March 2007

منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

Item 5.1 of the Draft Provisional Agenda

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Eleventh Regular Session

Rome, 11-15 June 2007

PROGRESS ON THE DRAFT CODE OF CONDUCT ON BIOTECHNOLOGY AS IT RELATES TO GENETIC RESOURCES FOR FOOD AND AGRICULTURE: POLICY ISSUES, GAPS AND DUPLICATIONS

1. The attached document, *Progress on the Draft Code of Conduct on Biotechnology as it Relates to Genetic Resources for Food and Agriculture: policy issues, gaps and duplications,* was presented to the last Tenth Regular Session of the Commission. It responds to the Commission's request, at its Ninth Session, that "the Secretariat [...] prepare a study, in order to identify what is done in other forums, what remains to be done on the issues raised in the document, *The Status of the draft Code of Conduct on Biotechnology; Report of Surveys of FAO Members and Stakeholders,* and which issues were relevant to FAO, and in particular, its Commission. In the preparation of the study, there should be consultations, as appropriate, with relevant international organizations. The aim of the study would be to assist the Commission to identify issues on which it should concentrate in the future, with respect to a Code of Conduct, Guidelines, or other courses of action".

2. In considering the document, at its Tenth Regular Session, the Commission recognised the importance of the subject. Members of the Commission identified the following fields, amongst those listed in the document, as the most appropriate for further work: conservation of genetic resources for food and agriculture in the centres of origin and *ex situ* collections; appropriate biotechnologies that apply to genetic resources for food and agriculture; access and benefit-sharing issues related to biotechnologies that apply to genetic resources for food and agriculture; national capacity-building and international cooperation; biosafety and environmental concerns; genetic use restriction technologies (GURTs); GMO gene flow and the question of liability; and incentives to promote appropriate biotechnologies. These should be taken into account, in designing the Commission's Multi-Year Programme of Work (MYPOW).

3. Some countries, noting the importance of the issues, and that they had not had sufficient time to study the document, asked for more time to do so. They therefore requested that the document be referred to the Eleventh Session of the Commission. The Commission agreed, so that at this session decisions could be reached on which issues should be taken forward and in what form (a code or codes of conduct, guidelines or other approaches).

October 2004

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Item 8 of the Draft Provisional Agenda

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Tenth Regular Session

Rome, 8-12 November 2004

PROGRESS ON THE DRAFT CODE OF CONDUCT ON BIOTECHNOLOGY AS IT RELATES TO GENETIC RESOURCES FOR FOOD AND AGRICULTURE: POLICY ISSUES, GAPS AND DUPLICATIONS

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I. BACKGROUND

1. In 1991 the FAO Council agreed to a request from the Commission on Genetic Resources for Food and Agriculture (CGRFA)[1] that a draft "International Code of Conduct on Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources" be prepared.

2. The first draft was considered by the Commission in 1993.[2] It agreed that the objectives of the Code should be to help maximise the positive effects of biotechnology, and to minimise any potential negative effects, especially in developing countries. However, noting that the Convention on Biological Diversity (CBD) was developing a Biosafety Protocol, the Commission recommended that the "biosafety and other environmental concerns" component of the draft Code be forwarded to the CBD. It was suggested by the Commission that FAO further develop the remaining components of the Code, in collaboration with others. These were:

- promotion of appropriate biotechnologies (Article 5);
- action at the national level (Article 6);
- international cooperation in appropriate biotechnologies (Article 7);
- prevention and mitigation of possible negative effects (Article 8);
- access to plant genetic resources and related biotechnologies, intellectual property rights, and compensation for informal innovators (Article 9); and
- exchange of information and early warning (Article 10).

3. At its sixth Regular Session, the Commission received a *Report on Recent International Developments of Relevance to the Draft Code of Conduct for Plant Biotechnology*,[3] and postponed further development of the Code until the negotiations on the International Treaty on Plant Genetic Resources for Food and Agriculture had been concluded. Following the broadening of the scope of the Commission, in 1995, the Commission has received periodic reports on developments in plant and animal biotechnology of relevance to the draft Code.[4]

4. At its ninth Regular session, the Commission reviewed the document *The Status of the draft Code of Conduct on Biotechnology; Report of Surveys of FAO Members and Stakeholders*[5], which summarised views of Member countries and stakeholders on issues considered to be of relevance to the Code development. It "recognized the need to go ahead with the aim to maximize the positive effects of biotechnologies and minimize any potential negative effects or risks, and that the focus should be on biotechnologies related to genetic resources for food and agriculture." However, there were different views as to whether this should be through the revision and up-dating of the draft Code or whether it should be a phased approach with consideration of additional options. The Commission accordingly "requested the Secretariat to prepare a study, in order to identify what is done in other forums, what remains to be done on the issues raised in the document *The Status of the draft Code of Conduct on Biotechnology; Report of Surveys of FAO Members and Stakeholders*, and which issues were relevant to FAO and in particular its Commission. In the preparation of the study, there should be

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[1] Then called the "Commission on Plant Genetic Resources". The scope of the Commission was broadened in 1995 to cover all components of biodiversity of relevance to food and agriculture, and its name was changed accordingly.

