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BIOLOGICAL AND PLANT GENETIC RESOURCES AND ELEMENTS OF A CODE OF CONDUCT FOR BIOTECHNOLOGY

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BIOTECHNOLOGY AND PLANT GENETIC RESOURCES, AND ELEMENTS OF A CODE OF CONDUCT FOR BIOTECHNOLOGY

I. INTRODUCTION

1. At the Third Session of the Commission on Plant Genetic Resources, the FAO Secretariat presented a background paper on the "Implications of new biotechnologies for the International Undertaking" (CPGR/89/9). Besides reviewing the implications for the Undertaking, the paper gave a brief overview of the ways by which the new biotechnologies might affect the conservation, utilization and free exchange of plant genetic resources. The Commission requested FAO to continue to monitor actively the developing new biotechnologies. It also requested the FAO to prepare a Code of Conduct for Biotechnology as it effects the conservation and use of plant genetic resources.

2. This paper first reviews progress in this field, concentrating on the implications for agriculture in developing countries. It then describes related legal developments, with a special focus on regulations governing the deliberate release of genetically modified organisms, and on intellectual property rights over plant genetic resources. In its last part, it describes possible elements of a Code of Conduct for Biotechnology, based on responses to a survey of large number of experts in this field.

II. DEVELOPMENTS IN BIOTECHNOLOGY

3. In this section, the current status of the new biotechnologies, as they affect the conservation, exchange, and use of plant genetic resources, is updated and reviewed. The survey concentrates on plant biotechnology. The conservation and use of plant genetic resources, however, is also directly affected by developments in other fields of biotechnology. The new techniques are not only eliminating the biological barriers between plant species, but also those between biological kingdoms in general: this increasingly results in a common genepool of all organisms, and implies that a wide range of biotechnologies can be of great relevance in the conservation and use of plant genetic resources.

II.1 Conservation

4. Progress in the new biotechnologies offers, or promises to offer, not only techniques to improve the conservation of plant genetic resources, but also new methods to identify, isolate, and transfer and express genes in different organisms. This will have profound implications for the utilization of plant genetic resources, will broaden the germplasm base from which new genetic combinations can be created, and will allow scientists to pursue their plant breeding efforts with greater focus and speed. Progress in the field of enzyme and fermentation technologies will also improve food processing, and alter international trade in agricultural products.

5. There has been progress in the field of the conservation of plant genetic resources with respect to in vitro collecting, disease screening and eradication, and to the safer storage of germplasm, especially for vegetatively propagated crops, and those with recalcitrant seeds. In vitro techniques for the international distribution of disease-free germplasm may also prove considerably more efficient than conventional methods. A review of biotechnology, as it relates to the conservation of plant genetic resources, was presented to the Fourth Session of the Commission in document CPGR/89/9.

II.2 Evaluation

6. The evaluation of germplasm is as important as collecting, maintenance and storage. The identification and elimination of duplicate accessions from collections could reduce the genebanks' costs. Biochemical and molecular methods for the rapid screening of germplasm collections - such as isozyme or protein analysis, and RFLP (Restriction Fragment Length Polymorphism) - are being developed. With these tools, genes and gene complexes can be more precisely located and compared. RFLP maps are being developed for several crops, including rice, tomato and maize, as well as for certain forest species.

II.3 Propagation

7. Biotechnology also offers important possibilities to improve and speed up the propagation of plants. The most widely used and commercially successful application of plant biotechnology is the rapid and large-scale multiplication of plants through clones produced in tissue culture. Tissue and cell culture is currently used to mass-produce many ornamental, fruit, vegetable, medicinal plant, and tree species. However, in the case of several of the main staple crops, mass reproduction through tissue culture remains difficult. Tissue culture is also already widely used to produce virus-free planting material of crops such as potato, cassava, sugarcane, and banana.

8. Important research is being carried out, with the aim of producing artificial seeds from somatic plant cells. The mass development of embryonic tissue tanks results in numerous genetically identical clones, which may then be encapsulated in a jelly-like coating, resulting in a manageable end-product that may be stockpiled, sold and sown. The coating of the artificial seed may contain a variety of products, such as growth hormones and other agrochemicals, to regulate and promote plant germination and development. Although efforts are being undertaken to automate the process and bring down the cost, artificial seed technology is still too expensive and technically underdeveloped to be applied economically to many species.

II.4 Pest and Disease Resistance

9. While the mass production of planting materials has obvious advantages, it also carries the danger of genetic wipeout, and genetic erosion, as the materials, and their offspring, are genetically identical. If cloned crops or artificial seeds become widely used, they may broadly replace many sexually reproducing crops, and the genetic diversity they contain, thus increasing crop vulnerability.

10. In the field of crop protection, gene transfer technology is being used to insert foreign genetic material which codes for resistance against pests and diseases into various crops. Although the production of such transgenic plants is still difficult for a number of important species, including certain cereals and grain legumes, due to problems with transformation and regeneration, successes have been obtained in other crops and pasture species, such as transgenic potato and tomato plants with built-in resistance against various insect pests.

11. An alternative strategy to improve pest control is offered by the genetic engineering of micro-organisms that attack pests and disease vectors. Some one hundred fungus species, and many bacteria species, are known to have insecticidal effects, and research is being carried out to improve these effects. The new biotechnologies are also providing novel diagnostic methods: nucleic acid and monoclonal antibody probes can be used to diagnose accurately the presence or absence of pathogens. Such new diagnostic methods may result in less pesticide being used, by allowing a more precise measuring of the pest population thresholds at which chemical treatment becomes necessary.

