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COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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CROSS-SECTORIAL INTERNATIONAL POLICY ISSUES AND GENETIC RESOURCES: STATUS AND NEEDS

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CROSS-SECTORIAL INTERNATIONAL POLICY ISSUES AND GENETIC RESOURCES: STATUS AND NEEDS

I. INTRODUCTION

1. At its last Session, the Commission requested its Secretariat to document the status and needs of sectors of genetic resources for food and agriculture, other than plants and animals, including the various areas of biodiversity for food and agriculture, and the agro-ecosystem approach to genetic resource conservation and cross-sectorial matters.[1]

2. This document identifies various relevant international policy questions, and describes relevant developments and trends. It concludes with proposals for covering these issues in the Multi-Year Programme of Work (MYPOW) of the Commission, and establishing a framework of goals, targets and indicators for this work.

II. CROSS-SECTORIAL INTERNATIONAL POLICY AND GENETIC RESOURCES FOR FOOD AND AGRICULTURE IN A TIME OF GLOBALIZATION

3. Rapidly increasing globalization marked the late twentieth century, with the ever closer integration of countries and peoples, through an increased flow of resources, goods and services, ideas and knowledge. There is a growing awareness of increasing inter-dependence, where actions in one country or region can have positive and negative impacts on others. The 1990s saw a number of new international agreements and organizations, to help manage globalization processes, including the World Trade Organization and the Rio Conventions.

4. Biodiversity and genetic resources are central in the discussion of globalization. Various international bodies, conventions, agreements and guidelines now govern the use and conservation of genetic resources. The Commission was the first, and remains the only inter-governmental institution, to address all biodiversity for food and agriculture.

5. Globalization has had a strong impact on management of the food and agriculture sector, and, in particular, agricultural genetic resources. Decision-making on core subjects has tended to move piecemeal to new forums that deal with aspects of agricultural development as part of trade and environment agendas. These not only bring different perspectives to genetic resource management, but have different memberships. There is now, however, a renewed recognition of the centrality of food and agriculture, with the Millennium Development Goals' focus on achieving a significant reduction of hunger and poverty by 2015.

6. The FAO Strategic Framework provides for a twin-track approach to FAO's involvement in the international agenda:

- a strengthened contribution to negotiations in other forums, to ensure that the specific needs and concerns of the food, agriculture, fisheries and forestry sectors are adequately reflected; and
- the provision of a neutral global forum for the development of relevant international policy frameworks, in particular the Commission.

7. The Commission needs to consider the international context in adopting its MYPOW. At its last Session, it called for strengthening cooperation with relevant international organizations and agreements, in particular the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture. Documents of this Session explore

[1] CGRFA-10/04/REP, paragraph 89.

how to strengthen such cooperation,[2] for synergy and complementarity, and a reduced reporting burden on Members of the organizations.

8. This document reviews international policy issues regarding the conservation and sustainable use of genetic resources for food and agriculture. While some relate to the use and safety of, and access to new technologies that make use of genetic resources – in particular biotechnologies[3] – the international debate has increasingly focused on access to genetic resources, as well as on the intended and unintended effects of access policies. This paper therefore identifies two key international policy issues: (1) access and benefit-sharing; and (2) intellectual property rights. It also considers the Commission's possible contribution to setting and monitoring goals and targets for collective policy action in fields of relevance to food and agriculture.

III. MAPPING THE INTERNATIONAL POLICY ENVIRONMENT

A. Access and benefit-sharing

9. Only two binding international instruments regulate access and benefit-sharing for genetic resources: the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture.

10. The Commission retains a specific interest in access and benefit-sharing for genetic resources for food and agriculture generally, which is a key matter in addressing food security and poverty reduction. At its last Regular Session, the Commission recommended that it "contribute to further work on access and benefit-sharing, in order to ensure that it move in a direction supportive of the special needs of the agricultural sector, in regard to all components of biological diversity of interest to food and agriculture".[4] Moreover, the Conference of the Parties (COP) to the CBD has recognized that the preparation of *The State of World's Animal Genetic Resources*, under the auspices of the Commission, "will contribute to [...] access and benefit-sharing of animal genetic resources for food and agriculture".