[2] Documents relating to the International Code of Conduct on Biotechnology can be found on the FAO website: http://www.fao.org/ag/cgrfa/biocode.htm

[3] Document CPGR-6/95/15, ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa6/R6W15E.pdf

[4] *Recent Developments in Biotechnology as they Relate to Plant Genetic Resources for Food and Agriculture*, Spillane. C. (1999), Background Study Paper 9, ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp9E.pdf; *Recent Developments in Biotechnology as they Relate to Animal Genetic Resources for Food and Agriculture*, Cunningham E.P. (1999) Background Study Paper 10, ftp://ext-ftp.fao.org/ag/cgrfa/BSP/bsp10E.pdf

[5] Document CGRFA-9/02/18, ftp://ext-ftp.fao.org/ag/cgrfa/cgrfa9/r9w18e.pdf

consultations, as appropriate, with relevant international organizations. The aim of the study would be to assist the Commission to identify issues on which it should concentrate in the future, with respect to a Code of Conduct, Guidelines, or other courses of action."[6]

5. The present document provides a summary of the main outcomes (duplications and gaps) identified in the study and seeks the Commission's guidance on the future development of the Code of Conduct, guidelines or other courses of action.

II. STUDY OF ISSUES, GAPS AND DUPLICATIONS IN RELATION TO THE CODE OF CONDUCT ON BIOTECHNOLOGY

6. A questionnaire was developed and sent to relevant international organizations working in different sectors of biotechnologies: agriculture, environment, trade, intellectual property, health, education and others. The list of the organisations that provided substantive responses is provided in *Appendix I*. All of the responses received were very positive towards the further elaboration of the Code, guidelines or other courses of action to address many of the key issues raised in document CGRFA-9/02/18. Furthermore, intergovernmental organisations identified additional policy gaps of relevance that they considered should be addressed at the international policy level, a summary of which is at *Appendix II*.

7. A parallel survey was also conducted within FAO to ensure that any future code, guidelines or other courses of action are integrated with and supportive of existing FAO activities in this area.

8. The scope of the draft Code is currently limited to biotechnologies as they affect the conservation and utilization of plant genetic resources. Commission members have stressed that, in light of the broadened mandate of the Commission, the draft Code should address all components of genetic resources, including plants, livestock, fish and micro-organisms as they relate to food and agriculture. Of relevance to the scope of the draft Code are decisions II/15 and V/5 of the CBD CoP which recognized the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions.

9. The "gap analysis" study identifies what is done in other international forums involved in policy setting in the area of biotechnologies for food and agriculture. The 58th Session of the UN General Assembly considered a report on the "Impact of new biotechnologies, with particular attention to sustainable development, including food security, health and economic productivity". In 2003, the UN General Assembly Resolution 58/200 took note of the Secretary General' proposal for an integrated framework for biotechnology within the UN system and the need for strengthening coordination between relevant organizations and bodies of the system in the area of biotechnology.

10. A wide range of broader international policies with stated aims of poverty reduction, make recommendations regarding the role of technologies (including biotechnologies) for poverty alleviation.These policies and forums include:

- The Rome Declaration on World Food Security and the WFS Plan of Action.
- The FAO State of Food & Agriculture Report on Agricultural Biotechnologies (2003-2004).
- The Millennium Development Goals (MDGs).
- Inter Academy Council's Science & Technology Strategy for Africa.
- The UN Commission on Science & Technology for Development.
- The UN Conference on Trade and Development (UNCTAD) Plan of Action.

[6] CGRFA-9/02/REP, *Report of the Ninth Regular Session of the Commission on Genetic Resources for Food and Agriculture*, paragraph 65

- The Global Biotechnology Forum.
- The World Summit on Sustainable Development.

