

CONFERENCE ON
NEW BIOTECHNOLOGY FOOD AND CROPS: SCIENCE,
SAFETY AND SOCIETY
BANGKOK, THAILAND, JULY 10-12, 2001.

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Organisation, the United Nations Environment Programme, the Convention on
Biological Diversity, and the Government of Thailand*

RAPPORTEURS' REPORT

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This rapporteurs report reflects the discussions at the conference and is not intended to be a consensus document and does not reflect the official views of governmental participants.

CHAPTER 1: INTRODUCTION

Objectives:

The objectives of the Conference were:

- To explore, in consultation with international organizations and interested bodies, ways to integrate the best scientific knowledge available into the international processes for consensus building on new biotechnology¹ in relation to food and crop safety;
- To further the concept of open and transparent consultation with an involvement of all stakeholders, including representatives of civil society, supported by shared scientific understanding, which is a key component of a credible food and crop safety system.

The event was based on the principles of inclusiveness, transparency, openness and independence. The Conference Chairman's conclusions will inform discussions in international fora.

Participants

There were more than 250 participants from 58 countries, including experts from intergovernmental organisations, scientific institutions, consumer and environmental interest groups, industry, government regulators, policy makers, and media from North and South.

Opening Themes

A strong theme for the conference was presented by the British Deputy Prime Minister John Prescott who called on participants to pursue their discussions "on the basis of rational, factual and honest debate, noting that "global problems require global solutions and global consensus based on facts, reason, free and open discussion." Biotechnology, he added, "has the potential to bring tremendous benefits. But the public's real concerns must be addressed and there must be greater transparency of information in the labelling of GM foods."

Continuing this theme, Suwit Khunkitti, Deputy Prime Minister of Thailand, emphasized in his opening speech "the potential and the pitfalls" of new biotechnology and new biotechnology foods. Acknowledging the wide range of opposing views on GM foods, he drew attention to the fears of smallholders in developing countries about the possible consequences for their livelihoods as a result of the introduction of new biotechnology plant and animal products. He also stressed the need for full information for consumers.

1. "New biotechnology" includes genetically modified organisms, living modified organisms, novel foods and feeds.

"The rights of consumers are supreme and must be respected," he said. "Consumers have the absolute right to know what is in the food that they consume."

OECD Deputy Secretary General Herwig Schlögl said that, while individual governments are responsible for regulating production and sale of new biotechnology foods, they need to cooperate on an international basis to tackle the issues raised by new biotechnology. The OECD's role, he explained, is to provide governments with "a platform to analyse complex issues, using science as far as possible, and to discuss and hopefully develop common policy approaches in order to make national rule-making internationally consistent."

Conference Program

The program focussed on three major themes, complemented by breakout groups to explore six issues emerging from these themes in more detail. The programmatic themes covered in the three plenary sessions were:

Science

Safety: International Consensus Building on New Biotechnology Food and Crop Safety, including the role of intergovernmental organisations (IGOs)

Society: How stakeholder views inform national and international decision-making

The plenary sessions were complemented by a series of breakout groups that addressed the following six issues:

- Generating Knowledge: Scientific knowledge and its validation
- Sharing Knowledge: Availability of information
- Perspectives of Developing Countries- needs and capacity building
- Stakeholder Dialogue
- Risk communication
- Socio-economic impacts

Two background papers were prepared for the conference. These covered:

- *Scientific issues in relation to the safety of new biotechnology food and crops* (Persley)
- *A review of activities of intergovernmental organizations pertaining to safety of foods and crops derived by modern biotechnology* (Köing)

Rapporteurs' Report

This report by the conference rapporteurs (Dr G J Persley and Dr Fee Chon Low) summarizes the plenary sessions and seeks to synthesize the discussion on the key issues in the plenary sessions and at the breakout groups. This draft report is complementary to the web cast of the entire meeting and the papers presented that are available on the web site (<http://www.oecd.org/bangkok/>).

This working document reflects a summary of the discussions at the conference and is not intended to be a consensus document nor to reflect the official views of government delegations.

CHAPTER 2: PLENARY THEMES: SCIENCE, SAFETY AND SOCIETY

Theme 1 - Science

The first plenary session commenced with four presentations, followed by a panel and plenary discussion on the key issues raised. The presentations were on:

- *Science and its Role in Seeking Common Ground* (Gaza)
- *Scientific issues in relation to GM food and crops* (Persley)
- *Developments in the science of environmental impacts* (Regal)
- *Public attitudes to biotechnology: where are they heading?* (Dickson)

The following points summarize the issues discussed, under some common themes that emerged:

A. *Expand approaches to anticipating unintended effects (benefits and harm) by:*

- Enhancing analytical capabilities.
- Broadening use of current approaches or developing new approaches for assessing functional consequences to health and the environment.
- Update approaches for application of substantial equivalence and precaution, particularly in relation to screening for unintended effects.
- Need to ensure sound regulatory framework.

