

Food and Agriculture Organization of the United Nations



International Plant Protection Convention

REPORT

Expert Working Group

Reorganization and revision of pest risk analysis standards

(2020-001)

Virtual Meeting

26 October and

7–11 November 2022

IPPC Secretariat

IPPC Secretariat. 2022. Report on the meeting of the Expert Working Group on the A Reorganization and revision of pest risk analysis standards (2020-001), 26 October and 7-11 November 2022. Rome. Published by FAO on behalf of the Secretariat of the International Plant Protection Convention (IPPC). 21 pages. Licence: CC BY-NC-SA 3.0 IGO.

The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations (FAO) concerning the legal or development status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these have been endorsed or recommended by FAO in preference to others of a similar nature that are not mentioned.

The views expressed in this information product are those of the author(s) and do not necessarily reflect the views or policies of FAO.

© FAO, 2022



Some rights reserved. This work is made available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <u>https://creativecommons.org/licenses/by-nc-sa/3.0/igo/legalcode</u>).

Under the terms of this licence, this work may be copied, redistributed and adapted for non-commercial purposes, provided that the work is appropriately cited. In any use of this work, there should be no suggestion that FAO endorses any specific organization, products or services. The use of the FAO logo is not permitted. If the work is adapted, then it must be licensed under the same or equivalent Creative Commons licence. If a translation of this work is created, it must include the following disclaimer along with the required citation: "This translation was not created by the Food and Agriculture Organization of the United Nations (FAO). FAO is not responsible for the content or accuracy of this translation. The original English edition shall be the authoritative edition."

Disputes arising under the licence that cannot be settled amicably will be resolved by mediation and arbitration as described in Article 8 of the licence except as otherwise provided herein. The applicable mediation rules will be the mediation rules of the World Intellectual Property Organization http://www.wipo.int/amc/en/mediation/rules and any arbitration will be conducted in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law (UNCITRAL).

Third-party materials. Users wishing to reuse material from this work that is attributed to a third party, such as tables, figures or images, are responsible for determining whether permission is needed for that reuse and for obtaining permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

Sales, rights and licensing. FAO information products are available on the FAO website (<u>www.fao.org/publications</u>) and can be purchased through <u>publications-sales@fao.org</u>. Requests for commercial use should be submitted via: <u>www.fao.org/contact-us/licence-request</u>. Queries regarding rights and licensing should be submitted to: <u>copyright@fao.org</u>.

CONTENTS

1. Opening of the meeting					
	1.1	Welcome by the IPPC Secretariat and introductions			
	1.2	Presentation of the standard setting process and the role of participants4			
2.	Meeting	g arrangements			
	2.1	Selection of the chairperson			
	2.2	Selection of the rapporteur			
	2.3	Adoption of the agenda			
3.	Admini	strative matters			
4.	Review	of the specification			
5.	Review	of discussion papers			
	5.1	Discussion paper: reorganization and revision of pest risk analysis standards - Prepared by Gritta Schrader, Dirk Jan van der Gaag, Alan MacLeod, with comments of the EPPO PRA team			
	5.2	Discussion paper on reorganization and revision of pest risk analysis standards - Prepared by Jeya Jeyasingham			
	5.3	Discussion paper on specification 72 - Prepared by Tiago Lohmann			
	5.4	Discussion paper on reorganization and revision of pest risk analysis standards (2020-001) - Prepared by Leah Millar			
	5.5	Pest risk analysis in South Africa - Integration of the sections of ISPM 2 and ISPM 11 that are relevant to the three stages of pest risk analysis - Prepared by PP Tshikhudo			
	5.6	Comments on the draft PRM			
	5.7	Discussion paper from CABI on the Reorganization and revision of pest risk analysis (PRA) standards			
	5.8	TPG proposal on consistency of the use of the terms in ISPMs and recommendation of the EWG on the revision of ISPM 2			
	5.9	The Vision of the Pest Risk Analysis Standard - Prepared by La-Tanya Richards, Plant Quarantine/Produce Inspection Branch, Jamaica			
	5.10 Int	ervention from New Zealand			
6.	Development of the Reorganization and revision of pest risk analysis standards (2020-001)				
	6.1	Brainstorming session to draft the reorganization and revision of PRA standards			
	6.2	Elaboration of the text of the draft reorganization and revision of PRA standards			
7.	Any other business				
8.	Close of	f the meeting			
App	pendix 1:	Agenda			
App	pendix 2:	Documents list			
Ар	pendix 3:	Participants list			

1. Opening of the meeting

1.1 Welcome by the IPPC Secretariat and introductions

- [1] The Standard Setting Unit Lead, Mr Avetik Nersisyan opened the meeting on behalf of the IPPC Secretariat (hereafter referred to as "the secretariat") and welcomed all participants to the meeting of the Expert Working Group (EWG) on the Reorganization and revision of pest risk analysis standards (2020-001) and thanked the Italian NPPO, in particular the Region of Lombardi, for hosting the EWG. He also thanked all members for participating in the meeting.
- [2] The Lombardy Region Councilor for Agriculture, food and green systems, Mr Fabio Rolfi was not able to participate, and on behalf of the local host, the Deputy Director and Head of the Phytosanitary Service, Mr Andrea Azzoni welcomed the participants. He highlighted that the Lombardy regions plant protection service delivers their work within the framework of the IPPC, focusing on export authorization and import and export checks, and having an important laboratory in the region. He noted that the Lombardy region has important agricultural production that is threatened by quarantine pests. The reorganization will affect the risk management process, and its importance is recognized in safe international trade. He noted the contributions of the region to the International Year of Plant Health.
- [3] The participants introduced themselves.

1.2 Presentation of the standard setting process and the role of participants

[4] The secretariat gave a presentation summarizing the standard setting process¹. The secretariat also outlined the roles of the EWG participants, explaining that the experts should consider the topic of the standard from a globally acceptable perspective, rather than as national or regional representatives.

2. Meeting arrangements

2.1 Selection of the chairperson

[5] The EWG selected Mr Jeya Kanapathi Jeyasingham (Australia) as chairperson.

2.2 Selection of the rapporteur

[6] The EWG selected Mr Tiago Rodrigo Lohmann (Brazil) as rapporteur.