The Convention on Biological Diversity and the "Bonn Guidelines"

11. The CBD, in Article 1, provides for the

> *"fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."*

12. In reaffirming the sovereign right of States over their natural resources, and the authority of national governments to determine access to their genetic resources, the CBD aims to facilitate access to the benefit of both providers and recipients of genetic resources. Access, where granted, shall be on mutually agreed terms, and subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.[5] The Convention sets a

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[2]
- CGRFA-11/07/16, *Mechanisms for Cooperation between the Commission and the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture*,
- CGRFA-11/07/17, *Cooperation with the Convention on Biological Diversity*;
- CGRFA-11/07/18, *Cooperation with the World Intellectual Property Organization*.

[3] CGRFA-11/07/13 (CGRFA-10/04/13), *Progress in the Draft Code of Conduct on Biotechnology as it Relates to Genetic Resources for Food and Agriculture: policy issues, gaps and duplications*, introduces a number of such policy issues and seeks guidance to the Commission on how to address them.

[4] CGRFA-10/04/REP, paragraph 76.

[5] Article 15.5 of the CBD.

general framework for access and benefit-sharing. It has also recognized "the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions."[6] The International Treaty provides one such set of solutions, for plant genetic resources for food and agriculture.

13. At the national and regional level, various efforts have been made to establish access and benefit-sharing laws and instruments.[7]

14. The COP to the CBD, at its Fourth Meeting, established a process:

> *"to draw upon all relevant sources, including legislative, policy and administrative measures, best practices and case-studies on access to genetic resources and benefit-sharing arising from the use of those genetic resources, including the whole range of biotechnology, in the development of a common understanding of basic concepts and to explore all options for access and benefit-sharing on mutually agreed terms including principles, guidelines, and codes of conduct of best practices for access and benefit-sharing arrangements."* [8]

15. This lead to the development and adoption, at the sixth meeting of the COP in 2002,[9] of the voluntary "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization." [10] These are meant to assist Parties and stakeholders with the implementation of the access and benefit-sharing provisions of the Convention.

The International Treaty on Plant Genetic Resources for Food and Agriculture

16. Like the CBD, the Treaty provides for

> *"the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity"; however,* this is qualified as being specifically *"for sustainable agriculture and food security"*.

17. With regard to access and benefit-sharing, Contracting Parties have established a Multilateral System of Access and Benefit-sharing for Plant Genetic Resources for Food and Agriculture, as an expression of their sovereign rights over these resources. They recognise that, in the exercise of these rights, they mutually benefit from the creation of an effective multilateral system for facilitated access to a negotiated selection of these resources, and for the fair and equitable sharing of the benefits arising from their use.[11] The crops covered by the Multilateral System ("*Annex I*") are recognized as being of crucial importance for food security, in regard to which countries are inter-dependent. In addition, the Treaty provides for International Institutions holding *ex situ* collections of plant genetic resources for food and agriculture to bring these –

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[6] Decisions II/15 and V/5.

[7] For an overview, see:

- Carrizosa, S. *et al.* [eds.], (2004): Accessing Biodiversity and Sharing the Benefits Lessons from Implementing the Convention on Biological Diversity, IUCN Environmental Policy and Law Paper No. 54.
- Garforth, K. et al. (2005) Overview of the National and Regional Implementation of Access to Genetic Resources and Benefit-Sharing Measures. Third Edition. Available at: http://www.cisdl.org/pdf/ABS_ImpStudy_lg.pdf.

[8] Decision IV/8.

[9] Decision VI/24.

[10] Available at: http://www.biodiv.org/doc/publications/cbd-bonn-gdls-en.pdf.

[11] Recital 14 of the Preamble of the International Treaty.

whether or not they are in *Annex 1*– under the Treaty, and its access and benefit-sharing arrangements.

