BUILDING BIOSAFETY CAPACITIES

FAO'S EXPERIENCE AND OUTLOOK

An overview of the experience gained from FAO capacity building projects in agricultural biotechnology and biosafety

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ACRONYMS

ADB	Asian Development Bank
CAC/GL	Codex Alimentarius Commission/Guidelines
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
COAG	FAO Committee on Agriculture
ComDev	Communication for Development
DNA	Deoxyribonucleic Acid
ECCAS	Economic Community of Central African States
FAO	Food and Agriculture Organization of the United Nations
GCP	Government Cooperative Programme
GEF	Global Environment Facility
GM	Genetically Modified
GMOs	Genetically Modified Organisms
INFOODS	International Network of Food Data Systems
ISTA	International Seed Testing Association
ITPGRFA	International Treaty on Plant Genetic Resources
KAP	Knowledge, Attitude and Practices
LMOs	Living Modified Organisms
MDGs	Millennium Development Goals
NENA	Near East and North Africa
NGO	Non-governmental Organization
OECD	Organisation for Economic Co-operation and Development
OVM	Organismos Vivos Modificados
PCR	Polymerase Chain Reaction
R&D	Research and Development
SSC	South-South Cooperation
SPPD	Support for Policy and Programme Development
SPS	Sanitary and Phytosanitary Measures
TB	Tuberculosis
TBT	Technical Barriers to Trade
TCCT	Technical Cooperation among Countries in Transition
TCDC	Technical Cooperation among Developing Countries
TCP	Technical Cooperation Programme
ToT	Training of Trainers
UN	United Nations
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNU-IAS	United Nations University – Institute of Advanced Studies
WB	World Bank
WHO	World Health Organization

FOREWORD

Capacity building is at the heart of FAO's mandate. This work is the result of an in-depth monitoring and review of FAO capacity building activities in biosafety. Its publication coincides with the need to share the key considerations and recommendations stemming from the first round of projects developed and implemented by FAO since 2002, at a time when similar evaluations are carried out by the Global Environment Facility - in its capacity as the designated financial mechanism of the Convention on Biological Diversity and its Biosafety Protocol[1] - and other UN partner agencies involved on this matter.

The analysis has been developed through an in-house desk review of reports, studies, project documents and key issues emerged from the meetings of the FAO working group on biosafety, as well as external inputs. These inputs have been constantly collected during the implementation of the projects' activities and further addressed at an ad-hoc expert meeting and through regular contacts with national counterparts.

[1] The Cartagena Protocol on Biosafety was adopted in January 2000 and entered into force in September 2003

This publication highlights the key issues in biosafety capacity building project development and implementation, as well as future orientations. It is expected not only to contribute to the improvement of future activities of the Organization in this area, but also to provide inputs to the formulation of shared biosafety strategies at global level, in line with the Cartagena Protocol and other related international instruments.

The first part of this publication provides a general presentation of FAO's conceptual framework on biosafety as part of the broader Biosecurity framework.

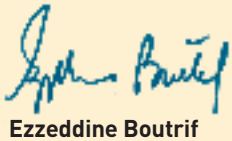
The second part of the paper illustrates the portfolio of 26 (past and current) biosafety capacity building projects at national, regional and global level as well as their structure, components and financing modality. Training is presented as the pivotal activity on which FAO's approach is based so as to build strong technical, institutional and information sharing capacities, and ensure the safe use of modern biotechnologies to enhance sustainable agriculture and food production.

Each section contains considerations on experience gained. Conclusions on the way forward indicate that partnerships, regional dimension and expansion/strengthening of existing networks of expertise will play an increasingly important role in future initiatives.

All the activities analysed in this publication have been made possible through the efforts of numerous institutions in the interested countries, including national biosafety

committees, ministries, universities and research institutes, NGOs and the private sector. The precious contribution of national project coordinators, the national and international consultants, the experts of the FAO's Partnership Programme (TCDC/TCCT[2]), the people who participated in the training activities, as well as FAO's officers from headquarters and decentralized offices, is gratefully acknowledged.

These results could not have been achieved without their enthusiasm, competence, and dedication. We are confident that we can count on similar pro-active participation for FAO's future activities in this area.



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[2] Technical Cooperation among Developing Countries / Technical Cooperation among Countries in Transition

INTRODUCTION

In line with the Millennium Development Goals (MDGs), the overall objective of the Food and Agriculture Organization of the United Nations (FAO) is to enhance long-term food and livelihood security through sustainable and environment-friendly increases in the quantity and quality of agricultural produce.

Modern biotechnology[3], when appropriately integrated with other agricultural production methods, has the significant potential to contribute towards meeting the food needs of an expanding and increasingly urbanized population and to offer opportunities for diversification into value-added production, improved processing systems and trade in food and agriculture. Furthermore, it provides powerful tools for the sustainable development of agriculture, fisheries and forestry by releasing pressure on natural resources and reducing their degradation.

However, with the portfolio of modern biotechnology applications increasing at a very rapid pace, there is a crucial need to ensure that these tools are used judiciously, that benefits are shared more equitably within developing countries and resource-poor farmers, and that the race towards progress

[3] "Modern biotechnology" means the application of: a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles; or b. fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection (Cartagena Protocol on Biosafety)

does not overlook potential risks for the environment and human health. Agriculture and food production are indeed one of the main fields of modern biotechnologies application, to which FAO attaches strategic importance in order to ensure the conservation and sustainable use of genetic resources, namely *"the great diversity of plants... and animals... farmers, livestock keepers, and other agriculturalists now and in the future may draw upon"*[4].

FAO's corporate strategy on biosafety recognizes the potential benefits of biotechnology in ensuring:

- access of all people at all times to sufficient nutritionally adequate and safe food, ensuring that the number of chronically undernourished people is reduced by half by no later than 2015;
- the continued contribution of sustainable agriculture and rural development, including fisheries and forestry, to economic and social progress and the well-being of all; and
- the conservation, improvement and sustainable utilization of natural resources, including land, water, forests, fisheries and genetic resources for food and agriculture.

It is acknowledged that the relationship between sustainable agriculture[5] and biological diversity is complex, in terms of management of biological resources, and that agriculture may have a significant potential impact on biological diversity, including that associated with the use and release of Living Modified Organisms (LMOs) resulting from modern biotechnologies. This complex relation and reciprocal dependency are summarized in Box 1.

[4] *Biodiversity and Agriculture: Safeguarding Biodiversity and Securing Food for the World, Secretariat of the Convention on Biological Diversity*, CBD, Montreal, 2008, page 12

[5] Agriculture is taken to include the management of fisheries and forestry

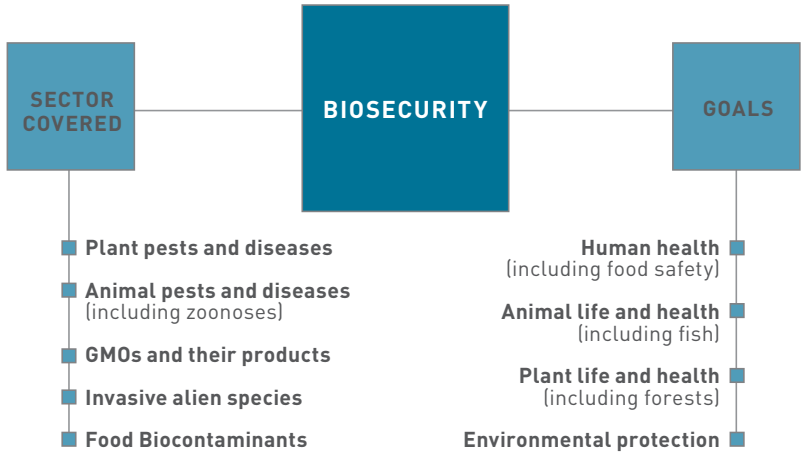
BOX 1 // AGRICULTURE AND BIODIVERSITY

(Secretariat of the Convention on Biological Diversity, Biodiversity and Agriculture: Safeguarding Biodiversity and Securing Food for the World, Montreal, 2008)