11. There are no international policy instruments specifically addressing the aims and objectives of the draft FAO Code of Conduct on Biotechnology. The study revealed that there are currently no international policy instruments specifically dealing with the issue of how agricultural biotechnologies might be focussed on poverty reduction and food security. The overall intergovernmental policy guidance gap highlighted by the study was a need for a short policy "Declaration" on Agricultural Biotechnology outlining general principles for consideration if agricultural biotechnologies are to meet the needs of the poor, in an environmentally sustainable manner.

12. The specific conclusions of the survey of international organisations and the associated gap analysis study are presented below. The survey headings used below closely follow those of document *The Status of the draft Code of Conduct on Biotechnology; Report of Surveys of FAO Members and Stakeholders*.[7]

1. Conservation of genetic resources for food and agriculture (paragraph 16 of document CGRFA-9/02/18)

Duplication

13. The most relevant forums and policies are those of the FAO Commission on Genetic Resources for Food and Agriculture and the Convention on Biological Diversity's (CBD) programme of work on agricultural biodiversity (CoP decisions III/11, V/5, VI/5 and VII/3).

Gaps

14. The following possible gaps were identified:

- There are no international policy instruments to promote the conservation & sustainable utilization of non-plant genetic resources for food and agriculture (e.g. animal, fish, forestry and microbial).
- There are no international policy instruments which specifically focus on minimising possible negative effects on biodiversity that might be caused by agricultural biotechnologies that do not result in products classified as LMOs (e.g. plant micro-propagation, artificial insemination).
- There are no international policy instruments which promote the use and deployment of agricultural biotechnologies in order to increase crop and non crop agricultural genetic diversity and reduce genetic crop genetic vulnerability.

2. Appropriate biotechnologies that apply to genetic resources for food and agriculture (paragraphs 17 - 19 of document CGRFA-9/02/18)

Duplication

15. None identified.

Gaps

16. The following possible gaps were identified:

- There is no international policy instrument to complement broader international development policy objectives (e.g. Millenium Development Goals, World Food Summit Plan Of Action, etc) that promotes the development of appropriate agricultural biotechnologies that maximise the benefits and minimise the risks, particularly in relation to the needs of the poor.

[7] CGRFA-9/02/18

- Scientific (biosafety, food safety) and non-scientific (socio-economics, ethics, IPRs, trade) aspects of biotechnology are not evaluated in an integrated manner and there is no inter-governmental framework within which to do so.
- There are no generally recognised criteria to distinguish and identify appropriate agricultural biotechnologies.

3. Access and benefit-sharing issues related to biotechnologies that apply to genetic resources for food and agriculture (paragraphs 20 - 26 of document CGRFA-9/02/18)

Duplication

17. There are no direct links between access and benefit sharing and the development of agricultural biotechnologies. However, there are now a number of forums (CGRFA, CBD, WIPO, TRIPs Council) and policy instruments (CBD, International Treaty on Plant Genetic Resources, WTO, WIPO) that could address:

- Issues of access and benefit sharing (including technology transfer) relating to the application of biotechnologies that use genetic resources for food and agriculture are considered by the Convention on Biological Diversity, the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization, and by the International Treaty on Plant Genetic Resources.
- Issues relating to the protection of formal and informal innovation (including Farmer's Rights) are now being addressed by the International Treaty on Plant Genetic Resources, the Convention on Biological Diversity, the WTO TRIPs Council, and WIPO's Intergovernmental Committee on Intellectual property and Genetic Resources, Traditional Knowledge and Folklore (IGC).
- Many issues raised regarding IPRs in the context of transgenic biotechnologies for food and agriculture are being considered by WIPO. Other international agreements of relevance to IPRs include the International Treaty on Plant Genetic Resources for Food and Agriculture and the Convention on Biological Diversity.
- At present the two major international policy-setting forums for intellectual property rights are the World Intellectual Property Organization (WIPO) and the WTO TRIPs Council. The WHO Commission on Intellectual Property, Innovation and Public Health and the UK Commission on Intellectual Property Rights (which was established to look at how intellectual property rights might work better for poor people and developing countries)[8] are also relevant.

Gaps

18. The following possible gaps were identified:

- There is no international policy instrument that makes an explicit link between access and benefit-sharing and products or processes generated by modern biotechnologies and the use of genetic resources.
- As much of the groundwork and analysis is already available, more could now be done to develop and promote policies to facilitate access to biotechnology products and processes essential to food security.
- There is no international policy instrument on how agricultural biotechnology IPR policy could be managed to ensure that agricultural biotechnologies can better meet the needs of the poor.
- There is no agreed international model to protect informal innovation embodied in traditional knowledge. There are few legislative models in practise for the protection of informal innovation in the area of traditional knowledge and/or agricultural biotechnologies.