12. While work on pest and disease resistance, as well as on biological pesticides, offers interesting possibilities of decreasing the use of toxic chemicals, several researchers have pointed out that current technology is often limited to the transfer of single genes which code for resistance traits. Such vertical resistance is relatively easy for pests to overcome. Concern has also been expressed that current research is focusing essentially on a very limited number of sources of resistance. For example, a substantial part of all research on insect resistance uses a gene from Bacillus thuringiensis, a microorganism that produces an insecticidal toxin. The wide incorporation of such a narrow source for resistance into many crops could increase crop vulnerability, as insect pests and pathogens are likely to overcome the uniform source of resistance.

13. Research is at present being carried out to introduce resistance to herbicides into cultivars of virtually all the major crops. The aim is to increase productivity by making it easier to control weeds, but a number of writers have pointed out that the incorporation of herbicide-tolerance into a wide range of crops will inevitably lead to

an increased herbicide use. Moreover, there is a growing consensus that such herbicide-tolerance may itself be transferred, by natural introgression and hybridization, to the close weedy relatives of these crops, many of which are important weeds in their own right, thereby making them much more difficult to control.

II.5 Plant Physiology

14. In the field of optimizing plant growth and yield, modern biotechnology's potential to substantially raise crop yields has received much publicity. However, it is now widely recognized that a more complete understanding of plant growth and development, and of the structure, function, regulatory behaviour and expression of agronomically important genes is needed before the full potential benefit of plant biotechnology may be realized. Most important agronomic characters - such as root structure, plant stature and growth, yield, and nutritional uptake - are multigenetically controlled, and current transfer techniques only allow for the integration of one or two foreign genes in plant hosts. Three main areas on which research is currently focused are the improvement of photosynthesis, resistance to abiotic stress factors, and the enhancement of nitrogen fixation. Due to the extreme complexity of these processes, practical success in these areas has been limited, and is likely to remain so in the near future.

II.6 Harvest and Post-Harvest

15. The new biotechnologies will also have a profound impact on harvesting and storage. The use of clones and artificial seeds could lead to lesser variation between individual plants, which would facilitate mechanized harvesting, as the fruits would all ripen at the same time. Characteristics which made them easier to handle might also be deliberately incorporated. This would facilitate the further mechanization of agriculture, but might have negative side-effects on employment and farm workers' income.

16. The application of biotechnology also promises to help reduce post harvest losses in many countries. For example, technology is being developed to produce tomatoes with a lower content of the enzymes that cause ripe tomato fruit to soften, thus increasing its shelf life. As with the engineering of pest resistance into crop varieties, genes that increase resistance against post harvest pests and diseases could also be inserted into crops. Biotechnology also offers the possibility of improving the efficiency of fermentation techniques, through enzyme technology and genetically engineered micro-organisms.

II.7 New Processes and Products

17. in economic terms, perhaps the most important effects of the new biotechnologies on agricultural production might result from research underway to genetically modify plants to produce higher yields of specific components of value to the food processing and pharmaceutical industries. Efforts are also being made to engineer plants that produce entirely new substances, such as high value pharmaceutical peptides.

18. At the same time, the food processing industries are seeking biotechnologies to derive commodities from crops other than those they are currently derived from, or from non-agricultural sources. Several food processing companies, for example, are working to produce cocoa butter substitutes from cheaper vegetable oil sources, such as palm oil, or from genetically engineered micro-organisms. Others are genetically modifying rapeseed to yield high-priced speciality oils that are currently derived from coconut and palm kernel.

19. Such application of the new techniques are likely to result in cheaper production processes, and lower commodities prices. They also increase the interchangeability of crops, as the same basic components can be extracted from an increasing range of different crops. This is giving rise to large-scale substitution processes, with food processors switching easily from one raw material to another. For example, improved enzyme technology has already led to the partial substitution of sugarbeet and cane-based sweeteners by maize-derived products. As a result, patterns of international trade flows in agricultural products may suddenly change. Furthermore, increased product substitution is exercising a continuous downward pressure on the world market prices of agricultural commodities, and threatens the exports of those countries that cannot quickly respond to the new situation, and the livelihood of their farmers.

III: DEVELOPMENTS IN LEGAL AND REGULATORY MATTERS

III.1 The handling and release of genetically modified organisms

20. One of the most controversial subjects in the development of new biotechnologies is the potential hazard associated with the handling, and introduction into the environment of genetically modified organisms (GMOs). The need to promote "biosafety" has centred on two related issues: firstly, the practices for the handling of GMOs at the laboratory level that are necessary to protect workers, and prevent the accidental liberation of such organisms into the surrounding ecosystem ("contained use"), and, secondly, the need for regulatory systems to govern the deliberate release of GMOs into the environment, either for testing purposes or on a commercial scale.