- **Biodiversity is the basis of agriculture. Its maintenance is essential for the production of food and other agricultural goods and the benefits these provide to humanity, including food security, nutrition and livelihoods.**
- **Biodiversity is the origin of all crops and domesticated livestock and the variety within them. Biodiversity in agricultural and associated landscapes provides and maintains ecosystem services essential to agriculture.**
- **Agriculture contributes to conservation and sustainable use of biodiversity but is also a major driver of biodiversity loss. Farmers and agricultural producers are custodians of agricultural biodiversity and possess the knowledge needed to manage and sustain it.**
- **Sustainable agriculture both promotes and is enhanced by biodiversity. Sustainable agriculture uses water, land and nutrients efficiently, while producing lasting economic and social benefits. Barriers inhibiting its widespread adoption need to be reduced.**
- **Agricultural producers respond to consumer demands and government policies. To ensure food security, adequate nutrition and stable livelihoods for all, now and in the future, food production must be increased while adopting sustainable and efficient agriculture, sustainable consumption, and landscape level planning that ensure the preservation of biodiversity.**

The Biosecurity Framework[6] was adopted by FAO's governing bodies to promote a strategic and integrated approach that encompasses the policies and regulatory frameworks that analyse and manage risks in the sectors of food safety, animal and plant life and health, including associated environmental risk. It is a holistic concept of direct relevance to the sustainability of agriculture and food production, food safety and the protection of the environment, including biodiversity. The framework covers the introduction of plant pests, animal pests and diseases, and zoonoses, the introduction and release of Genetically Modified Organisms (GMOs) and their products, and the introduction and management of invasive alien species and genotype. Biosafety (Box 2) is an integral part of the FAO Biosecurity Framework (Figure 1).

FIGURE 1 // SECTORS AND GOALS



[6] For more information, please refer to the *FAO Biosecurity Toolkit*, 2007

BOX 2 // BIOSAFETY WITHIN BIOSECURITY

(Report of the Expert Consultation on Biosafety within a Biosecurity Framework, FAO, Rome, 28 February - 3 March 2006)

Biosafety is a term generally used to describe frameworks encompassing the policy, regulation and management to control potential risks associated with the use of modern biotechnologies. This includes the use, release and transboundary movements of LMOs resulting from modern biotechnology. Such "biosafety" frameworks may occur at international, regional or national levels. Biosafety frameworks may also address risk communication issues, or even more generic impacts such as potential positive or negative economic or social impacts.

Biosafety within the biosecurity framework refers to safe use of new biotechnologies within the framework of managing, in a holistic manner, biological risks associated with food and agriculture (which is understood to include fisheries and forestry). FAO's mandate requires it to address the safe use of such new technologies, in order to contribute to sustainable agriculture and food production.

FAO has been addressing biosafety and related aspects since the late 1990s, before the Cartagena Protocol came into force. As the subject has evolved, many environment, trade and food related aspects of biosafety and its impact on agriculture have been considered by FAO's intergovernmental bodies, including its Committee on Agriculture (COAG), regional conferences, the Commission on Genetic Resources for Food and Agriculture (CGRFA), as well as the Secretariat of the International Treaty on Plant Genetic Resources (ITPGRFA). In order to facilitate a consistent approach, FAO has established a Working Group on Biosafety

comprising members from its various technical divisions. Through this group, FAO promotes its corporate strategy on biosafety and regularly participates in the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety and working groups on biotechnology, risk assessment, capacity building and communication.

Capacity building represents the main challenge in the safe application of modern biotechnologies in developing countries, as well as in the implementation of the related biosafety frameworks. As highlighted in the United Nations University-Institute of Advanced Studies (UNU-IAS) study, 'capacity building in biotechnology and biosafety differs from other areas as it poses unique challenges to existing morals, ethics, norms and policies, therefore making this area of activity of particular sensitivity'[7].

Together with other UN agencies and relevant stakeholders, and in line with Article 22 of the Cartagena Protocol on Biosafety, FAO has carried out numerous capacity building initiatives in biosafety as it relates to food and agriculture. Since 2002, FAO has launched a series of projects to assist countries and regions in building strong technical, institutional and information sharing capacities to ensure the safe use of modern biotechnologies and enhance sustainable agriculture and food production. This has been done through interdisciplinary expertise combined with normative and operational experience in policy and development of regulatory frameworks on modern biotechnology.

To date, the total funding of biosafety capacity building projects amounts to approximately USD 7.5 million.

Out of these 26 projects (Figure 2):

[7] "Sam Johnston, Catherine Monagle, Jessica Green with Ruth Mackenzie (2008) *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?* United Nations University – Institute of Advanced Studies, Yokohama, Japan.

FIGURE 2 // FAO BIOSAFETY ACTIVITIES UP TO 2009

Africa:
Benin, Kenya, Swaziland, Uganda, the United Republic of Tanzania

Asia:
Bangladesh, Malaysia, Sri Lanka

Eastern Europe:
Croatia

Latin America and the Caribbean:
Argentina, Bolivia, the Dominican Republic, Grenada, Nicaragua, Paraguay

Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand, Viet Nam

Armenia, Georgia, the Republic of Moldova

Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay

Jordan, Lebanon, the Sudan, Syria, United Arab Emirates, Yemen

Training and policy development workshops in the Caribbean; Near East; Central and Eastern Europe; Central Asia and Latin America

Training programmes in:

- GMO detection in seed samples and variety verification (80 countries)
- GM Food safety assessment (28 countries)

- *eighteen projects* have a *national* focus, and aim at supporting countries in meeting the obligations arising from the Cartagena Protocol on Biosafety as well as establishing effective linkages among all relevant stakeholders. Capacity building activities include the development and implementation of regulations, training personnel of regulatory bodies in risk assessment and detection of GMOs, upgrading infrastructure and improving communication, public awareness and participation in biosafety decision-making;
- *four projects* are carried out at *subregional* level, and assist countries by establishing biosafety networks, delivering issue-specific training (GMO detection and GM food safety assessment, etc.) and organizing technical meetings for subregional harmonization of rules and regulations. Furthermore, within an *interregional* project, training in various aspects of biosafety is provided to Eastern Europe and Central Asia. A series of *workshops* were also carried out in the Caribbean, Central and Eastern Europe, Central Asia, the Near East and Latin America on topics ranging from the establishment of a common biosafety policy to more specific technical and managerial issues, such as risk analysis and appropriate communication approaches;
- *two global projects* consist of training programmes targeting the enhancement of specific technical capacities in:
  1) GMO detection and monitoring; and
  2) GM food safety assessment.

FAO has also taken the lead in expanding the knowledge base in areas such as public communication, post–release monitoring, socio-economic issues and consumer concerns arising from the use of modern biotechnology through expert workshops, consultations and technical publications. All these activities are being carried out in full partnership with national agencies, international agricultural research centres, donors, other UN bodies and civil society organizations.

INTRODUCTION

This paper intends to illustrate the main findings and lessons learned from the past and ongoing biosafety capacity building initiatives, in order to improve future interventions and better shape strategic planning, so as to maximize results and fully meet countries' needs.

FAO BIOSAFETY CAPACITY BUILDING PROJECTS: STRUCTURE AND COMPONENTS

FAO's commitment in biosafety and biosecurity has to be seen within its wider mandate to eradicate hunger and reduce poverty in developing countries and economies in transition.

Based on this, FAO biosafety activities aim at assisting countries in building human, institutional and policy development capacities within their main regulatory bodies in order to efficiently and effectively handle the products of modern biotechnology, including GMOs and processed products.

Generally, all the FAO biosafety capacity building projects – at national, subregional, regional and global level (Figure 3) - revolve around a common axis: the training programme. Training touches on biosafety aspects of relevance to agricultural biotechnology, and is shaped to meet specific capacity building needs.

