UNEP

CBD

CONVENTION ON BIOLOGICAL DIVERSITY

Distr.
GENERAL

UNEP/CBD/ICCP/2/INF/3
2 October 2001

ENGLISH ONLY

INTERGOVERNMENTAL COMMITTEE FOR THE CARTAGENA PROTOCOL ON BIOSAFETY
Second meeting
Nairobi, 1-5 October 2001

DRAFT PROPOSED CALL FOR COOPERATION BETWEEN THE INTERIM COMMISSION ON PHYTOSANITARY MEASURES (ICPM) AND THE INTERGOVERNMENTAL COMMITTEE FOR THE CARTAGENA PROTOCOL ON BIOSAFETY (ICCP) ON PLANT PEST RISKS THAT MAY BE PRESENTED BY LIVING MODIFIED ORGANISMS

Report of the ICPM Open-Ended Working Group (OEWG) on specifications for an International Standard for Phytosanitary Measures on LMOs

Information note by the Bureau of the ICCP

1. The International Plant Protection Convention (IPPC) is an international treaty for cooperation in plant protection, which is deposited with FAO, entered into force in 1952, and was most recently modified in 1997. It is widely recognized as the primary instrument for international cooperation in the field of protection of plant resource from pests.

2. The IPPC has the objective to protect plant health in general, and is not limited to cultivated plants or systems nor to direct damage from pests, and therefore also extends potentially to natural flora and indirect effects. Its purpose is to "secure common and effective action to prevent the spread and introduction of pests [any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products]", and to promote appropriate measures for their control.

3. In its promotion of appropriate measures, it develops international standards (see UNEP/CBD/ICCP2/12, para. 111) to achieve its purpose. The IPPC calls, in particular, for measures to be based on a pest risk analysis, which covers, among other matters, environmental factors, including possible detrimental effects on natural vegetation. In this respect, both the IPPC and the Cartagena Protocol on Biosafety may have common coverage as regards adverse effects on the conservation and sustainable use of parts of biological diversity.

* UNEP/CBD/ICCP/2/1.

/...

4. At its third session, the Interim Commission on Phytosanitary Measures (ICPM) (see UNEP/CBD/ICCP/2/12, para 103) established an Open-Ended Working Group (OEWG) to develop specifications for international standard(s) aimed at providing guidance on pest risk analysis procedures as regards the phytosanitary risks that may be presented by LMOs.

5. The OEWG met at FAO in Rome from 12 to 14 September, and the report of this meeting is attached. This report contains, as its appendix II, a proposal for a draft specification for such an international standard on LMOs. This proposal shall be presented to the fourth session of the ICPM, scheduled to take place in March 2002, for its consideration. The proposal recommends specifically that an expert group (approx. 10 experts) be formed, including expertise on the provisions and implementation of the CPB, and that it meets in September 2002 to formulate a first draft of a standard on LMOs according to the specifications proposed.

6. Delegations may wish to note, in particular, the references to the Biosafety Protocol and the ICCP work in paragraphs 5, 6, 7.2, 7.3, and the sections on "tasks", "expertise", and "participants" of the draft specifications in appendix to the report.

Report of the ICPM Open-ended Working Group on Specifications for an International Standard for Phytosanitary Measures on Living Modified Organisms[1]

1. The Third Session of the Interim Commission on Phytosanitary Measures (ICPM) endorsed the following statements regarding the role of the IPPC with respect to living modified organisms (LMOs):

The ICPM:

- *Notes* that, consistent with the IPPC mandate to protect plant health, plant pest concerns that may be presented by LMOs/products of modern biotechnology fall within the scope of the IPPC.

- *Notes* that IPPC risk analysis and management systems are appropriate for assessing and managing, if necessary, the direct or indirect risks of pests to cultivated and wild flora and plant products that may be presented by LMOs/products of modern biotechnology.

- *Notes* that IPPC systems and procedures are relevant to, and adequate for, managing the risks posed by LMOs/products of modern biotechnology as they relate to the protection of plant health.

- *Notes* that the existing national mechanisms and structures for phytosanitary systems may form a basis or a model for developing other practical approaches to managing risks associated with LMOs/products of modern biotechnology.

