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COMMISSION ON PLANT GENETIC RESOURCES

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**TOWARDS AN INTERNATIONAL CODE OF CONDUCT FOR PLANT BIOTECHNOLOGY AS IT AFFECTS THE CONSERVATION AND UTILIZATION OF PLANT GENETIC RESOURCES**

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## I. INTRODUCTION

1. The FAO Council, in November 1991, endorsed the request of the Commission on Plant Genetic Resources that a draft Code of Conduct on biotechnology as it affects plant genetic resources be prepared for the Fifth Session of the Commission.
2. At the Fourth Session of the Commission it was generally agreed that the Code of Conduct should address *inter alia*: (i) the promotion of sustainable use of biotechnology in the conservation and utilization of plant genetic resources; (ii) the promotion of access to plant genetic resources; (iii) the promotion of biosafety to minimize environmental risks throughout the world; and (iv) the equitable sharing of the benefits of biotechnology between the owners of the technology and the donors of the germplasm it uses.
3. A preliminary draft code has been prepared and is annexed to this document. Inputs have come from many sources. A symposium on "Plant Biotechnology for Developing Countries" was organized by FAO and the Technical Centre for Agricultural and Rural Co-operation in Luxembourg in June 1989. In 1990, the Secretariat of the Commission sent a questionnaire to some 500 experts involved in biotechnology research and development in private companies, national and international organizations, and non-governmental public interest groups. A draft was prepared by experts in a workshop organized by the FAO Regional Office for Latin America and the Caribbean in Santiago, Chile, in December 1991. Its four working groups developed elements for the code on: intellectual property rights; biosafety; the socio-economic impact of biotechnology; and appropriate biotechnology. The views and work of other relevant organizations have been taken into account, for instance an important part of the draft code --Chapter II on "Biosafety and other environmental concerns" -- complements and draws upon the draft elements on biosafety elaborated by the UNIDO/UNEP/FAO/WHO joint working group.
4. The preliminary draft code is organized into four chapters as follows:
  - Chapter I: "Objectives, scope, definitions, nature of the code and its relationship with other legal provisions";
  - Chapter II: "Promoting Biotechnology for the Conservation and Sustainable Utilization of plant genetic resources" including provisions to maximize the positive effects of biotechnology, and to minimize the potential negative effects of biotechnology, as well as to promote access to relevant biotechnologies and to the plant genetic resources to which they are applied;
  - Chapter III: "Biosafety and other Environmental concerns" including provisions for risk assessment and management, particularly with regard to genetically modified organisms related to plant genetic resources for food and agriculture;
  - Chapter IV: Reporting, monitoring and updating.

5. Since the last meeting of the Commission, a number of discussions and agreements on policy matters related to biotechnology including those which affect the conservation and use of plant genetic resources have taken place particularly in the context of UNCED Agenda 21, the Convention on Biological Diversity and associated complementary resolutions. Other important fora include the General Agreement on Tariffs and Trade (GATT), and the International Union for the Protection of New Varieties of Plants (UPOV).

6. On the one hand, many of these developments, reaffirm and reinforce the need for international agreements on the issues addressed in the proposed code. On the other hand, some of the developments may affect some of the reasons behind the recommendations of the Commission to prepare a draft Code as well as the issues it should consider and the strategy it should follow. By changing some of the premises of the rationale for a code, these changes have also augmented the already difficult task of the Secretariat in complying with the mandate of the Commission to prepare a draft code which addresses so many diverse issues. Therefore the draft annexed to this paper should be considered as a preliminary one only. The Commission might wish to take into account recent developments, before taking further steps to elaborate a draft code or deciding on other ways forward (such as, for example, proposing the use of elements of the draft Code in the development of other instruments). In order to facilitate the discussions of the Commission, this document also reviews recent relevant agreements and processes which bear on the subject of the proposed code, and presents issues and options for further consideration of the Commission.

## II. ISSUES AND OPTIONS CONCERNING THE DEVELOPMENT OF THE PROPOSED CODE

### A. Promoting Biotechnology for the Conservation and Sustainable Utilization of PGR

#### *(1): Maximizing Positive Effects and Minimizing Possible Negative Effects of Biotechnology*

7. The Commission has earlier recognized the great potential of the new biotechnologies as tools for increasing food production to feed growing populations, and in promoting sustainable agriculture. However, it has also recognized that since research in new biotechnologies is mainly conducted in industrialized countries, and therefore focused on their needs and on major crops, developing countries may not necessarily benefit from them fully. Also since the technologies would be likely to become available first in developed countries, it is considered that agriculture in the developing countries might suffer from a reduced competitiveness, at least in the short run.

8. The Commission felt that the potential advantages of biotechnology should be made available to the developing countries, particularly through a focus on:

- crops of great social and economic importance though not necessarily of international market importance;

- the needs of local farming systems including low-external-input systems;
- training of scientists and technicians.

