QUALITY AND SAFETY ASSESSMENT OF FOODS DERIVED BY MODERN BIOTECHNOLOGY AND THEIR INTERNATIONAL REGULATION*

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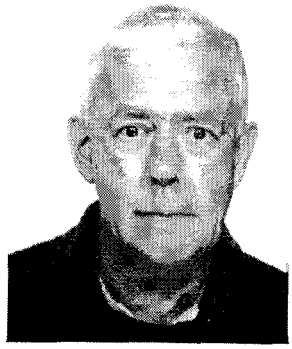

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ABSTRACT

Biotechnology has a long history of use in food production and processing. It represents both traditional breeding techniques and the latest techniques based on molecular biology. The increasing development of genetically modified organisms is accompanied by the need for all-necessary controls related to their testing, relevance, use and cross-border movements. Adequate national legislation is necessary to protect the environment, biodiversity, and human health. There is also need to consider how to carry out adequate levels of risk management of genetically modified organisms in the products, mechanisms and instruments for application and control of biotechnology. This paper discusses the work done at the international level to assure the quality and safety of foods derived from modern biotechnology. It explores the code of conduct for biotechnology as it affects the conservation and use of plant genetic resources. Particular biotechnology-related issues have been considered by a series of FAO/WHO expert consultations and workshops. Emphasis is placed on generic work done at the United Nations level on the 1992 Convention on Biological Diversity and the accompanying Cartagena Protocol on Biosafety, and more specific work on food and agriculture aspects carried out by the Food and Agriculture Organisation on the UN (FAO), often performed jointly with the World Health Organisation and The International Atomic Energy Agency (IAEA). The paper also gives a brief history and scope of the Codex Alimentarius Commission as regards biotechnology and food safety, and implementation of the Joint FAO/WHO food standards. Also explained are Codex Committees such as the Codex Committee on Food Labelling, and the Codex Committee on Food Certification and Inspection Systems, and the interrelationship between FAO/WHO Codex Alimentarius Commission, the World Trade Organisation and International Plant Protection Convention (IPPC).

Key words: biosafety, genetically modified organisms, food quality and food safety

EVALUATION DE LA QUALITÉ ET DE LA SÉCURITÉ DES ALIMENTS DÉRIVÉS AU MOYEN DE LA BIOTECHNOLOGIE MODERNE ET LEUR REGLEMENTATION INTERNATIONALE

RESUME

La biotechnologie a une longue histoire par son utilisation dans la production et le traitement alimentaires. Elle représente aussi bien les techniques traditionnelles d'élevage que les techniques les plus récentes basées sur la biologie moléculaire. Le développement croissant d'organismes génétiquement modifiés s'accompagne du besoin de tous les contrôles nécessaires liés à leur test, leur pertinence, leur utilisation et leurs mouvements trans-frontières. Une législation nationale adéquate est nécessaire pour protéger l'environnement, la diversité biologique, et la santé humaine. Il faut également considérer comment mettre au point des niveaux adéquats de gestion des risques des organismes génétiquement modifiés dans les produits, des mécanismes et des instruments d'application et de contrôle de la biotechnologie. Ce document expose le travail fait au niveau international en vue d'assurer la qualité et la sécurité des aliments dérivés de la biotechnologie moderne. Il explore le code de conduite en matière de biotechnologie étant donné qu'elle affecte la conservation et l'utilisation des ressources génétiques

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végétales. Les questions particulières qui ont trait à la biotechnologie ont été considérées à travers une série de consultations et d'ateliers des experts de la FAO/OMS. Un accent particulier est mis sur le travail générique fait au niveau des Nations Unies dans le cadre de la Convention de 1992 sur la Diversité Biologique et dans le cadre du Protocole de Cartagena qui l'accompagne sur la Prévention des Risques Biotechnologiques, ainsi que le travail plus spécifique sur les aspects de l'alimentation et de l'agriculture accompli par l'Organisation des Nations Unies pour l'Alimentation et l'Agriculture (FAO), souvent effectué conjointement avec l'Organisation de la Santé Mondiale et l'Agence Internationale de l'Energie Atomique (AIEA). Ce document donne également une brève historique et un champ d'action de la Commission Codex Alimentarius en ce qui concerne la biotechnologie et la sécurité alimentaire et la mise en œuvre des normes alimentaires conjointement par la FAO et l'OMS. Les Comités Codex, qui sont le Comité Codex sur l'étiquetage des produits alimentaires, et le Comité Codex sur les Systèmes de Certification et d'Inspection Alimentaires et l'interrelation entre la FAO/OMS, Codex Alimentarius Commission, l'Organisation Mondiale du Commerce et la Convention Internationale sur la Protection des Plantes (IPPC), sont également expliqués.