21. While the first national guidelines for biosafety dealt primarily with contained use, efforts have recently been made to regulate the deliberate release of GMOs into the environment. These stem largely from concern that the modified organisms might cause unforseeable ecological damage, for example, by evolving into virulent pathogens as a consequence of modifications in their genetic make-up, or by exchanging part of their genome with other organisms. It is generally recognized that there is a lack of scientific data on such environmental risks. However, the agricultural applications of most relevance are biologically engineered micro-organisms intended to enhance agricultural production, and genetically engineered crops: it must be stressed that genes of the engineered cultivars may naturally transfer to wild and weedy relatives of the crop, with unforeseeable consequences. This is a matter of special concern when they are released in, or close to a centre of genetic diversity of that crop, as numerous relatives are present in such areas.

22. The question of the release of genetically modified micro-organisms is even more complex, as very little is known about microbial communities. Most micro-organisms have not yet been identified, named or studied. It is, however, known that the natural transfer of genes between different species and genera of micro-organisms is relatively frequent. Newly inserted genes that confer distinct selective advantage could conceivably spread throughout the microbial world, and this makes it difficult to assess the long-term impact of introducing a particular genetically modified micro-organism.

23. Most developed countries have established, or are establishing national regulatory guidelines for safety in handling recombinant DNA at the experimental stage, and have constituted advisory committees on biosafety, often on the model of the United States. Guidelines for the deliberate release of GMOs into the environment during field testing, based broadly on the recommendations of the OECD, also exist in several industrialised countries. While drawing on common principles, national regulations differ in several respects, and reflect varying levels of public concern over the potential risks of biotechnology.

24. The twelve member states of the European Community have recently adopted a harmonized set of regulations to govern the deliberate release of GMOs. These cover monitoring procedures and labeling requirements, and provide for environmental impact assessments. The European Community has also adopted guidelines for the contained use of GMOs, and is currently discussing common rules for the safety of workers handling them.

25. Some developing countries with active national biotechnology programmes are currently drawing up guidelines similar to those of the industrialised countries, as are the International Agricultural Research Centres, and the International Centre for Genetic Engineering and Biotechnology. The fact remains, however, that most developing countries do not have the laws, regulations and enforcement capability necessary to ensure the safe testing and release of recombinant organisms.

26. There are, as yet, no internationally accepted biosafety standards. There are two major areas of concern. Firstly, as GMOs know no political boundaries, organisms with potentially deleterious characteristics may be released in one country, and multiply and spread, and transfer their genes to plants in other countries. For example, a herbicide-resistant or insect-resistant crop approved for release in one country could share the resistance gene with weedy relatives in another, causing major pest control problems there, as well as in the country of release. Secondly, countries with insufficient legislation may be used as testing sites for experiments that are forbidden elsewhere, and which may represent health and environmental hazards. Both these concerns underline the need for an internationally agreed set of principles for the handling and release of GMOs.

27. An informal ad hoc working group on safety in biotechnology, established in 1985, and composed of UNEP, WHO, UNIDO and FAO, has reviewed the current situation regarding biosafety, particularly in the laboratory and during research, but has not, as yet, made specific recommendations. Several other bodies, including the World Bank and the Rockefeller Foundation, have been considering the particular needs of developing countries, and in 1989, the Consultative Group on International Agricultural Research (CGIAR) established a "Taskforce on Biotechnology" (BIOTASK), which includes regulatory issues and release into the environment on its agenda.

III.2 Intellectual property rights over plant genetic resources

28. The emerging new biotechnologies may significantly improve our ability to conserve and utilize plant genetic resources. In particular, recombinant DNA techniques, in combination with a series of other technologies such as tissue culture, cell fusion, fermentation and enzyme technology, move the focus of the biological sciences to cellular and molecular structures, and are increasingly overcoming the natural barriers that prevent the exchange of genetic materials between different species. Although numerous technical problems still remain to be resolved, it is now in principle possible to isolate any DNA fragment from any organism, and incorporate it into any other organism. This enhances the potential economic value of genetic resources. It also has resulted in pressure to bring genetic resources - such as DNA segments, genes, and cell lines - under the protection of the industrial patent system.

29. Advances in the development of the new biotechnologies have prompted intense debate on whether, and how, to provide for intellectual property rights over multi-cellular life forms and the genetic resources they harbour. Genetic resources are both the building blocks of all living matter, and the raw material for the fast growing plant breeding and biotechnology industries. This is the main cause of the controversy over the patenting of genetic resources.

III.2.1 The patenting of plant genetic resources.

30. The first country to allow plant, animal and gene patenting was the United States of America. In the USA, a patent may be granted to any new and useful process or product. US patent law does not exclude any subject matter from protection. In 1980, the US Supreme Court ruled that man-made micro-organisms were patentable. There was, however, no rush to patent plants, because the legal implications of the Supreme Court decision were rather uncertain, due to the existence of two laws, the Plant Patent Act, and the Plant Variety Protection Act. In 1985, the United States Board of Patent Appeals and Interferences overturned a half century of federal patent policy, and approved a patent on the tissue culture, seed, and the whole plant of a maize line selected through tissue culture. It was the turn of an oyster in 1987 and a mouse in 1988. However, the question of patenting higher life forms in the United States is still controversial and several bills are being examined in the US Congress.

31. The European Community is now considering a draft directive for the regulation of both the patent and the plant breeders' systems. The draft directive lays the foundation for a new patent law applicable to all life forms. It advocates the extension of patents to all inventions, and living and non-living material, including multi-cellular life forms. This draft directive, which is to be incorporated into the legislation of all EC member states, is currently being debated by the European Parliament. A complicating factor is that most EC member states are signatories to the European Patent Convention (EPC), which stipulates that plant and animal varieties, as well as processes that are essentially biological, are not patentable. To circumvent the problem, the draft directive excludes plant and animal varieties, as such, from patentability, but allows for the patenting of varieties that are the products of patented processes, and components of varieties (such as genes, genetic sequences, and cells), as well as all "biological classifications other than plant or animal varieties" (EC COM(88) 496 final, Article 3).

