[PleaseReview document review. Review title: 2021 First Consultation: Draft Specification for Reorganization of Pest Risk Analysis standards (2020-001). Document title: 2020-001\_DraftSpec\_reorganization\_PRA\_En.docx]

[1]**DRAFT SPECIFICATION FOR ISPM: Reorganization of pest risk analysis standards (2020-001)**

[2]Status box

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| [3]This is not an official part of the specification and it will be modified by the IPPC Secretariat after approval | |
| [4]**Date of this document** | [5]2021-04-22 |
| [6]**Document category** | [7]Draft specification for an ISPM |
| [8]**Current document stage** | [9]*To* consultation |
| [10]**Major stages** | [11]2020-07 CPM Bureau added topic *Reorganization of pest risk analysis standards* (2020-001) to the *List of topics for IPPC standards*.  [12]2020-07 Standards Committee (SC) decided to open an e-forum to discuss and draft the specification for the topic (2020\_eSC\_Nov\_09).  [13]2020-10 SC commented on the draft specification via e-decision (2020\_eSC\_Nov\_09).  [14]2020-11 SC reviewed the draft specification.  [15]2021-02 SC revised the draft specification via the Online Comment System.  [16]2021-04 SC revised the draft and approved for consultation. |
| [17]**Steward history** | [18]2020-09 SC Masahiro SAI (JP, Lead Steward)  [19]2020-09 SC Hernando Morera GONZÁLEZ (CR, Assistant Steward)  [20]2020-09 SC Joanne WILSON (NZ, Assistant Steward) |
| [21]**Notes** | [22]2021-04 Edited |

[23]Title

[24]Reorganization of pest risk analysis standards (2020-001).

[25]Reason for the revision of the standards

[26]Pest risk analysis (PRA) is a core process within the scope of the IPPC and an important science-based evaluation tool for national plant protection organizations (NPPOs). It is used to determine quarantine pests and to identify the phytosanitary measures that are appropriate to manage the risk of pest introduction and spread in a specified PRA area. Guidance for NPPOs on the evaluation of technical, scientific and economic evidence to justify their decisions is currently documented in ISPM 2 (*Framework for pest risk analysis*, adopted in 1995, revised in 2007) and ISPM 11 (*Pest risk analysis for quarantine pests*, adopted in 2001, revised in 2003, 2004 and 2013).

[27]ISPM 2 describes the overall process of PRA for pests of plants, with a particular focus on the initiation stage (Stage 1 of the PRA process). ISPM 11 describes the factors to consider when conducting a PRA to determine if a pest qualifies as a quarantine pest. The emphasis in ISPM 11 is on the integrated process for pest risk assessment and guidance on selection of pest risk management options (Stages 2 and 3, respectively, of the PRA process). In addition, this ISPM includes guidance on the analysis of risks posed by pests to the environment and biological diversity, the evaluation of potential risks to plants and plant products posed by living modified organisms, and the conduct of PRA for plants as quarantine pests.

[28]The revision and reorganization of the standards related to PRA was proposed following discussions on the draft ISPM on *Pest risk management for quarantine pests* (2014-001). The following aspects were identified:

* [29]the need to strengthen the draft ISPM with appropriate requirements on pest risk management;
* [30]the need to integrate PRA standards for quarantine pests (ISPM 2, ISPM 11 and the draft ISPM on pest risk management) into one standard to avoid redundancy and ensure consistency.

[31]The Commission on Phytosanitary Measures (CPM) Bureau discussed the revision of PRA standards and recommended that they be integrated into one overarching standard on the PRA process, with an annex for each stage of PRA.[[1]](#footnote-1) This approach is considered the best because it will ensure that PRA is viewed as a conceptual process composed of three different stages (each supported by a more comprehensive annex), and it will establish a framework that enables NPPOs to conduct PRA appropriately.

[33]Scope

[34]This standard should establish a conceptual framework for PRA for quarantine pests within the scope of the IPPC and provide guidance on the PRA process.

