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RECENT INTERNATIONAL DEVELOPMENTS OF RELEVANCE TO THE DRAFT CODE OF CONDUCT FOR PLANT BIOTECHNOLOGY

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RECENT INTERNATIONAL DEVELOPMENTS OF RELEVANCE TO THE DRAFT CODE OF CONDUCT FOR PLANT BIOTECHNOLOGY

I. INTRODUCTION

1. Genetic resources from all over the world are the raw materials of modern plant biotechnologies, which offer enormous possibilities for the more extensive use of the world's diverse gene pool for agriculture, particularly through genetic engineering.[1] However the rapid advance of plant biotechnological research may also raise uncertainties and possible risks that require analysis, particularly in relation to agriculture in developing countries.

2. The 1991 FAO Council endorsed the Commission's request that FAO draft a Code of Conduct on Biotechnology, as it affects the conservation and use of plant genetic resources, and a draft Code was accordingly prepared and submitted to the Commission. In 1993, the Commission recognized that, while several agencies and institutions are active regarding plant biotechnology and related issues, it is the only international forum for considering matters specific to biotechnology in the context of plant genetic resources for food and agriculture.

3. The aim of the draft Code is to maximize the positive effects and minimize the possible negative effects of biotechnology. It includes aspects such as the promotion of appropriate biotechnologies (Article 5); national action and international cooperation (Articles 6 and 7); the prevention and mitigation of possible negative effects (Article 8); access to plant genetic resources and related biotechnologies, and intellectual property rights and compensation for informal innovators (Article 9); information exchange and early warning (Article 10); and biosafety and other environmental concerns (Articles 11-16).

4. The Commission's Fifth Session discussed the draft Code, making comments and recommendations on specific chapters. It recommended that the biosafety and other environmental concerns component of the draft Code be considered an input to the work of the Governing Body of the Convention on Biological Diversity (CBD) on the matter, and that FAO participate in that work on aspects related to agro-biodiversity. It requested FAO to further develop the other components of the Code, in close collaboration with relevant organizations.

5. The Commission's also indicated that the Working Group should advise the Secretariat whether a revised draft Code should be prepared for the Commission's Sixth Session. The Tenth Session of the Working Group (3-5th May 1995) considered that the Commission's agenda in this session would be very full, and that a number of the themes dealt with in the draft Code were being discussed in the context of the revision of the International Undertaking and the preparation of the Fourth International Technical Conference. It therefore felt it better to defer consideration of a new draft of the Code to a later session, though the Commission's Sixth Session should consider a document to be prepared by the secretariat on developments in biotechnology over the last two years that affect various aspects covered in the first draft Code.

6. This is the purpose of the current document. Section II reviews some recent technical developments in plant biotechnology and provides updated information relevant to the draft Code; section

III describes action taken regarding the biosafety component of the draft Code and reviews recent technical and policy developments on biosafety matters; and section IV requests the Commission's guidance for follow-up.

II. RECENT DEVELOPMENTS OF RELEVANCE TO THE DRAFT CODE

Recent technical developments in plant biotechnologies

7. The Commission, in its Fifth Session, recognized the importance of the new biotechnologies for increased food production and sustainable agriculture, and their great potential for the conservation and utilisation of plant genetic resources. It agreed to critically examine developments in biotechnology concerning the conservation and sustained, equitable, and efficient use of plant genetic resources for food and agriculture, so that appropriate policy advice could be provided to member countries. The following paragraphs briefly review some recent developments.

8. Biotechnologies based on plant genetic resources are advancing rapidly, faster in developed than in developing countries, with new applications to agriculture appearing every week. These new developments further strengthen countries' interdependence in the conservation and exchange of plant genetic resources.

9. A number of large-scale plant genome projects are rapidly identifying and characterizing various genes of potential use to agriculture. The sequencing of the entire genome of the plant model organism, *Arabidopsis thaliana*, is the most advanced, and expected to be completed by 2004.[2] In the Rice Genome Research Programme, 4,500 of the estimated 30,000 rice genes have now been identified, and a genetic map of the twelve rice chromosomes is almost complete.[1] Genetic maps being developed for some crop species are also expected to allow rapid marker-assisted breeding of complex agronomic traits, by identifying parental contributions to traits of interest.[2] Numerous individual plant genes for a diversity of agronomic traits are being isolated, including, in the past two years, at least nine genes for resistance against fungal, bacterial and viral pathogens (from tomato, tobacco and flax among other plant species)[3].

10. About sixty plant species are reported to have been genetically engineered for a wide variety of characteristics.[3] Some 2000 field trials of transgenic plants, involving 36 crop species, were undertaken in the USA between 1987 and 1994. The main genetic improvements tested were quality (42%), herbicide tolerance (28%), and virus (20%) or insect-resistance (12%).[4] Transgenic plants with increasingly diverse characteristics are becoming available on certain markets: these include herbicide-resistant cotton and soyabean, low-water quick-fry potatoes, extended shelf-life tomatoes, high laurate[5] canola, virus-resistant squash and insect-resistant cotton and maize.[6] Transgenic plants are currently under development for a wide range of characteristics: these include production of pharmaceuticals (such as alpha-tricosanthin or berberine) and vaccines (including anti-hepatitis B), altered oil-constituent levels,[7] plastic production (polyhydroxybutyrate), nutritional enhancement, non-allergenicity, improved mineral

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1 Stevens J.E. (1994) "Japan picks a winner in the rice genome project" Science, 18 November:1186-1187.