B. *Assessment of oft-cited benefits of biotechnology*

- Review status of the science for the diverse promises of benefit to human health and the environment.
- Assess likely roles in sustainable agriculture.
- What infrastructures are needed in industrial and emerging economies to realise benefits and avoid harm (e.g. human capacity, intellectual property rights (IPR), regulatory framework and capacity, technology assessment).

C. *Funding/Support*

- Enhance public funding of research, in addition to, research by private sponsors.
- Revisit Intellectual Property Rights (IPR) structure and relevance of present structure and options to enhance realisation of benefits.
- Review present academic/business relationships, so as to ensure the impartiality of scientific advice on food safety and environmental impacts.

D. Validation of Information

- It is not clear if initial technical assessments are best achieved within existing governmental/political structures rather than in alternative settings without regulatory/normative responsibilities.
- The best available science is not necessarily readily available or captured by the intergovernmental processes for developing an international consensus on the safety, risks and benefits of transgenic foods and crops.

E. Environmental impact of new biotechnology crops

- *Direct effects:* Assess effects on case by case basis on key issues such as horizontal gene flow, trait effects, non target effects, weediness and worker safety.
- *Indirect effects through changing agricultural practices:* Assess impact of changing agricultural practices, such as herbicide and pesticide use resulting from the use of transgenic crops.

F. Knowledge gaps

- The need for further ecological research in different environments was recognised by several speakers.
- There is a need to develop methodologies and standards for ecological monitoring of GMOs in the environment.

G. Research in the Public Good

- There is a need for independent science, and increased publicly funded and publicly available research to address some of the concerns on effects of new biotechnology food and crops on human health and the environment.
- Need for more publicly funded research to develop methodologies and standards for risk assessments were stressed by several speakers.

H. CBD and the Biosafety Protocol

- The importance of the Cartagena Protocol on Biosafety was noted. Although over 100 countries have signed the protocol only five have ratified it so far. There were many calls for other countries to do so as soon as possible. Capacity constraints in implementing the Protocol were also raised as important factors limiting ratification.

I. Risk acceptability

Who decides what is an *acceptable* level of risk?

J. Risk Assessment Methodologies

- Some considered that the present methods for risk assessments were inadequate. In particular, there was a lively debate about *substantial equivalence*. Some considered substantial equivalence neither useful nor scientific. Others stressed that substantial equivalence was not considered a safety or risk assessment principle but one possible starting point guiding further food safety assessments steps. This issue will continue to be debated in international fora.

K. Other Issues

Appropriate Technology Options

- Several speakers stressed the need for emerging economies to consider various other technology options.
- Some questioned the appropriateness of new biotechnology foods and crops in some countries. Other technology options may offer more immediate benefits to developing countries. These options included more sustainable agricultural practices, reducing post harvest losses, improved agronomy, agri-ecological approaches, improved food distribution, nationally and internationally and governance.
- Others gave examples where the applications of biotechnology and gene technology, including transgenic food and crops, offer prospects for reducing poverty and hunger in emerging economies and developing countries. These are discussed in more detail in later sessions.

Intellectual Property Rights

- The increasing use of intellectual property (IP) in the life sciences and the potential effect of IP regimes on access to new technologies and protection of indigenous knowledge were raised.
- There were concerns expressed about the potential consequences of *biopiracy*, whereby biological resources of developing countries may be misappropriated, without adequate compensation to their traditional owners.

International Plant Protection Convention (IPPC)

- A statement by the Secretariat of the IPPC showed that the parties to the IPPC consider that the scope of the Convention is not limited to cultivated plants and includes the wild flora, and damage is not limited to direct damage. They also consider plant pest risks (including weediness) associated with living modified organisms (LMOs)/products of modern biotechnology fall clearly within the scope of the IPPC.

CHAPTER 3: SAFETY

Theme 2 - Safety: International Consensus Building on New Biotechnology Food and Crop Safety

The activities of various intergovernmental agencies were described in the background paper for the meeting. Presentations were made by the following intergovernmental organisations on:

1. *The Work of FAO, WHO and the Codex Alimentarius Commission*
2. *The International Plant Protection Convention (FAO)*
3. *The Work of the United Nations Environment Programme (UNEP)*
4. *The Biosafety Protocol (CBD Secretariat)*
5. *Harmonisation in Biotechnology at OECD: Incorporating Science and Public Concerns*
6. *World Trade Organization (WTO)*

The key issues arising from the presentations and the subsequent discussion are summarized below:

Cartagena Protocol

- The importance of implementing the Cartagena Protocol on Biosafety was recognised.

Science

- The importance of independent scientific assessments was stressed.