[8] Commission on Intellectual Property Rights (2002) Integrating Intellectual Property Rights and Development Policy, Commission on Intellectual Property Rights/DFID: UK. http://www.iprcommission.org

- There is no international policy instrument to advise countries in developing national legislation regarding IPRs and agricultural technology.
- There is no international policy instrument to help governments develop national legislation on Farmers' Rights.
- There is no international recognition of Farmers' Rights for non-plant agricultural genetic resources, though for domestic animals, the process to develop the first State of the World Animal Genetic Resources is relevant.

4. National capacity-building and international cooperation (paragraphs 27 - 30 of document CGRFA-9/02/18)

Duplication

19. There are a range of international projects and programmes which aim to strengthen national expertise and increase international cooperation programmes and action plans in the area of agricultural biotechnologies that apply to genetic resources for food and agriculture. In addition, there are some inter-governmental forums (e.g. UN CSTD) where capacity strengthening for biotechnology has been considered.

Gaps

20. The following possible gaps were identified:

- There are no international or regional inter-governmental policy instruments (e.g. Global or Regional Plans of Action on Agricultural Biotechnology) specifically focussed on the area of agricultural biotechnologies.
- There may be a need to develop integrated approaches towards developing policy instruments (e.g. Plan of Action, Guidelines, etc) to promote the strengthening of national expertise and increasing international cooperation programmes and action plans for agricultural biotechnologies for development for both crop and non-crop genetic resources for food and agriculture.
- There are no policy instruments specifically emphasising the critical importance of publicly funded pro-poor agricultural biotechnology research, especially for addressing issues such as public goods, poverty reduction and food security which may not have market-based solutions.

5. Biosafety and environmental concerns (paragraphs 31-33 of document CGRFA-9/02/18)

Duplication

21. There are already a wide range of international policy-setting forums and policy frameworks dealing with most issues relating to biosafety and environmental concerns regarding genetically modified organisms (GMOs), including their use in food and agriculture. These include the CBD's Cartagena Protocol on Biosafety, the WTO SPSS Agreement, the FAO/WHO Codex Alimentarius Commission, the FAO IPPC, the WTO TBT Agreement and the OIE.

Gaps

22. The following possible gaps were identified:

- There are no internationally agreed technical guidelines or codes of practice to provide guidance regarding use of transgenic crop and non-crop genetic resources for food and agriculture in centres of diversity/origin.
- There are no internationally agreed technical guidelines on environmental risk for the release of Genetically Modified Organisms of relevance to food and agriculture.
- A possible need to include social needs in biosafety regulation and assessment.

6. Information dissemination and public awareness (paragraphs 34 - 35 of document CGRFA-9/02/18)

Duplication

23. Many international policy instruments make provisions for information dissemination and public awareness within their mandate. There are a number of forums and frameworks focussing on these issues, particularly in relation to GMOs (Aarhus Convention, CBD).

Gaps

24. The following possible gaps were identified:

- More could be done to promote dialogue and consensus building on what roles (if any) agricultural biotechnologies that apply to genetic resources for food and agriculture can play to strengthen food security and reduce poverty in line with international commitments (e.g. MDGs).

7. Ethical questions regarding biotechnologies as they relate to genetic resources for food and agriculture (paragraphs 37-39 of document CGRFA-9/02/18)

Duplication

25. A number of forums, panels and policies are active on the issue of ethics regarding biotechnologies in general (e.g. the UN Inter-Agency Committee on Bioethics, UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology (COMEST), UNESCOs Bioethics Programme, the FAO Panel of Eminent Experts on Ethics in Food and Agriculture and the WHO Ethics and Health Initiative). UNESCO is well advanced in the development of a Declaration on Universal Norms on Bioethics.

Gaps

26. The following possible gaps were identified:

- There is no international framework for the consideration of ethical issues in the application and use of biotechnologies, including in the area of food and agriculture.
- There may be a case to develop a Declaration which parallels the structure of the UNESCO declaration specifically for bioethics in relation to biotechnologies relevant to genetic resources for food and agriculture.

8. Substitution of traditional agricultural products by new biotechnological products (paragraph 40 of document CGRFA-9/02/18)

Duplication

27. None identified.

Gaps

28. The following possible gaps were identified:

- There are few mechanisms established to assess impacts of agricultural biotechnologies in socio-economic terms.
- There are no measures to promote technology assessment (capacity building, studies and systems) measures to identify sectors and peoples whose livelihoods may be threatened by economic substitution effects directly due to market domination by novel agricultural biotechnology products.
- There are no international policies or other mechanisms to mitigate the possible temporary adverse effects of substitutions due to agricultural biotechnology on developing countries' economies.