18. The Treaty recognizes that facilitated access to the resources in the Multilateral System is itself a major benefit. Other benefits to be shared fairly and equitably include the exchange of information; access to and transfer of technology; capacity-building; and the monetary and other benefits of commercialization. [12]

Towards an international regime on access and benefit-sharing

19. The CBD is currently debating an international regime on access and benefit-sharing, in response to a mandate in paragraph 44(o) of the Plan of Implementation of the World Summit on Sustainable Development, which calls for action to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources". The target date for completion of this process is 2010.[13]

20. Decision VII/19(d) of the COP, in 2004, established the framework for these negotiations, to be conducted through its *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing, with the collaboration of the *Ad Hoc* Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions. It invited FAO, and a number of other international institutions to cooperate with the *Ad Hoc* Working Group. It recognizes the important contribution of the Treaty. It categorizes the nature of the international regime as "composed of one or more instruments within a set of principles, norms, rules and decision-making procedures, legally-binding and/or non-binding". It lists a large number of legally binding and non-binding elements that may be considered.

21. The eighth meeting of the COP, in 2006, requested the *Ad Hoc* Open-ended Working Group on Access and Benefit-sharing to continue the elaboration and negotiation of the international regime, and to complete its work before the tenth meeting of the COP, in 2010.

22. The Secretariat of the Commission has participated in a number of the meetings within this process, in order to provide information on the specific nature, problems and needs of the food and agriculture sector, including for plant and animal genetic resources for food and agriculture in general, and the Treaty in particular.

Certificate of origin/source/legal provenance of genetic resources

23. The eighth meeting of the COP to the CBD also established a group of technical experts "to explore and elaborate the possible options, without prejudging their desirability, for the form, intent and functioning of an internationally recognised certificate of origin/source/legal provenance and analyse its practicality, feasibility, costs and benefits, with a view to achieving the objectives of Article 15 and 8(j) of the Convention."[14] This is in the context of the above negotiations, and is of relevance to WIPO and the WTO TRIPS Agreement, as there are proposals that such a certificate be required in patent application. The group of technical experts met in January 2007.[15]

24. While the Standard Material Transfer Agreement that regulates access to materials under the Treaty's Multilateral System is likely to obviate the imposition of such a certificate for these

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[12] Article 13.2a, b c and d, respectively, of the Treaty.

[13] Related processes are underway, as well, in WIPO's Inter-governmental Committee on Genetic Resources, Traditional Knowledge and Folklore, and in the WTO/TRIPS Council.

[14] Decision VIII/4.

[15] Its report is at http://www.biodiv.org/doc/meetings/abs/abswg-05/official/abswg-05-02-en.doc.

materials, there is as yet no recognition of the possible effects on the exchange and use of other genetic resources for food and agriculture that the imposition of such transaction costs would entail, and the Commission may wish to consider this more general question.

Genetic resources for food and agriculture outside areas of national jurisdiction

25. There are various categories of genetic resources of actual or potential value to food and agriculture that are not under national sovereignty.[16] One major area is marine biological diversity.

26. In November 2004, the General Assembly of the United Nations established an Ad Hoc *Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction*.[17] It was mandated to survey the past and present activities of the United Nations and other relevant international organizations with regard to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction; to examine the scientific, technical, economic, legal, environmental, socio-economic and other aspects of these issues; to identify key issues and questions where more detailed background studies would facilitate consideration by States of these issues; and to indicate, where appropriate, possible options and approaches to promote international cooperation and coordination for the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction.[18]

27. The Working Group's report,[19] submitted to the 61st session of the General Assembly, recorded differing views regarding the legal status of genetic resources found in the areas beyond national jurisdiction.[20]