Multilateral processes-stakeholder participation

- Role of multilateral intergovernmental processes was broadly recognized as useful, as a means of sharing information and knowledge, and moving towards the establishment of comprehensive, rigorous, and credible regulatory frameworks and their harmonization. As well, standards and protocols on risk assessment and food safety, through intergovernmental negotiations were identified.
- Various organizations had lead responsibility for different aspects of new biotechnology food and crops (e.g. FAO/WHO Codex for Food Safety, Convention on Biological Diversity (CBD)/Biosafety Protocol for Environmental Impact, United Nations Environment Program (UNEP) for capacity building in biosafety (with Global Environment (GEF) funding), International Plant Protection Convention (IPPC) for plant health and quarantine-related aspects).
- The intergovernmental organizations stressed that their processes were open and transparent, and involved stakeholder participation.

- Some stakeholders find it difficult to participate fully in all Intergovernmental Organization (IGO) processes, due to their multiplicity and limitations of human and financial resources.
- Participation was especially a problem for some developing countries, due to lack of sufficient expertise as well as financial constraints for developing national capacity.
- It was also identified that participation of developing countries in standard setting activities should be enhanced through the support of trust funds and other sources.
- Lack of national capacity affects countries in three ways, in participating actively in international negotiations, secondly, in implementing international treaties, agreements, protocols, guidelines and standards developed in international fora, and, thirdly, ability to establish and implement systems for effective regulation.
- Capacity building is necessary to address these constraints (e.g. UNEP addressing this issue to some extent in relation to the development of biosafety frameworks).

Improving dialogue between intergovernmental organizations and stakeholders

- More proactive approach needed to stimulate dialogue amongst IGOs and stakeholders.
- Proactively share information, including data on risk assessments.
- Seek to identify concerns of various stakeholders and how these can be better addressed in intergovernmental processes.
- Greater opportunities for dialogue at national and international fora were suggested, using existing mechanisms and institutions.
- FAO is addressing the issue of regulatory frameworks and capacity building for food safety and plant health.

Monitoring LMOs in the environment

- Need for internationally acceptable guidelines for ecological monitoring of LMOs.
- This would stimulate more ecological research at a national level in different countries and environments, particularly in centers of origin and centers of diversity of crops.
- Some indicated international guidelines for traceability of new biotechnology crops and food are required.

Role of science in intergovernmental organizations: Science and policy

- IGOs have access to scientific expertise, through various means. Science can inform the policy and political processes, but science cannot and should not drive the political processes.
- Science could make a greater contribution if policy makers (and their scientific advisors) are able to *frame the questions* to which they require answers, in order to move forward in the policy making process. This also gives a policy environment into which independent scientific advice may contribute.

- Independent science and scientists are required to address these key questions; the science must then be conducted independently from the IGOs and the stakeholders, with high quality, peer review, and independence, in order to increase its credibility and usefulness to policy makers and politicians. This applies both nationally and internationally.
- This approach implies a need for greater public investments in science to answer key questions of public concern, with the results being made publicly available.
- Greater interaction amongst IGOs, the scientific community and other stakeholders may also enable emerging issues to be addressed more quickly.

Trade related issues

- Some trade related issues of gene technology may come under WTO processes (TRIPS, SPS, TBT). These may become more important in trade of agricultural commodities.
- WTO processes can accommodate these issues, while also having flexibility to enable different countries to deal with social and ethical concerns, while not using these to establish non-tariff trade barriers.
- WTO agreements do not affect its members' right to determine the level of protection which they deem appropriate in specific instances provided that these regulations are not used in a protectionist or discriminatory manner and are not unnecessary obstacles to trade.

Availability of Data

- Much data is available, from a variety of national and international sources, and in the scientific literature.
- Some stakeholders wish to have raw data so that they are able to make their own interpretations and analysis. Other stakeholders wish to have interpreted data that draws out its implications for different groups. This interpretation needs to be done by national or international institutions and groups trusted by the stakeholders.
- Two way communication between IGOs and stakeholders is critical. Transparency is desirable, but common understanding as to what transparency means to different stakeholders is necessary to promote increased understanding of the plurality of views, on both processes and issues.
- Access to information was also identified as a concern, improvements should be made to help developing countries. For example, it was noted that the FAO would be improving access to information by testing a web based system on food safety.

CHAPTER 4: SOCIETY

Theme 3 - Society: How Stakeholder Views Inform National and International Decision-making

This session addressed the perspectives of the various stakeholders (scientists, developing countries, industry, consumers, environmentalists and farmers) on food security, food safety, the benefits and risks of biotechnology, information sharing and participation in decision making and public awareness.

Eight papers were presented. These included the science and development of national biotechnology projects, China's experience of applying new biotechnology, and concerns of farmer, consumer and environmental organizations, and industry. The following summarizes the main points of these presentations.

A) Science

The adoption of herbicide-tolerant soybeans in Argentina was shown to be beneficial to both the farmers and the environment. The application of molecular marker techniques to determine the effectiveness of refuge areas for *Bt*-targetted insects, and for genetic diversity analysis of transgenic crops were also discussed. Sunflower was chosen as a national biotechnology project because of its importance in trade. This provided sound training for local molecular biologists, ecologists and geneticists.

B) Developing Countries and Development Issues

Three papers were presented in this session.