Based on countries' requests for assistance, national projects may also include other components on:

- policy development and formulation;
- regulatory aspects;
- GMO detection and monitoring;
- communication, participation and public awareness.

FAO BIOSAFETY CAPACITY BUILDING PROJECTS: STRUCTURE AND COMPONENTS

Depending on situations, regional and subregional projects also include national activities (Figure 2). Projects and related activities are briefly described in the next sections, together with key lessons emerging from their execution.

NATIONAL PROJECTS

TRAINING PROGRAMME

Each national project has a training component. This component, as shown in Figure 3, is central to all FAO biosafety capacity building projects, and consists of delivery of training courses on agricultural biosafety and supporting training materials.

The basic training programme for regulators and technical staff developed by FAO, comprises theoretical lectures and practical exercises aiming at: 1) providing basic knowledge of various subjects of relevance to agricultural biosafety; and 2) integrating competencies of the different actors involved.

Training is therefore composed of the following modules:

- *Agricultural biotechnology*, which reviews the very basic scientific concepts and principles employed in producing GMOs, with specific emphasis on the following key areas:
  - basic concepts of biotechnology;
  - genes: structure and function;
  - promoters, vectors and transformation cassettes;
  - plant transformation and selection techniques;
  - biotechnology for the improvement of animal breeding;
  - genetic engineering of micro-organisms of interest to agriculture;
  - detection methods for GMOs.

  It also provides a brief description of current and emerging uses of biotechnology in crops, livestock and fisheries with a

view to understanding the technologies themselves and ways in which they complement and extend other approaches. These concepts and principles are critical in ensuring pro-active participation to the process of reviewing dossiers and taking part in decision-making.

- *Ecological aspects*, which provide the necessary background information on ecology and evolution needed to analyse and understand the consequences of introducing GMOs into the environment, and to show that many areas in ecology can benefit from research tools based on applications of molecular genetics and biotechnology. These tools include investigations into population biology and evolution, and conservation and use of genetic resources for both human requirements and environmental protection.
- *Risk analysis*, which provides basic information on biological risks, concepts, principles, and methodologies of risk assessment, risk management and risk communication (except post-release monitoring and detection techniques, which are addressed in Module 4). It focuses on crop biotechnology and environmental risk assessment of GM crops since these are of immediate interest to most countries.
- *GMO monitoring*, which addresses use and monitoring of GMOs under containment, confinement and limited field trials, as well as post-release monitoring of GMOs. It also covers surveillance and emergency planning.
- *Legal aspects*, which provides an overview of the existing legal tools and frameworks on biotechnology and biosafety, and offers a thorough description of the international instruments that regulate biosafety and their interactions. It also includes considerations of legal relevance for drafting and implementing national biosafety frameworks.

However, on countries' request, in-depth hands-on training courses were carried out on:

- GMO detection (in the Dominican Republic, Kenya, Malaysia, Paraguay, Uganda and the United Republic of Tanzania).
- Communication for development (ComDev) and public awareness in Bangladesh, Nicaragua, Paraguay and Sri Lanka.
- Economic and trade aspects of biotechnology application in Sri Lanka.

Despite using the **same structure**, the actual implementation of the training programme **differs** greatly in **content and approach**. Differences in countries' biotechnology and biosafety policy, as well as regulatory and institutional contexts, are taken fully into consideration together with the capacity building needs of specific recipients, namely regulatory officers, technical staff, researchers, extensionists, port authority officers, and plant quarantine officers, etc. In Grenada, for example, training activities were organized on three different levels:

- a training workshop for officers, scientists and technicians indirectly involved in the biosafety system but not expected to directly participate in the risk analysis process. This training focused on basic concepts and general principles of agricultural biotechnology, ecology, risk assessments, and biosafety legislation at national and international level;
- a training course for members of the national biosafety committee and other technicians and officers expected to take part directly in the risk analysis process (Biotechnology Laboratory, Bureau of Standards, Produce Chemist Laboratory, etc.);
- in-service training to communication specialists in order to design target biosafety communication strategies and to better appreciate how ComDev can enhance stakeholder participation in related biosafety decision-making.

Training materials, including brochures, books, PowerPoint presentations, videos and exercises, constantly updated to keep abreast of any development in biotechnology and biosafety, form part of the training programme.

Over time, and in line with the recommendations of the Expert Consultation on Biosafety held in February 2006, FAO has been engaged in providing long-term, sustained access to biosafety information, particularly in developing countries, by providing appropriate training materials on electronic support, such as CD-ROMs, etc. Considerable progress was made in fine-tuning and better adapting lectures and training tools to the training needs. In this respect, background lectures are currently being synthesized and collected in the *FAO Agricultural Biosafety Compendium*, which will serve as reference material for future capacity building activities. So far, the training activities have reached approximately 2 500 people in total.

Engaging experts from developing countries as trainers has contributed to promote South-South Cooperation, expand biosafety networks and better serve the biosafety technical assistance neeeds of the countries involved

FAO's training courses follow a specific policy: whenever possible, experts from developing countries (making use of the Technical Cooperation among Developing Countries/ Technical Cooperation among Countries in Transition [TCDC/TCCT] Experts Programme[8]) are employed as trainers. Under the direct coordination and supervision of the FAO project manager, TCDC experts are responsible for preparing/revising lectures and training materials of each training session, in line with the characteristics and needs of the recipient country.

In line with the broader UN development cooperation objectives, special attention has also been devoted to ensuring gender balance within each training workshop and in other project activities.

Experience gained and the way forward

- The analysis of the characteristics of targeted trainees has proved essential. The training activities need to be tailored to a target audience and carefully planned.
- The training programme for regulatory officials has helped to expand the critical mass of technical expertise on agro-related biosafety issues at national, subregional and regional level. Nevertheless, sustainability is constantly challenged by the frequent turnover of personnel in regulatory agencies. As a mitigation measure, FAO is targeting a larger number of participants to create a building block of in-house knowledge with a higher chance of long-term continuity. Frequent employee turnover is also being addressed through Training of Trainers (ToTs) workshops.
- The *FAO Agricultural Biosafety Compendium* will serve as reference material for future capacity building activities and

[8] Information on the Technical Cooperation among Developing Countries/Technical Cooperation among Countries in Transition (TCDC/TCCT) Partnership Programme is available at http://www.fao.org/GENINFO/partner/en/exptechcoop/index.html

will represent the basis for further local training, thus improving sustainability of project results. It will be made available to countries upon request and will be placed on the Web site for easy access and downloading. If possible, the training package will be translated into the official UN languages to ensure accessibility and wide divulgation. Further divulgation would be facilitated by translation into local languages.

- Experience has shown that training activities, beyond their educative nature and purpose, have become informal round tables for analysing country situations, identifying options and settling disputes among regulatory authorities.
- The Expert Consultation on Biosafety held in 2006 recommended FAO to add to the training a session on how to search for biosafety information by remote-training or self-training modules. This is progressively being integrated into the training package.
- As mentioned above, and in accordance with the Organization's policy, experts from FAO's Partnership Programme (i.e. TCDC/TCCT[9] experts,) are preferably employed as trainers. This approach has contributed to the promotion of South-South Cooperation (SSC), expanding biosafety networks among developing countries, and better serving the biosafety technical assistance needs in complex and fragile social, economic and environmental contexts.
- Gender balance in each of the training activities ensures coherence with the development cooperation objectives set out in the mandate of FAO, and that of the UN in general.