28. A number of delegations stated that such genetic resources should be considered within the framework applicable under the United Nations Convention on the Law of the Sea (UNCLOS) to the "seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction" (the "Area"). Genetic resources would be considered as common heritage of mankind, and the regime for exploitation and benefit-sharing foreseen in Section 3 of Part XI of UNCLOS would apply, where the International Sea Bed Authority (ISBA) has the exclusive competence of authorizing and managing activities linked to "resources" for the benefit of mankind. A regulatory mechanism, including the adoption of improved norms or an implementing agreement to UNCLOS, could address issues such as access and legal options for benefit-sharing. However, "resources" under Part XI of UNCLOS are defined as 'mineral resources' (Article 133a).[21]

29. Some delegations stated that genetic resources were covered by the regime of the high seas, under part VII of UNCLOS, which provides, in Section 2, for a set of rules and principles for the conservation and management of "living resources".[22] They argued that there was no legal gap with respect to such resources. However, although 'living resources' embraces "genetic

[16] "Agriculture", in FAO usage, being understood to include forestry and fisheries.

[17] Resolution 59/24.

[18] General Assembly Resultion 59/24, paragraph 73.

[19] A/61/65.

[20] Areas beyond national jurisdiction include: the high seas, which are all areas of the water column that are not included in the Exclusive Economic Zones, the territorial sea of the internal waters of a State, or in the archipelagic waters of an archipelagic State (Article 86 of the United Nations Convention on the Law of the Sea (UNCLOS)); and the Area, defined as the seabed and ocean floor and subsoil thereof beyond the limits of national jurisdiction (UNCLOS, Article 1.1(1)).

[21] A/61/65, paragraph 29.

[22] A/61/65, paragraph 30.

resources", Section 2 primarily aims at the conservation and management of fish and marine mammals.

30. A view was also expressed that the freedoms of the high seas, in particular the right to conduct marine scientific research, as foreseen in Article 238 of UNCLOS, embrace the right to access marine genetic resources. However, UNCLOS does not define the term "marine scientific research".

31. The Co-Chairpersons concluded that "further discussion on the legal status of marine biological diversity, including genetic resources beyond national jurisdiction, is needed in order to clarify how such resources may have to be regulated, whether existing tools and arrangements are sufficient or whether new tools are required for their conservation and sustainable use, including consideration of access and benefit-sharing. (...) Any further discussion on this issue should take into account the legitimate interests of all States and could also address the development of codes of conduct, including an international code of conduct for responsible marine scientific research, guidelines and impact assessments."[23]

32. The General Assembly then requested the Secretariat to prepare a comprehensive report on developments and issues relating to ocean affairs and the law of the sea for consideration at its 62nd session, and to make the report available to the Informal Consultative Process on Oceans and the Law of the Sea (ICP), which, at its Eighth Session (25-29 June 2007) will focus on marine genetic resources. An advance and unedited version of the Report of the Secretary General on Oceans and the Law of the Sea, dated 12 March 2007, has been made available.[24] The General Assembly also requested the Secretary General to reconvene the Ad Hoc *Open-ended Informal Working Group.*

33. These processes will need to be taken into account, if, as proposed, the Commission decides to initiate a process for the development of an international policy framework for management of aquatic genetic resources through analysis of the FAO Code of Conduct for Responsible Fisheries.[25]

Policy issues for consideration

34. In the light of its recommendation that FAO and the Commission contribute to further work on access and benefit-sharing, in order to ensure that it move in a direction supportive of the special needs of the agricultural sector, in regard to all components of biological diversity of interest to food and agriculture, a number of matters arise that the Commission may wish to address.

35. Access and benefit-sharing rules and policies should be coherent and mutually supportive. The Commission may wish to contribute to further work on access and benefit-sharing by advocating the idea that access and benefit-sharing regimes be sufficiently flexible to allow the development of sector-specific regimes that are adapted to the distinctive features and needs of the food and agriculture sector.[26] Other areas that the Commission may wish to consider addressing include genetic resources of interest to food and agriculture outside national jurisdictions, and collections of genetic resources of relevance to food and agriculture formed before the entry into force of the CBD, and not covered by the International Treaty. The

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[23] A/61/65, Annex 1, paragraph 12.

