 field crops, fruits, vegetables and other economically important plants. Dr. Sharma opined that these and other genetically modified crops have the potential to overcome major constraints in crop productivity.

Dr. Ravi Khetarpal, Head, Plant Quarantine Division, National Bureau of Plant Genetic Resources (NBPGR), New Delhi, elaborated on environmental and health related concerns in his lecture on “Biosafety issues of transgenic crops”. He provided detailed information on gene flow in some important crop species and the development of invasiveness in crop related weedy species. He pointed to the apprehensions about the evolution of super pests and super diseases in response to pest and disease resistance genes incorporated in transgenic crops. Horizontal transfer of marker genes from plants to microorganisms rendering them resistant to common antibiotics is another highly debated issue. Dr. Khetarpal emphasized that transgenic crops should be grown with appropriate refugia and monitored for environmental impact. Food and feed allergenicity and toxicity concerns need to be addressed with appropriate scientific studies. Dr. Khetarpal highlighted that so far no internationally agreed standards have been finalized for risk assessment and management of living modified organisms (LMOs). He also pointed to the conflict between obligations for compliance to the CPB and World Trade Organization (WTO).

Dr. Ranjani Warriar, Additional Director, Ministry of Environment and Forests, Govt. of India, made a presentation on “Cartagena Protocol on Biosafety”. Dr. Warriar traced the development of the CPB and explained its various elements and their implications in transboundary movement of the LMO. She elaborated on the Precautionary Principle aspects of the CPB whereby lack of scientific certainty regarding potential adverse effects of a given LMO cannot prevent a party from taking its own decision on the import of LMOs. She also highlighted the importance of the Biosafety Clearing House of the CBD as a focal point of scientific information on biosafety aspects of LMOs. Detailed explanation of decision procedure, risk assessment, handling, transport, packaging and verification as given in the CPB, was provided by Dr. Warriar. The stand taken by developing countries and the decisions taken in COP-MOP meetings held in Brazil in March 2006 on Article 18 regarding handling, transport, packaging and identification of LMOs were also elaborated.

During the discussion, following issues emerged:

- The importance of gene flow as a biosafety issue depends upon several factors; the transgene, breeding system of the crop, availability of compatible wild species and crop ecology.

- Compliance with the CPB has been relatively slow. However, since most of the Asia-Pacific countries are party to the CPB steps towards compliance need to be taken. The countries could benefit from mutual expertise and experience.
- Apart from biosafety issues, intellectual property rights (IPR) issues of transgenes and the crop varieties that carry them also need attention as they can hinder the free use of technology for the benefit of farmers and other stakeholders. Developing own genes, sharing material as International Public Goods and developing appropriate modalities of benefit sharing are some of the options available for dealing with IPR issues.

Technical Session II: Country Reports on Biosafety Regulations and Guidelines

This session comprised one keynote lecture and 12 Country Report presentations.

Dr. Behzad Ghareyazie, Member, Higher Council of Biotechnology, Iran delivered keynote lecture entitled “Biosafety at international agreements”. The lecture provided a comprehensive coverage of various international agreements including the trade aspects of the CPB and standard setting organizations recognized by WTO. He



Participants attending the workshop

highlighted the importance of biotechnology in increasing crop productivity and improving human and animal health citing achievements made by Iran and other national and international organizations. Dr. Ghareyazie emphasized the need to address the biosafety issues by following the standard norms. While giving details of various food safety protocols developed by international organizations, he pointed out that there are no internationally approved norms of safety assessment.

Country reports were presented by Mr. Mohammed Solaiman Haider (Bangladesh), Dr. Li Junhong (China), Mrs. Lu'lu' Agustina (Indonesia), Dr. T.V. Ramanaiah (India), Dr. M.A. Malboobi (Iran), Dr. D.K.N.G. Pushpakumara (Sri Lanka), Dr. Vithet Srinetr (Thailand), Mr. Phanindra Gautam (Nepal), Dr. A. Ramakrishna (Papua New Guinea), Dr. Reynaldo V. Eborra (the Philippines), Dr. Nagulendran Kangayatkarasu (Malaysia) and Dr. Nguyen Van Van (Vietnam). The status of the countries on policy, research and development aspects of biotechnology and biosafety as detailed by the above speakers is summarized below.

National Policy on Biotechnology

- All the participating countries appreciate the importance of biotechnology in agriculture and the same is reflected in their national policies, strategic plans and programs.

Regulatory Status

- Four countries, viz. China, India, Indonesia and the Philippines have legislations with rules and guidelines in place for addressing biosafety issues.
- Five countries, viz. Iran, Malaysia, Papua New Guinea, Thailand and Vietnam have drafted legislations that are at different stages of approval by the respective governments.
- In Sri Lanka and Thailand, existing legislations on environment and quarantine aspects also cover biosafety issues to a great extent.
- In Bangladesh, biosafety guidelines were approved in July 2006 whereas the guidelines drafted in Sri Lanka and Nepal are yet to be approved.

