Developing and Harmonising Biosafety Regulations for Countries in West Asia and North Africa

Editors

Michael Baum
André de Kathen
John Ryan

International Center for Agricultural Research in the Dry Areas

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ICARDA serves the entire developing world for the improvement of lentil, barley and faba bean; all dry-area developing countries for the improvement of on-farm water-use efficiency, rangeland and small-ruminant production; and the Central and West Asia and North Africa region for the improvement of bread and durum wheats, chickpea, and farming systems. ICARDA's research provides global benefits of poverty alleviation through productivity improvements integrated with sustainable natural-resource management practices. ICARDA meets this challenge through research, training, and dissemination of information in partnership with the national agricultural research and development systems.

The results of research are transferred through ICARDA's cooperation with national and regional research institutions, with universities and ministries of agriculture, and through the technical assistance and training that the Center provides. A range of training programs is offered extending from residential courses for groups to advanced research opportunities for individuals. These efforts are supported by seminars, publications, and specialized information services.

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Developing and Harmonising Biosafety Regulations for Countries in West Asia and North Africa

Proceedings of a Workshop held
11-13 September 2000
ICARDA, Aleppo, Syria

Edited by

Michael Baum
André de Kathen
and
John Ryan

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Adel El-Beltagy, Director General, ICARDA.
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Maria Zimmermann, Biosafety Focal Point, FAO.
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André de Kathen, BioTechConsult.

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Subhash Gupta, APHIS, US Department of Agriculture.
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John Dodds, Patent Attorney, Washington.
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Magdy Madkour, AGERI, Giza, Egypt.
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André de Kathen, BioTechConsult.
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Kauser Malik, Pakistan.
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David Duthie, UNEP/GEF, Nairobi, Kenya.

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Group 2: Institutional Arrangements for Biosafety (by countries and sub-regions).
Moderator: *Magdy Madkour*; Rapporteur: *André de Kathen*.

Group 3: Containment Facilities, Testing and Result-Sharing.
Moderator: *John Dodds*, Rapporteur: *Bassam Al-Safadi*.

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Group 2: Institutional Arrangements for Biosafety (by countries and sub-regions).

Group 3: Containment Facilities, Testing and Result-Sharing.

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15:30-17:00 Wrap-up and Closure.

Invitees

Dr André de Kathen (GTZ)	Germany
Prof. Dr Magdy Madkour (AGERI)	Egypt
Dr Maria Zimmermann (FAO)	Italy
Dr David John Duthie (UNEP/GEF)	Kenya
Dr Kauser Malik (PARC)	Pakistan
Dr John Dodds	USA
Dr Subhash Gupta (USDA-APHIS)	USA

NARS Participants

Dr Zouaoui Bouznad	Algeria
Dr Belcacem Hadj-Lakehal	Algeria
Dr Ramadane Boussenadji	Algeria
Dr Abdelazim El-Hamady	Egypt
Dr Fauzi Rashid Ali Al-Ani	Iraq
Dr Ibrahim Jaddouh El-Jabouri	Iraq
Dr Naser Abed El-Saheb	Iraq
Mr Naser Hamed Abboud Al-Dulaimi	Iraq
Dr Ghazi El-Kuleibi	Jordan
Dr Majed El-Zoubi	Jordan
Ms Oula Harzallah	Jordan
Mrs Hala Zahreddine	Lebanon
Dr Mustapha Labhilili	Morocco
Dr Mustapha Bouchoutrouch	Morocco
Mr Imad Al-Baba	Palestine
Dr Radwan Barakat	Palestine
Dr Ahmed Abd El-Kader	Syria
Dr Bassam Al-Saffadi	Syria
Prof. Dr Najem Eddin Sharabi	Syria
Dr Abdebagi Mukhtar Ali	Sudan
Dr Ahmed Hassan Mohamed	Sudan
Dr Mohamed Ahmed Ali	Sudan
Dr Abdderrazak Daaloul	Tunisia
Dr Ahmed Jemmali	Tunisia
Ms Munevver Gocmen	Turkey
Dr Servet Kefi	Turkey
Dr Sinan Aktas	Turkey

ICARDA/IPGRI Participants

Prof. Dr Adel El-Beltagy, DG	Dr Sripada Udupa
Dr Mohan C. Saxena, ADG (A-L)	Dr Imad Eujayl
Dr William Erskine, ADG (R)	Dr Wafa Choumane
Dr Mahmoud Solh, ADG (IC)	Dr Kamel Chabane
Dr Michael Baum	Dr Carmen de Vicente, IPGRI

Introduction

This workshop on the safe use of biotechnology, the second in a series of four, aimed at intensifying the cooperation of the Arab countries in the region. Notwithstanding the fact that modern biotechnology offers new tools for solving problems in agriculture, food processing, and veterinary and human medicine, *these tools are new, and the experience and capacities are limited*, especially in countries of the developing world. To share experiences, facilities and expertise within the region, and to identify and make use of synergistic effects are, therefore, of prime importance and are major objectives of this series.

The first meeting was held in Cairo in January 1999, and was jointly organized by the Egyptian Agricultural Genetic Engineering Research Institute (AGERI) and the United States Department of Agriculture (USDA). In that workshop, biosafety developments in several regions of the world, e.g., Latin America, Asia and North America, were reviewed. This was the first time that a number of WANA country representatives came in contact with the developments in other parts of the world. It also became clear that to gain more information, more workshops had to follow in order to strengthen the development of biosafety policies in the region. It was at the end of the first workshop that FAO, AGERI and ICARDA discussed the possibility of organising a number of workshops to promote the different aspects of biosafety development in the region.

The second meeting was to bring together policy- and decision-makers of ten nations of the region for three days, to identify and discuss issues related to biosafety and biotechnology, and to further support and enforce a regional harmonisation of these issues.

This workshop consists of three parts: following his opening remarks, the pace was set by the Director General of ICARDA, Prof. Dr Adel El-Beltagy, and Dr Michael Baum, Biotechnologist at ICARDA, introducing the objectives of the workshop. Experts from outside the region then explained the international environment within which national and regional biosafety frameworks develop and from where assistance can be expected. The second part was dedicated to the presentation by the participants of their national approaches towards biotechnology and biosafety, whereas the third and final part was designed as three different seminars, addressing major issues for regional harmonisation:

(i) Defining needs within national and sub-regional risk and impact assessment.

(ii) Discussing necessary institutional arrangements at the national and sub-regional level.

(iii) Finding common ground on containment facilities, testing and result-sharing.

The results, formulated as country conclusions and final recommendations, are also included here.

Foreword

Genetic engineering to some people means a miracle, to others, a menace. But most people believe that the tools provided by biotechnology and genetic engineering will help us to increase food production by developing crops resistant to disease, pests, salinity, drought and other environmental constraints.

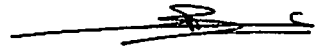
What is needed is to make sure that biotechnology not only provides more food, but also safe food to the people. But no one can guarantee safety without input from scientific research. It is a very dynamic frontier; therefore, it needs solid biosafety regulations that guarantee the safety of food developed using biotechnology and genetic engineering.

While in the industrialized countries people are concerned about food quality, in the Third World it is the food quantity that is of primary concern. Currently over 900 million people go to bed hungry everyday. In the next 20 years, developing countries face the challenge of doubling their food production to cope with their rapidly increasing populations. Doubling food production by 2020 needs expansion of agricultural land, but most of the world's prime land is already under cultivation. Therefore, biotechnology and genetic engineering, as tools to increase food production, are needed more in developing countries than elsewhere.

The challenges facing farmers and agricultural scientists are extreme weather conditions, factors such as water salinity and pest infestation. But for ordinary people it is the fear of the unknown. To allay the fear of biotechnology and genetic engineering, scientists themselves will have to be the guardians. Countries in the West Asia and North Africa (WANA) region have to develop their own biosafety regulations that are regionally respected. These regulations will not only protect the people but also establish a code of ethics and conduct for the scientists.

I hope that the WANA region will soon have a solid biosafety code in place in each country, respected regionally with a spirit of harmony. This is a challenge against time. Also, biosafety is dynamic; therefore, regulations have to change with time. To enable changes, we need knowledge and knowledge can come only through research.

This volume of proceedings embodies the knowledge and ideas generated at a workshop on biosafety regulations for WANA, held at ICARDA, 11-13 September 2000. I believe it provides a solid foundation for developing clear, well-defined biosafety regulations for each country in the WANA region.



Adel El-Beltagy
Director General
ICARDA, Aleppo, Syria

Workshop Objectives

Michael Baum
International Center for Agricultural Research in the Dry Areas

The long-term objectives of the workshop relate to what ICARDA and the National Agricultural Research Systems (NARS) in West Asia and North Africa want to achieve with respect to biosafety in the region, i.e., to support the establishment and harmonisation of national biosafety regulations. These can be achieved by complementing existing efforts, taking into account the diversity of countries and their national policies. In order to support such national efforts, we will first analyse what has already been done in individual countries, and what policy framework the country wants to develop. Based on that analysis, we can decide which countries can develop collaborative efforts towards addressing biosafety regulations in sub-regional or regional approaches.

Countries in WANA need to establish capacity in biotechnology and biosafety and to harmonise qualification standards if cross border movement and exchange of Genetically Modified Organisms (GMOs) are to be addressed. Additionally, public understanding needs to be promoted and national policies developed. Regional approaches to biosafety would help strengthen the negotiating power in international conventions. The independent development of national systems needs to be discussed, advantages and disadvantages of bilateral and multilateral agreements must be analysed, and possibilities of regional initiatives, projects and programmes should be investigated.

In order to develop national policies, two options exist: policies can either be developed from scratch or countries could capitalise on existing experience. This latter option could be as simple as adopting systems of other countries in the region, such as those of Egypt or Syria, or at least certain elements of their national policies.

To explain the requirements that come with the existence of the International Biosafety Protocol, the workshop will introduce the international setting and related policies. National approaches and initiatives will be presented and discussed. We will attempt to (a) define and document the needs and the status of biosafety in individual countries in the region, (b) determine the level of harmonisation that is available and what will be possible, and (c) look for complementary and synergistic effects. We will try to formulate recommendations in the workshop sessions that could be utilized and followed to help develop harmonised policies between the countries.

I

PRESENTATIONS BY INTERNATIONAL AND NATIONAL ORGANISATIONS

PRESENTATIONS BY INTERNATIONAL/NATIONAL ORGANISATIONS

Trade and international treaties and conventions demonstrate that biotechnology and biosafety have also an international dimension, the latest being the adoption of the Cartagena Protocol on Biosafety, the first protocol under the Convention on Biological Diversity. Therefore, several international experts and experts with international experience have been invited to share their views.

Dr Maria Zimmermann, Biotechnology and Biosafety Focal Point of FAO, explained the different aspects of biotechnology and the role of other UN organisations involved in biotechnology and biosafety issues, like Codex Alimentarius, the International Plant Protection Convention (IPPC), and the International Code of Conduct for Plant Germplasm Collection and Transfer (ICCP). She then elaborated on the role of FAO in biotechnology, and provided ideas and views on how FAO can support the process of establishing and implementing biosafety frameworks.

Dr André de Kathen, consultant on biosafety issues for GTZ, pointed out that after years of negotiation, the transboundary movement of genetically modified organisms (GMOs) will be regulated by the legally binding Cartagena Protocol on Biosafety, on which he described options and implications for national regulatory systems.

Dr Subhash Gupta, from the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA), explained the regulatory mechanism for the release of GMOs in the U.S. With almost 30 million hectares under transgenic crops, the USA accounts for almost two-thirds of the global area under these crops, with more than 6000 experimental field trials, and have therefore much experience with the regulation of GMOs . However, the natural environment in the USA is different, as is the regulatory structure. This point was taken up by Dr John Dodds, patent attorney, who referred to the role of biosafety laws within an international framework.

Dr Magdy Madkour (AGERI, Egypt) and Dr Kauser Malik (PARC, Pakistan) used the opportunity to explain to the participants how their countries approached this issue. Both countries are somehow unique in the developing world since they have established research institutions that are specifically dedicated to the exploitation of modern biotechnology tools for research and development.

Dr André de Kathen then introduced the decision-support tools, which are thought to provide guidance and assistance in developing and implementing national biosafety systems.

Finally, Dr David Duthie, from UNEP/GEF, gave a valuable introduction into the UNEP Pilot Biosafety Project, its outcome, and the possibility to apply for an upcoming UNEP/GEF project, aiming at assisting about 100 countries in establishing and implementing their national biosafety systems.

Introduction to Biosafety: International Aspects of Biotechnology and Biosafety

Maria José de O. Zimmermann
Food and Agriculture Organisation

Biotechnology

CBD: Any technological application that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for specific uses.

Modern biotechnology: In the narrow sense.

Types of Impact

- Environmental.
- Health.
- Scientific.

Impact

- Micro-propagation (tissue culture).
- Vaccines.
- Reproductive technologies.
- Special products.

Impact depends on type of product and production procedures

Raw materials (food and fibres):

- Production in confined conditions.
- Production in the open.
- For industrial utilisation.
- For health.

Biosafety

The safe and environmentally sustainable use of all biological products

- Human health.
- Biodiversity.
- Environmental sustainability.

External factors

- Climate.
- Soil.

- Water.
- Biodiversity.

Factors inherent to the species

- Mating system.
- Pollen dispersal.
- Seed dispersal.
- Cross compatibility.
- Position in food chain.

Factors related to the nature and method of transformation

- Introduced gene.
- Procedure.
- Tissue of expression.
- Selective markers used.

Potential problems for human health

- Allergenicity.
- Unexpected toxin.
- Expression in wrong tissue.
- Antibiotic resistance.

Potential problems for the existing biodiversity

- Displacement/elimination of genotypes.
- Transgenic escape.
- Effects over non-target species.
- Perturbation of biotic communities.

Displacement/elimination of genotypes

- Alien species (African bee in America, rabbits in Australia).
- New varieties: Similar.
- New species: More extreme.

Transgenic escape

- Outcrossing rates.
- Wild relatives.
- Centres of origin.

Effects over non-target species

- *Bt* effects over monarch butterflies.
- Selectable markers might affect animals that eat plants

Perturbation of biotic communities

- Any new genotype, that is more aggressive or more competitive.

Needs

- Risk analysis.
- Benefits: Reduction in health and environmental risks.
- Costs: Increasing time to release increases transaction costs.

FAO perspectives on biotechnology

- A powerful tool in agricultural development.
- Provides new solutions for problems hindering sustainable rural development and achievement of food security.
- Offers unique opportunities to solve many environmental problems through bio-remediation.

Global status of transgenic crops

- Area planted increasing rapidly.
- Number of crops and varieties increasing.
- More countries have approved commercialisation.

Biosafety includes:

- Safe handling.
- Testing.
- Movement.
- All types of biological products.

FAO instruments that deal with biosafety-related issues

- IPPC and SPS.
- Commission on Genetic Resources for Food and Agriculture.
- Codex Alimentarius.
- Code of Conduct for Responsible Fisheries.

International Plant Protection Convention (IPPC) and Sanitary and Phyto-Sanitary (SPS) measures

- Objective: To secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote appropriate measures for their control.
- Prominent role in the agreement on the application of sanitary and phyto-sanitary measures (SPS).
- Allows for phyto-sanitary measures (preventing introduction and spread of pests).

- Based on risk analysis.
- Any living modified organism (LMO) that may be a pest is under IPPC.
- Adopted in 1951, 107 countries.
- Application is not limited to cultivated plants or cultivated systems.
- Protection is not limited to direct damage from pests.
- Scope extends to the protection of natural flora from indirect pest damage.
- A broad interpretation supported and reinforced universally.

Commission on Genetic Resources for Food and Agriculture

- Established in 1983.
- 159 countries.
- The International Code of Conduct for Plant Germplasm Collection and Transfer (ICCP).
- Adopted in 1993.
- The International Undertaking on Plant Genetic Resources.
- Adopted by the FAO Conference in 1983.
- Currently 113 countries.
- Revision is currently being negotiated.
- Draft Code of Conduct for Biotechnology.

Codex Alimentarius

- Adopted in 1962, FAO/WHO Food Standards Programme.
- 163 countries.
- Health safety standards.
- All food safety considerations.
- Food hygiene.
- Quality.
- Recommendations for labelling of foods obtained through biotechnology.

Code of Conduct for Responsible Fisheries

- Adopted in 1995.
- Reflected in UN Law of the Sea.
- Promotion of fisheries and protection of living aquatic environments.

FAO technical assistance and advice

- Provides information.
- Provides a forum for international debate for food and agricultural issues.
- Renders technical assistance to its member nations.
- Seeks to fully realise the positive impact of biotechnology and to minimise possible negative effects.

- Helps to promote international trade in agricultural products.
- Since its foundation in 1945, FAO has had, at the heart of its mandate, a responsibility to provide its member with technical advice and assistance related to agricultural production and trade in food and agricultural products.
- FAO provides scientific and technical expertise to its members on a wide range of agriculture and food-related topics.

Areas of assistance

- Development of national strategies for biotechnology and biosafety.
- Drafting or revision of national legislation.
- Training and manpower development, including inspection, laboratory analysis and management of control programmes.
- Import and export control systems and programmes.
- Risk analysis.
- Awareness and understanding of international treaties, agreements and conventions.
- Assistance in programme development.
- Assistance in data/data systems management.
- Assistance in the development of facilities.
- Facilitating technical cooperation between institutions and governments.

Technical assistance to FAO members in legislation

- Advises its members in relation to renewable natural resources legislation, regulations and systems through cooperation between the technical departments and the FAO Legal Office.
- Provides developing countries with a broad range of legal advice in agriculture and renewable natural resources management.
- Reviews and provides advice about the adequacy of national laws and regulations on:
  - Environment, in particular forests and fisheries
  - Food trade and safety.
  - Seed quality control.
  - Plant protection and animal health.
- Assists in developing and implementing appropriate biosafety legislation for agricultural sectors and related institutions.
- Assists member countries in the definition of criteria for the formulation and implementation of regional and national agricultural policies, programmes and legislation.
- Enhances cooperation between developed and developing countries.
- Assists national authorities in analysing their needs and identifying appropriate policy options.

- Formulates or revises the relevant national legislation and advises on the structure and functions of the institutions involved.
- FAO's experience over many years has shown that justice cannot be done to the particular needs and circumstances of individual countries by theoretical studies or model laws.

Approach to technical assistance in legal advice and legislative drafting

- Review and analysis of the statutory instruments in force and of the institutional framework.
- Identification of the specific objectives, to be attained by means of the proposed legislation, in the light of the government's priorities.
- Elaboration of a draft act and regulations, or amendments to the existing legislation.
- Submission of recommendations and their discussion with the relevant national authorities.

Conclusions

- FAO is prepared to assist governments of developing countries in developing and utilising biotechnology and its products when necessary or required.
- FAO is prepared to help develop and implement pertinent biosafety legislation, in agreement with the biosafety protocol, and to provide technical advice and assistance.
- FAO remains at your service for any other interactions that might pertain to food and agriculture and continues to work closely with its members and other international and national organisations.

The Cartagena Protocol: Options and Implications and Decision-Support Tools for Implementing Biosafety Frameworks

André de Kathen
BioTechConsult

Introduction

In late January 2000, after several years of negotiations, the Extraordinary Conference of the Parties to the Convention on Biological Diversity adopted the so-called Cartagena Protocol on Biosafety. This Protocol is the first binding document arising from the "Convention", signed by more than 170 countries, addressing the need and generating tools and modalities for protecting the environment and biodiversity for ourselves and future generations. Modern biotechnology, and in particular some of its products, namely, genetically living modified organisms (LMOs), may represent, by itself or by changes in agricultural practice when deployed, a risk to environment, society and, perhaps, also to human health.

Now, what is the status of LMOs in a global setting? Field trials have been documented in more than 40 countries (over 130 countries have agreed on the final text of the Protocol and almost 70 have already signed, and it will come into force after more than 90 days after the fiftieth party has ratified). Only a minority of developing countries have conducted field trials with transgenic crops, and an even smaller number has the capacity to develop them, not to mention the vast majority which, as yet, does not have any operational biosafety system in place, neither technical guidelines nor legally binding regulations.

The vast majority of field trials have been conducted in Canada and the U.S.; they account for more than 90% of all test releases. Argentina, Canada and the U.S. account for more than 95% of the area under transgenic crops. Almost 99% of the global area under LMOs is covered with two or three traits, alone or in combination; and the picture is not much different if you break it down by species. Although this represents a whole lot of experience, the question is: What does it mean in the context of WANA, sub-Saharan Africa or the Meso-American? Do these traits cover important breeding objectives? Are the respective crops used? Are the environment and the agricultural practise sufficiently considered? Moreover, since private investment into biotechnology on a global scale follows research capacities, market volume and options for rapid return of investment, the development focus is not only on better agronomic performance. Modified oil and carbohydrates, synthetic polymers, xenogenic proteins for industrial purposes and pharmaceuticals,

such as vaccines, antibodies, selected metabolites and peptides, are field-tested or already in clinical trials.

Considering breeding objectives and the need for better crops and higher yield-stability, especially in developing countries, one may come to the conclusion that investment in biotechnology is not necessarily reflecting developing country needs. Regulations may even add directly to the costs of biotechnology and may aggravate its demand-driven application. On the other hand, without regulations, internalising the potential benefits will be difficult, if not impossible. Therefore, in addition to developing biosafety frameworks, there is a need to:

(a) Create awareness of agricultural research, including biotechnology;
(b) Call for a substantial increase of domestic and developmental assistance into agro-biotechnology research and the development sector; and
(c) Address questions such as socioeconomic impact, liability and public participation as being equally important for sustainable development.

Regulatory infrastructure, enforceable regulations, public acceptance, transparent decision-making, and competence and capacity of all stakeholders are important factors for generating a positive environment for successful implementation of operational biosafety systems and for realising the benefits of modern biotechnology.

After more than a decade of transgenic releases and almost 20 years of research, no risks or harm have been documented or have resulted in some specific or serious damage. But, as demonstrated, experience is limited because long-term effects may appear in the long term, and developments in this area are breathtaking.

With this background, it is reasonable to describe the Biosafety Protocol as an enabling tool to avoid or minimise risks and maximise benefits of modern biotechnology. Its existence is not a result of identified harm and experienced damage, but it respects and considers scientific and public uncertainty. LMOs are new, and not inherently dangerous. This idea is realised by the proactive strategy and, in particular, by strengthening the "Precautionary Principle" as an operational concept in an international protocol.

Of course, the language of the Protocol is diplomatic and flexible and allows interpretation and, of course, comments on its implications, and opinions on potential measures for realising that it differs significantly. One may even come to the conclusion that more than one protocol exists. On the other hand, this provides opportunities for the development of regional strategies and initiatives, facilitating the development of those systems, which consider capacity, culture, regulatory systems and structure in a region, without compromising other international laws. The regulatory infrastructure, scientific expertise, legal tradition, agricultural practice, local and regional biodiversity, and consumer needs, concerns and habits are those factors which differ but have to be considered and may contribute to the final shape of a biosafety regulatory framework.

The Protocol

The text of the Protocol is included in the Proceedings, and important information on the Biodiversity Convention and the Biosafety Protocol can be viewed and downloaded at http://www.biodiv.org. The following points seek to explain what is written in the Protocol and what is not, since the Cartagena Protocol on Biosafety has to be understood as the basis for establishing biosafety frameworks that focus on LMO/GMO.

So, what is special?

The protocol:

- is a legally binding document, focusing on LMOs,
- provides modalities for transboundary movements of LMOs,
- considers trade and environment as equally important issues,
- includes the recourse to the Precautionary Principle as an operational concept,
- demands socioeconomic considerations and public participation in decision-making, and
- has the same standing, although not intending to compromise, as WTO.

There are, of course, several issues in the Protocol which demand a closer look and need detailed analysis. Some still await a consolidated technical procedure labelling or liability, while others are under debate like the triggers and modalities for recourse to the Precautionary Principle. This may lead to some confusion and may also result in a "mish-mash" of decision procedures; however, the scope and objective can be realised in different ways and there is substantial technical and procedural information provided by the Protocol.

Two major topics will be tackled here; one concerns the variability of decision procedures available under the Protocol, the second is the Precautionary Principle. The latter is of importance, since under which circumstances the Precautionary Principle applies, and what measures are appropriate, is a matter of much debate.

1. Advanced Informed Agreement

Probably the most important tool of the Biosafety Protocol is the Advanced Informed Agreement (AIA), meaning that the (first) transboundary movement of LMOs for intentional release in a country is not possible without an agreement of the receiving Party.

An AIA procedure is shifting the responsibility towards the exporting Party and involves three steps: *notification*, *acknowledgement of receipt*, and *decision* (including the review of decisions). This AIA procedure is not applicable to (human) pharmaceuticals, LMOs in transit or to contained use, LMO commodities, and those LMOs which the Conference of Parties has decided are unlikely to have an adverse effect.

Moreover, the AIA procedure provides the option to follow the procedure

described in the Protocol (Article 10) or a national framework, provided it is consistent with the Protocol. The decision procedure in Article 10 defines a temporal and, when considering the Annex, also a technical framework.

The debate on AIA procedures is initiated by the different views on the actual demand or philosophy of the protocol. For some, it represents a trade barrier and, therefore, the Protocol represents the maximum restriction possible. However, the Protocol explicitly allows more stringent regulations, provided they do not violate international law. Moreover, the Protocol is a compromise, a result of difficult negotiations. Consequently, there is also substantial evidence for understanding the Protocol as a minimum requirement, the smallest common nominator.

There are other decision procedures possible. Commodities, currently accounting for almost 90% of the traded LMOs, do not require an AIA procedure. Bulk commodities can be identified as "may contain LMOs". Detailed information requirements are subject to ongoing negotiations within the next two years. However, here, the Precautionary Principle also applies. Also, here, information requirements exist, although they have to be forwarded to the Biosafety Clearing-House and not to the Party of Import. There is also a legal requirement for providing accurate information.

The Party of Import needs to inform the BCH on existing national legislation covering the import of transgenic commodities. If no such legislation exists, import is not possible without a decision, including a science-based risk assessment; the failure to do so does not represent a refusal or consent. Again, and not only for the time being, countries are free to develop their own regulatory structure as long as it is within the objective of the Protocol and does not violate existing international law.

One short remark on labelling is worth mentioning. Two major issues need to be considered here. First, how can the separation of LMOs for food, feed and processing (FFP), and LMOs for intentional release be realised and organised? From the environmental viewpoint, there is no difference between the unintentional release of LMO-FFP and the intentional release of LMOs; they both grow. Second, it appears that a limited number of crops are genetically engineered with an increasing number of traits.

Despite the problem of decreasing agricultural biodiversity, there is an increasing demand for precise labelling and separation. As it might be tolerable (from a risk perspective, not necessarily from the consumers' perspective) that transgenic Bt-maize and non-transgenic maize are mixed in bulk commodities. What about mixing Bt-maize, maize with modified starch or protein content, maize producing industrial xenogenic proteins, herbicide-resistant maize, and non-transgenic maize? Without labelling, not only is safety assessment aggravated, but so also is the reliability of application.

Countries may also decide to provide for a "fast-track" procedure or develop a

decision system within regional, bilateral and multilateral agreements. Since one of the biggest LMO-producers and exporters is a Non-Party, e.g., the USA, it is important to note that the objective of the Protocol also applies under these conditions.

The intrinsic variability of decision procedures is not only a result of diplomatic wording, it also respects national sovereignty within a specific framework. However, there are numerous technical and procedural issues to be dealt with in subsequent negotiations and when developing national regulatory systems.

2. The Precautionary Principle

Risk assessment is part of the decision procedure under AIA. The Protocol sets minimum standards for information to be requested or provided by the applicant and a timeframe for decision-making. Risk assessment needs to consider possible adverse effects of LMOs on the environment and human health, and also socioeconomic impacts; if relevant scientific evidence is lacking, countries are entitled to use the precautionary approach – this is done with strong wording but without specific explanation.

The major question here is what is the trigger, allowing the recourse to the Precautionary Principle, and what measures are allowed, e.g., result from this recourse? Limited scientific information may appear qualitatively, e.g., by contradicting scientific evidence, or quantitatively, e.g., by the amount of evidence needed. It may also reflect what is considered an acceptable risk in a society. In my view, this clearly separates science-based risk assessment and decision-making–and there are more arguments (public information and participation, and socioeconomic considerations).

This does not mean that the Precautionary Principle substitutes any risk assessment. In contrast, risk assessment and evaluation precede the political decision, and delegate responsibility to those having a legitimisation to decide (of course, it could be a political decision to delegate decisions to scientists). In fact, the trigger for recourse to the Precautionary Principle can be regarded as a part of risk assessment, whereas the resulting measures can be identified as part of a risk management scheme. This could include the request for additional information, specific restrictions, a refusal of import, or simply an information campaign on potential adverse effects.

3. Economic Implications

A regulatory system seeks to minimise and internalise externalities, e.g., "accident" costs. However, the system (state-based, national or regional) needs to balance the costs of the regulatory system to society, research institutions, and to the developing (private) industry against those which could be managed by applying the regulatory system and the impact on the ability to realise the potential benefits. Proactive regulations seek to internalise at least some of the potential costs for

future generations; with no regulations in place, the current generation may internalise the benefits at the costs of future ones.

Despite this rather philosophical question, the following factors add to the total costs of biotechnology research and application:

- Documentation and review.
- Institutional capacity and communication.
- Consultants and external expertise.
- Public participation, information and education.
- Training of regulators and biosafety officers.
- Monitoring and surveillance.
- Developing regulations and checking for compliance (including challenges).
- Education and extension of farmers, border control, etc.

The list is probably not complete. In addition, indirect costs and effects can be expected. For example, proactive regulations are not always likely to increase consumers' confidence. Discrimination and unnecessary restrictions represent additional costs which could influence the market, e.g., shifting investment towards crops and traits promising high and short-term returns. Obviously, respective products and research objectives are not necessarily demand-driven.

4. Other Issues

The Protocol demands a form of public participation in the decision-process and the consideration of potential socioeconomic impacts. Since this is very much dependent on existing national or regional environments, the Protocol lacks substantial technical information on how to organise public participation and information and how socioeconomic considerations are contributing to the decision process.

The question of liability and redress is also excluded or postponed to a later stage. However, this has implications on national regulations. Of course, there is a need for an interim mechanism, and one has to decide on different opportunities, e.g., *ex-post* liability, *ex-ante* regulations, or a combination of both.

Dispute resolution is another issue. The Protocol uses the Convention's provisions, e.g., the International Court of Justice. But any trade restrictions resulting from the Cartagena Protocol might be perceived as an infringement of the WTO and, therefore, may end at the WTO dispute panel. It appears that to state an infringement of the Cartagena Protocol is even more difficult to substantiate. To avoid dispute development due to limited exchange of information, the Protocol (Article 20) established a Biosafety Clearinghouse. This exchange might be limited by confidential business information (CBI, Article 21), but the Protocol also states that a summary of a risk assessment covering environment and human health cannot be part of CBI, and the Party of Import has the opportunity to question whether the information provided qualifies for confidential treatment.

