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BIOSAFETY ISSUES RELATED TO BIOTECHNOLOGIES FOR SUSTAINABLE AGRICULTURE AND FOOD SECURITY

The paper contained in the current document was presented by FAO to the Biosafety Enabling Workshops, organized by UNDP/GEF in late 1998 and early 1999, to provide information on the full range of FAO's activities and mandates, in relation to biosafety issues. This document, which may be of interest to the Commission, is provided for information.

Biosafety Issues Related to Biotechnologies for Sustainable Agriculture and Food Security

This paper describes relevant FAO instruments in the field of biotechnology that deal directly or indirectly with issues related to biosafety, and that are of relevance to the development and application of the Biosafety Protocol being negotiated within the context of the Convention on Biological Diversity (CBD). It also describes relevant bodies and ongoing processes within FAO, and outlines FAO's mandate and capacity to advise its member nations on matters relevant to biosafety and food and agriculture.

FAO works closely with its members and with other international and national organizations to ensure the synergy of instruments and harmonization and cooperation between agencies.

Introduction

Agriculture (including crops, fishery, forestry, and animal husbandry) must feed an increasing human population, forecast to reach 8 000 million by 2020, of which 6 700 million will be in developing countries. Although population growth rate is steadily decreasing, the increase in absolute numbers to be fed will require steady increased gains in productivity, often in countries where environmental degradation threatens decreased productivity.

To meet future needs and to be able to sustain agricultural production, agricultural research will have to use all available technologies, including the rapidly developing modern biotechnologies.¹ FAO recognizes that these biotechnologies are powerful tools in agricultural development, with great potential to benefit agriculture. There are, at the same time, a number of uncertainties and possible risks associated with their use, which are addressed through the concept of "biosafety". Coupled with other technologies, the new biotechnologies should provide solutions for some of the problems impeding sustainable rural development and the achievement of food security. Biotechnology may also offer, through bioremediation, a tool to resolve certain environmental problems, some of which derive from unsustainable agricultural and industrial practices.

Biosafety and Agriculture

Biosafety means the safe and environmentally sustainable use of all biological products and applications for human health, biodiversity and environmental sustainability in support of improved global food security.

Within biosafety in general, there is a sub-set of questions that relate to the applications of the new biotechnologies to food and agriculture. In this connection, it should be recalled that the Conference of the Parties for the Convention on Biological Diversity (COP) in its decision II/15, recognised "the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions".

¹ The CBD defines biotechnology as "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific uses." In agriculture, biotechnology includes the application of tissue culture, immunological techniques, molecular genetics and recombinant DNA techniques in all facets of agricultural production and agro-industry.

The increasing development of living modified organisms (LMOs) is accompanied by the need for controls related to their testing, release, use and cross-border movements. Adequate national biosafety legislation is necessary to protect the environment, biodiversity and human health. There is the need to develop capacities for risk assessment and risk management of LMOs and their products and mechanisms and instruments for the application and control of biotechnology. Some of the potential risks of LMOs relate to the evolution of new pests, the generation of new weeds, the spread of species with undesirable phenotypes and the inadvertent production of toxins and allergens².

Since 1995, a CBD Biosafety Protocol has been under negotiation, touching particularly trans-boundary movement of LMOs and possibly the products thereof. The Protocol is expected to be adopted at an Extraordinary Conference of the Parties to the Convention in 1999. As a result of the developments related to biotechnology and the obligations associated with the Biosafety Protocol, countries need to develop the appropriate national legislation and controls for biosafety. The national legislation should be consistent with international agreements.

The International Plant Protection Convention (IPPC)

The IPPC is an international treaty for cooperation in plant protection, deposited with FAO and administered by FAO through the Secretariat for the IPPC. The purpose of the Convention is *“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”*.

The Convention was adopted by the FAO Conference in 1951 and came into force in 1952. It is recognised as the primary instrument for international cooperation in the protection of plant resources from harmful pests³. There are currently 107 governments that are contracting parties to the IPPC.

Prior to the conclusions of the Uruguay Round of multilateral trade negotiations in 1993, it was clear to Contracting Parties of the IPPC and FAO that the IPPC would have a prominent position in the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement). The role envisioned for the IPPC was to foster international harmonisation in phytosanitary matters affecting trade and establish standards to help ensure that phytosanitary measures were not used as unjustified barriers to trade.