[9] Please refer to footnote 8 on page 17

FIGURE 3 // SCHEMATIC REPRESENTATION OF FAO PROJECT COMPONENTS

TRAINING — **core component** of the FAO biosafety capacity building activities at national, regional and global level

TRAINING PROGRAMME

- Agricultural biotechnology
- Ecological aspects
- Risk analysis
- Post-release monitoring and detection techniques
- Legal, administrative, socio-economics and ethical aspects of a biosafety regulatory regime
- GMO detection
- Communication and participation

OTHER ACTIVITIES CARRIED OUT AT NATIONAL LEVEL

POLICY
- National policy development and formulation
- Participatory approaches
- Consultation with stakeholders

REGULATION
- Review of national legislation
- Consultation with stakeholders
- Support in the formulation or revision of the biosafety legislation and related implementing regulations and guidelines

MONITORING AND DETECTION
- Laboratory establishment

COMMUNICATION, PARTICIPATION, PUBLIC AWARENESS
- KAP surveys
- Communication strategy development and implementation
- ComDev skills and methods

OTHER ACTIVITIES CARRIED OUT AT REGIONAL AND SUBREGIONAL LEVEL

REGIONAL/SUBREGIONAL HARMONIZATION
- Harmonization of guiding principles, regulatory frameworks, standards and guidelines
- Establishment of regional biosafety networks
- Delivery of issue-specific training
- Sharing the limited available human and infrastructural resources to foster the pooling of resources and economies of scale

POLICY AND REGULATORY ASPECTS

Regulatory frameworks on agricultural biotechnology address safety issues, meet the requirements of the Cartagena Protocol and are in line with other related international instruments.

To date, FAO has supported several countries, including Bangladesh, Nicaragua, Paraguay and Sri Lanka, in developing national biotechnology policies and strategies, and provided legal assistance to Benin, Bolivia, Grenada, Paraguay and Swaziland.


NATIONAL PROJECTS

Capacity building support on legal aspects is structured to be non-intrusive, systemic and forward-looking. In so doing, it comprised expert advice, analysis of pros and cons associated with the available options, and legal assistance in drafting policies and legislation based on country decisions and the anticipated regulatory results.

In brief, it includes:

- review of national (environmental legislation, plant and animal health and quarantine, food quality and safety, seed production and certification, etc.) and international legislation related to biosafety;
- consultation with stakeholders (ministries, regulatory bodies, farmers' associations, private sectors, Non Governmental Organizations [NGOs]);
- support in the formulation of draft policies, (biosafety) laws, regulations, and implementation guidelines;
- revision of the draft or existing biosafety legislation, in conjunction with interested parties.

In some cases the legislative process resulted in the swift adoption of a policy or a law, while in others the drafted texts are still being discussed by the relevant institutional authorities. As a result, the success of the legal assistance differs consistently from country to country.

Nevertheless, the participatory process launched at all levels for policy development and law formulation, proved to be as relevant as the result itself. Although time-consuming, involvement of the main stakeholders (Ministries of Agriculture, Environment, Science and Technology, research and technology centres, extension and technical advisory services, NGOs, the private sector, including seed companies, and civil society organizations, farmers and their associations) stimulated debate, ownership and commitment. In Nicaragua and Paraguay, for example, a series of participatory workshops was held in each district. The resulting draft policy and legislation documents were therefore widely shared and, in principle, likely to be more readily approved and implemented. The incorporation of ComDev tools in this phase adds clarity and builds greater consensus among stakeholders.

FAO has progressively gathered and made available in its Web site a collection of national and subnational biotechnology policy documents[10]. A description of the FAO Biotechnology Web site is given on page 39.

Experience gained and the way forward

- The development of an effective coordination mechanism, involving the main stakeholders and ensuring coordination of roles and responsibilities among the relevant authorities dealing with biosafety, forms the base for a solid institutional setting at national level. It is essential that the coordination mechanism be clearly outlined and agreed upon by the parties involved before being regulated.
- A clear agricultural national biotechnology/biosafety policy, setting goals and priorities, as well as providing guiding

[10] The biotechnology policy documents are available at the URL: http://www.fao.org/biotech/country.asp

principles, is the basis for the development of a robust national regulatory regime and related institutional setting.

- Regional and subregional harmonization of biosafety regulatory and administrative aspects (notification forms, for example) is highly recommended to countries sharing economic interests.

GMO DETECTION AND MONITORING

The GMO detection and monitoring component was devised for those situations where there was a need to build or strengthen capacities e.g. the Dominican Republic, Kenya, Malaysia, Paraguay and the United Republic of Tanzania.

Indeed, inadequate capacities, lack of coordination and insufficient access to information have major consequences in applying the national regulatory frameworks. At the national level, one of the most frequent problems faced by regulatory agency personnel is the lack of some basic technical information to deal with issues related to GMO detection.

Increased capacity in GMO detection and monitoring is a key issue for countries to meet technical requirements deriving from international obligations, as well as a key element of enhanced autonomy

There is consequently a greater dependency on external structures for any GMO detection activity that may be deemed necessary, and its associated costs. At regional and subregional level, different detection methodologies, protocols, standards and certification schemes imply an unharmonized biosafety scenario which could impede trade relations, or any agreed approach to addressing them.

Experience gained and the way forward

- Increased capacity in GMO detection and monitoring is a key issue on which FAO will continue to focus in the years to come. It not only enables countries to meet technical requirements deriving from international and national obligations, but is also a key element of enhanced scientific, and political, autonomy of the countries and regions, reducing dependency on external/foreign laboratories' support for GMO detection and related activities.
- The possibility of laboratories being paid for the services they provide (GMO monitoring and detection), and benefiting from the financial resources that these activities generate, depends on national regulations, and has to be accurately assessed in line with the country's national budget organization and functions.
- FAO has addressed GMO detection and monitoring at all the operational levels - national, subregional, regional and global. As a first action at national level, FAO has included a specific module on GMO detection and post-release monitoring, and hands-on training practice in its training programme. This approach is considered of great use by the regulatory staff and personnel, since they receive first hand knowledge and increased awareness for direct use in the assessment of GMO-related applications and submissions. Where needed, FAO has strengthened infrastructure and laboratory facilities for regulatory agencies to provide greater capacity to detect and

handle biotechnology products. While the experience has been positive, FAO support to laboratories needs further consideration so as to ensure the appropriate use and maintenance of equipment in the long term.

- Sharing laboratory facilities among regulatory bodies of neighbouring countries could in some case reduce the costs and improve sustainability of GMO detection activities, but the real and effective establishment and implementation of subregional collaboration remains problematic in many instances.

COMMUNICATION AND PUBLIC PARTICIPATION

Projects in Bolivia, the Dominican Republic and Grenada comprised a communication and participation component: they all made use of the Knowledge, Attitude and Practices (KAP) survey approach as a first step towards the development and formulation of a communication and public awareness strategy.

A KAP survey[11] is a 'representative study of a specific population to collect information on what is known, believed and done in relation to a particular topic, in this case biosafety. In most KAP surveys, data are collected orally by an interviewer using a structured, standardized questionnaire. These data can then be analysed quantitatively or qualitatively depending on the objectives and design of the study. However, differently from simple polls, KAP surveys address broader cultural issues through questions about general practices and beliefs'.

In addition to these standard KAP measures, however, the ComDev approach makes use of participatory, qualitative tools to

[11] World Health Organization (2008) Advocacy, communication and social mobilization for tuberculosis (TB) control, *A Guide to Developing Knowledge, Attitude and Practice Surveys*. WHO/HTM/STB/2008.46.
http://www.stoptb.org/resource_center/assets/documents/ACSM_KAP%20GUIDE.pdf

Training is central to FAO biosafety projects

engage stakeholders in situational analysis and needs assessment. This not only yields KAP baseline data for monitoring and evaluation, but also enhances consensus and helps to construct culturally relevant and appropriate messages and media products.

KAP survey data are essential "to help plan, implement and evaluate advocacy, communication and participation work.

The survey can be conducted at any point, but is most helpful if conducted in the early phases of the communication activity development, as it sets the basis for planning further"[12], in this case, a communication and participation strategy.

As a result, the communication and participation strategies produced in the above-mentioned countries are based on targeted awareness building activities and tools, and ensure access to information and public participation in the decision-making process.

[12] ibid.