For this, the Protocol demands cooperation and support, especially for develop-

ing countries and countries in transition. This goes beyond financial assistance and includes scientific and technical training and the development of respective institutional and technological capacities (Article 22.28 and Article 11.9).

Another short remark on risk or safety assessment is worth mentioning. *Risk assessment is not always pure science*. A risk has a subjective dimension: it depends on perception and short- or mid-term benefits. Obviously, the more geriatric societies in the North with sufficient food production are more likely to accept recombinant pharmaceuticals, functional food or nutraceuticals, despite their direct effect on human health. Other societies may tolerate higher risks when yield and food production are concerned. In other words, communicating risks should not only be restricted to the risk itself, but should also consider the environment within which "risks" are perceived.

Decision-Support Tools for Implementing Biosafety Systems

1. Introduction

Whereas biosafety in the biotech context is restricted to potential adverse effects resulting from LMOs, there is, of course, a broader definition possible, *i.e.*, biosafety as a description for any strategy to protect biodiversity and habitats–actually any biological system–from adverse effects. The categorisation of LMOs in terms of risk (not in terms of "uncertainty") and the narrowed view, excluding the assessment of alternatives or "non-action", is part of a misconception or intrinsic contradiction in the debate on biotechnology and biosafety.

Establishing and harmonising a biosafety system is comparably easy if only technical aspects are considered; copying technical guidelines could be a sufficient activity. However, recognising national or regional political, cultural, religious, agricultural, economic and social differences, the concept of an operational biosafety system is much more difficult to realise. This may account for the focus on technical and scientific aspects in previous training and education on biosafety, but it is unlikely that such an isolated, technique-oriented view gains long-lasting political and consumer support and confidence. However, both appear to be necessary to realise potential benefits resulting from genetic engineering and biotechnology.

Additional factors may account for recent failures in establishing reliable biosafety systems:

- Scientists are often the first in the country to consider the need for a biosafety system.
- Scientists are quite reluctant to regulate themselves, and often do not have (or fail to establish) the necessary links to the political class and responsible decision-makers.
- Time–pressure encourages the adoption of poorly adapted technical guidelines,

lacking political support and commitment that are necessary for their enforcement.
- Regulators have formulated policies, decrees or laws, not considering the capacities, institutional infrastructure and needs within the country.
- Biosafety systems are implemented in an environment, often unfamiliar with the handling of toxic or radioactive waste, hazardous organisms, or impact assessment in general.
- Agriculture and biodiversity, two fields considered to be most likely affected by modern biotechnology, do not receive sufficient attention within national policies despite their importance for the economies of developing countries.
- Milestones or evaluation criteria have not been part of developmental strategies.

This enumeration intends, by no means, to disqualify previous initiatives or question the necessity for developing flexible, technical guidelines. But non-binding guidelines alone, neither represent the spirit of the Protocol nor create confidence in the biotech products or reliability of decision-making for those developing and those trading these products.

2. Biosafety Facilitating Tool

In order to address some of the shortcomings described above, GTZ, within a supra-regional project on the development of frame conditions for the utilisation of biotechnology and genetic engineering, funded the development of a biosafety-facilitating tool, BioFACT. This decision-support system intends to foster awareness through a participatory and multidisciplinary approach, by enforcing the dispute on specific needs, capacities and resources, by involving all stakeholders in the process, and by initiating a political debate. In addition, BioFACT aims to promote the view of biosafety as a system, as an integral part of biotechnology and sustainable development (for details on the supra-regional project view: http://www.gtz.de/Biotech).

Unlike other available decision-support systems or decision trees (e.g., UNIDO's Dtree or the Edmonds' Manual), BioFACT is a training tool which does not restrict itself to risk assessment, but includes additional topics like policy development, legislation, success control, monitoring, etc. BioFACT does not intend to prejudice decisions or promote certain directions. It serves as a kind of manual, facilitating decision-making, trying to assist in creating an environment in which respective decisions on the shape of a biosafety system can be made. In this respect, it is hoped that BioFACT would contribute to the implementation of the Cartagena Protocol. It understands policy development, legislation, assessment procedure, and institutional and human capacity as equally important elements of an integrated approach.

Consequently BioFACT intends to:
- Assist in defining existing regulations related to biosafety (e.g., plant quarantine

regulations) within a given country,
- Suggest a participatory mechanism for the formulation of biosafety policy,
- Comment on the minimum requirements of a legal and administrative infrastructure,
- Provide advice and scientific knowledge on the development of risk assessment procedures based on the Precautionary Principle,
- Enable and facilitate decision-making
- Determine benefits, objectives and limitations of monitoring procedures, and
- Formulate evaluation criteria for assessment of biosafety policy.

In its first extension phase, BioFACT consists of:
- Documenting and providing orientation, background information, and explanation of suggested exercises (including hyperlinks to an off-line library and the Internet).
- Providing a set of transparencies and training modules to be used in education and extension, workshops, seminars, and training courses.
- Setting up an off-line library with relevant Internet documents, including national and model biosafety guidelines and publications on policy development, biosafety management and risk assessment.
- Developing a database which provides a "biosafety profile" of UN-member countries.
- Indicating a list of relevant (electronic) publications and Internet links for further information.
- Listing case studies as examples for monitoring, assessment and reviewing procedures.

BioFACT is extensible in terms of scope and content. Its participatory and facilitating structure calls for suggestions, ideas and feedback in future workshops and seminars.

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Biotechnology Safety Assessment Research at USDA's Agricultural Research Service: Current Programmes and Future Priorities for Agricultural Biotechnology Research

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Executive Summary

This report provides an inventory of biotechnology safety assessment research supported by the Agricultural Research Service (ARS), the in-house research arm of the U.S. Department of Agriculture (USDA), and identifies priorities for further investment by the Federal Government. At USDA-ARS, current funding of research that could provide data for biotechnology safety assessment totals approximately $5.43 million, split between intramural research ($4.61 million) and extramural research, through a granting programme administered by USDA's Consolidated State Research, Education and Extension Service (CSREES) ($0.82 million). Of the intramural funding, the largest concentration is in environmental effects (40%) and evaluation of animal health products (32%).

Modifications in the scope and focus of the research portfolio will continue to occur as the research agencies consult with stakeholders about the scope of their research agendas. Examples of shifts in research priorities can be seen in recent USDA-ARS intramural initiatives that address issues of increasing global concern, such as:

- Blocking gene transfer from crops to neighbouring, closely related weedy plants;
- Monitoring and reducing impact of Bt crops on non-target insects;
- Assessing offsite transport of herbicides whose usage increases on herbicide-tolerant crops; and
- Removing antibiotic-resistance genes from genetically engineered crops.

Consultation between the research and regulatory agencies needs to be improved to ensure that the orientation of grant and contract solicitations and intramural research programmes is truly supportive of the needs of the regulatory and public health sectors. Changes in focus and direction will need to be monitored over time.

Introduction

USDA Biotechnology Risk Assessment Research Grants Programme (BRARGP)

The goals and objectives of the annually funded BRARGP are to assist federal regulatory agencies in making science-based decisions about the safety of introducing genetically modified plants, animals, and microorganisms into the environment. The Programme accomplishes the mission by providing scientific information derived from the risk assessment research conducted under it. The Programme's emphasis is on risk assessment and does not fund risk management research.

Section 1668 under Subtitle H, Miscellaneous Research Provisions of the 1990 Research Title, authorised a grants programme for environmental assessment research concerning the introduction of genetically engineered organisms into the environment. This provision is funded by two mechanisms: (1) an authorisation of appropriations for such sums as necessary, and (2) a one percent set-aside from outlays of the Department for Research in Biotechnology as defined and determined by the Secretary. The Programme became fully operational in FY 1992 and is administered by USDA's two main research agencies: CSREES and ARS. A solicitation of applications is published annually in the Federal Register.

Areas of research that are supported include: (a) introduction into the environment of genetically engineered organisms; (b) large-scale deployment of genetically engineered organisms; (c) assessing the effects of transgenes in wild relatives of crop species; (d) assessing the effects of genetically engineered plants with "stacked" resistance genes or genes that confer broad resistance to insects or diseases; and (e) developing statistical methodology and quantitative measures of risks associated with field testing of genetically modified organisms.

The Programme will, subject to resource availability, provide partial funding to organise a scientific research conference that brings together scientists and regulators to review the science-based data relevant to risk assessment of genetically modified organisms released into the environment. Both USDA's Animal and Plant Health Inspection Service (APHIS) and the Environmental Protection Agency (EPA) officials are consulted each year on specific emphasis areas to be added to the areas of research.

From FY 1992 through FY 1999, ARS, CSREES, and the Forest Service (FS) assessed biotechnology research projects to provide funding for the Programme. Annual funding has ranged from $1.3 million to $1.9 million since the Programme's inception. Approximate funding available for FY 2000 is $1.9 million. Funding is awarded competitively and a total of 66 projects have received funds since the Programme's inception in FY 1992. For FY 2000, a total of 26 proposals were evaluated by a peer review panel, which met on 20-21 July 2000. Ten proposals are recommended for funding this fiscal year.

Examples of Funded Research

1. Researchers from the University of Florida and Baylor University have investigated the probability that virus-resistant crops will facilitate the production of novel, hybrid viruses, as field viruses recombine with viral transgenes in crops. Using tobacco mosaic virus and the wild tobacco plant *Nicotiana benthamiana*, and working under conditions closely resembling an actual field scenario, researchers detected no recombination between transgenes and viruses. These results indicate a low risk that virus-resistant crops will contribute to the development of more virulent viruses.
2. Researchers at Rutgers University investigated whether insect-parasitic nematodes engineered to produce a heat-shock protein show enhanced attributes of infection, virulence, or survival that might pose an environmental threat. They found no differences between transgenic and wild-type nematodes in their ability to infect and kill 11 species of invertebrates, and no differences in virulence or survival. Sold as a commercial biological insecticide, this transgenic nematode is more likely to survive storage under sub-optimal warehouse or transport conditions than its wild type, and poses no detectable environmental risk.
3. Researchers at Oregon State University are investigating whether movement of genes from transgenic hybrid poplar pose an environmental risk due to the potential for long-distance dispersal of pollen and seed. Working with established stands of poplars growing near hybrid poplar plantations, they found that a very small percentage of wild poplar progeny resulted from pollination by hybrid pollen, and that while hybrid seedlings established and grew at about the same rate as wild seedlings, hybrid progeny comprised only about 1% of natural regeneration in the vicinity of plantations. Therefore, while there is substantial potential for gene flow from plantations, observed rates of gene flow are relatively low.
4. In 1999, a proposal was submitted to the Department for the purpose of completing a review and synthesis of risk assessment research results to aid the public and the research community in identifying which risks require further investigation and/or management, and which concerns may be laid to rest, based on scientific evidence.

The resulting report is intended to summarise all relevant research findings (including, but not limited to, studies funded by BRARGP) from peer-reviewed literature, and is to be written in non-technical language by experts in the field. A steering group for the project, comprised of members from the Department, other regulatory agencies, and experts in the field, will be chaired by Dr Dean Gabriel of the University of Florida. CSREES and ARS have contributed $24,000 in funding for the project, which has a projected completion date of fall 2001.

Since the inception of the USDA Biotechnology Risk Assessment Research Grants Programme in 1992, ARS has been a contributor, using a "set-aside" of one

percent of the prior year's research funding for biotechnology. Within the last year, as more and more stakeholder groups became concerned about biotechnology safety, ARS has developed plans to address their concerns. The first step has been to identify in-house research that is already in place, which addresses issues of biotechnology safety. This in-house research is included in the estimates that follow in the next section.

Initiative for Future Agriculture and Food Systems (IFAFS)

Finally, there is the IFAFS, which is a one-time, $100 million programme to fund research, education, and extension activities on critical agriculture and food issues. It includes $10 million for agricultural biotechnology in two areas: (1) effects of agricultural biotechnology on human, animal, and plant health, including management of pest resistance, pollen drift, effects on non-target species, antibiotic resistance, and food allergens; and (2) social and economic effects of agricultural biotechnology on trade, business, economics, industry structure and consolidation, regulatory sufficiency, product labelling, consumer acceptance, and diverse value systems. ARS scientists are recipients of numerous IFAFS grants.

Current ARS Biotechnology Safety Assessment Research Programmes

The USDA-ARS current portfolio of in-house research projects addressing biotechnology safety, as determined by ARS headquarters, totals approximately $4.61 million. This is divided among the indicated breakout categories as follows:

- Safety: $534,000.
- Animal pharmaceuticals: $1,495,000.
- Modified environment: $1,822,000.
- Gene flow-plants: $378,000.
- Gene flow-microbes: $385,000.

In addition, ARS supports the USDA extramural grants programme in biotech safety, which at various times addresses all these issues. In FY 2000, the ARS funds for competitively awarded grants totalled $813,000.

Health Issues

Safety (e.g., toxicity, allergens, product nutrition, genetic stability, other health effects)

(1) **Goal**: Modify milk composition as a basis for new and safer products (Robert Wall, Plant Gene Expression Lab, Beltsville, Maryland).
Status: Technology of transgenesis in mammary glands is in development.

Recommendations: Evaluation is needed of the quality and safety of transgenic products once produced; this includes short-term and long-term evaluation of the suitability of transgenic animal products from modified milk.

(2) **Goal:** Develop a hypo-allergenic soybean for use by persons with allergic reactions to soy, especially babies who cannot tolerate milk-based formulas (Elliott Herman, Climate Stress Research Lab, Beltsville, Maryland).
Status: Allergenic proteins, and their genes, were identified in soybean. Soybean plants with reduced allergen content have been created. Product is now beginning to undergo testing as a hypo-allergenic material for formula and other uses.
Recommendations: Continuing cooperation with medical school-based cooperators is needed to evaluate the allergenicity and other attributes of the modified soybean; long-term evaluation of the genetically engineered crop is also required. Future efforts should include similar initiatives for other allergenic crops.

(3) **Goal:** Develop a potato with reduced or no toxic glyco-alkaloid content (William Belknap, Crop Improvement/Utilisation Research Unit, Albany, California).
Status: Reduced-glyco-alkaloid potato plants have been produced through genetic engineering, and are being tested for disease resistance and other agronomic traits.
Recommendations: Tests of the engineered plants need to be extended to include monitoring of gene flow in the presence of wild relatives (in the Andes), and the survival and vigour of reduced-alkaloid plants when under heavy pest pressure.

Animal Pharmaceuticals (e.g., contamination, change in the derived food, change in animal health)

1. **Goal:** Evaluate newly developed animal vaccines against serious diseases and parasites: (1) avian leukosis virus in chickens (A.M. Fadly), and Marek's Disease (R.L. Witter, Avian Disease and Oncology Lab, East Lansing, Michigan); (2) controlling swine parasites (J.F. Urban), parasitic infections in cattle (L.C. Gasbarre), protozoan parasites (R. Fayer, Immunology and Disease Resistance Lab, Beltsville, Maryland); (3) transgenesis in cattle (V.G. Pursel, Gene Evaluation and Mapping Lab, Beltsville, Maryland); and (4) African Swine Fever (J. Neilan and D. Rock, Foreign Animal Disease Lab, Plum Island, New York).
Status: New vaccines are being developed using recombinant organisms that have reduced virulence compared to the unmodified pathogen.

Recommendations: Much of this work has international significance, as many of these diseases have not yet entered the USA because of quarantine barriers. When successful vaccines are available, they should be evaluated as thoroughly as possible through cooperative work at numerous locations, especially overseas research locations where the diseases are endemic. Data to be collected include efficacy, animal health effects, and changes in meat and other animal products used as food. International coalitions to accomplish these goals need to be formed and funded.

Environmental Issues

Gene Flow-Plants (e.g., cross pollination, transfer into viruses and microorganisms, transfer of seeds)

(1) **Goal:** Develop technology to prevent lateral transfer of genes from crops to closely related weedy plants (M.J. Oliver, Plant Stress and Germplasm Development Research Unit, Lubbock, Texas).
Status: A patented system to control gene expression, of which ARS is co-owner, is the only technology currently available to prevent the spread of transgenes from crops to closely related species. This system will make the progeny of such outcrossing sterile. The genetic control is currently being assembled in a crop plant (each of several component transgenes being brought into the same plant by conventional crossing) for demonstration.
Recommendations: The utility of this patented system to manage gene flow needs to be very carefully tested, under controlled conditions, to determine effectiveness. The potential of sterile seeds showing up where they are not wanted (e.g., in neighbouring fields of the same crop) must also be tested in carefully designed experiments. The practices that promote safe use of this technology will require several years of more intensive investigation, probably in cotton as the first target crop, then followed by other self-pollinated crops.

(2) **Goal:** Develop technology to place transgenes in optimum locations in the target genome (David Ow, Plant Gene Expression Centre, Albany, California).
Status: Genetic systems to accomplish the goal are under development.
Recommendations: Locating transgenes appropriately in the genome will accomplish several beneficial purposes, including, in some cases, protecting them against transfer to related weedy species. This technology is not yet mature, and needs several more years of research before it will be ready to evaluate in "real-world" conditions.

Gene Flow-Microbes (e.g., recombination, antibiotic resistance)

(1) **Goal:** Replace selectable marker genes carrying antibiotic-resistance traits with new, more benign selectable markers, to allay concerns about the spread of

antibiotic resistance in the environment (T. Weeks, Wheat, Sorghum, and Forage Research Unit, Lincoln, Nebraska).

Status: Alternative selectable marker genes that convert non-toxic, non-nutritive materials into compounds supplying essential nutrients to plant cells have been developed. This is intended to replace the use of antibiotic resistance markers, which have raised fears that antibiotic resistance might spread from the transgenic plants to bacteria.

Recommendations: The utility of this system needs to be thoroughly explored, and other selectable markers with benign consequences need to be developed.

(2) **Goal:** Remove selectable markers after all selections have been completed and they are no longer needed (David Ow, Plant Gene Expression Centre, Albany, California).

Status: Removal of selectable markers means that the antibiotic resistance trait will not be present in the food end-product that is eaten.

Recommendations: This technology is developed, patented, and licensed to a company. Further work to use the system will be cooperative with the company.

Gene Flow-Animals (e.g., accidental release)

Modify environment (e.g., resistant organisms, recombinant viruses, displacement effects-fitness/persistence, non-target effects, ecosystem effects)

(1) **Goal:** Detect Bt resistance in pests of Bt corn and cotton, and develop improved strategies to prevent the development of resistance (D.A. Streett, Southern Insect Management Laboratory, Stoneville, Mississippi; R.L. Helmich, Corn Insects and Crop Genetics Research Unit, Ames, Iowa; T.J. Henneberry, Western Cotton Research Lab, Phoenix, Arizona; J.N. Jenkins, Genetics and Precision Agriculture, Mississippi State, Mississippi).

Status: Long-term experiments are in place to determine the effectiveness of current strategies to prevent insect resistance to Bt. These experiments are in early stages, as Bt crops were not widely planted until the late 1990's. Resistance to Bt has not yet significantly increased over the base level.

(2) **Goal:** Quantify effects of Bt corn on Monarch butterfly (R.L. Helmich, Corn Insects and Crop Genetics Research Unit, Ames, Iowa).

Status: Studies have indicated that Bt-containing corn pollen on the leaves of milkweed, the sole food for Monarch larvae is, at the most, a very small problem. Milkweed is not common within or near cornfields, where weeds are tightly controlled, and virtually all corn pollen falls to the ground very near the field.

(3) **Goal:** Optimise weed and herbicide management in herbicide-resistant crops (K.N. Reddy and W.T. Molin, Southern Weed Science Research Unit, Stoneville, Mississippi; M.J. Shipitalo, North Appalachian Experimental Watershed, Coshocton, Ohio).

Status: Long-term studies are in place to follow changes in weed populations, weed characteristics, and herbicide fate and transport when herbicide-resistant crops, particularly glyphosate-resistant soybeans, are introduced.

(4) **Goal:** Follow the decomposition of cornstalk residues in Bt and non-Bt fields and the persistence of Bt toxin in the soil, and identify changes in the soil microflora that affect long-term processes (J.L. Hatfield, National Soil Tilth Lab, Ames, Iowa).
Status: Unconfirmed reports that Bt cornstalk residues decompose more slowly are being followed up. This work is in its initial stages.

(5) **Goal:** Optimise the management of low-phosphorus manure from animals fed engineered low-phytate acid grain (high phosphorus bioavailability), to keep excess nutrients out of surface and ground waters (G. Varvel, Soil and Water Conservation Unit, Lincoln, Nebraska).
Status: The case for making nutrients in feed more bioavailable to animals is very compelling. Low-phytate corn (produced by conventional breeding) is available today, and there is little doubt that it can change the nutrient balance of the soil and alter manure disposal practices, to the betterment of water quality. These practices need to be optimised for each animal production system and for the engineered low-phytate acid feed grains to follow. This is long-term integrative research, requiring multidisciplinary teams (experts in plants, animals, soils, microbiology, water chemistry, and economics).

Recommendations

These issues, listed above, are all long-term ecological studies that require sustained, multidisciplinary research. Many of the hypothesised environmental changes due to genetically engineered crops will not become visible until several years have passed. The integrated research requires continuing support, and, as the available products expand, the research programme must also expand.

Surveillance and Monitoring Issues

Detection sensitivity and specificity (organisms, genes, proteins, carbohydrates, products).

Social and Economic Issues

These are being addressed under IFAFS.

Conclusions

In general, there are two approaches to assessing and reducing risk from genetically engineered crops, and both are necessary.

1. We need new biotechnology research to be able to control the process better (for example, to prevent outcrossing and gene spread); and
2. We need stable-funded, long-term ecological studies to monitor changes in the health of agroecosystems, and to determine best management strategies.

ARS is already addressing some of these issues with in-house projects funded at approximately $4.61 million. Planning is underway to expand this in-house ARS research programme. ARS recently organised a committee to: (1) identify potential risks associated with anticipated products of current biotechnology research in ARS, and recommend actions to the agency; and (2) develop a coding system to identify and track research projects that address biotechnology risks. The committee includes membership from USDA-CSREES and USDA-APHIS as well as ARS. Anticipated future expansion will depend in part upon the recommendations of the committee.

Appendix A

The following information reflects expenditure data for FY 1999 with future projections based on actual budget figures for FY 2000. Please note that, in general, numbers of projects are not given for FY 1999 or FY 2000.

USDA-ARS will request additional funds in its FY 2002 budget proposal and for the out years to support an expansion of biosafety assessment research. This will be primarily for research that is long-term and requires stable funding that cannot be guaranteed by competitive grants or other funding sources. For FY 2001, the projected expenditures on biotechnology research related to safety assessment will be slightly increased over 2000 (intramural: projected $4.61 million; extramural: projected $0.88 million).

Funding

Total for ARS:	$5,427,000	Gene flow-plants	$ 378,000
Extramural funding:	$ 813,000	Gene flow-microbes	$ 385,000
Health:	$2,029,000	Modified environment	$1,822,000
Safety	$ 534,000	Surveillance/monitoring:	None
Animal pharmaceuticals	$1,495,000	Social/economic:	None
Environment:	$2,585,000		

Appendix B

List of ARS Scientists Conducting Biosafety Research
(and main contact information)

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Agricultural Biotechnology: Science, Regulation and Policy for Products

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Abstract

Science-based decisions have been utilised for regulating agricultural biotechnology in the United States. Information pertaining to risk assessment procedures used for agricultural products derived through modern molecular methods will be discussed in my presentation. Three lead federal agencies, the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS), the Department of Health and Human Services' Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), have the responsibility for implementing the nation's biotechnology regulatory framework. Within this framework, the U.S. regulatory process is constantly being reassessed and refined for all foods, both bio-engineered and traditional.

In this presentation, I will focus on the role of USDA in regulating agricultural biotechnology products. Deliberate environmental releases of genetically modified organisms (GMOs) in the U.S. are subject to regulations developed under the Federal Plant Pest Act and the Federal Quarantine Act. Information on the reproductive biology of the organism, engineered trait, environment and conditions of the release, including measures taken to prevent persistence and dissemination into the environment, inspection and monitoring, security, termination and disposal plans, are considered during the evaluation of potential risks to the environment, including impacts on non-target organisms and human health.

A simplified, expedited notification process has nearly replaced the permitting process. Developers can petition APHIS to deregulate regulated articles based on evidence that these articles do not pose a plant pest risk. Petitioners submit copious amounts of pertinent scientific information, including data collected during field trials to support their petition. Safety or risk issues and concerns are addressed in documents prepared by APHIS. By using science-based, transparent and timely regulatory decisions, APHIS has been able to approve 53 different products in 11 crop species for large-scale production. Most have completed all of the applicable regulatory requirements from EPA and FDA. Some of these have entered commercial production.

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Introduction

In recent months, agricultural biotechnology has been in the forefront in the media because of perceived consumer and environmental concerns. I believe that with any new technology there are always some questions, and this technology appears to be no different in this respect. But we, as scientists and decision-makers, should use science as a basis to address environmental and food safety issues. With this in mind, I would like start with discussing the authority granted to three different agencies for regulating genetically engineered organisms in the United States.

U.S. Coordinated Framework for the Regulation of Biotechnology

The policy which laid out the "Coordinated Framework for Regulation of Biotechnology" among the various federal agencies in the United States was published in the official government publication, the Federal Register, Vol. 51, No. 123, 23302-23350, June 26, 1986. This policy stated that products developed through biotechnology do not differ fundamentally from conventional products and that the existing framework is adequate to regulate products derived through biotechnology.

This policy defined the responsibilities of the Department of Agriculture, the Food and Drug Administration (FDA), and the Environmental Protection Agency (EPA), and set policy for any subsequent regulations based on existing statutes or laws. Thus, it is important to note that when this framework was established in 1986, a conscious policy decision was made that existing laws will be used to make regulations to regulate genetically engineered organisms.

USDA-APHIS Regulatory Authority

The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has the responsibility to protect American agriculture from plant and animal health risks. As such, it was the first federal agency to promulgate a set of codified rules governing the safe introduction of certain genetically modified organisms into the U.S., under the authority of the Federal Plant Pest Act and the Plant Quarantine Act.

These regulations, codified in Title 7 of the Code of Federal Regulations (CFR), Part 340, and originally published in the Federal Register on June 16, 1987 (52 FR 22892-22915), provide procedures for obtaining a permit or for providing notification, prior to "introducing" a regulated article. Regulated articles are considered to

be organisms and products altered or produced through genetic engineering that are plant pests or for which there is reason to believe are plant pests. Introduction refers to any importation into or interstate movement through the United States, or release into the U.S. environment outside an area of physical confinement.

The regulations were modified in 1993 to provide for a petition process for the determination of non-regulated status for a product. Once a determination of non-regulated status has been made, the product (and its offspring) no longer requires APHIS approval under these regulations for such introductions. Veterinary biologics, including those derived through biotechnology, are also regulated by APHIS under the Virus, Serum, and Toxins Act.

EPA Regulatory Authority

The Environmental Protection Agency ensures the safety of pesticides, both chemical and those that are produced biologically. The Biopesticides and Pollution Prevention Division of the Office of Pesticide Programmes uses the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to regulate the distribution, sale, use and testing of plants and microbes producing pesticidal substances.

The EPA issues pesticide registrations and experimental use permits under FIFRA. Under the Federal Food, Drug and Cosmetic Act (FFDCA), EPA also sets tolerance limits for substances used as pesticides on and in food and feed, or it establishes an exemption from the requirement of a tolerance. EPA also establishes tolerances for residues of companion herbicides used on novel herbicide-tolerant crops, and considers the potential for changes in herbicide use patterns. In 1994, EPA published a proposed rule and policy on how it intends to apply FIFRA and FFDCA to pesticides expressed in plants (59 FR 60496, 60519, 60535, 60542, 60545). A final rule has not yet been published.

Under the authority of the Toxic Substances Control Act (TSCA), EPA's TSCA Biotechnology Programme regulates microorganisms, intended for commercial use, that contain or express new combinations of traits which, for all practical purposes, do not fall under the other existing laws or regulations, for example, microorganisms designed for bioremediation or as biosensors of other products. This includes "intergeneric microorganisms" formed by deliberate combinations of genetic material from different taxonomic genera.

FDA Regulatory Authority

The Food and Drug Administration (FDA) regulates food (except poultry and most meats) and feed, food additives, veterinary and human drugs, and medical devices

also under FFDCA. In 1992, FDA published a "Statement of Policy: Foods Derived from New Plant Varieties" (57 FR 22984) based on the existing authority of FFDCA. This policy requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. FDA's biotechnology policy treats substances intentionally added to food through genetic engineering as food additives if they are significantly different in structure, function, or amount than substances currently found in food.

Most food crops currently being developed using biotechnology do not contain substances that are significantly different from those already in the diet, and thus do not require pre-market approval. The policy describes when consultations with FDA are necessary, when labelling is required, and what information should be conveyed in labels. Consistent with this policy, FDA expects developers to consult with the agency on safety and regulatory questions.

USDA-APHIS Regulations and Reviews of Transgenic Plants

Laboratory and greenhouse research is not regulated by USDA, but researchers and developers generally follow the National Institute of Health (NIH) or USDA biosafety guidelines. Experimental protocols for laboratory and greenhouse experiments using genetically engineered organisms are submitted to the Institutional Biosafety Committee (IBC) to get its approval to conduct proposed laboratory and greenhouse experiments.

However, for a field test on a new product derived through genetic modification, a USDA-APHIS permit or notification is required. For large-scale cultivation, a step towards commercialisation of an agricultural biotechnology product, the developer is required to remove that product from the USDA regulations by petitioning to APHIS.

Safety reviews are focused on rigorous risk analyses based on sound scientific data. Attention to process without a credible risk basis is avoided. Existing laws and regulations have been supplemented to deal with transgenic organisms in the United States.

Permits

Field testing of genetically engineered organisms is possible in an open environment, but for confined releases, it is subject to regulations under the laws administered by USDA. A permit is required for the introduction (importation, interstate movement and environmental release) of organisms and products altered or produced through genetic engineering, from APHIS under the Federal Plant Pest Act (FPPA) and Plant Protection and Quarantine Act (PPQA).

How are environmental risk assessments performed? Broadly speaking, we follow Annex 3 of the UNEP Guidelines for Safety in Biotechnology, which lays out the broad steps in biosafety review. These can be paraphrased as:

(1) identifying hazards;
(2) assessing actual risks that may arise from the identified hazard;
(3) determining how the identified risks can be managed and whether to proceed with the proposed action; and
(4) comparing the assessed risks with those posed by actions with comparable organisms.

Field testing under controlled conditions involves the following components:

- Scientific review.
- Appropriate confinement.
- Oversight of testing.

APHIS has, until recently, prepared environmental assessments (EAs) in accordance with the National Environmental Policy Act, prior to issuing permits for all environmental releases. These EAs provide background information on:

- the reproductive biology of the organism,
- engineered trait,
- environment and conditions of the release, including measures taken to prevent persistence and dissemination into the environment, and
- inspection and monitoring, security, termination and disposal plans.

These factors are considered in the evaluation of potential risks to the environment, including impacts on non-target organisms and human health. However, new APHIS guidelines recognising our increased experience require that EAs be written for confined releases only when the release involves new organisms or species or novel modifications that raise new issues not previously addressed.