2.3 Adoption of the agenda

[7] The EWG adopted the agenda (Appendix 1).

3. Administrative matters

- [8] The secretariat introduced the documents list (Appendix 2) and the participants list (Appendix 3), and invited participants to notify the secretariat of any information that required updating in the participants list or was missing from it. It was noted that Ms Stephanie Bloem, Mr Hernando Morera González, Ms Gritta Schrader and Mr Dirk Jan Van der Gaag was unable to attend the face to face meeting. Ms Gritta Schrader and Mr Dirk Jan Van der Gaag attended the virtual pre-meeting. The following members joined the face to face meeting virtually: Ms La-Tanya Suzane Richards, Ms Helen Mary Harman, Ms Ying Huang,
- [9] The host representative, Ms Mariangela Ciampitti informed the participants of the local arrangements.

4. Review of the specification

[10] The Steward, Mr Masahiro Sai introduced Specification 72 (*Reorganization and revision of pest risk analysis standards*), laying out the tasks of the EWG.² He noted, that the main task for the EWG is to

¹ 16_EWG_FF_2022_Jan.

² Specification 72: <u>https://www.ippc.int/en/publications/90498/</u>

integrate sections of ISPM 2 (*Framework for pest risk analysis*) and ISPM 11 relevant to the three stages of PRA, together with the draft ISPM on *Pest risk management for quarantine pests* (2014-001), to create one annex per stage of PRA. According to Specification 72 (*Reorganization and revision of pest risk analysis standards*) the generic material, such as background information and guidance on documentation should be placed in the core text of the new, integrated standard, together with Annex 1, Annex 2, Annex 3 and part of Annex 4 of ISPM 11.

- [11] He also noted that if the EWG determined that further revisions outside the scope of the Specification would be needed, the EWG could identify these, and submit it to the Standards Committee (SC) for consideration.
- [12] The Steward noted that the potential implementation issues identified by the EWG under Task 9 would be captured and presented to the SC, who would consider and forward the relevant ones to the Implementation and Capacity Development Committee (IC).
- [13] The Steward also introduced his paper³ on the proposed restructuring of the ISPMs that outlined the new structure and presented his proposal on how the sections of the ISPM 2, ISPM 11 and the draft ISPM on Pest risk management are incorporated into the new ISPM.
- [14] EWG members thanked the Steward for preparing the document, noting that it was very helpful starting point.

5. Review of discussion papers

[15] Most discussion papers were reviewed during the virtual pre-meeting, held 12 days prior to the face-to-face meeting.

5.1 Discussion paper: reorganization and revision of pest risk analysis standards -Prepared by Gritta Schrader, Dirk Jan van der Gaag, Alan MacLeod, with comments of the EPPO PRA team

[16] Ms Gritta Schrader (Germany) presented the discussion paper⁴ jointly prepared by Gritta Schrader, Dirk Jan van der Gaag (The Netherlands), Alan MacLeod (United Kingdom), with comments of the EPPO PRA team providing detailed comments on the revisions.

5.2 Discussion paper on reorganization and revision of pest risk analysis standards -Prepared by Jeya Jeyasingham

[17] Mr Jeya Jeyasingham (Australia) presented the discussion paper⁵, noting the importance of bilateral negotiations when conducting PRA and setting up import requirements.

5.3 Discussion paper on specification 72 - Prepared by Tiago Lohmann

[18] Mr Tiago Lohmann (Brazil) presented the discussion paper⁶, giving suggestions on how to approach restructuring the draft, and the concept of LMOs.

³ 14_EWG_PRA_2022_Nov

⁴ 06_EWG_PRA_2022_Nov

⁵ 07_EWG_PRA_2022_Nov

⁶ 08_EWG_PRA_2022_Nov

5.4 Discussion paper on reorganization and revision of pest risk analysis standards (2020-001) - Prepared by Leah Millar

[19] Ms Leah Miller (USA) presented the discussion paper⁷ providing detailed suggestions on improvements on specific aspects of the process.

5.5 Pest risk analysis in South Africa - Integration of the sections of ISPM 2 and ISPM 11 that are relevant to the three stages of pest risk analysis - Prepared by PP Tshikhudo

[20] Mr PP Tshikhudo (South Africa) presented on the Pest risk analysis in South Africa⁸ and introduced the discussion paper on Integration of the sections of ISPM 2 and ISPM 11 that are relevant to the three stages of pest risk analysis⁹.

5.6 Comments on the draft PRM

[21] Ms Ying Huang (China) presented Comments on the draft ISPM on Pest risk management¹⁰.

5.7 Discussion paper from CABI on the Reorganization and revision of pest risk analysis (PRA) standards

[22] The EWG ddiscussed the paper from CABI on the Reorganization and revision of pest risk analysis (PRA) standards¹¹.

5.8 TPG proposal on consistency of the use of the terms in ISPMs and recommendation of the EWG on the revision of ISPM 2

[23] The Secretariat introduced the TPG proposal on consistency of the use of the terms in ISPMs and recommendation of the EWG on the revision of ISPM 2¹².

5.9 The Vision of the Pest Risk Analysis Standard - Prepared by La-Tanya Richards, Plant Quarantine/Produce Inspection Branch, Jamaica

[24] Ms La-Tanya Richards (Jamaica) presented a discussion paper¹³ outlining the process in the Caribbean region. It was mentioned, that the region heavily relies of importation of products. She noted that the effectiveness of a country's plant health system is linked to the ability to implement pre-border measures to protect itself from the entry and spread of plant pests.

5.10 Additional comments from New Zealand

- [25] Ms Helen Mary Harman (New Zealand) provided additional comments on the PRA process and its challenges in New Zealand.
- [26] The Chair thanked all participants providing discussion papers.

6. Development of the Reorganization and revision of pest risk analysis standards (2020-001)

[27] The secretariat drew the attention of the EWG to the reference documents for drafting ISPMs: the *IPPC* style guide, ISPM 5 (Glossary of phytosanitary terms) and the Guidelines for a consistent ISPM

¹⁰ 11_EWG_PRA_2022_Nov

⁷ 09_EWG_PRA_2022_Nov

⁸ 10_EWG_PRA_2022_Nov

⁹ 16 EWG PRA 2022 Nov

¹¹ 12_EWG_PRA_2022_Nov

¹² 13_EWG_PRA_2022_Nov

¹³ 15 EWG PRA 2022 Nov

terminology (in the *IPPC procedure manual for standard setting*).¹⁴ The secretariat highlighted the need for consistency in the use of terms, both within the draft and with other ISPMs. When drafting the annex, if a suitable term was available in ISPM 5 then that term should be used; new terms could be defined or, if they could be used in other ISPMs, proposed for inclusion in ISPM 5.