[24] http://www.un.org/Depts/los/general_assembly/documents/text_advance_unedited_62nd_session.pdf.

[25]
- CGRFA-11/07/15.2, *The world's aquatic genetic resources: status and needs.*
- CGRFA-11/07/21, *The Multi-year Programme of Work of the Commission on Genetic Resources for Food and Agriculture.*

[26] The Bonn Guidelines, for example, "are without prejudice to the access and benefit-sharing provisions of the FAO International Treaty for Plant Genetic Resources for Food and Agriculture" (paragraph 10.

Commission may wish to contribute to relevant processes, in order to ensure that that the distinctive features and problems of genetic resources relevant for food and agriculture are taken into account.

Access and benefit-sharing for genetic resources for food and agriculture

36. With the implementation of its full mandate, the Commission may wish to now consider access and benefit-sharing for genetic resources for food and agriculture in general, in order to contribute to the current CBD processes in a manner supportive of the special needs of the agricultural sector, in particular the need to achieve global food security and sustainable agriculture.[27] In agricultural ecosystems, the genetic resources of plants, animals, aquaculture and microbes are all key factors required to ensure the health of the trophic chain of food production, and are managed by farmers in a cross-sectorial manner. Indeed, the application of the ecosystem, approach to food and agriculture would be impossible if this were not the case. There is therefore a strong case for approaching access and benefit-sharing for genetic resources for food and agriculture in the same integrative manner.

37. There is no analysis yet of how different policies and regulations at national and regional level are treating the various types of genetic resources for food and agriculture, and there is no mapping either of current practice of genetic material exchange in different community of users in the food and agriculture sector. As a first step, the Commission may request its Secretariat to conduct an analysis for its next session.

Material Transfer Agreements passed in accordance with agreements with the International Agricultural Research Centres under the Auspices of the Commission

38. Before the entry into force of the Treaty, and the signature, on 16 October 2006, of agreements with the International Agricultural Research Centres under Article 15 of the Treaty, the Centres held their *ex situ* collections in trust for the international community within the International Network of *Ex Situ* Collections under the Auspices of FAO. These materials were provided to users under the terms of MTAs established by the Commission, which remain valid contracts. The Commission may wish to maintain a watching brief over the application of these MTAs passed under its auspices, in cooperation with the Governing Body of the Treaty.

Plant genetic resources for food and agriculture

39. The Multilateral System of the Treaty covers the crops in *Annex 1* to the Treaty. The Commission may wish to contribute to further work on access and benefit-sharing for other crop resources, by considering possibilities to address these genetic resources for food and agriculture, and exploring ways and means through which it can be ensured that the distinctive features and problems of the plant genetic resources sector in general are taken into account in any on-going or forthcoming negotiations and processes. This could be one item of its cooperation with the Governing Body of the Treaty.

Plant genetic resources for agricultural non-food/feed purposes

40. The Multilateral System provides access to the crops in *Annex I* of the Treaty "solely for the purpose of utilization and conservation for research, breeding and training for food and agriculture, provided that such purpose does not include chemical, pharmaceutical and/or other non-food/feed industrial uses". [28] The Commission, in collaboration with the Governing Body of the Treaty, may wish to explore ways and means through which facilitated access for agricultural

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[27] • CGRFA-11/07/21, *The Multi-year Programme of Work of the Commission on Genetic Resources for Food and Agriculture*, paragraph 20.

• CGRFA-11/07/17, *Cooperation with the Convention on Biological Diversity*, paragraphs 53 and 54.

[28] Article 12.3a of the Treaty.

non-food/feed purposes may be provided and benefits be shared, including in the case of *ex situ* collections formed before the entry into force of the CBD.

B. Intellectual property rights

41. Another international policy issue that is relevant for all sectors of genetic resources is intellectual property rights (IPRs). The Commission, at several of its past sessions, has addressed such matters, in the context of the International Undertaking; the International Network of *Ex Situ* Collections put under the auspices of FAO; and in the negotiation of the Treaty. At the Ninth Session, a number of countries expressed concern over the effects of the inappropriate granting of IPRs over materials from the *International Network of* Ex Situ *Collections under the Auspices of FAO*, including in the "Enola Bean" case.