Notifications

This is a streamlined permit process used for the release, interstate movement, and importation of eligible transgenic plants. This process was put in place in March 1993 by APHIS. If the transgenic plant meets specific eligibility criteria and can be introduced in accordance with the stipulated performance standards, field tests can proceed 30 days after notifying APHIS. There are six eligibility criteria that specify what plant species/trait combinations are eligible for notification.

In the amendments of 1993, only six crops (corn, cotton, potato, soybean, tobacco, and tomato) were eligible if the other five criteria were also met. The remaining five criteria specify requirements that must be met by the transforming genetic materials. The performance standards establish safety goals without specifying exact design protocols for how these goals should be met. Their primary goal is to

preempt any safety issues by preventing the establishment of the transgenic plant and its progeny in the environment. In 1997, the rule was further streamlined to include all crops.

Eligibility Criteria and Performance Standards

As specified in the regulations, the first criterion is that the plant species are corn (*Zea mays*), cotton (*Gossypium hirsutum*), potato (*Solanum tuberosum*), soybean (*Glycine max*), tobacco (*Nicotiana tabacum*), or tomato (*Lycopersicon esculentum*). In 1997, APHIS streamlined the process further to include all other crops, provided they meet other criteria.

The second criterion is that the introduced genetic material is stably integrated. This criterion excludes regulated articles with genetic material maintained in an extra-chromosomal manner, whether on plasmids or on viral vectors, or maintained on transposable elements.

The third criterion is that the function of the introduced genetic material is known and its expression in the regulated article does not result in plant disease. If the nucleotide sequence encodes a protein, then the enzymatic reaction it carries out or its structural or other intracellular roles should be known. This criterion excludes nucleotide sequences whose sole identification and/or characterisation is the fact that they are expressed in response to a particular chemical or physical stimulus. This criterion excludes many sequences expressing pathogenesis-related proteins. Sequences obtained from messenger RNA libraries and with no assigned function are also excluded. The Guidance on Assigning Protein Function details how sequence homology to proteins of known function may be used to fulfil this criterion.

The fourth criterion is that the introduced genetic material does not:

(1) cause the production of an infectious entity,
(2) encode substances that are known or likely to be toxic to non-target organisms known or likely to feed or live on the plant species, or
(3) encode products intended for pharmaceutical use.

This criterion ensures that the plant has not been modified to produce a plant virus, an animal virus, a human virus, a viral satellite RNA, or a defective interfering RNA molecule. It allows the notification alternative for plants expressing a toxin that may be toxic to non-target organisms which are not likely to feed or live on that plant species.

The fifth criterion is that the introduced genetic sequences derived from plant viruses do not pose a significant risk of the creation of any new plant virus. Plant virus sequences that are eligible include:

(1) non-coding regulatory sequences of known function,
(2) sense or antisense constructs derived from viral coat protein genes, or
(3) antisense constructs derived from non-capsid viral genes

Sense and antisense constructs must be derived from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species.

For a non-coding regulatory sequence to be eligible, the DNA sequence must be a promoter, enhancer, intron with enhancer activity, upstream activating sequence, polyadenylation signal, transcription terminator, or other known regulatory sequence. This criterion excludes the release of plants expressing sense constructs to viral genes other than the coat protein gene. Plants expressing sense non-capsid viral proteins can still be introduced under permit. A list of plant viruses and geographic locations is available from APHIS for the determination of eligibility of viral gene constructs for notification.

The sixth criterion is that the plant has not been modified to contain certain genetic material derived from an animal or human pathogen. Plants containing any nucleic acid sequence derived from an animal or human virus are not eligible for notification.

In addition, plants containing coding sequences whose products are known or likely causal agents of disease in humans or non-target animals are not eligible (e.g., expression of Cholera Toxin A).

Performance Standards for Field Testing

These are:

- Contained shipping.
- No inadvertent mixing from planting.
- Recognisable
- No viable vector agent.
- Regulated article or offspring cannot persist in the environment.
- Viable material and volunteers removed.

APHIS has approved or acknowledged over 6000 field trials (of which 88% were commercial) under the permitting and notification process for at least 52 plant species and eight microorganisms. Plant species range from agriculturally important crops such as corn, soybean, tomato and potato, to other organisms such as Arabidopsis thaliana, barley, broccoli, carrot, chicory, cranberry, creeping bentgrass, eggplant, gladiolus, grape, pea, pepper, raspberry, strawberry, sugarcane, sweetgum, watermelon and wheat.

Petition Process

This is a provision for individuals to petition USDA-APHIS to deregulate regulated articles based on evidence provided that the articles do not pose a plant pest risk. The petitioner submits a petition that includes *information, experimental data, field data reports, and publications to substantiate* that the regulated article is unlikely

to pose a greater plant pest risk than the *unmodified organism from which it was derived*, including, but not limited to, plant pest-risk characteristics, disease and pest susceptibilities, expression of the gene products, new enzymes or changes to plant metabolism, weediness of the regulated article, impact on the weediness of other sexually compatible plants, agricultural or cultivation practices, effects on non-target organisms, including humans, direct or indirect plant pest effects on other agricultural products, transfer of genetic information to non-sexually compatible organisms, and any other information deemed relevant to a determination by the Director. In addition to this information, the petitioner certifies that the petition includes all information and views for the basis of a determination, and data and information unfavourable to the petition.

The petition for "*Determination of Non-regulated Status*" involves the following components:

- Scientific review.
- Public input.
- Determination.

Prior to deregulation, APHIS reviews the information provided by a petitioner, seeks public input, and prepares an EA which further addresses the potential environmental and human health risks posed by the unconfined growth and distribution of the regulated article in many environments.

Safety or risk issues and concerns addressed in this EA include the following: (1) the potential for the GMO to exhibit increased weediness compared to the non-modified recipient organism; (2) potential impacts associated with possible gene introgression from the GMO to sexually compatible plants, including cultivated and wild relatives both in the U.S. and in the centres of diversity for the GMO; (3) the potential to cause injury, disease, or damage to raw or processed agricultural products such as through the production of toxicants, infectious agents or increased susceptibility to plant pests; (4) the potential for the GMO or its products to have damaging or toxic effects directly or indirectly on non-target organisms, particularly those that are recognised as beneficial to agriculture and on those which are recognised as threatened or endangered in the U.S.; and (5) potential impacts from cultivation of the GMO on current agricultural practices.

APHIS Authorisations

Fifty-three different products in 11 crop species have completed all APHIS reviews. Most have completed all of the applicable regulatory requirements from EPA and FDA as well. Some of these have entered commercial production. Many have entered traditional breeding programmes to have the new traits crossed via conventional means into additional useful genetic backgrounds.

Harmonisation

There have been a number of international initiatives to ensure harmonisation of regulatory review of biotechnology products in the past 10 years. We have worked through international organisations to develop consensus on scientific principles as the basis for review and to develop international documents that can be used as part of a review.

These organisations have included the Organisation for Economic Cooperation and Development (OECD), the North American Plant Protection Organisation (NAPPO), Inter-American Institute for Cooperation in Agriculture (IICA), various FAO forums, and, most recently, the Asia Pacific Economic Community (APEC) and International Plant Protection Convention (IPPC). This work is critical to develop understanding with multiple countries over principles and approaches.

Conclusions

The "Coordinated Framework" established a science-based approach for risk assessment of the products of biotechnology, based on currently existing statutes, that has allowed for the safe and rapid development of products in the U.S. at a time when the technology was quickly progressing. Unfortunately, this development has been too fast for some consumers and policy-makers, as with many new technologies.

The USDA is attempting to address many of the policy, regulatory, and scientific concerns posed by biotechnology through the establishment of a new advisory committee, and it continues to coordinate with other agencies to facilitate technology transfer and capacity-building through many international and regional workshops on biosafety.

Hopefully, through these efforts and those of other governments, industry, and academia, we can safely enjoy the benefits of biotechnology while exercising an appropriate level of regulatory review to minimise risks and ensure public confidence in this technology. Government decision-makers thus have an important responsibility to serve their public, including, not only consumers, but also scientists and producers. The development in science and technology cannot, or should not, be stopped while meeting consumer needs.

I wish to end my presentation with a statement from an article published in the January 11, 1999 issue of *Time Magazine*, where James Watson, the Nobel Laureate, said: "Recombinant - DNA may rank as the safest revolutionary technology ever developed. To my knowledge, not one fatality, much less illness, has been caused by a genetically manipulated organism". We can safely draw one conclusion from this statement, that we should not postpone experiments or use products that have clear benefits for fear of dangers that **cannot** be quantified.

The Impact of GMOs on the Environment and Our Nutrition

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New Plant Materials Deployed, But Are They Safe?

Background and Prior Debate

Genetically modified organisms (GMOs) have a better predictability of gene expression than the conventional breeding methods, and these new "transgenes" are not conceptually different from the use of native genes or organisms modified by conventional technologies. For some people, the real issues with transgenic plants might well be that they perceived that the risks are not well investigated or known. In conventional plant breeding too, one can neither foresee nor control what the physiological impact of new genes might be, given the genetic background of the host plant.

The focus of biosafety regulations needs to be on safety, quality, and efficacy. The need and extent of safety evaluation may be based on the comparison of the new food and the analogous food, if any. Further, the interaction of the new genes with the environment needs to be investigated. The potential of recombinant technologies to allow greater modification than is possible with the conventional technologies has a greater bearing on the environment. The management, interpretation, and utilisation of information will be an important component of risk assessment to determine the effectiveness and reliability of this technology.

Identification of Key Issues

Biosafety assessment requires that risks, benefits and needs be given a balanced assessment in relation to transgenic organisms. In 1998, over 40 million acres of transgenic crops were grown around the globe. As these products are traded and pass from one country to the other, it is important to ensure that domestic regulatory regimes are in place to ensure the safe use of these products. What is safe in one country may not be safe in another because of genetic background of the flora. A genetically engineered potato in Idaho has different safety issues than the same potato in the highlands of the Andes, where its wild relatives are to be found.

There are many initiatives underway to work with developing countries on biosafety matters; some are directly through the CGIAR Centres, like ICARDA, and others are under UN organisations, such as FAO. Other biotechnology providers such as ISAAA, ABSP, and others are also providing training in this area.

Future Trends

As with any new and evolving technology, due caution must be exercised until the products of the technology are proven safe and attain a deregulated status after satisfying the concerned regulatory authorities. Transgenic technology is similar in this regard and emphasis should be on the product rather than on the process. The ultimate choice should lie with the well-informed consumer and not on the proponent or opponent of the technology or the product.

The recommendations from a working group comprising policy-makers and scientists from six countries, under the auspices of the National Academy of Sciences of the USA, have suggested that, as is the case with the development of any new technology, a careful approach is warranted before development of a commercial product. Further, it must be shown that the potential impact of a transgenic plant has been carefully analysed and that, if it is not neutral or innocuous, it is preferable to the impact of the conventional agricultural technologies that it is designed to replace.

Major Constraints and Opportunities

Research on transgenic crops, as is the case with conventional plant breeding, aims to alter selectively and add or remove a character of choice in a crop plant, bearing in mind the regional needs and opportunities. However, the promise of biotechnology for increasing the production and productivity of crops for sustainable crop production has been dimmed by the perceived safety of the transgenic organisms and evolution of resistant strains of insects.

In some developed countries, public interest and environmental groups have raised concerns about the real or conjectural effects on non-target organisms, while in the developing world, caution has given rise to fear because of lack of information. In response to these concerns, a biosafety working group has been formed by the Food and Agricultural Organisation (FAO), United Nations Environment Programme (UNEP), United Nations Industrial Development Organisation (UNIDO), and World Health Organisation (WHO), and guidelines for handling and release of genetically modified organisms have been published.

Biosafety and Food Safety: Maybe It is Safe to Grow, but is It Safe to Eat?

Background and Prior Debate

Genetically improved foods are not intrinsically good or bad for human health. Their health effects depend on their specific content. Hence, the risks and opportunities associated with genetically improved foods should be integrated into the gen-

eral food safety regulations of a country. The regulatory systems of a country are needed to govern food safety and assess any environmental risks, monitor compliance, and enforce such regulations. The regulatory arrangements should be country-specific and reflect relevant risk factors. As a result of such intervention, the possible commercialisation of soybeans with a Brazil nut gene that also carried with it a major allergenic factor was avoided. Another intervention may be the need to label the content for cultural and religious reasons or simply because the consumers may want to know what their food contains and how it was produced. The public sector must design and enforce safety standards; it is a fundamental role and the responsibility of governments.

Recent studies conducted by the National Academy of Sciences of the USA on the safety of genetically modified organisms have concluded: "**Crops modified by molecular and cellular methods should pose risks no different from those modified by classical genetic methods for similar traits**". The focus of analysis, if science-based, should be on the product and not the process and, hence, the steps used to conduct a risk assessment should be the same whether the risk assessment is performed by a government regulatory agency, an institutional variety release committee, or a private organisation; the assessment process as well as the conclusions on safety should be in the public domain.

Several traditional detection methods have been proposed to detect recombinant allergens in transgenic foods. These methods are well established, specific, sensitive, and reproducible, and have been effectively used to investigate recombinant food proteins in the assessment of transgenic food products for their potential allergenicity. As an example, an allergen was detected in a transgenic soybean that originated from Brazil nuts and expressed in soybeans to increase their sulphur content. It bound IgE from Brazil nut-sensitive individuals, and was identified as a major Brazil nut allergen. This demonstrated the possibility of testing for new products for allergens when proteins are transferred from sources that contain known allergenic material. Hence, a safer approach would be to avoid the transfer of genes encoding for known food allergens. Genes transferred from sources known to be allergenic should be assumed to encode for an allergen, until proven otherwise.

Future Trends

Some of the ongoing discussions on transgenic crops have placed undue stress on risk assessment, while the potential advantages are relegated to the background. Furthermore, food allergies are a high priority in industrial countries than in countries with emerging economies, where allergy is a lower priority than nutrition. Hence, the increased productivity benefits of genetically modified foods may far outweigh any potential risk of allergic reactions. With reasonable biosafety regulations, this can be done with little or no risk to human health and the environment.

The rapid escalation of increasingly stringent biosafety regulations regarding

transgenic plants or food, in the absence of any scientifically proven generic risk, may limit any application of transgenic research to meeting either sustainable staple food production or poverty alleviation needs.

The global community must keep its sights set on the goal of assuring food for all and cannot afford to be philosophical and elitist about any part of a possible solution, including agricultural biotechnology.

Major Constraints and Opportunities

Allergies to foods are, in general, a significant public health concern throughout the world. About 2% of adults and 4 to 6% of children suffer from food allergies, which are defined as an adverse immunologically mediated reaction to antigenic molecules present in foods. Moreover, in the case of transgenic plants, since the transgenes code for proteins that ordinarily may not be present in the particular non-transgenic plants, there is particular concern about the potential allergenicity or toxicity of these new varieties to both human and livestock health.

A major concern is that a protein encoded by an introduced gene may be allergenic and cause allergic reactions in exposed populations. An adverse reaction to a food is a clinically abnormal response attributed to exposure to a food or food additive and includes both immunological and non-immunological reactions.

Genetic engineering approaches have been used to introduce genes into various microorganisms and plants that are sources of foods and food components. Some such traits include insect and virus resistance, herbicide tolerance, and changes in composition or nutritional content. However, typically, the amount of protein expressed by the introduced genes is small and, in some cases, inactivation of a native gene that results in the absence of a specific protein yields the desired trait (e.g., the tomato genetically engineered to delay ripening). In fact, this technology has the potential to reduce or eliminate the expression of major allergens by using novel technology.

Overview of Biosafety Status in Egypt

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Introduction

In Egypt, as in other developing countries, a national biosafety system should ensure the safe development of biotechnology products and facilitate collaborative research activities with other countries. Until 1995, Egypt's regulations did not include guidelines for handling transgenic materials under contained conditions, nor did they cover the release of genetically modified organisms (GMOs) into the environment.

The Agricultural Genetic Engineering Research Institute (AGERI) is the primary institute dealing with biotechnology in Egypt. As AGERI's research projects have now reached the stage of field evaluation of GMOs, the Egyptian government has moved forward to build a national biosafety policy to regulate such activities. Ministerial Decree 85 established the Egyptian National Biosafety Committee (NBC) in January 1995. This committee is responsible for putting together policies and procedures to govern the use of biotechnology in the country.

To formulate a biosafety system for Egypt, information was gathered from different counties regarding their regulations, guidelines, and systems design. A draft document entitled "The Establishment of a National Biosafety System in Egypt: Regulations and Guidelines," was prepared by AGERI, with regulations and guidelines adapted to Egyptian conditions. This document was revised by NBC and approved by government authorities as a binding law for biosafety in Egypt (Ministerial Decree 136, February 1995).

The NBC includes representatives from the ministries of agriculture, health, industry, environment, education, and scientific research. Representatives from the private sector, policy-makers, and consultants knowledgeable in policies and applicable law, as well as non-technical members representing community interests (nongovernmental organisations) are also active members of NBC.

NBC Activities

1. **Formulation, Implementation, and Updating of Safety Codes**
   In order to establish safety research policies, NBC shall formulate guidelines for both contained and uncontained applications to cover laboratory practices, greenhouse facilities, small-scale field trials, and, finally, commercial release. This will include guidelines for research with natural organisms that are exotic to the host country.

2. **Risk Assessment and License Issuance**
   NBC shall review new initiatives to evaluate the benefits and potential risk of conducting research with modified organisms to the environment and to the human community. If a license is issued after performing risk assessment analysis, NBC should periodically review containment measures and facilities to ensure that adequate safety guidelines are being followed.
3. **Coordination with International and National Organisations**
   NBC would establish contact and maintain communication with international and national organisations, taking into account new scientific and technical knowledge as they evolve. It would also monitor changes in intellectual property rights issues at the national and international level.
4. **Provide Training and Technical Advice**
   NBC is responsible that all personnel involved in biosafety issues receive adequate training on the most recent developments in safety procedures. It would also provide technical advice to the Institutional Biosafety Committees (IBCs).
5. **Report, at Least Annually, to Governmental Authorities**
   An annual progress report would be submitted to governmental authorities covering NBC activities throughout the year.

Principal Investigator

The National Biosafety Committee would designate one or more Principal Investigators, whose duties include:

1. Inspect to determine whether the institute facilities adhere to the local regulations and guidelines of NBC.
2. Upon receiving a permit request, the principal investigator will visit the location to evaluate its facilities. Next, he will submit a report to NBC upon which the permit will be issued or denied.
3. Instruct and advise staff in practices and techniques to assure levels of safety concern.

The Institutional Biosafety Committee

The National Biosafety Committee should request that all institutions conducting R-DNA research assemble an Institutional Biosafety Committee (IBC).

Roles and Responsibilities

An IBC is responsible for ensuring that the R-DNA research is carried out in full conformity with the provisions of the NBC Guidelines. As part of its general

responsibilities for implementing the NBC Guidelines, the IBC may establish additional procedures as deemed necessary to govern the institution's activities.

Committee Members

In order to ensure the competence necessary to review R-DNA research activities, it is recommended that:

- The IBC includes persons with expertise in R-DNA technology that covers the research directions of the institute.
- The IBC includes persons with expertise in biological safety and physical containment.
- The IBC has available, as consultants, persons knowledgeable in institutional commitments, policies and applicable law.
- The IBC designates a Biological Safety Officer (BSO) who meets the requirements set in section 1.4 in the Biosafety Regulations and Guidelines for Egypt.

Activities

- Assemble a comprehensive set of research and containment-oriented guidelines that are tailored to the research activities of the institute and that comply with the NBC Guidelines.
- Establish a programme for inspection to ensure that the physical containment facility continues to meet the requirements.
- Assess the facilities procedures and practices and the training and expertise of R-DNA personnel.
- Review periodically R-DNA research being conducted at the institute to insure that the requirements of the NBC Guidelines are being fulfilled.
- Adopt emergency plans covering accidental spills and personnel contamination resulting from such research.
- Periodically review containment measures and facilities taking into account new scientific and technical knowledge relevant to treatments for disposals and spills of bio-hazardous wastes.
- Monitor changes in intellectual property rights issued at the national and international levels.
- Report annually to the National Biosafety Committee.

Biological Safety Officer

The institute should appoint a Biological Safety Officer (BSO) who should be familiar with the biosafety requirements for the R-DNA work and the facilities. His duties include the following:

- Enforce approved policies and regulations ensuring that these regulations are not compromised by other considerations.

- Ensure, through periodic inspections, that laboratory standards are rigorously followed.
- Ensure safety of laboratory work and prevent the accidental escape of R-DNA modified organisms.
- Maintain a database on all aspects of biosafety related to mandate crops.
- Check and give advice on biosafety issues on a day-to-day basis.
- Monitor worldwide biosafety requirements for R-DNA, and act as member of the biosafety committee, reporting all related issues.

Risk Assessment

Risk to the health of workers and others in the immediate vicinity of the workplace is one of the main concern in assessing the hazards associated with the contained use of GMOs. These risks are considered proportional to the scale of the operation, and all regulatory systems distinguish small-scale use for research and development. As for large-scale use, the risk to health and possible risks to the environment, in the event of escape of organisms from the production area, must be evaluated and an appropriate level of containment applied. Containment may be physical, e.g., barriers limiting the escape of the organisms, or biological, e.g., physiological limitations to the survival and replication of the organism outside the process environment.

The following three questions are used to judge risk:

- Are we familiar with the properties of the organism and the environment into which it may be introduced?
- Can we confine or control the organism effectively?
- What are the probable effects on the environment should the introduced organism or a genetic trait persist longer than intended or spread to a non-target environment?

The development of new technology opens up a series of questions on risks for which there is limited or no data to help in its evaluations. A definition that was suggested is:

$$Risk = Probability\ of\ Hazard \times Magnitude\ of\ Hazard$$

As mentioned earlier, biotechnology aims to produce crops with new properties, presumably for the benefit of mankind. This means that if there is any increase in risk, it has to be balanced against the benefits which would accrue from using that transgene, and we should consider redefining risk as "acceptable risk".

$$Acceptable\ Risk = \frac{Probability\ of\ Hazard \times Magnitude\ of\ Hazard}{Benefits\ from\ Product}$$

In order to understand the circumstances under which a genetically engineered crop plant might become a persistent agricultural weed or become invasive of natural habitats, it is essential to know the value of the parameters in the following model:

The transgenic plants rate of increase = Plant development rate in a given habitat.

Factors (positive or negative) in risk:

+ Its seed production (timing and duration)
+ Survival of vegetative parts
- The effects of competition with other plants of the same kind
- The effects of competition with other plant species
- The effects of herbivores (insects and vertebrates)
- The effects of fungi and other plant diseases
+ Immigration of transgenic seed from other sites
+ Establishment of transgenic plants from dormant seed in the soil (seed bank)

The conditions under which research with a genetically modified organism can be conducted safely should be assessed relative to the conditions that are normally accepted for conducting research with the parental organism. Therefore, the safety evaluation for determining the level of safety concern is essential.

Determination of the Level of Safety Concern

The Agricultural Biotechnology Research Advisory Committee (ABRAC) has recommended a stepwise process to the Assistant Secretary for Science and Education for the evaluation of the level of safety concern (LSC) of a genetically modified organism into three levels. Determining the LSC is of great importance for analysing the risks to human health and the natural ecosystem for the GMOs.

Step 1: Level of Safety Concern of Parental Organism

Depending on two criteria:

- Whether the organism poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem.
- The ability to manage or control the organism during its planned introduction into the environment so that the research is conducted in a safe manner.

Level 1. The organism poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem. Some attributes, in combination, might indicate *Level-1* organisms are:

- No history of adverse effects in the accessible environment.
- Low evolutionary potential to become a harmful organism. in the accessible environment.
- Low probability of survival in the accessible environment.

Level 2. Organisms whose ecological attributes in the accessible environment may pose a risk to human health that is not negligible or may pose an unreasonable risk to managed or natural ecosystem, which can and must be managed or controlled by appropriate confinement.

Level 3. Organisms whose ecological attributes in the accessible environment may pose a risk to human health that is not negligible or may pose an unreasonable risk to managed or natural ecosystem, and no feasible confinement will ensure safe conduct of the research outside contained facilities.

Some attributes, in combination, might indicate Level 3 organisms are:

- History of adverse effect in the specified environment.
- Ability to survive and proliferate in the environment.
- Non-indigenous status in the environment.
- High frequency of exchange of genetic information with adverse effect.
- Lack of effective techniques to minimise the escape of the organisms.
- Lack of adequate techniques to recapture or kill if escape occurs.

Step 2: Determining the Effect of Genetic Modification on Safety Concern Level

The genetic modification should be evaluated in terms of its effect on the attribute of the parental organism evaluated in Step 1, where the genetic modification may have no effect on safety or it may increase or decrease safety.

The effect of the genetic modification on safety must be evaluated with reference to:

- Direct effect of the organism on human health or the environment.
- Indirect effect of the organism through the substances it produces.
- Effects of genetic exchange with other organisms.

In Step 2, investigators should examine the method of genetic modification; the molecular characterisation and stability of the modified genes; and the expression, function, and effects of the modified genes.

Type 1. Decreased Safety Concern

Modifications that delete or disrupt the expression of a gene or genes responsible for traits, such as pathogenicity, fertility, survival or fitness, in a way that increases safety of the organism.

Type 2. No Effect on Safety Concern
Sustainable understanding of the molecular biology and other information, including relevant experience, which shows that the modification is well-characterised and that the gene functions and effects are adequately understood to predict safety. Modifications include:

- Insertions of nucleic acid, deletions, or rearrangement that have no phenotypic or genotypic consequences in the environment.
- Insertions of nucleic acid, deletions, or rearrangement that have known or predictable phenotypic or genotypic consequences in the environment that are unlikely to result in additional adverse effects on human health and the environment.

Type 3. Increased Safety Concern
Modifications include:

- Insertions of nucleic acid, deletions, or rearrangement that affect the expression of genes, but the functions or effects are not sufficiently understood to determine with certainty if the modified organism poses greater risk than the parental organism.
- Insertions of nucleic acid, deletions, or rearrangement that have known or predictable phenotypic or genotypic consequences in the environment that are likely to result in additional adverse effects on human health and the environment.

Step 3: Determining the Safety Concern Level for Genetically Modified Organisms

The genetically modified organisms should be assigned to one of three levels of safety concern by considering the effect of the genetic modification on safety and if any affected attributes alter the level of safety concern for the modified organism compared to the parental organism.

The level of safety concern for the genetically modified organism is dependent on the same criteria applied to the determination of the level of safety concern for the parental organism.

Level 1. Parental organism

1. **Level 1** of safety concern for the parental organism with **Type 1** modification is considered as LSC-1 for the genetically modified organism.
2. **Level 1** of safety concern for the parental organism with **Type 2** modification is considered as LSC-1 for the genetically modified organism.
3. **Level 1** of safety concern for the parental organism with **Type 3** modification results in LSC-1, LSC-2 or LSC-A genetically modified organism, depending on the degree of safety concern as follows:

- If **Type 3** modification results in minimal increase in safety concern so that risk to human health remains negligible and risk to managed or natural ecosystem remains reasonable without the need for confinement measures, then the genetically modified organism remains LSC-1
- If **Type 3** modification increases the safety concern to the extent that the risk to human health is no longer negligible or the risk to the environment is no longer reasonable, but feasible confinement measures are available to conduct research with negligible risk to human health and the environment, then the genetically modified organism is LSC-2.
- If **Type 3** modification increases the safety concern to the extent that introduction into the environment cannot be adequately managed or controlled to achieve negligible risk to human health and no unreasonable risk to the environment, then the genetically modified organism is LSC-3.

Level 2. Parental organism

1. **Level 2** of safety concern for the parental organism with Type 1 modification results in LSC-1 or LSC-2 genetically modified organism, depending on the degree of safety concern as follows:
   - If **Type 1** modification decreases the safety concern to the extent that the organism poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem without the need for confinement measures, then the genetically modified organism is LSC-1.
   - If **Type 1** modification decreases the safety concern and the risk to human health is negligible and the risk to managed or natural ecosystem is reasonable only when managed by use of confinement measures, then the genetically modified organism is LSC-2.
2. **Level 2** of safety concern for the parental organism with Type 2 modification remains LSC-2 genetically modified organism. Appropriate confinement measures are necessary for planned introduction into the environment.
3. **Level 2** of safety concern for the parental organism with Type 3 modification results in LSC-2 or LSC-3 genetically modified organism, depending on the degree of increase in safety concern as follows:
   - If **Type 3** modification increases the safety concern, but the planned introduction into the environment can still be managed or controlled by appropriate confinement measures, then the genetically modified organism is LSC-2.
   - If **Type 3** modification increases the safety concern to the extent that there is no reasonable certainty that planned introduction into the environment can be managed or controlled, then the genetically modified organism is LSC-A. Research must remain under confinement measures until there is a certainty that it could be controlled in a safe manner.

Level 3. Parental organism

1. **Level 3** of safety concern for the parental organism with Type 1 modification results in LSC-1, LSC-2 or LSC-3 genetically modified organism, depending on the degree of decrease in safety concern as follows:
   - If **Type 1** modification decreases the safety concern to the extent that planned introduction into the environment poses negligible risk to human health and no unreasonable risk to managed or natural ecosystem without confinement measures, then the genetically modified organism is LSC-1.
   - If **Type 1** modification decreases the safety concern but confinement measures are necessary for the planned introduction into the environment with negligible risk to human health and no unreasonable risk to managed or natural ecosystem, then the genetically modified organism is LSC-2.
   - If **Type 1** modification decreases the safety concern but not to the extent that planned introduction of the organism can be managed or controlled to achieve negligible risk to human health and no unreasonable risk to managed or natural ecosystem, then the genetically modified organism is LSC-3.
   - Research must be conducted in a contained facility.
2. **Level 3** of safety concern for the parental organism with **Type 2** or **Type 3** modification results in LSC-3 genetically modified organism.

Biosafety Guidelines

Biosafety guidelines are designed to ensure that the products of biotechnology will not have adverse effects on the environment and agriculture, to prevent unintentional release of hazardous organisms, and to protect the surrounding communities as well as employees and researchers involved in the use of such products from the research stage up to commercialisation.