6.1 Brainstorming session to draft the reorganization and revision of PRA standards

- [28] Ms Joanne Wilson, the Steward of the draft ISPM for Pest risk management introduced the draft text that is proposed to be incorporated into the new draft reorganizing all PRA standards. This was drafted by the EWG on Guidance on Pest Risk Management in 2018¹⁵. The Secretariat noted that the Specification 72 would allow one member of the EWG on pest risk management to attend this EWG, but that no one was available upon the prompt of the Secretariat.
- [29] The EWG noted that there is a lot of repetition in the draft ISPM on pest risk management with ISPM 11. They also briefly reviewed Specification 63¹⁶.
- [30] One EWG member noted that the pest risk management and pest risk seem to be used interchangeably in the draft for pest risk management, and the EWG agreed to use consistent terms in the revision.
- [31] **PRA stages in Annex or Core text?** The EWG discussed the structure of the draft and noted that having the stages of PRA as annexes would result in a hierarchy where the three stages are on the same level with the annexes on LMOs, environmental risks and plants as pests. The EWG was divided whether to recommend to the SC to re-establish the 3 stages into the core text, to make them more prominent and highlight their importance. If they were to be re-established in the core text, they should be put before the generic sections. However, there was no consensus and the EWG noted the instructions of the Specification, regarding presenting the 3 stages of PRA as annexes, and agreed to go ahead with the revisions and reorganization according to the specification.
- [32] Scope of the revision. The EWG also discussed the scope of the revision, noting that further suggestions may be made to the SC of changes that are outside of the scope of this revision. Some member suggested that although the tasks do not permit extensive revision, the EWG should still address the inconsistencies and where there is lack of clarity (transfer to host, possibility of establishment, and inconsistencies of using these terms, e.g. regarding endangered area). The Steward clarified that the Specification suggests to keep the "intent of the original test" but that revisions could be made if they improve clarity.
- [33] **Transfer vs establishment vs entry.** Entry of a pest into a PRA area, may not mean the pest can establish. Transfer to a suitable host is the first step to establishment; therefore it was suggested, that the section on probability of transfer to a suitable host should be moved to the establishment section. The EWG agreed that this does not change the intent, and thus should fit within the scope for the specification, noting that the topic on the concept of probability of transfer to a suitable host and establishment¹⁷ was removed from the IPPC List of Topics considering that this EWG might address the issue.
- [34] Environmental risk. The content of Annex 1 of ISPM 11 "Comments on the scope of the IPPC in regard to environmental risks in ISPM 11" was also included into the new annex on environmental risk.

¹⁴ *IPPC* style guide: <u>www.ippc.int/en/publications/132/</u>; ISPM 5: <u>www.ippc.int/en/publications/622/</u>; *IPPC* procedure manual for standard setting: <u>www.ippc.int/en/core-activities/ippc-standard-setting-procedure-manual/</u>

¹⁵ 2018-03 Report of the Expert Working Group on Guidance on Pest Risk Management: <u>https://www.ippc.int/en/publications/86428/</u>

¹⁶ Specification 63 - Guidance on pest risk management: <u>https://www.ippc.int/en/publications/81795/</u>

¹⁷ Specification 68 - Supplement on Guidance on the concept of probability of transfer to a suitable host and establishment as used in a pest risk analysis for quarantine pests (2015-010) to ISPM 11 (Pest risk analysis for quarantine pests): <u>https://www.ippc.int/en/publications/86598/</u>

- [35] Economic and other impacts. The EWG noted that the current ISPM 11 focuses on the economic impact of a potential pest introduction. Although the EWG noted that "Supplement 2: Guidelines on the understanding of "potential economic importance" and related terms including reference to environmental considerations" of ISPM 5 5 explains that all types of impacts are included under the term "economic consequences,", the EWG felt that it is important to explicitly say in the new standard, that when assessing the impact of the introduction of a pest, social, environmental and cultural impact should also be considered, not only the economic consequences. Although the EWG recognized that the inclusion of all this would mean a bigger revision than possible under the current scope, they agreed to make changes in this regard as much as possible and highlight this issue to the SC.
- [36] Environmental risk, LMOs, and plants as quarantine pests. Throughout the drafting the EWG noted, that although part of the Specification, the inclusion of the ISPM 11 annexes into the description of the PRA process (annexes 1, 2 and 3) would make it unbalanced, harder to read and less comprehensive. The EWG reviewed the information contained in the supplementary text and the annexes and decided on a case by case basis whether to retain the supplementary information in the text or move it into the new annexes created on environmental risk, living modified organisms (LMOs), and plants as quarantine pests in three additional annexes: Annex 4, Annex 5 and Annex 6, respectively.
- [37] LMO. The EWG noted that using PRA to assess the impact of LMO is not considered standard practice, and thus it is more appropriate to present information related to the PRA of LMOs as a separate annex, including both 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.
- [38] In summary, the EWG agreed to follow the approach outlined below:
- [39] The first three annexes of the new standard will correspond to the three stages of PRA:
 - Annex 1 on the initiation stage will combine section 1 of ISPM 2 and section 1 of ISPM 11, modified in line with the reorganization and with text on environmental risk and LMOs moved to the new annexes 4 and 5.
 - Annex 2 will focus on pest risk assessment and will include mainly section 2 of ISPM 11, with text on environmental risk and LMOs moved to the new annexes 4 and 5. The EWG agreed to move the subsection on the probability of transfer to host from the end of the probability of entry section to the section on probability of establishment; this was because, in the glossary definition of "entry", which is complete when a pest enters the area, whereas in ISPM 11, entry is complete when a pest is transferred to another host. The EWG were of the opinion that this move did not constitute a substantial revision.
 - Annex 3 will be mainly drawn from section 3 of ISPM 11, together with text from the draft ISPM on pest risk management. The text will be integrated and modified for consistency.
- [40] The EWG concluded that inclusion of the current ISPM 11 annexes into the core text would make it unbalanced. They also concluded that distributing the supplementary information on environmental risk throughout the new standard, in the same way that it is currently distributed throughout ISPM 11, would not be user-friendly. The EWG had therefore decided to place information on environmental risk, living modified organisms (LMOs), and plants as quarantine pests in three additional annexes: Annex 4, Annex 5 and Annex 6, respectively. Throughout the revision the EWG reviewed all the supplements previously integrated into ISPM 11 and decided on a case-by-case basis whether to retain it, remove it (when repeated elsewhere) or move it into the new annexes 4, 5 or 6.
- [41] **Numbering of ISPMs**. The EWG discussed the place of the new ISPM in relation to the old ones, and suggested that a new ISPM number be allocated to the one drafted at the EWG and to revoke ISPM 2 and 11. However they noted that this decision is up to the Standards Committee.