Gender balance ensures coherence and commitment with the UN development cooperation objectives

The implementation of these strategies has been further promoted through the following tools:

- workshops with targeted audiences;
- information toolkits;
- local media;
- conveying messages through *credible witnesses*.

For example, the project in Sri Lanka assessed the communication behaviour patterns of targeted audience, such as farmers, researchers, extensions workers, and scientists with regard to agricultural biotechnology. It likewise explored their perception of agricultural biotechnology, as well as newspapers' coverage.

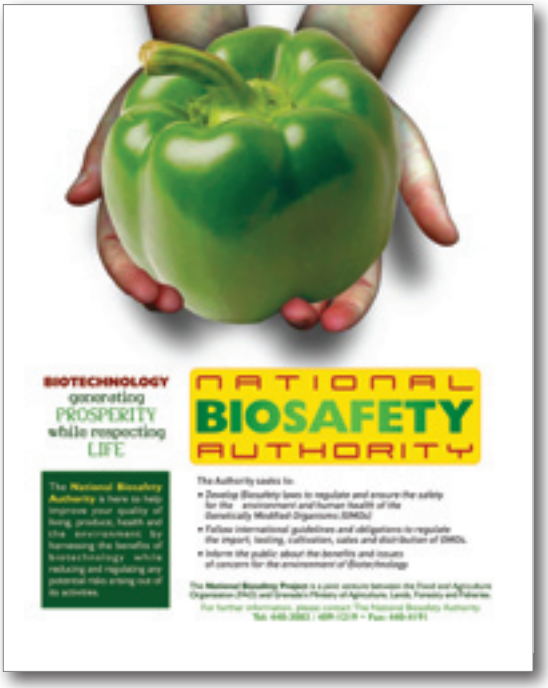
Communication behaviour includes information sources, specific topics or messages sought and received, information-seeking models (passive or active), media preferences and information utilization.

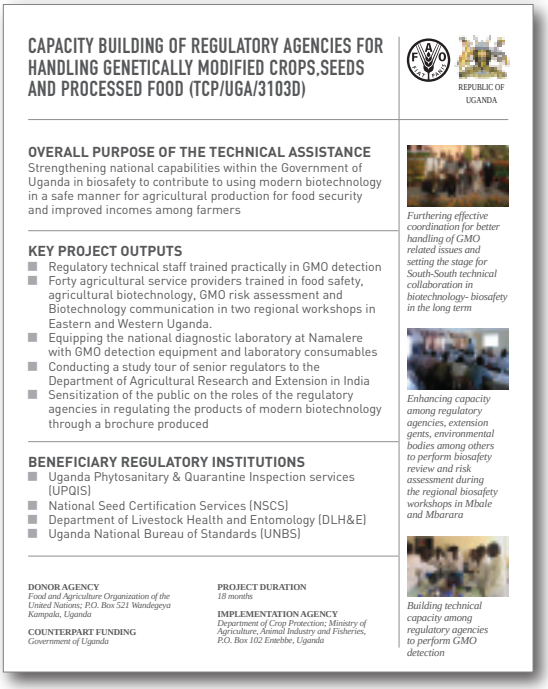
The perception study was helpful in determining possible reasons for the target audience's bias for or against agricultural biotechnology. This and the findings of the assessment, formed

the basis of recommendations concerning the promotion of public awareness and participation in support of the National Agricultural Biotechnology Research and Development Programme and Investment Plan in Sri Lanka.

Experience gained and the way forward

- KAP surveys, communication patterns and perception studies provide an insight of the social situation at local level and perception of what the communication efforts should address. They are at the base of the communication and participation project component and should employ ComDev tools and methods.
- For the purpose of information and communication strategies and plans, translation into the local languages is highly recommended.
- Strategies implementation promoters (workshops, toolkits, local media, credible witnesses) have proved to be an easy yet effective way to facilitate communication and participation.





Posters prepared within the information and communication activities carried out in Grenada (TCP/GRN/2902) and Uganda (TCP/UGA/3103)

REGIONAL, SUBREGIONAL AND INTERREGIONAL PROJECTS

To date, FAO has implemented four biosafety capacity building projects at regional and subregion level in:

- **Asia (Asia BioNet) - participating country: Bangladesh, China, India, Indonesia, Malaysia, Pakistan, Philippines, Sri Lanka, Thailand and Viet Nam.**
- **Eastern Europe - participating countries: Armenia, Georgia and the Republic of Moldova.**
- **Latin America (MERCOSUR Ampliado) - participating countries: Argentina, Bolivia, Brazil, Chile, Paraguay and Uruguay.**
- **Near East and North Africa (NENA) - participating countries: Jordan, Lebanon, the Sudan, the Syrian Arab Republic, United Arab Emirates and Yemen.**

Of the four, the one for Asia has been completed and is moving towards Phase II; two are at an advanced stage of implementation (Eastern Europe and MERCOSUR ampliado); and the NENA project has just started. In addition, a subregional project for biosafety capacity building in the Economic Community of Central African States (ECCAS) has been formulated and submitted to the Global Environmental Fund (GEF) for funding. Participating countries are Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, and Gabon.

Building on the similarities of the countries within the regions/subregions (shared borders, economic interests, strong trade relations, including imports of food products), the projects aim at promoting collaboration, facilitating harmonization of biosafety

guiding principles, regulatory frameworks, standards and guidelines, and sharing the limited available human and infrastructural resources.

While the responsibility for formulating national biosafety policies and legislation lies with national governments, each country needs well-established capacities to develop a regulatory framework with a solid institutional base, and enforce regulations. It is equally evident that subregional/regional collaboration and harmonization in biosafety can offer important opportunities of mutual benefit and determine consistent environmental and economic gains, not least the attraction of funding and investments.

In the case of Asian BioNet, diversity in the levels of development of national biosafety systems in the participating countries represented both a challenge and an opportunity.

While the disparities hindered equitable participation in regional/subregional activities, they provided nevertheless opportunities for collaboration and enabled countries with least developed biosafety systems to learn from those with more advanced systems[13].

For MERCOSUR Ampliado, the disparities among countries' biosafety operational contexts are less remarkable. The initial dialogue and information exchange was slow but improved markedly in the course of project execution, leading to the achievement of the expected outcomes, namely increased cooperation, creation of shared understanding, development of common tools and procedures that will possibly be adopted by the participating countries.

Within the NENA project, collaboration in GMO detection and monitoring among national reference GMO laboratories is supported

[13] Sonnino A. (2008) *FAO regional project on Capacity Building in Biosafety of GM crops in Asia*. Biosafety Protocol News, vol. 3, no. 5, pp. 8-9, http://www.cbd.int/doc/newsletters/.

so as to harmonize activities and certification schemes based on common standards and good practices. Such collaboration is expected to be formalized through an agreement for the establishment of the 'regional platform for GMO detection', taking into account subregional and regional specificities and interests. As a result, many more countries in the area have put forward requests to expand the project and become involved.

Finally, recommendations for a subregional strategy on agricultural biotechnology were provided as part of the project involving Armenia, Georgia and the Republic of Moldova.

At subregional level, a series of training activities were carried out in the Caribbean, Middle East and Central and Eastern Europe on technical and managerial issues.

As part of an interregional project, training in various aspects of biosafety is being provided to scientists and decision-makers from Eastern Europe and Central Asia and from 2006 to 2008 three training workshops were organized in the Czech Republic.

EXPERIENCE GAINED AND THE WAY FORWARD

- Regional and subregional harmonization of standards, guidelines, protocols and methodologies is highly recommended when countries share borders, socio-economic interests and trade relations.
- The creation of regional/subregional networks represents an economic opportunity, fostering resources pooling, economies of scale and international coordination. In the specific case of NENA, it could reduce dependency and costs associated with GMO detection activities, as well as generate additional resources through the charges from the services provided by the reference laboratories.