2 The ability to identify parental contributions could make it technically feasible in certain cases to trace the genetic contributions of known parental plant genetic resources to a particular variety. See Document CPGR-6/95/8 Supp., *Appendix 2.*

3 Dangl J.L. (1994) "Pièce de résistance: Novel classes of plant disease resistance genes" Cell, 80:363-366.

4 Hemming D., *loc.cit.*

5 Conventional canola does not contain commercial levels of laurate, a valuable fatty acid previously commercially available only from coconut and palm kernel oils.

6 Schmidt K., *loc.cit.*

7 Several oils are currently only available from crops that for geo-climatic reasons are not grown in Europe and North America, where the key markets are. Rather than domesticate new temperate crops, such as *Cuphea* and *Umbelliferae* spp., or adapt tropical or subtropical crops, such as oil palm and castor bean, to temperate climates, current research focuses on genetic engineering to introduce genes for the production of these oils into temperate region oilseed crops. For example, there have been initial attempts to genetically engineer oilseed rape to produce oil currently only available from jojoba (*Simmondsia chinensis*) (US Patent No. 5370996).

uptake, altered lignin content, flower colour, sterility, extended post harvest storage or quality, cold, drought and salinity tolerance, and resistance to viruses, bacteria, fungi, nematodes and insects.[8]

Promotion of appropriate biotechnologies

11. In the context of the draft Code,[4] "appropriate biotechnologies" refers in particular to technologies which promote the development of sustainable agriculture through the rational use of plant genetic resources, while properly considering local culture and techniques. The Commission has recognised that current biotechnological research is concentrated in the industrialised countries, and therefore focuses on their needs and major crops, rather than on local crops and farming systems of great social and economic importance to developing countries.[9] The Commission's Fifth Session therefore highlighted the urgency of meeting the challenges posed by biotechnological applications that might lead to the neglect of crops of local importance.

12. Some potentially appropriate biotechnologies include virus-eradication through tissue culture; diagnostic tests for plant pathogens; the isolation and use of genes for pathogen resistance, drought and salt tolerance, nutrient assimilation and photoperiodicity; and the improvement of staple crops' nutritional qualities. Some recent biotechnological research concentrates on crops important for developing countries' food security, such as cassava,[5] sweet potato[10] and plantain.[11]

13. Some recent plant biotechnology projects aim at reducing external inputs, while maintaining or increasing yields: one example is research for the development of apomictic[6] food crops. Apomixis is a genetically determined trait, whereby certain plants produce seeds asexually. In an agricultural context, apomixis has the potential to fix clonally the characteristics of particularly well adapted cultivars - including hybrids - from generation to generation, while maintaining heterosis. This is not possible with sexual seeds. Progress is being made in developing apomictic food crops, such as maize and millet, by introgressing apomictic traits from wild relatives.[12] The Hunan Hybrid Rice Research Centre in China is seeking to identify sources of apomictic rice germplasm. Progress in the isolation of apomictic genes for future direct transfer into crops without apomictic wild relatives, by genetic engineering, has also been reported.[13]

Prevention and mitigation of possible negative effects

14. The Commission's Fifth Session recognized that there may be negative effects for some farming communities and developing countries, due to the use of certain new biotechnological applications, for example through the substitution of key export commodities. It suggested that the Code help minimise any resultant economic distortions,[7] and recommended that these issues be kept under review and analyzed. Article 8 of the draft Code advocates national and international monitoring of the potential socio-economic impact of agricultural and food biotechnologies, to prevent and mitigate possible negative effects, and Article 10 promotes the information exchange and early warning role of the FAO World Information and Early Warning System (WIEWS).

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8 Hemming D., *loc.cit.*

9 Documents CPGR/93/9 para. 7-8; CPGR/91/12 para. 73,76-78; CPGR/89/9 para. 26-28,38,43-45.

10 Prakash C.S. (1994) "Sweet potato biotechnology: Progress and potential" Biotechnology and Development Monitor, 18:18-22.

11 Huggan R.D. (1993) "Are bananas and plantains catching up?" Biotechnology and Development Monitor, 14:14-16.

12 A joint project between ORSTOM (Institut français de recherche scientifique pour le développment en coopération) and CIMMYT (Centro Internacional de Mejoramiento del Maiz y del Trigo) for the introgression of apomixis from *Tripsacum* into maize is reportedly nearing completion, while a USDA project is making substantial progress in introgressing apomixis from *Pennisetum squamulatum* into pearl millet.

13 The Centro Internacional de Agricultura Tropical (CIAT) is mapping a single gene locus associated with apomixis in the tropical forage, *Bracharia.* CAMBIA, in Australia, is establishing an international molecular apomixis project, to coordinate and conduct genetic engineering for the development of apomictic food crops.