Mots clés: Prévention des Risques Biotechnologiques, Organismes Génétiquement Modifiés, Qualité de la nourriture et Sécurité Alimentaire.

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[1]. 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 productivity[2].

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. FAO recognizes that these biotechnologies are powerful tools in agricultural development, with great potential to benefit agriculture, and at the same time, there are a number of uncertainties and possible risks associated with their use.

New technologies, such as modern biotechnologies, if properly focused, should provide solutions for some of the problems hindering sustainable rural development and the achievement of food security. Biotechnology may also offer a tool to resolve certain environmental problems, some of which derive from unsustainable agricultural and industrial practices [3].

BIOTECHNOLOGY IN FOOD

Biotechnology has a long history of use in food production and processing. It represents both traditional breeding techniques and the latest techniques based on molecular biology. Modern biotechnological techniques, in particular, open up great possibilities of rapidly improving the quantity and quality of food available [4].

The 1992 Convention on Biological Diversity (CBD) defined 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 [5].

Within the past few years, a variety of foods produced using biotechnology have been approved in many countries. Examples are crops such as maize, potatoes, soybeans, tomatoes and oilseeds [6]. The benefits of biotechnology are many and include providing resistance to crop pests to improve production and reduce chemical pesticide usage, thereby making major improvements in both food quality and nutrition. Biotechnology is also being used in a wide range of applications in fermentation techniques and in animals and plants for the production of food additives and pharmaceuticals.

It is important to consider any potential human health or environmental risks when foods are developed using biotechnology. It is vitally important to encourage worldwide efforts to develop and apply appropriate strategies and safety assessment criteria for food biotechnology research and to ensure the wholesomeness and safety of the food supply [7].

The increasing development of genetically modified organisms is accompanied by the need for all necessary controls related to their testing, release, use, and cross-border movements. Adequate national legislation is necessary to protect the environment, biodiversity, and human health. There is also the need to consider how to carry out adequate levels of risk assessment and risk management of genetically modified organisms and their products, mechanisms and instruments for the application and control of biotechnology [7].

The Resumed Extraordinary Conference of the Parties to the Convention on Biological Diversity held in Montreal, Canada adopted the Cartagena Protocol on Biosafety. The objective of the Protocol is to contribute, in accordance with a precautionary approach, to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMO) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health, and specifically focussing on trans boundary movements [5,7].

While there are a number of contradictions and imprecise statements in this new Protocol, the key concept seems to be the notion of Advance Informed Agreement (AIA), which should be given by the country of import prior to the trans-boundary movement of an LMO. Many of the provisions of the Protocol need further discussion before they can be implemented and the Protocol contains provisions for such discussions. For example, it appears that the advance informed agreement procedure in the Protocol might not apply to LMOs intended for direct use as food or feed, or for processing. At the same time, The Protocol contains an article on the handling, transport, and identification of LMOs intended for *"food, feed or processing"* (LMO/FFPs). Such contradictions require further discussion, preferably based on sound science [5,6,7].

The Protocol promotes a *"precautionary approach"* in assessing the usefulness and safety of LMOs and LMO/FFPs. The Protocol provides that risk assessments shall be carried out in a scientifically sound manner taking also into account risks to human health. The Protocol does not imply a change in the rights and obligations of a Party under any existing international agreement including WTO SPS and TBT Agreements. It is understood that the Protocol and trade agreements should be mutually supportive and none of them should be subordinated to the other [7].

International organizations such as FAO have recognized the need to take a balanced and comprehensive approach to biotechnological development by considering its integration into various areas of the Organization's work program [8].

This paper describes an overview of relevant instruments in the field of biotechnology that deal directly or indirectly with issues related to biotechnology, with particular reference to FAO and relevant bodies and ongoing processes within FAO, and outlines FAO's mandate and capacity to advise its member governments on matters and international regulations relevant to biotechnology and food and agriculture. Cooperation between FAO, the World Health Organization and the World Trade Organization is also covered as necessary.

To facilitate the quality and safety assessment of foods derived by means of modern biotechnology, action at the international level has been necessary to provide timely expert advice in this matter to all Member States.

INTERNATIONAL WORK ON BIOTECHNOLOGY

FAO has been involved in biotechnology in order to advise and assist its Member Countries to adopt useful methodologies and monitor development in the area. In 1984, an FAO/IAEA* meeting discussed the role of relevant international organizations in biotechnology, and since then numerous sectoral and general meetings have included specific aspects of biotechnology in the FAO context [9].