[35]General guidance on the PRA process should be provided in the core text of the standard and detailed guidance on each stage of PRA (Stage 1. initiation, Stage 2. pest risk assessment, Stage 3. pest risk management) should be consolidated in the annexes to the standard: one annex for each stage.

[36]The standard should include general guidance on pest risk management, such as criteria related to the rational relationship between the pest risk and the strength of phytosanitary measures, harmonization, and equivalence of phytosanitary measures (as in ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) and ISPM 24 (*Guidelines for the determination and recognition of equivalence of phytosanitary measures*)).

[37]Guidance on the analysis of risks posed by pests to the environment and biological diversity, the evaluation of potential risks to plants and plant products posed by living modified organisms, and the conduct of PRA for plants as quarantine pests should also be included in the standard.

[38]The standard should not include guidance on regulated non-quarantine pests, which is provided in ISPM 21 (*Pest risk analysis for regulated non-quarantine pests*).

[39]Purpose

[40]The purpose of this standard is to facilitate harmonization of the different stages of the PRA process – initiation, pest risk assessment and identification of appropriate pest risk management options – and to support the rational relationship between the pest risk identified through pest risk assessment and the strength of the corresponding phytosanitary measures identified through pest risk management.

[41]This will be achieved by reorganizing ISPM 2, ISPM 11 and the draft ISPM on *Pest risk management* *for quarantine pests* (2014-001) into one standard. Revised text to improve guidance on the risk analysis process should be included where relevant.

[42]The new, reorganized guidance on the PRA process will help NPPOs to improve their implementation of this concept.

[43]Tasks

[44]The expert working group (EWG) should undertake the following tasks:

1. [45]Integrate pertinent sections of ISPM 2 and ISPM 11, and the draft ISPM on *Pest risk management for quarantine pests* (2014-001), into one overarching standard outlining the main concepts of the IPPC framework on pest risk analysis, with more comprehensive guidance provided in annexes to the standard (one annex for each stage of the PRA process). Refer to the following outline as a proposed starting point for EWG discussion and drafting:

* [46]Core text of the standard: overarching framework for PRA:
* [47]includes current Background and section 3 (Aspects common to all PRA stages) of ISPM 2 and other pertinent sections of ISPM 2,
* [48]includes current Annex 1 (Comments on the scope of the IPPC in regard to environmental risks), Annex 2 (Comments on the scope of the IPPC in regard to pest risk analysis for living modified organisms), and Annex 3 (Determining the potential for a living modified organism to be a pest) to ISPM 11,
* [49]seeks to maintain the original intent of the text but with streamlined descriptions (the original text being modified where needed in line with the structure of this reorganized standard, but without substantially revising the original requirements and guidance);
* [50](New) Annex 1. PRA Stage 1 (Initiation):
* [51]combines section 1 of ISPM 2 and section 1 of ISPM 11,
* [52]includes Stage 1 of current Annex 4 (Pest risk analysis for plants as quarantine pests) to ISPM 11,
* [53]expected to involve no substantial revision of the original requirements and guidance of Stage 1 (the revision instead focusing on modification of the text for proper alignment with the structure of the new annex);
* [54](New) Annex 2. PRA Stage 2 (Pest risk assessment):
* [55]combines section 2.2 of ISPM 2 and section 2 of ISPM 11,
* [56]seeks to maintain the original intent of the text but with streamlined descriptions (the revision instead focusing on modification of the text for proper alignment with the structure of the new annex, with no substantial revision of the original requirements and guidance of Stage 2 expected),
* [57]includes Stage 2 of current Annex 4 to ISPM 11;
* [58](New) Annex 3. PRA Stage 3 (Pest risk management):
* [59]aligns elements of section 2.3 of ISPM 2, section 3 of ISPM 11 and the draft ISPM on *Pest risk management for quarantine pests* (2014-001) (Specification 63) considering the discussion points of the Standards Committee (SC) regarding the latter draft,
* [60]includes Stage 3 of current Annex 4 to ISPM 11.

