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para la
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y la
Alimentación

INTERIM COMMISSION ON PHYTOSANITARY MEASURES

Third Session

Rome, 2-6 April 2001

Standard Setting Priorities

Agenda Item 4 of the Provisional Agenda

1. At its Second Session, the ICPM identified topics and priorities for standards to be included in the work programme. ICPM01/10 describes the status of standards development to date. Described below are:
 - topics identified by the ICPM previously but not yet included in the work programme;
 - topics for standards arising from other standards; and
 - new topics based on suggestions from Members and observations of the Secretariat.
2. Certain activities from previous years are carried forward for the ICPM to decide their priority for completion in future work programmes. Other activities (e.g. Glossary review) are ongoing. These are included in the final section to distinguish them from new proposals.

I. TOPICS NOT YET INCLUDED IN THE WORK PROGRAMME

A. REVISION OF ISPM NO. 1, *PRINCIPLES OF PLANT QUARANTINE AS RELATED TO INTERNATIONAL TRADE*

3. The FAO Conference adopted ISPM No. 1 in 1993. This was before the revision of the IPPC and also before the completion of the GATT Uruguay Round negotiations that resulted in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the establishment of the World Trade Organization. The adoption and coming into force of the SPS Agreement (1995) and the adoption of the New Revised Text of the IPPC (1997) represent further development of the original concepts that formed the basis for ISPM No. 1. This means that the standard is now inconsistent with the IPPC (1997) and describes principles differently than equivalent concepts in the SPS Agreement. Revision of ISPM No. 1 is needed to correct and update the standard.
4. The revision of ISPM No. 1 may be done at two levels. First, it may simply be corrected for the use of terms consistent with the New Revised Text of the IPPC. This primarily involves modifications to reflect the application of the principles to *phytosanitary* rather than *quarantine*

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and editing for other corrections in terminology. A second level of revision may be undertaken to add, remove or modify concepts to more accurately reflect their relevance as distinct principles and to align more closely with the concepts as they are expressed in the IPPC (1997) and the SPS Agreement. For instance, the principle of *non-discrimination* in ISPM No. 1 incorporates both the principles of non-discrimination and *national treatment* found in the SPS. Likewise, the principle of *emergency action* as described in ISPM No. 1 includes both the concepts of emergency action and *provisional measures*. These are distinctly different concepts in the SPS Agreement that are treated differently in ISPM No. 1.

B. PRA FOR WEEDS AND GENETICALLY MODIFIED ORGANISMS

5. At its Second Session (1999) the ICPM noted the need to develop ISPMs describing risk analysis processes for weeds and phytosanitary aspects of genetically modified organisms (GMOs). The ICPM Exploratory Open-ended Working Group on Phytosanitary Aspects of GMOs, Biosafety, and Invasive Species (June 2000, Rome) recommended the development of supplemental standards for PRA specifically addressing GMOs and also environmental risks. The meeting suggested that this not interfere with the completion of the current draft *Pest risk analysis for quarantine pests*. The meeting also recommended that all ISPMs be reviewed for their application to environmental concerns. [see also ICPM01/7] In sum, three new standards are suggested and review all existing standards is encouraged. The topics identified for the three new standards are:

- pest risk analysis for weeds;
- pest risk analysis for living modified organisms and products of modern biotechnology;
and
- risk analysis for the environmental hazards of plant pests.

6. In principle, risk analysis for the environmental hazards of plant pests can include weeds if the interpretation of the term “environment” is extended to include agricultural systems, but because weeds are so important to agricultural ecosystems, two standards may be considered.

C. TRAINING AND ACCREDITATION OF INSPECTORS

7. A standard on the accreditation of inspectors was proposed by the Ninth Technical Consultation among Regional Plant Protection Organizations (1997) and was considered a medium to high priority by the ICPM at its second session (1999). At least one regional plant protection organization (NAPPO) has already adopted such a standard for regional application. An ISPM on the accreditation of inspectors may be facilitated by drawing from the existing work and experience.

D. LOW PEST PREVALENCE

8. The concept of low pest prevalence is defined and included in provisions of the IPPC (1997), but existing ISPMs do not describe the concept or provide guidance on its application in practice. An ISPM or a short explanatory document such as a supplement to the Glossary of Phytosanitary Terms may be useful guidance for the understanding and harmonized use of the concept of low pest prevalence.

II. TOPICS ARISING FROM OTHER STANDARDS

A. REVISION OF ISPM NO. 2, GUIDELINES FOR PEST RISK ANALYSIS

9. The ICPM has the opportunity at its Third Session to adopt a new standard, *Pest risk analysis for quarantine pests*. If the new standard is adopted, the ICPM may consider also withdrawing ISPM No. 2 for review and revision.

10. The FAO Conference adopted ISPM No. 2, *Guidelines for pest risk analysis*, in November 1995. This was before the revision of the IPPC and also before many national plant protection organizations had experience with pest risk analysis. Subsequent revision of the IPPC and the rapid advancement of pest risk analysis practice create the need for updating the guidance provided by ISPM No. 2. In particular, the standard provides no guidance on regulated non-quarantine pests, and it has certain key deficiencies such as not considering the feasibility of measures in risk management.