- Regional/subregional networks support the involved countries in:
  - sharing information and experience;
  - harmonizing means and methods for handling GMOs;
  - reducing the costs of specific activities, e.g. GMO detection;
  - exchanging technical protocols and guidelines;
  - practicing double verification methods;
  - creating critical mass of expertise in the area;
  - establishing common certification schemes;
  - harmonizing policies, regulation, and trade practices (forms, administrative fulfilments, etc.).
- A regional/subregional approach tends to attract more funding from private and public donors/funding agencies (including development banks).
- There is a need to synchronize the national, subregional and regional dimensions of biosafety capacity building. Regional and subregional collaboration in biosafety should be further promoted and expanded through regional and subregional projects, and well coordinated with national biosafety capacity building efforts.

GLOBAL PROJECTS

Since 2002 two training programmes were launched at global level to respond to a call for assistance in:

- **seed testing and variety verification, including GM seeds and varieties, in collaboration with the International Seed Testing Association;**
- **Training of Trainers (ToT) on GM food safety assessment.**

The aim of the GMO detection programme is to train the seed technicians from national agencies and other relevant stakeholders in methods of verification of species, cultivars and hybrids, as well as qualitative and quantitative GMO detection. Training in electrophoretic methods and Polymerase Chain Reaction (PCR) techniques for variety verification and GMO detection were conducted at regional and subregional levels throughout the world in collaboration with the International Seed Testing Association (ISTA).

The following seven hands-on courses were conducted between 2002 and 2005 and trained approximately 250 technicians from 80 countries:

- Carribean and Central America Subregion: Kingston, Jamaica, 2005.
- Greater Mekong Subregion: Beijing, China, 2005.
- Near East and North Africa: Cairo, Egypt, 2004.
- Central and Eastern Europe: Ljublijana, Slovenia, 2004.
- Asia and Pacific: Bangkok, Thailand, 2003.
- Southern and Eastern Africa: Johannesburg, South Africa, 2003.
- Latin America and the Caribbean: Buenos Aires, 2002.

The ToT Workshops on GM food safety assessment, conducted within the biosecurity approach, aim to provide a common knowledge base on GM food safety assessment and create a critical mass at key agencies in research and development, health, agriculture, plant and animal health inspectorates, standards bodies and coordination of biotechnology/biosafety.

Codex Alimentarius principles on risk analysis and guidelines on the conduct of food safety assessment of foods derived from modern biotechnology provide a framework for GM food safety assessment. They are important tools for everyone involved in GM food chain research, development, trade and regulation. To ensure that these tools are effectively applied in risk assessment and regulation, countries have requested capacity building support for GM food researchers, developers and regulators.

During 2007 and 2008, two regional training courses were carried out in Kenya and the Philippines (country groups 1 and 2). Two more training courses are planned for 2009 in Chile and South Africa (country groups 3 and 4). It is estimated that by the end of 2009, 120 GM food researchers, developers and regulators from 28 countries will have been trained.

EXPERIENCE GAINED AND THE WAY FORWARD

- Issue-specific multicountry training programmes proved to be a very effective tool to fill technical knowledge gaps, to create networks of technical expertise, and to enhance SSC.
- The ToTs approach helps to face the rapid turn-over of officers in regulatory bodies and to ensure sustainability in the long term. It will be replicated in future training programmes.

PROJECT MANAGEMENT AND FINANCIAL ISSUES

Technical Cooperation Programme (TCP) projects are implemented by national counterpart institutions and directed by National Project Coordinators. FAO headquarters staff regularly provide technical advice and project backstopping. The execution of project activities relies mainly on a team of international consultants from FAO's Partnership Programme (TCDC/TCCT[14]) and national consultants, and benefits from the managerial/administrative/logistic support of FAO's country and regional offices.

Monitoring project activities to achieve the set objectives is carried out on a regular basis by the National Project Coordinator and the backstopping technical unit at headquarters. When appropriate, it is also backed by a national project steering committee.

With the exception of the regional project for Asia (Asia-Bionet), and an interregional project focusing on Eastern Europe and Central Asia, biosafety capacity building projects were financed through FAO resources, under the TCP or through other trust funds. The budgets ranged between USD 100 000 and USD 350 000 for national projects, and USD 300 000 and USD 1 300 000 for regional and global projects. Current efforts aim at diversifying the funding portfolio and collaborating more consistently with other UN partner organizations.

[14] Please refer to footnote 8 on page 17

EXPERIENCE GAINED AND THE WAY FORWARD

- Resources made available by FAO are precious but do not always suffice, and are especially very limited when upgrading of GMO detection laboratories is needed. Other funding sources should be approached and partnering with other agencies enhanced.
- FAO's in-house technical capacity has guaranteed smooth project implementation and flexibility.
- Different FAO technical units, including the Nutrition and Consumer Protection Division, the Plant Production and Protection Division, the Research and Extension Division, and the Legal Office, contributed to project implementation, allowing the adoption of an interdisciplinary approach.

COORDINATION, INFORMATION AND OUTREACH

FAO actively participates in the Biosafety Capacity Building Coordination Mechanism established by Conference of the Parties to the Cartagena Protocol on Biosafety, to facilitate exchange of information, with a view to promoting partnerships and maximising synergies and complementarities between various capacity building initiatives for the implementation of the Protocol. Through the Coordination mechanism, government agencies, relevant organizations and donors involved in implementing or funding biosafety capacity building initiatives share information and experiences on their ongoing initiatives; identify key biosafety capacity building issues, priority needs and ways to address them; identify overlaps and potential opportunities for collaboration; and facilitate interaction, dialogue, and collaboration.

Examples of collaboration between biosafety capacity building projects implemented by different international agencies include the case of Swaziland, where the same steering committee served two projects: the FAO project, "Strengthening national capacities in the formulation and implementation of legal instruments on genetically modified organisms"; and the United Nations Environment Programme/Global Environment Facility (UNEP/GEF) initiative for the "Development of the National Biosafety Framework". For regional projects, the steering committees involve focal points from the participating countries, members of the technical expert group, the project secretariat, representatives from the donor government, if any,

FAO officers and representatives from other agencies working in biotechnology.

An FAO multilingual Web site on Biotechnology in Food and Agriculture[15] was launched in 2001 as illustrated in Box 3. It is subdivided into 12 areas, ranging from FAO documents to country biotechnology policy documents.

Information on biosafety capacity building projects is currently available on the Biosafety Clearing House information sharing mechanism at http://bch.cbd.int/database/, which FAO, according to Article 20 of the Cartagena Protocol, is actively part of. Specific project Web sites were also set up for the two subregional initiatives in Asia and MERCOSUR Ampliado.

However, with a growing portfolio of biosafety-related activities, FAO is compiling the biosafety capacity building project documentation in a systematic manner in order to make it available on the FAO web page as well as through regularly up-to-date outreach material. This will ensure better visibility to FAO's activities and will amplify opportunities for establishing new partnerships and collaborations.

EXPERIENCE GAINED AND THE WAY FORWARD

- The Organization is taking corrective actions to ensure that more attention be devoted to outreach activities and information on its biosafety capacity building project activities at different operational levels.

[15] http://www.fao.org/biotech

BOX 3 // FAO WEB SITE ON BIOTECHNOLOGY IN FOOD AND AGRICULTURE

(The FAO Biotechnology Web site - http://www.fao.org/biotech)

The Web site, launched in Arabic, Chinese, English, French and Spanish in 2001 and expanded to include Russian in 2007, provides information on FAO's work and international developments regarding biotechnology techniques and products, as well as on related policy and regulatory issues surrounding research and deployment of agricultural biotechnology.