Laboratories

- Food storage, eating, drinking and smoking are prohibited in laboratory.
- Mouth pipetting is prohibited.
- Laboratory coats are obligatory and should be removed when exiting the laboratory.
- Working surfaces must be decontaminated using soap and alcohol after each working day.
- Waste products must be decontaminated by incineration or by autoclaving.
- Frequent hand washing is obligatory (at least one hand wash sink should be available).
- Avoid contact with GMOs and other exotic biological agents; disposable gloves

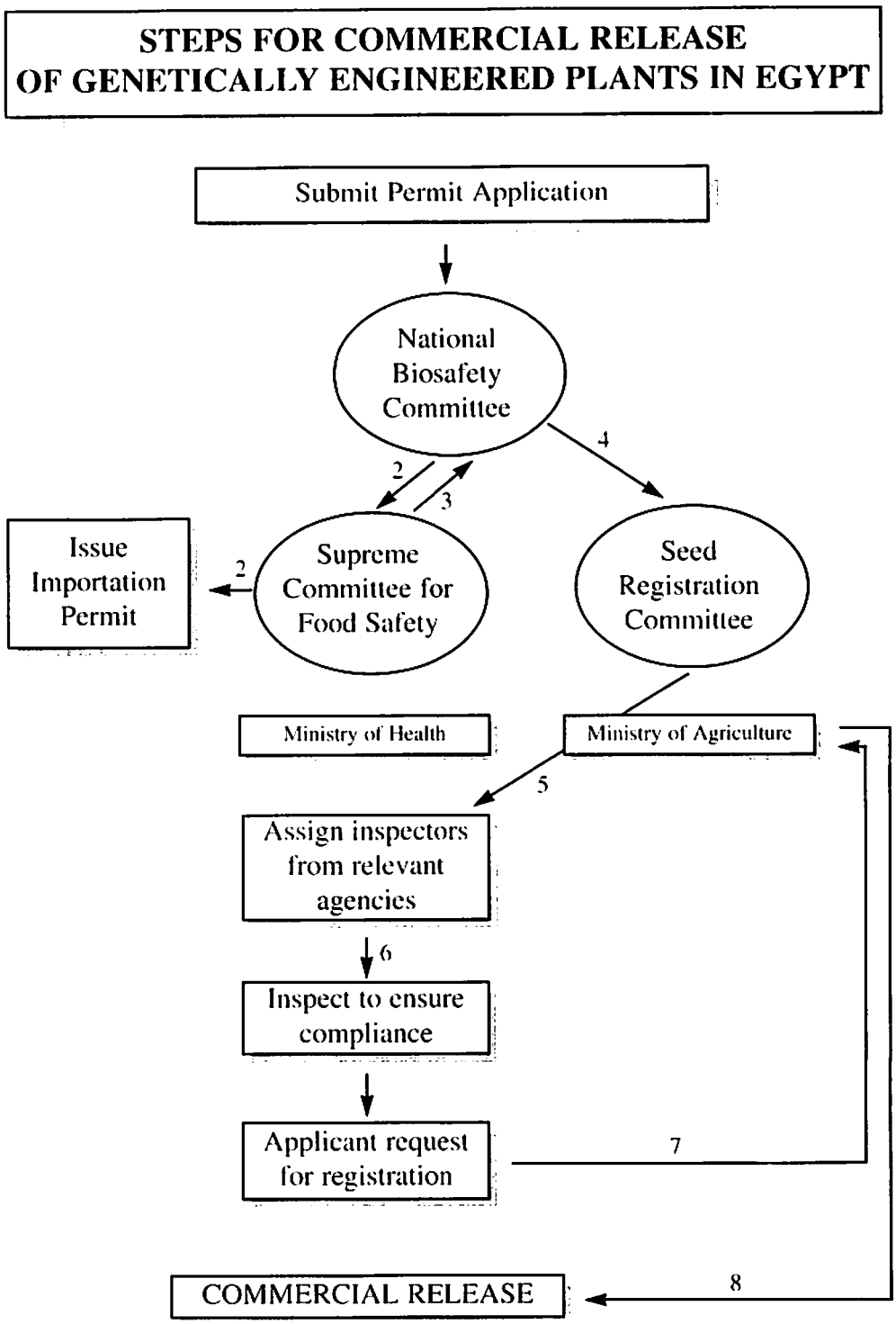
should be worn when handling such items.
- Laboratory doors should be closed at all times.
- Working with fume-producing chemicals must be under the laboratory hood.
- Biohazard warning signs should be always posted in the labs.

Containment Greenhouse

- The greenhouse should be locked at all times.
- Biosafety categories and safety codes should be posted at the entrance.
- The air-circulation system should not allow dispersal of pollen or GMOs from the greenhouse.
- Non-living plant material, parts, or viable exotic biological agents should not leave the greenhouse except for:
  - Disposal, where they have to be autoclaved before disposal.
  - Storage in other facilities; in this case, they should undergo adequate decontamination before transport.
- The outgoing water must be chemically treated before being drained.
- Coats should be worn at all times in the greenhouse and autoclaved before removal from the greenhouse for any reason.
- Hand-washing is required upon entering and exiting the greenhouse.
- A disinfecting pad embedded with a decontaminating substance must be located at the greenhouse entrance.
- Daily records of all experiments carried out in the greenhouse should be kept.

Field Trials

Small-scale field testing:
- Experiments with exotic plant pests and pathogens are prohibited.
- Plants must be prevented from spreading pollen, by removal of flowers.
- If flowers are needed for testing and further experimentation, the inflorescence flowers must be covered before maturation.
- Suitable plot isolation must be provided, avoiding pollen transmission to nearby plots.
- Entry of plots by unauthorised personnel is prohibited.
- Special protective measures should be taken to ensure complete isolation of harvested plant parts.
- Plots must be protected from the entry of animals or insects, using border rows.


STEPS FOR COMMERCIAL RELEASE
OF GENETICALLY ENGINEERED PLANTS IN EGYPT
Submit Permit Application
National Biosafety Committee
2
3
4
Issue Importation Permit
2
Supreme Committee for Food Safety
Seed Registration Committee
Ministry of Health
Ministry of Agriculture
5
Assign inspectors from relevant agencies
6
Inspect to ensure compliance
Applicant request for registration
7
COMMERCIAL RELEASE
8

Permits issued by the NBC-Egypt from 1995–1999

No.	Date Submitted	Date Approved	Crop	Trait	Applicant	Scale Application
1	01/09/'96	24/12/'96	Musk melon, Squash	Resistance to ZYMV	AGERI/MSU	Biocontainment
2	09/09/'96	24/12/'96	Potato	Resistance to PTM	AGERI/MSU	Biocontainment
3	25/09/'96	24/12/'96	Potato	Resistance to PLRV	AGERI/Scottish Crop Res. Inst.	Biocontainment
4	09/10/'96	24/12/'96	Potato	Resistance to PTM	AGERI/MSU	Biocontainment
5	26/10/'96	24/12/'96	Tomato	resistance to TYLCV	AGERI/ILTAB/MSU	Open field
6	21/11/'96	24/12/'96	Potato	Resistance to PTM	AGERI/MSU	Open field
7	15/11/'96	24/12/'96	Sugarcane	Resistance to Mosaic Virus	Sugar Crops Res. Inst.	Biocontainment
8	01/12/'96	24/12/'96	Musk melon, Squash	Resistance to ZYMV	AGERI/MSU	Open field
9	08/12/'96	24/12/'96	Potato	Resistance to PTM	AGERI/MSU	Biocontainment
10	10/12/'96	24/12/'96	Tomato	Resistance to TYLCV	AGERI-ILTAB/MSU	Biocontainment
11	12/09/'97	22/11/'97	Potato	Resistance to PVY	AGERI/MSU	Open field
12	15/10/'97	22/11/'97	Potato	Resistance to PTM	AGERI/MSU	Open field
13	10/11/'97	22/11/'97	Musk melon, Squash	Resistance to ZYMV	AGERI	Open field
14	14/11/'97	22/11/'97	Musk melon, Squash	Resistance to ZYMV	AGERI	Open field

15	17/11/'97	22/11/'97	Squash	Resistance to ZYMV	AGERI/MSU	Biocontainment
16	01/10/'98	24/11/'98	Recombinant DNA Construct	FMDV	Theodore Bilharz Res. Inst.	Biocontainment
17	07/10/'98	24/11/'98	Potato	Resistance to PLRV	Max-Planck	Open field
18	10/10/'98	24/11/'98	Potato	Resistance to PTM	AGERI/MSU	Open field
19	04/05/'98	07/07/'98	Maize	Resistance to Corn-borers	Novartis/Fine Seeds International	Biocontainment
20	27/10/'98	24/11/'98	Maize	Resistance to Corn-borers	Pioneer Hibred	Biocontainment
21	28/01/'99	06/05/'99	Squash	Resistance to ZYMV-E	AGERI	Biocontainment/ Open Field
22	28/01/'99	06/05/'99	Squash	Resistance to ZYMV	AGERI	Biocontainment/ Open Field
23	28/01/'99	06/05/'99	Melon	Resistance to ZYMV	AGERI	Open Field
24	28/01/'99	06/05/'99	Cucumber	Resistance to ZYMV	AGERI	Open Field
25	27/04/'99	Pending	Maize	Resistance to Corn-borers	Verneuil Semences	Open field

Permits issued by the NBC-Egypt (by crop)

Crop	Trait	No. of Applicaions	Date Submitted	Date Approved	Company or Institute
Potato	Resistance to PTM	6	09/09/'96 09/10/'96 21/11/'96 08/12/'96 15/10/'97 10/10/'98	24/12/'96 24/12/'96 24/12/'96 24/12/'96 24/11/'97 22/11/'98	AGERI/MSU
Potato	Resistance to PLRV	2	25/09/'96 07/10/'98	24/12/'96 24/11/'98	AGERI/SCRI AGERI/ Max-Planck Institute
Tomato	Resistance to TYLCV	1	26/10/'96	24/12/'96	AGERI/ILTAB/ MSU
Squash	Resistance to ZYMV	7	01/09/'96 01/12/'96 10/11/'97 14/11/'97 17/11/'97 28/01/'99 28/01/'99	24/12/'96 24/12/'96 22/11/'97 22/11/'97 22/14/'97 06/05/'99 06/05/'99	AGERI/MSU
Maize	Resistance to Cornborers	3	04/05/'98 28/10/'98 28/01/'99	07/07/'98 24/11/'98 Pending	Novartis/Fine Seeds International Pioneer Hibred Verneuil Senences
Recombinant DNA Construct	Foot & Mouth Disease Virus FMDV	1	07/10/'98	24/11/'98	Theodore Bilharz Research institute
Cucumber	Resistance to ZYMV	1	28/01/'99	06/05/'99	AGERI
Melon	Resistance to ZYMV	1	28/01/'99	06/05/'99	AGERI

Harmonising Regulatory Biosafety Frameworks: Opportunities for a UNEP/West Asia and North Africa Regional Biosafety Project

David Duthie
Biodiversity Planning Support Programme

Summary

The West Asia and North Africa (WANA) region forms a natural ecological, cultural and linguistic grouping which could form the basis of a regional approach to capacity-building in preparation for the entry into force of the Cartagena Protocol on Biosafety. The United Nations Environment Programme/Global Environment Fund (UNEP/GEF) plans to implement a major project to assist eligible countries to develop national biosafety frameworks. There is considerable scope for the WANA countries to participate in this project.

Introduction

The UNEP/GEF project entitled "Development of National Biosafety Frameworks" has been approved by the GEF Secretariat (September 2000) and should be endorsed by the GEF Council in November 2000. Project implementation is likely to start in early 2001. The project will provide an opportunity for up to 100 (mostly developing) countries to collaborate and harmonise the development of their national biosafety frameworks in preparation for the entry into force of the Cartagena Protocol on Biosafety.

The current UNEP/GEF project proposal represents the latest development in a long association between UNEP and biosafety, and has been shaped, to a large extent, by the four requirements summarised below.

The 1992 Convention on Biological Diversity

This Convention (CBD), together with the Rio Declaration and Agenda 21, provides the foundation for all recent UN initiatives on biosafety, requiring that, under the Convention, Parties establish regulatory frameworks for biosafety and, also, that they consider development of an international protocol for biosafety.

1. **Article 8(g)** of CBD calls on Parties to "*establish or maintain means to regulate,*

manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health".

2. **Article 19(3)** requires that Parties shall consider "*the need for and modalities of a protocol on biosafety setting out appropriate procedures, including, in particular, advanced informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity*".

Two important initiatives were undertaken by UNEP in response to these Articles. The UNEP International Technical Guidelines for Safety in Biotechnology were developed in 1995 and the UNEP/GEF Pilot Biosafety Enabling Activity Project was approved by the GEF Council in November 1997 (see below).

UNEP/GEF Pilot Biosafety Enabling Activity Project

This project was approved in 1997 for US$ 2.74 million to assist 18 countries in the preparation of regulatory frameworks for biosafety. The project comprised two parts:

1. *The National Level Component*, with a budget of US$ 1,875,000, provided assistance to 17 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Poland, Russian Federation, Tunisia, Uganda and Zambia)[1] to prepare national biosafety frameworks.
2. *The Global Level Component*, with a budget of US$ 764,000, organised regional workshops in Africa, Latin America/Caribbean, Asia/Pacific and Central/Eastern Europe. The aim of the workshops was to promote greater awareness, understanding and appreciation of biosafety and biotechnology issues by scientists and administrators, in particular, in developing countries and countries with economies in transition.

These workshops brought together many government-nominated biosafety experts, as well as representatives from the scientific community, UN agencies, bio-industry, NGOs and other organisations, to discuss and exchange views on a wide range of issues related to safety in biotechnology. In total, 79 countries were represented at the workshops.

Countries which completed the Pilot Biosafety Project have all developed National Regulatory Frameworks of some kind and are now in a position to move

1. Pakistan was initially included in the project but was unable to fully participate, it has subsequently completed a draft framework.

forward into implementation of the frameworks (possibly with further GEF support). This will assist these countries to meet with the requirements and obligations of the Cartagena Protocol when it enters into force.

The Cartagena Protocol on Biosafety

The Protocol was adopted by the resumed, first extraordinary session of the Conference of the Parties to the Convention on Biological Diversity, held in Montreal, Canada, on 24-28 January 2000. It was opened for signature in Nairobi, 15-26 May 2000 at the Fifth Conference of the Parties, during which a Special Signing Ceremony was held on 24 May 2000. The Protocol provides the foundation on which tensions between environmental concerns associated with the trade in, and development of, living modified organisms (LMOs) can be reconciled with global aspirations and investments in biotechnology. A total of 76 countries have signed the Protocol since May, and more are expected to do so between 5 June 2000 and 4 June 2001 in New York, where the Protocol is open for signature at the UN.

- **Articles 1 and 2** of the Protocol require Parties to: "*ensure an adequate level of protection in the field of the safe transfer, handling and use of these LMOs*", *and to ensure that "the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health*". Each Party is required to "*take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol*".
- **Article 28(2)** of the Protocol provides that the financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for the Protocol. Accordingly, GEF is the financial mechanism of the Protocol.
- The Protocol also establishes a Biosafety Clearing House **(Article 20)** to facilitate the transfer of scientific, technical, and environmental information between Parties and to "*assist Parties to implement the Protocol, taking into account the special needs of developing-country Parties, in particular the least developed and small island-developing countries among them, and countries with economies in transition, as well as countries that are centres of origin and centres of genetic diversity*" **(Article 20 1b)**.

Countries are required to make available to the Biosafety Clearing House any information as set out in **Article 20(3)**. The Biosafety Clearing House should be in place before the Protocol comes into effect; therefore, any preparatory work that may need to be done within countries to enable their input into this new mechanism should be in place as soon as possible.

Fifth Conference of the Parties to the Convention on Biological Diversity, Nairobi, May 2000

The Fifth Conference of the Parties (CoP) to the Convention on Biological Diversity (CBD) provided the first opportunity for Parties to the CBD to start planning for the entry into force of the Cartagena Protocol. The decisions adopted by the Conference on "*further guidance to the financial mechanism*" (Decision V/13) as well as on the Biosafety Protocol (Decision V/1) welcomed "*the decision taken by the Council of the Global Environment Facility at its fifteenth meeting with regard to supporting activities which will assist countries to prepare for the entry into force of the Protocol*".

In addition, a Ministerial Round-table Meeting on "*Capacity-building in Developing Countries to Facilitate the Implementation of the Protocol*" was held in Nairobi on 23 May 2000 during the Fifth CoP to the CBD. The Ministerial Meeting acknowledged the need for capacity building at the national level, in order to allow "*the safe use of modern biotechnology, in particular the safe transfer of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity between countries which may have very different climatic, social and economic conditions*".

Paragraph 9 of the Statement of the Ministerial Round-table emphasises "*the importance of the financial mechanism and financial resources in the partnership that the Protocol represents and welcome the commitment of GEF to support a second phase of the UNEP/GEF Pilot Biosafety Enabling Activity Project*".

Development of National Biosafety Frameworks

In response to the events summarised above, UNEP has prepared a project proposal for GEF funding to assist up to 100 eligible countries to prepare national biosafety frameworks.

The UNEP/GEF "Development of National Biosafety Frameworks" project would assist countries to complete the following activities:

- Strengthening national capacity in order to implement biosafety procedures and maximise the potential for the safe use of biotechnology.
- Applying biosafety procedures to enhance environmental management.
- Applying biosafety guidelines under the Convention and the Protocol and in response to decisions of the Inter-governmental Committee for the Cartagena Protocol on Biosafety (ICCP), taking into account the UNEP International Technical Guidelines for Safety in Biotechnology.

- Harmonising regional and sub-regional legal instruments to simplify the process of applying and conforming to regulations.
- Raising public awareness of the issues involved in the release of living modified organisms and their products, to promote informed debate and to ensure that where any use of biotechnology is permitted, it is done in an open and transparent way.
- Providing all stakeholders with an opportunity to be involved in the design and implementation of a national framework for biosafety.
- Carrying out an assessment of technological capacity, its effect on implementation of national biosafety frameworks and means to improve it.
- Increasing the overall safety of biotechnology so that the citizens may reap the benefits with minimum adverse effects on health and environment, where it is decided to allow the use to proceed.

A major part of the project proposal relates to promoting regional and sub-regional collaboration and exchange of experience. The project proposes to hold four regional workshops, one each for Africa, Latin America and the Caribbean, Asia and the Pacific, and Eastern Europe, at an early stage of the project.

These workshops will be followed by 15 sub-regional workshops involving participants from their respective regions. The following sub-regions have been identified: North Africa, West Africa, Central Africa, Eastern Africa, Southern Africa, Caribbean region, South America, Central America, West Asia, South-East Asia, South Asia, Central Asia, Pacific Islands, Eastern Europe, and the Baltic countries.

This regional approach is necessary because national biosafety decisions and activities need to take into account legislative measures and biosafety regulatory systems implemented in adjacent countries from an early stage. The Protocol is primarily an agreement about (intentional and unintentional) transboundary movement of LMOs. Sub-regional cooperation in information-sharing and harmonising legal and regulatory instruments is crucial for effective management of transfer of LMOs across borders.

The information needed for the safe introduction of LMOs into the environment may not necessarily be available within a single country, but expertise may be able to be exploited at the sub-regional level. Maximising the use of scarce institutional, financial, technical, and human resources within a region is essential for effective and efficient establishment of national frameworks on biotechnology and biosafety, as is the involvement of international experts from other parts of the region and other regions.

Since no country is isolated completely from its neighbours, there is a clear need to strengthen regional ties between countries, either by assisting in setting up regional networks or by helping to set up systems with the necessary authority to oversee the development of biotechnology within the region. Cooperation at sub-regional and regional levels is a key to the successful implementation of the objec-

tives of the Protocol. It is recognised that many countries will not have the full complement of expertise needed to allow a comprehensive assessment of risk, but the full range may be available within a sub-region or region.

The West Asia and North Africa region, defined within the work programme of ICARDA, provides a natural grouping which could form the basis of a strong and effective regional partnership in biosafety. This geographical region has strong ecological, cultural and linguistic similarities, and ICARDA is well positioned to provide an institutional hub for the organisation of biosafety in the region.

UNEP hopes that eligible countries from the region will register their interest in participating in the project summarised above. Further details of the project can be obtained via:

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II

COUNTRY REPORTS

Summary

This second part of the meeting was devoted to presentations by the national representatives. Participants from Algeria, Iraq, Jordan, Lebanon, Morocco, Palestine, Sudan, Syria, Tunisia, and Turkey elaborated on the current status of biotechnology and biosafety in their countries. This is of particular importance, since the prerequisite for harmonisation is to elaborate where the links are. Participants also used the opportunity to explain their expertise and their limitations in human, institutional and financial capacities.

This part clearly shows that the countries in the region follow different objectives in research and development. They realise different procedures and strategies to regulate biotechnology, and do this at different speeds. This diversity, on the one hand, may aggravate a harmonised approach, but, on the other, serves as a pool of experience from which other countries can profit. The organisers would like to take the opportunity to thank all national representatives for their valuable contributions, which are summarised in the following pages.

Current Status and Future Prospects of Agricultural Biotechnology Research in Syria

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Introduction

The Syrian Arab Republic has a total area of 185,180 km² and a total estimated (1998) population of 15.6 million, with an average growth rate of over 3.3%. This number is expected to reach 18.9 million in 2005 and 32.5 million by the year 2025.

Agriculture is a very important sector in Syria, where it accounts for 30% of the GDP and 28% of the labour force. The agricultural production value for 1997 by fixed prices amounted to US$ 5,545 million, including US$ 3,655 million in plant production value, US$ 1,795 million in animal production value, and US$ 95 million in customs duties.

The total value of agricultural commodities for commercial exchange and their percentage to the total exchange of the country in 1997 are as follows:

Commercial exchange	Value (million US$)	Percentage
Import	90	9.2%
Export	230	24.0%

Land use (as of 1998, Fig. 1) can be divided as follows:

- 32% cultivated land (5,981,410 ha).
- 20% uncultivated land (3,729,883 ha).
- 45% steppe and pasture (8,269,841 ha).
- 3% forests (536,836 ha).

The total irrigated area in Syria is about one million hectare.

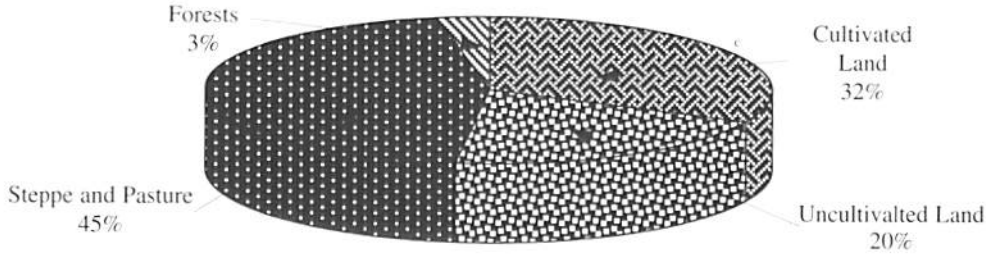

Fig. 1. Land Use, 1998

Syria is considered a *centre of origin and biodiversity* for many crops and fruit trees (wheat, barley, lentil, chickpea, olive, almond, pear, plum, pistachio, etc.). It is one of the few nuclear centres where numerous species of temperate-zone agriculture originated thousands of years ago, and where their wild relatives and landraces of enormous genetic diversity are still present. Many fruit trees, such as almond, olive and pistachio, also originated from this region, and have dominated its traditional agricultural systems.

The Levantine uplands, which comprise Lebanon, western Syria, small parts of Jordan, northern Palestine, and the associated Mediterranean coasts and valleys, are considered one of the major centres of plant diversity and endemism in the world, especially in southwest Asia. Seven genera of vascular plants are endemic to this region. Moreover, drylands are most outstanding for their within-species genetic diversity.

Indigenous crops and food plants of the Near East region are known for their resistance to diseases and abiotic stresses, making them a valuable source of genetic material for germplasm enhancement, upon which global food security depends. Tables 1 and 2 show the area, production, and yield of the major crops as well as the numbers of fruit trees in Syria.

Table 1. Area, production, and yield of major crops in Syria.

Crop	Area (ha)	Yield (kg/ha)	Production (t)
Wheat	1,721,412	2,389	4,111,625
Barley	1542,619	563	868,848
Lentil	142,649	1,080	154,120
Chickpea	108,012	783	84,617
Dry broad bean	7,842	2,004	15,712
Dry pea	238	1,097	261
Green pea	1,817	6,591	11,975
Green broad bean	4,708	8,006	37,691
Cabbage	3,231	22,115	71,453
Cauliflower	2,617	21,901	57,314
Maize	72,634	3,924	285,009
Cotton	274,585	3,707	1,017,800
Sugar beet	28,663	41,941	1,202,153
Tomato	19,031	29,172	555,167
Watermelon	24,048	16,737	402,485
Soybean	4,455	1,624	7,233
Potato	22,177	22,197	492,264

Source: Annual Agricultural Statistical Abstract, 1998. Syrian Ministry of Agriculture and Agrarian Reform, Department of Statistics and Planning.

Table 2: Area, production, and number of fruit trees in Syria.

Crop	Area (ha)	Production (t)	Trees (thousand)
Apple	48,492	362,000	16,150
Pear	5,520	26,661	1,912
Quince	951	6,719	411
Cherry	19,306	56,003	5,523
Apricot	12,408	67,192	3,187
Plum	2,584	22,186	1,199
Peach	5,230	43,087	2,613
Almond	38,198	67,150	14,363
Olive	459,669	785,000	62,300
Grape	69,495	590,000	55,300
Fig	10,721	47,049	2,649
Walnut	4,554	16,378	740
Pistachio	59,434	35,684	10,096
Pomegranate	6,649	84,926	3,449
Lemon	3,468	68,049	1,175
Orange	13,112	438,960	5,340
Other citrus trees	10,419	232,991	4,230
Palm	1,000	2,500	170

Source: See Table 1.

Syria has ratified the Convention on Biodiversity (CBD) and has established a Supreme Council for Biodiversity and Genetic Resources in the Syrian Arab Republic, which is responsible for planning and carrying out programmes for the conservation, management and sustainable use of biodiversity and genetic resources of plants and animals. Syria is implementing a project entitled "Conservation and Sustainable Use of Dry Land Agro-Biodiversity in Syria", which is funded by the United Nations Development Programme (UNDP)/Global Environment Fund (GEF).

With the pressure exerted by the rapid population growth and the expansion and intensification of agricultural and other activities, it is likely that the degradation of resources (vegetation, soil and water) will continue. Genetic diversity is seriously eroding, particularly through the degradation of natural habitats, intensification, expansion of cultivation, and overgrazing in natural rangelands. The result is that now wild relatives of crop species grow only in marginal land areas such as field borders, shallow soil, and remnants of natural vegetation. The type of habitat supporting these precious resources is either patchy or degraded. During the last four decades, the forest cover has continued to decrease in Syria despite substantial reafforestation.

Traditionally, farming systems have maintained diversity in order to preserve stability of production under climatic, disease and pest risks. Wild relatives of fruit trees used to be left growing on field borders to supply seeds or rootstocks for planting. The replacement of the traditional farming systems by modern agricultural practices is endangering these wild relatives. Food demands and market forces have encouraged the replacement of the locally adapted varieties (landraces and local varieties) of both fruit trees and field crops with higher-yielding cultivars, hence, hampering the gene pools of the crops.

Demands for higher-yielding food crops that must also be adapted to the ever-changing weather and biotic stresses, and disease and pest resistance, require continuous and reliable access to genetic resources which can be used to impart such superior qualities.

Agricultural Research in Syria

National agricultural research programmes in Syria started in the early sixties to establish agricultural research centres and open faculties of agriculture through comprehensive development plans aiming to modernise Syrian agriculture and to increase the total agricultural production factors in order to meet the rapid population growth. Consequently, there is always high demand for agricultural products, either for domestic consumption or for exportation. The agricultural research system is considered by policy-makers as one of the most important elements for improving the whole agricultural sector and achieving the strategic goals of national development programmes in Syria.

Directorates and Organisations Involved in Agricultural Research

National agricultural research in Syria is carried out by the following directorates and organisations:

1. Ministry of Agriculture and Agrarian Reform:
   - Directorate of Agricultural Scientific Research (DASR).
   - Directorate of Soils.
   - Directorate of Irrigation and Water Use.
   - Cotton Bureau.
   - Citrus Bureau.
   - Olive Bureau.
   - Tobacco Research Centre.

2. Atomic Energy Commission.
3. Faculties of Agriculture (Damascus, Aleppo, Tishreen, and Al-Baath Universities).
4. Faculty of Veterinary Medicine (Al-Baath University).

Biotechnology in Syria

Syria has adopted tissue-culture techniques to improve plant propagation and multiplication of major horticultural crops and fruit trees, and as a tool to facilitate conventional methods of plant breeding. A high priority was to obtain virus-free plants utilising tissue-culture techniques. The technique is currently applied to potato, banana, citrus fruit trees, and ornamental species. The large-scale propagation of potato is currently being carried out in Aleppo.

Syria started its biotechnology programmes in the 1990s, with the foundation of plant tissue-culture laboratories at the governmental institutes, including the ones listed below.

Ministry of Agriculture and Agrarian Reform

The Ministry has established plant tissue culture and biotechnology laboratories at the following institutes:

1. Directorate of Agricultural Scientific Research

The Directorate of Agricultural Scientific Research (DASR) is one of the central directorates of the Ministry of Agriculture and Agrarian Reform. Its main tasks are to conduct scientific research in the following areas: field crops, vegetables, undercover cultivation, horticulture, pesticides, plant tissue culture and biotechnology, plant protection, livestock production, food industry, and socioeconomic studies. It is carrying out the following activities:

- National gene bank management.
- Exchange of genetic resources.
- Collection, documentation and *ex-situ* conservation of genetic resources of field crops, and food and forage legumes.
- Live collection of the local varieties of field crops, fruit trees, and forest trees in ten agricultural research stations throughout Syria.
- Evaluation of landraces and many other activities.

The Directorate has 42 centres around the country, each of them specialising in research in certain fields; for example, Quneitra Agricultural Research Station specialises in genetic resources of wild and cultivated plants, with a 50-hectare live gene bank. The Directorate is considered the main research centre that is involved

in utilising biotechnology; it supports both basic and applied research in the agricultural sciences, including agricultural biotechnology. One of its main goals is to contribute to the promotion of biotechnology research and development (R&D). As part of this objective, DASR is striving to improve and develop knowledge and expertise in biotechnology and genetic engineering.

The Directorate is involved in applying tissue-culture techniques for the production of virus-free plants, as well as propagating newly developed and introduced varieties. It is the leading research institute involved in biotechnology research and in the introduction of new trends in biotechnology in Syria. The Plant Tissue-Culture Laboratory (PTCL) at DASR in Douma, which was established in 1993, is involved in using biotechnology techniques. The current research activities at PTCL and DASR include the following:

- Developing techniques for *in vitro* propagation of some important horticultural and ornamental crops.
- Developing methods for propagation of some recalcitrant and valuable plants.
- Propagating new promising varieties from breeding programmes or introduced varieties.
- Propagating healthy and virus-free material.
- Conducting research on *in vitro* regeneration and organogenesis.
- Cold storage *in vitro* (gene bank).
- Inducing somaclonal variations by in vitro methods for breeding purposes.
- Surveying and diagnosing stone fruit trees and grape viruses at the plant protection department of DASR.

  Future research includes biotechnology research and production of genetically engineered plants resistant to biotic and abiotic stresses.

2. General Organisation for Seed Multiplication

At the General Organisation for Seed Multiplication (GOSM) in Aleppo, there is a programme for virus elimination in potato tubers and banana using apical meristem culture, together with serological diagnosis of viruses by ELISA tests. A micropropagation system for date palm is also being developed.

3. Citrus Bureau

At the Citrus Bureau in Tartous, micro-grafting is being done to produce virus-free material of citrus trees. Also, integrated pest control and bio-control is being applied in citrus groves. Further, there is a programme of bud-wood certification and periodical tests and indexing for mother fields in terms of virus disease infection.

