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Proposal on Pest Risk Assessment (PRA) Standards - Options for the proposed revision and reorganization of Pest Risk Analysis Standards

Agenda item 10.5

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I. Background

1. The proposal on the revision and reorganization of Pest Risk Analysis (PRA) standards, ISPM 2 (*Framework for pest risk analysis*) and ISPM 11 (*Pest risk analysis for quarantine pests*), was revived following discussion at the Standards Committee (SC) on the draft ISPM on *Pest risk management for quarantine pests* (2014-001) (hereafter referred to as “draft ISPM (2014-001)”). During its November 2018 meeting, the SC discussed the need to strengthen the draft ISPM (2014-001) with more requirements, as well as the proposal of the Expert Working Group (EWG) that developed the draft ISPM (2014-001) and suggested that it may be worthwhile to revise or reorganize the ISPMs related to PRA.
2. The SC noted that a review of all PRA standards has already been identified as a gap in the *Framework for Standards and Implementation*. The SC agreed that a small group of SC members should continue to develop the draft ISPM (2014-001) based on the SC discussions and with the aim of providing a revised draft for presentation to the next SC meeting. The group would also explore whether the text could be a stand-alone ISPM, or incorporated in the ISPM 11 as a core text or a supplement/annex.
3. The small working group provided input towards further modification of the draft ISPM (2014-001) and proposed considering revision of ISPM 11 to address concerns raised by the EWG and the SC,

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including duplication of text. The revision of ISPM 11 could be done following one of the two options that had been suggested by the EWG:

- integrating the new text of the draft ISPM (2014-001) into the core text of ISPM 11 (section 3 on stage 3 of the PRA) or;
 - focusing ISPM 11 on the pest risk assessment stage of the PRA (stage 2) and having a new ISPM focused on the pest risk management stage of the PRA (stage 3).
4. In the latter case, the draft ISPM (2014-001) would need to be reviewed as a standalone ISPM and inclusive of all PRM related information that would need to be removed from ISPM 11.
5. During the SC discussion, some SC members recognized that, if revising ISPM 11, it might also be beneficial to revise ISPM 2 to align it with ISPM 11. One option would be to follow the same approach as used for the reorganization of the fruit fly standards. The proposal to revise and reorganize PRA standards would be ambitious, but it would serve to raise awareness of international plant health standards at the Fifteenth session of the Commission on Phytosanitary Measures (CPM-15) and in the International Year of Plant Health, both in 2020, and would be consistent with the *Framework for standards and implementation*.
6. At its meeting in May 2019, the SC agreed that a small working group of SC members be set up to draw up a proposal on the revision and reorganization of the PRA standards, ready for consideration at the SC November 2019 meeting, with an expectation to submit it to CPM-15 in 2020. The SC small working group was asked to consider the following:
- the content of ISPM 2, ISPM 11, and if appropriate ISPM 24 (Guidelines for the determination and recognition of equivalence of phytosanitary measures) and ISPM 32 (Categorization of commodities according to their pest risk);
 - two options for the suite of PRA standards:
 - a suite of three standards (one for each of the three stages of the PRA process); or
 - a suite of four standards, including an overarching standard to provide a framework for the whole PRA process; and,
 - how to separate out the supplement sections of ISPM 11.

II. Options for structure of PRA Standards and SC November 2019 discussions

7. The SC small working group proposed a list of six options specific to the PRA process for quarantine pests, focusing primarily on ISPM 2, ISPM 11 and the new draft ISPM (2014-001). ISPM 21 (*Pest risk analysis for regulated non-quarantine pests*) was not considered as part of this analysis because it is specific to regulated non-quarantine pests (RNQPs) and it sufficiently details the initiation, risk assessment and risk management stages.

8. At its November 2019 meeting, the SC considered the six options identified by the small working group for reorganization of the PRA standards:

- Option 1: new stand-alone draft ISPM on pest risk management, with no revision of ISPM 11
 - Option 2: revision of ISPM 11, section 3 on pest risk management
 - Option 3: revision of ISPM 11 and stand-alone ISPM on pest risk management
 - Option 4: three standards – one for each stage of PRA
 - Option 5: four standards – overarching standard on the PRA process and one for each stage of PRA
 - Option 6: one overarching standard on PRA process with an annex for each stage of PRA.
9. Many SC members were in favor of Option 5, on the basis that it provided the best solution in terms of clarity of guidance and avoiding duplication of content, with some SC members also supporting

Option 4, which is very similar. One SC member thought that Option 4 would involve less work than Option 5, but other SC members commented that the work involved for Options 4 and 5 would probably be similar and it would be better to choose the option that provides the best solution. In terms of managing the workload, some SC members suggested that it would be best to start with the ISPM on pest risk management and then follow with the other ISPMs.

10. One SC member disagreed and preferred Option 2, indicating that this represented the least workload and the most straightforward way of integrating additional information on pest risk management.

11. The SC could not agree on the best option for the reorganization of the PRA standards but agreed to submit a paper to CPM-15 (2020), explaining the background, outlining options 2 and 5, referring to the discussion at the November SC meeting, and seeking the decision of the CPM on the most suitable option.