11. Although the new standard is generally consistent with ISPM No. 2, it provides significantly more detail and includes modifications that take account of the 1997 revisions to the IPPC and experience gained through several years of experience with risk analysis. However, the new standard is limited in scope to its application to quarantine pests. This design follows recommendations of the Interim Standards Committee (formerly the Committee of Experts on Phytosanitary Measures) to develop two specific and complementary standards on PRA: quarantine pests, and regulated non-quarantine pests. It was envisioned that ISPM No. 2 would be revised as a concept standard *General guidelines for PRA*.

B. PEST RISK ANALYSIS FOR REGULATED NON-QUARANTINE PESTS

12. A consequence of creating the standard *Pest risk analysis for quarantine pests* is the need to provide similar guidance for regulated non-quarantine pests. In the early stages of the consolidation of supplemental standards to form the draft standard *Pest risk analysis for quarantine pests*, there were attempts by the Secretariat and pest risk analysis experts to incorporate guidelines for regulated non-quarantine pests into the draft standard under formulation. This proved to be difficult for several reasons. First, there was no standard on regulated non-quarantine pests to make clear the nature and application of the concept. Second, the existing supplementary standards became much more complicated and lengthy with extra provisions for regulated non-quarantine pests. Finally, problems arose from exceptions and deviations in particular because the probability of introduction is almost irrelevant for regulated non-quarantine pests, and the economic impacts that are considered for regulated non-quarantine pests are different than those considered for quarantine pests.

13. The Fifth Meeting Committee of Experts on Phytosanitary Measures in May 1998 recommended that formulation of a standard on pest risk analysis for regulated non-quarantine pests be delayed until the concept standard on regulated non-quarantine pests was completed. This standard is in advanced stages of development and could be adopted in 2001. In addition, the Secretariat is aware (through notifications to the WTO) that countries are beginning to incorporate regulated non-quarantine pests in their regulations. These factors lend increasing importance to the value of reference guidelines for pest risk analyses for regulated non-quarantine pests.

C. SAMPLING CONCEPTS

14. Issues that hinder agreement on certain aspects of *Guidelines for surveillance for specific pests: citrus canker, Inspection methodology* and, to a lesser extent, *Systems approaches for risk management*, relate to a proper understanding of (and agreement on) the application of fundamental statistical concepts related to sampling. This includes concepts such as tolerance, confidence levels, and acceptance levels. The formulation of a standard or the development of technical guidelines regarding the statistical basis for sampling may be useful to support the understanding, completion, and application of these standards.

D. ECONOMIC IMPACTS

15. The development of the standards *Pest risk analysis for quarantine pests* and *General considerations and specific requirements for regulated non-quarantine pests* has been complicated by lack of understanding and agreement on the components of direct and indirect economic impacts and methodologies for their evaluation. The formulation of a standard or the

development of technical guidelines identifying relevant elements and explaining the concepts and methodologies associated with their application in a phytosanitary context may be useful to support the understanding and application of these standards.

16. The need for clarification regarding the meaning and relationship of certain terms associated with economic impacts has also been noted. This includes terms such as:

- potential economic importance (Article II, in the definition of a quarantine pest);
- economically unacceptable impact (Article II, in the definition of a regulated non-quarantine pest);
- economically important loss (Article II, in the definition of endangered area); and
- direct and indirect economic impacts (in draft standards on risk analysis and regulated non-quarantine pests).

17. Clarification of these terms in a standard (or standards) or in a supplement to the Glossary may be helpful for furthering an understanding of the relationship of these terms to the concepts expressed in relevant definitions and standards.

E. EFFICACY OF PHYTOSANITARY MEASURES

18. Expert working groups for the standards on *Systems approaches for risk management and Guidelines for regulating non-manufactured wood packing in use for the transport of commodities* identified the need for a standard (or standards) regarding the criteria to be used for determining the efficacy of phytosanitary measures. In particular, it was noted that harmonization was required on the quantity and quality of data needed to evaluate efficacy, analytical methods for the assessment of efficacy, and the criteria used to judge the equivalence of measures. The formulation of relevant ISPMs and the establishment of procedures for the evaluation of efficacy are fundamental to the core mandate of the ICPM in the global harmonization of phytosanitary measures.

III. SUGGESTIONS FROM MEMBERS AND OBSERVATIONS OF THE SECRETARIAT

A. IRRADIATION

19. The Secretariat is aware of several regional and national initiatives to elaborate standards for the use of irradiation as a phytosanitary treatment. Interest in this topic is increasing significantly as countries become more concerned about adopting treatment alternatives for methyl bromide fumigation. The formulation of an ISPM for irradiation as a phytosanitary treatment is facilitated by several factors:

- a significant amount of background material (including draft standards) and expertise regarding the use of irradiation as a phytosanitary treatment is readily available;
- most countries now accept irradiation as a treatment for food commodities;
- at least one regional standard for the application of irradiation for phytosanitary purposes is already in place (NAPPO); and
- the International Atomic Energy Agency, which has a joint division with FAO, has indicated the willingness to provide some resources to assist the ICPM with the development of an ISPM for irradiation as a phytosanitary treatment.