The representative of Kenya viewed crop biotechnology as an option of great potential in improving agricultural production. Since misinformation appeared to be the main cause of concerns, Kenya built upon sensitization and consensus building among all stakeholders, prioritization of agricultural commodity, and adaptation of appropriate technologies through strategic partnerships. Kenya needed capacity building in human and physical resources, information and technology transfer and a public awareness program.

The widespread cultivation of *Bt*-cotton in China has allowed China to undertake a comprehensive risk/benefit assessment of this technology. Though the benefits (such as increased yield, better health of farmers and reduced pesticide use) were impressive, the current global debate on biotechnology has compelled China to review biotechnology policy, for potential trade difficulties in biotechnology products. However, these benefits have resulted in China not changing their policy on implementation. China is moving ahead in the use of biotechnology with the following provisions: evaluation on a case-by-base basis; strong biosafety management; promotion among consumers (dialogue); and, caution with export crops, because of trade.

Some stressed the importance of biotechnology to reduce hunger, especially in the developing countries. Recognising that biotechnology is not a panacea, it may provide a

biological safety net for poor farmers. Others questioned this idea, saying there was little evidence to suggest such a conclusion. The ethics of conviction were questioned against the ethics of accountability. Science and technology may bypass the poor, who may need that technology most.

C) Industry

Industry has a strong business responsibility to foster and maintain consumers' trust by ensuring that biotechnology products meet national and international standards of safety and quality. Industry is also prepared to be open and transparent in transactions, share information and technological innovation and participate in capacity building. Industry supports the building of international consensus on crop biotechnology based on independent science, inclusiveness and openness.

D) Consumer Organisations

Consumers are concerned mainly with the safety of transgenic food and whether the technology will solve food problems. A holistic approach is called for and consumer participation in decision making is needed. Other consumer concerns include the need for comprehensive, rigorous, and credible regulation, sustainability of agriculture, consumer preferences, patenting of life forms, religious and ethical issues.

E) Environmental Organisations

Several representatives of environmental organizations voiced their concerns about potential hazards associated with modern biotechnology. They also urged further studies to fill in knowledge gaps and risk assessment based on the "precautionary principle". They believed that tools and methodologies for risk assessment need to be developed and alternative ecological agricultural systems besides biotechnology should be supported. Some considered that there should be no patenting of life forms, rights of farmers and indigenous communities to their biodiversity and knowledge should be protected and a liability regime under the Cartagena Protocol should be put in place.

F) Farmer Organisations

Farmers and society need biotechnology to meet the demand for increased food production. However, the main concern of some farmers in developing countries is that innovations in agricultural biotechnology should ensure their right to save and utilise seeds for their own use. In relation to this, the issue of control of seeds by a few multinational companies was raised and repeatedly stressed, emphasizing the need to reverse this trend. Some farmer organisations believe that knowledge and biotechnologies which reduce poverty should be either available freely or at a highly discounted cost. Many farmers want to participate in decision making and there is a need for meaningful dialogue between the various stakeholders of biotechnology.

CHAPTER 5: SUMMARY OF ISSUES

The following are some of the key issues that emerged from the discussion and debate, as identified by the rapporteurs, not as points of consensus but as issues which might merit further exploration. Divergent views were expressed on many of these issues at the conference.

1. *Key Issues for Consideration:* The importance of considering the issues relating to food safety and human nutrition, environmental impacts and benefits of foods and crops derived from new biotechnology, as well as related issues such as socio-economic impacts, consumer choice, religious and ethical concerns was widely recognised.
2. *Environmental impacts* will be influenced by the characteristics of the environment and there is likely to be a need for more case/location-specific assessments of new biotechnology crops in different countries and regions, perhaps more so than for foods derived from new biotechnology, which are less location specific. This should be complemented by environmental monitoring on the basis of internationally acceptable guidelines to be developed for this purpose.
3. *Health impacts* may be both direct and indirect and both positive and/or negative. The evaluation of health effects should involve toxicological, nutritional and other effects.
4. *Capacity Building* is important, especially for emerging economies and developing countries. The needs vary amongst countries, and cover a range of biotechnology-related skills, including biosafety, establishment of regulatory frameworks, risk assessment, technology development and evaluation, intellectual property management and policy making.
5. *Cartagena Protocol on Biosafety:* Strengthened capacity may assist countries in ratifying and implementing the Cartagena Protocol on Biosafety. Although over 100 countries have signed the protocol, at the time of the conference, only five had ratified it. Some countries were constrained in signing or ratifying the Protocol as they lacked the capacity and the human and financial resources necessary to implement it.
6. *Stakeholder Dialogue:* Strengthened capacity would enable more countries and a wider range of stakeholders to participate more effectively in national and international dialogues and other specific stakeholder fora convened under the auspices of national and international organizations. The range of stakeholders who need to be involved include farmers, food processors, industries, consumers, environmental groups, scientists and academia, regulatory authorities and policy makers. Dialogue should take place in a transparent, open and inclusive manner and be held early in the decision making process. Greater access for all stakeholders to

data supporting decision making and information on new biotechnology food and crops would be beneficial in enhancing efficiency in the dialogue. Dialogue also needs to facilitate the exchange of experiences among countries, while bearing in mind the cultural, scientific, and socio-economic conditions of each country, especially in the case of developing countries.