32. Most developing countries do not allow the patenting of plants, animals, or their genetic components. The patent laws of many developing countries exclude not only plants and animals, but often food products, pharmaceuticals, and chemicals as well. For example, among the 100 member states of the Paris Union for the Protection of Industrial Property, at least 45 countries exclude plant or animal varieties from patent protection; 48 countries exclude pharmaceutical products; while food products and food processes are excluded from patentability by 35 and 9 countries respectively. Many developing countries apply compulsory licensing systems to foreign inventors.

III.2.2 The revision of the Plant Breeders' Rights system

33. The present system of Plant Breeders' Rights is a form of intellectual property right specifically tailored to the art of plant breeding, and the nature of modern cultivars. There are therefore important differences between such rights, and rights under patent. These include the recognition of the "Breeder's Exemption", and the "Farmers' Privilege". The Breeder's Exemption allows plant breeders to use freely protected plant varieties as a source of genetic variability for further breeding, without having to seek permission, or pay royalties. Most breeders see this exemption as the cornerstone of current plant breeding, which , they believe, requires unrestricted access to germplasm for continued improvement to be achieved. The Farmers' Privilege is the right to re-use seed they have harvested for the next year's sowing, without either having to ask permission, or pay royalties to the holder of the Plant Breeders' Rights over the crop variety in question.

34. In addition to these important principles, Plant Breeders' Rights has traditionally been the exclusive regime protecting plant varieties in those countries that are members of the Union for the Protection of New Varieties of Plants (UPOV), which, under the present regulations, maintains the fundamental principle of unrestricted access to genetic resources.

35. However, as a response to the increasing pressure to allow the patenting of genetic materials, UPOV member states have began negotiations for a major revision of the UPOV Convention, with the objectives of strengthening the rights of breeders, and extending the scope of the protection granted. The final negotiations, to take place at a UPOV Diplomatic Conference in March 1991, will consider a "Basic Proposal" (UPOV Doc. DC/91/3) prepared by the UPOV Secretariat, and adopted by its Council. The matters covered in the following paragraphs, among others, are likely to be the focus of discussion.

36. The UPOV Convention currently prohibits "double protection", that is, it prevents member states from extending more than one form of intellectual property right to the same genus or species of plants. In the proposed revision, this principle has been eliminated, opening the way for the patenting of plant varieties in those countries that permit it

37. The proposed revision also introduces the principle of "essentially derived varieties", which would require a greater genetic distance between protected varieties. This could result in a broadening of the genetic base of agriculture, as breeders, for reasons of cost, seek alternative sources of germplasm, but it could also put some limits on the current Breeder's Exemption, whereby breeders can freely use each other varieties as a source of initial variation. It might also lead to monopolies, as other breeders paid for access to a particularly valuable crop variety or gene.

38. While the current UPOV convention embodies the Farmers' Privilege as a universal principle, the proposed version would leave it up to individual member states to decide whether or not to enact the Farmers' Privilege. In several countries, this could result in the elimination of the Farmers' Privilege to freely reuse harvested seed for the next year's sowing.

39. The proposed revision also extends the scope of the protection to imports, exports and harvested material. If adopted, this might mean that holders of Plant Breeders' Rights might prevent the importation of varieties protected under these rights, and their harvest, into UPOV member states, if these had been grown without their consent. This could have important consequences for the flow of agricultural trade from developing countries which are not parties to the UPOV Convention.

III.2.3 Developments in other fora

40. The Paris Convention for the Protection of Industrial Property has been updated a number of times. Between 1886 and 1967 eight conferences for the revision of the convention were held. The ninth conference is due for June 1991, and will deal with the harmonization of patent laws, in the light of the present broad differences in the patent practices of its member states. The World Intellectual Property Organization (WIPO), which administers the Paris Convention, has established an expert group to prepare the Treaty on the Harmonization of Patent Laws, while another expert group on biotechnological inventions has met four times since 1984. The negotiations on harmonization are proceeding slowly as a result of the diverging interests of the various parties. In the most recent draft of a proposed Treaty, the possibility is proposed that "Patent protection shall be available in all fields of technology" (WIPO Doc. HL/CE/VIII/3), although allowing for certain exclusions to be made, under certain conditions.

41. The Uruguay Round of the General Agreement on Tariffs and Trade (GATT) is another forum in which an intense debate on patenting has taken place. The question has been dealt with under the rubric of Trade Related Aspects of Intellectual Property Rights (abbreviated as "TRIPs"). During the discussions, some countries proposed worldwide patent protection, without exclusion, while others wished to leave the question more open. In particular, fourteen developing countries presented a proposal to exclude from patent protection plant and animal varieties or essentially biological processes, as well as materials or substances already existing in nature. Countries were unable to reach a final agreement on the Uruguay Round in December 1990, and further negotiations at a later date were proposed. It is therefore at present unclear what the result of the TRIPs negotiations will be; this is of the utmost importance, particularly for developing countries as, unlike most other treaties, GATT agreements provide for trade sanctions to be enacted if a contracting party does not respect the agreement.