The role of the Convention with respect to trade has changed significantly as a result of the SPS Agreement. This is reflected in substantial amendments found in the New Revised Text approved by FAO Conference in 1997. However, it is to be noted that although clearly having applications to the regulation of trade, the Convention is not limited in this respect. International cooperation in many forms falls within the scope of the Convention.

² FAO/IAEA 1996 Report of a Consultants Meeting, “Biotechnology in the Next Millennium”, December 1996.

³ “pests” are defined in the IPPC to be “any species, strain, or biotype of plant, animal or pathogenic agent injurious to plants or plant products”.

The IPPC is not limited in its application to cultivated plants or to cultivated systems, and protection is not limited to direct damage from pests. Therefore, the scope of the Convention is implicitly extended to the protection of natural flora from indirect pest damage (as with many weeds). Likewise, the IPPC does not only consider injury or damage by pests in terms of direct commercial impacts and trade. A broad interpretation has been universally supported and continuously reinforced through a history of interpretation and negotiation.

The Convention allows parties to take phytosanitary measures i.e. - any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of pests. These cover the pest concerned and may also cover any plant, plant product, storage place, packaging, conveyance, container, soil and any other organism, object or material capable of harbouring or spreading pests that are deemed to require phytosanitary measures.

The IPPC calls for phytosanitary measures to be based on a pest risk analysis, which covers both economic and environmental factors including possible detrimental effects on natural vegetation. The Convention also allows for the prohibition or restriction of the movement of biological control agents and other organisms of phytosanitary concern claimed to be beneficial into the territories parties.

Any LMO that can be considered a pest of plants falls within the scope of the IPPC and will be subject to the provisions of the Convention.

Four issues determine the area of overlap between IPPC and the Protocol:

- standards for risk analysis (risk assessment) related to plant pests;
- the interpretation given to the term “injurious” in the definition of the term pest;
- the interpretation of the word “economic” in the definition of quarantine pest and regulated non-quarantine pest (in the ISPM on pest risk analysis this is interpreted to include environmental effects); and
- the interpretation of the term “phytosanitary concern” in Article 7.1.d of the Convention.

(For example, a wide interpretation that would include effects on plant biodiversity under “injurious” or “phytosanitary concern”, would allow for regulating certain LMOs under national phytosanitary legislation and providing quarantine services with the authority to take measures.)

The Commission on Genetic Resources for Food and Agriculture

The Commission on Plant Genetic Resources was established by the FAO Conference in 1983. The mandate of the Commission was broadened to include all genetic resources that pertain to food and agriculture in 1995. The current Membership of the Commission on Genetic Resources for Food and Agriculture is 159 countries and the European Community.

The Commission has developed the following international agreements relevant to the biosafety protocol and to CBD:

- The International Undertaking on Plant Genetic Resources, adopted by the FAO Conference in 1983. There are 113 countries that have adhered to the Undertaking. The revision of the Undertaking in harmony with the Convention on Biological Diversity is currently being negotiated by countries through the Commission.
- The international Code of Conduct for Plant Germplasm Collecting and Transfer, adopted by the FAO Conference in 1993.

In 1989 and 1991 the Commission considered reports on technical and policy issues regarding Biosafety, within the context of biotechnology in general, and requested the Secretariat to prepare a draft Code of Conduct for consideration at its Fifth Regular Session in 1993. Following a survey of more than 400 international experts, four major areas to be covered in the draft Code of Conduct were identified, one of which was biosafety.

In 1993 the Commission considered the preliminary draft “Code of Conduct for Biotechnology” which included a module on biosafety. The aim of the draft code was to maximise the positive effects and minimise the possible negative effects of biotechnology. Noting that the intergovernmental Committee on the Convention on Biological Diversity (IGC/CBD, the predecessor of the COP) was considering the development of a biosafety protocol to the Convention, the Commission recommended that FAO participate in this work, in order to ensure that the aspects of biosafety in relation to plant genetic resources for food and agriculture were appropriately covered and to avoid duplication and inconsistencies. The biosafety and other environmental components of the draft FAO Code were accordingly forwarded to the Executive Secretary of the CBD, at the request of the Commission, as an input to the CBD’s proposed protocol. In its Sixth Regular Session in 1995, the Commission considered the report “Recent developments of relevance to the Draft Code of Conduct for Plant Biotechnology”⁴.