15. In recent years, a number of international organizations, including the Intermediary Biotechnology Service (IBS),[8] OECD,[14] UNESCO[15] and ILO,[16] have begun to assess biotechnologies in relation to their potential socio-economic impact. Other organizations, including the African Centre for Technology Studies (ACTS) in Kenya, help develop relevant policy formulation capacity, and advise countries on appropriate biotechnology policies. The Research and Information Centre for the Non-aligned and other Developing Countries (RIS), in India, provides information on economic issues related to biotechnology. The Rural Advancement Foundation International (RAFI) monitors biotechnology developments for their potential negative environmental or socio-economic impacts.[17] The International Development Research Centre (IDRC), in Canada, operates joint programmes with some Latin American countries, to assess the potential impact of biotechnologies. Both the International Programme on Rice Biotechnology[18] and the Cassava Biotechnology Network[19] contain modules on impact assessment.

16. However, even when potentially negative impacts of agro-biotechnologies for some developing countries have been identified, this has infrequently led to the establishment of effective mitigation mechanisms, at national or international levels, such as foreseen in Articles 8 and 10.3 (on the role of the WIEWS in monitoring possible adverse effects) of the draft Code. Other mechanisms that may help prevent and mitigate possible negative effects include consumer information provisions, the labelling of genetically-engineered products, and civil liability regulations. These are not covered in the draft Code, and the Commission may wish to advise on their possible integration.

14 Brenner C. and Komen J. (1994) "International initiatives in biotechnology for developing countries agriculture: Promises and problems" Technical Paper No. 100, OECD Development Centre.

15 Sasson A. and Costarini V. (eds.) (1991) "Biotechnologies in Perspective" UNESCO:Paris.

16 Galhardi R. (1993) "Employment and Income Effects of Biotechnology in Latin America: A speculative assessment" Geneva:International Labour Office; Ahmed I. (*ed.*) (1992) "Biotechnology: A hope or a threat?" UK:Macmillan.

17 Pistorius R. (1993) "RAFI after 15 years" Biotechnology and Development Monitor, 17:22.

18 Van Roozendaal G. (1993) "The International Program on Rice Biotechnology" Biotechnology and Development Monitor, 15:20-21.

19 Thro *et al., loc.cit.*

Access to plant genetic resources and related technologies:
Intellectual Property Rights and compensation for informal innovators

17. The Commission[9] has expressed the view that intellectual property rights should not become an obstacle to the exchange of germplasm, information or technology for scientific purposes,[20] and that intellectual property rights systems for plant genetic resources should be equitable and take into account the rights of informal innovators, including farmers. These issues (which are considered in the draft Code) are currently under discussion within the context of the revision of the International Undertaking.[21]

18. Since the Commission's Fifth Session, there have been a number of important discussions and agreements on policy matters related to intellectual property rights of relevance to the conservation and utilization of plant genetic resources, particularly in the context of the International Union for the Protection of New Varieties of Plants (UPOV),[10] and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) within the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), which both contain provisions on the protection of plant varieties and biotechnological innovations.[22]

19. The draft Code aims at facilitating access to plant genetic resources, and balancing the rights of formal and informal innovators. It also deals with the re-use by farmers of seed from their own harvests, generally permitted in plant breeders' rights systems, as the "farmer's privilege". The 1978 UPOV Convention provided for the farmer's privilege as the rule; the 1991 UPOV Convention, however, does not provide for the farmer's privilege, unless specifically established by national legislation.[11] Article 14 of the 1991 Convention strengthened the variety holder's rights, by modifying the "breeder's exemption" (which allows the use of protected varieties, without compensation to the holder of varietal rights, for the purpose of breeding new varieties) by requiring the permission of the variety holder for the registration of an "essentially derived variety".

20. Countries may ratify either the 1978 or the 1991 Convention until 31 December 1995, and afterwards only the 1991 Convention. Argentina, Austria and Uruguay have recently joined UPOV under the 1978 Convention, while Mexico is preparing to do so. Chile, Paraguay, Portugal, the Russian Federation[12] and the Ukraine have submitted their legislations for examination, preparatory to joining UPOV under the 1978 Convention. In 1993, by Decision 345 of the Commission of the Junta of the Cartagena Agreement, the Andean Pact Countries (Bolivia, Colombia, Ecuador, Peru and Venezuela) approved a common plant breeders' rights statute,[23] which represents a true regional protection system, and Colombia subsequently submitted its legislation to UPOV for examination, preparatory to joining under the 1978 Convention.[24]

21. Countries that have acceded to the 1991 UPOV Convention have slightly differing legislations. For example, the European Community Plant Variety Rights (1994) Regulation and the US Plant Variety Protection Act (1994) differ in their provisions regarding the farmer's privilege.[13] The USA and the EC allow patenting of genetically engineered plants or animals, but in the EC plant varieties cannot be patented. Patents covering all genetically engineered plants of particular species (cotton and soyabean)

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[20] When twelve CG Centres in 1994 placed their germplasm collections under the auspices of FAO, it was with the provision that recipients of germplasm they had "designated" may not seek intellectual property protection over the material, and that the same provision be imposed upon subsequent recipients (see document CPGR-Ex1/94/Inf.5 Add. 1).