9. Genetic Use Restriction Technologies (GURTs) (paragraph 42 of document CGRFA-9/02/18)

Duplication

29. The CBD is the main other policy framework looking at issues related to GURTs and biodiversity. Decision VI/5 of the Conference of the Parties invited the FAO "[...] to consider genetic use restriction technologies in the further development of the *Code of Conduct on Biotechnology as it Relates to Genetic Resources for Food and Agriculture.*

Gaps

30. The following possible gaps were identified:

- There are no international policy instruments that provide guidance on the specific issue of technological protection of innovations in agriculture, including GURTs.
- A need to respond to the invitation of the CBD to address the issue of GURTs within the Code of Conduct on Biotechnology.

10. Biotechnology and increasing control over the global agro-food system (paragraphs 43 -44 of document CGRFA-9/02/18)

Duplication

31. None identified.

Gaps

32. The following possible gaps were identified:

- There are no international forums or policy frameworks addressing issues (e.g. anti-trust or competition policy) relating to biotechnology and control over the global agro-food industry.

11. GMO gene flow and the question of liability (paragraphs 45-47 of document CGRFA-9/02/18)

Duplication

33. Most issues relating to GMO geneflow and issues of liability/redress are already being addressed within the policy framework of the CBD and the Cartagena Protocol on Biosafety.

34. The CGIAR is drawing up draft guiding principles for policies to address the possibility of adventitious presence of transgenes in CGIAR *Ex Situ* Collections.

Gaps

35. The following possible gaps were identified:

- There is limited economic and impact analysis of the issues of geneflow, liability and redress that considers the effects of such issues on farmers and consumers.
- There is limited analysis of the distributive impacts of diverse national traceability systems in the context of the international trading system, particularly on those countries facing severe public resource constraints.
- There are no international policy instruments or other mechanisms on co-existance, to avoid or minimise the effect of GMO geneflow on the integrity of genetic resources for food and agriculture populations, varieties or breeds in in situ conditions.
- There are no internationally agreed guidelines, for use by national and international genebanks, regarding the possible introgression of genes from GMOs into ex situ conditions, although the CGIAR is finalizing a set of principles that may of use as model.

12. Incentives to promote appropriate biotechnologies (paragraph 48 of document CGRFA-9/02/18)

Duplication

36. None identified.

Gaps

37. The following possible gaps were identified:

- There are no international forums or policy frameworks addressing issues relating to incentives to promote use of appropriate biotechnologies that are specifically targeted at reducing poverty, improving human livelihoods and/or increasing food security (e.g. meeting the MDGs).

13. International voluntary certification schemes (paragraph 49 of document CGRFA-9/02/18)

Duplication

38. None identified.

Gaps

39. The following possible gaps were identified:

- There are no international forums or policy frameworks addressing issues relating to international voluntary certification schemes for products obtained through biotechnologies.

14: Universal FAO genome declarations for Plants and Livestock Animals (paragraph 50 of document CGRFA-9/02/18)

Duplication

40. None identified.

41. While there are no duplications of such policy at the international level, given the extent of selective breeding of agricultural species (with concomitant effects on their genome structure when compared to wild species), it would seem that there is less of a gap for an Agricultural Genome Declaration that precisely parallels the content of the UNESCO Human Genome Declaration.

Gaps

42. The following possible gaps were identified:

- There may be scope for the development of a short FAO Universal Genome Declaration that highlighted, collated and drew upon the overarching principles and philosophies that currently underpin the relevant international policies regarding genetic resources, biodiversity and biotechnologies (e.g. the CBD, the International Treaty on Plant genetic Resources for Food and Agriculture).

III. CONCLUSIONS

43. It is apparent from the study requested by the Commission that many international organisations see positive benefits in FAO further developing its work in this area. In the 14 fields identified by Members of the Commission as being of potential relevance to a code of conduct, guidelines or other courses of action, it is clear that there are many areas where there is little or no duplication with the work of other international organisations. Many gaps were also identified within those fields that might form the basis for the development of a code or codes of conduct, guidelines or other course of action. The international organisations consulted also identified a list of other related issues which might also be included in this work. These are described in *Appendix II*.

44. It is important that clear guidance is provided by the Commission on whether and how this work should now be taken forward.