The Commission, in recognizing possible negative downstream effects of the new biotechnologies, for example by commodity substitution, suggested that an objective of the Code should be to help minimize the economic distortions produced in various countries and regions as a result of the application of the new biotechnologies, particularly changes in patterns of international trade. (CPGR/89/Rep para 48, and CPGR/91/Rep para 102-5)

9. Chapter II of the preliminary draft code addresses these points. Measures for maximising the opportunities by developing countries for deriving the benefits from biotechnologies are proposed in Articles 5, 6 and 7. Article 5 proposes action to promote the development of appropriate technologies. Article 6 proposes action to be undertaken at the national level, with an emphasis on research and training. This is supported in article 7 by proposals for international cooperation. Article 8 includes measures to foresee and prevent or mitigate possible negative effects, both socio-economic and environmental which might be introduced by countries in the context of mechanisms for technology assessment.

10. It is envisaged that the World Information and Early Warning System on PGR (PGR/WIS)<sup>1</sup>, one of the main components of the Global System, would act as a focal point for the exchange of information relevant to Chapter II of the draft code in line with the objectives of the PGR/WIS (formally PGR/GIEWS, CPGR/91/7 para 12). In line with this, Article 10 of the preliminary draft code presents activities which could be carried out by the PGR/WIS to promote appropriate biotechnologies for the conservation and utilization of plant genetic resources and thereby help to make operational the proposed Code, particularly Articles 5, 6 and 7.

11. In the preliminary draft code it is proposed that governments should consider establishing mechanisms to make available assistance (i) to promote the use of appropriate technologies (Art. 7.2), and (ii) to mitigate against negative socio-economic effects of the new biotechnologies, particular as they affect farming communities (Art 8.4). Technical and financial assistance might be provided through existing or already approved funding mechanisms. Such assistance might be designed, *inter alia*, to facilitate access by the affected communities themselves to the new technology, or to promote alternative forms of development.

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1. The term and acronym "World Information and Early Warning System for Plant Genetic Resources (PGR/WIS)" is proposed rather than the previously used term and acronym of "Global Information and Early Warning System for Plant Genetic Resources (GIEWS/PGR)" to avoid confusion with either the "Global System" itself or the "Global Information and Early warning System" on food security (GIEWS).

12. Many issues related to Chapter II of the code are included in Agenda 21<sup>2</sup>, and the transfer of biotechnologies is addressed by the Convention on Biological Diversity. The advice of the Commission is sought on (i) the role of the Commission in addressing these issues; (ii) prioritizing the issues; and (iii) which issues should be retained within the context of a Code of Conduct and which should be developed through other mechanisms.

*(2): Access and Sharing the Benefits of PGR and related technologies;  
intellectual property rights (IPRs) and Farmer' Rights.*

13. The Commission in noting the large number of legal, ethical, and political implications of the new biotechnologies, has expressed concern about their possible negative consequences. It has recognized that intellectual property rights (IPRs) should not become an obstacle to the exchange of germplasm, information and technology for scientific purposes, and that any system of IPR system pertaining to PGR should be equitable and take account the rights of informal innovators, including farmers, who had domesticated crops and developed landraces (CPGR/89/Rep para 50 and CPGR/91/Rep para 100).

14. The preliminary draft code addresses, within Chapter II, the issue of access to genetic resources and technologies including the role of IPRs (Article 9) as requested by the Commission. The provisions proposed here are concerned specifically with the needs of farmers and breeders for access to plant genetic resources and with balancing the rights of informal innovators with those of formal innovators. The Commission may wish to advise on what other matters related to access, sharing of benefits and IPRs should be included in the code, or addressed by other means.

15. On the subject of sharing the benefits derived from plant genetic resources through biotechnologies, the Convention on Biological Diversity makes a number of provisions mainly on a bilateral basis<sup>3</sup>. Within the context of the Global System, the agreement that: "Farmers' Rights will be implemented through an international fund on plant genetic resources" (Res C 3/91) will also contribute to the sharing of the benefits, and will be given further impetus by the development of a Global Plan of Action on PGR through the International Technical Conference on PGR and its preparatory process (see CPGR/93/10). While these issues need to be developed further within the context of the

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2. For example, chapter 16 of Agenda 21 on "Environmentally Safe Management of Biotechnology" outlines objectives and activities in five programme areas, one of which is "Increasing the availability of food, feed and renewable materials". This programme includes international and regional cooperation to promote collaborative research programmes in biotechnology with particular reference to cooperation with local and indigenous people and their communities, and the acceleration of technology acquisition, transfer and adaptation by developing countries.

3. The Convention provides for the sharing of benefits derived from genetic resources with the country of origin, or the country providing such resources where they have been acquired in accordance with the Convention (see CPGR/93/7).

Global System<sup>4</sup>, it may not be necessary for all to be addressed in the context of a Code of Conduct on Biotechnology.

16. On the subject of IPRs, there are a number of recent and ongoing discussions in other fora such as the World Intellectual Property Organization (WIPO)<sup>5</sup> and the General Agreement on Tariffs and Trade (GATT)<sup>6</sup>, as well as in the International Union for the Protection of New Varieties of Plants (UPOV)<sup>7</sup>, which the Commission may wish to take into consideration (these discussions are reflected in the footnotes below). It should be noted that these other fora do not have the goal or mandate to deal with the full range of issues involved on plant genetic resources. However, the Commission has not had the opportunity to take into account fully the developments in these fora. The Commission might consider therefore the need for further studies on these matters in order to clarify the issues, and to hold further discussions in order to suggest possible solutions, and to define further the Commission's role.