[21] Documents CPGR-6/95/Inf. 1, CPGR-6/95/7, CPGR-6/95/Inf 2, CPGR-6/95/8, CPGR-6/95/8 Supp., CPGR-6/95/9).

[22] Document CPGR-Ex1/94/5 Supp. para. 25-36.

[23] Jaffe W. and Rojas M. (1994) "Attempt to implement the Biodiversity Convention in the Andean region" Biotechnology and Development Monitor, 21:5.

[24] Brazil also has a plant breeders' rights law under discussion in parliament (Jaffe W.R. (1994) "Agricultural biotechnology policies in Latin America and the Caribbean" AgBiotech News and Information, 6:237N-241N).

have been awarded (and subsequently contested) in the USA,[25] while the European Parliament rejected a proposed EC directive on patent harmonisation for biotechnological inventions in March 1995.[26]

22. Article 27.3 (b) of the TRIPS Agreement (1994) requires all members to protect plant varieties either by means of patents or an "effective *sui generis* system", or by a combination of both.[14] It specifically provides that members may exclude "plants" and "animals" (other than micro-organisms) from patentability, however the recent EC draft legislation, and actual US legislation, would both allow the patenting of plants and "parts of plants".

23. The Commission's current discussions, in the context of the revision of the International Undertaking (especially on access to plant genetic resources and related technologies, including consideration of intellectual property rights and the realization of Farmers' Rights), may assist countries to identify and analyze the advantages and disadvantages of patenting crops. They may also help countries assess the appropriateness of instituting *sui generis* systems for the protection of agricultural plant varieties, in the light of their specific agro-ecological, economic and social conditions, as no single reward-system for agricultural innovation is likely to be appropriate for all countries, at all times. (For instance, with the development of its member countries' agriculture, UPOV has found it necessary progressively to modify the original 1961 Convention, in 1978, and in 1991). Countries may then decide upon appropriate and optimal reward-systems for agricultural plant-related innovation, which confer intellectual property rights (through patents, a *sui generis* system, or a combination of both) in a way that promotes access to germplasm and maintains agro-biodiversity,[15] while encouraging research and breeding activities.[27]

24. In considering the establishment of "effective *sui generis* systems" at the national level, some developing countries are considering the inclusion of mechanisms to realize Farmers' Rights: for instance, proposed legislation in India envisages returning a share of royalties on seed sales to a fund for strengthening farmers' plant genetic resource activities.[16]

25. The Commission's current negotiations on the revision of the International Undertaking may also provide useful input to the deliberations of the WTO TRIPS Council, and facilitate international consensus on the criteria for "effective *sui generis* systems" for the protection of agricultural plant-related innovations.

International cooperation and technology transfer

26. The importance of international cooperation is underlined in Article 7 of the draft Code: the identification and effective transfer to developing countries of appropriate plant biotechnologies remains a major challenge.

27. There are an increasing number of international plant agro-biotechnology programmes.[17] Many deal primarily with crop research, but some provide support and advice on biotechnology research management, such as priority setting, product development, technology assessment and transfer, biosafety and intellectual property rights.

28. These programmes involve *funding organisations*, such as UNDP, the Rockefeller Foundation, the McKnight Foundation, USAID and the Netherlands' Directorate General for International

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25 Mestel R. (1994) "Cotton patent left hanging by a thread" New Scientist, 17 December:4; Lehrman S. (1994) "Soy-bean patent comes under fire as threat to research" Nature, 372:488.

26 O'Brien C. (1995) "European Parliament axes patent policy" Science, 267:1417-1418.

27 The scope of the "research exemption" under patent law, and the "breeders' exemption" under UPOV, could be considered in this context. For an analysis of the "research exemption", and proposals to review it, see: "Intellectual Property Rights: Protection of Plant Materials",(1993) Madison:Crop Science Society of America Special Publication No. 21.

Cooperation (DGIS); *crop research networks*[18] *and programmes*, including FAO,[28] the International Programme on Rice Biotechnology,[29] REDBIO, the Asian Rice Biotechnology Network,[30] the Cassava Biotechnology Network[31] and the Asia Network for Small-scale Agricultural Biotechnologies (ANSAB); *international and regional research institutes*, including the CGIAR Centres, the International Centre for Genetic Engineering and Biotechnology (ICGEB),[32] the Centre de coopération en recherche agronomique pour le développement (CIRAD),[33] the International Laboratory for Tropical Agricultural Biotechnology (ILTAB),[34] the Agricultural Biotechnology for Sustainable Productivity project (ABSP),[35] the United Kingdom Overseas Development Administration (ODA) Plant Sciences Research Programme[36] and the African Biosciences Sub-Network for Biotechnology (ABN-BIOTECHNET);[37] *broker organisations*, such as the ISAAA;[38] and *programmes concentrating on policy and management issues*, run by organizations such as the Inter-American Institute for Cooperation on Agriculture (IICA),[39] the IBS, ACTS, RIS and RAFI.