7. *Information access and sharing*: It was recognized that all stakeholders are interested in more information on new biotechnology and biosafety. The need for information includes scientific/technical information, food safety and quality, environmental impact and socio-economic impacts. The need for information to enable consumer choice was also recognised, including through labeling of new biotechnology foods. Some also raised other issues related to risk management, labelling, monitoring and traceability.
8. *International regulatory harmonization, standards and protocols*: The international organizations should continue their important work on harmonization of regulatory approaches and the development of commonly agreed standards and protocols for measuring risk assessment and environmental impact, with wider stakeholder participation, and in a manner which supports existing national and regional regulatory processes. International standard setting bodies need to ensure the participation of developing countries at all stages of the standard setting process. At the international level, there needs to be increased collaboration amongst intergovernmental organizations (IGOs) responsible for food safety, nutrition, environment, socio-economic, and ethical considerations to provide a more holistic evaluation regime.
9. *Regulation of biotechnology*: comprehensive, rigorous, and credible regulation serves the purpose of minimising the possibility that unsafe products will be sold or that these products or their manufacture will mislead or cause harm to consumers or the environment. Regulations should thereby increase consumer confidence in new products and technologies.
10. *Substantial equivalence* was noted to be a conceptual tool in the assessment of risk. It was noted that the use of this concept in risk assessment methodologies needed further discussion.
11. *Precautionary approach*: There was much discussion about this term. It was debated when or how the precautionary approach should be applied and what the term “precautionary principle”, or simply “precaution” means. As well, the relationship between the precautionary approach and sound science was still a matter of debate. It was noted that further discussion regarding this issue will need to take place.
12. *Assessment of the risks and benefits* posed by new biotechnology food and crops should be science-based. Data supporting those assessments and regulatory approvals should be shared wherever possible, to increase consensus about where the scientific evidence lies. Exclusions for reasons of commercial confidentiality should be clearly defined. The continued development of robust, science based methods for

risk/benefit assessments and monitoring of new biotechnology foods and crops should be encouraged so that, for example, government regulators can continue to address their safety for human consumption and for release into the environment. .

13. *Science should inform the policy and decision-making processes* but it cannot and should not be the sole factor. Science can best contribute when decision-makers frame the questions to which science may be able to provide advice, answers or options, and identify what we know, what we do not know, and how best we can fill in these gaps in scientific knowledge.
14. *Independent scientific investigations, in addition to industry-sponsored research,* have an important role in contributing together understanding of the risks and benefits associated with new biotechnology foods and crops. Such independent scientific investigations can also assist in improving the credibility of regulatory processes. For example, they can assist in developing improved methodologies, techniques and protocols for measuring the constituents and the behaviour of food and crops derived from biotechnology. The independence, transparency and credibility of these investigations and the avoidance of conflicts of interest in funding are especially important in developing a meaningful two-way debate. Clear declaration of interests and transparency of funding sources could facilitate rebuilding trust.
15. *Public interest research:* Some of the independent scientific investigations need to be publicly funded, to increase their independence, ensure public availability of information, and provide public goods, for example through research on orphan crops. Given the rapid advances in the life sciences there is opportunity for research on the long term and possible unintended effects of new biotechnology foods and crops funded by governments, in the public interest and to inform regulatory decisions.. Such public research would complement private research investments that are aimed at product development and commercialization.
16. *Benefits:* There are benefits from the safe applications of new biotechnology in addressing specific problems in food, agriculture and the environment, in both developing and industrial countries. Countries need to have access to new scientific developments, the capacity to assess and regulate new biotechnology foods and crops, including for access to export markets under applicable trade agreements.

G J Persley and F.C.Low
December 24 2001

ANNEX A: CHAIRS' REPORTS FROM BREAKOUT SESSIONS

Issue 1: Scientific Information and its Validation

(Report prepared by Chairs of Working Group 1)

Key Points

- Assessments to be science-based.
- Peer-review of data highly desirable.
- Sources of “scientific” information are variable – Quality, availability and accessibility are key.

Stakeholders

- Important to be clear who stakeholders are.
- Include international organisations, governments, regulators, scientific community, civil society, industry and media.
- Draw on varied and variable sources of information including dossiers, published articles in journals, magazines, newspapers and other media.