1. [61]Consider how the content of the current Annex 4 (Pest risk analysis for plants as quarantine pests) to ISPM 11 should be included in the reorganized standard. Options include incorporation into the body text, creation of an additional annex, or inclusion of an appendix or supplementary text that is referenced throughout (as per the references already used: “S1: the supplementary text on environmental risks” and “S2: the supplementary text on living modified organisms”).
2. [62]If any parts of the original requirements and guidance on Stage 2 (Pest risk assessment) may require revision that is beyond the scope of this specification, identify the parts that need more clarity or improvement and propose a short outline of the review required, for future reference.
3. [63]Consider implementation of the revised standard by contracting parties and identify potential operational and technical implementation issues. Provide information and possible recommendations on these issues to the SC.

[64]Consider whether the revised standard could affect in a specific way (positively or negatively) the protection of biodiversity and the environment. If this is the case, the impact should be identified, addressed and clarified in the draft standard

[65]Review all references to the ISPMs under revision in other ISPMs, as well as references to other ISPMs in the ISPMs under revision, to ensure that they are still relevant and propose consequential changes if necessary.

[66]Provision of resources

[67]Funding for the meeting may be provided from sources other than the regular programme of the IPPC (FAO). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants. Please refer to the *Criteria used for prioritizing participants to receive travel assistance to attend meetings organized by the IPPC Secretariat* posted on the International Phytosanitary Portal (IPP) (see <https://www.ippc.int/en/core-activities/>).

[68]Collaborator

[69]To be determined.

[70]Steward

[71]Please refer to the *List of topics for IPPC standards* posted on the IPP (see <https://www.ippc.int/core-activities/standards-setting/list-topics-ippc-standards>).

[72]Expertise

[73]Experts with collective expertise in:

* [74]pest risk assessment, preferably with experience in using or conducting PRA according to ISPM 2 and ISPM 11;
* [75]pest risk management, including experience in evaluating and selecting pest risk management options according to the pest risk identified through the pest risk assessment;
* [76]risk communication;
* [77]the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and phytosanitary regulation.

[78]Participants

[79]Eight to ten experts. A former member of the EWG on Guidance on Pest Risk Management (2014-001) and an IC member may be invited as invited experts. The Assistant Stewards may also be invited to participate.

[80]References

[81]The IPPC, relevant ISPMs and other national, regional and international standards and agreements as may be applicable to the tasks, and discussion papers submitted in relation to this work.

[82]**ISPM 1.** 2016. *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade.* Rome, IPPC, FAO.

[83]**ISPM 2.** 2019. *Framework for pest risk analysis*. Rome, IPPC, FAO.

[84]**ISPM 5.** *Glossary of phytosanitary terms.* Rome, IPPC, FAO.

[85]**ISPM 11.** 2019. *Pest risk analysis for quarantine pests*. Rome, IPPC, FAO.

[86]**ISPM 21.** 2019. *Pest risk analysis for regulated non-quarantine pests*. Rome, IPPC Secretariat, FAO.

[87]**ISPM 24.** 2017. *Guidelines for the determination and recognition of equivalence of phytosanitary measures*. Rome, IPPC, FAO.

[88]Discussion papers

[89]Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat ([ippc@fao.org](mailto:ippc@fao.org)) for consideration by the EWG. The draft ISPM on *Pest risk management for quarantine pests* (2014-001)and the“Detailed breakdown of sections of PRA related ISPMs”[[2]](#footnote-2)should also be considered*.*

1. [32] CPM Bureau 2020-07 (virtual meeting), agenda item 9.2 ([https://www.ippc.int/en/publications/88659/](https://www.ippc.int/en/publications/88659/%20)). The CPM Bureau, noting advice from the FAO Legal Counsel, acted on behalf of the CPM in 2020 as the CPM meeting had to be postponed because of the global COVID-19 pandemic. [↑](#footnote-ref-1)
2. [90] SC 2021-05 (agenda item 4.1), paper 2020-001, Appendix 1. [↑](#footnote-ref-2)