6.2 Elaboration of the text of the draft reorganization and revision of PRA standards

[42] The EWG decided to review the text prepared by the Steward merging the relevant parts of ISPM 2, 11 and the draft ISPM on Pest risk management.

[43] The EWG started by developing the core text of the new standard including mostly the generic information from ISPM 2 and some parts of ISPM 11 that are considered applicable across all stages of the PRA.

Scope

- [44] The EWG discussed how to merge the two scopes, and decided to revise the scope and discussed how to highlight risk communication as particularly important throughout the whole process. They also considered whether to use the term "quarantine pests" or "organisms". The EWG preferred to use "organism" to indicate that PRA could be conducted on any organism, even before it has been determined to be a pest, noting that it is also included in the definition of PRA in ISPM 5, however, ultimately they reworded the scope and did not mention organism nor pest.
- [45] Where does the PRA process end? The scope contains a brief description of the PRA process reflected in a flowchart and the EWG discussed that although not part of the pest risk management stage, monitoring and re-evaluation of options is an important step, and in practice it is part of the NPPO tasks to follow how the management option selected performs.
- [46] **Explanation of the revision.** The EWG discussed that explanation on the purpose of the revision is not needed in the text, but is better suited to the "Adoption" section. It was also clarified that the publication history usually provides a description of the changes made throughout the life of the standard. They suggested to include something along these lines based on Specification 72: The purpose of the reorganization and revision was to streamline and align the concepts of ISPM 2 and ISPM 11. It brought greater consistency to the different stages of the PRA process initiation, pest risk assessment and pest risk management– and clarified the relationship between the pest risk identified through pest risk assessment and the strength of the corresponding options for phytosanitary measures identified through pest risk management. Redundant and repetitive text was removed but the substantive guidance remained.
- [47] **Supplements.** The earlier version of the scope mentioned the supplements, but as the EWG decided to either move to annexes or incorporate the text of supplements, they deleted separate mention of supplements from the scope.

Impacts on biodiversity and the environment

[48] The EWG revised the section to reflect that conducting PRA should consider the risk to the environment and management options should be selected accordingly.

Outline of requirements

- [49] The EWG noted that this section should contain the brief list of requirements for NPPOs, and revised the text accordingly.
- [50] **Consequences.** The EWG agreed that consequences to be considered include environmental, economic, social etc. consequences, and economic consequences don't need to be mentioned specifically.
- [51] **Outline**. The relevant section of the PRM draft was also included into the outline of requirements section of the new standard to explain that the selection of appropriate measures is included in the standard as well as this is a new addition.

Background

[52] **Background information on IPPC provisions**. Most of the background section includes the text from ISPM 2, however the EWG decided that streamlining was needed and removed some sections. The concepts from the PRM draft were also included in the background.

Requirements

[53] **Structure**. The EWG discussed the structure of the core text and agreed on the following: first to explain the generic concept, and the framework of the PRA. Then the core text goes on to describe

aspects common to all PRA stages: Uncertainty, information gathering, documentation, risk communication, consistency, and the avoidance of undue delay. Additionally the EWG decided to add another section on the scope of PRAs and include brief summaries of the concepts around environmental risks, living modified organisms (LMOs), and plants as pests, referring to the appropriate annex, where each of these concepts are described at length.

- [54] **Plants as pests.** The EWG decided to remove the text related to plants as pests coming from ISPM 2 as the annex coming from ISPM 11 gives more details, and it would have been redundant to repeat.
- [55] **LMOs**. The EWG decided to combine the 2 Annexes of ISPM 11 addressing LMOs. The title of the new annex that incorporates both of these will be simplified to "LMOs as pests".
- [56] **Organism vs Pest**. The EWG decided that in general it is better to use organism, as it may turn out to be pest or not (e.g. in case of biological control agents).
- [57] **Types of pests**. The EWG added a chapeau section under the section "Scope of PRA", to explain that LMOs, and plants as pests may also be covered.
- [58] **Flowchart.** The EWG agreed that the flowchart from ISPM 11 should be revised, and it should not be prescriptive, therefore to move it into an Appendix.
 - The EWG decided to express with direct arrows for all stages that information gathering, uncertainty, documentation, consistency and risk communication, and avoiding undue delay is important and crosscutting issues across all steps, and communication is needed throughout the process even if it is stopped at one point.
 - They agreed to include monitoring into the flowchart, although it was agreed that it is technically not part of the PRA process. The EWG discussed that monitoring of management measures are important after the completion of the PRA and the results of the monitoring may result in a reevaluation of the management options, and that emergent threats could also be monitored and that would trigger a review of the completed PRA.
 - They also included the steps of the 3 stages of the process on the flowchart
 - The EWG noted that mentioning both pest and organism (as possible initiation points) would allow to evaluate for example a biological control agent that may or may not be determined to be a pest. They also noted that the arrow on the top is reflecting that it is possible to move between the stages back and forth.