In 1995, FAO broadened the scope of the Commission to cover all components of biodiversity of relevance to food and agriculture, beginning with animal genetic resources. Mammalian and avian species contribute some 30% of the total value of food and agriculture, and there is growing interdependence between countries in regard to these genetic resources, and growing trans-boundary movement. As they are higher species, closer to humankind, a growing range of biosafety issues arise, including the possibility of inter-species disease transmission.

FAO is fully committed to assisting Member States to develop policies and to promote and implement standards, guidelines and instruments developed by the Commission concerning genetic resources for food and agriculture.

Codex Alimentarius

The Codex Alimentarius Commission (CAC) was formed by FAO and the World Health Organisation in 1962 to implement the Joint FAO/WHO Food Standards Programme. The objectives of the Programme are to ensure consumers health and fair practices in the food trade.

⁴ Document CPGR 6/95/15.

The CAC is an intergovernmental statutory body of FAO and WHO. Its current membership is 163 countries.

The scope of Codex standards includes all food safety considerations, description of essential food hygiene and quality characteristics, labelling, methods of analysis and sampling, and systems for inspection and certification. Codex standards, guidelines and recommendations are based on current scientific knowledge including assessments of risk to human health. The risk assessments are carried out by FAO/WHO expert panels of independent scientists selected on a world-wide basis. The range of standards developed by the CAC covers all foods whether processed, semi-processed or raw, intended for sale to the consumer or for intermediate processing. Over 200 standards, 45 Codes of Practice and 2,000 Maximum Limits for residues of agricultural and veterinary chemicals have been established.

Codex standards, guidelines and other recommendations are not binding on Member States, but are a point of reference in international law (General Assembly Resolution 39/248; Agreement on the Application of Sanitary and Phytosanitary Measures; Agreement on Technical Barriers to Trade).

The CAC is presently developing Recommendations for the Labelling of Foods Obtained through Biotechnology. The CAC is also considering the development of a general standard which would apply basic food safety and food control disciplines to foods derived from biotechnology. The advice of prior FAO/WHO expert consultations on biotechnology and food safety will be used as guidance for the conditions required for foods prepared from biotechnology. Foremost among these are consideration of potential allergenicity, possible gene transfer from LMOs, pathogenicity deriving from the organism used, nutritional considerations and labelling.

The CAC has also been considering matters related to risk analysis in Codex since its 20th Session in 1993. FAO and WHO have held expert consultations on the application of risk analysis to food standards issues, risk management and food safety, food consumption and exposure assessment of chemicals, and risk communication. At present risk analysis is considered to be an integral part of the decision-making process of Codex. The process of risk analysis should be applied to biotechnology and food safety.

FAO is fully committed to assisting Member States, particularly developing countries, to promoting and implementing the standards, guidelines and other recommendations of the Codex Alimentarius Commission.

Code of Conduct for Responsible Fisheries

The FAO Code of Conduct for Responsible Fisheries was adopted in 1995 by the 28th Session of the FAO Conference and provides a framework for the sustainable use and conservation of aquatic biodiversity. The code was created through negotiations with Member Countries, NGOs and IGOs and contains articles on:

- General Principles
- Fisheries Management
- Fishing Operations
- Aquaculture Development

- Integration of Fisheries into Coastal Area management
- Post-harvest Practices and Trade
- Fisheries Research

Although the Code is voluntary, parts of it are based on relevant rules of international law, including those reflected in the United Nations Convention on the Law of the Sea.

Objectives of the Code that are relevant to the biosafety protocol include, *inter alia*, the promotion of fisheries in contributing to food security and food quality; the protection of living aquatic resources and their environments; the promotion of trade in fish and fishery products, in conformity with relevant international rules; and the avoidance of the use of measures that constitute hidden trade barriers.

Article 11 on Post Harvest Practices and Trade, recognizes the principles and agreements of the World Trade Organization.

Aquaculture is a primary means for the purposeful introduction of aquatic alien species, as well as the main motivation for the use of living modified aquatic organisms.

Therefore, Article 9 on Aquaculture Development deals specifically with these topics: Article 9.2 on the “responsible development of aquaculture including culture based fisheries within trans-boundary aquatic ecosystems” and Article 9.3 on the “use of aquatic genetic resources for the purpose of aquaculture, including culture-based fisheries”.

FAO is fully committed to assisting Member States, particularly developing countries, to promote and implement the Code of Conduct for Responsible Fisheries.

FAO and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures

The relationship of FAO to the Agreements under the World Trade Organization is highlighted by the critical role played by Codex Alimentarius and the IPPC in the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement).