III.2.4. Free access and the FAO International Undertaking

42. In recent meetings of the FAO Commission on Plant Genetic Resources, and the FAO Conference, the principle that plant genetic resources are a common heritage of mankind has been further clarified: it has been stressed that "free access" does not mean free of charge; and it has been pointed out that the principle of a common heritage is not incompatible with national sovereignty. The discussions surrounding the recognition of Plant Breeders' Rights and Farmers' Rights, and the establishment of the International Fund for Plant Genetic Resources, have turned on the need to establish a mechanism, or mechanisms, to compensate farmers throughout the world - and especially in developing countries - for having developed and preserved, over thousands of generations, the plant genetic resources that plant breeding uses, and for making those resources available to today's breeders and scientists.

43. The "Agreed Interpretation of the Undertaking" simultaneously recognizes Plant Breeders' Rights, as provided for under UPOV, and Farmers' Rights. A major difference between the sets of rights, however, is that Plant Breeders' Rights are incorporated in the national legislation of several industrialized countries, while mechanisms to give practical expression to Farmers' Rights, and provide adequate compensation to farmers, have still to materialise. Another important difference is that Plant Breeders' Rights are vested in individuals and companies, while Farmers' Rights are a collective right, vested in the International Community as trustee for present and future generations of farmers. With the elaboration of mechanisms for the enforcement of Farmers' Rights, the two systems could together provide a balance of rights and obligations, and help ensure that the world's genetic resources are properly conserved and freely exchanged.

44. However, both the extension of the industrial patent system to plant genetic resources, and the proposed revision of the UPOV Convention, will interfere with this balance. If the UPOV Convention is revised in such a way that plant breeders must seek permission from the holders of Plant Breeders' Rights, in order to use certain existing crop varieties as a source of genetic variability, the principle of unrestricted access may be undermined. This could also be the case if the present Farmers' Privilege is eliminated in several countries. Similarly, and more profoundly, if the patent system is applied universally to living matter, including plants and animals, and their genetic resources, then the principle of unrestricted access will be severely eroded.

IV. ELEMENT'S OF A CODE OF CONDUCT FOR BIOTECHNOLOGY

IV.1 Introduction

45. The Commission on Plant Genetic Resources, at its Third Session in April 1989, requested FAO to draft a Code of Conduct for Biotechnology, as it affects the conservation and use of plant genetic resources, in cooperation with other relevant international organizations, for the consideration of the Working Group, and submission to the next session of the Commission.

46. In order to collect a wide range of views on the objectives of such a code, the matters to be covered, and the mode of its implementation, the Secretariat of the Commission sent a questionnaire to some 500 experts engaged in biotechnological research and development in private companies, national and international organizations, and nongovernmental public interest groups. Some 100 replies were received, from all over the world, and from people with different backgrounds and interests, and with different types of expertise.

47. Every effort was made to send the questionnaire to as wide a range of people and opinions as possible. Nonetheless, the response may not represent all points of view, as those with firmly held opinions replied more frequently, and at greater length. This notwithstanding, the replies received covered a good number of points of view, and brought a large spectrum of concerns and ideas to the attention of the Secretariat.

48. In reporting on these responses, the Secretariat is aware that a number of the suggested elements for the proposed Code may be difficult to contain within its framework. Nonetheless, an attempt is here made to include all the major themes, as these concerns are of value in themselves.

49. With regard to the objectives of the Code, the responses to the questionnaire fall in four main areas:

- Promotion of the sustainable use of biotechnology in the conservation and utilization of plant genetic resources;

- Guaranteed unrestricted access to plant genetic resources;

- Promotion of biosafety so as to minimize environmental risks throughout the world; and

- Promotion of an equitable sharing of the benefits of biotechnology between the developers of that technology, and the donors of the germplasm it uses.

50. Relating to the matters to be covered, and the mode of implementation of the Code, many ideas and suggestions were put forward by the experts consulted. For the purpose of clarity, they may be grouped under the following rubrics:

- Biosafety, and other environmental concerns;
- Intellectual Property Rights and Farmers' Rights.
- Appropriate biotechnology for developing countries; and
- Minimizing the possible negative results of biotechnology.

51. Conscious that the Commission had requested that the Code be prepared in cooperation with the other relevant international organizations, the questionnaire was sent to a large number of experts in such agencies in their personal capacities. The Commission may now wish to give its guidance on the areas of possible cooperation with other agencies. The main focus of the Code, as directed by the Commission, is the conservation and use of plant genetic resources: the limits are, however, imprecise, and there are inevitably areas of overlap with the mandates and work of other organizations.

52. It is proposed that cooperation be established with the organizations most concerned with the various matters to be covered. For environmental concerns - including biosafety and genetic erosion - the primary bodies involved would be the other members of the Inter-Agency working Group, that is, UNIDO, UNEP and WHO. Other organizations with an interest in this field include the CGIAR, OECD, the World Bank, and various bodies of the European Community, as well as a range of international non-governmental organizations, including IUCN and WWF.

53. The question of intellectual property rights might require collaboration with Unesco, UNEP, UPOV and WIPO. In considering appropriate biotechnologies for the developing countries, the CGIAR, the World Bank, and a range of international and regional governmental and non-governmental organizations might be involved. The European Commission and UNCTAD both have displayed interest in the question of minimizing the possible negative effects of biotechnology. In all these matters, the further development of the Code may be of value in the preparation of the UNCED.