IV. GUIDANCE SOUGHT FROM THE COMMISSION

45. Noting that during the ninth Regular session, the Commission "recognised the need to go ahead with the aim to maximise the positive effects of biotechnoligies and minimise any potential negative effects or risks, and that the focus should be on biotechnologies related to genetic reosurces for food and agriculture" and that the aim of the study was "to assist the Commission to identify issues on which it should concentrate in the future, with respect to a Code of Conduct, Guidelines, or other courses of action", the Commission may wish to:

- indicate which of the 14 fields identified by the Commission should be further developed and in what form they should be taken forward (codes of conduct, guidelines or other approaches); and

- advise on the means by which the work should be taken forward, in particular whether it would like to establish one or more technical consultations to deal with the different fields identified, whether it would like to continue to work on an inter-governmental basis, possibly through the establishment of an Ad Hoc Working Group, or a combination of these processes.

APPENDIX I: LIST OF INTERNATIONAL ORGANISATIONS CONSULTED AND CONTRIBUTING TO THIS STUDY AND THE ASSOCIATED BACKGROUND STUDY PAPER

- Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (UNECE)
- Codex Alimentarius Commission (FAO/WHO)
- Convention on Biological Diversity (CBD)
- CGIAR Science Council
- International Atomic Energy Agency (IAEA)
- International Labour Organisation (ILO)
- International Union for the Protection of New Varieties of Plants (UPOV)
- United Nations Common Fund for Commodities
- United Nations Commission on Human Rights (UNHCR)
- United Nations Department of Economic & Social Affairs (DESA) / UN Commission on Sustainable Development (CSD)
- United Nations Educational, Scientific and Cultural Organization (UNESCO) - Division of Ethics of Science and Technology.
- United Nations Millennium Development Goals (MDGs) Task Force on Hunger
- World Bank (Agriculture and Rural Development Department)
- World Health Organisation (WHO): Food Safety Department; Access to Essential Drugs Initiative; Ethics & Health Initiative
- World Intellectual Property Organisation (WIPO)
- World Trade Organization (WTO): Agriculture and Commodities Division; Trade & Environment Division; Agriculture and Commodities Division; SPS & TBT Committees; Intellectual Property Division; TBT Committee; TRIPs Council

APPENDIX II: ADDITIONAL ISSUES, RAISED BY THE INTERNATIONAL ORGANISATIONS SURVEYED, CONSIDERED OF RELEVANCE TO A CODE OR CODES OF CONDUCT, GUIDELINES OR OTHER COURSES OF ACTION

The survey conducted resulted in a number of proposals for additional policy issues. These are summarised below.

APPROPRIATE BIOTECHNOLOGIES

Prioritization of research and development agendas

- A code of conduct, guidelines or other mechanisms could be developed to achieve an integrated approach to the evaluation of biotechnology, taking into account both scientific (risk levels, biosafety, food safety) and non-scientific (poverty, socio-economic, ethical, IPR and trade) considerations.
- Guidance could be provided on how such an integrated framework could be initiated at the UN agencies level.

Appropriateness of biotechnologies

- The concept of appropriate biotechnologies may be considered vague and could benefit from identification of criteria and indicators to distinguish and identify appropriate agricultural biotechnologies.
- Guidelines could be developed on how countries and stakeholders can determine the appropriateness of particular biotechnologies and whether an integrated approach to such evaluations is necessary.

ACCESS AND BENEFIT SHARING

- Consideration could be given to whether there is a need for models for consultation, benefit sharing and contractual arrangements between stakeholder groups regarding the benefit-sharing interface between biodiversity and biotechnology.

INTELLECTUAL PROPERTY RIGHTS OVER AGRICULTURAL BIOTECHNOLOGIES

- A code of conduct, guidelines or other courses of action could build upon recent developments and issues raised in WIPO, the report of the UK Commission on Intellectual Property Rights, WTO, and others to address the question on whether IPRs in agricultural biotech promote technology generation or restrict access, and by whom? Guiding principles could be developed to advise countries in developing their national legislation regarding IPRs and agricultural biotechnology.

NATIONAL CAPACITY BUILDING AND INTERNATIONAL COOPERATION

Strengthening national expertise and increasing international cooperation programmes and actions plans for agricultural biotechnology.

- There is a need for assistance to countries to assess their capacity-building needs and priorities and to develop strategic agricultural-biotechnology action plans and programmes to address them. Policies could be promoted to facilitate the development of strategic agricultural biotechnology action plans at the national and regional levels.
- Because developing countries are faced with multiple resource constraints for policy implementation that meets their needs, mechanisms could be promoted that facilitate greater collaboration between agencies that provide assistance in order to maximise the use of resources wherever possible.