29. Agricultural biotechnology transfer programmes vary in their approach; most are technology-driven[19] but demand-driven participatory technology development approaches have recently emerged.[40] Some examples of this approach are the UNDP/FAO farmer-centred agricultural resource management programme (FARM),[41] which works with resource-poor farmers[42] to identify appropriate biotechnologies for transfer, and the biovillage concept of the M.S. Swaminathan Research Foundation in India, which attempts to diffuse appropriate biotechnologies in rural areas.[43] Another approach, promoted by the International Service for the Acquisition of Agri-biotech Applications (ISAAA), involves acting as an "honest broker", to match proprietary agricultural biotechnologies to developing countries' needs.[44]

30. A recent IBS survey of forty-five organisations involved in agricultural biotechnology transfer revealed that most transfer initiatives concentrate on the few developing countries with relatively advanced scientific and technological capabilities,[20] and that developing country scientists and administrators are not always directly involved in planning and designing them. This may result from a concentration on advanced biotechnology training opportunities at doctoral and post-doctoral level.[45]

31. During discussion of the draft Code at its Fifth Session, the Commission requested to be informed about the FAO Plant Biotechnology Programme, and recommended that it particularly emphasize the training of scientists and technicians, and increasing policy makers' understanding (especially in

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28 See *Appendix 1* of this Document.

29 Van Roozendaal G., *loc.cit.*

30 Van Roozendaal G., *loc.cit.*

31 Thro *et al., loc.cit.*

32 Komen J. (1993b) "ICGEB coming of age" Biotechnology and Development Monitor, 14:21.

33 Schwendiman J., Diem H.G. and Lefevre P.C. (1994) "CIRAD and biotechnology" AgBiotech News and Information, 6:269N-272N.

34 Cohen J.I. and Komen J., *loc. cit.*

35 Komen J. (1993c) "New Initiative Links US Universities and Companies to Developing Country Partners" Biotechnology and Development Monitor 15:22; ABSP was established as a follow-up to USAID's Tissue Culture for Crops Project in the USA. It facilitates biotechnology transfer, by working with developing country scientists to solve specific agricultural problems.

36 Cohen J.I. and Komen J., *loc.cit.*

37 *Ibid.*

38 Altman D.W. (1994), *loc.cit.*

39 *Ibid.*; IICA has a regional programme (PROCISUR) on technology generation and transfer, cooperative research and development, and information exchange, to assist Latin American countries in policy matters relating to agricultural biotechnology.

40 This approach is presented in Scoones I. and Thompson J. (*eds.*) (1994) "Beyond Farmer first: Rural Peoples' Knowledge, Agricultural research and Extension Practice" London:Intermediate Technology; and in De Boef W., Amanor K., Wellard K. and Bebbington A. (*eds.*) (1993) "Cultivating Knowledge: Genetic Diversity, Farmer Experimentation and Crop Research" London:Intermediate Technology.

41 Document CPGR-6/95/5.1 para. 38.

42 About 1,400 million people are dependent on resource-poor farming systems (Chambers R. in "Beyond Farmer First: Rural Peoples Knowledge, Agricultural research and Extension Practice", (1994) Scoones I and Thompson J. (eds.) London:Intermediate Technology, p. xiii).

43 Dhar B. and Pandey B. (1994) "Biovillages in India: An attempt to diffuse biotechnology in rural areas" Biotechnology and Development Monitor, 18:16-17; in the Netherlands, the Centre for Low-External Input and Sustainable Agriculture (ILEIA) and the Centre for International Research and Advisory Networks (CIRAN) promote low external input sustainable agricultural systems, and the use of indigenous knowledge in relation to agricultural development, respectively.

44 Altman D.W. (1994) "Technology transfer initiatives of the International Service for the Acquisition of Agri-biotech Applications" AgBiotech News and Information, 6:131-134; Knudsen H. (1993) "ISAAA: Proprietary technology for small farmers?" Biotechnology and Development Monitor, 14:12-13.

45 Brenner C. and Komen J., *loc.cit.*

developing countries) of the need to develop and adopt appropriate biotechnologies. Information on FAO's Plant Biotechnology Programme is provided in *Appendix 1*.

III. FAO'S INPUT TO THE POSSIBLE CBD PROTOCOL ON BIOSAFETY, AND RECENT DEVELOPMENTS IN AGRO-BIOSAFETY

32. The draft Code contained a chapter on biosafety and other environmental concerns. The Commission's Fifth Session noted that the Intergovernmental Committee of the CBD was to consider the possible development of a biosafety protocol, and recommended that, in order to avoid duplication, the "biosafety and other environmental concerns" component of the preliminary draft Code constitute an input to the work of the governing body of the CBD, and that FAO participate in this work to ensure that plant genetic resources for food and agriculture were appropriately covered.[21]

33. Following the Commission's recommendation, the relevant chapter was transmitted to the CBD Secretariat, and FAO expressed its readiness to cooperate in developing a protocol on the safe transfer, handling and use of living modified organisms resulting from biotechnology, which may have adverse effects on the conservation and sustainable use of biodiversity. As decided by the 1994 Conference of the Parties to the CBD, FAO will assist an expert group to be established in 1995 to prepare a background document for the possible protocol.[22] At the request of the CBD Secretariat, a focal point has been designated within FAO.