Sources

- Quality, availability and accessibility to the stakeholders are the key issues.
- Different stakeholders use different sources (regulators use dossiers; much of civil society relies more on general literature).
- Not all sources of equal quality.
- There is information for regulatory dossiers – where there is a high level of quality assurance and validation – and information in general scientific literature which is peer-reviewed but not necessarily subject to quality assurance procedures (e.g., Good Laboratory Practice). The frameworks and designs for work generating data are important determinants of quality.
- Peer-review a useful guarantor of quality.
- Several types of peer-review possible, including review by scientific assessors advising regulatory authorities.
- Data for safety assessment not always publishable.
- Group agreed that, where possible, data should be adequately peer-reviewed.
- There is a need to be open with information in dossiers and to continue to identify ways to be more open.
- Data should be relevant to assessment
- Appropriate social science data can be considered as “scientific” for the purposes of this note.

Validation

- Scientific validation including methodology and substance is absolutely key.
- Uncertainty must be recognised. “Predictive power” might be better understood and articulated.
- Where possible data sets might be added as issues of uncertainty are addressed. Process could be more dynamic and iterative.
- Uncertainty is a particular issue in attempting to predict long term effects.
- Regulatory assessment – and the scientific advice regulators draw on – is a form of validation.
- Different stakeholders may have different understandings of the meaning of “validation”.
- Multidisciplinary approaches more likely to generate broader acceptance of “validation”.

Developing Countries

- Developing countries may need additional sources of information where there are local environmental, cultural, value or language issues.
- Availability of and access to information locally – for example in scientific journals – may be problematic. The group applauded recent efforts to increase accessibility of journals in developing countries.
- Important not to “re-invent the wheel” in generating new data for developing country assessments.

Further Research

- Research needs to be appropriate to relevant local environments. In some cases some further specific work might be necessary.
- All relevant work should be drawn into science-based assessment, not just specifically work on biotechnology.
- Future work might focus on specific parameters that are predictive of specific potential end points. One view was that further toxicological work might be required on new biotechnology foods.
- Future work might consider appropriate analytical methodologies for the detection of organisms derived from biotechnology.

Other Points

- There was agreement that assessment should continue to be science-based.
- Though not discussed, the view was put that assessment might consider potential benefits as well as risks.

Issue 2: Availability of information

(Report prepared by Chairs of Working Group 2)

Who is interested in information on biotechnology and biosafety?

- 1) Consumers
- 2) Farmers
- 3) Scientists
- 4) Government Officials/Policy-makers
- 5) Environmental Groups

Which information is of particular interest to different stakeholder groups?

- 1) Basic scientific/technical information
- 2) Food safety and quality
- 3) Environmental impacts (sustainability)
- 4) Socio-economic concerns (IPR, food quality, structural impacts)
- 5) Institutional structures (who does what?)
- 6) Regulations and legislative framework

"Quality" of information?

- 1) Must be geared to specific stakeholder needs
- 2) Use language appropriate for intended stakeholder
- 3) Provide balanced information (costs and benefits, range of views)
- 4) Ensure relevance for local conditions
- 5) Need for reliable sources and appropriate use (public vs. private, develop guidelines for use)
- 6) Promote standardization to facilitate comparative analysis

Do the current arrangements provide for sufficient access to information?

- 1) A question of what information should be made publicly available (too much "confidential" information?)
- 2) Need to be proactive (extent of government effort to disperse information, need for adequate funding)

- 3) Internet is the main provider (poses problems for developing countries)
- 4) Labelling for consumer choice (need for appropriate legal framework)
- 5) Need for stakeholder dialogue - need for interaction and two way communication
- 6) Need for wider dissemination of information on national decisions and international guidelines (e.g. through Cartagena Biosafety Protocol, Codex, etc.), including through the internet

Need for more discussion/action

- 1) On appropriate roles of government, IGOs, media, NGOs, industry, academics as information providers
- 2) On questions of funding (level, sources, applications)
- 3) On process of validation of information

Issue 3: Capacity Building

(Report prepared by Chairs of Working Group 2)

Capacity Building and needs of developing countries

- Definition of stakeholders and their needs for access to information in decision making. These include: researchers, regulators, consumers and producers, each using information in a different way.
- Developing countries are not homogenous in their information needs and capacity building requirements.
- Access to reliable information by the scientific community and regulators was considered to be a fundamental element in the capacity building of the developing countries, which was often impeded due to limited Internet access. It is imperative that funding be made available to increase connectivity to permit countries to access the scientific information already available. This may be done through donor support.
- In addition to general scientific information, concern was expressed for making available information on local ecology systems needed for risk assessments and for determining investment capacities. Some concern was expressed about the quality of information available. How can one distinguish the different levels of quality of information available on the Internet.
- Role of the international organisations in providing valid data was seen as important and the present work of the Biosafety Clearing-House of the Biosafety Protocol was seen as particularly important in the development of capacity building for Biosafety.
- The role of peer reviewed scientific information was viewed as necessary for assessing the capacities of biotechnology and its products for meeting developing country needs. However, important international efforts at providing information could help the process. It is necessary for countries to develop their own capabilities for continuing the access to information. Educating the media was also seen as important in many countries as this is important for consumers and farmers. In addition to the Internet, other approaches to information dissemination were also seen to be needed. These could be through the traditional print, radio programmes as well as conferences, dialogue groups and the like.
- In addition, certain countries emphasized the need for not only scientific information availability but also for economic market data, or market intelligence to determine whether investments might be viable in the market place in the longer run. Here again the specificity of the country in defining its informational needs in terms of its objectives becomes critical.
- Increasing regional interlinkages in terms of information networks is also useful. It was suggested that use be made of existing networks, building upon these in a first instance. Technologies must be adapted to the needs of the country and perhaps even local informational needs may need to be defined more precisely. Regional collaboration was suggested when possible, though such efforts are not always easy to

undertake. This could be particularly important in developing information networks on risk assessment methods and information.