Annex 1: Initiation

- [59] Sections of ISPM 2 and 11 were merged in this Annex, retaining all concepts and streamlining the text to remove repetition.
- [60] **Supplements on LMOs (S2)**. As agreed earlier, the EWG reviewed the supplement sections from ISPM 11 to be moved to annex 5 unless retaining it was needed in the text. The previously titled section "1.1.2 Identification of a pest PRA initiated by the identification of a pest" was kept as part of the Initiation stage and was modified, creating a new section called "PRA initiated by the identification of a pest" that includes the concept that a PRA may be initiated when "an organism is genetically altered in a way which clearly identifies its potential as a plant pest (LMO).
- [61] **Supplements.** Supplements on the environmental impacts (S1) and the section addressing plants for planting were also moved to annex 4 and 6 respectively.
- [62] **Initiation of a new or revised PRA**. One member pointed out that in ISPM 11 the lists of initation points are exclusive, whereas in ISPM 2 it is just examples "such as": The EWG agreed to use the less restrictive version, from ISPM 2.
- [63] **PRA initiated by the identification of a pest.** ISPM 11 talks about emergency in section "1.1.2 PRA initiated by the identification of a pest", whereas ISPM 2 only mentions other scenarios. The EWG decided to merge and remove repetitions.

- [64] **Review of phytosanitary policies**. The EWG compiled the points from ISPM 2 and 11.
- [65] **Dispute.** The EWG discussed that a dispute could initiate the PRA process, potentially on a national level too. The word "international" was removed to make it more general.
- [66] **Determination of an organism as a pest**. The EWG revised the section, including the explanation from the previous supplement 1 from ISPM 11 on what constitutes a pest according to the IPPC. The EWG included reference to the new annexes 5 and 6 in this section on plants as pests and LMOs.
- [67] **Biocontrol agents**. One member suggested that ISPM 3 (Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms) be referenced in the revised ISPM on PRA, as PRA for biological control agents require specific considerations.
- [68] Section on LMO and plants as pests from ISPM 2. Both of these sections were moved to the respective annexes.
- [69] **Defining PRA area**. The EWG decide to keep the ISPM 2 version of the text relating to defining the PRA area, as it is less restrictive.
- [70] **Information gathering in stage 1**. The section from ISPM 11 is specific to the initiation stage, so the WG decided to include it here, noting that the core text includes generic information on information gathering.
- [71] **Time horizon**. One EWG members proposed to consider the time frame that the PRA is relevant for. Although that is not currently part of the requirements, and it is beyond the scope of this revision, it was recommended to consider at the next revision to include this concept, as it would facilitate the inclusion of climate change issues to be considered as part of the PRA process and the potential changes (e.g. likelihood of floods or the frequency of rainin the next 10 years in PRA area). They also suggested that implementation material supporting this standard could address this issue.

Annex 2: Assessment

- [72] Most of the assessment stage is identical to the original description in ISPM 11. It was modified only to move the supplemental information on LMOs, plants as pests and the environmental impacts to the respective Annexes, and some further modifications are described below.
- [73] **Definition of terms.** The EWG suggested a new approach to marking up the terms defined in ISPM 5: they suggested to possibly bolden the text in ISPMs where an ISPM 5 definition exists, and hyperlink it to the definition, where a pop-up window would appear when hovering over the text with the definition).
- [74] The EWG decided to include the ISPM 5 definition for quarantine pest in the core text.
- **Probability of transfer to a suitable host.** The EWG decided to move the whole subsection from the "Probability of entry of a pest" to the "Probability of establishment" section, because part of establishment is to have a suitable host and the original place under entry is not in line with the ISPM 5 definition of entry, as entry (of a pest) does not include transfer to a suitable host. The ISPM 5 definition defines entry (of a pest) as "Movement of a pest into an area where it is not yet present, or present but not widely distributed and being officially controlled". This captures the concept of the proposed topic described in Specification 68 on the Likelihood of establishment, which was removed from the LOT with the justification that this EWG might address it. The EWG considered that this change increases the logical flow of the process and increases consistency across ISPMs.
- [76] **Probability of establishment**. The EWG aligned the bullet points to the subheadings of the section.
- [77] **Probability of spread after establishment**. Supplemental text regarding the potential delayed effects of some pests was kept as part of the section, as it was felt that the information is valuable and is not only related to plants as pests.

- [78] **Conclusion regarding endangered areas**. The subsection was incorporated into the section on "Conclusion on the probability of introduction and spread", and the EWG inserted the word "help" before "define endangered area" to indicate that other factors may also define endangered areas.
- [79] Assessment of potential economic consequences. The EWG proposed to remove the wording "economic" as in instances before, to consider that the consequences should include environmental, and social consequences as well. The third step of the assessment stage was modified to not specifically mention the economic impact, as environmental and social impacts should also be considered. A new chapeau section was drafted under the revised titled "Assessment of potential consequences" to clearly spell this out using the wording of "4.1 Types of economic effect" from Supplement 2 of ISPM 5 as a basis.
- [80] However, the EWG discussed that there are 3 techniques described later in the subsections that are used by economists, and thus the section cannot be completely generalized. They included reference to the supplement 2 to ISPM 5 and placed subsections on economic and non-economic consequences (which are already included in the current ISPM 11 section 2.3.2.4 Non-commercial and environmental consequences) into the section.
- [81] The EWG noted that a complete assessment of potential consequences of pest introduction is a difficult aspect of PRA in practice as well, and it is hard to assess these impacts that are not easily quantifiable (as opposed to economic consequences).
- [82] The EWG recommended that the concept in Supplement 2 of ISPM 5 on economic impact of a pest and how it applies to conducting PRA should be included and expanded on in a future implementation material produced to support the implementation of this standard, and to express more clearly that PRA should consider more than just the economic (monetary) consequences of the introduction of a pest.
- **[83]** Non-commercial and environmental consequences. A new subsection was created under the assessment section, after the new subsection on economic consequences, to include Non-commercial and environmental consequences. Part of the text was moved up from the following section on analysis of consequences and was revised slightly. As examples for social effects, the employment a tourism was removed and replaced by "mental wellbeing, spiritual, religious and cultural connections" as they are defined as such in the concept of ecosystem services. "Amenity value" was removed as the previous modification covers it.
- [84] **Pest effects.** Supplement 1 on environmental impacts was kept in the text instead of moving it to the annex 4 on environment as with other S1 sections, however moved to the section on "non-commercial consequences".
- [85] **Time and place factors**. The EWG included the word "could" to express that this is a hypothetical situation, when the analyst considers the worst case scenario.
- [86] **Analysis of commercial consequences**. "Where possible" was included to indicate that commercial consequences may not always be possible to identify.
- [87] **Conclusion of the assessment of economic consequences**. "Uncertainty" was included in the list of things to specify when defining the conclusion.
- [88] Endangered area. The EWG decided to rename the subsection from "Endangered area", to "identifying endangered area" to better reflect the contents.
- [89] **Conclusion of the pest risk assessment stage**. The EWG added "and spread" to "probability of introduction and spread" in line with earlier decision.