54. Similarly, if various elements of the proposed Code are now developed in detail, they could, in the future, be incorporated in any wider process, or more generally Code of Conduct on biotechnology, that develops in other fora. However, it is felt that matters are so pressing that to await the ideal framework for a more comprehensive approach would be to fail to realize the urgency of the situation; in such a case, the best may be the enemy of the good.

55. To further the work of the Commission, the following gives a general overview of the observations made, the objectives proposed and suggestions for matters to be covered by the Code. The Commission's assessment and guidance is now indispensable, so that the Secretariat may advance the preparation of the draft Code of Conduct for Biotechnology.

IV.2. Biosafety, and other environmental concerns

IV.2.1 Observations

56. It was generally felt that the safe use of modern biotechnology called for the establishment of adequate environmental regulations, as the research on, and the field testing and general release of GMOs might cause changes in ecogenetic equilibria, with unforseeable and deleterious consequences. The widespread use of genetically identical clones, or artificial seeds might also result in accelerated genetic erosion, increased crop vulnerability, and the heavier use of agrochemicals.

57. In the absence of universally accepted regulations and enforcement agencies, many experts felt that the international community would benefit from an FAO Code which included and promoted basic biosafety standards for the contained use and deliberate release of GMOs, and for their importation and exportation. In order to avoid overlapping, it was felt important to closely coordinate this work with that of other agencies.

IV.2.2 Objectives

58. Objectives suggested included the following: to ensure the responsible use of the new biotechnologies, and to set international standards for the testing, exportation and importation, and commercial use of GMOs; and to ensure that the release of GMOs is based on a sound and comprehensive scientific assessment which takes into account ecological and other risks. It was suggested that the Code could also provide a framework in which help might be provided to countries that cannot at present afford to build up the scientific capabilities required to make such an assessment. The Code might also propose measures to safeguard genetic diversity, and to minimize the consequences for plant genetic diversity of the massive use of clones.

IV.2.3 Matters to be covered

59. It was felt that in making decisions regarding the possible introduction of GMOs, national governments should act to protect their ecosystems and genetic diversity, as well as the health and well-being of their citizens. In general, such decisions should be made on a

case-by-case basis, taking into account the organism's genotype, and the environment into which it would be released. Recognizing that the release of GMOs might have negative implications for genetic 'diversity, the Code might contain elements to ensure that such implications were systematically investigated before release was authorized, and that steps be taken to minimize potential problems. The Code might define the parameters for such decisions, and provide for an international framework in which they may be made.

60. The Code might define responsibilities to review and monitor the introduction of GMOs at national and international level. National governments should establish appropriate policies, laws and regulations, as well as enforcement mechanisms, for the control of any proposed introductions, either for testing, or for releases on a commercial scale. Many countries, however, have insufficient scientific expertise and resources to adequately evaluate the ecological risk of proposed releases; the Code could provide for an international mechanism to develop national capabilities, and offer technical and financial assistance, both to establish regulatory programmes, and to evaluate specific proposals for the introduction of GMOs.

61. Release, when approved, should be conducted in such a manner as to minimize the dispersal of GMOs, and the modified genetic material they contained. To this end, the Code might provide for containment measures during the process of genetic engineering, after the release of the organisms, and during transportation, importation and exportation. The Code might also provide international guidelines on the ecological information that the entity that proposes the release is required to provide, so as to assist the relevant authorities in coming to a decision.

62. With regard to the exportation of GMOs, the Code might include a clause which permitted exportation, on the condition that the receiving state was notified; and provided with the information it needed to adequately assess the risk in question. A further possible step might be to require a "prior informed consent" clause - such as that now embodied in the FAO International Code of Conduct on the Distribution and Use of Pesticides, which requires that the exporter must obtain the informed consent of the importer before the transaction may take place. A further suggestion was generally to ban the export of GMOs that have not yet been approved for use in the exporting country.

63. Finally, the Code could include monitoring procedures to consider the actual effects that organisms have had on the environment in the light of the possible effects identified before their release. This would provide information of use in evaluating other possible releases. On the basis of such information, continuously collected, the Code could also provide for mechanisms regularly to provide member states with up-to-date information on the deliberate release of GMOs, so that more adequate guidelines might later be established.

IV.3. Intellectual Property Rights and Farmers' Rights

IV.3.1 Observations

64. Plant genetic resources are at present generally considered a common heritage that is accessible with relatively few restrictions. In those countries with legislation on Plant Breeders' Rights, protected varieties cannot be multiplied and sold for commercial purposes without the breeder's consent, but the germplasm they contain may be freely used to develop new varieties. In these countries, the developers of new varieties are compensated, but the genetic resources they contain are available without the donors of germplasm receiving any reward or compensation.

65. There are, however, limited exceptions. Some industrialized countries have already begun granting industrial patent protection over genetic materials and plants, and some developing countries have placed restrictions on the exportation of indigenous germplasm. Although Farmers' Rights have been formally endorsed, appropriate means to implement Farmers' Rights and compensate farmers as the donors of germplasm, have not yet been formally established.

66. Many of the experts consulted expressed deep concern over the further privatization of plant genetic resources, and stressed the importance, for conservation and crop improvement, of maintaining unrestricted access to these materials. Several emphasized that assuring unrestricted access to germplasm should be one of the main objectives of the Code, and a wide range of proposals were formulated.