Atomic Energy Commission

The Atomic Energy Commission (AEC) of Syria has been involved in biotechnology research for the last 8 years through departments of agriculture and biology. A

newly established department, the Department of Biotechnology and Molecular Biology, is carrying out various biotechnology activities. Agricultural research involving biotechnology and molecular biology techniques include:

1. Protein and DNA marker techniques

- Utilisation of protein markers using A-PAGE and SDS-PAGE electrophoretic techniques in genetic studies such as:
  - Establishing fingerprints of major cereal and legume crops for identification purposes.
  - Establishing a relationship between some bands/sub-units and characters of importance related to quality in wheat.
  - Using these techniques as a tool to identify different isolates of some important plant pathogens.
- Use of RAPD techniques in genetic diversity studies of some important trees such as pistachio, fig, and olive (the protocol for such studies is being optimised).
- Use of RAPD techniques as a possible tool in marker-assisted selection in mutants resulting from our breeding programmes.

2. In vitro techniques

- Use of plant cell and tissue culture to facilitate induction and isolation of useful mutants in potato, garlic, and barley.
- Use of co-cultures for *in vitro* selection of potato mutants tolerant to biotic and abiotic stresses.
- Development of *in vitro* technique for mass propagation of potato mini-tubers.
- Development of *in vitro* techniques to detect irradiated vegetables.
- Development of doubled haploid and co-culture techniques to select barley mutants tolerant to biotic and abiotic stresses.
- Development of *in vitro* techniques for quantitative estimation of disease infection.

3. Future programme

The Department of Biotechnology and Molecular Biology will start, in the near future, research using transformation techniques aiming at the improvement of the resistance of some major crops to insects and their tolerance to abiotic stresses.

Universities of the Ministry of Higher Education

At the Universities of Damascus, Aleppo, Al-Baath and Tishreen, tissue culture techniques are being demonstrated to the students for teaching purposes. Also, biocontrol is taught to the students.

International Center for Agricultural Research in the Dry Areas

Based in Aleppo, ICARDA is conducting activities in plant biotechnology (legumes, cereals, and barley). ICARDA has established non-radioactive marker technology in its crop improvement programme to enable marker-assisted selection for the key biotic and abiotic stresses. To tag host-plant resistance, recombinant inbred line populations were developed for specific traits in barley, lentil and chickpea, and Restriction Fragment Length Polymorphism (RFLPs), Amplified Fragment Length Polymorphism (AFLPs), and microsatellite-based markers are used for genetic mapping and gene-tagging. A well-equipped marker laboratory with further upgrading will allow atomisation for marker-assisted selection programmes in ICARDA's germplasm enhancement programmes. The Tissue Culture Laboratory focuses on the use of doubled haploids for ICARDA's cereal breeding programmes as well as on the development of somaclones in lathyrus in recent years.

Current research at ICARDA includes the following activities, conducted in collaboration with the national agricultural research systems (NARSs) in the West Asia and North Africa region and advanced research institutes in the region and overseas:

- Development and use of DNA markers for gene-tagging and marker-assisted selection in ICARDA's mandated crops: chickpea, lentil, barley and wheat.
- Development and use of DNA markers for identification and characterisation of pathogens, viruses and pests.
- Development and use of DNA markers for estimation of genetic diversity in cereals and legumes.
- Wide hybridisation in lentil, chickpea and durum wheat.
- Production of doubled haploids in cereals.
- Development of regeneration and transformation systems for ICARDA's mandated crops in collaboration with the Agricultural Genetic Engineering Research Institute (AGERI) in Cairo, Egypt.

However, the type of research undertaken in Syria from 1980 to 1999 is mainly conventional biotechnology, including bio-control, soil amendments, food/beverage, tissue culture, farm waste utilisation, animal reproduction, and vaccines.

Objectives of Biotechnology Research and Development in Syria

The main goals of biotechnology R&D in Syria are to:

- Advance Syrian agriculture using biotechnology and genetic engineering capabilities available worldwide for solving contemporary problems.

- Broaden the research and development capabilities.
- Harness the potential of this technology to increase productivity of all commodities in agriculture.

Biotechnology will therefore play a major role in the selection and breeding of new varieties of plants and breeds of animals. It will also provide the inputs required such as bio-fertilisers and bio-control of harmful pests and diseases. Biotechnology will also be utilised to produce genetically improved crops with resistance to harmful pests and diseases, for accurate diagnosis and control of diseases in plants and animals, and for remediation of the environment.

Foundation and Implementation of a National Policy on Biotechnology

Some of the laboratory facilities and equipment for upstream biotechnological research exist at a number of institutions in Syria, including DASR and AEC.

Agricultural Biotechnology Development Priorities

There is no process for defining and implementing national programmes in agricultural biotechnology in Syria, but the government institutions are striving to establish national programmes to promote the development of biotechnology. No priorities in biotechnology research have already been set. However, the following priorities should be emphasised:

1. **General Programme priorities:**
   - Development of high-calibre human resources to rapidly understand technology developments and develop technological applications, as well as to set up medium-scale production plants.
   - Training of scientists at the highest level of scientific, technical, and management expertise.
   - Strengthening linkages between scientists and the production sector.
   - Developing legal mechanisms for the protection of intellectual property rights, biosafety, and the use of germplasm.
   - Capacity building for monitoring scientific and industrial activities in biotechnology.
   - Use of genetic engineering techniques to produce crops resistant to biotic and abiotic stresses with special emphasis on drought- and heat-tolerant crops, and to improve, characterise, and use plant genetic resources efficiently.
2. **Biodiversity:** In the context of biodiversity, and the identification, conservation,

and use of plant genetic resources, it might be worth mentioning that there is a project entitled "Conservation and Sustainable Use of Dry Land Agro-Biodiversity in Syria", which is implemented by DASR and funded by the United Nations Development Programme (UNDP)/Global Environment Fund (GEF).

3. Integrated pest and plant disease management.
4. Elaborate research policies and R&D programmes in agricultural biotechnology. However, since budgets for agricultural research are limited, we have to consider cost-effective ways of initiating new projects on biotechnology and integrating these new initiatives into conventional agricultural research programmes.
5. High capacity to establish collaborative programmes with other institutions in developed countries for assistance in the fund and management of biotechnology research programmes.
6. Determining clear objectives that could serve as a reference for priority setting and conducting country studies to identify priority problems for which biotechnology could offer a solution, then identifying the appropriate system.
7. High efficiency and flexibility in the transfer and introduction of technologies.
8. Access to and efficient dissemination of information.
9. Holding workshops, conferences, and symposiums at the national, regional, and international levels to promote knowledge and increase contacts among scientists.

Biosafety Issues in Syria

In Syria, handling and production of r-DNA organisms, has not yet started. However, since the establishment of the National Biosafety Committee (NBC) in Syria on 30 May 1999, it has been working on establishing biosafety guidelines for the propose of developing basic requirements concerning the appropriate application of recombinant DNA organisms in agro-industry, so as to ensure the safe use of recombinant organisms and to achieve sound overall development. These guidelines cover laboratory, glasshouse and fieldwork, and the importation and/or release of genetically modified organisms (GMOs) into the environment.

The establishment of institutional biosafety committees (IBCs) at various public institutes and private companies is required by the NBC. The rules governing the importation of prohibited materials under Plant Quarantine Law No. 437 of 17 July 1960, implemented by the Ministry of Agriculture, also control, to a certain degree, the use of GMOs. Permission from the Ministry of Agriculture and from NBC is required to perform field testing of GMOs brought into the country. So far, there has been no permission given regarding importation, or field release of GMOs into the environment.

The public seems to pay more attention to the introduction of GMOs into the country by agricultural companies than to considerations of technological information. Syria is rich in biodiversity and several genes resistant to biotic and abiotic stresses embedded in wild plants/landraces and other bio-resources need to be discovered and utilised. This illustrates the potential benefits of biotechnology and genetic engineering. There is no institute in Syria which has genetic engineering work at present.

Nevertheless, the most important challenge for the future of GMOs in Syria is not completely technical in nature; it is mainly the attitude of the public towards the technology. These issues need to be studied and debated among the scientists, the public, and the policy-makers, and the optimal policy needs to be developed. We realise that genetic engineering depends critically on public support. For this reason, NBC emphasises public education through introducing information programmes on biotechnology and GMOs to the public and to industry.

There are no active non-governmental organisations in Syria that address biotechnology or biosafety issues. Also, there are no companies applying modern biotechnology tools or releasing transgenic crops. Further, there are no active donor agencies in the field of biotechnology and biosafety in Syria.

Constraints

We are now faced with the need to increase the sustainability of agricultural production. Recent progress in biotechnology is rapidly increasing the possibility of modifying crops genetically to make them highly tolerant to various kinds of adverse conditions. These new crops should contribute to the increase and stabilisation of agricultural production. However, the lack of funding and human resources results in the application of limited aspects of biotechnology where genetic engineering is too costly. It is hardly possible to carry out molecular breeding at present.

Thus, advanced research institutes in the public sector of industrialised countries, in collaboration with international organisations, may take the initiative to promote programmes for the development of biotechnology techniques. However, a mechanism for the appropriate training of researchers, skilled scientists, biosafety officers, and technicians should be developed by international experts. These training activities should be handled at the national and regional levels.

Conclusions

In conclusion, a few words related to the main theme of the present conference are in order. It is essential that we strictly maintain scientific quality and objectivity to

evaluate biosafety issues and promote an internationally harmonised framework for the safe handling of recombinant DNA organisms within a short time. It is necessary to improve public acceptance, thus contributing to the safe application of biotechnology and promoting the global exchange of biosafety information. Such an international framework should not cause negative impact on research and development in biotechnology and technology transfer.

Finally, it is necessary to emphasise the importance of establishing the following:

- Efficient and cost-effective regulatory systems at the institutional and national level.
- Clear guidelines for field tests and commercial release of living modified organisms, as well as for imported materials.
- Informative labelling of novel products for consumers.
- Systematic capacity-building.
- International support mechanisms for early warning of good or bad developments with living modified organisms.
- More scientific research on the possible short- and long-term effects of living modified organisms on the environment and the risks to biodiversity.
- Developing and promoting knowledge and expertise in molecular biology and genetic engineering.

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Current Status of Biotechnology and Biosafety Regulations in Sudan

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Introduction

Sudan is the largest African country in terms of area, which is 2.5 million square kilometres. It shares borders with nine countries. The country can be divided into six climatic regions: hot continent desert, tropical semi-desert, tropical sub-humid, tropical wet-dry, tropical rainy, and regions of special climates such as those of Marra and Imatong mountains.

Sudan's population is about 30 million, and the population growth rate is 2.7%. More than 65% of the population works in agriculture. The agricultural sector contributes 48% of the GDP in Sudan and 90% of the foreign currency earnings from exports.

The cultivable land in Sudan is 84 million hectares, of which only 17 million are utilised. The cultivated land includes 2 million hectares in the irrigated sector, 9 million under traditional rainfed agriculture and 6 million under mechanised rainfed agriculture. Land occupied by ranges and forests is about 66 million hectares.

Sudan's share of Nile water is 20.5 billion cubic meters. In addition, there are considerable amounts of underground water. Annual rainfall ranges from less than 50 mm in the north to more than 1500 mm in the south. Sudan also has diversified soils, including desert sandy soil, heavy clay, loamy silt, and volcanic soils.

A variety of crops are grown in Sudan, such as sorghum, millet, wheat, sesame, peanut and cotton, as well as different types of vegetable crops and fruit trees. The country is considered to be a centre of origin for some crops like sorghum and some cucurbits like melon and watermelon. Diversified genetic resources are available in Sudan for different types of crops like pearl millet and okra. The country is also rich in animal wealth, the population of which is estimated at about 102 million, including cattle, sheep, goats and camels. Moreover, Sudan has a considerable number of wild animals.

Current Status: Use of Biotechnology in Sudan

Biotechnology, by definition, is being applied in Sudan in different areas, including food, agriculture, industry, medicine, veterinary medicine and general research.

However, modern biotechnology has limited applications so far due to the lack of trained personnel and appropriate facilities.

Traditional biotechnology is applied in the field of biofertilisers using different strains of *Rhizobium*. Biological control of cotton pests was applied for the control of the white fly and the African bollworm using both indigenous and introduced predators and/or parasites. Biotechnology is also used in fermented foods.

Tissue culture, as a tool for modern biotechnology, has been applied for the improvement of different vegetatively propagated crops (banana, sugarcane and potato), and for *in vitro* conservation of bananas. However, the production of virus-free planting material is not yet developed due to the lack of facilities. Double haploid of wheat is now established to shorten time for variety release.

Current Status of GMOs in Sudan

In plant production, genetically modified organisms (GMOs) are not produced or grown in Sudan. We are not aware of any introductions of GMOs among the imported food commodities. In the last few years, some firms in the GMO business approached the Agricultural Research Corporation (ARC), attempting to introduce Bt-cotton and herbicide-resistant cotton, but they were reasonably rejected.

ARC participated in the Workshop on Biological Control of Plant and Pests in the Near East, organised by FAO in Iran in November 1998. ARC adheres to the recommendation of the workshop with respect to GMOs, at least in the field of plant protection. The recommendation reads: "The use of transgenic plants at field level be avoided in the developing countries until the approach is better understood in relation to its impact on the environment and agro-ecosystems".

Current Status on Issues Related to Biosafety

With regard to these issues, so far Sudan has two main laws:

The Pesticides Law of 1994

Under this law, bio-pesticides are considered as products governed by the Pesticide Law. The latter is executed by a national body known as the National Pesticides Council, headed by the Undersecretary of the Ministry of Agriculture. The regulations issued under this law treat aspects such as pesticide registration, testing, handling, transportation, storage, banning, trade and importation, as well as personnel safety. With regard to the latter aspect, and in addition to many safety measures, pregnant women and under-aged children are not allowed to work in the field where pesticides are applied.

Legislation Relating to Plant Diseases and Agricultural Pests

The aim of this legislation is "to provide the requisite measures for the protection of plants and plant products from infestations of pests and diseases in the country. In addition, it affords a medium for circulating information on Plant Quarantine Regulations governing the import of plants and plant material into Sudan in order to facilitate trade with other countries and to avoid losses of rejected consignments not conforming with the said regulations". Plant Quarantine officers are allocated at air-, land- and seaports of the country where permission of eligible plant material is granted with form PQ/No. 3.

According to this legislation, many ordinances and regulations dealing with plant material import and export have been issued. These dated back to 1911. Local orders, notices, etc., dating back to 1907, have also been issued. It is to be noted that special attention was paid to cotton, the main cash crop of the country.

However, it should be stated that updating the laws and regulations to cope with international trade within the context of globalisation as well as with the ethics of the country is deemed necessary. With regard to the importation of genetically modified plant material for research purposes or otherwise, the regulations are lagging behind. Not only that, but the techniques of identifying GM plants at the quarantine level, if any, are not yet known. Hence, facilities and training in the field of molecular biology are badly needed to cope with new, expected situations.

Recent Developments in Issues Related to Biosafety

Sudan ratified the Convention on Biological Diversity (CBD) in 1995. Since then, Sudan has become a member of the Conference of the Parties (CoP) to the Convention. The national focal point representing Sudan in the CoP is the Higher Council for Environment and Natural Resources (HCENR). Being a member of CoP, Sudan participated in the different rounds of negotiations on the Biosafety Protocol, which has been finalised and agreed upon in Montreal, Canada, in January 2000. At present, Sudan is considering signing the protocol when it is open for signature in June 2000.

A National Biodiversity Strategy and Action Plan has been developed recently in Sudan. Such strategy and action plan has referred to the need for capacity building in the areas of genetic resources and biosafety. It has stressed the need for establishing the necessary legislation in these areas. Endorsement and implementation of biosafety and risk assessment laws have been recommended as well as laws that prohibit bio-piracy.

Current Status of Biotechnology and Biosafety in Tunisia

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Institutional and Legislative Status of Biosafety in Tunisia

Ministry Departments Involved in Biosafety

1. Environment and Territory Management.
2. Agriculture.
3. Public Health.
4. Industry.
5. Trade.
6. Higher Education and Scientific Research.

Regulations in Force

The actual regulations in force do not explicitly cover biotechnological procedures nor their products. However, some of them need only little modifications to be applicable to the biotechnology and biosafety domains. The main regulations are cited below.

Environmental Sector

- Decree 91-362 of 30 March 1991:
  "Obligatory impact studies before starting any activity that may have suspected effects on the environment".
- Decree 93-304 of 1 February 1993:
  "Biological diversity maintenance and enrichment of the local genetic patrimony".

Agriculture sector

This is the largest sector that is concerned with biotechnological applications and risks.

- Law 76-1163 of 25 November 1976:
  "Organisation and control of plant and seed production and commercialisation".
- Law 92-72 of 3 August 1992, recently modified by Law 99-5 of 11 January 1999:
  "Phyto-sanitary control and plant protection", especially concerning quarantine organisms, homologation, and pesticide commercialisation.

Public Health Sector[1]

- Decree 81-793 of 7 June 1981:
  "Fight against vectors of transmissible human diseases".
  "Control of importation, manufacturing, distribution and consumption of medicaments".
  "Control of the therapeutic use of blood, or its derived plasma ".

Concerning human genetic manipulation, Law 91-73 of 29 July 1991 established a national ethic committee that prohibited any human cloning or genetic modification. Animal genetic manipulations must be limited to the necessary minimum.

Industrial Sector

- Decree 95-917 of 22 May 1995:
  "Elaboration of quality standards for the agro-food products".
  "Assistance of manufacturers in the creation of new industries".

Commercial Sector

- Decree 95-915 of 22 May 1995:
  "Definition of government policies on the matter of consumption, quality and commercialisation".
  "Coordination of quality control activities".
- Decree 93-1886 of 7 December 1993:
  "National Council for Consumer Protection".
- Law 91-41 of 7 March 1994:
  "Control of the conformity to national and international standards and techniques".
  "Specific control of veterinary and phyto-sanitary imported products".

Higher Education and Research Sectors

Biotechnologies were first taught at high schools and faculties, which needed laboratories for practical applications. The concerned institutions are the Faculties of

1 Concerning medicines that may contain GMO-derived products, Law 90-79 of 7 August 1990 established a National Laboratory for Medicament Control.

Biological Sciences, Medicine, Pharmacy, and Agronomy.

Biotechnologies like *in vitro* cultures were used for several years in research institutes such as the Institut National de la Recherche Agronomique de Tunisie (INRAT), Institut National de la Recherche Scientifique et Technique (INRST), Centre de Biotechnologie de Sfax (CBS), etc.

Advent of Biosafety in Tunisia

Constitution of an Ad-hoc Committee on Biosafety

In January 1993, an authorisation request was submitted by INRAT to the Direction Générale de la Production Agricole (DGPA) in order to test agronomic performance and resistance to the potato tuber moth of imported genetically modified potato containing Bt gene.

As a consequence to this request, an ad-hoc committee on biosafety was created within the Ministry of Agriculture in order to study this request and all eventual future propositions. It is composed of:

- President of the Institution de la Recherche et de l'Enseignement Supérieur Agricoles (IRESA).
- Director General of DGPA.
- Specialised researchers and teachers.
- Designated member from each concerned ministry.

Since then, this committee has been the unique authority with statues on propositions, particularly those related to agricultural products and organisms.

Other Examples of Submitted Propositions

- Introduction of parasitoids and predators to be used for biological control of citrus insects, 18 May 1998[2].
- Introduction of transgenic tomato, 12 January 1999[2].
- Request for an open field trial of a locally transformed potato resistant to PVY and LMV, 22 December 1999[2].
- Importation of insects usable in biological control, 26 July 2000[2].
- Importation of predator insects for biological control.

Tentative Promulgation of a National Law on GMO Utilisation and Biosafety[3]

According to the directives of the United Nations Environment Programme (UNEP), the Tunisian Government has instructed the Ministry of the Environment

2 The first four requests were submitted either by official or by private organisations.

3 There has been no official promulgation of the law to date.

to prepare and present a proposed law on the use and risk assessment of genetically modified organisms (GMOs). Reference terms of this proposal were established during a workshop held in Tunis on 17-18 November 1998. Participants from all concerned ministries, particularly the Agriculture Department, were present.

A draft of the law has been proposed in April 1999 to be discussed by the Biosafety Ad-Hoc Committee. Some fundamental comments and suggestions have been formulated by consultant scientists and jurists. These suggestions should be taken into account in the final version of the law and its associated decrees and orders.

Biotechnology Status Between the Past and Present[4]

Before the nineties, biotechnological techniques were limited to *in vitro* culture, e.g., meristem-tip culture, micro-propagation, anther culture, etc. Sometime afterwards, research was initiated on molecular genetics and mapping in the laboratory of Professor Marrakchi at the Science Faculty of Tunis. Most studies, based on PCR and relevant techniques, were particularly aimed to find selective molecular markers for some important organisms like viruses or plants. Genetic modification of plants, in particular, has been often done in collaboration with international laboratories. Examples are:

- Artichoke has been transformed by INRST researchers with the aid of an Italian laboratory.
- Potato has been transformed by CBS researchers with the aid of a French laboratory.

4 Actually, we do not think that Tunisian laboratories have the appropriate structures which allow manipulation of GMOs in the required confinement because most of them were initially intended for tissue culture research.

Biotechnology Research in Morocco

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Introduction

Agriculture is an important sector of the Moroccan economy since it contributes 17-24% of the GDP, provides employment for 50% of the total active population, and accounts for 30% of the export earnings. To feed the rapidly increasing population of Morocco (28 million in 1997 and an estimated 40 million in 2025), food production should double, even in dry seasons, without increasing the agricultural area.

Traditional breeding technologies have reached their limits in improving varieties due to the extended time needed for combining genes and selecting improved varieties. Today, new biotechnology tools, such as tissue culture, marker-assisted selection and genetic transformation, are contributing to improving varieties of different crops. However, their use presents some risks to the environment and the consumer. For these reasons, biosafety regulations should be introduced to protect both the environment and the people.

Status of Biotechnology

In Morocco, the application of biotechnology has started only recently. Research programmes were launched first on plant tissue-culture technologies and later on various aspects of animal and food biotechnology (molecular biology, transgenesis, and genetic engineering).

Research is carried out in various public, semi-public, and private institutions. Institutions involved in agro-biotechnology are under the authority of the Ministry of Agriculture and Rural Development (INRA, IAV Hassan II, ENA, CNRF, Biopharma, SODEA, SOGETA, and CTCS) and the Ministry of Higher Education (universities). For some crops, private companies are developing their own research.

Collaboration exists between these institutions, and most of the research development projects conducted in biotechnology integrate at least two institutions. The biotechnology research programme has benefited from cooperation among a number of national and international institutions. Collaboration in biotechnology concentrates mainly on training, research, and development.

Major Research Projects

Research is focused on more than 30 plant species, but horticultural crops are prevalent. Since 1982, research programmes have been carried out on tissue culture of banana, date palm, citrus fruit, strawberry, olive, potato, tomato, pistachio, cereals, food legumes, medicinal plants and some arid-land species. Embryo rescues and micro-propagation have been used to produce healthy plants of date palm and potato, or for the regeneration of plants by combining genes that are resistant to viruses and diseases of cereals and tomato. Mass propagation was used to produce date palm, and forest and fruit tree explants for farmers. Research in molecular biology has been initiated at public institutions (INRA, IAV Hassan II, ENA, universities, SO.GE.TA and by the private sector. Animal and agricultural food crops were of concern.

Assessment of genetic diversity and development of molecular markers were initiated in many crops with RFLP and PCR-RAPD markers. Cereals and date palm have been the subject of intensive research programmes in several laboratories for many years at the National Research Institute (INRA) of Morocco. Development of molecular markers for abiotic and biotic stresses and pasta quality, and the use of these markers for marker-assisted selection in breeding programmes was the main objective.

Related work has been started on the Hessian fly, the most destructive insect to barley and wheat (Lhaloui et al., 1992; El Bouhssini et al., 1997, 1998), and abiotic stresses (drought and salt tolerance). Genetic diversity of the Moroccan Hessian fly has been studied using RAPD techniques (Naber et al., 1996). Assessment of genetic diversity of cereals, food legumes, and forages is ongoing; this will be used to evaluate Moroccan germplasm.

Biotechnology application in industry is limited to isolated examples. At the National Centre for Sugarcane in Kenitra, research has been carried out since 1985 on clone selection and micro-propagation of local and newly introduced varieties of sugarcane. At the Universities of Sciences in Fez and Meknes, biotechnology research on sunflower has been recently initiated.

Biotechnology research in forestry is restricted to a few laboratories. Tissue culture of eucalyptus and holm-oak is carried out at the National Centre of Research in Forestry (CNRF) in Rabat and the Laboratory of Plant Biotechnology and Physiology at the Horticultural Complex of IAV Hassan II. At Agadir, a research programme on argan (*Argania spinosa*) has been under way since 1993. There is also work being done on cedar and holm-oak.

In medicinal biotechnology, veterinary departments at the Institute of Agronomy and Veterinary, IAV Hassan II, are conducting studies on the isolation, purification, and characterisation of antigens as possible candidates for vaccines. The Food Microbiology and Biotechnology Department at IAV Hassan II is carrying out studies on the production of industrial enzymes from hyper-thermophilic bacteria.

Major Institutions Working in Biotechnology

A large number of research units and laboratories in Morocco carry out projects in biotechnology. Most of these projects involve collaboration between at least two research institutions. Institutions involved in agricultural biotechnology are under the authority of the Ministry of Agriculture and Agricultural Development-INRA, IAV Hassan II, Ecole Nationale d'Agriculture (ENA), Société de Gestion des Terres Agricoles (SO.GE.TA.), Centre Technique de la Canne à Sucre, and the Ministry of High Education (universities). In the case of certain crops, private companies (like Domaine Royal) are building up their own research groups.

Table 1. Institutions and areas of research on biotechnology in Morocco.

Laboratory	Research/Techniques	Plant Species
1. Institut National de la Research Agronomique (INRA)		
Plant Biotechnology Research Laboratory, Marrakech	*In vitro* selection, micro-propagation, protoplast culture, protoplast fusion, somatic embryo-genesis	Date palm
Plant Pathology Laboratory, Marrakech	Molecular diagnosis of polymorphism	Date palm, olive
Biotechnology Laboratory, Rabat	Doubled haploid production Development of molecular marker-assisted selection for abiotic and biotic stress, assessment of genetic diversity	Cereals Cereals and food legumes, horticulture crops and fruit trees
Biotechnology Laboratory, Settat	Doubled haploid productions	Cereals, chickpea
Biotechnology Laboratory, Meknes	Doubled haploid production, molecular diagnostics	Cereals, food legumes, olive, grapevines
2. Institut Agronomique et Vétérinaire Hassan II (IAV)		
Plant Biotechnology Laboratory,Hort. Department, Rabat	*In vitro* selection, protoplasts culture and fusion, somatic embryo-genesis	Artichoke, eucalyptus, fig, olive, pistachio, potato
Department of Genetic Improvement, Rabat	Embryo rescues, assessment of genetic diversity and development of molecular markers for disease	Cereals, food legumes
Plant Biotechnology Laboratory, Hort. Department, Rabat	*In vitro* selection, protoplasts culture and fusion, somatic embryo-genesis.	Artichoke, eucalyptus, fig, olive, pistachio, potato

3. Plant Biotechnology and Physiology Laboratory, Agadir		
Plant Biotechnology and Physiology Laboratory, Agadir	Micro-propagation, protoplast culture, somatic embryo-genesis	Argan, banana, caper, carnation, potato, rose, strawberry
Molecular Biology and Genetic Engineering, Laboratory, Plant Ecology Department	Molecular biology, molecular markers, transgenesis	Potato, sunflower, wheat
Plant Tissue Culture and Cytogenesis Laboratory, Agronomy Plant and Breeding Department	Plant double haploid production, micro-propagation, somatic embryo-genesis	Cereals
4. Ecole Nationale d'Agriculture (ENA), Meknes		
Animal Production Department	Genetic engineering, immunological diagnostics, molecular biology, molecular markers	Livestock
Pomology Department	Bioenergy, isozymes, fig and olive tree molecular diagnostics	
5. Faculty of Sciences, Semlalia, Marrakech		
Algology and Hydrophyte Laboratory	Biogas production, bioenergy, microbiology	
Phyto-chemistry and Biorganic Chemistry Laboratory	*In vitro* selection	Fungus FAO
Plant Physiology Laboratory	*In vitro* selection, micro-propagation, somatic embryo-genesis	Arid-zone plants, date palm
6. Office Regional de Mise en Valeur Agricole (ORMVAG), Kenitra		
Tissue Culture Laboratory	Micro-propagation	Sugarcane
7. Water and Forest Administration, Rabat Chellah		
Micro-propagation Laboratory, Sidi Amira	Micro-propagation	Eucalyptus, oak
National Centre of Hydrobiology	Artificial insemination, embryonic transplantation	Black bass, carp, pike, trout
8. Société de Gestion des terres Agricoles (SO.GE.TA), Rabat		
Tissue Culture Laboratory	Micro-propagation	Potato

State of Transgenic Plants

Regarding the development and use of transgenic plants, with the exception of the private foreign company that expressed willingness to test and introduce transgenic tomatoes and corn, no transgenic plants are grown in Morocco. A private company, Forbio Europe, has expressed its interest to launch a joint venture with Morocco on the genetic transformation of date palm for resistance to the Bayoud disease. Morocco is collaborating with ICGEB in training of manpower on biology aspects, including transgenic plants.

Needs for Research on Transgenic Plants

The potential of biotechnology tools to contribute to substantial genetic gains in productivity, quality and resistance to biotic stresses of major crops and the success achieved in many countries, encourage developing these research aspects in Morocco. The creation of transgenic plants depends on the specificity constraints such as drought, pests and diseases, and the priority setting of crops.

For cereals and food legumes, the success of transferring genes from wild relatives to cultivated plants has been handicapped by the poor grain quality of the progenies. The Hessian fly, Russian wheat aphid, and tan spot are example of pests that cause serious damages to cereals in Morocco. The yield loss due to Hessian fly infestation is estimated at 33%, but the total crop failures are frequent in the semi-arid regions and under late-sowing conditions.

For food legumes, Orobanche devastates faba bean and lentil crops in many growing zones of Morocco. It has significantly reduced their annual acreage and transformed Morocco from an exporter to an importer of food legumes in a 10-year period. So far, no adequate sources of resistance are found and the use of Glyphosphate is the only control measure available to farmers. However, the effectiveness of this technology and its adoption by farmers is limited by the skills required for adequate treatment application (determination of the appropriate stage and dose). Creation of resistant transgenic plants could be beneficial in these specific cases.

Bayoud disease, caused by *Fusarium oxysporum* f.sp. *albedenis*, has destroyed 70% of the palm trees (10 million trees) in the last 50 years and, consequently, has significantly affected the oasis system and its economy. Very few crops with adequate resistance have been selected from the existing genetic resources. However, the best quality and highly appreciated varieties are very susceptible to this disease. The use of genetic transformation appears to be the most rapid and effective approach to develop resistant varieties compared to the classical approach based on crosses and back crosses. The use of resistant cultivars will limit the extension of

the disease to the Maghreb countries and its spread to other similar regions.