Pest risk management

[90] The EWG started by compiling the draft ISPM on PRM and the relevant sections of ISPM 11 and worked on the compiled version in session, removing repetitions. The EWG also reviewed the sections

of the draft ISPM on PRM that were included when this was going to be a standalone ISPM, giving context and repeating other sections of the ISPM 11 and removed those.

- [91] **Background and outline of requirements of the draft ISPM on PRM**. The EWG felt that these sections are superfluous, and removed most of it. They added some text to the Background section of the core text to reflect the new content coming from the draft on PRM.
- [92] **Measures vs options**. The EWG discussed the use of the terms "measures" and "options" and agreed with the explanation (in line with earlier SC discussions) that the measures are called management options until the selection happens when they become phytosanitary measures. This is also spelled out at the beginning of the Introduction section.
- [93] Acceptable level of risk. The EWG noted that at the end of the assessment stage, the decision whether the risk is acceptable needs to be made, and it is not specified in the ISPM who makes that decision. In some countries it is the risk manager in some countries it is the risk assessor. The EWG agreed to keep the text generic, to allow flexibility for countries to assign roles as they see fit.
- [94] **Introduction** *and spread*. The EWG discussed that in general the pest risk management focuses on prevention of introduction, but the prevention of spread is also important and is included in the definition of "pest risk (for quarantine pests)" according to ISPM 5.
- [95] **Matrix**. The draft on PRM included the matrix on determining the strength of measures as Appendix 1. The EWG agreed that this is better suited in an implementation guide and possibly further work on it might be necessary.
- [96] **Risk vs hazard based measures**. Hazard is a risk term not generally used by IPPC. This section appears to come from FAO Biosecurity toolkit, and probably from animal health and/ or food & feed safety. The EWG decide to delete this section, as it is unclear and not necessary.
- [97] **Arrival window.** One member considered that this bullet point should be removed from the list under the pest free concept section, as it describes an option where the pest is present but will not be able to survive (e.g. winter). New section was created called "Timing of imports" to include this concept.
- [98] **Evaluation of measures**. The EWG decided to remove the reference to cost effectiveness (used to be one of the principles from ISPM 1 highlighted in ISPM 11), as part of their concept of moving away from considering only economic consequences.
- [99] **Probit.** The EWG decided to add a footnote with explanation, to ensure common understanding on what probit analysis is: Probit analysis is a statistical method used to calculate a dose-response relationship and is commonly used in plant health and quarantine to derive the appropriate dose for a specific degree of mortality.
- [100] **Prohibition.** The EWG considered to reestablish this section from ISPM 11 into the draft on PRM and explain that if there are no suitable management options, prohibition would be a last resort. The EWG members had diverging opinions on whether prohibition was a phytosanitary measure or not. Ultimately the EWG moved all prohibition related information into one section.
- [101] **Documentation and communication.** The EWG agreed to keep the documentation and communication section in the annex, even though there is a section in the core text as well, as it provides information on documentation and communication that is specific to pest risk management.
- [102] **Regulated area**. The EWG discussed that in Stage 2, the endangered area is identified, and reference is made to Stage 3, however there is no further elaboration in stage 3 about this. They included a short mention of regulated area into the Conclusion section of the PRM stage. The regulated area may, however, be designated as wider than the endangered area if technically justified and not in conflict with the principle of non-discrimination.

- [103] **Phytosanitary certificates**. The EWG discussed whether to place the section on phytosanitary certificates under documentation or monitoring or as a standalone section, and agreed that it should be a standalone section as it was in the PRM draft.
- [104] Additional annexes. The EWG reviewed all text relevant to environmental impacts, LMOs and plants as pests throughout the draft, moved the text bits that were not kept as part of the description of the PRA process into the relevant annexes. The collated text was reviewed and revised slightly for clarity.

Potential implementation issues

- [105] The EWG suggested the following implementation issues to be considered by the SC:
 - in a future implementation material to highlight that PRA should consider more than just the economic (monetary) consequences of the introduction of a pest, including in the definition of endangered area., in line with the concept in Supplement 2 of ISPM 5 and
 - in a future implementation material to consider the time frame that the PRA is relevant for, as it facilitates the inclusion of the impact of climate change to be considered in PRA.
 - to consider the matrix on the strength of measures as part of the implementation material. The EWG agreed that this is better suited in an implementation guide and possibly further work on it might be necessary. The 2 paragraphs describing the matrix should also be moved to a guidance document.
 - the risk communication part of annex 6 (plants as pests) should be reviewed if repeated in the risk communication guide, if not, it is recommended to be included.
 - The various exit points (places to stop the PRA process) should be described in detail in implementation guidance. For example, if it was unlikely for a pest to transfer to the host, it was justified to stop the PRA.

[106] The EWG:

(1) *invited* the SC to consider the revision and reorganization of PRA standards.

7. Any other business

[107] There was no other business.

8. Close of the meeting

- [108] The chairperson thanked the EWG members for all their hard work, the steward and assistant steward for their guidance, and the secretariat for their support.
- [109] The steward and the secretariat thanked the chairperson for his skilful chairing of the meeting.
- [110] The Secretariat thanked the participants and the host and invited the participants to provide their feedback via an online survey after the meeting.
- [111] The participants expressed their appreciation to the excellent hosting of the meeting by the Italian NPPO and the chairperson closed the meeting.