- What are the best mechanisms to insure that existing scientific information is used and exchanged? It was suggested that cooperative efforts be made to disseminate information through the Internet, but that conferences, journals and other meetings of scientists, regulators and policy makers could be quite useful, though funding for these was becoming more and more difficult.
- Capacity building can not be limited only to biotech products or biosafety but also needs to deal with a wider set of issues involving plant and animal health to which biotechnologies may be able to make a significant contribution. And, building capacity also involves developing research capacities through manpower training and funding. But discussion also called for a balance between the general issue of information for capacity building and the specific needs of each developing country in its approach to biotechnology and biosafety, for which capacity building needs to go hand in hand.

Other Issues

Capacity building: To build capacity for making informed decisions/choices

- Biosafety
- Risk assessment
- Monitoring e.g. genetic markers for terminator genes
 - Harmonised methodologies
- Certification & labelling e.g. trade
- National dialogue should be initiated to complement international dialogue, with participation of farmer groups, consumer groups, and other civil society organisations. The participation of all stakeholders should also be encouraged at international levels.
- Research should also be conducted on local and sustainable agricultural technologies.
- An assessment of multi-national companies' influence over policy making/decision making processes could be of value.

Information

- Availability: traditional & indigenous knowledge, joint-research
- Access: Sharing, dialogue and openness, e.g. Publishing in national newspapers
- Quality: Independent capacities and capabilities to evaluate

Agenda setting

- Research priority setting - Participation research approval
- Trade - TRIPS
- Centres of diversity

Public & Private Partnership

- Constraints

Financial Aspects

- National and International

Issue 4: Stakeholder Dialogue

(Report prepared by Chairs of Working Group 4)

- Dialogue needs to be fostered between all stakeholders within a country.
- Dialogue is also needed between developing countries as well as between developing and developed countries on these critical issues.
- To have an informed debate or dialogue between stakeholders, basic information is needed. Simple but basic agreement on terminology was seen as fundamental to beginning any debate. It was also suggested that a mechanism to provide systematic information gathering would be useful. This would also permit information gaps to be identified and eventually filled.
- Need to facilitate dialogues among stakeholders.
- Stakeholders need to have clear objectives for their participation and to be consulted early in the decision-making processes. Their participation must be perceived to matter to the overall decision-making process. Attempts must also be made to avoid polarization of views in the discussions.
- Producers: critical issue is to bring farmers and researchers together to discuss and find approaches to resolving their needs. This may entail an exchange of information on crop production methods or pest protection. In some cases it also requires basic education on biotechnology so as to permit a useful discussion for specific applications. The use of concrete cases may help to focus on basic issues.
- *Consumers* need to be consulted about issues of concern to them with respect to the biotechnology used in food production, that is food and environmental safety. Again educational efforts prior to dialogues may be necessary in order to enhance participation.
- *Consensus* conferences on biotechnology issues have been used in many countries to provide policymakers with information on consumer opinion as well as guidance in a number of countries.
- Different groups in society often feel marginalised in the decision making process. Ways to bring all groups to the table for discussion are necessary and efforts must be made to avoid emotionally laden discussions.
- When stakeholders participate in a dialogue with government, they may find that at times their concerns transcend those of the regulators or policy makers. It was suggested that the use of well-defined applications could remedy this difficulty.
- Concrete results, such as policy measures or regulations, from the stakeholder dialogues was also seen as an important element to the process.

Additional points on stakeholders' dialogue

- Diverse national experiences were presented: Thailand, France, Cameroon, Kenya Canada, United Kingdom.
- Certain criticisms were made concerning the forms of past 'dialogue meetings', which limited communications to a one way discourse from scientists to the public without engaging in a two way exchange of ideas.
- Another criticism was that of restricting participation to a selected group of stakeholders and limiting information accessibility of developing countries.
- Lack of participation by farmer's associations in determining the direction of research was also a repeated criticism.
- Access to relevant information as well as training and education in the field of biotechnology was requested.
- The lack of basic knowledge on biotech often makes communications among stakeholders difficult.
- The problem of the 'representativeness' in the composition of the different 'dialogue groups' was often underlined .
- The necessity to engage the different parties that are to serve as intermediaries. This means the intermediaries between base stakeholders and decision makers)

Other Issues

Consultative Fora and Other Mechanisms

- Use of consultative fora and other mechanisms for deliberations at both the national and international level were discussed.
- These mechanisms should bring together the different stakeholders in an even handed manner (from the farm to the dinner plate): Farmers, seed producers and industry , agro-food processors, consumers, scientists.
- Stakeholder dialogue should take place early in the consensus building process.
- Use of concrete examples would permit a better analysis of the advantages and disadvantages of the technology. It would avoid a dialogue that is often polarised between pro- and anti- GMO groups.
- Such fora should be based on clear separation between evaluation and risk management. Evaluation is a scientific procedure, it should be a help to decision-making for the risk manager, who takes into account science, but may also take into account other factors, such as economics, sociology, ethics and beliefs.