In addition to an overview of FAO's activities in agricultural biotechnology; a synthesis of biotechnology in the agro-industry, crop, fisheries, forestry and livestock sectors; links to other relevant Web sites and to national biotechnology policy documents of FAO Members, the site contains the following key features:

- **the *FAO Biotechnology Glossary* (published originally in English and later translated to Arabic, French, Russian, Serbian, Spanish and Vietnamese), that is also available as a multilingual searchable database at http://www.fao.org/biotech/index_glossary.asp;**
- **the *FAO Statement on Biotechnology* (http://www.fao.org/biotech/stat.asp), produced by the FAO Interdepartmental Working Group on Biotechnology in response to the many requests to know "where FAO stands on the biotechnology issue";**
- ***a documents section* (http://www.fao.org/biotech/doc.asp), currently providing over 180 web links to a wide range of articles, books, meeting reports, proceedings and studies published by FAO, or prepared in collaboration with FAO, in recent years concerning biotechnology in food and agriculture;**
- **the *FAO Biotechnology Forum* (http://www.fao.org/biotech/forum.asp), making a neutral platform available for people to exchange views and experiences on biotechnology in developing countries. The Forum has almost 3 500 members worldwide and has hosted 15 moderated e-mail conferences since the year 2000, with about 50 percent of all messages posted coming from participants living in developing and developed countries respectively.**

- ***FAO-BioDeC*** **(http://www.fao.org/biotech/inventory_admin/dep/default.asp), a searchable database providing data on agricultural biotechnologies in use or in the pipeline in developing countries and countries with economies in transition. Launched in 2003 for the crop sector only, it now contains over 4 000 entries from the crop and other agricultural sectors of more than 100 countries (end of 2008). The entries come predominantly from the crop and forestry sectors, with less extensive coverage for livestock and fisheries. A network of national correspondents has also been established for data validation and updating. In 2004, it was extended by including "Developing Country Biotechnology Profiles", a searchable database which aims to provide easy access to key, updated sources of information regarding biotechnology-related policies, regulations and activities of 128 individual developing countries;**
- ***news and events*****. The home page includes news and events that are relevant to applications of biotechnology in food and agriculture in developing countries. The items' main focus is on the activities of FAO, of other United Nations agencies/bodies and of the 15 Consultative Groups on International Agricultural Research (CGIARs) research centres. All items posted since January 2002 are available on the Web site.**

CONCLUSIONS AND THE WAY FORWARD







Overall, the projects have achieved their objectives. Enhanced skills have enabled the regulatory agencies to be of greater technical and advisory assistance to national biosafety committees and other competent authorities, and foster more effective collaboration on biosafety among the relevant authorities, including ministries with different perspectives and competencies on biotechnology applications. This was mainly achieved through the involvement of relevant stakeholders from different areas and disciplines in project preparation and execution and facilitation of dialogue.

The projects have also created strong and purposeful links between regulatory agencies and advanced biotechnology laboratories in universities and regional centres of excellence, as well as consolidated biotechnology networks at national, regional and international level. Networks and information platforms are considered crucial to enable SSC among regulatory agencies, and to promote self-sustained efforts in biosafety activities in the future.

The following conclusions can be drawn from the experience gained so far:

- FAO's commitment to biosafety and biosecurity has to be seen within its wider mandate to eradicate hunger and reduce poverty in developing countries and economies in transition. Such a mandate is not thematic, but requires a coordinated

approach among and within different sectors of activity, as well as intergovernmental and interagency collaboration. With recent statistics showing an increase in the number of a worldwide hungry population, currently estimated at 1 020 million, FAO is actively committed to promoting the sustainable intensification of agriculture to revert such a trend, helping to raise levels of nutrition by regular access to sufficient high-quality food, modernizing and increasing agricultural productivity through simple, sustainable tools and techniques, improving lives of rural populations and contributing to the growth of the world economy.

- Biosecurity covers three main sectors: food safety; plant life and health; animal life and health. The *biosafety within biosecurity approach*, encompassing all policy and regulatory frameworks to manage biological risks associated with food and agriculture (including relevant environmental risks), is necessary to protect: 1) agricultural production systems, agricultural producers and their associated interests; 2) human health and consumer confidence in agricultural products; and 3) the environment.
- With a view to conserving crop genetic diversity for long-term food security and ensuring access to quality products which are safe, useful and relevant, FAO has increasingly integrated environmental considerations into agricultural issues.

  Among others, FAO has fully integrated the ecosystem approach to management of land, water and living resources at local, national and regional levels into its action and planning. "There are already sectors and governments that have developed guidelines that are partially consistent, complementary or even equivalent to the ecosystem approach – an example of which is the 'Code for Responsible Fisheries.'[16]

[16] Beginners' Guide to using the Ecosystem Approach, http://www.cbd.int/ecosystem/sourcebook/beginner-guide.shtml

- FAO's efforts have been concentrated on specific technical issues of relevance to biosafety as it relates to food and agriculture. In this respect, the Organization uses its comparative advantages to complement other agencies' work in:
  - providing specialized scientific and technical training and assistance in many areas associated with biosafety, including those associated with new biotechnologies, nanotechnologies and new applications in organisms, such as aquatic organisms, insects and other animals; and
  - providing appropriate information material, facilitating efforts to develop best management practices for production of GM and non-GM seed, especially for use by the national seed production agencies.
- With an eye towards the future, FAO will not only make use of its technical in-house expertise to meet capacity building needs; in order to mobilize action and respond to country needs, the Organization intends to enhance its role of exchange node to activate and coordinate existing networks of technical expertise.
- FAO only provides capacity building support upon request from Member Governments. These needs depend on country specific conditions and countries are encouraged to identify their own needs, priorities and development objectives. In this respect, biosafety mainstreaming into national development plans and involvement of relevant stakeholders at national level are crucial to the success of any assistance intervention. Currently, at a stage when many countries are moving from drafting to implementing their biosafety frameworks, FAO responds to an increasing number of requests for intensifying efforts and focusing on aspects related to risk analysis (risk assessment, management and communication), GMO detection and post-release monitoring, as well as communication and socio-economic considerations. Specific training tools have been fine-tuned and are in use. Attention will continue to be addressed to creation of on-the-ground capacity.







- National biosafety capacity building needs are increasingly linked to the regional dimension because of shared environmental, human health, animal health and socio-economic issues, as well as political realities. Issues related to safety of modern biotechnology products often go beyong the control of single countries, so that a strong regional, as well as international, collaboration among countries is assuming increasing importance. In this respect, FAO intends to play a leading role in clarifying, elaborating and communicating the scientific basis for regional approaches (both among and within countries) towards biosafety risk analysis. For example, there could be several aspects of the characterization of the transgenic genotypes that might be possibly standardized through regional approaches. Within the environmental context any possible standardization would need to be specific to the type of risk and take into account the environment and the agro-ecosystems present in a region. Such efforts should be treated initially on a purely scientific level, and the geopolitical realities should be considered in time.
- Despite being an active partner of the Biosafety Capacity Building Coordination Mechanism, information on FAO's biosafety/biosecurity activities was fragmented and insufficiently disseminated. The Organization intends to pay more attention to outreach activities and information at different operational levels. This is also necessary to highlight achievements and progress of actions, as well as enhance opportunities for synergies and collaboration among different initiatives.
- FAO is progressively strengthening its collaboration with the GEF based on its comparative advantages. FAO's competitive advantages have been recognized in biodiversity, climate change (bioenergy and adaptation), international waters, land degradation and persistent organic pollutants, and in the cross-cutting themes of sustainable forest management and

integrated chemicals management (GEF Council Meeting, December 2006[17]). The close causal linkages among hunger, poverty and environmental degradation underscore the need for multidimensional approaches towards their reduction and have been important considerations in the development of FAO's strategic and programmatic priorities.