International Obligations

- All the 12 countries are members of the CBD and, excepting Papua New Guinea, Thailand and Vietnam, all have signed the CPB. However, all except Nepal and the Philippines* have ratified the CPB.
- Excepting Iran and Vietnam, all the countries are members of WTO.

*The Philippines ratified the CPB on 5 October 2006

Status of Research, Field Cultivation and Import of GM Crops

- Apart from research, large-scale field cultivation of GM crops is being undertaken in China, India, Iran and the Philippines.
- Bangladesh and Malaysia have undertaken a few research programs on GM crops. Bangladesh has also imported some GM crops for research purposes.
- In Nepal and Vietnam, GM crops are neither cultivated nor allowed for import. Also, there are practically no programs on research and development of GM crops.
- Import of GM products for consumption is being done by China, Indonesia, Malaysia, Papua New Guinea, the Philippines and Thailand.
- In Iran, no special approvals are required to import GM crops.
- Some countries suspect that there has been illegal/uninformed import of GM crops/crop products but the same could not be verified due to lack of facilities and expertise.

Risk Assessment and Management

The expertise for risk assessment and risk management varies across the countries of Asia-Pacific. China, India, Iran, Indonesia and the Philippines seem to have a good capacity in these areas.

Capacity Building Requirements

All the countries emphasized the need for capacity building in areas of risk assessment and management, and detection procedures and protocols for transgene



Participants attending the workshop

testing. Other capacity building requirements highlighted during the workshop were: post-release monitoring, socio-economic assessment, biosafety database development and exchange, stakeholders' awareness, and addressing liability, redressal and IPR issues.

Plenary Session

The session was chaired by Dr. Raj Paroda, Executive Secretary, APAARI and co-chaired by Dr. Rex Navarro, Director of Communication, ICRISAT. The session began with a welcome to Chair and Co-Chair, which was followed by presentation of proceedings of each session. Dr. J. L. Karihaloo presented the draft recommendations for discussion which were approved after incorporating the agreed amendments.

In his remarks, Dr. Rex Navarro highlighted the importance of communication in creating public awareness and correct opinion among various stakeholders about genetic modification technology, GM crops and the biosafety issues related to them. He mentioned that effective information dissemination could be done through networking with scientists, research organizations, civil society organizations (CSOs), farmer groups and the media. Dr. Raj Paroda, in his Chairman's remarks, expressed satisfaction that the workshop had brought together several stakeholders in agricultural biotechnology and biosafety including national biosafety focal points of the Asia-Pacific region, DBT, ICRISAT and ISAAA. Public awareness needs to be given high priority to dispel misapprehensions about biotechnology and provide correct science-based information. He suggested creation of national forums on the pattern of APCoAB, which would work as neutral agencies for creating public awareness about agricultural biotechnology in the region.



Participants visiting ICRISAT facilities

Recommendations

Preamble

The workshop recognizes that modern biotechnology is a powerful tool for overall agricultural growth and can help in alleviating hunger and malnutrition, reducing pesticide application and their residues in food, minimizing environmental pollution, conserving and enhancing genetic diversity and also reducing the cost of pharmaceuticals. At the same time, the application of modern biotechnology in agriculture has given rise to concerns about safety of the transgenic crops and their products for environment and use as food, feed etc. Hence, there is a need for developing appropriate measures for safe application of biotechnology in the Asia-Pacific region as contemplated under the Cartagena Protocol on Biosafety.

The workshop also felt that enhancement of domestic capabilities through collaborative upstream research activities on development of transgenics for public good should be given due importance in accordance with specific national needs.

Recommendations

- 1. Harmonization of regulations:** There was a consensus that the countries in the Asia-Pacific region should move towards identifying major issues that need harmonization at the regional level, while recognizing that each country would have their own rules and regulations on the subject. Such a process would also provide opportunities to better understand the biosafety systems prevailing in the region, help the countries in formulating their regulations in keeping with overall regional needs, and eventually facilitate transboundary movement of transgenic crops and their products.
- 2. Capacity building:** The workshop strongly felt the need for strengthening capacity building efforts (training, sharing of knowledge/expertise etc.) that are critical for harmonizing the procedures and protocols, as recommended under para **1** above. The prioritized areas for capacity building are:
 - 2.1 Risk assessment and management.
 - 2.2 Sampling and GMO detection.
 - 2.3 Communication of science-based information on biosafety issues of transgenics.
 - 2.4 Developing suitable mechanisms for information sharing.

3. Other issues: Other issues considered appropriate for needed action are:

- 3.1 Developing common strategies for risk assessment and management in the Asia-Pacific countries.
- 3.2 Establishing gene bank of transgenic crops and sharing of materials for the mutual benefit of countries in the region.
- 3.3 Detecting adventitious presence of transgenic seeds in the national gene banks.

4. Future strategies: It was felt that more futuristic role will be needed such as:

- 4.1 Intensifying national and regional efforts to follow up on the above-identified recommendations.
- 4.2 Catalyzing the countries in the region interested in harnessing the benefits of biotechnology to put in place the national biosafety regulations and associated systems.
- 4.3 Developing collaborative projects on areas of mutual interest, including biosafety data generation and validation.
- 4.4 Developing common minimum biosafety data requirements needed for developing bilateral/multilateral agreements for future cooperation.