### B. Biosafety and other Environmental Concerns.

17. The Commission recognized that the safe use of modern biotechnology called for the establishment of adequate regulations. It felt that with respect to biosafety, the code could include provisions for ensuring the responsible use of the new biotechnologies; the setting of basic standards for the testing, importation and exportation, and commercial use of genetically modified organisms (GMOs); and ensuring that the release of GMOs is based on a sound and comprehensive scientific assessment, which includes an analysis

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4. "Resolution 3" on the "Interrelationship between the Convention on Biodiversity and the Promotion of Sustainable Agriculture", approved as part of the Nairobi Final Act, noted the need to seek solutions to the "outstanding matters" of access to existing *ex situ* collections of genetic resources and the question of farmers' rights within the context of the Global System (see CPGR/93/7).

5. A draft treaty on patent harmonization, which would extend patentability to all inventions, is being elaborated by WIPO. National patent systems which currently provide for exclusions for food, pharmaceuticals and for living organisms, would need to be revised for countries adhering to the new treaty.

6. Trade Related Intellectual Property Rights (TRIPs) are being negotiated within the framework of the Uruguay Round of trade negotiations under the auspices of GATT. The latest complete draft of an agreement on TRIPs (December 1991) proposes that parties shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system (such as the plant breeders' rights system of UPOV).

7. In March 1991 the Convention for the Protection of New Varieties of Plants was revised at a Diplomatic Conference under the auspices of the International Union for the Protection of New Varieties of Plants (UPOV). The UPOV Convention applies to plant breeders' rights (PBR) enforced in several countries, mostly developed ones. In the revised Convention the right to freely use protected varieties for further breeding "the breeder's exemption" will no longer be automatically provided for; permission of the variety holder may be necessary to market any modified form considered as "an essentially derived variety". Similarly, the right of farmers to resow seed of protected varieties "the farmers' exemption" is no longer guaranteed. Varieties protected under the revised UPOV system will also be open to protection under national patent systems. Thus the revisions will have important implications for access to genetic resources in protected varieties.

of ecological and other risks. The Commission, recognizing that many countries had insufficient scientific expertise and resources to adequately evaluate the risks of proposed releases, considered that the Code could provide for an international mechanism to develop national capabilities and to offer technical and financial assistance. (CPGR/91/Rep para 97-9)

18. Chapter III of the preliminary draft Code addresses the points identified by the Commission. It proposes that governments designate appropriate authorities for biosafety (Article 11) and that there should be international cooperation to facilitate this (Article 12). Further articles detail procedures for risk assessment, management, and monitoring (Articles 13 & 14), and for the transport, import and export of genetically modified organisms (Article 15). It proposes that programmes of public education be held (Article 16). The scope of the code (Article 2) is limited to the effects of plant biotechnology and the effects of other organisms modified by biotechnology in cases where they might have adverse effects on plant genetic resources.

19. Since the last meeting of the Commission, the UNIDO/UNEP/WHO/FAO working group on biosafety has finalized a "Voluntary Code of Conduct for the Release of Organisms into the Environment". The UNIDO Code offers general provisions covering the full range of GMOs both in the field and in the laboratory, and is not concerned, in particular, with those of relevance to plant genetic resources.

20. UNEP has initiated preparatory work for the elaboration of a possible protocol on biosafety to the Convention on Biological Diversity<sup>8</sup>. Such a possibility is envisaged in the Convention<sup>9</sup>, and in Agenda 21<sup>10</sup>. The Commission might wish to consider the possibility of submitting Chapter II, or a revised form thereof, to the Intergovernmental Committee for the Convention on Biological Diversity (ICBD). The Commission may also wish to consider what specialized input it might make to the ICBD, for example on the prevention of genetic erosion.

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8. Panel 4 of the expert panel meeting on biodiversity convention follow-up, December 1992 and February 1993.

9. Article 19.3: "the Parties shall consider the need for (...) a protocol (...) in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biotechnology". The Resolution "International Cooperation for the conservation of biological diversity and the sustainable use of its components pending the entry into force of the Convention on Biological Diversity", agreed as part of the Nairobi Final Act suggests that the Intergovernmental Committee on Biological Diversity should consider this matter (see CPGR/93/7).

10. Chapter 16 of Agenda 21 includes a recommendation for international cooperation on biosafety". The programme area on "Enhancing safety and developing international mechanisms for cooperation" includes a statement that "there is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level".