In 1991, the FAO Council endorsed a draft *"Code of Conduct for Biotechnology as it affects the Conservation and Use of Plant Genetic Resources"*. A draft was prepared following a survey among 400 experts worldwide requested by the Commission on Genetic Resources for Food and Agriculture (CGRFA). Its aim is to minimize possible negative effects of biotechnology on the overall conservation of plant genetic resources. Noting that CBD was considering the development of a biosafety protocol , the Commission recommended that FAO participate in this work in order to ensure that aspects of biosafety in relation to genetic resources for food and agriculture are appropriately covered [8,9].

In 1995, the Commission (CGRFA) considered a report on Recent International Development of Relevance to the Draft Code of Conduct for Plant Biotechnology. Further work on the draft Code awaits the completion of the current negotiations for the revision of the International Undertaking on Plant Genetic Resources.

A number of FAO publications - both meeting reports and technical bulletins - have addressed aspects of biotechnology, as a means of assisting member governments to acquire the technology and information on implications for agriculture, and trade-related issues [10].

Particular biotechnology-related issues have been considered by a series of FAO/WHO expert consultations and workshops such as two Joint FAO/WHO Expert Consultations in 1990 and 1996 which addressed safety assessments of food derived by modern technology and outlined the procedures to be followed in establishing the quality and safety of such food.

The first Joint FAO/WHO Consultation on the

*International Atomic Energy Agency

Assessment of Biotechnology in Food Production and Processing as Related to Food Safety (November 1990) reviewed the status of biotechnology as used in food production and processing and discussed foods derived from plant, animal and microbial sources [10,11].

The consultation proposed safety assessment paradigms for each food source and recommended that safety assessment strategies should be based on the molecular, biological and chemical characteristics of the food to be assessed. It noted that traditional food safety assessment techniques, based on toxicological testing as used for food additives, for example, may not always apply to foods or food components produced by biotechnology.

A fundamental conclusion of the consultation concerning modern biotechnology was that, *"The use of these techniques does not result in food which is inherently less safe than that produced by conventional ones."*

Another Joint FAO/WHO Consultation on Biotechnology and Food Safety held in 1996 recommended international guidelines for safety assessment of foods and food components which have been produced by techniques that change the heritable traits of an organism, such as recombinant DNA (rDNA) technology [11].

The 1996 Joint FAO/WHO Consultation established the concept of substantial equivalence, which is a dynamic, analytical exercise in the assessment of the safety of a new food relative to an existing food. This comparative approach was based on the possibilities that it may be possible to demonstrate that a genetically modified organism, or a food or food component derived from it, is substantially equivalent to a conventional counterpart already available in the food supply. Substantially equivalent in this context refers to both conventional nutritional equivalencies and to safety considerations [7,10,11].

If it is not possible to demonstrate substantial equivalence, it may be possible to demonstrate that a genetically modified organism or food/component derived from it is substantially equivalent to its conventional counterpartapart from certain defined differences. Thirdly, it may not be possible to demonstrate substantial equivalence between the genetically modified organism or food/component derived there from and a conventional counterpart, either because differences are not sufficiently well defined or because there is no appropriate counterpart with which to make a comparison.

While recognizing there may be limitations to the application of the substantial equivalence approach to safety assessment, the Consultation recommended that safety assessment based upon this concept be applied in establishing the safety of food products derived from genetically modified organisms to provide comparable or increased assurance of the safety of food products derived from biotechnology.

There have been three more expert consultations in 2000 and 2001 designed to provide expert advice to the Codex Ad Hoc Task Force (see Codex below), and to FAO and WHO Member Countries. In June 2000 FAO/WHO convened an Expert Consultation on Foods Derived from Biotechnology that reviewed previous FAO/WHO recommendations and strongly re-endorsed the concept of *"substantial equivalence"* as the best method of assessing the safety and suitability of foods derived from biotechnology [11,12].

In January 2001 FAO/WHO held a further Expert Consultation on Foods Derived from Biotechnology, concentrating on the possible allergenicity of such food. This meeting pointed out that no problems with allergenicity have yet occurred with foods derived from biotechnology, mentioned that some food allergens might be removed from foods by future biotechnology developments, devised some suggested methods for testing new foods for possible allergenicity, and again endorsed the concept of *"substantial equivalence"*.

In September 2001 FAO/WHO held a third Expert Consultation on Food Derived From Biotechnology, to consider safety and suitability aspects of genetically modified microorganisms [12]. The report of this session will be published on the FAO website (http://www.fao.org) as have been most of the previous reports. The meeting confirmed in general the recommendations of previous expert consultations, and pointed out some of the special features of genetically modified microorganisms in the human gut. It did not find any causes for immediate concern, recommended a system for evaluating genetically modified microorganisms, and again endorsed the concept of *"substantial equivalence"*.