5. Future role of APCoAB: The workshop participants were unanimous that APCoAB, being a timely initiative at the regional level, involving all stakeholders, should take proactive role in the following:

- 5.1 All available information on biosafety regulations in different countries of the region be compiled and put at one place for dissemination through APCoAB website or on CD to be distributed widely, especially to those National Agricultural Research Systems (NARS) who are in the process of putting such legal instruments in place. APCoAB could develop broad guidelines for the benefit of developing NARS for framing their biosafety rules and procedures.
- 5.2 Creating a network for information sharing on agricultural biotechnology and biosafety in the Asia-Pacific region with the support of National Nodal Points (NNPs). To begin with, the participants of the workshop representing respective countries could act as NNPs and help in getting concerned authorities/institutions involved in moving forward in this regard.
- 5.3 Facilitate organization of group meetings/workshops/seminars/training programs and generation of well-conceived public opinion on biosafety in the region.
- 5.4 Facilitate development of regional project proposals addressing the identified priority areas, for suitable donor funding.

Annexure I

Workshop on Biosafety Regulations for Transgenic Crops and the Need for Harmonizing them in the Asia-Pacific Region

Program

31 July 2006

09:00 - 09:30 **Registration**

Inaugural Session

Chairman: Dr. William Dar

09:30 - 09:45	Welcome and introduction to the workshop	<i>Dr. J.L. Karihaloo</i>
09:45 - 09:50	Introduction of participants	
09:50 - 10:10	Chairman's address	<i>Dr. William Dar</i>
10:10 - 10:15	Vote of thanks	<i>Dr. Kiran Sharma</i>
10:15 - 10:45	Coffee break and group photograph	

Technical Session I: Keynote lectures

Chairman: Dr. David Hoisington

Rapporteur: Dr. A. Ramakrishna

10:45 - 11:30	Transgenic crops: applications and status of commercialization	<i>Dr. Kiran Sharma</i>
11:30 - 12:15	Biosafety issues of transgenic crops	<i>Dr. Ravi Khetarpal</i>
12:15 - 13:00	Cartagena Protocol on Biosafety	<i>Dr. Ranjani Warriier</i>
13:00 - 14:00	Lunch break	

14:00 - 17:00 **Technical Session II: Country reports on biosafety regulations and guidelines**

Coordinator: Dr. Ravi Khetarpal

1 August 2006

Technical Session II continued: Country reports on biosafety regulations and guidelines

09:30 - 10:15	Keynote lecture: Biosafety at international agreements	<i>Dr. Behrad Ghareyazie</i>
10:15 - 10:30	Coffee break	

10:30 – 12:00 Country reports

Technical Session III: Group discussion on harmonization of biosafety regulations

Coordinator: Dr. J.L. Karihaloo

12:00 – 13:00 Discussion on:

(i) Regulatory mechanisms

13:00 – 14:00 Lunch break

14:00 – 18:00 **Technical Session III continued: Group discussion on harmonization of biosafety regulations**

Discussion on:

(ii) Capacity building

(iii) Information sharing

(iv) Future strategies for regional cooperation

19:30 Invited dinner

2 August 2006

08:30 – 10:30 **Visit to ICRISAT biotechnology laboratories, Agri-Science Park and greenhouse/quarantine facilities** *Dr. Kiran Sharma*

10:30 – 11:00 Coffee break

11:00 – 12:30 **Plenary Session**

Chairman: Dr. Raj Paroda

Co-Chair: Dr. Rex Navarro

Summary of workshop proceedings

Dr. J.L. Karihaloo

Presentations of recommendations of sessions

Rapporteur/Coordinators

Chairman's address

Dr. Raj Paroda

Vote of thanks

Dr. J.L. Karihaloo

12:30 – 13:30 Lunch

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Asia-Pacific Consortium on Agricultural Biotechnology

The Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB), was established in 2003 under the umbrella of the Asia-Pacific Association of Agricultural Research Institutions (APAARI) — an initiative of Food and Agriculture Organization that has been promoting appropriate use of emerging agri-technologies and tools in the region.

APCoAB's mission is "To harness the benefits of agricultural biotechnology for human and animal welfare through the application of latest scientific technologies while safeguarding the environment for the advancement of society in the Asia-Pacific Region".

APCoAB's main thrust is:

- To serve as a neutral forum for the key partners engaged in research, development, commercialization and education/ learning of agricultural biotechnology as well as environmental safety in the Asia-Pacific region.
- To facilitate and promote the process of greater public awareness and understanding relating to important issues of IPR's *sui generis* systems, biosafety, risk assessment, harmonization of regulatory procedures, and benefit sharing in order to address various concerns relating to adoption of agricultural biotechnology.
- To facilitate human resource development for meaningful application of agricultural biotechnologies to enhance sustainable agricultural productivity as well as product quality, for the welfare of both farmers and consumers.