34. The following paragraphs identify some recent developments regarding bio-safety that may be relevant to agricultural aspects of the possible CBD protocol on biosafety and to FAO's contribution to its development, as requested by the Commission.

35. Many factors need consideration in assessing risks specific to agriculture associated with the introduction of transgenes into crop species. These include their potential for crossing with wild relatives, invasiveness, weediness, toxicity and allergenicity, and the possibility of selecting for novel virulent pathogens.[23]

36. Recent studies of the risk of transgenes "escaping" from a transgenic crop into the gene pool of its wild relatives suggest that such risks need to assessed separately for each species and region involved, perhaps through an analysis of the potential for gene-flow between the crop and its wild relatives in the area (particularly in its centres of agro-diversity).[24] The geographical distribution of wild relatives influences the risk. For instance, although potato (*Solanum tuberosum*) cannot hybridise with its most common wild relatives in Europe, it can in the Andean region.[46] Similarly, where maize and teosinte are found in proximity to each other, low levels of two-way gene-flow occur, despite introgression: however, the limited geographical distribution of teosinte means that the risk of transgenes escaping from maize into teosinte only exists in a limited geographical range. The risks associated with transgenic crop species with more broadly distributed wild relatives (such as *Sorghum bicolor* and the weed *Sorghum halapense*) are potentially greater. In this context, it is worth noting that transgenic plants are now being developed where the transgenes are only inherited maternally, through the cytoplasm, which will lessen the risk of transgene "escape", through pollen, into wild relatives.[47]

37. The invasiveness of a plant is another important factor in assessing risk. One study of the invasiveness of transgenic oilseed rape lines indicated no significant differences in their invasiveness in natural habitats, when compared to their conventionally bred counterpart.[25] In the case of transgenic

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46 Eulander R. and Stiekama W.J. (1994) "Biological containment of potato (*Solanum tuberosum*) outcrossing to the related wild species, black nightshade (*Solanum nigrum*) and bittersweet (*Solanum dulcamara*)." Sexual Plant Reproduction, 7:29-40.

47 Svab Z. and Maliga P. (1993) High frequency plastid transformation in tobacco by selection for a chimeric *aadA* gene. Proc. Natl. Acad. Sci. USA, 90:913-917.

crops with herbicide-resistance genes, the possible introgression of such transgenes from the crop to related weed species could increase their invasiveness, by making them herbicide-resistant.

38. Recent experiments have demonstrated that transgenes derived from viral genomes, when expressed in transgenic plants for the purpose of crop protection, have the potential to recombine with other related viruses infecting that crop, in the presence of a selection pressure for the interaction event, potentially resulting in new viral strains.[26]

39. The number of reported trials of transgenic crops continues to increase: some 3,000 field trials have now been reported throughout the world.[27] Between 1987 and 1994, approximately 2,000 such field trials, involving 36 crop species or microbes, were conducted in the USA alone.[48] In Europe, by 1994, 190 field trials (mainly of four crops: oilseed rape, maize, potatoes and sugarbeet) were conducted.[49] It is estimated that at least 42 trials of transgenic plants took place between 1989 and 1993 in Latin America.[50]

40. Biosafety regulations for release of genetically modified organisms have recently been established, in many developed countries, but only in a few developing countries. Mexico, Chile, Argentina, Brazil, Costa Rica, Bolivia, Nigeria, Zimbabwe and Cuba, among others, have either established *ad hoc* biosafety committees, or are drafting relevant regulations.

41. In the light of these considerations, and its request at its Fifth session (see para. 33), the Commission may wish to provide further guidance on how FAO and the Commission itself may ensure that biosafety issues related to plant genetic resources for food and agriculture are adequately addressed, through cooperation with the CBD in the development of its possible protocol.

IV. GUIDANCE REQUESTED FROM THE COMMISSION

42. The Commission may wish to indicate when the next draft of the Code should be presented to the Commission.

43. The Commission may also wish to make recommendations on the various matters covered in this document, particularly in para. 16, 22-25, 30 and 41.