QUALITY AND SAFETY ASSESSMENT

The use of biotechnological processes, particularly genetic modification, is extremely important in devising new ways to increase food production, increase pesticide resistance and reduce use of pesticides, improve nutrient content, and provide better processing or storage characteristics. It follows that when new foods or food components are developed using biotechnology, there are both national legal requirements and consumer expectations for effective systems and procedures to assess the safety of the food and food component for consumption [13].

With regard to these needs, there is a series of instruments and international regulations in the field of food and agriculture in FAO that deal directly or

indirectly with biosafety and biotechnology related issues which would be of relevance to the quality and safety assessment of foods derived by modern biotechnology [3,13].

FAO PROGRAMMES ON FOOD QUALITY AND SAFETY

The Food Quality and Standards Service is a service within the Food and Nutrition Division of the Food and Agriculture Organization of the United Nations (or FAO), located in Rome. The Secretariat of the Codex Alimentarius Commission is also located here. The Regular Programme of the Food Quality and Standards Service provides the technical and scientific basis for FAO for all food quality matters, including food safety. This includes providing the secretariat for the Joint Expert Committee on Food Additives (or JECFA) and participation in both the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (or JMPR).

The Food Quality and Standards Service of FAO develops and publishes guidelines and manuals (including the FAO Food and Nutrition Series, Manuals of Food Quality Control), arranges expert consultations and conferences (examples of recent consultations include the Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety, 30 September - 4 October 1996; the Joint FAO/WHO Expert Consultation on the Application of Risk Management to Food Safety Matters, 27-31 January 1997; the Joint FAO/WHO Consultation on Food Consumption and Exposure Assessment to Chemicals, 10-14 February 1997; the FAO Consultation on Animal Feeding and Food Safety, 10-14 March 1997; the Joint FAO/WHO Expert Consultation on Risk Communication to Food Standards and Safety Matters, February 1998; and the Joint FAO/WHO Expert Consultation on Risk Assessment of Microbiological Hazards in Foods, March 1999) and has a major and continuing programme of providing technical assistance related to food standards and food control to member countries, particularly developing countries and countries in transition from a centrally planned to a market economy.

Two expert committees, the JECFA and JMPR provide the independent scientific advice that forms the basis for the development of food quality and safety recommendations used in international trade. These committees are fora in which independent, invited experts assess the state of scientific knowledge of food additives, pesticide and veterinary drug residues in food, mycotoxins and other chemical contaminants in food, and make recommendations to member governments and to Codex on such matters.

FAO's Food Quality and Standards Service also develops and publishes Manuals of Food Quality Control which provide recommendations for the development and operation of food quality and safety systems. While aimed primarily at providing advice to developing countries, they document modern approaches including the development of quality control programmes throughout the food chain that are applicable to all countries. Such an approach is instrumental in facilitating international trade in food. Key titles in the series include Food Inspection, Food for Export, Management of Food Control Programmes, Imported Food Inspection and Quality Assurance in the Food Control Laboratory.

The programme of technical assistance projects undertaken by FAO's Food Quality and Standards Service includes assistance in food quality control including safety and such projects have established or strengthened the food control systems in a number of developing countries. Typically, they assist in establishing the infrastructure for an enhanced food control programme, assessing laboratory service requirements, providing guidance to develop legislation and procedural manuals, setting up reputable inspection and certification systems and providing training and staff development. In these assistance projects, the standards established by the Codex Alimentarius Commission are basic guides to international requirements.

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. The CAC is an intergovernmental statutory body of FAO and WHO. Its current membership is 165 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. As mentioned above, risk assessments are carried out by FAO/WHO expert panels of independent scientists selected on a worldwide basis, and the results of their review and deliberations are provided to Codex for use in Codex work, and to FAO/WHO Member Countries [13]. 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.

In 1999, the Codex Alimentarius Commission established the Ad Hoc Intergovernmental Codex Task Force on Foods Derived from Biotechnology to develop standards, guidelines or other recommendations on foods derived from biotechnology. The first Session of the Ad Hoc Intergovernmental Codex Task Force was held in Chiba, Japan from 14 to 17 March, 2000. The second Session was held in Chiba from 26-30 March 2001 [13].