42. Questions regarding various– often linked – aspects of IPRs applied to genetic resources (including genetic resources for food and agriculture) are currently under discussion in a number of forums: the CBD and the process for the developing of an international regime of access and benefits sharing, discussed above; the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore; and WTO Trips Council. The Commission secretariat accordingly follows these processes carefully and represents FAO in relevant meetings. Information on current developments is therefore given below.

The "Enola Bean" case, and the possible effect of IPRs on the availability and use of genetic resources

43. The Commission has been regularly informed of ongoing litigation by the International Centre for Tropical Agriculture (CIAT), undertaken with the Commission's support, for the re-examination of US patent number 5,894,079 on the "Enola Bean", on the grounds that it might restrict the use in plant breeding of materials from the International Network. Up-dated information on this case is made available to this session.[29]

44. In this context, at its Ninth Regular Session, the Commission requested the World Intellectual Property Organization (WIPO), to "cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty."[30] Progress in this regard was reported to the Commission at its last regular session,[31] and its second meeting as Interim Committee for the Treaty (which "welcomed this Preliminary Report, which was of significant value to the agricultural community, and the continuing cooperation with WIPO"),[32] as well as to the Governing Body of the Treaty.[33]

45. The Preliminary Report identified the need for more extensive examination of the patent landscape, and the broader legal context that surrounds particular crops, before practical assessments can be made of the effect on availability and use of material that may be covered by patents. It identified possible follow-up activities, which included: "deepening the study of IP issues by focusing on specific technologies … Such studies would provide detailed information

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[29] CGRFA-11/07/10, CGRFA-11/07/Inf.10*, Updated information provided by the International Centre for Tropical Agriculture (CIAT), regarding its request for a re-examination of U.S. patent No. 5,894,079*.

[30] CGRFA-9/02/REP, paragraph 31.

[31] CGRFA-10/04/REP, paragraph 66.

[32] CGRFA/MIC-2/04/Inf.5, *Preliminary report on work towards the assessment of patent data relevant to availability and use of material from the International Network of* Ex Situ *Collections under the Auspices of FAO and the International Treaty on Plant Genetic for Food and Agriculture*.

[33] IT/GB-1/06/Inf.17, *Progress report on work towards the assessment of patent data relevant to availability and use of material from the International Network of* Ex Situ *Collections under the auspices of FAO and the International Treaty on Plant Genetic Resources for Food and Agriculture: a draft patent landscape surrounding gene promoters relevant to rice.*

about the patent landscape surrounding selected inventions … Certain specific technology areas would need to be selected for pilot studies in this area. Such follow-up studies could focus on particular patent families and technologies."[34] Further progress is discussed in the document for this session, *Cooperation with the World Intellectual Property Organization*.[35]

Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

46. The Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC), established by the WIPO General Assembly in 2000, has dealt with a range of issues concerning the interplay between intellectual property and genetic resources. The Commission Secretariat has followed these proceedings throughout. The IGC has, *inter alia*, covered intellectual property aspects of access to genetic resources and equitable benefit-sharing arrangements that govern the use of genetic resources; disclosure requirements in patent applications that relate to genetic resources; and associated traditional knowledge used in a claimed invention. At the invitation of the COP of the CBD, the IGC prepared a technical study on this issue, with input from many WIPO Member States.[36] Additional work on this issue is being undertaken in WIPO, partly in response to a further invitation from the CBD.