For horticultural crops, most of the species are severely infested by viruses, diseases, and nematodes. Recently, the tomato yellow leaf curl virus (TYLCV) has become the most devastating disease to tomato. The virus has spread in all cultivated tomato field areas in Morocco, using the white fly as a host. Chemical treatment is usually not efficient, and repeated treatment is expensive and could adversely affect the environment.

These examples clearly suggest the need for the use of biotechnology tools. The introduction of transgenic plants is limited by many factors, including the specific adaptation of the varieties to environmental conditions (climate, biotypes, etc.). Transfer of candidate genes to adapted genotypes will reduce the impact to the environment and help in obtaining useful plants. The transfer of such technologies requires the development of strong partnerships and benefit-sharing with leading institutions.

Prospects for the Use of Transgenic Plants in Morocco

Transgenic varieties offer opportunities for improving productivity and quality. However, as any new technology, they can induce risk to human and animal health, as well as to the fauna and flora. Therefore, it is important to identify these risks and control them in order to ensure the safety of the consumers and the environment.

Transgenic varieties of soybean, corn, tobacco, cotton, safflower, cereal, rice and tomato are grown over more than 20 million hectares throughout the world, particularly in the USA, China, Argentina, Canada, and the European countries. These countries, and some international institutions, have issued and implemented legislations and regulations so as to ensure biosafety and the control of products generated by this new biotechnology.

In Morocco, no transgenic plants are grown. The use of transgenic varieties in Morocco will depend on the development of biosafety regulations and formation of ethics groups to ensure conformity with international biosafety legislation. To develop biosafety regulations, an ethics committee under the authority of the Prime Minister was created. The role of this committee will be to follow up on the progress realised in biotechnology and to examine the research conducted in this area in order to suggest legislative measures and regulations and to monitor their application. The national ethics committee will be supported by sectorial groups (agriculture, health, environment, etc.). On the other hand, a project on legal biosafety is under preparation at the Ministry of Agriculture. This project will be finalised according to the recommendations set up by the Cartagena Protocol which has been ratified by Morocco.

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Biotechnology in Algeria: Status, Evolution and Prevention of Risk

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Introduction

The Algerian population is about 30 million, with a growth rate of 2.1% per year. Food and energy needs are provided mainly through imported products (cereals, fats, sugar and milk). Under these circumstances, Algeria has been attracted to the application of biotechnology. Since the beginning of 1970, biotechnologies, using living organisms, have significantly contributed to the development of various areas of economic importance, i.e., health, food processing, and the environment

Like many other countries of the Third World, biotechnology in Algeria will help to improve the diet of the population and to protect its environment. However, Algeria is insufficiently prepared, quantitatively and qualitatively, to make use of its scientific and technological potential and to control the developments on the international markets.

This situation is best explained by the ongoing discussion between two parties; the first is resolutely for the development of biotechnologies, including transgenic products, the second is resolutely opposed to these products in consideration of measurable risks.

It is anticipated that these new technologies will affect the economic development of countries during this millennium. At the same time, the development of these biotechnologies, including the dissemination of genetically modified organisms (GMOs) and the cloning of both animals and humans, is a topic of controversy among the people, the society and the environment. Between the hopes and fears, Algeria should develop a strategy and establish programmes. The challenge is to assure food self-sufficiency to be able to control imports of transgenic products. The responsibility of policy-makers is to take into consideration socioeconomic issues.

Present Status and Use of Biotechnology in Algeria

Since 1980, Algeria has discussed strategies and means to develop biotechnological inventions. The first National Committee of Biotechnology was created in 1983 in order to:

- Identify the economic needs for developments related to the applications of biotechnologies.
- Set up a national research and development programme.
- Develop proposals for the legislative handling of biosafety and bioethics.
- Assure coordination among education, research and production areas.

Education

There are about 30 cities in Algeria with 15 universities and 40 academic establishments, with about 500,000 students and 16,000 teachers. Recently, amendments have been made to the teaching programme, including the addition of biotechnology. Post-graduate education in biotechnology is favoured, and scholarships are provided for studies outside the country to train about 100 qualified individuals per year. Unfortunately, many students do not return to Algeria. Therefore, another strategy should be applied.

Research

Until 1994, the research budget in Algeria was less than 0.28% of GDP, currently it is 1%. The number of researchers has increased from 1,500 to 4,500.
Some deficiencies persist, such as:

- Researcher-to-population ratio is very low. There is only one researcher for every 6,000 habitants (in France it is 2 for 1,000, 3.8 in the U.S., and 4.7 in Japan).
- Limited investment of private industries in research, i.e., less than 8%.
- Limited research and industry relationships. However, since 1980, progress has been made and results have been obtained in various fields of biotechnology, such as:
  - Bio-control agents.
  - Production of methylotroph yeast in 1979.
  - Setting up lactic acid fermentation banks.
  - Micro-propagation of date palm, potato, citrus and other economically important species.
  - Selection and production of *Bacillus thuringiensis*.
  - Selection of *Rhizobium* strains on saline soils.

The lack of interest of private industries did not help the transfer of the results

of biotechnology research to a commercial level. Recently, a national research and development programme on biotechnology has been developed; it includes four research areas: agriculture, food industry, the environment, and human and animal health.

Scientific Information

The creation of the National Centre for Scientific and Technical Information and Research (CERIST) in Algeria, which is equipped with modern communication technology (e-mail and the Internet), can play an important role in the development of biotechnology.

Cooperation

Supported by international agencies (FAO, UNDP, ICGEB, EEC, etc.), the Algerian authorities have, for the last 20 years, made large efforts for the development of biotechnology. This has allowed developing the necessary human capacity and experience which has produced research results that can be applied today to commercial-scale production.

Expanding of Biotechnology Perspectives

The scientific community and policy-makers in Algeria are giving priority to this new technology field. These priorities were recently confirmed by a law on scientific research adopted by the Algerian Parliament in August 1998 for the following fields:

- Biotechnology in the food industry.
- Biotechnology applied to agriculture.
- Biotechnology applied to environmental protection.
- Biotechnology applied to pharmaceutical production.

The objectives of institutions involved in biotechnology are:

- In education, graduate and post-graduate programmes should be improved to fulfil the specific needs.
- Foundation of a national centre for biotechnology to develop the objectives of biotechnological research.
- Foundation of a national agency to evaluate scientific research.
- Local and international cooperation should be a priority.

GMOs and Biosafety

Recent progress in the field of molecular biology and genetic engineering allowed for the development of all the biotechnology sectors. This progress has made available transgenic products in the world market that are not without risk.

Currently, transgenic products are not produced in Algeria. However, through world trade, GMO products could be introduced into the Algerian markets. The presence of GMOs in the world markets has initiated important discussions in Algeria. Even if the advantages of GMO crops exist, their risks to health and the environment are not well studied.

Risk Assessment

As in many other countries, Algeria is still not able to develop high-level research in all fields of biotechnology, but is putting in place relevant regulations and inspection procedures. The first step towards a national strategy in biosafety was the development of technical competence, represented by the Inter-Ministerial Group for Biotechnologies. The National Committee of Biotechnology (NCB) should work actively to develop national procedures harmonised with those used at the international level.

For imported products, rules adopted by the World Trade Organisation (WTO), in which Algeria is a member are applicable. Surveys directed by the Ministry of Trade for examining dangerous products in the national market are being developed.

Agriculture

According to western experts, the technological revolution may have direct consequences on agricultural production and derived products. FAO experts have underlined the potential risk to agriculture: the dissemination of genes from GMOs could increase the character in the wild species that cause herbicide and insect resistance.

Health

The applications of genetic engineering should be controlled and the potential consequences of GMO products, such as allergic reactions, need to be studied.

Environment and Biodiversity

It is well known that biodiversity is a major resource of variability used in plant breeding to improve crop production. The spread of GMO crops could indirectly reduce this biodiversity through gene-flow.

Informing Citizens

The changes introduced by the progress of genetic engineering could affect people throughout the world; therefore, scientific clarification of the effects should be provided. Unfortunately, the availability of transgenic products in the food markets has not been without problems to the public.

Labelling

Biosafety and Information for Consumers

The current discussion about commercialised GMO products has created some opposition by the consumers. However, the rules of free movement of commercial products are guaranteed by WTO.

Two types of information related to GMOs are requested: labelling of the transgenic products and assurance of hygienic and sanitary security for buyers and consumers. In Algeria, there is no information available on GMO imports.

Control Quality

The world trade of technology and economy regulates the trading between countries. This should be taken into consideration until the results of research on the potential risks are obtained. Therefore, preventive measures must be considered (labelling, quarantine, etc.). Policies should be established to suitably control importing GMO products, which should conform to international standard procedures. Recently, the Ministry of Agriculture has created a specialised committee.

Monitoring

Labelling of a final product identifies how this product can be followed from its origin all the way through the food-chain procedure. The monitoring and control of movement of GMOs should be possible. For this reason, the tools of control and detection of transgenic products are necessary. Through international collaboration, such tools need to be established in Algeria. It is necessary to develop a system to reduce the constraints of monitoring.

Conclusions

Because of world trade in biological products, particularly transgenic products, Algeria has resolutely chosen, as a strategy, to consider devoting its research activities to this area as one of its high priorities. Recently, the Algerian Parliament has adopted a law to create a national centre for biotechnology. Also, the active participation of Algeria in different networks has allowed the establishment of protocols and ratifying the international Convention on Biological Diversity and, recently, the international Biosafety Protocol.

Algeria has made efforts to establish the Agency of African Biotechnology (AAB) in Algeria. Perhaps, in the future, the regional African Centre of Biosafety will follow. These two institutes are proof of the interest of Algeria in biotechnolo-

gy. However, the potential risks to human and animal health and to biological diversity and the environment have to be taken seriously. For these concerns, Algeria is developing policies related to the transport of GMOs across borders.

Concerning the production of GMOs, suitable regulations are being developed which put in place means to assure clear labelling and monitoring of commercialised transgenic products. In Algeria, the utilisation of genetic engineering, is still under discussion. The challenge is not only to ensure food self-sufficiency, it is necessary to manage a number of challenges that arise from world trade regulations.

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Studies on Biotechnology and Biosafety in Turkey

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Introduction

The Ministry of Environment is responsible for the coordination of biosafety protocols in Turkey. For this purpose, subsequent meetings were organised between all related governmental institutions, including ministries, the prime-ministry, undersecretaries, universities, and the Turkish Council for Scientific and Technical Research. Thus, the current position with respect to biotechnology is:

1. Modern biotechnology is one of the tools that will contribute to food safety of the world population and will lead to medical improvements against human genetic diseases. Turkey has given priority in its academic activities to research and development (R&D) in biotechnology. Appropriate safety and emergency measures are taken during R&D activities, and the interaction of genetically modified organisms (GMOs) with the environment is fully prevented.
2. GMOs have potential adverse effects on biological diversity and human health. Full risk assessment must be undertaken before marketing GMOs and their products. Precautionary measures against unexpected effects of GMOs and accidental situations must be taken for all intended uses, including research and development activities, production, consumption, and processing.
3. Risk-management procedures must be developed as applicable for particular conditions of the target environment. Labelling of GMOs and their products and segregation from traditional products are the measures that must be applied at the international level, since adverse affects of GMOs are of global concern.

Biosafety Measures

1. All related governmental institutions have been advised of the risks associated with the use of GMOs.
2. Importers are requested to declare whether the crop that is to be imported to Turkey is a GMO or not. Immediate regulatory measures are taken to ensure that no GMO is released to the environment or marketed without conducting a full risk assessment that includes field trials. There will be no permission for release and marketing of GMOs before completion of procedures related to legislative, administrative, and institutional mechanisms. Therefore, no GMOs are permitted for marketing or production in Turkey.

3. Studies to establish a labelling system for GMOs and their products have been initiated.
4. A specialised commission has been established by the State Planning Organisation (DPT) to consider relevant problems, including capacity-building requirements for risk assessment and risk management of GMOs within the context of the next five-year development programme (2000–2005).
5. In the beginning of 1998, when some firms applied for importing genetically modified plants (GMPs) into Turkey, the Ministry of Agriculture and Rural Affairs prepared rules for the field trials, and conducted field trials on potato, cotton, and corn at the agricultural research institutions under strictly controlled conditions to prevent risks of accidental release and gene escape from the GMOs.

   Pre-conditions which are necessary for the acceptance of an application for field trials include:
   - The GMP should be registered in its origin country at least 3 years before the time of application for the field trials.
   - The GMP shall be subjected to production for the purpose of marketing among countries having regulations on GMP, particularly in the country where the GMP is registered.
   - Risk assessment and scientific reports and data focusing on the effects of the GMP on the environment and on human and animal health, including possible interactions of the GMP with the natural flora and fauna, should be available.

Regulations in Force

The regulations are based on the Directive on the Principles of Field Trials of Genetically Modified Plants, which became effective on 14 May 1998 by the Ministry of Agriculture and Rural Affairs. Its objectives are to establish the rules for the procedures and principles of application, and to address the concerned authorities on the principles of undertaking field trials on GMPs intended for agricultural production. The directives apply to all GMPs, whether imported or locally developed. The national competent authority is the Ministry of Agriculture and Rural Affairs, whose function is to evaluate the eligibility of application through a special commission, which is composed of representatives of:

- General Directorate for Development of Agricultural Production (GDDAP), which issues permits for importing agricultural products, plants and livestock animals.
- General Directorate of Agricultural Research (GDAR), which undertakes agricultural research through institutions and competent to planning, issuing and implementation of the field trials and risk assessment.

- General Directorate of Protection and Control (GDPC), which is responsible for food safety and health certificates of imported or marketed plants and animals.
- Seed Registration and Certification Centre (SRCC), which is responsible for seed registration and certification.
- Agricultural research institutions, whose proficiency to undertake field trials is approved by GDAR.

The decision of the commission is based on scientific data and information provided by the applicant on the method of transformation, inserted construct, stability of gene transfer, possible effects of the GMP on biodiversity, gene escape risk, and assessment of acute toxicity and allergenicity. If the commission permits application of the field trials, GDAR mandates appropriate research institutes to undertake the activity.

Implementation of Appropriate Field Trials

1. The plan of the trial is prepared by the mandated research institute on a case-by-case basis.
2. The commission evaluates the plan of the trial on a multidisciplinary basis.
3. If the plan is approved by the commission, the research institute implements it.
4. All expenses of the trial are provided by the applicant.
5. The implementation of the plan is controlled by the commission during and after the field trial.

Legislation and Framework

The legislative framework is based on "Principles of Use, Handling, Release and Marketing of Genetically Modified Organisms and Products Thereof Imported or Domestically Produced" and "Principles of Registration of Genetically Modified Plants" (Ministry of Agriculture and Rural Affairs). The main points of the framework are:

- GMOs or products thereof must be registered in accordance with the regulation.
- Requirements of use, handling, and release must be determined in accordance with the results of risk assessment and field trials on a case-by-case basis.
- The qualifications of personnel who will release the GMOs into the environment must be determined.
- A notification procedure is required.
- Conditions of marketing must be set up in accordance with the intended packaging.

- All related institutions should take the necessary legal and administrative measures regarding the safe development, handling, transfer and use of GMOs.

Field Trials in Turkey, 1999

Field trials on three cotton (herbicide-resistant and herbicide/pesticide-resistant) GMP varieties, five corn (resistant to *Sesamia nonogrioides* Lef. and *Ostrinia nubilalis* Hübn) GMP varieties, and one potato (resistant to *Leptinotarsa decemlineate* SAY.) GMP variety were undertaken within the restricted areas of agricultural institutions at five locations. Second-year field trials in 2000, including risk assessment for these GMP varieties, were undertaken by the institutions at the same locations.

Biotechnology and Biosafety in Jordan

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Introduction

Traditional breeding has been a very effective tool for improving plants. For many decades, there has been unlimited potential for genetic manipulation of crops to enhance productivity. This traditional breeding is now considered a time-consuming process that produces unwanted traits.

In the last two decades, with biotechnology, plant breeders have been able to develop novel varieties of plants by introducing selected useful genes into a plant to express a specific and desirable trait(s). This powerful technique allows scientists to isolate genes and to transfer them across biological barriers.

Farmers in many countries have quickly adopted the new modified plants that are known as genetically modified organisms (GMOs) or genetically modified crops (GMCs). The big questions, in an international context, are: Are these products safe to eat? Are they safe for the environment?

Policies and standards are then focused on ensuring that novel foods are safe and nutritious. The approach to food safety assessment has been based upon the concept of equivalence. Therefore, the new varieties have been evaluated for human, animal and environmental safety through regulatory mechanisms.

Jordan is a country in a region which is the centre of origin of many plants. It has varying geographical, climatic and geological features. It is rich in biological diversity. There is insufficient knowledge of the risks on human and animal health of the novel crops. Therefore, these crops need to be evaluated prior to their commercialisation as GMCs. Additionally, the concern about the gene flow to wild relatives is legitimate since the products of the GMOs might change the rate at which crops hybridise with wild relatives.

Jordan supports the international concern that the need for international harmonisation of approaches to food safety assessment is increasingly important. The importance of regulatory cooperation in the area of biosafety is recognised and desirable. The realisation of regional harmonised approaches to environmental safety assessment, and of international harmonised approaches to food safety assessment, will continue to ensure the safety of the environment and foods derived from modern biotechnology in the global market.

Current Status of Biotechnology

Jordanian scientists are trying to increase the use of plant species through biotech-

nology in order to discover genes of value to transfer them into commercial crops. They also try to expand, via cloning, many wild relatives of crops that might be threatened with extinction.

However, two national conferences, held in Al-Bayt University in 1997 and 1999, reviewed biotechnology research and activities at the national level. The topics of the conferences focused on the following:

1. Improving microorganisms, plants and animals by genetic engineering.
2. Biotechnology in agriculture for plant tolerance to drought and salinity.
3. Biotechnology in industry for improving animal feed, organic acids, enzymes and vitamins.
4. Biotechnology in the environment for developing new methods for treating sewage water.
5. Biotechnology in medicine for antibiotics.
6. Tissue culture techniques for plants, animals and gene transfer.
7. Biodiversity of plants, animals and microbes.

Biosafety

With increased seeds of the released varieties of many genetically modified (GM) crops, and increased GMO-derived products into the world market and through transboundary movement, biosafety assessment becomes an important aspect of concern in biotechnology.

There are three agencies responsible for controlling GMCs in Jordan:

- Ministry of Agriculture (MoA), responsible for ensuring that new varieties are safe to grow.
- Ministry of Health (MoH), responsible for ensuring that new varieties are safe to consume.
- General Corporation for Environment Protection (GCEP), responsible for ensuring that new varieties are safe for the environment.

The Ministry of Agriculture has established the National Biosafety Committee (NBC) in May 1999 to ensure human, animal, and environment safety. The aim of the Committee is to make sure that no genetically modified food is allowed in the local market unless the Jordanian authorities had sanctioned it. The Committee has to consider a number of issues on biosafety such as:

1. Propose a national policy on biosafety.
2. Identify risks associated with the use of GMOs.
3. Advise on risk assessment and management associated with the use of GMCs, considering the consumers' safety in general, and with permanent focus on the protection of the environment.
4. Establish appropriate national standards and regulatory framework for GMO products.

5. Develop mechanisms for regional and international cooperation and consultation.
6. Inform the general public on issues related to GMOs.

The NBC is composed of representatives of the following eight institutions:
- Ministry of Agriculture.
- National Centre for Agricultural Research and Technology Transfer.
- Ministry of Health.
- Ministry of Industry and Trade/Quality Department.
- Ministry of Industry and Trade/WTO Unit.
- Jordanian universities.
- General Corporation for Environment Protection.
- Institution for Standards and Metrology.

The NBC has formulated the national biosafety guidelines, which are in harmonisation with the national policies of existing regulatory agencies and with international biosafety guidelines or protocols. The Committee shares information on principles or guidelines for national regulations on developments of risk analysis and management in order to facilitate harmonisation of approaches to biosafety among different institutions. NBC is also continuously monitoring progress made in biosafety practices in other countries, so that policies and guidelines on biosafety in Jordan can be updated regularly.

However, the Ministry of Agriculture has recently issued a statement indicating that novel plant varieties produced by biotechnology would be regulated, which will assist in the formulation and amendment of pertinent laws related to the implementation of national policies on biosafety. It will also try to build national confidence through organising workshops, meetings, and issuing publications. This will widely inform the Jordanian consumers of the growing knowledge on GMCs.

Four sub-committees will be formed under the umbrella of NBC in order to deal with the wide-range issues of GMCs. These four issues are:
- Biosafety guidelines for agricultural related GMOs
- Biosafety guidelines for research on GMOs
- Labelling of GMO or GMO-derived products
- Public awareness programme on GMOs.

However, the focal points for biotechnology activities at the universities and research institutions will be formed soon.

Biosafety Regulations

The principle of biosafety is to apply policies and procedures to ensure proper and safe application of biotechnology, without endangering the people, the environ-

ment, and the biological diversity of the country. Biosafety can be achieved simply by regulating, monitoring and assessing risks to humans, animals and the environment.

The regulations are applied through the guidelines which provide a common framework for:

- Plant and food safety which depend on the concept of substantial equivalence,
- Assessment of risk of GMCs to human and animal health and the environment, and
- Approval mechanisms for production and release of GMCs in Jordan.

Biosafety regulations, however, include all the activities related to GMCs and their derivatives. They include production, importation activities, consumption, exporting, and use of GMOs. There must be an official application submitted to obtain a legal permit to deal with GMO products and their derivatives. The application must contain all the detailed information in order to help in evaluating the product. The evaluation process by NBC will be on a case-by-case basis.

Applications of GMC seeds will be submitted to MoA, and those of GMO-derived products submitted to MoH. The application will then be conveyed to NBC, which will evaluate the application and refer it, if necessary, to the sub-committee(s) to be evaluated for safety to human and animal health and the environment. The sub-committee(s) will consist of a team of scientists in molecular biology, toxicology, chemistry, nutritional sciences and microbiology. The sub-committee(s) will then make recommendations to NBC in order to endorse the approval to grant a permit for the relevant GMO, if it is found to be safe. The relevant agencies, i.e., MoA, MoH or GCEP will, however, use their existing legislation for control before the biosafety law is approved.

Biosafety laws will address production, importation, consumption, use, trade, export, trial release, general release of GMOs, etc. They will also address food safety and provide labelling of foods to meet the consumers' "right to know" if the product has been derived from GMOs.

There are many advantages to incorporating biosafety regulations in the existing legislation and institutional arrangements in order to avoid creating a new regulatory infrastructure. New guidelines, usually linked with the relevant existing legislation, are being formulated and implemented at the time being. However, the future national interests require formulating a national biosafety law for biotechnology products.

Regional and International Protocols

Biosafety has emerged and is identified in the international area as an important issue of concern in biotechnology. The concern for biosafety is legitimate, because of the transfer of genes from GM plants to wild plant species, which may affect bio-

diversity, and to edible plants, which may produce toxic or allergenic effects in the consumed foods.

The objective of the biosafety protocol is mainly to ensure an adequate level of protection across the borders. The biosafety protocol should have its basis in methods of crop improvement. However, plant breeding, crop improvement, and gene-transfer techniques should provide the regulatory officials with sufficient information for risk assessments. Therefore, the protocol should be applied to the transboundary movement, transit, handling and use of all GMCs that may have adverse effects. The protocol should include an advance-informed agreement given by the country of import prior to the transboundary movement of the GMO.

These principles will promote free circulation of GMO products among the different countries. Therefore, the protocol needs to develop standards with regard to identification, handling, packaging, and transport practices, etc., in consultation with other international bodies. The standards have to be integrated into the overall regulatory systems in the countries. The regulatory system, however, should be flexible and capable of quickly adopting the new knowledge and rapid advances in biotechnology.

Consumption of GMO Products

Consumption of GMO products in Jordan requires an official approval that the GMO products are consumed in the produced countries. Additional consultations with scientific bodies on risks and/or safety of the product will also be required. The GMO products will be re-evaluated periodically for toxic substances of new expression through testing toxicological, allergenic, and similarity of the transgenic product with known allergens and nutritional modifications.

Methods of biosafety assessment of GMC seeds or products, if required by NBC, will consider the field testing to increase the knowledge about the relative safety or risk of large-scale use of GMCs. Methods of spatial separation of plants will be used. The minimal isolation distances for the maintenance of seed purity will be used as a practical guide to the actual distances of gene flow from GM crops. Temporal separation of plants and destruction of volunteer plants will also be used. Environmental containment will be considered too, because crop plants with no relatives in the region presents no risk of gene flow.

Finally, the safety assessment proceeds until a conclusion of substantial equivalence can be reached. Differences identified in the comparison are the focus for further intense monitoring, which involves nutritional, toxicological and immunological testing as appropriate. If the assessment indicates that longer-term studies are required, the product will not be approved and the applicant will need to submit additional data.

Conclusions

GMC plants which are designed to resist pests or diseases and environmental stresses, such as frost, drought and salinity, may have unexpected genetic effects by introducing allergens or toxins into food. The use of antibiotic-resistance markers may also endanger human health.

Safety assessment of GM plants is usually based on the nature of the organisms and the environment into which it will be introduced. Field tests should provide information about GM plants, their phenotypic expression, and their interactions with the environment. It is therefore important to have international harmonisation of biosafety standards.

While Jordan is aware of the benefits of modern biotechnology for agriculture, it is also concerned with the risks associated with modern biotechnological practices that might affect its environment and biodiversity. Jordan has taken steps towards the formulation and implementation of its national guidelines. Since Jordan's experience in this area is developing, it seeks close cooperation with other countries to upgrade its capacity building, risk assessment, and other aspects concerned with biosafety.

Biotechnology and Biosafety in Palestine

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Introduction

The agricultural resources of the Palestinian Territories are very limited. The total land area of the West Bank and Gaza Strip is about 6,245,000 dunums or 6,245 km^2, of which an estimated 1,980 km^2 (31.7%) are cultivated, 1,900 km^2 are rangeland, and 260 km^2 are considered forestland. It is worth mentioning that access to most rangeland and forestland areas is restricted since they are still under Israeli control.

Water resources of the West Bank and Gaza Strip are also very limited, and the largest portion is still under Israeli control. This scarcity of water resources has a major impact on the Palestinian pattern of agriculture, as the vast majority of cultivated land is dependent on rainfall, while irrigated cultivation is very limited.

Due to the existence of various climatic micro-regions, the agricultural products of the West Bank and Gaza Strip cover a wide diversity of commodities, while the agricultural exports constitute a major source of foreign exchange earnings and contribute to improving the trade balance.

Biotechnology

Biotechnology refers to any technique that uses living organisms or substances from these organisms to modify or improve the quality of crops and food, drugs and health care products, vaccines, industrial chemicals, and their products. It consists of a gradient of technologies ranging from the widely used techniques of traditional biotechnology through modern biotechnology that is based on the use of new techniques of recombinant DNA (r-DNA) technology, known as genetic engineering.

The past decade has seen an enormous increase in biotechnology research. In particular, the novel possibilities of genetic engineering technology, i.e., the identification, isolation, and transfer of genes, have given rise to a completely new type of research in scientific institutions and in industry. Genetic engineering has proved to be a great scientific success and, in many cases, an excellent tool for research in various disciplines. The important question for the coming years is whether the new biotechnology will also be a commercial success.

Applications of biotechnology are on the verge of great expansion in this decade. The production and release of the resulting genetically modified organisms (GMOs) have raised many concerns about possible risks to humans and to the environment.

Accordingly, all biotechnology research has to be carried out within a regulatory biosafety framework. The coming decade will be decisive for applications of genetic engineering. What will the attitude of society be towards the new biotech products and, closely associated with this, what will the authorisation policy of the various governments be?

Biotechnology in Palestine is still in its infancy stage. Biotechnology is addressed to solve problems facing Palestinian agriculture, with special emphasis on developing a high-calibre research body capable of understanding and executing developed technologies. Biotechnology research offers new approaches to sustainable agriculture whereby the environment must be enhanced rather than destroyed. Non-reusable natural resources could be used more efficiently and farm operation could be salvaged.

Importance of Agricultural Biotechnology to Palestine

Agriculture has remained one of the major economic forces in the Palestinian society, despite the many political drawbacks that had negative influence on this important sector. Agricultural biotechnology, which is still new to us, is a technology which could contribute in various ways to solving agricultural problems in Palestine. The following are just some examples:

- Plant and animal breeding can contribute a great deal to Palestinian agriculture in terms of productivity, disease resistance, and marketing.
- Genetic engineering can help develop cultivars that are not only resistant to diseases but also to different kinds of stress as well, such as drought, which can contribute a great deal to solving the problem of water scarcity in Palestine.
- Agricultural biotechnology can give a chance to Palestinian agricultural products to compete with surrounding countries in terms of marketing.
- In the field of plant protection, biotechnology can offer a range of environment-friendly techniques that can reduce the Palestinian dependence on agrochemicals.

During the last 10 years, some efforts were being exerted to promote research in agricultural biotechnology. These efforts have been made possible through various governmental and non-governmental research institutions, as given below.

Institutions Involved in Biotechnology

Governmental Institutions

These include the two Palestinian ministries:

- Ministry of Agriculture, represented in this respect by the National Agricultural Research Centre (NARC), which was established in 1994 to conduct and coordinate agricultural research activities by the government in Palestine. It is involved

in several research activities related to biotechnology:
- Research on micro-propagation, including tissue culture activities.
- Integrated pest management, including biological control.
- Molecular techniques in detection and identification of plant pathogens.
- Improvement of olive production under semi-arid conditions.
- Agro-biodiversity.

• Ministry of Environment is involved in some activities in biotechnology including:
- Energy production through fermentation activities.
- Biodiversity research.

Non-Governmental Institutions

These are represented mainly by the Palestinian universities which are involved in several academic (educational) and research activities in the field of agricultural biotechnology. These includes the following institutions:

1. Biotechnology Educational and Training Centre (BETCEN) in Bethlehem **University** was established in 1995 by UNESCO Biotechnology Action Council (BAC). This centre is one of five biotechnology centres established by UNESCO in five regions of the world: China, South Africa, Mexico, Hungary and Palestine. The centre is involved in the following activities in biotechnology:

- Educational and training activities in which courses in various fields of biotechnology are offered to young scientists from Palestine and the Arab countries. Topics include plant tissue culture, molecular biology, genetic engineering, and biological control.
- Research activities that involve various topics in biotechnology such as the use of nematodes in biological control of insect pests, and molecular techniques in plant-pathogenic bacteria.

2. Hebron University is involved in various research activities related to biotechnology, including non-chemical control of plant pests and diseases, such as biological control, the use of phyto-hormones in controlling grey and white mould of vegetables, the use of pheromones against army worms, and research on herbicide-resistant weeds. This is, of course, in addition to the academic activities in the field of biotechnology, where specialised courses such as plant and animal breeding, IPM, biological control, micro-propagation, and others are offered.

3. Al-Quds University, which is also involved in some educational and research activities in biotechnology, includes research in biological control of soil-borne plant pathogens as an alternative to lethal soil fumigants.

Genetically Modified Organisms (GMOs)

In Palestine, there is no use of genetically modified organisms until now. However, there are several research projects under way, including the use of drought-resistant transgenic tomato plants, transgenic bioagent fungi, and others.