IV.3.2. Objectives

67. It was suggested that an objective should be to provide a fair balance between the rights of innovators in the field of biotechnology to receive remuneration and protection, and the interest of the international community to obtain an equitable diffusion, in both developed and developing countries, of the products of these new technologies. It was also felt that the Code should provide for a balance between the rights of "formal innovators" in the field of biotechnology, and the rights for farmers and other "informal innovators", that is the countries and communities that have developed and conserved the genetic diversity on which many of the formal innovations are built.

IV.3.3 Matters to be covered

68. Several of the experts gave great importance to the need to reach a negotiated agreement on intellectual property rights over plant genetic resources, within the framework of the Code of Conduct for

Biotechnology. Such an agreement would retain the principle of unrestricted access to plant genetic resources, while establishing a balanced system of compensation for both the donors of germplasm and the developers of new varieties. This might be seen as a logical expression of the International Undertaking, its agreed interpretation, and the resolution recognizing Farmers' Rights.

69. If the Code was to be in accordance with the International Undertaking, the basic principle of unrestricted access to genetic resources should be retained. This would ensure that no monopolistic restrictions were put upon the exchange of germplasm for crop improvement. It would require that the patent system not be further extended to cover genetic resources or - at least, in the context of the current negotiations on the harmonization of patent laws - that countries be permitted to, and in fact exclude genetic resources from patent protection. It would also mean that the proposed revision of the UPOV Convention should retain the full provisions of the breeder's exemption and the farmer's privilege.

70. A negotiated agreement would include a mechanism whereby the donors of germplasm might be compensated for their contribution in developing, maintaining and making available the genetic diversity necessary for plant breeding and biotechnology. Several experts were of the opinion that this mechanism might be best achieved through mandatory contributions to the International Fund for Plant Genetic Resources, particularly by, or on behalf of the main users of germplasm. The result of such a negotiated agreement, in the context of the Code, would be remuneration for the providers of both germplasm and technology, which will, at the same time, favour continued unrestricted access to genetic resources.

71. Many experts also expressed concern about what might be the consequences of the lack of such a negotiated agreement. A lack of agreement might lead many developing countries to restrict access to germplasm found within their territories. As a result, conservation and breeding, in both the informal and formal sectors, would face severe problems, to the detriment of all concerned.

72. The Code would clarify the status of plant genetic resources, and the conditions of access to these. It might build upon the present discussions regarding the International Fund for Plant Genetic Resources, and Farmers' Rights, and elaborate on practical and workable mechanisms to institutionalize Farmers' Rights and generate income for the Fund, and on how to use the Fund in support of the principles of the International Undertaking.

IV.4 Appropriate Biotechnology for Developing Countries

IV.4.1 Observations

73. While the new biotechnologies may have considerable potential to improve sustainable agricultural production, especially in developing countries, it is generally recognized that most current research takes place in the industrialized world. Much of this research takes place in the private sector, which means that the marketability of the product, and the potential return on investment are crucial factors in deciding what research to undertake. This leads to a focus on crops that are widely grown in the developed countries and commodities for which there is an important global market. It was felt that ways should be sought to ensure that major local crops of great social and economic importance, but of little international market importance, also benefit fully from the new technologies. Similarly, attention should be given to the needs of local farming systems which, in many cases, were based on low-input systems of agriculture and needed crops adapted to this situation.

74. In themselves, the new biotechnologies neither favour nor disfavour the maintenance of genetic diversity; it was, however, felt that their use might have consequences for genetic diversity which depended on who used them, and for whose benefit and with which objectives they were developed and employed. It was felt that there needed to be a balance between research and development, and between the objectives of high input and of sustainability. Participation in the development and use of the new biotechnologies should also be balanced. The importance was stressed of special efforts to promote the development of biotechnologies that favoured sustainable forms of agriculture, and fitted the needs of the majority of farmers in the developing countries.

IV.4.2 Objectives

75. It was suggested that an objective should be that existing plant genetic resources should not only be conserved, but also fully utilized, with the aim of improving sustainable agriculture throughout the world, especially in developing countries. Biotechnology should be used not only to increase agricultural production, but also to contribute to the improvement of living conditions in the rural and urban areas of the developing countries, by increasing income and employment, supporting more stable and durable development, and reducing the need for external inputs, or reducing their costs. Balanced economic growth in such societies would be of long-term social and economic value, and for this reason, special attention should be paid to applying biotechnology in ways which benefited those groups which most needed support. Measures were also needed to make full use of the new biotechnologies for the improved conservation of plant genetic resources.

IV.4.3 Matters to be covered

76. To reach such objectives, the Code should contain elements that stimulated and promoted sustainable agriculture, particularly in the developing countries, and should propose mechanisms to facilitate this. Work on certain staple tropical food crops should be encouraged, as well as research to improve indigenous farming systems. The Code might also promote a more effective flow of information between researchers, policy-makers and local communities.

77. The Code might provide mechanisms for greater international cooperation between developed and developing countries in the application of agricultural biotechnology. Without duplicating the efforts of bodies such as the Consultative Group on International Agricultural Research, and the International Centre for Genetic Engineering and Biotechnology, the Code should stimulate bilateral and multilateral cooperation in research on conservation methodologies and novel breeding strategies, utilising new biotechnologies.