47. The next session of the Committee will be held in Geneva from 3 -12 July 2007. It will receive (i) a document listing options for work in the areas of the disclosure requirement and alternative proposals for dealing with the relationship between intellectual property and genetic resources; the interface between the patent system and genetic resources; and the intellectual property aspects of access and benefit-sharing contracts; and (ii) a factual update of relevant international developments.[37]

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

48. The Council for TRIPS of the World Trade Organization (WTO) is responsible for administering the TRIPS Agreement. FAO has observer status in the TRIPS Council and the Commission Secretariat has attended relevant sessions. Of relevance to agricultural genetic resource policy are the provisions of Article 27.b(b), which provide that:

> *"Members may also exclude from patentability:*
>
> *"(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
>
> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective* sui generis *system or by any combination thereof."*

49. The TRIPS Agreement requires a review of Article 27.3(b). Paragraph 19 of the 2001 Doha Declaration has broadened the discussion. Topics raised in the TRIPS Council's discussions include:

- "how to apply the existing TRIPS provisions on whether or not to patent plants and animals, and whether they need to be modified;

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[34] CGRFA/MIC-2/04/Inf.5, paragraph 56(ii).

[35] CGRFA-11/07/18.

[36] World Intellectual Property Organization (2004): *Technical study on disclosure requirements in patent systems related to genetic resources and traditional knowledge*, http://www.wipo.int/tk/en/publications/technical_study.pdf

[37] WIPO/GRTKF/IC/10/7 Prov, *Initial Draft Report*, at http://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_10/wipo_grtkf_ic_10_7_prov.pdf.

- "the meaning of effective protection for new plant varieties (*i.e.*, alternatives to patenting such as the 1978 and 1991 versions of UPOV). This has included the flexibility that should be available, for example to allow traditional farmers to continue to save and exchange seeds that they have harvested;
- "how to handle moral and ethical issues, *e.g.*, to what extent invented life forms should be eligible for protection;
- "how to deal with the commercial use of traditional knowledge and genetic material by those other than the communities or countries where these originate, especially when these are the subject of patent applications
- "how to ensure that the TRIPS Agreement and the UN CBD (CBD) support each other".[38]

50. The present debate focuses primarily on how the TRIPS Agreement relates to the CBD. Ideas put forward include an amendment to the TRIPS Agreement which would require patent applicants to disclose the country of origin of genetic resources and traditional knowledge used in the inventions, evidence that they received "prior informed consent", and evidence of "fair and equitable" benefit-sharing. The proposed "Certificate of origin/source/legal provenance of genetic", discussed above, is relevant here. Another proposal foresees an amendment to WIPO's Patent Cooperation Treaty (and, by reference, WIPO's Patent Law Treaty) that would allow domestic law to require inventors to disclose the source of genetic resources and traditional knowledge, when they apply for patents. Others do not envisage linking access and benefit-sharing requirements to patent law.

Policy issues for consideration

51. Given that discussions in the three forums (CBD, WIPO/IGC, and the TRIPS Council) may have a variety of implications for the conservation and sustainable use of genetic resources for food and agriculture and the fair and equitable sharing of the benefits, the Commission may wish its Secretariat to continue to follow developments closely, and to report regularly to it. In close cooperation with other relevant international organizations, the Commission may then wish to promote synergies that take into account the specific nature of genetic resources for food and agriculture, and the sector's problems and needs.

C. Goals, targets and indicators for the assessment of progress in the implementation of policy measures

52. Internationally agreed goals, targets and indicators are increasingly used in various areas of public policy, to provide common grounds for action and investment. Indicators are planning tools to assess the impact and effectiveness of policy interventions and other actions, in order to fulfil agreed goals and targets. Goals and targets established at the global level also provide a flexible framework, within which national and regional targets may be developed.

53. The establishment of goals, targets and indicators requires both policy and technical expertise. This helps to build bridges between the policy and technical spheres. Once selected, targets and indicators give direction to monitoring systems.

54. The international community has recently adopted a wide range of goals and targets, some of which are relevant to the work of the Commission. These include the Millennium Development Goals and the targets of the Plan of Implementation of the World's Summit on Sustainable Development, but also biodiversity-related goals. The CBD has established, for example, a framework of goals, targets, and indicators for monitoring the achievement by 2010 of

[38] Quoted from http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm.

significantly reducing the current rate of biodiversity loss (2010 target) and is integrating these into its thematic programmes of work, including the programme on agricultural biodiversity.[39]

55. A number of international organizations, including FAO, are exploring the relevance of translating general biodiversity targets into targets that can be internalized within relevant agri-sector processes, and that take into account the differences of wild biodiversity and biodiversity for food and agriculture.