- There is a need for an in-depth international dialogue on the present models of biosafety regulations and their enforcement. Most biosafety regulations are being adopted or adapted from developed country models, where plenty of resources are available to satisfy the regulators. Guidance could be provided on whether such resource-intensive regulatory models might be rational for developing countries with limited resources for implementation.
- There is a need of additional financial and technical resources for capacity building in biotechnology and biosafety at the national level. Currently, GEF is the only main source of funding for biosafety activities available. Guidance could be provided in this regard.

Public-private sector partnerships in agricultural development for poverty reduction and food security.

- There is a need for 'best practice' models for public sector support in public-private partnerships. There are many questions remaining as to how to engage the private sector and its knowledge and funding resources to benefit developing country agriculture in research, technology transfer and in awareness and capacity building. Guidance could be provided in this area.

The continuing need for public sector agricultural biotechnology research.

- Consideration could be given as to whether international policy should encourage governments to pay special attention to recognizing and promoting the importance of public sector agricultural research particularly in developing countries, Criteria could be established to identify areas where there is a need for public sector agricultural research (e.g. non-commercial markets, food security, public health, minor and orphan crops, poverty reduction etc).

BIOSAFETY AND ENVIRONMENTAL CONCERNS

Risk assessment and management of GMOs

- The concept of "substantial equivalence" may need to be further elaborated, particularly as base-line data (e.g. on composition of nutritional or anti-nutritional compounds, yield, and other agronomic qualities) for a wide range of existing cultivars and varieties in each crop genepool is lacking. Consideration could be given to the development and dissemination of base-line data for crop genepools that could be used for assessing the substantial equivalence of transgenic varieties within each crop.

International standards for the testing & release of GMOs

- Policies could be developed that place an emphasis on strengthening policy prioritization skills, so that countries develop the capacity to evaluate potential regulatory needs/ systems against other costly endeavours and in the context of limited financial resources.
- The use of risk analysis techniques could be encouraged in the development of national measures in this area by strengthening networks among stakeholders in international standards setting bodies and national regulatory agencies.
- Examination of the private and public systems of standards related to biotechnology products could be promoted. Consideration could be given to the promotion of policies and mechanisms that enhance the dialogue between public and private actors in this area, possibly leading to models for greater engagement of the private sector in capacity building for risk assessment.

Research in biosafety

- Comparative studies (e.g. with conventional and organic practices) could be promoted to study whether different types of GMOs have any long-term environmental impacts that exceed existing impacts from substantially equivalent non-GMOs.
- Consideration could be given to the promotion of the examination of the financial and human resource constraints faced by developing countries in implementing risk assessments and seek mechanisms to address them in a manner that contributes to food security and poverty reduction.

- Support to biosafety research relevant to developing country agro-ecologies and socio-economic situations needs to be highlighted and supported. Regional cooperation to reach sufficient critical mass is necessary. Policy guidance could be provided on these issues.

Guidelines for release of GMOs in crop centres of diversity/origin.

- At present there are no internationally agreed guidelines or codes of practice to provide guidance regarding use of transgenic crops in crop centres of diversity/origin and there is an urgent need for policy guidance in this area. Consideration could be given to whether commissioning the development of such guidelines/codes may be useful in order to guide decision-making for the list of the major food crops currently covered by the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture.

INFORMATION DISSEMINATION AND PUBLIC AWARENESS

Information dissemination and public awareness regarding agricultural biotechnologies.

- Mechanisms (e.g. national platforms) to promote public awareness, debate and information dissemination could be considered, with the objective of disaggregating the term "biotechnologies" into different types of agricultural biotechnologies and highlighting those biotechnologies which are less contested than others.
- Consideration could be given to the development of a joint agricultural-biotech information platform by international (e.g FAO, CBD, World Bank etc) and scientific organizations (e.g. Academies of Science) might be helpful to provide updated and balanced information on agricultural biotechnology for development.
- Consideration could be given to the establishment of basic criteria to ensure that representatives on national platforms are actually representative of the needs of stakeholder groups (e.g. membership based organisations, unions, etc) and democratically accountable (including liability for misrepresentation of interests) to their stakeholders. Such approaches could help to improve the good governance of debate and policy-making regarding appropriate biotechnologies for development.
- Access by developing countries to essential tools and enabling technologies necessary to implement international policy and regulatory provisions in the area of biotechnologies for food and agriculture could be promoted.