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[48] Hemming D., *loc.cit.*
[49] *Ibid.*
[50] Jaffe W.R., *loc.cit.*

APPENDIX 1

THE FAO PLANT BIOTECHNOLOGY PROGRAMME

Aims of the Programme

1. The FAO Programme on Plant Biotechnology[28] aims to maximise the positive effects of biotechnology, by concentrating FAO activities on plant biotechnology on:

i) Information dissemination: the promotion of information exchange between laboratories at the forefront of plant biotechnology research in developed or developing countries, acting as a "broker" to stimulate exchange of information on: research and field testing; technologies available for improving specific crops; sources of plant diagnostics; plant germplasm characterization and evaluation; public and private plant biotechnology laboratories; and relevant guidelines for plant germplasm exchange.

ii) Advisory services: advice to member states on policy and technical issues relating to crop propagation, breeding, germplasm conservation and exchange, and legal and biosafety issues, both on an *ad hoc* basis and through a scientific technical advisory committee, to guide the implementation of plant biotechnology programmes.

iii) Institutional capacity-building: the fostering of international collaboration for the appropriate use of plant biotechnologies, by promoting the establishment of *in vitro* tissue-culture laboratories in the least developed countries; strengthening existing crop-specific networks; fostering private and public sector cooperation; and the provision of grants for training and research, and equipment and maintenance costs.

iv) Technology transfer and adoption: the rapid transfer of the results of applied research down to level of the end-user farmers is a priority, including through by the promotion of strategic "up-stream" research to strengthen national agricultural research capacities in developing countries.

2. The Programme's activities involve close collaboration with other UN agencies such as UNESCO and UNIDO; major funding institutions, such as UNDP, the World Bank and regional development banks; the CG Centres; relevant private industry organisations; and non-governmental organizations. The participation of inter-institutional task forces for the international or regional planning of major projects is sought.

Progress made in implementing the programme

3. The Programme supports the development of regional plant biotechnology networks in Latin America (REDBIO),[29] Africa (APBNet)[51]88 and Eastern Europe.[52] REDBIO is already operational and a model for the other two.

4. The Programme is assisting the following countries in the planning of national goals and priorities based on their medium-term and long-term resources: Brazil, Chile, Costa Rica, Cuba, India, Iran, Nigeria, Pakistan, Senegal and Uruguay.

5. The Programme, in collaboration with IPGRI, supports research on *ex situ* conservation methods for vegetatively propagated and recalcitrant seed species, and aims to promote the application of molecular biology, both for the assessment of the genetic variability of plant genetic resources for food and agriculture, and for the increased utilization of such variability in breeding programmes. For example, a project in Cuba has established cold storage facilities and related tissue culture conservation techniques for sugar cane. It is hoped that such techniques will be extended to coffee, cassava, and banana, among other crops.

6. Additional information on plant biotechnology projects supported by FAO is provided in document CPGR-6/95/5.1, *Report on FAO's Plant Genetic Resources Activities*.[30]

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51 APBNet: African Plant Biotechnology Network.
52 Biotechnology Network for Eastern European Countries.

APPENDIX 2

STATES PARTY TO EITHER THE 1978 OR 1991 UPOV CONVENTIONS FOR THE PROTECTION OF NEW VARIETIES OF PLANTS[31]

State	Convention[53]
Argentina	1978*
Australia	1978
Austria	1978*
Belgium	1991
Canada	1991
Czech Republic	1978*
Denmark[54]	1991
Finland	1991
France[55]	1991
Germany	1991
Hungary	1978
Ireland	1991
Israel	1991
Italy	1991
Japan	1978
Netherlands	1991
New Zealand	1991
Norway	1978*
Poland	1978
Slovakia	1978*
South Africa	1991
Spain[56]	1991
Sweden	1991
Switzerland	1991
United Kingdom	1991
United States of America[57]	1991
Uruguay	1978*

1 Documents CPGR/89/9, CPGR/91/12 and CPGR/93/9 provide more extensive information and discussion of the potential of plant biotechnologies for international agriculture. See also "Biotechnologies in agriculture, forestry and fisheries" (1993) Rome:FAO.

53 States which have signed either the 1978 or the 1991 Act. The asterisk (*) indicates those countries which have signed the 1978 Act after 1 January 1991.

54 With a declaration that the Convention of 1961, the Additional Act of 1972 and the 1978 Act do not bind Greenland and the Faroe Islands.

55 With a declaration that the 1978 Act applies to the territory of the French Republic, including the Overseas Departments and Territories.

56 With a declaration that the Convention of 1961 and the Additional Act of 1972 apply to the entire territory of Spain.

57 With a notification under Articles 37(1) and (2) of the 1978 Act.

2 Hemming D. (1994) "Conference Report: 4th International Congress of Plant Biotechnology" AgBiotech News and Information, 6:217N-230N. While *Arabidopsis* is not a crop plant, the identification and functional characterization of many of its genes will facilitate the identification of their agronomically useful counterparts in many crop plants.

3 Schmidt K. (1995) "Whatever happened to the gene revolution" New Scientist, January 7th:21-25.

4 Article 3 defines "appropriate biotechnologies".

5 Thro A.M., Henry G. and Lynam J.K. (1994) "Biotechnology and small scale farmers" Biotechnology and Development Monitor, 21:18-19; Thro A.M. (1993) "Cassava Biotechnology Network: Research Achievements" Cassava Biotechnology Newsletter, 17:9-10.

6 Jefferson R.A. (1994) "Apomixis: A social revolution for agriculture?" Biotechnology and Development Monitor, 19:14-16.