Other Questions Raised

- The need to develop an international consensus on definitions used.
- The possibility to develop an international review of stakeholder dialogue groups.
- The financing of these stakeholder dialogue groups needs to be done by national governments and not to be beholden to any other particular vested interest group/industry.

Issue 5: Risk and Risk Communication

(Report prepared by Chairs of Working Group 5)

Key Points

- Increased openness and transparency is key.
- International organisations have increased their capacity to assess risk but more might yet be done on two-way communication of risk.
- Lack of choice is likely to reduce tolerance of risks.

Scope

- There was discussion – but no clear consensus – about whether the debate should address benefits as well as risks.
- Communication of benefit raised challenges of its own. There were some similarities to communicating risk, such as that they should be science-based and how to deal with uncertainty, but also some differences.
- It was suggested that the discussion might also consider the burden of proof, though this was not discussed due to time limitations.
- “Communication” was deemed to include perception for the purpose of the discussion.
- The nature and characteristics of risk might also be included in discussion.

Openness and Transparency

- Uncertainty needs to be clearly identified and communicated. Assessment and communication should make clear what is known, what gaps exist and how remaining uncertainty might be addressed. Complexity should be acknowledged.
- There should be transparency about differences of scientific opinion when relevant.
- Improving open availability of assessment dossiers could help improve understanding and communication of risk. Withholding of confidential business information should be kept to the minimum amount possible.
- Involvement of a broader stakeholder set in the assessment and decision-making process might facilitate broader and more effective risk communication. This could improve the credibility and perceived validity of information.
- Effective Risk Communication needs to be a two-way process. Developing meaningful systems for delivering on this often remains a challenge. More thought needs to be given to different stakeholder expectations.

The Role of International Organisations

- International organisations have significantly developed capacity for risk assessment in recent years and so making a tangible resource commitment.
- Further capacity might yet be developed in risk communication, but additional resources and support from member countries likely are required to deliver this (ongoing work under the UNECE Aarhus Convention might be a good example for others).
- Meaningful two-way risk communication remains a particular challenge, in and for, some international organisations.

Credibility and Trust

- Credibility of sources and trust in fair, unbiased communication of risk will be essential to develop a meaningful two-way debate.
- There are worrying signs of loss of trust in and perceived credibility of many institutional actors engaged in this debate.
- Clear declaration of interests and transparency of funding sources may help to go some way to re-building trust.
- The group spoke of the need for less dogmatic stances on issues and more openness to and discussion of opposing viewpoints on risk.

Nature of Risk and Choice

- The articulation of risk needs to be more subtle and differentiated. Issues are rarely simply good or bad, safe or unsafe, and the complexities and uncertainties in risk need to be acknowledged.
- The group noted that risk taking is a normal part of everyday life and that most of us were to some extent comfortable with managing day to day risk. However, personal choice on whether to face risks is an important element in dealing with risk. Lack of choice was likely to reduce tolerance of risks and acceptance of assessments of them.

Issue 6: Socioeconomic Impacts

(Report prepared by Chairs of Working Group 6)

Discussion in this group emphasized the lack of data and information about socioeconomic impacts of new biotechnology.

What do we mean by socio-economic issues/impacts

- Economic costs and benefits
- Impact of science on society
- Implication for industry structure

Common observations

- Socio-economic impacts are significant and require analysis
- Socio-economic issues are separate from risk assessment
- Social sciences can make an important contribution to the assessment of biotechnology

What are some of the key socio-economic issues for analysis?

- Economic impacts:
 - Comparative cost-benefit studies of biotechnologies / alternative farming systems (identify cost and benefits of different groups)
 - Capacity to make well informed investment decisions
 - How to address socio-economic issues in the context of an international trading system
- Social impacts
 - food security
 - rural urban migration
 - employment impacts
- Structural impacts
 - market concentration
 - market segmentation
 - market power
 - farming systems (particularly for developing countries)

Proposed analytical approaches

- Need for “ex ante” research (before introduction of new biotechnologies)
- Recognise responsibility of national governments and international organisations to carry out socio-economic impact analysis (potential for more analysis by IGOs)
- Do not examine socio-economic impacts of new biotechnologies in isolation (comparative analysis)
- Use case by case approach (specific biotechnologies, local conditions)
- Involve social scientists in future research