This Task Force is elaborating standards, guidelines or recommendations, as appropriate, for foods derived from biotechnology or traits introduced into foods by biotechnology, on the basis of scientific evidence, risk analysis and having regard, where appropriate, to other legitimate factors relevant to the health of consumers and the promotion of fair trade practices. It must take full account of existing work carried out by national authorities, FAO, WHO, and other international organizations with relevant programmes, in coordination and collaboration with appropriate Codex Committees within their mandate as relates to foods derived from biotechnology. In its second meeting in 2001, the Task Force prepared *"Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology"* and a *"Proposed Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants"*. Both of these documents were discussed and adopted by Codex 5 of the Codex Procedures at the July 2001 24th Session of the Codex Alimentarius Commission. There will be a further discussion of these documents at the 3rd Session of the Task Force in 2002, and, hopefully, agreement will be reached on all aspects of the texts so that final approval at Step 8 of the Codex procedures can be gained at the next Commission Session [8,10,13].

Other Codex Committees such as the Codex Committee on Food Labeling, and the Codex Committee on Food Import Certification and Inspection Systems are discussing biotechnology-related topics such as voluntary or mandatory labeling systems, and means of assuring *"Traceability"* of foods and ingredients for foods (and feeds) derived from modern biotechnology.

The Uruguay Round of Multilateral Trade Negotiations established a new World Trade Organization (WTO) and included negotiations on reducing non-tariff barriers to international trade in agricultural products, and included Agreements on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), and on Technical Barriers to Trade (the TBT Agreement). Both Agreements have implications for the work of the Codex Alimentarius Commission.

The SPS Agreement confirms the right of WTO Member countries to apply measures necessary to protect human, animal and plant life and health provided that *"such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade"*.

With respect to food safety, the SPS references the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, residues of veterinary drugs and pesticides, contaminants, methods of sampling and analysis, and codes and guidelines of hygienic practice [10,13].

Therefore, measures need to be taken with respect to foods to ensure adherence to the Codex maximum levels or guidelines levels for contaminants, and to the Codex maximum residue limits (MRLs) for pesticide and veterinary drugs. Measures also need to be taken to ensure that the appropriate hygienic practices are followed at all stages of the animal feeding chain to prevent, eliminate or reduce potential hazards in the food.

The objective of the TBT Agreement is to prevent the use of national or regional technical requirements, or standards in general, as unjustified technical barriers to trade. It covers all types of standards, including all aspects of food standards other than those related to SPS measures, and includes a very large number of measures designed to protect the consumer against deception and economic fraud. The aspects of food standards it covers relate specifically to quality provisions, nutritional requirements, labelling and methods of analysis. The TBT Agreement basically provides that all technical requirements and regulations must have a legitimate purpose and that the impact or cost of implementing the measure must be proportional to the purpose of the measure. It also places emphasis on international standards. 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).

However, increased scientific, legal and political demands are being made on the standards, guidelines and recommendations elaborated by Codex. This is in part due to increased consumer interest in food safety, the WTO's SPS and TBT Agreements, harmonization initiatives, calls for increased scientific rigour, the need for transparency, and shrinking national regulatory resources.

The CAC is 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 in

this area will be used as guidance for the conditions required for foods prepared from biotechnology [10-13].

OTHER FAO INSTRUMENTS THAT DEAL WITH ISSUES PERTAINING TO BIOSAFETY

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 158 countries and the European Community [8].

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 as explained previously.

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.

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 [10-13]. Therefore, Article 9 on Aquaculture Development deals specifically with these topics, specifically: Article 9.2 on the *"responsible development of aquaculture including culture-based fisheries within transboundary aquatic ecosystems"* and Article 9.3 on the *"use of aquatic genetic resources for the purpose of aquaculture, including culture-based fisheries"*.

The International Plant Protection Convention (IPPC)

Some of the potential environmental risks concern plant pests. The inclusion of pest resistance in plants should be carefully evaluated for potential development of resistance in pests and possible side effects on beneficiary organisms.

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 had its beginnings in 1951 and came into force in 1952. It is recognized as the primary instrument for international cooperation in the protection of plant resources from harmful pests . There are currently 106 governments that are contracting parties to the IPPC.

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.

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 [8-14].

CONCLUDING REMARKS

Biosafety refers to environmental and human health safeguards concerning genetically modified organisms (GMO) produced by modern biotechnology. It should eventually strive to protect resources for food and agriculture, while allowing for their sustainable use, development of international trade and their commercialization.

Adequate biosafety regulations, risk assessment of quality and safety of foods derived from biotechnology, mechanisms and instruments for monitoring use and

compliance are necessary to ensure that there will be no harmful effects on the environment and the health of people.

FAO is at the service of Member States to assist in building capacities and provide technical advice and assistance in priority assignment, resource allocation, and international regulations. FAO also remains at their service for any other interactions that might pertain to food and agriculture.

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