78. The Code might also promote collaboration between industrialized and developing countries in research for the improvement of low-input farming systems, and crops currently neglected by the private sector in the industrialised world, through joint programming, training, the transfer of technology, and the building of national capabilities in the developing countries.

79. However, as much current technology and knowledge of relevance to the conservation and use of plant genetic resources came under varying forms of intellectual property protection, the Code might contain provisions to facilitate access to these vital tools. The idea of establishing a "clearing house for the transfer of technology", within the framework of the Code, to promote cooperation among developing countries, was suggested.

IV.5 Minimizing the possible negative results of biotechnology

IV.5.1 Observations

80. It was pointed out that modern biotechnology is usually first used in developed countries, then in the most advanced developing countries, before reaching other countries. This is likely to reduce the competitiveness of agriculture in the poorer countries, at least in the short run. As with any other productivity-enhancing technology, the more successful an application of biotechnology is, the greater its effects will be throughout the world. Since considerable time may elapse before developing countries can assimilate the new developments, biotechnological advances in developed countries might have a negative impact on developing countries for a long time before they can put them to their own advantage.

81. The likelihood of crop substitution is particularly problematic for agriculture in developing countries, because many of the poorest countries largely depend on the export of a few agricultural commodities. Product substitution has, of course, taken place many times in the past, in many cases with benefits for humanity in general. However, the speed at which the new technologies are diffused leaves those countries whose crops are substituted with very little time to adapt their economic structures; moreover, a number of crops are sometimes affected at the same time.

82. It was noted that biotechnology can give rise to various forms of substitution. It may help increase production of a crop in a particular region, to the cost of other regions in the same country, or of other countries. It can also stimulate the production of alternative crops, by making it possible to obtain commercially valuable components from a variety of crops. And, increasingly, it makes possible the production, by industrial means, of agricultural commodities, such as cocoa, butter, and vanilla. While the dependence on imports of net importers of food and agricultural products may be reduced, exporting countries may see their markets threatened. Export substitution is also likely to affect relations between developing countries, as the new biotechnologies may help expand the exports of one developing country at the expense of another.

IV.5.2 Objectives

83. It was 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.

IV.5.3 Matters to be covered

84. Many experts felt that, in order to obtain a clear understanding of the possible social and economic implications of the new biotechnologies, especially for the developing countries, the Code might make provision for mechanisms to assess such questions, and for an early warning system to alert those countries likely to be affected, and advise on possible adjustment policies and alternative crops, with the aim of minimizing possible economic distress.

85. It was also felt that the Code might also provide for mechanisms to identify potentially disadvantaged farming communities, and promote the incorporation of socio-economic research on the problems they face in the research programmes of the relevant national and international agencies.

86. Where it appears that crop substitution is likely to result in increased genetic erosion, through the disappearance of local varieties of the crop being substituted, the Code might provide for mechanisms to assess this danger and recommend immediate action to conserve the plant genetic resources involved.

IV.6 Monitoring

87. The Code should be published and observed through collaborative action by individual governments and regional groupings, appropriate organizations of the United Nations system, and international governmental and non-governmental organizations.

88. The Code should also be brought to the attention of all concerned with biotechnology research and development, so that governments, the industry, and international institutions understood their shared responsibility to ensure that the objectives of the Code were achieved.

89. The Commission on Plant Genetic Resources should periodically review the relevance and effectiveness of the Code, and revise it as necessary to take into account technical, economic and social developments.

V. POINTS FOR POSSIBLE DISCUSSION BY THE COMMISSION

90. The Commission may wish to discuss a number of the main points raised regarding the Code. Further guidance from the Commission is important for the Secretariat to be able to pursue further the preparation of the Code.

91. In general, the Commission might wish to consider what should be the objectives of the different sections of the Code, as well as the range of issues the Code should cover. In this context, it may wish to give its guidance on the scope and nature of cooperation with other bodies on the development of the Code. (Paragraphs 49-55).

92. With regard to biosafety, the Commission might discuss concrete mechanisms for the regulation, assessment and monitoring of the release of GMOs, as it affects the conservation and use of plant genetic

resources. It may wish to address the form and function of an international regulatory mechanism, strategies to enhance scientific capabilities and make available the resources required, and measures to regulate the exportation of GMOs. (Paragraphs 56-63).

93. With regard to intellectual property rights, and Farmers' Rights and the rights of other informal innovators, the Commission may wish to work towards a framework for a negotiated agreement. In the course of developing such a framework, it may be necessary to discuss the implications for the present systems of intellectual property rights of the principle of unrestricted access to plant genetic resources, as well as operational mechanisms to compensate the donors of germplasm for the contribution they have made, and continue to make. (Paragraphs 64-72).

94. With regard to the needs of developing countries for appropriate biotechnology, it may be necessary to define the scope of the measures that might be promoted within the context of the Code, and the practical form that such measures might take. (Paragraphs 73-79).

95. With regard to minimizing the possible negative results of biotechnology, the Commission may wish to give more concrete shape to the proposed early warning system, and to discuss adequate mechanisms to buffer the effects in countries likely to suffer economic or social disruption as a result of the application of biotechnology, through crop substitution or other techniques. (Paragraphs 80-86).

96. The Commission may wish to discuss modalities by which it might periodically review and revise the Code (paragraph 89).