12. The details of Option 2 and Option 5 are presented below:

Option 2: Revision of ISPM 11, section 3 on pest risk management

- ISPM 2: No changes
- ISPM 11: Focused revision
 - Integrating the text developed as part of the draft ISPM (2014-001) into section 3 of ISPM 11
 - New text elaborating on the elements of section 3 of ISPM 11, plus additional tasks as outlined in Specification 63 and issues identified through discussions at the SC.

Points to consider

- Incorporation of the new text from the draft ISPM (2014-001) into ISPM 11 would result in an unusually large standard.
- Duplication of content in the existing ISPMs:
 - Section 1 (Initiation) of ISPM 2 and Section 1 (Initiation) of ISPM 11
- Represents least workload.

Option 5: four standards – overarching standard on PRA and one for each stage of PRA

- Overarching standard: Framework for PRA process
 - Including current Background and section 3 (aspects common to all PRA stages) of ISPM 2
 - Including Annexes 1, 2 and 3 of ISPM 11
- New standard on Stage 1 (Initiation)
 - Combining sections 1 of both ISPM 2 and ISPM 11
- New standard on Stage 2 (Pest risk assessment)
 - Revision and elaboration of section 2 of ISPM 11
 - Including current Annex 4 of ISPM 11
- New standard on Stage 3 (Pest risk management)
 - Elaborating on the elements of section 3 of ISPM 11, plus additional tasks as outlined in Specification 63 and issues identified through discussions at SC.

Points to consider

- There was general agreement among SC members that it was better to have separate standards on PRA, each ISPM dealing with a different stage of PRA (SC May 2019).
- This option is one of the options tasked by SC to the small group to analyze.

- Several SC members pointed out that it was important to revise ISPM 11 as a whole because many risk analysts feel that it was not flexible enough and could lead to a lengthy PRA process (SC November 2018).
- A review of all PRA standards has already been identified as a gap in the *Framework for Standards and Implementation*. If there is an urgent need to revise an ISPM, the SC may propose it to CPM. This would address the concern that Contracting Parties have not been consulted about the proposal or a topic has not been adopted by the CPM in order to initiate the reorganization of PRA standards.
- ISPM 11 was last revised in 2013 with the addition of Annex 4, but its core text remains unchanged since 2004. Some sections in ISPM 11 might benefit from revision, as technical knowledge in these areas is now far greater than when the ISPM 11 text was written. Revision of ISPM 2 would align it with ISPM 11.
- The EWG tasked with drafting Annex 4 of ISPM 11 made some recommendations for changes to ISPM 11 when next revised (Appendix 1 to this discussion paper).
- This option avoids duplication of contents.
- The length of the process to develop four standards is an important point to consider.

III. Recommendations

13. The CPM is invited to:

- 1) *consider* the options 2 and 5 recommended by the SC for the proposed revision and reorganization of the PRA standards; and,
- 2) *decide* on a suitable option for the proposed revision and reorganization of the PRA standards.
- 3) *add* a topic to the List of Topics accordingly

Appendix 1: Recommendations for changes to ISPM 11 when next revised

(Extracted from: *Report of the Expert Working Group on Pest Risk Analysis for Plants as Quarantine Pests*¹ 25–29 May 2009, Paris, France)

1. The group discussed needed revisions in the long term to ISPM 11, 2, and 21 based on their recent experience reviewing these standards as background for drafting the Annex to ISPM 11, and proposed that the following changes be considered when ISPM 11 is next revised.

- IPSMs number 11 (Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms), number 2 (Framework for pest risk analysis), and number 21 (Pest risk analysis for regulated non-quarantine pests) should be revised at the same time, and if possible, combined into one standard to make more sense for readers and so that new elements from ISPM 2 are more easily implemented in the other PRA standards.
- The initiation section of ISPM 11 needs to include elements that are currently in stage 2, such as identity of pest, absence and presence in PRA area, and regulatory status. Stage 2 should start at the current section 2.2, Assessment of probability of establishment and spread.
- The concepts of *pre-selection* and *categorization* need to be examined and made consistent.
- The probability of establishment as laid out in ISPM 11, section 2.2.2., needs to be revised because it does not present steps in a logical order.
- Pest effects:
 - Careful consideration should be given to reorganizing and simplifying the section on direct and indirect effects and removing duplications and inconsistencies. Concepts could be referred to in a broad sense, but should not be used as headings to categorize examples of types of impacts.
 - Inconsistencies in other parts of standard should also be addressed (eg, inconsistency for competition, which is a direct effect in standard and indirect in Annex 1).
 - The impact assessment section needs more guidance regarding how to conduct environmental assessment.
 - In section 2.3 of *Assessment of potential economic consequences*, it should be made clear that the first concern is plants and plant products, not other factors currently cited, like tourism.
 - Guidance should be developed for probability of establishment on the basis of pest behaviour, history of establishment, and intrinsic factors.
 - Native Spanish speakers noted that ISPM 11 is very confusing in Spanish and is much easier to understand in English.
 - ISPM 2, section 1.2.1: the above discussion on suitability of the indicators for pre-selection should be considered.
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¹ EWG report: <https://www.ippc.int/en/publications/1163/>