The scope of the SPS Agreement covers measures in trade that are intended to protect human, animal, and plant health or life. Although other WTO Agreements refer to international standards, only the SPS Agreement identifies specific organizations to be used for international harmonization under the Agreement. Codex is named for human health and food safety while the IPPC is responsible for plant health.

The SPS Agreement is based on several important principles. These include for example, the principles of sovereignty, necessity, harmonization, transparency, and equivalence. The same principles are reflected in the work programmes for global harmonization under Codex and the IPPC. These principles provide the foundation for the elaboration of standards, guidelines and recommendations noted in the SPS Agreement as the basis for the global harmonization of sanitary and phytosanitary measures.

Measures based on the SPS principles and conforming to corresponding standards from the designated standard setting organizations are deemed acceptable without further justification. In instances where measures deviate from established standards, or where measures are established in the absence of standards, the SPS Agreement requires justification based on scientific principles and evidence. Risk analysis methods elaborated by Codex and the IPPC provide systematic frameworks for this purpose. Both Codex and the IPPC offer extensive experience and information in this area.

While Codex and the IPPC clearly have strong relevance to trade in food and agricultural products, it is important to recognize that protection is their primary objective. To this end, both organizations strive to provide standards that allow member governments to achieve an appropriate level of protection while ensuring that measures are not unjustified or arbitrary barriers to trade. The result is that free trade and fair trade also become safe trade.

FAO technical assistance and advice

Since its founding 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. Consequently, FAO provides scientific and technical expertise to its members on a wide range of agricultural and food related topics.

In line with its mandate and the three major areas of its programme which include providing information, providing a forum for international debate for issues related to food and agriculture, and rendering technical assistance to its Member Nations, FAO seeks, within its means and resources, to help countries realize the positive impact of biotechnology and to minimize possible negative effects.

FAO's technical assistance and advice is provided in the following areas:

- development of national strategies for biotechnology and biosafety;
- drafting or revision of national legislation in the fields of biotechnology and biosafety;
- training and manpower development including inspection, laboratory analysis, and management of control programmes;
- import and export control systems and programmes;
- risk analysis (risk assessment, risk management and risk communication);
- awareness and understanding of international treaties, agreements and conventions;
- review and assessment of administration, management and control systems and programmes;
- assistance in programme development;
- assistance in the development of facilities (including laboratories);
- assistance in data/ data systems management;
- facilitation of technical cooperation between institutions and governments.

Technical assistance to FAO members for legislation

FAO advises its members in relation to their renewable natural resources legislation, regulations and systems. Through cooperation between the appropriate technical departments and the FAO Legal Office, developing countries are provided with a broad range of legal advice on agriculture and renewable natural resources management, in particular reviewing and providing advice about the adequacy of national laws and regulations in the fields of forest and environment, fisheries, food trade and safety, seed quality control, plant protection and animal health, including intellectual property rights related to plant and animal breeding, as well as the development and implementation of appropriate biosafety legislation for the agricultural sector and related institutional questions, as part of agricultural biotechnology regulation.

FAO assists member countries in the definition of criteria for the formulation and implementation of regional and national agricultural policies, programmes and legislation, including cooperation between developed and developing countries. In many cases, relevant national economic policy decisions have not yet been backed by the adoption of new and pertinent legal frameworks

The focus of FAO's work in this regard is to assist national authorities to analyse their needs and identify appropriate policy options; to formulate or revise the relevant national legislation; and to advise 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.

FAO's approach to technical assistance in legal advice and legislative drafting normally comprises the following steps, involving the relevant technical divisions of FAO (and their technical experts and consultants in the field), in close collaboration with the national authorities:

- review and analysis of the statutory instruments in force (or draft bills already prepared by the Government) 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; and
- submission of recommendations, and their discussion with the relevant national authorities.

Concluding Remarks

The modern biotechnologies, although only two decades old, have wide implications for human health, veterinary medicine, food technology, fibre production, industrial raw material supply, forestry, aquaculture and agriculture. With the development of the Biosafety Protocol, the issue of biosafety takes on additional importance. FAO has for many years provided a forum for governments to discuss issues of biosafety, and will continue to do so.

FAO also has a particular mandate to assist, in particular, developing countries, in all aspects of agriculture. It will support them in making the best use of modern biotechnologies, in a way that respects human health and the environment. FAO is also prepared to help them to develop and implement pertinent biosafety legislation, in agreement with the biosafety protocol, and provide technical advice and assistance.