2. The ICPM also decided that an Open-ended Working Group (OEWG)[2] should be formed to develop specifications for an ISPM on pest risk analysis for LMOs/products of modern biotechnology to be considered by the ICPM at its Fourth Session (March 2002). Terms of reference for this meeting were agreed (Appendix I).

3. The OEWG met at FAO in Rome 12 –14 September 2001. The meeting considered that there was a need to provide detailed guidance on pest risk analysis for LMOs and recommended that an Expert Working Group be formed to draft a standard according to the specification proposed in Appendix II. The OEWG also developed statements elaborated below in response to the specific terms of reference.

4. The OEWG considered that the phytosanitary risks of any LMOs should be considered.

5. The OEWG recommended that the IPPC Secretariat explore the best approach to ensure that the IPPC standard setting process is coordinated with the activities under the Cartagena Protocol. The OEWG recommended that ICPM formally invite

---

[1] The OEWG discussed the issue of living modified organisms and recommended that the standard setting process concentrate on LMOs as defined by the Cartagena Protocol (see para. 6).Therefore this document refers only to LMOs.

[2] The ICPM endorsed an Open-Ended Expert Working Group. The organization of this meeting used the title Open-Ended Working Group rather than Open Ended Expert Working Group.

representatives of the Cartagena Protocol to cooperate on the development of the PRA for LMOs.

6. The OEWG recommended that the scope of the IPPC's standard setting activities in this area be limited to LMOs as they are defined in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CP). The terminology used in this document is consistent with this recommendation and the term "products of modern biotechnology" has not been used.

7. Terms of Reference for the OEWG:

7.1 Pest risk associated with LMOs

Potential phytosanitary risks include:

7.1.1 Changes in adaptive characteristics which may increase the potential invasiveness including for example:
- drought tolerance of plants;
- herbicide tolerance of plants;
- alterations in reproductive biology;
- dispersal ability of pests;
- pest resistance; and
- pesticide resistance.

7.1.2 Gene flow including for example:
- transfer of herbicide resistance genes to compatible species; and
- the potential to overcome existing reproductive and recombination barriers.

7.1.3 Potential to adversely affect non-target organisms including for example:
- changes in host range of biological control agents or organisms claimed to be beneficial;
- effects on other organisms such as biological control agents, beneficial organisms, soil microflora that result in a phytosanitary impact (indirect effects).

7.1.4 Possibility of phytopathogenic properties including for example:
- phytosanitary risks presented by novel traits in organisms not normally considered a phytosanitary risk;
- enhanced virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences; and
- phytosanitary risks associated with nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

The potential phytosanitary risks identified above could also be associated with non-LMOs. It was acknowledged that risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. Genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.

The OEWG considered that all phytosanitary risks were within the scope of the IPPC including those posed by the unintentional and intentional presence of organisms.

7.2. Identify elements relevant to these plant pest risks:

In identifying elements of PRA for LMOs the OEWG:

- considered that there was a need to amplify elements of PRA for LMOs;
- considered that the normal components of PRA (Initiation, Risk Assessment and Risk Management) were appropriate for PRA of LMOs;
- considered that there was a need for more detailed guidance for each of these components; and
- recommended that the Expert Working Group consider Annex III of the CP, ISPM No. 11, the draft NAPPO standard(s) on transgenic plants and any other relevant regulatory framework and guidelines.

7.3. Consider existing international regulatory frameworks and guidelines

Development of the PRA on LMOs should take into account relevant aspects of the CP, the OECD activities on biotechnology oversight and any other relevant regulatory frameworks and guidelines. The IPPC draft supplement on environmental risk should also be taken into account. In addition to the working papers provided for this meeting, the OEWG discussed aspects of the OECD "Safety Considerations for Biotechnology: Scale-Up of Crop Plants" and the UNEP "International Technical Guidelines for Safety in Biotechnology".

7.4. Identify areas within pest risk analysis (PRA) standards and other ISPMs that are relevant to the phytosanitary aspects of LMOs

The OEWG noted that the IPPC Secretariat's Discussion Paper (OEWG-2001/REF 5) identified areas within PRA and other aspects of ISPMs that may be relevant to assessing the phytosanitary risks of LMOs. This paper should be considered by the expert working group with the other information documents provided to the OEWG in developing the PRA for LMOs.