7 Documents CPGR/93/9 Para. 8;CPGR/91/12 Para. 80-83; CPGR/89/9 Para. 32-33,36-37,45.

8 Komen J. (1993a) "The Intermediary Biotechnology Service" Biotechnology and Development Monitor, 17:18-19; The Intermediary Biotechnology Service (IBS) was established at ISNAR by an international group of donor agencies, to act as an independent advisory service on issues of biotechnology research management, information exchange, institution building, policy formulation and the assessment of the socio-economic impact of biotechnologies. The IBS has a collaborative project with Giessen University (Germany) and the Federal Institute of Technology (Switzerland) to assess the potential socio-economic impact of new plant biotechnologies on cocoa production and competitiveness.

9 Documents CPGR/89/Rep para. 50 and CPGR/91/Rep para. 100.

10 The UPOV Convention (for membership see *Appendix 2*) applies plant breeders' rights to approximately 30,000 protected varieties, in 27 countries.

11 The 1991 Convention also strengthened the variety holder's rights by modifying the "breeder's exemption", which allows the use of protected varieties, without compensation to the holder of varietal rights, for the purpose of breeding new varieties. Article 14 of the 1991 Convention requires the permission of the variety holder for the registration of an "essentially derived variety".

12 Russian Federation legislation allows the farmer's privilege for two years.

13 Both EC and US legislation allow farmers to re-use proprietary seed on their own holdings. EC Regulation No. 2100/94 requires equitable remuneration be paid to the breeder for this right and applies to a list of plant species. There is an exemption from remuneration payment for farmers producing less than a certain tonnage (92 tonnes for cereals). While US farmers may save seed for replanting, they cannot sell seed for reproductive purposes without the breeder's permission, or royalty payments ("Congressional Passage of New PVP Law a Triumph for Seed Industry" (1994) Diversity 10:34-35).

14 Article 27.3 (b) is the only Article in the Agreement that must reviewed four years after entry into force of the WTO Agreement (1 January 1995). For further discussion of the TRIPS agreement, see documents CPGR-6/95/8 Supp. para. 25-41 and Background Study Paper No. 2.

15 Community Regulation 2078/92, on "Agricultural production methods compatible with the requirements of the protection of the environment and the maintenance of the countryside", provides for annual incentive payments to farmers who maintain useful plants adapted to local conditions and threatened by genetic erosion, or endangered breeds of farm animals, on the basis of the area involved.

16 "India: Vigorous public debate over expanding seed legislation" (1994) Asian Seed, 1:3-5.

17 Cohen J.I. and Komen J. (1994) "International agricultural biotechnology programmes: Providing opportunities for national participation" AgBiotech News and Information, 6:257N-267N.

18 For further information on crop-specific networks supported by FAO, see Document CPGR-6/95/5.1, *Appendix 1*.

19 Altman D.W. (1993a) "Plant biotechnology transfer to developing countries" Current Opinion in Biotechnology, 4:177-179.

20 Reported by IBS to be Kenya, Zimbabwe and Egypt in Africa; Indonesia, Thailand and India in Asia; and Costa Rica, Mexico and Brazil in Latin America.

21 An earlier UNEP Expert Panel report stated that the possible protocol "does not include organisms modified by traditional breeding methods" (Expert Panels Established to Follow up on the Convention on Biological Diversity, Report of Panel IV, UNEP/Bio.Div./Panels/Inf. 1, 28 April 1993).

22 The open-ended *ad hoc* group of experts on safety in biotechnology will consider, *inter alia*, existing knowledge and experience of risk assessment and management, and guidelines and/or legislation already prepared by governments and by national and competent sub-regional, regional and international organisations.

23 "Proceedings of the pan-European conference on the potential long-term ecological impact of genetically modified organisms" (1993) Strasbourg:Council of Europe.

24 Doebley J. (1990) "Molecular evidence for gene flow among Zea species." BioScience 40:443-448. A related factor is the potential for the transgene in question to become fixed in the wild relative population through selection.

25 Crawley M.J., Hails R.S., Rees M., Kohn D. and Buxton J. (1993) "Ecology of transgenic oilseed rape in natural habitats" Nature, 363:620-623. The authors also commented on the fact that some non-transgenic plants such as bermuda grass (*Cynodon dactylon*) have become invasive weeds, citing Ellstrand N.C. and Hoffmann C.A. (1990) "Hybridisation as an avenue of escape for engineered genes." Bioscience, 40:438-442.

26 Hull R. and Gibbs M. (1994) "Risks in using transgenic plants?" Science, 264:1649-1651.

27 Schmidt K., *loc.cit.*

28 The FAO Programme mandate and proposed activities are outlined in detail in the Report of the Expert Consultation on the FAO/AGP Programme on Plant Biotechnology, 15-17 March 1993. For an overview of the Programme see, Villalobos V. (1995) "Brave new technologies" Ceres, 153:18-20.

29 REDBIO: Technical Cooperation Network on Biotechnology.

30 See, in particular, para. 20,36,38,39.

31 As of April 15, 1995; Based on UPOV/C/29/2 Annex.