B. TRANSIT

20. The Secretariat is aware that most countries have no phytosanitary requirements regarding the movement of consignments in transit. However, the Secretariat has noted that several countries notified the WTO of proposals to put such regulations in place and many other countries have contacted the Secretariat requesting assistance with the design of transit legislation and

regulations. The formulation of an ISPM providing guidelines for transit requirements could be an important contribution to harmonization at this time.

C. UNCERTAINTY - THE PRECAUTIONARY APPROACH

21. A key issue currently under international scrutiny and debate is the role and use of precaution in the regulation of hazards to plant, animal, and human health and the environment. A concept known as the precautionary approach (and also as the “precautionary principle”) has emerged from the international framework for environmental protection to become a contentious issue in other fora where the concept is not understood or expressed in the same terms. The lack of clarity in this regard is often mistaken for the lack of precaution or the lack of concern for the importance of precaution.

22. Within the IPPC framework, precaution is an element of decision making related to the level of uncertainty in risk analysis. However, because of the emphasis placed on scientific evidence and principles, the importance of uncertainty in risk analysis and the criteria for governments to use for disciplining their judgements on uncertainty are not well understood or internationally harmonized. Significant opportunity currently exists to articulate the role and importance of uncertainty in risk analysis as the basis for phytosanitary measures and thereby clarify the application of the precautionary approach within the framework of the IPPC.

D. EQUIVALENCE

23. Recent meetings of the WTO SPS Committee have highlighted special issues for developing countries, including provisions of the SPS Agreement regarding equivalence. The Committee has commended Codex Alimentarius for guidelines adopted by that organization for the development of equivalence agreements. The Committee noted that the IPPC and the Office International des Epizooties (OIE) were lacking similar guidelines. Several SPS Committee Members encouraged the formulation of guidelines for equivalence by IPPC and OIE to help developing countries understand and benefit fully from the application of the concept.

IV. OTHER

A. STANDARDS UNDER DEVELOPMENT

24. The following standards under development are listed in the order of their current priority in the work programme:

- *Guidelines for regulating non-manufactured wood packing;*
- *General considerations and specific requirements for regulated non-quarantine pests;*
- *Systems approaches for risk management;*
- *Guidelines for an import regulatory system;*
- *Inspection methodology; and*
- *Guidelines for surveillance for specific pests: citrus canker.*

25. As mentioned above, the completion of certain of these standards could be facilitated by the formulation of other supporting standards. The priority for completing these standards should be considered in light of decisions that may be taken on the development of relevant supporting standards and other additions to the work programme that may be suggested.

B. GLOSSARY

26. The Glossary is a fundamental reference and a key tool for harmonization. Routine review and updating is essential to ensure consistency regarding the relationship, interpretation and use of terms. In recent years, the revision of the Convention and the addition of many new standards created the need for at least one Glossary Working Group every year. Many essential adjustments

to the Glossary were completed with the adoption of the revised *Glossary of phytosanitary terms* by the ICPM at its second session (1999).

27. There continues to be a significant number of issues related to terms and definitions arising from standards and differences in interpretation among Members. In addition to checking terms and definitions for consistency and accuracy, there is increasing need to provide clarity regarding the relationship between certain terms. Examples include:

- transit, export, re-export, consignment in transit, and re-exported consignment;
- country of origin, place of origin, and country of re-export;
- emergency actions and provisional measures;
- phytosanitary measures, phytosanitary actions, and phytosanitary procedures;
- not widely distributed and limited distribution;
- endangered area, protected area, quarantine area, and controlled area; and
- potential economic importance, economically unacceptable impact, economically important loss, and direct and indirect economic impacts (see also II.D above).

28. It has been suggested that explanatory text is needed to make these terms and their relationships clear. Supplements to the Glossary (such as the supplement done for *official control*) may be useful for this purpose.

C. REVIEW OF STANDARDS

29. The need for review and revision of ISPMs No 1 and No. 2 is noted above. The remaining standards also require periodic review and updating for consistency in the use of terminology, the understanding of concepts and editorial or formatting changes. Examples include:

- modification of terms and definitions for consistency with the revised *Glossary of phytosanitary terms*;
- the addition of references to other standards.

30. The Secretariat suggests that the routine review of standards for updating could be a task assigned to the Glossary Working Group. This is because updating very often involves terminology and the Glossary Working Group has a high level of familiarity with the relationships between concepts, terms, and provisions of the range of standards.

31. **The ICPM is invited to:**

1. *Consider* the topics described above and *recommend* topics and priorities for additions, deletions, or modifications to the work programme for standard setting.
2. *Recommend* actions regarding ISPM No. 2, in light of the adoption or not of *Pest risk analysis for quarantine pests*.
3. *Propose* terms to be added, deleted, or reviewed and *recommend* priorities for the further review and updating of the Glossary, including the possible development of supplements.
4. *Recommend* procedures and priorities for the review and updating of existing standards.