Biosafety is one term that is used to describe the policies and procedures adopted to ensure the environmentally safe application of modern biotechnology. It is a term that is gaining wider currency as more countries seek to benefit from the application of modern agricultural biotechnology without endangering public health or environmental safety.

In Palestine, a National Committee for Biosafety (NCB) was recently established by an initiative from the Palestinian Ministry of Agriculture. It includes members from three ministries (Agriculture, Health, and Environment) in addition to three universities (Hebron, Al-Quds, and An-Najah). The Palestinian Ministry of Environment has proposed another recent project for the implementation of biosafety measures on biotechnology in Palestine. In the context of this project, a Biosafety Working Group is to be established to identify the existing biotechnology expertise (individuals, firms, organisations, research organisations, etc.) and assess the status of legislation related generally to biotechnology and specifically to biosafety.

In Palestine, we still do not have regulations and legislation that govern biotechnology application by research institutions, or even by industry. On the other hand, some other closely related activities have started in Palestine such as "agricultural quarantine". The General Administration of Plant Protection that belongs to the Ministry of Agriculture has recently established the Department of Agricultural Quarantine and Inspection. This department, by law, controls the movement of agricultural products getting into or out of Palestinian Territories.

Biotechnology Constraints in Palestine

- Limited human resources in this field (qualified staff).
- Lack of adequate funding for research in this area.
- Lack of legislation and regulations to organise biotechnology applications.
- Inadequate equipment and research tools necessary for this highly specific field of science.
- Insufficient incentives and encouragement given to scientists working in this field.
- Constraints related to Israeli occupation and control on Palestinian sovereignty.

Conclusions

Agricultural biotechnology is not a product in itself. It is a powerful set of tools that can contribute significantly to our ability to meet agricultural challenges. In spite of some skeptics, most of us are convinced of the vital impact this technology can have on improving agricultural productivity. As with any innovative technology, agricultural biotechnology will change economic and competitive conditions in the market. For industries active in this area, the price ticket will be high.

The development of new plant varieties, and the applications of new technological approaches need significant resources and time. In addition, based on the structure of the market, specific adaptations are required to fulfil demands of the various segments of the market. Successful implementation of agricultural biotechnology in the development of improved agricultural products and productivity does not only depend on the willingness of the industry to invest in this area; supportive policies by governments are also needed to create the appropriate conditions for industrial applications.

International coordination of legislation is essential so as to avoid unreasonable restraints on certain industries or competitive disadvantages of one region versus others. Transparency will be the key word; transparency in procedures, regulations and real information on the technological possibilities and limitations. Transparency will strengthen public confidence, confidence in the progress of new technologies which, when used prudently, can benefit society.

International aid and support should be granted to developing countries in this field. This is very important to narrow the gap that already exists in agricultural technology applications in the developed versus developing countries. It is not logical to witness a farmer in the Netherlands using a transgenic fungal bioagent to control plant pathogens in his field while a farmer in Bangladesh is still using DDT.

Biosafety in Iraq

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Introduction

Research on the use of microorganisms in the production of cell biomass or some biological products is conducted in Iraq using conventional techniques such as chemical and physical mutagens. Most of the research programmes are academic, and are carried out at the universities, but few have developed to large-scale production. International biosafety measures are followed during the work. *Officially, no local regulations or additional measures have been issued for such work.* Large-scale production or importing and application of bio-control agents requires a series of official measures and conducting field experiments to prove the safety of the bioagents to humans, animals, and the environment.

Conventional, physical and chemical mutagens are used for crop improvement. Mutants of certain crop plants are involved in conventional selection programmes for recording new varieties by a special committee. Tissue-culture techniques are also applied in some research programmes to improve crop production and/or tolerance to environmental stresses. Exposure to mutagens or stress is carried out on a cell suspension or tissue of the target plant to obtain biodiversity and then select the proper plants. These plants also go through a long selection programme in the laboratory, greenhouse, and field. Research on animal tissue culture is carried out for medical purposes such as for the diagnosis of some diseases and/or in chromosomal studies.

Genetically Modified Organisms (GMOs)

Genetically modified organisms (GMOs) produced using conventional methods are enrolled in long-range selection programmes for the best production and economic characteristics, including susceptibility to insects and phytopathogenic microorganisms in the cultivated area. Research on organisms using gene manipulation techniques is still not applicable because of the limitations enforced by the United Nations.

Legislation or measures governing the importation of GMOs have not yet been issued. Certain preliminary measures are taken, however, such as the need for a specific certificate from the exporter of a product to ensure that the product is not genetically modified, and the prohibition of importing any GMOs into the country.

Quarantine

Regulations that control the movement of plants and plant products into the country officially go back to 1924. A list had been issued of plants that were considered as pest hosts, and required certain measures before entering the country. Quarantine measures were developed within the past decades. A separate establishment was founded, the capacity of specialised staff was developed, and separate facilities were built. Regulations and measures were issued to control the movement of pests in and out of the country on a scientific basis. At least eleven quarantine establishments exist in Iraq. Cooperation with scientific centres takes place to solve problems which require in-depth scientific studies.

III

GROUP DISCUSSIONS AND RECOMMENDATIONS

Summary

Following the reports given by the national representatives, the third part of the meeting focused on the identification of common needs and specific expertise available in the region, which should facilitate the establishment and further implementation of national biosafety systems within a regional framework. A regional framework does not only strengthen negotiation power, it also opens the opportunity to share resources. Resources available and expertise needed were clearly explained during the national presentations. In this third part, the objective was expressed, during sessions by three discussion groups, as determining and formulating recommendations and a common position on three major issues:

- Risk/safety/impact assessment and management (human capacities).
- Tasks and terms of reference for institutional arrangements (institutional capacities).
- Containment facilities, testing and result sharing (infrastructure and communication).

Group 1: National and/or Sub-Regional Risk Assessment Needs.

Risk Assessment for GMO Products

The group discussed the requirements for risk analysis and risk management. It was obvious that depending on the application, risk analysis and management could be different. Different categories for genetically modified organism (GMO) application could be for research, for release, for industry, for human consumption or for use in livestock feed. Depending on their use for the different objectives, the conditions for containment have to be defined.

If regulations are clear and understandable, and strong sanctions are in place, most people will comply with existing regulations. However, a monitoring system has to be established. The group members felt that the national agricultural research systems (NARS) are currently not well trained to pursue the tasks of risk assessment. There is a considerable requirement for training on risk assessment and risk management techniques and for training for GMO detection and monitoring.

Environmental Risk Assessment

In that regard, it was pointed out that for the WANA region, as a centre of origin of many agricultural crops, environmental risk assessment needs special attention. Long-term biosafety research needs to be initiated to monitor gene flow from cultivated agricultural crops to their wild relatives. There are "hot spots" of recombination in the centres of origin, and the use of GMOs should be monitored.

Capacity-Building

Hand-in-hand with the need for training on risk assessment and risk management, the NARS require capacity-building in all aspects of agricultural biotechnology, development of facilities, and training of biosafety officers.

Networking for Dissemination and Sharing of Information

Many NARSs felt that they did not have access to appropriate information related to biosafety. It was therefore requested that organisations such as ICARDA, in cooperation with AGERI (and others such as ACSAD and IPGRI), should organise an information network on biosafety.

Research Projects and Projects for Capacity-Building

There is a need for the NARSs to develop projects that will allow receiving training on risk assessment and management. It was emphasised that there are already a number of bi- and multilateral projects existing that could provide training on the topics requested. The FAO Technical Cooperation Project provides project funds, and the proper and existing channels have to be used for seeking FAO assistance. The UNEP/GEF project provides funds for capacity-building in biosafety, and the proper and existing channels have to be used to be eligible for funding. Other bilateral donors, such as GTZ and others, also have funds available for capacity building and training in the area of biosafety. Additionally, there are research projects needed, projects on biosafety research and on the detection and monitoring of GMOs.

Conditions for Research Projects

It was evident to the group members that research projects should be given to laboratories under the condition that research would be done under confinement, and that biosafety regulations in the concerned country are in the process of development.

Laws and Regulations

It is necessary to establish rules and regulations in each country. International codes of conduct are available to cover the interim period until biosafety regulations are in place in each country (e.g., the Cartagena Protocol on Biosafety is available). However, there is a need to adapt the regulations into national laws. Every country needs to establish its own regulations.

Moderator: Maria Zimmermann, FAO.
Rapporteur: Michael Baum, ICARDA.

Group 2: Institutional Arrangements on Biosafety

The major task of Group 2 was to discuss and define minimum requirements for the institutions involved in the "realisation" of safety in biotechnology. Besides those directly involved, the Cartagena Protocol on Biosafety also calls for public participation in the decision process. Consequently, the group discussed minimum requirements for the following issues:

1. National Biosafety Committee (NBC)/Institutional Biosafety Committee (IBC) and competent authorities.
2. Public participation.
3. Labelling.

Another issue, monitoring and surveillance, was found too complex to be dealt with in the given setting. There was also the feeling that the respective capacity and expertise was not sufficiently represented to discuss details. It was thus agreed to save this topic for one of the upcoming workshops.

National Biosafety Committee/Institutional Biosafety Committee

To facilitate the discussion, the group initially discussed some guiding questions, which would lead to fulfilling some criteria. This is of importance since the final organisation has to consider and respect the national organisations and institutions, capacities, facilities and expertise available. The guiding questions are:

- What is the importance of establishing NBC/IBCs?

For this, it is necessary to consider a respective policy document (or an equivalent) to be developed for the country. An easier way is to consult respective international guidelines and suggestions. However, in any case, it is important to define the Terms of Reference of an NBC/IBC with respect to responsibility, tasks and expertise required. It is necessary to clarify what has to be regulated and what is outside the focus, what is the task and what is not the task, and finally, what expertise is needed or can be requested for which purpose and on who's costs.

- How is the legal and political power of the NBC/IBC acquired?

This means, what strategies are defined for enforcing the NBC/IBC decisions and what kind of control mechanism is envisaged. Is there an opportunity to challenge a decision? Are there any fines for non-compliance with the rules and decisions formulated or decided upon by NBC/IBC? This leads to questions four and five: How should communication be organised within the regulatory system, and how should communication with external expertise be?

Both questions should guide in terms of setting up formalised and transparent

structures of information flow. It was agreed by the group that the biosafety structures available in the region could serve as "pioneering" examples and models, that the NBC structure is defined by assigned tasks and there was a general agreement on the need to establish an operational NBC in each country, even if consultations are organised on a regional level.

With respect to the Terms of Reference for an NBC, Group 2 already formulated some details. The major responsibilities are briefly summarised as follows:

The NBC should:

- Serve as a focal point for expertise,
- Be linked to and advise regulatory institutions,
- Be activated or triggered by living modified organisms (LMOs),
- Streamline decisions on LMOs,
- Facilitate a regional approach to gain confidence and expertise,
- Build capacity and exchange information on existing capacity, and
- Develop a roster/database of experts.

In addition, the group considered the need to have national sovereignty to regulate, the need for harmonisation and communication, and the need to link with international structures.

By reflecting on previous experience in and outside the region and capitalising on the expertise available, the group also identified some major tasks for an NBC:

- Carry out a survey on existing capacity.
- Identify expertise (academic, public, private).
- Submit a report with a conclusion for deciding on future directions.
- Review and evaluate proposals/assessments for release/import of food/feed with respect to health/environment/biodiversity.
- Recommend/forward expert opinion.
- Link to institutions with respective expertise (for example, in seed, pesticide and drug registration) without substituting existing regulatory structure.
- Communicate with NBCs and facilitate communication within research institutions (IBC, if appropriate); link to the private sector and with experts on the international level.
- Advise on standards for qualification.
- Advise on frameworks of responsibilities.
- Advise on training for experts in related institutions.

Given the diversity within the region in terms of existing facilities, potential, experience and capacity in biotechnology, it was felt that there is a need to have an instrument for streamlining, coordinating, and speeding up the development. The group strongly suggested requesting ICARDA to be a focal point in disseminating and updating information and to facilitate liaison between Central and West Asia and North Africa (CWANA) countries and the Biosafety Clearing-House.

Finally, the group decided to define some immediate action necessary to gain

and maintain political momentum, and to capitalise on the experience gained from this workshop. It was agreed to report and recommend to the responsible national ministries. The result of this process should be distributed within the region. Furthermore, ICARDA was requested to compile results, prepare proceedings, and inform ministries. It was also discussed that other regional organisations or structures involved in trade, medicine or science in general (for example, ACSAD) could serve as an additional mechanism to support and strengthen a regional approach on biosafety.

In conclusion, there is a consensus to establish NBCs with specific (perhaps varying) tasks to profit from structures and concepts available within the region (e.g., in Egypt and Syria, without compromising national interests and visions) and that it is a national duty to clarify and specify terms of reference and to establish and support an institutional framework. There was also a consensus to request ICARDA's expertise as a moderating instrument and to strengthen political and public awareness as well as scientific expertise in order to speed up the process of establishing and implementing biosafety systems. In the meantime, it was suggested to develop an interim mechanism, for example, to establish ad-hoc committees (on the basis of the Protocol) to take over advisory responsibilities and to establish or work on a biosafety regulatory system.

Public Participation

With respect to public participation, it was agreed that the public had to be involved in the decision-making body (which may or may not be NBC). In addition, public participation and information can also be realised by involving associations (producer, trader, consumer, scientific community, etc.), public persons and opinion leaders, chambers of commerce, farmer unions or local people/communities. However, there is a minimum requirement defined: the public representative/representation has to have a message from the public to the public. The question to be answered is: Who is the "public", how is the public selected, and where does it stand in the process?

It was agreed that a science-based risk assessment process is not a public issue. Consequently, public participation is not operational in this respect; however, transparency is necessary to generate confidence. This does not exclude public involvement in impact assessment or decision-making. However, besides in what aspects the public is involved, another question is of equal importance; how is the public informed? The group found almost no limits to useful and relevant instruments for this purpose: the media, flyers, books, pictures, etc. It was found important to use existing channels, i.e., extension services, schools, universities, networks and different media, such as television, radio, the Internet, newspapers, etc. The minimum

requirement would be to use a "medium" which is efficient in creating awareness and trust and transporting the message.

Labelling

Labelling was the last point to be discussed. The group was unable to see common ground or realise general rules. The major questions were: What has to be labelled since food labelling will be decided by Codex Alimentarius? Should there be labelling on the process, and if there is labelling, what information should be on the label? The group finally suggested that, with respect to food, labelling should focus on the safety of the product. It was also felt that with commodities, labelling is not triggered by a safety issue but by uncertainty. On the other hand, there is the ethical dimension or the "right to know", which contributes to transparency.

Since there is an ongoing process of defining quality and industrial standards, and because there are international standards and perhaps national standards in the exporting or importing country, the group was unable to reach an agreement, and suggested to initially collect information on how labelling is done in other cases in order to visualise the framework within which LMO labelling should be considered.

Moderator: Magdy Madkour, AGERI.
Rapporteur: André de Kathen, BioTechConsult/GTZ.

Group 3: Containment Facilities, Testing, and Result-Sharing

Initially, the group discussed the major objectives and identified the issues. With respect to the topic, the participants wanted to (1) get an indication of what every individual country needs, and (2) exchange ideas and acquire an impression of every country's plans and agenda.

The major concern raised by the participants was that the meeting had shown that there was lack of facilities, technology, expertise and, of course, funds. Furthermore, this was not true only in applying appropriate biotechnology tools in medicine and agriculture, but also with respect to the safe use of biotechnology, including assessment, control, surveillance and certification.

In defining the major bottlenecks mentioned above, the group formulated some guiding key issues that are presented below.

Facilities

In order to identify the actual needs, it was questioned whether each country in the region would need a containment facility. In turn, it was suggested to share facilities or to make use of existing ones beyond national boundaries.

Qualified Personnel

There is no doubt that a need exists for training at different levels. However, it is important to assess the need for training in risk and impact assessment and to identify and contact sources and experts who are able to provide the required training.

Information

There was a strong demand for establishing a regional network so that information could be shared on testing and risk assessment, even beyond the Biosafety Clearing-House. However, within the region, it is important to define and agree upon which information is valuable or confidential and in what form it should be presented.

Funds

With respect to financial support, it was clear that the costs involved could not be provided only by the governments; the private sector has to contribute, notwith-

standing the fact that there is still a need for external help, i.e., by international organisations and donors.

Recommendations

It did not take long for the group to agree on some major recommendations for future activities. Regarding facilities and training, it was stated that, irrespective of future activities, the short-term plan should include recommendations on the use of existing facilities (e.g., those at AGERI) and to make use of training opportunities in the region; for example, to train personnel for 4-6 months at qualified establishments, such as AGERI and ICARDA.

Some recommendations also related to the long-term plan. Realising the need to have individual facilities as requested, it was recommended that any facility that was planned and constructed should be flexible enough to accommodate other activities in the future.

Training people at different levels and developing a network to share results among countries of the region were two additional tasks for the future. With respect to training and harmonising, the focus should be on which testing procedures will be applied and how are results shared between countries.

In order not to take advantage of the momentum created by this meeting and to ensure the continuity of future activities, it was suggested that ICARDA starts immediate steps to establish the network together with AGERI, and then expand it with other countries. However, the participants noted that this activity should not be meant to substitute immediate action on the part of the national systems. It was also decided that, because of the many duties being faced, responsibilities should be divided among the countries.

To ensure sustainability of the activities, mobilising political support is necessary. Therefore, the national participants need to encourage decision-makers to provide support, so that when biosafety regulations are developed, they would be enforced by a sound legislative structure. However, this would also mean convincing officials to allocate more money for capacity building in biosafety, and encouraging the private sector to contribute. Cooperative projects could be one option, but they should not substitute national commitment.

Moderator: John Dodds, Patent Attorney.
Rapporteur: Bassam Al-Safadi, Syrian Atomic Energy Commission.

Conclusions

The second workshop brought together national representatives of ten countries within the WANA region (decision- and policy-makers), involved in the development of national biotechnology and biosafety regulations and policy.

The national presentations demonstrated the dedication and national commitment towards biosafety issues, and the will to support a regional approach. Therefore, the recommendations summarised above, also outline the framework within which a regional biosafety initiative can operate in the future. It is also demonstrating the will for further national commitment.

The following points have been made and may represent the major outcome of this meeting:

- With respect to biotechnology and biosafety, the two most advanced countries in the region, Egypt and Syria, will further provide expertise and share their experience in setting up and implementing biosafety systems.
- Egypt, in particular, may also assist in conducting field trials and providing containment greenhouse facilities, due to the fact that its respective experience and facilities are available and unique in the region.
- It is also understood that this does not substitute national efforts to develop systems and facilities under their own sovereignty.
- The development of policies and legal structures regulating biotechnology within a country is a sovereign right of the country. However, this does not ignore the obligations for the exchange of information under international law.
- In addition, the region intends to improve and strengthen the exchange of information and experience and release of data by setting up an information network. The International Center for Agricultural Research in the Dry Areas (ICARDA) has been asked to serve as a focal point and moderator in this network.

IV

NATIONAL GUIDELINES AND REGULATIONS

Biosafety Guidelines and Regulations for The Syrian Arab Republic (2000)[1]

[1] *This official version was approved April 2001*

The purpose of these guidelines is to ensure that the production and use of genetically modified organisms take place in an appropriate way, in accordance with the principles of sustainable development and without damaging effects on health and environment.

Introduction

The recent advances in biotechnology have made it possible to manipulate the genetic material in ways never feasible before. The new techniques, based on recombinant DNA (r-DNA) technology, known as Genetic Engineering have opened the way to many applications in agriculture, medicine, industry and environment. These new techniques, however, have created a great deal of concern among scientists working in biological areas regarding the safety of such applications to humans and the environment. Many scientists feel that there should be ways to safely carry out the research in the field and also possible means to regulate the work involving pathogenic microorganisms and virulent genes.

With the safety considerations in view, the Atomic Energy Commission of Syria (AECS) is mandated to establish the Recombinant DNA Safety Guidelines. The AECS has set up the Syrian National Biosafety Committee (SNBC) for this purpose. On the basis of current scientific information, and international biosafety guidelines, a document on the recombinant DNA safety guidelines has been brought out on the use of this technique in the area of research and applications.

International documents taken into consideration in formulating these guidelines include:

- The UNIDO Voluntary Code of Conduct for Release of Organisms into the Environment, 1991.
- ISNAR, Biosafety, the safe application of biotechnology in agriculture and the environment, 1993.
- BIOSAFETY, Regulations and Guidelines, Egypt, 1994.
- Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering, China, 1996.
- The Indian Recombinant DNA Safety Guidelines and Regulations, 1989.

- Guidelines on Biosafety for Nigeria, 1994.
- Draft Official Mexican Standard 68-FITO to establish the plant health requirements for interstate movement, importation and conduct of field trials with regard to organisms manipulated by the application of genetic engineering, 1994.
- Philippine Biosafety Guidelines, 1991.
- Guidelines for Handling Genetically Modified Plants, University of Wisconsin-Madison (1999).

Definitions

Animal: Any living stage or form of any member of the animal kingdom. This includes all terrestrial, aquatic and subterranean macroscopic vertebrates and invertebrates, whether parasitic or free-living, and sessile or motile.

Biodiversity: The variability of living organisms, from whatever source, including, among others, terrestrial and marine ecosystems and other aquatic ecosystems, as well as the ecological complexes of which they form part: it includes the diversity within each species, between species and in ecosystems.

Biological control measures: Biological means adopted to restrict the survival, spread and residual of genetic engineered organism and its products outside the experimental area, and to restrict the transfer of genetic materials from the genetic engineered organism to other organisms.

Biosafety: The policies and procedures adapted to ensure the environmentally safe application of biotechnology.

Biotechnology: Any technique that uses a living organisms, in their entirety, or parts or subparts thereof or substances from those organisms to make or modify a product, improve plants or animals or develop microorganisms for specific uses.

Confinement: Measure that restrains or limits the spread or survival of the organisms and their products in research involving planned introduction of organisms into the environment.

Contained facility: A structure, (e.g., a laboratory or greenhouse) which surrounds and encloses the organism to effectively restrict its movement outside the structure.

Control system: The confinement or semi-confinement operation system established through physical and biological controls. Any operation, system not fitting in with the above-mentioned control conditions is called an open system.

DNA: Deoxyribonucleic acid, is the genetic material for genetic information of living things.

Environment: The soil, air or water and all living organisms that are associated therewith or reside therein.

Environmental control measures: Methods which make use of environment conditions to restrict the reproduction of genetic engineered organisms and their products outside the experimental areas, e. g., controlling temperature, moisture, photoperiod, etc.

Environmental release of genetic engineered organisms: Research, production and application of genetic engineered organisms in an open system, including releasing genetic engineered organisms into natural ecological environments, such as cropland, grazing land, forests, mineral deposits and water areas, etc.

Environmental hazards: Hazards that are usually due to an organism which, is exotic to a given location and having a selective advantage allowing an undesirable change in the ecosystem.

Exposure: The amount, frequency, and duration of contact with an environmental agent.

Gene: A functional and structural unit of genetic information, which controls characteristic of living things. It is the DNA fragment with genetic information.

Genetic engineering products: Products of the genetic engineered organisms, its components or products coming from the expression of target gene in genetic engineered organisms.

Genetic engineering: Techniques used in the handling of deoxyribonucleic acid and ribonucleic acid, recombining *in vitro* or under special laboratory conditions.

Genetic material: Any material of plant, animal, microbial or any other origin that contains functional inheritance units.

Genetically Modified Organism (GMO): An organism whose hereditary traits have been modified by human intervention using any method that results in the introduction, rearrangement or removal of genetic material from the genome of an organism.

Genome: The sum total of the chromosomes and all extra chromosomal genetic materials of a specific organism.

Host: Means an organism whose genetic material has been altered by modification of a part of its own genetic material by the insertion of foreign genetic material or both.

Organism: Any biological entity, cellular or noncellular with the capacity for self-perpetuation and response to evolutionary forces.

Parental organism: Refers to the initial organism, which is to be the recipient of introduced genetic material, or whose genome is to be altered by removal or rearrangement of genetic material.

Pathogen: Means any organism that can cause disease.

Pest: Form of plant or animal life or pathogenic agent that is damaging or potentially damaging to plants or harmful to animals.

Physical control measures: Physical means adopted to restrict the survival and

spread of genetic engineered organism and its products outside the experimental areas.

Plant: Any member of the plant kingdom or any of its parts.

Plasmid: A self-replicating, circular, extra-chromosomal DNA molecule, exist in an autonomous state and is transferred independently of chromosomes.

Recipient organism: An organism that receives genetic material from a donor organism.

Recombinant DNA (r-DNA) technology: The technology, which artificially modifies the genetic constitution of the organisms with vector systems, i. e., the technology of recombining heterologous DNA and vector DNA with enzymes *in vitro* and introducing the recombinant DNA molecules into recipient cells with the objective to multiply heterologous DNA and realize its functional expression.

Release into the environment: The use of a manipulated product outside the normal physical confines of a closed area, laboratory, nursery, fermenunit or any other closed structure, under the biosafety conditions established by the NBC.

Risk: The combination of the likelihood that the adverse consequence of a biohazardous activity will occur and the magnitude of such a consequence.

Risk Assessment: Assessment of the risks of introducing r-DNA engineered organism into the environment, to human and natural or managed ecosystem.

Risk Management: The measures designated to ensure safety in the handling, use and release of GMOs.

Target gene: The gene for the modification of genetic constitution of recipient cells, and for the expression of genetic information of recipient cells.

Transformation: The introduction of one or more genes conferring potentially useful traits into plants, livestock, fish and tree species.

Transgenic material: Artificially modified genotypes, which, owing to their tendency to multiply and remain in the environment, are capable of transferring recombining genes to another organism.

Vector: Organism, material or object used to transfer genetic material from the donor organism to the recipient organism.

Abbreviations Used in the Document

BSO:	Biosafety Officer.
IBC:	Institute Biosafety Committee
ISNAR:	International Service for National Agricultural Research.
PI:	Principal Investigator.
SMAAR:	Syrian Ministry of Agriculture and Agrarian Reform.
SNBC:	Syrian National Biosafety Committee.
UNIDO:	United Nations Industrial Development Organizations.

The Syrian National Biosafety Committee

The Syrian National Biosafety Committee has been established by the decree 612/99 dated 30/5/1999 of the Atomic Energy Commission of Syria with the approval of the prime ministry number 1953/337 dated 31/3/1999. Members of the SNBC represent:

1. Atomic Energy Commission of Syria.
2. Scientific Studies and Research Center.
3. Colleges of Medicine.
4. Colleges of Agriculture
5. Colleges of Biology.
6. Colleges of Pharmacology.
7. Ministry of Agriculture.
8. Ministry of Health.
9. Ministry of Environment.
10. Ministry of Supply and Internal Trade.
11. Directorate of Military Medical Services.

Objectives

1. Establish biosafety regulations for genetic engineering research in the Syrian Arab Republic.
2. Collect and disseminate updated biosafety information to the designated agencies.
3. Provide consultation to designated agencies regarding biosafety issues.
4. Assess the risk of releasing genetically modified organisms or their products (foods, medicines, vacines, etc) into the environment and advise on whether they should or shouldn't be released.

Principal Investigator

The National Biosafety Committee must designate one or more principal investigators (PI) whose duties include:

1. Inspect to determine whether institute facilities, involved in genetic engineering work, adhere to the local regulations and guidelines of the SNBC and report to the SNBC to decide whether a permit will be issued or denied.
2. Instruct and advise staff in practices and techniques to assure levels of safety concern.

Institutional Biosafety Committee

All institutions (national and international) conducting R-DNA research in the Syrian Arab Republic must form an Institutional Biosafety Committee (IBC). The IBC would include experts in the r-DNA technology, and experts in biological safety and physical containment. Members of an IBC should not be involved in review or approval of their own project proposal(s) or commercial applications

Responsibilities of Institutional Biosafety Committee

1. Consult with and seek approvals from the SNBC.
2. Implement the recommendations of the SNBC.
3. Establish and implement policies that provide safe conduct of biotechnology research and ensure compliance with applicable guidelines.
4. Review and endorse applications from researchers.
5. Maintain a central reference file and library of related documents as a source of advice and reference.
6. Develop a safety and operations manual and assist researchers in the required staff training.
7. Certify the safety of facilities, procedures, and practices and that the level of training and expertise of the personnel involved have been reviewed and approved.
8. Establish a program of inspections to ensure that the physical containment facilities and field trials continue to meet requirements and that other procedures and practices specified in the guidelines are followed.
9. Maintain a list of researchers, project supervisors, and other supervisors approved by the IBC as competent to perform supervisory duties for particular projects.
10. Maintain individual records and files of individual research projects.
11. Investigate and report promptly to the SNBC all accidents and unexplained absences and illness.
12. Provide an annual report to the SNBC.
13. Undertake the assessment and review of all planned release proposals to identify potential hazards to human health and to the environment and to advise the project leader on their proper management.
14. Review the qualifications and experience of personnel involved in potentially bio-hazardous projects.
15. Take necessary steps to inform the public of the proposed planned release and provide the public with the opportunity to comment if possible.
16. Submit to the SNBC all required project documents for review and approval.

17. Ensure that all communications from the SNBC are conveyed to and, if applicable, compiled with by the project leader.
18. Ensure that all relevant regulatory agencies have been consulted and necessary permits, licenses or approvals have been obtained before any planned release is made.
19. Visit the release site periodically to monitor and evaluate the biosafety of ongoing projects and recommend additional safety measures, if necessary.
20. Notify immediately the SNBC of any accidents or incidents arising from or related to the planned release activity.
21. Submit a terminal report to SNBC at the end of the planned release project.
22. Appointment of Biosafety Officer.

Biosafety Officer

Every institute should appoint a Biosafety Officer (a member of the IBC). The BSO should be familiar with the biosafety requirements for the r-DNA work and the facilities and be able to make checks and advise on biosafety issues on day-to-day basis. Duties of the BSO include:

1. Ensure that policies and regulations approved by the SNBC are not compromised by other considerations.
2. Ensure through periodic inspections that laboratory standards are strictly followed.
3. Advise on safety of laboratory work to prevent accidental escape of GMO's.
4. Maintain a database on all aspects of biosafety related to mandate crops.
5. Check and give advice on biosafety issues on a day-to-day basis.
6. Monitor worldwide biosafety requirements for r-DNA and report to the IBC all related issues.

Insitutional Biosafety Committees of Small Institutions

The SNBC recognizes the difficulty that small institutions may have in setting up a competent IBC due to the limited number of scientists who can serve in the IBC. Hence, subject to the prior approval of the SNBC, potentially biohazardous activities of these institutions may be supervised by the IBC from another institution. However, this arrangement which shall be in writing, must specify, among others, the following:

1. That the heads of both institutions shall be jointly responsible in ensuring compliance with these guidelines.

2. That a senior member of the supervised institution shall liaise closely with the supervising IBC throughout the conduct of the proposed activity.