ETHICAL QUESTIONS REGARDING BIOTECHNOLOGIES AS THEY RELATE TO GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Ethics and agricultural biotechnology

- There is a need to develop an international framework for the consideration of ethical issues in the application and use of biotechnology, including in the area of food and agriculture. Consideration could be given to the development of an integrated process involving cooperation between all UN agencies that deal with some aspect of modern biotechnology.
- Consideration could be given as to how wide-reaching at the policy level the ethical discussions regarding agricultural biotechnology should be. It may be possible within the code to develop the core dimensions and principals for thinking and framing the policy discussion about ethical aspects of agricultural biotechnologies (e.g. doing good for human welfare; avoiding doing harm; justice; and respect (incl. right to choose, related to GMO labelling).
- Promotion of national, regional and international exchange between specialists in ethics, science and policy could be considered, in order to provide technical support for the establishment of regional networks of experts in the area of ethics and appropriate biotechnologies, as well as advisory services towards the decision making process.
- Within the context of a code of conduct, debate could be promoted around the idea of how could the industry and FAO Member States develop a more ethical R&D in biotechnology towards a sustainable agriculture.

Equitable distribution of the benefits of agricultural biotechnology R & D

- The biotechnology code could encourage governments to direct research towards the needs of local farming systems, especially the farming systems of poorer people.
- The code could draw attention to the need for sharper focus for public sector research to support resource poor farmers and consumers. Guidance to international and national organizations in doing this would be valuable.

SUBSTITUTION OF TRADITIONAL AGRICULTURAL PRODUCTS

Substitution of traditional agricultural products via agricultural biotechnologies.

- There is a need for the establishment of mechanisms to better assess biotechnologies in socio-economic terms. There is no international policy (or other) mechanisms to mitigate the possible temporary adverse effects of substitutions due to agricultural biotechnology on developing countries' economies. The development of international policies in this area would require consideration of international and regional policies on trade (e.g. WTO, EU CAP etc) in the context of whether mitigating mechanisms would constitute barriers to trade.
- Economic substitution effects due to agricultural biotechnologies can be envisaged which go beyond the remits of the Biosafety Protocol (e.g. effects not affecting biological diversity but instead affecting the socio-economic position of a developing country, perhaps in international commodity markets). Guidance could be provided on how to avoid or mitigate economic hardships of substitution effects of agricultural biotechnologies on poorer farmers and consumers.

GMO GENE FLOW AND THE QUESTION OF LIABILITY

- Examinaton of the distributive impacts of diverse national traceability systems in the context of the international trading system could be promoted, particularly on those countries facing severe public resource constraints.
- Consideration could be given to the promotion of consensus on definitions related to the allowable adventitious presence of GMOs in a non-GMO product in order to limit inefficiencies in the international trading systems.
- The development of appropriate sampling and testing methodologies for biotechnology products could be promoted to limit burdensome technical and financial requirements for developing countries.
- Policy guidelines could be developed on how functioning GM co-existence or GM-free zones could be established in a manner that reduces poverty and increases food security.
- Policies for managing geneflow from crops in different production systems (e.g. GMO vs. organic) are under construction in Europe and North America. In some developing countries this proposed approach is also emerging as an issue (e.g. India, China). The Code could provide guidance on how to effectively manage geneflow in small holder patterns of production.
- A review could be undertaken of experiences available from developed countries on land-use patterns that attempt to allow for co-existence of different farming systems (e.g. conventional, organic, GMO) to determine their effectiveness and whether they could be adapted (or not) to developing country situations; or how other measures could be developed (GM free or GM only provinces or countries, etc.).

INCENTIVES TO PROMOTE APPROPRIATE BIOTECHNOLOGIES

Incentives for appropriate biotechnologies

- A biotechnology code could incorporate minimum standards for good biodiversity and agricultural biotechnology management.

Agricultural biotechnology research on new, minor and underutilised crops.

- Guidelines could be developed for countries to establish orphan crop acts to promote agricultural biotechnology research on crops and varieties which poorer farmers and consumers are dependent upon for their livelihood security.
- While the public sector in some developing countries has developed relevant biotechnological products in orphan crops of importance to food security, one constraining issue is the cost of compliance with biosafety and food-safety regulations. This issue could be addressed in the code and guidance or models presented for cost-effective compliance presented.

INTERNATIONAL VOLUNTARY CERTIFICATION SCHEMES

- General principles or guidelines could be developed which could be taken as standards by independent national or international organizations and companies to certify products obtained through biotechnologies as compliant with the biotechnology code. Such standards could be developed by (a) the private sector (b) international development organisations (c) NGOs, ideally through a tri-partite coalition approach similar to that used by the International Labour Organisation to develop codes of conduct regarding labour issues.