7.5. Identify plant pest risks associated with LMOs that are not adequately addressed by existing ISPMs.

The OEWG identified the need for more guidance as regards risk analysis for LMOs. The phytosanitary risks identified in A above should be taken into account by the Expert Working Group in considering the adequacy of ISPMs in addressing the analysis of phytosanitary risks that may be presented by LMOs. The adequacy and relevance of the draft supplement to ISPM 11 should also be considered in the development process. The Expert Working Group should also consider the CP and other relevant systems and guidelines to ensure that the standard comprehensively addresses phytosanitary risks of LMOs.

7.6 Other issues

The OEWG considered that the standard should be clear, easy to understand and provide comprehensive guidance on PRA for LMOs.

Although not formally in the terms of reference for the OEWG, the meeting also discussed the issue of capacity building as regards risk analysis for LMOs. The OEWG considered that the needs of developing countries be taken into account in any standards development.

The OEWG recommended that the Expert Working Group also consider the need to develop background documents, manuals, training modules etc. to assist countries in understanding and conducting PRA for LMOs.

The OEWG recommended that the IPPC explore the possibility of extending assistance to developing countries in building capacity in developing or conducting PRA for LMOs.

Appendix I

Excerpt from the Report of the Third Session of the Interim Commission on Phytosanitary Measures (ICPM)

The ICPM Open-ended Expert Working Group for the Development of a Detailed Standard Specification on the Plant Pest Risks Associated with LMOs/Products of Modern Biotechnology

Terms of Reference

The Open-ended Expert Working Group will develop a detailed standard specification for consideration at ICPM 4 that:

1. identifies the plant pest risks associated with LMOs/products of modern biotechnology;
2. identifies elements relevant to the assessment of these plant pest risks;
3. considers existing international regulatory frameworks and guidelines;
4. identifies areas within PRA standards and other ISPMs that are relevant to the phytosanitary aspects of LMOs/products of modern biotechnology; and
5. identifies the plant pest risks associated with LMOs/products of modern biotechnology that are not adequately addressed by existing ISPMs.

In order to better prepare for the Open-ended Expert Working Group meeting, a discussion paper and recommendations should be developed in advance of the meeting.

Consistent with the objective of strengthening cooperation between the IPPC and the CBD, the Secretariat should make contact with the CBD and other relevant organizations to explain the purpose of the Open-ended Expert Working Group meeting.

The Secretariat should invite the secretariats of these organizations to designate experts to attend the Open-ended Expert Working Group meeting to contribute to the development of the specification for the standard.

Appendix II

Draft Specification for ISPMs: OEWG Proposal for ICPM-4

Title: Pest risk analysis for living modified organisms

Scope:
Provide guidance on pest risk analysis (PRA) procedures as regards the phytosanitary risks that may be presented by living modified organisms (LMOs).
(more details from Terms of Reference)

Tasks:
- Consider existing PRA procedures and standards (IPPC and others that may be relevant).
- Identify relevant hazards and methods for the evaluation of the potential phytosanitary risks presented by LMOs.
- Formulate a draft standard providing guidance on the conduct of PRA for LMOs consistent with relevant aspects of the Cartagena Protocol, taking account Annex III of the CP and statements from the OEWG (September 2001) [as amended by ICPM-4].
- The OEWG considered that the standard should be clear, easy to understand and provide comprehensive guidance on PRA for LMOs.

Provision of resources:
IPPC regular programme and other (to be determined).

Proposed work programme:
Expert Working Group in September 2002 to formulate first draft. (Venue to be determined).

Steward: (to be determined)

Collaborator: (to be determined)

Expertise:
Approximately 10 experts. Requires expertise in risk analysis (phytosanitary and environmental); expertise in relevant aspects of genetic engineering; familiarity with phytosanitary systems; and familiarity with the provisions and implementation of the Cartagena Protocol.

Participants:
Phytosanitary experts, technical expert(s) (e.g. GM technology) and representatives of the CBD/Cartagena Protocol, including adequate representation from developing countries.

Approval:
[ICPM-4, March 2002]

References:
ISPM Nos. 2, 3, and 11; Cartagena Protocol; Reference document No. 5 from the OEWG; other discussion or reference documents as may be provided by the participants or Secretariat.