### III. MAIN AREAS WHERE THE GUIDANCE OF THE COMMISSION IS SOUGHT

21. From the foregoing discussion it is clear that while recent agreements and developments may strengthen the need for measures on biotechnology as it affects plant genetic resources, there are now a number of processes taking place in other fora which are also dealing with these issues. In view of this, the Commission may like to consider the following points:

- (i) whether a code of conduct on biotechnology is the most appropriate way of treating the different issues presently covered by the preliminary draft or whether some of them may be better treated as guidelines or in other ways;
- (ii) whether the different matters (maximizing benefits; minimizing potential negative effects, IPRs, biosafety etc) should be all addressed by a single code on biotechnology or whether they should be separated;

More specifically, guidance of the Commission is sought on:

- (iii) whether the Chapter III of the draft Code, on "Biosafety and other environmental concerns", might be developed separately, and possibly as an input to the Intergovernmental Committee on the Convention on Biological Diversity (ICBD) for the elaboration of a protocol to the Convention;
- (iv) the need for further studies, consultations and discussions on various matters included in Chapter II "Biotechnology for the conservation and utilization of plant genetic resources", in the light of UNCED and in full consultation with other organizations;
- (v) in particular, the need for further studies and/or discussions on the issues of access to genetic resources and of the equitable sharing of the benefits (including the implications of intellectual property rights), taking into account the provisions already included in the Convention, but also addressing the issues left unresolved (the outstanding issues of access to existing *ex situ* collections and Farmers Rights as identified by Resolution 3 of the Nairobi Final Act), as well as developments in other fora.



Annex

**PRELIMINARY DRAFT INTERNATIONAL CODE OF CONDUCT  
ON PLANT BIOTECHNOLOGY AS IT AFFECTS THE CONSERVATION AND  
UTILIZATION OF PLANT GENETIC RESOURCES**

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## ELEMENTS FOR A PREAMBLE

*noting* that the new biotechnologies have a great potential for increasing food production and for promoting agricultural development;

*reaffirming* that plant genetic resources, and the information, technologies and funds necessary to conserve and utilize them, are all important and complementary; and that all nations are donors and users of plant genetic resources, information, technology and/or funds;

*recognizing* that the use, the conservation and the exchange of plant genetic resources are increasingly affected by the new biotechnologies and in particular by plant biotechnologies;

*recognizing* the need to promote a safe and responsible use of, and equitable access to, plant biotechnologies;

*recognizing* the need to promote the development and transfer of appropriate biotechnologies related to plant genetic resources and the assessment of their impacts so as to minimize environmental and socio-economical risks throughout the world;

*reaffirming* that plant genetic resources are a common concern of humanity and that nations have sovereign rights over their plant genetic resources in their territories;

*reaffirming* that plant genetic resources should be available for plant breeding and other scientific purposes of human benefit;

*noting* that a good way to promote the maintenance of plant genetic resources is to ensure their effective and beneficial utilization, in all countries;

*noting* that the farmers of the world have, over the millennia, domesticated, conserved, nurtured, improved and made available plant genetic resources, and continue to do so today;

*recognizing* the need to promote a balanced recognition of the rights of informal innovators, including farmers who develop landraces, and of formal innovators who are protected by intellectual property rights;

*noting* that advanced technologies, and local rural technologies, are both important and complementary in the conservation and utilization of plant genetic resources.

## CHAPTER I

### **Objectives, scope, definitions, nature of the Code, and its relationship with other legal provisions.**

#### Article 1: Objectives

The Code has the following objectives:

- 1.1 to promote the use of biotechnologies for the conservation and sustainable utilization of plant genetic resources in food production and agricultural development, especially in developing countries;
- 1.2 to provide recommendations for the safe, responsible and equitable use of biotechnologies, for agriculture and food by researchers and commercial users in the public and private sectors as well as governments;
- 1.3 to facilitate access to plant genetic resources so that they can be explored, characterized, preserved, evaluated and made available for breeding and scientific purposes, through biotechnological and other means;
- 1.4 to facilitate the flow of information and access to biotechnologies as applied to agriculture and food;
- 1.5 to balance the rights of formal and informal innovators;
- 1.6 to help assess and minimize possibly adverse socio-economic effects of biotechnology in agriculture and the food industry on farming communities and the economies of developing countries;
- 1.7 to ensure that the environmental impact of innovations in biotechnology in agriculture and food industry are fully assessed and measures taken to minimize and mitigate them;
- 1.8 to advance international cooperation in the use and application of safeguards for agricultural and food biotechnology;

#### Article 2: Scope

The scope of the code is limited to biotechnologies as they affect the conservation and utilization of plant genetic resources. It is also limited to the "new" biotechnologies as defined in Article 3. All such plant biotechnologies come within the scope of the code, since by definition, they utilize plant genetic resources. Other biotechnologies are included only if they affect, or are likely to affect, the conservation or utilization of plant genetic resources. In particular, measures on biosafety apply to plants modified by biotechnologies as well as to microorganisms and other organisms modified by

biotechnologies in cases where they might have adverse affects on plant genetic resources.

### Article 3: Definitions

For the purpose of the Code, the following definitions apply, within the scope set out in Article 2:

**Advance Informed Agreement**<sup>11</sup> refers to the principle that international exchange of transgenic plants and microorganisms that could adversely affect plants should not proceed without the informed agreement of, or contrary to the decision of, the competent authority in the recipient country.

**Appropriate biotechnologies** means biotechnological tools which contribute to sustainable development in that they are technically feasible, bring tangible benefits to the users and are environmentally safe, socio-economically and culturally acceptable. In the context of this code the term "appropriate biotechnologies" refers in particular to technologies which promote the development of a sustainable agriculture through the rational use of plant genetic resources while properly considering local culture and techniques.