- FAO has mainly relied on its own financial resources to fund biosafety capacity building activities. Other funding sources will be approached, including GEF, and partnering with other agencies further enhanced.
- To date, FAO is engaging in long-term alliances for the benefit of agriculture and the environment with UNEP, the World Bank (WB), the United Nations Development Programme (UNDP), Convention on Biological Diversity (CBD), Asian Development Bank (ADB), as well as with other stakeholders, including NGOs.
- The Expert Consultation held in 2006 also recommended that FAO collaborates with the Organisation for Economic Co-operation and Development (OECD), the International Network of Food Data Systems (INFOODS) and other relevant entities in the development of an international database on the compositional characteristics of food crops for use in a comparative evaluation/risk assessment of GM food crops. Arrangements are being made along these lines.
- The FAO policy to contract preferably experts from FAO's partnership programmes (i.e. TCDC/TCCT[18]) as trainers has proved to be very effective in promoting SSC, expanding biosafety networks among developing countries and countries in transition, and better serving the biosafety technical assistance needs in complex and fragile social, economic and

[17] (GEF/C.31/5 rev.1, 2007, Annex L, http://thegef.org/uploadedFiles/Projects/Templates_and_Guidelines/GEF-C-31-5%20rev%201-June%2018-2007.pdf)

[18] Please refer to footnote 8 on page 17







environmental contexts. The biosafety activities will continue to follow this approach.

- FAO is committed to ensure gender balance in any capacity building initiative, including biosafety. This ensures coherence with and commitment to the development cooperation objectives set out in the mandate of the Organization, and the UN in general.
- The Joint FAO/World Health Organization Codex Alimentarius Commission adopted in 2003 texts of direct relevance to biosafety, namely:
  - Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (CAC/GL 44-2003).
  - Guideline for the Conduct of Food Safety Assessment[19] of Foods Derived from Recombinant DNA Plants (CAC/GL 45-2003).
  - Guideline for the Conduct of Food Safety Assessment of Foods Produced using Recombinant-DNA Microorganisms (CAC/GL 46-2003).

  Since September 2005, further work has resumed on the elaboration of a guideline for the conduct of food safety assessment of foods derived from recombinant-DNA animals; and on an annex to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Alimentarius Commission/Guidelines [CAC/GL 45-2003]) regarding food safety assessment of foods derived from recombinant-DNA plants modified for nutritional or health benefits.

  The Codex texts provide guidance for conducting science-based safety assessment of foods derived from biotechnology, which should be consistent with the risk assessment requirements

[19] In the case of the safety of foods and animal feeds derived from biotechnology, most assessments are "safety assessments" rather than risk assessments. This recognizes that the conventional food or feedstuff may have potential risks associated with its consumption, for example phyto-estrogens in plants or residual heavy metal contamination in liver. The outcome of the assessment is to determine whether the food derived from biotechnology is "as safe as" the conventional counterpart. This approach may not be appropriate to foods that have been modified with the intent of making significant changes to the foods' composition.

of the Cartagena Biosafety Protocol, the Application of Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade (TBT) Agreements. Based on the biosafety within biosecurity approach, FAO encourages that food safety considerations be fully integrated.

ANNEX 1
LIST OF BIOSAFETY PROJECTS

NATIONAL PROJECTS		
Africa		
1	Benin TCP/BEN/3103 (D) Renforcement des capacités en vue de la mise en œuvre du cadre réglementaire en biosécurité	261 000
2	Kenya TCP/KEN/3001 (T) Capacity building of regulatory agencies for handling genetically modified crops, products and processed foods	238 000
3	Swaziland TCP/SWA/3003 (A) Strengthening national capacities in formulation and implementation of legal instruments on genetically modified organisms (GMOs)	174 000
4	The United Republic of Tanzania TCP/URT/3102 (A) Capacity building of regulatory agencies for safe handling of genetically modified plants and plant materials	342 000
5	Uganda TCP/UGA/3103 (D) Capacity building of regulatory agencies for handling genetically modified seeds, crops and processed foods (10 countries)	306 000
Asia		
6	Bangladesh SPPD BGD/02/005/A/08/12 Assessment of Utilization and Potential of Biotechnological Advancement for Agricultural Development in Bangladesh	330 000
7	Bangladesh TCP/BGD/3102 (D) Assistance in the formulation of enabling regulatory measures for research and sustainable application of biotechnology	195 000
8	Malaysia TCP/MAL/2901 (A) Capacity Building on Regulation of Import, Contained Use and Release of Genetically Modified Plants and Plant Material	156 000
9	Sri Lanka TCP/SRL/3101 (D) Formulation of a National Agricultural Biotechnology Research and Development (R&D) Programme and Investment Plan	182 000
Eastern Europe		
10	Croatia TCP/CRO/3102 Capacity building of regulatory agencies for handling and monitoring genetically modified crops, products and processed food	311 000
Latin America and the Caribbean		
11	Argentina TCP/ARG/2903 Ëvaluación de la capacidad, infraestructura y logistica de manejo poscosecha de Organismos Vivos Modificados (OVM) e identificación de estrategias para aplicar el articolo 18.2 a) del Protocollo de Cartagena	374 000

12	Bolivia TCP/BOL/2902 (A) Fortalecimiento institucional para la gestión de la seguridad de la biotecnología	248 000
13	Grenada TCP/GRN/2902 (T) Strengthening the national capacity in biotechnology and biosafety	237 000
14	Grenada TCP/GRN/3101 Strenghtening the national capacity in biotechnology and biosafety (Phase II)	25 500
15	Nicaragua TCP/NIC/3101 (A) Apoyo a la formulación de una política nacional de investigación y aplicación de la biotecnología agropecuaria	202 000
16	Paraguay TCP/PAR/0166 (A) Fortalecimiento del Sistema Nacional de Bioseguridad	240 000
17	Paraguay TCP/PAR/3001 (A) Apoyo a la formulación de una política nacional de biotecnología	205 000
18	República Dominicana TCP/DOM/3202 (D) Fortalecimiento de las capacidades institucionales para la investigación en biotecnología y bioseguridad	315 000
REGIONAL AND SUBREGIONAL PROJECTS		
Near East and North Africa		
19	Regional GCP/RAS/185/JPN Capacity Building in Biosafety of GM Crops in Asia	1 234 701
20	Subregional TCP/RER/3102 Capacity building in agricultural biotechnologies and biosafety (Armenia, Georgia, the Republic of Moldova)	454 000
21	Subregional TCP/RLA/3109 (D) Desarrollo de herramientas técnicas de referencia para la gestión de la bioseguridad en los países integrantes del MERCOSUR Ampliado (Argentina, Bolivia, Brazil, Chile, Paraguay y Uruguay)	288 000
22	Subregional TCP/RAB/3202 (D) Strengthening capacities towards the establishment of a regional platform for the detection of GMOs (Jordan, Lebanon, the Sudan, Syria, United Arab Emirates and Yemen)	413 000
23	Subregional workshops (Caribbean, Near East, Central and Eastern Europe, Latin America)	63 000
INTERREGIONAL ACTIVITIES		
24	Interregional GCP/INT/790/CEH Training Programme in Selected Areas (Albania, Republic of Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Bulgaria, Croatia, Georgia, Kazakhstan, Kyrgyz Republic, Kosovo, Lithuania, the Russian Federation, Serbia, Tajikistan, The former Yugoslav Republic of Macedonia, the Republic of Moldova, Turkey, Turkmenistan, Ukraine, Uzbekistan, Romania, Czech Republic)	160 515
GLOBAL PROJECTS		
25	Capacity building for GMO detection in seed samples (80 countries involved)	300 000
26	Training of trainers programme in GM Food Safety Assessment	150 000

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BUILDING BIOSAFETY CAPACITIES

FAO'S EXPERIENCE AND OUTLOOK

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This study is the result of the in-depth review of FAO's capacity building activities in biosafety. It provides a general presentation of FAO's conceptual framework on biosafety – the FAO Biosecurity framework – and illustrates the portfolio of past and current biosafety projects at national, regional and global level, together with their structure, components and financing modality.

This publication is expected not only to contribute to planning FAO future activities in this area, but also to provide strategic inputs to the formulation of shared biosafety capacity building strategies at the global level, in line with the Cartagena Protocol and other related international instruments.

For additional information
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