Responsibilities of the researcher

The researcher as an agent of an institution, is responsible for conducting r-DNA research in a safe manner and in compliance with the appropriate research guidelines and all applicable regulations. The responsibilities of the researcher include:

1. Obtain approval from the IBC before initiating or modifying a biotechnology research project. The researcher should remain in contact with the IBC as the research progresses. In submitting research proposals, the researcher should:
   a. Make the initial determination of the required confinement level in line with the relevant guidelines or regulations.
   b. Select the appropriate practices and techniques to be used in the research.
   c. Submit the initial research protocol and subsequent changes to the IBC for review.
   d. Take into account, in connection with environmental introduction of GMOs, the following:
      - Characteristics of the organism(s) used, including the introduced gene, genetic materials, and gene products.
      - Characteristics of the site and the surrounding environment.
      - Appropriate conditions of the release, including confinement, control, mitigation, and disposal procedures as appropriate.
2. Ensure that experiments, for which the researcher is responsible, are covered by institutional and national guidelines.
3. Evaluate potential risks at appropriate stages of research and development of an organism, prior to its formal review or assessment.
4. Notify and obtain approval from the NBC through the IBC, prior to the conduct of an activity involving the release of GMOs.
5. Instruct and train staff in the practices and techniques to maximize safety and in procedures for dealing with accidents.
6. Provide prompt reports to the IBC on any significant problems with implementation of relevant guidelines and regulations.
7. Provide reports to the IBC on any research-related accidents that have resulted or could result in human illness, in unanticipated plant or animal disease, or in the escape of organisms under study from the intended confinement.
8. Comply with applicable shipping requirements regarding human, plant, and animal health protection and policies, permit requirements, and containment conditions for possession of certain organisms.
9. The researcher should consider, in connection with field-testing of GMOs the following:

- Identification and taxonomy of the target organism, the anticipated mechanism of action of the modified organism on the target organism, and results of the interaction between the released organism and the target organism (if the modified organism has a target organism).
- Survival, replication, and dissemination characteristics of the modified organisms by wind, water, soil, mobile organisms, etc., and methods of application.
- Methods of detection and limits or sensitivity of sampling techniques, periodicity of sampling, and types of data to be obtained.
- Physical, biological, and other confinement incorporated in the experiments.
- Monitoring procedure, transportation of biological materials, and termination plans for the field test.
- Site characteristics and design, including diagrams of the experimental location and the immediate surroundings.
- Access restrictions and security measures for the area(s) in which the tests will be performed.
- Contingency plans for emergency termination.

Once a project involving r-DNA research has been reviewed and approved by the IBC, the project should be monitored periodically by IBC.

Risk Assessment

General considerations:

In assessing the risks involved in r-DNA technology, the following should be considered:

1. Safety assessment of a GMO should be based on the nature of the GMO and the environment into which it will be released rather than the method by which it was modified
2. Experience gained by other countries regarding risk and safety assessments of GMOs, can help in determining the degree of confinement or containment.
3. Types of risks to be assessed on GMOs, for example, in agricultural biotechnology, include:
   a. Possible toxicity and/or allergenicity of plants and plant materials to humans.
   b. Potential for the plants to become weeds.
   c. Potential for gene transfer from transgenic plants to weeds.
   d. Potential for evolution of pests resistant to genetically modified crops (Bt plants).
   e. Potential pathogenicity of microorganisms.
   f. Potential for animals to become pests.
   g. Potential for environmental hazards.
   h. Potential for harmful effects to biodiversity.

4. When field-testing of GMO's, risks can be minimized or eliminated by good confinement of the organisms when introduced to the target environment
5. Familiar does not necessarily mean "safe". Rather, to be familiar with the elements of an introduction means to have enough information to be able to judge its safety or risk.

The familiarity criterion is central to the suggested evaluation framework. It permits decision makers to draw on past experience in introducing plants and microorganisms into the environment, and it provides for flexibility. As field tests are performed, information will continue to accumulate about the organisms, their phenotypic expression, and their interactions with the environment. Eventually, the entire class of introductions may become familiar enough to require minimal oversight.

When knowledge of the type of modification, the species being modified, or the target environment is insufficient to meet the familiarity criterion, the proposed introduction must be evaluated according to whether the organism can be confined or controlled, as well as the potential effects of a failure to confine or control it, which define the relative safety or risk of the introduction.

6. Level of risk: In evaluating the potential risks associated with GMOs and new technologies, the appropriate questions are:
   a. What are the relative risks of the new technologies compared with the risks of the existing technologies?
   b. What are the potential risks of over regulation or failing to fully develop new technologies?
   c. How are risk determinations incorporated in cost and benefit evaluations?

The aim is not necessarily to achieve zero risk. Concerns over potential risks of introducing GMOs should not lead to very strict and expensive regulations which can hinder development of new technologies that can lead to beneficial organisms and products.

Safety classes

When considering potential risks associated with genetic engineering work, safety can be divided into four classes:

Safety class I: Genetic engineering work of this class has no threat to human health or ecological environment.

Safety class II: Genetic engineering work of this class has low-level risk to human health and ecological environment,

Safety class III: Genetic engineering work of this class has intermediate-level risk to human health and ecological environment.

Safety class IV: Genetic engineering work of this class has high-level risk to human health and ecological environment.

The following procedures should be followed in safety evaluation and safety class determination of genetically engineered organisms:

I. Safety class determination of recipient organism:

1. Recipient organism which accords with one or more than one conditions listed below will be classified as Safety Class I:
   a. Recipient organism which has never occurred unfavorable impact on human health and ecological environment.
   b. Recipient organism which has little possibility of evolving into harmful organism;
   c. Recipient organism which, due to the short life cycle, has extremely little possibility of survival in natural environment after the completion of the experiment.
2. Recipient organisms of Safety Class II refer to those, which produce low-level risk to human health and ecological environment, but their risk can be completely avoided by adopting safety control measures.
3. Recipient organisms of Safety Class III refer to those which produce intermediate-level risk, to human health and ecological environment, but their risk can be fundamentally avoided by adopting safety control measures.
4. Recipient organisms of Safety Class IV refer to those, which produce high-level risk to human health and ecological environment, and there is no appropriate safety measure to avoid the occurrence of such risk outside confined facilities. For example:
   a. Harmful organism which may exchange their genetic material with other organisms with high frequency.
   b. There is no effective technique to prevent the escape and spread of the harmful organism or its product.
   c. There is no effective technique to guarantee that the harmful organism, after its escape, can be captured or eliminated before it produces unfavorable impact on human health and ecological environment.

II. Determination of the impact of genetic manipulation on safety class

The main basis for the evaluation of the impact of genetic manipulation on safety class include : The direct and indirect impact of genetically engineered organism and its products on human health and ecological environment, as well as its impact

produced via the occurrence of genetic information exchange with other organisms. People involved in genetic engineering work must make precise evaluation on genetic manipulation, including gene transfer methods, characteristics of vectors, and the source, function, expression and stability of genes, etc. The impact of genetic manipulation on the safety of recipient organism is divided into three types, i.e., improving the safety of recipient organism, having no impact on the safety of recipient organism, and reducing the safety of recipient organism.

Type 1: Genetic manipulations which improve the safety of recipient organism include: Deleting certain gene (s) or inhibiting the expression of these genes, such as pathogenic genes, fertility genes, adaptability genes, etc.

Type 2: Genetic manipulations, which have no effect on the safety of recipient organisms include:

- Genetic manipulation in which the changes of the recipient organism's phenotype or genotype have no impact on human health and ecological environment, such as certain marker genes with no risks.
- Genetic manipulation in which the changes of the genetic trait of the known or expectable recipient organism have no unfavorable effect on human health and ecological environment, such as the storage protein gene for improving nutrition values.

Type 3: Genetic manipulations, which reduce the safety of recipient organisms, include:

- Genetic manipulations which cause the occurrence of known or expectable genetic changes of recipient organisms and produce additional unfavorable impact on human health and ecological environment. Such as gene introduction which can produce harmful toxins.
- Genetic manipulations which affect gene expression, have inadequate knowledge of its outcomes, and have uncertainty of whether or not the risk of the final genetically engineered organism is greater than that of the recipient organism.

III. Determination of the safety class of genetically engineered organisms

The safety class of genetically engineered organisms is determined on the basis of the safety class of the recipient organism as well as the impact type and impact level of the genetic manipulation on the recipient organisms.

1. Genetically engineered organism from recipient organism of safety Class I

The genetically engineered organism obtained from recipient organism of Safety Class I via Type I or Type 2 genetic manipulations still belongs to Safety Class I.

The genetically engineered organism obtained from recipient organism of Safety Class I via Type 3 genetic manipulation still belongs to Safety Class I only if the safety reduction is very small and there is no need to adopt any safety control measures. If the safety has certain degree of reduction but its potential risk can be avoided through appropriate safety control measures, the safety class should be deter-

mined as Safety Class II. If the safety has been seriously reduced but its potential risk can be avoided through strict safety control measures, the safety class should be determined as Safety Class III. If the safety has been seriously reduced and its potential risk can not be completely avoided through safety control measures, the safety class should be determined as Safety Class IV.

2. Genetically engineered organism from recipient organism of Safety Class II

The genetically engineered organism obtained from recipient organism of Safety Class II via Type 1 genetic manipulations belongs to Safety Class I, if the safety has increased to the extent that it no longer has any unfavorable impact on human health and ecological environment. If the safety level has been increased but it still has low-level risk on human health and ecological environment, the genetically engineered organism obtained from recipient organism of Safety Class II via Type 1 genetic manipulation belongs to Safety Class II.

The genetically engineered organism obtained from recipient organism of Safety Class II via Type 2 genetic manipulations belongs to Safety Class II.

The genetically engineered organism obtained from recipient organism of Safety Class II via Type 3 genetic manipulations belongs to Safety Classes II, III or IV on the basis of the extent of safety decrease, with the same classification standard as that of the recipient organisms.

3. Genetically engineered organism from recipient organism of Safety Class III

The genetically engineered organism obtained from recipient organism of Safety Class III via Type 1 genetic manipulations belongs to Safety Classes I, II and III on the basis of the extent of safety increase, with the same classification standard as that of the recipient organisms.

The genetically engineered organism obtained from recipient organism of Safety Class III via Type 2 genetic manipulations belongs to Safety Class III

The genetically engineered organism obtained from recipient organism of Safety Class III via Type 3 genetic manipulations belongs to Safety Classes III or IV on the basis of the extent of safety decrease, with the same classification standard as that of the recipient organisms.

4. Genetically engineered organism from recipient organism of Safety Class IV

The genetic engineered organism obtained from recipient organism of Safety Class IV via Type I genetic manipulations belongs to Safety Classes I, II, III or IV on the basis of the extent of safety increase, with the same classification standard as that of the recipient organisms.

The genetically engineered organism obtained from recipient organism of Safety Class IV via Types 2 or 3 genetic manipulations belongs to Safety Class IV.

Before conducting relevant experimental researches, pilot experiment environment release and industrial production, institutions carrying out genetic engineering work

should determine the safety class and work out corresponding safety control measures on the basis of the safety evaluation of the genetically engineered organism and its products.

Biosafety Guidelines

Biosafety guidelines have been developed on the basis of common elements and principles derived from national and international regulations and guidelines. They are designed to ensure that the products of biotechnology will not have adverse effects on the environment and agriculture, and to protect the surrounding communities as well as employees and researchers involved in the use of such products from the research stage till commercialization.

Biosafety Guidelines for Laboratories

In general, the basics of Good Laboratory Practices (GLP) in microbiology laboratory should apply to all concerned laboratories.

1. Laboratory personnel must receive instructions on the procedures conducted in the laboratory.
2. Never do direct mouth-pipetting of infectious or toxic fluids; use a pipettor.
3. Do not blow infectious material out of pipettes.
4. Do not prepare mixtures of infectious material by bubbling expiratory air through the liquid with a pipette.
5. Avoid using syringes whenever possible.
6. Sterilize discarded pipettes and syringes in pan where they were first placed after use.
7. Before centrifuging, inspect tubes for cracks.
8. Use centrifuge cups with screw caps or equivalent.
9. Avoid decanting centrifuge tubes; if you must do so, afterwards wipe off the outer rim with a disinfectant. Avoid filling the tube to the point that the rim ever becomes wet with culture.
10. Sterilize all contaminated discarded material.
11. Working surfaces must be decontaminated using soap and alcohol after each working day.
12. Develop the habit of keeping your hands away from your mouth, nose, eyes and face. This may prevent self-inoculation.
13. Hand wash is obligatory when contamination is suspected, after handling viable materials, and also before leaving the laboratory (at least one hand wash sink should be available).
14. Avoid smoking, eating, chewing, drinking, storing of food and applying cosmetics in the laboratory.

15. Make special precautionary arrangements for respira, oral, intranasal, and intratracheal inoculation of infectious material
16. Laboratory coats are obligatory and should be removed when exiting the lab.
17. Wear only clean laboratory clothing in the dining room, library and other non-laboratory areas.
18. Waste products must be decontaminated by incineration or by autoclaving.
19. Avoid contact with GMO's and other exotic biological agents. Disposable gloves should be worn when handling such items.
20. Laboratory door should be closed at all times.
21. Working with fume-producing chemicals must be under the laboratory hood.
22. Biohazard warning signs should be always posted in labs.
23. Materials for autoclaving or incineration must be transported without spillage in robust, leak-proof containers.
24. Effective disinfectants must be available for routine disinfection and for immediate use in the event of spoilage.
25. To ensure safety in laboratories, a person must be appointed in every laboratory to make sure that Good Laboratory practices are strictly followed.

Biosafety Guidelines for Glasshouse Containment

Biological containment involves the use of the combination of vector and host in such a way so that it

a. can limit the infection of vector to specific hosts.
b. control host vector survival in the environment

The growth of whole plants will, however, require special environmental conditions, which may be achieved by using glasshouse containment.

a. Glasshouse containment A: is appropriate for plant experiments involving no plant pathogen and would be suitable for experiments involving non-pathogen DNA vector systems and regeneration from single cells.
b. Glasshouse containment B: is recommended for experiments involving:
   - Genetically manipulated plant pathogens including plant viruses such as the propagation of genetically manipulated organisms in plant.
   - The growth of plants regenerated from cells transformed by genetically manipulated pathogen vector systems, which still contain the pathogen.

Strict guidelines should be followed in containment glasshouses. These guidelines include:

1. All containment glasshouses must be clearly marked with a biohazard sign.
2. Inspection by IBC will be required before approval.
3. Plants should be grown in a designated glasshouse or compartment.
4. Plants should be managed by suitably trained personnel with the principles of

good glasshouse hygiene.

5. The IBC should consider whether any additional factors such as pest control, screening to prevent ingress by vermin, birds and insects and destruction of surplus plants and seed are relevant to the particular experiment.
6. Special conditions may be needed to prevent dissemination of the genetically manipulated plant pathogen especially during transfer between glasshouse and laboratory, during disposal of plants and equipment and through survival of pollen, seeds or other biological vectors.
7. Need for negative pressure and air filtration, double doors etc. in cases where airborne dispersal is a potential hazard.
8. Need for effluent treatment plant where water borne or soil-borne dispersal is potential hazards.
9. Need to prevent pollination and seeding, or to contain pollen and seed in cases where pollen and seed-borne dispersal is a potential hazard.
10. Need for measures either to prevent contamination of, or to decontaminate the clothing of personnel or tools, pots, equipment etc., where mechanical transmissions is an above average hazard.
11. Need to limit the growth of host plants in the vicinity of the containment facility and to provide monitoring for escape.
12. Greenhouse should be locked at all times.
13. Non-living plant material, parts, or viable exotic biological agents should be removed from the greenhouse except for:
    a. Disposal, were it has to be autoclaved before its disposal.
    b. Storage in other facilities, in this case it should undergo adequate containment before transport.
14. The outgoing water must be chemically treated before its drainage
15. Coats should be worn at all times in the greenhouse, and autoclaved before removal from the greenhouse for any reason.
16. Hand washing is required upon entering and exiting the greenhouse.
17. A disinfecting pad embedded with a decontaminating substance must be located at the greenhouse entrance.
18. Daily record all experiments carried out in the greenhouse.

Biosafety Guidelines for Field Trials (Small-Scale Field Testing)

1. Field experiments with exotic plant pest and pathogens are prohibited.
2. For initial testing, plants must be prevented from spreading pollen by the removal of flowers until shown it is not necessary.

3. If flowers are needed for testing and further experimentation, the inflorescence flowers must be covered before maturation.
4. Suitable plot isolation must be provided to avoid pollen transmission to other near plots.
5. Entry of plots by unauthorized personnel is prohibited.
6. Special protective measures should be taken to ensure complete isolation of harvested plant parts.
7. Plots must be protected from the entry of animals or insects as necessary.

Release into the Environment

No person or institution shall release into the environment any GMO without the prior approval of the Syrian National Biosafety Committee (SNBC). However, approval by the SNBC does not in any way exempt the project proponent from complying with any rules, regulations or requirements of other government regulatory authorities. It is the sole responsibility of the project proponent to determine if the proposed genetic engineering work and /or planned release requires any permit, license or approval of such regulatory authorities, and to obtain the same if required. A plant health certificate, issued by the Syrian Ministry of Agriculture and Agrarian Reform (SMAAR), is required for the release into the environment and/or importation of transgenic products into the Syrian Arab Republic. Ministry of Environment must be informed of all planned releases of GMOs. The Syrian National Biosafety Committee (SNBC) must be notified of any country-wide movement.

I. Regarding the release of a transgenic product into the environment

- Anyone wishing to release a transgenic product must submit an application, in the appropriate format, to SMAAR, in one original and two copies. The proponent must answer all questions. The SMAAR shall respond within 60 calendar days, provided the information required in the application is complete.
- The SMAAR shall issue certificates for the environmental release of products manipulated using genetic engineering after a prior favorable opinion of the SNBC. SMAAR shall submit the application to the SNBC for review. A copy of the application and of the SNBC's opinion shall be sent to SMAAR within 30 calendar days.
- If the product has been moved and/or imported prior to the application for release into the environment, a copy of the relevant import and/or movement certificate must be attached.
- The applicant shall produce a letter of undertaking in which he assumes responsibility for the handling or destruction of the product in such a way as to prevent its escape into the environment, on completion of the trials, as well as a statement

that this has been carried out.
- The transgenic product released, moved and/or imported must be kept in the areas and premises set out in the application.
- When the transgenic product is released, moved and/or imported, it must be identified with a label giving the information indicated in section III.
- The individual or legal entity to whom the plant health release certificate is issued must send to the SNBC periodic reports and a final report on the behavioral characteristics of the transgenic product, as set out in the certificate.
- The SNBC must be notified in the following cases:
  In the event of accidental release of the transgenic product (notification within 24 hours).
  If the manipulated product or the associated host organism differs substantially from the characteristics set out in the application, if it shows signs of disease or if there are indications of mortality or any unforeseen effect in organisms for which it is not intended; written notification must be made within five days.
- At any time, the personnel authorized by the SNBC may inspect the place where the manipulated products are to be released into the environment, the closed areas before and after movement and the records relating to the product in question. The costs incurred in the checking procedure, by one or more members of the SNBC, shall be borne by the applicant.

II. Regarding plant/animal health import certificate for transgenic products and notification of movement:

1. The Directorate of Agriculture Quarantine at Ports, Airports, and Border Crossings shall issue a plant/animal health import certificate for transgenic products, in respect whereof the party concerned must submit the following documents to the customs office at the point of entry into the country and comply with the information set out thereon:
   a. Approval of SMAAR for the importation of transgenic products.
   b. The original of the document on plant/animal health requirements and biosafety measures for the importation of transgenic products.
   c. An international plant/animal health certificate from the country of origin.
2. The SMAAR shall be responsible for issuing the plant/animal health requirements and biosafety measures for the importation of transgenic products. The application shall be processed in the same way as an application for release into the environment.
3. In respect of the country movement of a transgenic product, the party concerned must notify the SMAAR accordingly. The SMAAR shall officially inform the party concerned whether the movement may be made within the deadline and according to the procedure set out for imports.
4. If the objective is solely and exclusively the import and/or movement of the

transgenic material, the application must contain the information indicated in II. The application must be sent to the SMAAR in the appropriate format, in an original and two copies. SMAAR shall respond within 45 calendar days, provided that the information required in the application is complete. If this is not the case, the party concerned shall be asked to provide the missing information and the 45 day period shall begin when the application is complete. A period of 30 calendar days shall be allowed for submission of the missing information. If the information is not provided in the time indicated, the application shall be cancelled.

5. The packing material, containers and any other material accompanying the transgenic product when it is imported or moved must be handled in such a way as to prevent the dissemination.
6. The individual or legal entity to whom the certificate for the importation of the transgenic product has been issued must inform the SMAAR of the date of arrival of the product at its final destination or if, for any reason, it did not arrive.
7. The transgenic products must comply with the plant health import requirements established in the official Syrian standards on plant quarantine, depending on the agricultural product (fruit, vegetables, seeds, propagational material and cut flowers) to be imported.

III. Regarding marking and identification

Any manipulated product that is to be moved, imported and/or released must have the following information clearly and correctly affixed to the container or package, on a label that must be visible externally.

1. General nature and quantity of the contents.
2. Country and/or place where the product was collected, developed, manufactured, cultivated or reproduced.
3. Name and address (including telephone and fax numbers) of the carrier and of the sender.
4. Name, address (including telephone and fax numbers) of the consignee.
5. Number of the plant health certificate for release and/or import.
6. Production date, validity, and lot number.

Inspection and Monitoring

1. The holder of a certificate for movement, importation or release into the environment and the owner, lessee, or manager in whatever capacity, of crops or installations used for testing products manipulated by genetic engineering shall be obliged to allow the inspection of their land or installations and to cooperate with and provide all facilities to plant health inspectors, and also to inform or

warn the personnel of the SNBC of any suspected irregularity in certificates for movement, import or release into the environment.
2. In the exercise of its functions, the SNBC may require the assistance of other offices or agencies, in the official and private sectors, in the application of these regulations.
3. The SNBC shall apply the plant health measures indicated in this official document.

Penalties

Any private institution or individual involved, in any way, in the process of importation, movement and release into the environment, or in the evaluation of manipulated products, who fails to comply with the provisions set out in this document shall be punished in accordance with the provisions of the Syrian Agriculture Quarantine Law 237 dated 1960 and the decree 91 of the Syrian Ministry of Agriculture dated 1991 and the Syrian Law 158 (prevention of fraud and cheating) dated 1960 and their future modifications on the basis of the inspection reports and the findings of the monitoring units and certification bodies which shall be submitted, as applicable, to the office responsible for supervising compliance with the regulations.

Biosafety Regulations in Turkey: Legislation in Force

Directive on the Principles of Field Trials of Genetically Modified Plants (GMPs) Ministry of Agriculture and Rural Affairs

Turkey
Became effective on 14 May 1998

Objective

Establish the rules for procedures and principles of application, and address authorities and principles for undertaking field trials of genetically modified plants (GMPs) intended for agricultural production.

Scope

The directives apply to all genetically modified plants, whether imported or locally developed.

Definitions

Genetically modified plant (GMP): A plant whose genetic material has been altered by using biotechnology.

Field trials: A set of laboratory, greenhouse, and field testing stages of GMPs to ensure stability of their novel traits and to identify their effects on the environment under controlled conditions at specific locations for specific uses by competent experts within specific sessions and for specific periods of time.

The authority: The national competent authority is the Ministry of Agriculture and Rural Affairs (MARA).

Thematic authorities:
- General Directorate for Development of Agricultural Production (GDDAP).
- General Directorate of Agricultural Research (GDAR).
- General Directorate of Protection and Control (GDPC).
- Seed Registration and Certification Centre (SRCC).

Authority to implement field trials: Agricultural research institutions whose proficiency to undertake field trials was approved by GDAR.

Procedure of Application to Undertake Field Trials of GMP

1. Place of Application: GDAR

Authority to evaluate eligibility of application: The Commission is composed of representatives of GDDAP, who issue import permits of agricultural products, plants and livestock animals.

GDAR undertakes agricultural research through institution competent to plan, issue and implement the field trials and conduct risk assessment.

GDPC is responsible for food safety and health certificates of imported or marketed plants and animals.

2. Deadline for Application: At the latest, 12 weeks prior to the intended field trial.

3. Requested Documentation:

The application form should include information about the name of the plant and its intended use; the purpose, number and location of the field trials; and the definition of the novel trait of the plant.

A document indicating the registration of the GMP in the exporting country and OECD's registration list should be included. A document should also be included that indicates that the GMP is subject to production for the purpose of marketing among countries having regulations on GMP, particularly in the country where the GMP is registered.

Documentation should be included on risk assessment and scientific reports and data focusing on the effects of the GMP on the environment, and on human and animal health, including possible interactions of the GMP with the natural flora and fauna.

Specific Information

Detailed information should be submitted on the characteristics of the parental/donor/recipient organisms and the GMP, including the mode of transmis-

sion of the genetic material, tendency for degeneration and invasion, and frequency of pollination between the same species and relatives.

Detailed information should also be provided on the modified genetic material and the methods used for the purpose of modification, including genetic map and expression of novel trait(s), vectors, markers and other sequences used for modification.

Information should also be supplied by the applicant on familiarity with the GMP, previous trials, nature of novel trait(s), stability of genetic material, unintended novel traits of the GMP, food safety assessment data, and scientific information and estimation of the effects of the GMP in the case of inclusion in nutrition cycles.

Pre-conditions Necessary for Acceptance of the Field Trial Application

1. The GMP should be registered in its origin country for at least three years before the time of application for field trials.
2. The GMP should be subjected to production for the purpose of marketing among countries having regulation on GMPs, particularly in the country where the GMP is registered.
3. Risk assessment and scientific reports and data focusing on the effects of the GMP on the environment, and on human and animal health, including possible interactions of the GMP with natural flora and fauna, should be available.

Decision

The Commission takes a decision to permit the field trial of the GMP based on:

- Scientific data and information.
- Possible effects of the GMP on biodiversity.
- Risk of gene escape.
- Documents and information provided by the applicant.

If the Commission permits the application of the field trial, GDAR mandates an appropriate research institute to undertake it.

Implementation of the Field Trials

1. The plan for the trial is prepared by the mandated research institute on a case-by-case basis.

2. The Commission evaluates the trial plan on a multidisciplinary basis.
3. If the plan is approved by the Commission, the research institute implements it.
4. All expenditures of the trial are borne by the applicant.
5. The implementation of the plan is controlled by the Commission during and after the field trial.

The implementation plan must include detailed information on:

1. Location and designation of the area (spatial isolation, buffer zone, labelling in the area).
2. Biodiversity of the area in and around the designation.
3. Conditions of contained use (measures and methods of isolation: isolation distances and destruction zones).
4. Amount of seed to be used.
5. Use of pesticide.
6. Emergency measures.
7. Method of harvesting.
8. Method of destroying the trial (whole plant materials).
9. Uses of the area after the trial is completed (post-harvest land use).
10 Monitoring.
11. Public awareness procedure (signboards).

Legislation and Framework Under Preparation

Safety Regulations on Biotechnology

The High Council of Science and Technology (Turkish Council of Scientific and Technical Research, TUBTAK) establishes the rules and conditions for laboratory and greenhouse testing for biotechnological research and development of GMOs and products thereof through separate working groups on Safety of Biotechnological Studies on Plant, Animal, Human and Microorganism.

Principles of Use, Handling, Release, and Marketing of Genetically Modified Organisms and Products Thereof

1. GMOs or products thereof must be registered in accordance with the regulations.
2. Requirements for use, handling and release must be determined in accordance with the results of risk assessment and field trial on a case-by-case basis.

3. The qualifications of the personnel who will release the GMOs into the environment must be determined.
4. A notification procedure is required.
5. Conditions of marketing (e.g., packaging) must be set up in accordance with the intended use.
6. All related institutions take the necessary legal and administrative measures regarding the safe development, handling, transfer, and use of GMOs. An example is the Regulation of *In-Situ* Conservation of Biological Diversity.

Regional and National Needs for the Safe Development, Use, Transfer, and Handling of GMOs

To ensure safety, the following is necessary:

1. Safety of the biotechnology method used for modification.
2. Safety of vectors, markers, and other genetic material used.
3. Safety of recipient/donor/parental organism.
4. Assessment of novel traits of the organism, both intended and unintended, depends on laboratory assessment.
5. Assessment of environmental effects depends on field trials.
6. Consideration of intended use and unintended uses.

Needs for Meeting Safety

1. **National and regional specialised biotechnology units for safety assessment**
   Transparency.
   Expertise.
   Cooperation.
   Country representation.

2. **Information exchange mechanism**
   Regional Coordination Committee.
   Establishment of network through national focal points.

3. **Capacity-building**
   Participation in biotechnology activities.
   Informing decision-makers of other sectors and institutions about risks arising from GMOs and products thereof, particularly in international platforms.

4. Registration and labelling of GMOs and products thereof
   Regional mechanism for registration.
   Cooperation against illegal trafficking.

5. **Public awareness**
   Journals to inform the public on the safe use of GMOs and products thereof.

Field Trials of Genetically Modified Plants Carried out in 1998

- Transgenic potatoes: two insect-protected varieties, resistant to the Colorado potato beetle (*Leptinotarsa decemlineata* SAY)
  One variety resistant to both Colorado potato beetle and potato virus Y.; two locations: Dinar/Afyon and Niðde, under the control of the Potato Research Institute.
- Transgenic maize: one insect-protected variety, resistant to the European corn borer (*Ostrinia nubýialis*) and the pink stock borer (*Sesamia cretica*), one location–Adana, under the control of Çukurova Agricultural Research Institute.
- Transgenic cotton: two herbicide-resistant varieties; two insect-protected varieties, resistant to *Heliothis* spp. and *Pectinophora* spp.; two locations: Antalya, under the control of the Mediterranean Agricultural Research Institute, and Akçakale/Þanliurfa, under the control of Harran Agricultural Research Institute.

Field Trials of Genetically Modified Plants Carried out in 1999

Besides the previous year's tested transgenic varieties, the varieties given below were tested in 1999.

- **Transgenic maize:** Five insect-protected varieties resistant to the European corn borer (*Ostrinia nubýialis*) and the pink stock borer (*Sesamia cretica*); one location: Adana, under the control of Cukurova Agricultural Research Institute and Adana Plant Protection Research Institute.
- **Transgenic cotton:** One insect-protected variety, resistant to *Heliothis* spp. and *Pectinophora* spp.; one herbicide-resistant variety; one variety both herbicide-resistant and insect-protected (resistant to *Heliothis* spp. and *Pectinophora* spp.); three locations: Adana, under the control of Çukurova Agricultural Research Institute and Adana Plant Protection Research Institute; Akçakale/Anliurfa, under

the control of Harran Agricultural Research Institute and Diyarbakr Plant Protection Research Institute; and Nazilli/Aydin, under the control of the Cotton Research Institute and Bornova Plant Protection Research Institute.

- **Transgenic potatoes:** One insect-protected variety, resistant to the Colorado potato beetle (*Leptinotarsa decemlineata* SAY); one location: NE, under the control of the Potato Research Institute and Ankara Plant Protection Research Institute.

The second year field trials, including risk assessment for these GMP varieties (except for the transgenic potatoes), have been undertaken by the institutions at the same locations (except for cotton in Akçakele/Anliurfa) in the year 2000.

Annex

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