**Biodiversity** means the variability amongst living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are a part; this includes diversity within species, between species and of ecosystems<sup>12</sup>.

**Biosafety** means safety aspects related to the application of biotechnologies and to the release into the environment of transgenic plants and other organisms particularly microorganisms that could negatively affect plant genetic resources, plant, animal or human health, or the environment.

**Biotechnology** means a set technologies, including, but not necessarily confined to, tissue culture and recombinant DNA techniques, used to exploit and modify living organisms so as to produce new tools, goods and products<sup>13</sup>.

**Competent authority** means a government agency or agencies responsible for regulating biotechnology, biosafety, intellectual property rights and other relevant aspects.

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11. "Advanced informed agreement" is the term used in the Convention on Biological Diversity; it refers to the same concept as "Prior Informed Consent".

12. This definition is taken from the Convention on Biological Diversity.

13. This definition is narrower than the one in the Convention on Biological Diversity. In effect it is restricted to the "new" biotechnologies.

**Deliberate release** means introduction into the environment for scientific or commercial purposes of transgenic plants and microorganisms.

**Donors of germplasm** means countries and communities that have conserved or improved plant genetic resources and made them available to others.

**Farmers' rights** means rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustees for present and future generations of farmers, for the purpose of ensuring full benefits to farmers and supporting the continuation of their contributions, as well as the attainment of the overall purposes of the International Undertaking<sup>14</sup>.

**Formal innovators** means each physical or juridical persons developing new technologies and products, that could be a private or a researcher working in formally recognized governmental or non-governmental institutions whose inventions may be formally recognized through the intellectual property rights system. "Formal innovators" are essentially scientists working in public or private institutions.

**Genetically modified organisms** means any living organism whose genome has been modified through genetic engineering technologies.

**Germplasm or genetic material** means the botanical seeds, pollen or any vegetatively propagating material of plants, including cultivated cells, tissues and organs.

**Informal innovators** means countries, communities and individuals, generally working at the local level, that have through generations developed and conserved local technologies and products including plant genetic resources without having obtained formal recognition of their innovative labour or right related to it. "Informal innovators" are farmers and local communities who have, often over generations, contributed to the collection, improvement and preservation of genetic material.

**Intellectual property rights** means proprietary rights, including but not limited to Plant Breeders' Rights and patents, granted to individuals in order to stimulate formal innovation and to promote investment by, and secure rewards, to innovators in the public and private sectors.

**Plant genetic resources** means the genetic material of plants which is of value or potential value for present and future generations of people.

**Public sectors groups** means (but is not limited to) scientific associations; farmers' groups; citizens' organizations; environmental, consumer and health organizations; other non-government organizations; and labour unions.

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14. As defined in FAO Resolution 5/89.

**Risk** means the expected frequency and severity of undesirable effects due to the introduction into the environment of transgenic plants and microorganisms that could affect plants.

Article 4: Nature of the Code and relationship with other legal provisions

4.1 The Code is voluntary.

4.2 The provisions of this Code should be promoted through collaborative actions by governments, appropriate organizations and professional societies.

4.3 The Code is addressed primarily to governments. It also addresses regional, supra-national and international organizations; researchers and research institutions, scientific associations; agro-industry including the biotechnology industry; the seed trade; trade associations; local communities, farmers, and public sector groups.

4.4 FAO and other relevant organizations are invited to observe the Code<sup>15</sup>.

4.5 The Code should periodically be updated to reflect the changes in the scientific, technological, ecological, economic and social environments.

4.6 The Code is to be implemented in harmony with:

- a) the Convention on Biological Diversity and other legal instruments protecting biological diversity or parts of it;
- b) the International Plant Protection Convention (IPPC) and other agreements restricting the spread of pests and diseases;
- c) other international agreements and understandings setting biosafety standard for the release, import and export of genetically modified plants and microorganisms; and for protecting biological diversity and plant genetic resources<sup>16</sup>; and
- d) the national laws of the host country.

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15. Other relevant organizations include the United Nations Environment Programme (UNEP), the United Nations Development Programme (UNDP), the United Nations Industrial Development Organization (UNIDO), the World Health Organization (WHO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the Consultative Group on International Agricultural Research (CGIAR), in particular the International Board for Plant Genetic Resources (IBPGR), the World Bank and other funding agencies, and national and international agricultural and biotechnology research institutions

16. such as the Voluntary Code of Conduct for the Release of Organisms into the Environment prepared by the Informal Working Group on Biosafety established by the United Nations Industrial Development Organization (UNIDO), the World Health Organization (WHO), the United Nations Environment Programme (UNEP) and FAO; the guidelines developed by the Organization for Economic Cooperation and Development (OECD) such as the Good Developmental Practice for small scale field research with genetically modified plants and microorganisms.

## CHAPTER II

### **Promoting Biotechnology and the Conservation and Sustainable Utilization of PGR; Maximizing Positive Effects and Minimizing Possible Negative Effects of Biotechnology**

#### Article 5: Promotion of Appropriate Biotechnologies

5.1 Governments, regional, and international organizations, researchers and research and educational institutions, industry and public sector groups should promote the transfer and development of appropriate biotechnologies applied to plant genetic resources that could contribute to improve living conditions, especially of developing countries, by increasing income and employment, reducing the need for external inputs or reducing their costs, supporting more stable and durable development, and preserving the environment and resources. Particular attention should be given to the meeting the needs of local farming systems.