Appendix 1: Agenda

	Agenda Item	Document No.	Presenter
1.	Opening of the Meeting		
1.1	Welcome by the IPPC Secretariat		Avetik NERSISYAN (virtually)
	Welcome by the host: - Lombardy Region Councilor for Agriculture, food and green systems	_	Fabio ROLFI
	 Deputy Director and Head of the Phytosanitary Service 		Andrea AZZONI
	Introductions		
1.2	Presentation of the standard setting process Roles of the Participants	05_EWG_PRA_2022_Nov	IPPC Secretariat
2.	Meeting Arrangements	-	
2.1	Selection of the Chairperson	_	IPPC Secretariat
2.2	Selection of the Rapporteur	-	Chairperson
2.3	Adoption of the Agenda	01_EWG_PRA_2022_Nov	Chairperson
3.	Administrative Matters	-	
3.1	Documents list	02_EWG_PRA_2022_Nov	IPPC Secretariat
3.2	Participants list	03_EWG_PRA_2022_Nov	IPPC Secretariat
3.3	Local information	04_EWG_PRA_2022_Nov	Local host
4.	Review of Specification		SAI (Steward)
4.1	Review of Specification and considerations for the reorganization and revision of PRA standards	<u>Specification 72 -</u> <u>Reorganization and revision</u> <u>of pest risk analysis</u> <u>standards</u>	SAI
	- Discussion paper	14_EWG_PRA_2022_Nov	
5.	Review of discussion papers	-	Chairperson
5.1	Discussion paper: reorganization and revision of pest risk analysis standards (Prepared by Gritta Schrader, Dirk Jan van der Gaag, Alan MacLeod, with comments of the EPPO PRA team)	06_EWG_PRA_2022_Nov	SCHRADER, VAN DER GAAG, MACLEOD
5.2	Discussion paper on reorganization and revision of pest risk analysis standards (Prepared by Jeya Jeyasingham)	07_EWG_PRA_2022_Nov	JEYASINGHAM
5.3	Discussion paper on specification 72 (Prepared by Tiago Lohmann)	08_EWG_PRA_2022_Nov	LOHMANN
5.4	Discussion paper on reorganization and revision of pest risk analysis standards (2020-001) (Prepared by Leah Millar)	09_EWG_PRA_2022_Nov	MILLAR
5.5	Pest risk analysis in South Africa Integration of the sections of ISPM 2 and ISPM 11 that are relevant to the three stages of pest	SPM 2 and ISPM 10_EWG_PRA_2022_Nov Se stages of pest	
	risk analysis (Prepared by PP Tshikhudo)	16_EWG_PRA_2022_Nov	

	Agenda Item	Document No.	Presenter
5.6	Comments on the draft PRM (Prepared by Ying Huang)	11_EWG_PRA_2022_Nov	HUANG
5.7	Discussion paper from CABI on the Reorganization and revision of pest risk analysis (PRA) standards	12_EWG_PRA_2022_Nov	All
5.8	TPG proposal on consistency of the use of the terms in ISPMs and recommendation of the EWG on the revision of ISPM 2	13_EWG_PRA_2022_Nov	IPPC Secretariat
5.9	The Vision of the Pest Risk Analysis Standard (Prepared by La-Tanya Richards, Plant Quarantine/Produce Inspection Branch, Jamaica)		RICHARDS
5.10	Intervention from New Zealand		HARMAN
6.	Development of the Reorganization and revision of pest risk analysis standards (2020-001) Reference documents: - IPPC Style Guide and annotated templates (particularly Part 1, sections 2, 3 and 5) Link to the IPPC Style Guide - ISPM 5 (Glossary of phytosanitary terms) Link to ISPM 5 - Guidelines for a consistent ISPM terminology (Section 3.3.2 of the IPPC Procedure Manual for Standard Setting) Link to the IPPC Procedure Manual for Standard Setting		Chairperson
6.1	Brainstorming session to draft the reorganization and revision of PRA standards	ISPM 2 - Framework for pest risk analysis ISPM 11 - Pest risk analysis for quarantine pests	Chairperson / All
	- Draft ISPM on pest risk management	2014-001	WILSON
6.2	Elaboration of the text of the draft reorganization and revision of PRA standards	Link to the Annotated template for draft ISPMs	All
7.	Any Other Business	-	Chairperson
8.	Close of the Meeting	-	IPPC Secretariat / Chairperson

Appendix 2: Documents list

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE	DATE POSTED / DISTRIBUTED
01_EWG_PRA_2022_Nov	2.3	Provisional Agenda (2022-11-02)	17 Oct 2022 02 Nov 2022
03_EWG_PRA_2022_Nov	3.2	Participants List	25 Oct 2022
04_EWG_PRA_2022	3.3	Local information document: Milan, Italy	06 Oct 2022
05_EWG_PRA_2022_Nov	1.2	Presentation of the standard setting process	17 Oct 2022
06_EWG_PRA_2022_Nov	5.1	Discussion paper: reorganization and revision of pest risk analysis standards (Prepared by Gritta Schrader, Dirk Jan van der Gaag, Alan MacLeod, with comments of the EPPO PRA team)	17 Oct 2022
07_EWG_PRA_2022_Nov	5.2	Discussion paper on reorganization and revision of pest risk analysis standards (Prepared by Jeya Jeyasingham)	17 Oct 2022
08_EWG_PRA_2022_Nov	5.3	Discussion paper on specification 72 (Prepared by Tiago Lohmann)	17 Oct 2022
09_EWG_PRA_2022_Nov	5.4	Discussion paper on reorganization and revision of pest risk analysis standards (2020-001) (Prepared by Leah Millar)	17 Oct 2022
10_EWG_PRA_2022_Nov	5.5	Pest risk analysis in South Africa (Prepared by PP Tshikhudo)	17 Oct 2022
11_EWG_PRA_2022_Nov	5.6	Comments on the draft PRM (Prepared by Ying Huang)	17 Oct 2022
12_EWG_PRA_2022_Nov	5.7	Discussion paper from CABI on the Reorganization and revision of pest risk analysis (PRA) standards	17 Oct 2022
13_EWG_PRA_2022_Nov	5.8	TPG proposal on consistency of the use of the terms in ISPMs and recommendation of the EWG on the revision of ISPM 2	17 Oct 2022
14_EWG_PRA_2022_Nov	4.1	Discussion paper: Review of Specification and considerations for the reorganization and revision of PRA standards	17 Oct 2022
15_EWG_PRA_2022_Nov	5.9	The Vision of the Pest Risk Analysis Standard (Prepared by La-Tanya Richards, Plant Quarantine/Produce Inspection Branch, Jamaica)	02 Nov 2022
16_EWG_PRA_2022_Nov	5.5	Integration of the sections of ISPM 2 and ISPM 11 that are relevant to the three stages of pest risk analysis (Prepared by PP Tshikhudo)	03 Nov 2022
2014-001	6.1	Draft ISPM on Pest risk management	17 Aug 2022
Other documents / links			