56. The Commission has already taken a number of decisions in this field. At its Tenth Session, the Commission adopted indicators for monitoring the implementation of the *Global Plan of Action for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture*. It also accepted the invitation of the CBD to consider how the *Global Plan of Action* contributes to the implementation of targets of the CBD *Global Strategy for Plant Conservation*. It also agreed that FAO should continue to lead the development of agricultural biodiversity indicators, including indicators on genetic resources for food and agriculture (*inter alia* of domestic animals, fisheries and plants). This field is therefore an emerging area for the Commission.

Policy issues for consideration

57. In planning its future work, the Commission may wish to develop a framework of goals, targets and indicators, within the process of developing the major outputs of its Multi-Year Programme of Work, taking into account on-going work in other forums. A number of existing FAO reporting and monitoring systems, including those already overseen by the Commission, provide tools to monitor the status and trends of biodiversity for food and agriculture.[40] The Commission may wish to make use of such information sources in the assessment of progress in achieving goals and targets. The Commission may wish to request the Secretariat to prepare a concept note for the establishment of a framework of goals, targets and indicators for the assessment of progress in the implementation of the Multi-Year Programme of Work, for consideration at its Twelfth Session, including as a further tool to support cooperation with other relevant institutions, dealing specifically with the food and agriculture aspects of genetic resources.

IV. GUIDANCE SOUGHT FROM THE COMMISSION

58. The Commission's guidance is sought as to

Access and benefit-sharing for genetic resources for food and agriculture, in particular,

- Its contribution to further work on access and benefit-sharing, in order to ensure that it move in a direction supportive of the special needs of the agricultural sector, in regard to all components of biological diversity of interest to food and agriculture;
- Further work on genetic resources of interest to food and agriculture that are outside national jurisdictions, and collections of genetic resources of relevance to food and agriculture formed before the entry into force of the CBD and not covered by the International Treaty;

[39] See CGRFA-11/07/17, paragraphs 35 to 40.

[40] These include *The State of the World's Animal Genetic Resources*, *The State of the World's Plant Genetic Resources* and the monitoring of the implementation of *The Global Plan of Action for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture*. The Interlaken Conference on Animal Genetic Resources may adopt a *Global Plan of Action for Animal Genetic Resources*, which may require a monitoring system as part of the implementation process. Future work on forest and aquatic genetic resources could also help understanding the status and trends of genetic diversity in these fields.

- Its contribution to the current CBD processes in a manner supportive of the special needs of the agricultural sector, in particular the need to achieve global food security and sustainable agriculture;
- A possible analysis to be prepared by the Secretariat as to how different policies and regulations at national and regional level deal with genetic resources for food and agriculture;
- Its role in relation to Material Transfer Agreements passed in accordance with the agreements between FAO and the International Agricultural Research Centres, preceding the agreements concluded in 2006 under Article 15 of the Treaty;
- Further work on access and benefit-sharing for other crops than those listed in *Annex I* of the Treaty;
- Further work on access and benefit-sharing for crops listed in *Annex I* of the Treaty where they are used for agricultural non-food/feed purposes, including in the case of *ex situ* collections formed before the entry into force of the CBD;

Intellectual property rights, in particular,

- Whether it wishes its Secretariat to continue to keep under continuous review developments in the field of intellectual property rights as they relate to genetic resources for food and agriculture, closely, and to report regularly to it; and

Goals, targets and indicators, in particular,

- Whether, in planning its future work, it wishes to develop a framework of goals, targets and indicators as an element of its Multi-Year Programme of Work, taking into account on-going work in other forums, and whether it wishes to request its Secretariat to prepare a concept note for the establishment of a such a framework, for consideration at its Twelfth Session.