5.2 Developers of relevant biotechnologies should support efforts directed to applying their discoveries to the needs of developing countries and the donors of germplasm, seeking to ensure that the improvements in human welfare which they bring are combined with the development of more sustainable agricultural systems, including the use of low-input systems and the enhancement of traditional crops.

#### Article 6: Action at the National Level

Governments should take actions to develop policies and programmes in agricultural and food biotechnologies focused on their incorporation into sustainable production systems in agriculture. In particular, they should:

6.1 establish committees for appropriate biotechnology or similar fora in which members from different disciplines and representing related interests can assess the needs for and likely benefits and other impacts of relevant biotechnologies and their influence on the productivity and sustainability of prevailing agricultural systems;

6.2 establish national research programmes in appropriate plant biotechnologies linking them to efforts to improve sustainable agriculture and to promote the conservation of plant genetic resources and biodiversity;

6.3 support research to define more clearly appropriate biotechnologies as they apply to agriculture, through a special focus on local needs and local farming systems, *inter alia* through the participation of representatives of farming communities and of public sector groups;

6.6 establish specific educational programmes for training of national and foreign scientific and technical experts in appropriate biotechnologies and sustainable agriculture.

Article 7: International Cooperation in Appropriate Biotechnologies

7.1 Governments, researchers and research institutions, industry and public sector groups should contribute to promote international cooperation for the development of appropriate agricultural and food biotechnologies and sustainable agriculture, in particular through:

7.1.1 the strengthening of international plant biotechnology programmes and existing networks and the establishment of new ones that could promote and help the exchange of scientific information on technical advances in appropriate biotechnologies for more productive, efficient and sustainable agriculture in developing countries;

7.1.2 promoting the exchange of technologies, expertise, experts, materials and plant genetic resources among countries;

7.1.3 helping developing countries to develop their own scientific and technical capacity in appropriate biotechnology, as applied to the sustainable exploitation of plant genetic resources, to the benefit of farming communities, *inter alia* through training programmes and the provision of international grants for research;

7.1.4 joint efforts to develop and apply new biotechnologies for the long-term conservation of plant genetic resources and biodiversity.

7.2 Governments and international organizations should cooperate to promote the establishment of an international mechanism to fund research and development programmes in appropriate biotechnologies as they apply to the sustainable utilization of plant genetic resources.

Article 8: Prevention and Mitigation of Possible Negative Effects

8.1 In order that they can act to foresee and prevent possible negative socio-economic effects of agro and food biotechnologies, Governments and international organizations should develop, as part of their procedures for Technology Assessment, monitoring and assessments of the socio-economic impacts of biotechnologies, in particular on developing countries and local communities.

8.2 Governments and international organizations should act to foresee and prevent possible negative long-term environmental effects of biotechnologies and, in particular, genetic erosion and the narrowing of the genetic basis of cultivated crops. Such task should be pursued through adequate monitoring and assessment of long-term environmental impact of biotechnologies, as part of normal procedures for technology assessment.

8.3 In order to minimize the possibility of negative effects of biotechnologies on genetic diversity, governments and international organizations should consider the need to widen



the genetic basis of the crops used in both prevailing and sustainable agricultural systems, in particular through the recovery of traditional and local crops.

8.4 Governments should consider the establishment of mechanisms to provide technical and financial assistance to affected farming communities and countries to mitigate adverse socio-economic effects due to particular developments in biotechnology.

Article 9 Access to Plant Genetic Resources and related biotechnologies: intellectual property rights, and compensation for informal innovators.

9.1 Governments shall endeavour to create conditions to facilitate access to plant genetic resources, to be explored, characterized, preserved, evaluated and made available for genetic improvement of cultivated crops, as well as to related biotechnologies. Access should be on mutually agreed terms with proper compensation for both formal and informal innovators.

9.2 Governments will cooperate to ensure that intellectual property rights (IPRs) on the products of biotechnologies do not unduly restrict the exchange of and access to plant genetic resources, including by farmers, breeders and scientists.

9.3 In particular, mechanisms and modalities should be developed to ensure that farmers, especially in developing countries, are guaranteed the right to reuse the seeds collected from their own harvests, including those obtained from protected varieties.

9.4 Governments should cooperate to develop mechanisms which provide effective incentives and/or compensation to informal innovations, that are not guaranteed by the formal intellectual property rights<sup>17</sup>.

9.5 Governments should also take initiatives to support informal innovation by:

- directing national and international research efforts on plant genetic resources, agriculture and biotechnology towards the needs of local farming systems;
- facilitating the participation of the farmers and local communities in deciding research and development activities on plant genetic resources, agriculture and biotechnology.

Article 10: Exchange of Information and Early Warning

10.1 The World Information and Early Warning System on Plant Genetic Resources (PGR/WIS) will be the focal point for the exchange of information related to the implementation of this Code.

10.2 Through its dissemination of information the WIS/PGR will support the development of appropriate biotechnologies for the sustainable use of plant genetic resources and biodiversity, in particular:

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17. such as through the International Fund for Plant Genetic Resources, referred to in FAO Resolution 3/91 that has now become the third annex to the International Undertaking on Plant Genetic Resources

- 10.2.1 to promote research aimed at defining more precisely criteria and indicators of the contribution of biotechnology to sustainability in agriculture and use of plant genetic resources. Such criteria should include both scientific (i.e. protection and development of biodiversity) and socio-economic aspects (i.e. whether innovations fit local farming systems);
  - 10.2.2 to promote and organize the training of scientific and technical experts in appropriate biotechnologies relevant to sustainable agriculture;
  - 10.2.3 to provide information on the activities of scientific networks on appropriate biotechnologies and their contribution to the development of sustainable agriculture;
  - 10.2.4 to provide information about international funds and financing mechanisms available for specific and international research and development projects of appropriate biotechnologies for sustainable agriculture;
  - 10.2.5 to promote the exchange of technologies, expertise, experts, materials and plant genetic resources between countries;
  - 10.2.6 to publicize international and national efforts to develop and apply new biotechnologies for the conservation of plant genetic resources and biodiversity;
- 10.3 Within the PGR/WIS the Early Warning System will:
- monitor biotechnology research that could affect biodiversity and plant genetic resources;
  - assess possible future developments and highlight possible adverse effects;
  - identify crops and farming communities at risk due to changes related to the introduction of biotechnologies;
  - notify governments of the eventual risks for crops, farming communities, and human and animal health.

### CHAPTER III

#### Biosafety and other Environmental Concerns

##### Article 11: Environmental Risks from the application of plant biotechnologies

Governments should designate the competent national authorities to review, assess, implement and monitor biosafety and other environmental concerns such as genetic erosion and agroecological disruption due to the introduction of biotechnological products. In particular, they should:

- 11.1 establish a National Committee on Biosafety and Other Environmental Concerns, including experts of related scientific disciplines and representatives of the different interests that could be affected;

11.2 elaborate specific laws and regulations;

11.3 when such specific laws and regulations are lacking, identify in existing legislation adequate mechanisms for guaranteeing biosafety, such as quarantine procedures regulating import, production or dissemination of new organisms;

11.4 collect, record and disseminate information on local conditions relevant to the safe development and application of new plant biotechnologies, such as data on vulnerability of the environment, local plant genetic resources (diversity and extent of erosion) and agricultural systems;

11.5 establish a mechanism to control and monitor deliberate releases and enforce laws and regulations on biosafety.

#### Article 12: International Cooperation

12.1 Considering that plants, and other organisms that could adversely affect plant genetic resources, modified by genetic engineering or not, do not respect national borders, countries should cooperate at regional and international levels to ensure an effective prevention of the risks associated with the application of biotechnologies to plant genetic resources and the deliberate release of transgenic plants and other organisms that could adversely affect plant genetic resources.

12.2 Countries lacking the scientific and technical expertise needed for guaranteeing biosafety should seek assistance from the United Nations system and other international organizations, through regional cooperation and from countries, industries, research centres and Universities involved in the handling transgenic plants and other organisms that could adversely affect plant genetic resources.

#### Article 13: Risk Assessment and Procedures for Authorization

13.1 Countries should ensure that there is a full review and risk assessment by both the proposer and the competent authority, of biotechnological applications to plant genetic resources and the deliberate releases of transgenic plants and other organisms that could adversely affect plant genetic resources.

13.2 The review according to article 13.1 should precede the authorization by the national authority,

13.3 The review and the risk assessment should be conducted on a scientifically sound basis and consider possible negative consequences for human and animal health and the environment, including agroecosystems, possible erosion of plant genetic resources and biodiversity.

13.4 The proposer's request for authorization should provide all information needed to assess health and environmental risks, in particular information on:

13.3.1 biological properties of the genetically modified organism, including genetic, morphological, physiological and agroecological characteristics of the parental organism, the characteristics of the genetic material introduced, both genes and vectors, and details of any previous release of the same organism;

13.3.2 size, location, geographical, climatic and agroecological characteristics of the environment into which the transgenic plant or microorganism will be introduced, with particular reference to potential risks to plant genetic resources and biodiversity;

13.3.3 the protocol of the proposed release, whether within national borders or not, including the method, the quantities of organisms to be released and details of any previous release at the same site;

13.3.4 the proposed procedures for containment, control, monitoring, wastes management at the end of the release and emergency response;

13.3.5 details on releases previously planned but not carried out along with the corresponding authorization or refusal, in the same as in other countries.

13.5 The assessment procedure should proceed on a case-by-case basis, considering the risks associated with each deliberate release.

13.6 Risk assessment should proceed on a step-by-step basis; this means that each step of the deliberate release should be evaluated, from the laboratory to small scale release and adequate tests preceding marketing of the novel product. Containment measures could be gradually reduced in each step, only if the effects of the tests conducted in the previous step justify it.

13.7 Details and depth of required information should be proportional to the estimated degree of risk; the competent authority can ask the proposer to provide further information.

13.8 The proposer should record and maintain records of all data regarding the preparation phase of the deliberate release, information useful for risk assessment, protocols, results, and monitoring data.

13.9 Liability for eventual environmental damages due to the deliberate release of a transgenic plant or of a microorganism that could affect plants should be specified in the authorization by the national competent authority.

#### Article 14: Risk Management and Monitoring

14.1 Once approved, the release must be conducted and implemented in such a way as to minimize the possible negative effects and the dispersal of transgenic plants, parts of plants, pollen, and organisms which affect plant genetic resources.

14.2 The step-by-step principle should apply also to risk management: the protocol of the release, containment measures and condition for the release should match the potential risks, looking for absence or control of reproduction, absence of transfer of genetic material and dispersal of biological material beyond the test site. Any scale-up of a deliberate release should be evaluated and authorized on the basis of the results of experiments conducted in the previous steps.

14.3 The proposer must ensure adequate and proportional monitoring of the actual effects that the organisms have had on the environment. In particular it is recommended:

14.3.1 that data on the actual effects of the deliberate release of a transgenic plant or a microorganism that could affect plants are compared with the expected effects;

14.3.2 that data on the actual effects on other species and varieties, with particular reference to plant genetic resources and biodiversity, are adequately monitored;

14.3.3 that unexpected effects of the deliberate release of a genetically modified plants or microorganism that could adversely affect plant genetic resources are notified to the competent authority;

14.3.4 that information regarding eventual negative effects are proportional to the degree of risk.

14.4 Governments and competent authorities should inform the competent authority of countries that could be affected by negative and unexpected consequences of a deliberate release.

#### Article 15: Transport, Import, Export and Advance Informed Agreement

15.1 Governments and competent authorities should ensure that adequate containment measures are respected during transportation of transgenic plants and other organisms that could adversely affect plant genetic resources.

15.2 No transgenic plants or other organisms that could adversely affect plant genetic resources intended for release should be imported into a country without that country's Advance Informed Agreement. The Advance Informed Agreement procedure should apply to all transgenic plants and other organisms that could affect plants independently of the risk assessment and authorization for release in the exporting country. Such Prior Informed Consent procedure requires:

15.2.1. a preliminary risk assessment by the competent authority of the exporting country;

15.2.2 the notification to the competent authority of the exporting country, together with all information needed to properly assess risk;

15.2.3 the level of the preliminary risk assessment by the competent authority of the exporting country and of the information provided to the competent authority of the importing country should be proportional to the expected degree of risk;

15.2.4 full authorization by the competent authority of the importing country.

15.3 A government that does not authorize the handling or release of transgenic plants or other organisms that could affect plant genetic resources in order to protect human health or the environment should notify the parties concerned and the Commission on Plant Genetic Resources as soon as possible after the action it has taken.

15.4 A transgenic plant, or microorganism that could adversely affect plant genetic resources, whose release has not been authorized in a country for its pathogenic effects on human health, animal and plants, independently of the environment, could be exported only following a specific request of the competent authority of the importing country.

15.5 If export of transgenic plants and other organisms that could affect plant genetic resources occurs without notification and authorization by the competent authority of the importing country, the country of export should inform the Commission on Plant Genetic Resources, as well as the importing country with relevant information on the material in questions.

15.6 Within the context of the PGR/WIS a data base of actions taken by member governments will be developed and national competent authorities and relevant international organizations will be informed of notification received under Article 15.3.

#### Article 16: Public Information

16.1 The public should be informed about possible risks for the environment and health; governments and competent authorities should apply transparent procedures in risk assessment, giving access to all the information that could be of public interest.

16.2 About specific deliberate releases, governments and public authorities should inform and consult the public, in particular local and farming communities that could be affected by the release.

16.3 National government should organize adequate programmes for public education and information on plant biotechnologies, in particular on recombinant technologies applied to plant genetic resources, and the associated risks.

## CHAPTER IV

### Reporting, Monitoring and Updating

#### Article 17: Reporting by Governments

17.1 Governments should inform the Commission on Plant Genetic Resources, through its Secretariat in FAO, of actions taken with regard to the application of this Code and on the state of application of the present Code of Conduct through periodic reports.

17.2 In particular, Governments should inform the Commission on Plant Genetic Resources on the positive results of their efforts directed to develop appropriate biotechnologies as applied to plant genetic resources, and on any negative effects, both environmental and socio-economic, due to the application of the new biotechnologies.

17.3 In case of non-observance by industries or researchers of the rules and regulations of a host country regarding the safe, responsible and equitable use of agro and food biotechnologies, governments and public sector groups should inform the Commission on Plant Genetic Resources. The industry and the researcher should receive copy of this communication and have the right to reply. This process should have the aim of settling any differences that may have arisen.

#### Article 18: Monitoring and Evaluating

18.1 Appropriate national and international authorities should periodically review the relevance and effectiveness of the Code. The Code should be considered a dynamic text that may be brought up to date as required, to take into account technical, economic, social, ecological, ethical and legal developments and constraints.

18.2 Professional associations and societies accepting the principles embodied in this Code could establish peer review ethics committees to consider their members' compliance with the Code.