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE	DATE POSTED / DISTRIBUTED
Specification 72 - Reorganization and revision of pest risk analysis standards	4.1	Specification 72 - Reorganization and revision of pest risk analysis standards	
Link to the IPPC Style Guide	6	IPPC Style Guide and annotated templates (particularly Part 1, sections 2, 3 and 5)	
Link to ISPM 5	6	ISPM 5 (Glossary of phytosanitary terms)	
Link to the IPPC Procedure Manual for Standard Setting (2020- 2021)	6	Guidelines for a consistent ISPM terminology (Section 3.3.2 of the IPPC Procedure Manual for Standard Setting)	
ISPM 2 - Framework for pest risk analysis	6.1	Brainstorming session to develop the outline of the ISPM	
ISPM 11 - Pest risk analysis for quarantine pests	6.1	Brainstorming session to develop the outline of the ISPM	
Link to the Annotated template for draft ISPMs	6.2	Elaboration of the text of the draft Annex to ISPM 37	

Appendix 3: Participants list

A check (\checkmark) in column 1 indicates in person attendance at the meeting, V indicates virtual participation, P indicates participation only at the virtual pre-meeting.

	Participant role	Name, mailing address, telephone	Email address
~	Steward	Mr Masahiro SAI Senior Researcher (Head of Section) Planning and Coordination Section, Research Division Yokohama Plant Protection Station Ministry of Agriculture, Forestry and Fisheries (MAFF) JAPAN Tel: +81-45-211-7165	masahiro_sai670@maff.go.jp;
~	Assistant Steward	Ms Joanne WILSON Principal Adviser, Risk Management Plant Imports Group Ministry for Primary Industries. NEW ZEALAND Tel: +64 489 40528 Mob: +64 2989 40528	joanne.wilson@mpi.govt.nz;
	Assistant Steward	Mr Hernando Morera GONZÁLEZ Pest Risk Analyst Servicio Fitosanitario del Estado 300 Sur de Teletica, Sabana Sur, San José, COSTA RICA Tel: +(506) 8660-8383	hmorera@sfe.go.cr;
v	Member	Ms Ying Huang Associate professor Chinese Academy of Inspection and Quarantine Ronghuananlu 11, Yizhuang, Beijing 100176, CHINA 13693200940@139.com +8613693200940	<u>13693200940@139.com;</u>
Р	Member	Ms Gritta Schrader Senior Scientist Julius Kuehn Institute, Institute for National and International Plant Health JKI, Institute for National and International Plant Health, Messeweg 11-12, 38102 Braunschweig, GERMANY +495312997565	gritta.schrader@julius-kuehn.de;
~	Member	Ms Leah Cantey Millar Risk Analyst (Entomologist) United States Department of Agriculture (USDA), Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ), Science and Technology, Plant Pest Risk Analysis 920 Main Campus Drive, Suite 400, Raleigh, NC 27606 USA +19198557522	<u>Leah.c.millar@usda.gov;</u>

	Participant role	Name, mailing address, telephone	Email address
~	Member	Mr Jeya Kanapathi Jeyasingham Assistant Director Department of Agriculture, Water and the Environment GPO Box 558 Canberra ACT 2601 AUSTRALIA +61411106944	jeya.jeyasingham@awe.gov.au;
~	Member	Mr Alan MacLeod Pest risk analyst Department for environment, food and rural affairs Defra, Sand Hutton, York, North Yorkshire, YO41 1LZ, UNITED KINGDOM +4407387055880	alan.macleod@defra.gov.uk;
V	Member	Ms La-Tanya Suzane Richards Manager, Pest Risk Analyst Ministry of Agriculture and Fisheries - Plant Quarantine/Produce Inspection Branch 193 Old Hope Road, Kingston 9, JAMAICA +18763492994	latanya.richards@moa.gov.jm
~	Member	Mr Tiago Rodrigo Lohmann Chief of Plant Quarantine Division Department of Plant Health and Agricultural Inputs Ministry of Agriculture, Livestock and Food Supply Esplanada dos Ministérios, Bloco D, Anexo B, 3º Andar Brasília – DF – Brasil.70.043- 900 BRASIL +5561982456896	tiago.lohmann@agro.gov.br;
V	Member	Ms Helen Mary Harman Specialist Adviser Plant Import Risk Analysis Ministry for Primary Industries, New Zealand Ministry for Primary Industries, P O Box 2526, Wellington 6140, NEW ZEALAND +642102207975	Helen.Harman@mpi.govt.nz;
~	Member	Mr Phumudzo Patrick Tshikhudo Scientist Production Grade B Department of Agriculture, Land Reform and Rural Development Private Bag X14, Gezina, Pretoria, 0031, SOUTH AFRICA +27609732875	PhumudzoT@dalrrd.gov.za;
Р	Member	Mr Dirk Jan Van der Gaag Senior advisor plant health Utrecht, the Netherlands Catharijnesingel 59, 3511 GG Utrecht THE NETHERLANDS +31651247096	<u>d.j.vandergaag@nvwa.nl;</u>

	Participant role	Name, mailing address, telephone	Email address
	Invited expert, representing the Implementation and Capacity Development Committee (IC)	Ms Stephanie BLOEM Executive Director North American Plant Protection Organization Secretariat 1730 Varsity Drive, Suite 145, Raleigh, North Carolina 27606 United States of America Tel: + 919 617 4040 / Mobile: + 919 480 4761	stephanie.bloem@nappo.org; tita.bloem@gmail.com;
~	Host representative	Ms Mariangela CIAMPITTI Servizio Fitosanitario DG Agricoltura Regione Lombardia Piazza Città di Lombardia 1 20124 Milano ITALY Tel: +39 3666603272	mariangela_ciampitti@regione.lombardia.it

IPPC Secretariat

	Region / Role	Name, mailing, address, telephone	Email address
 ✓ 	IPPC Secretariat	Ms Janka KISS Standard Setting Associate	Janka.kiss@fao.org;
√	IPPC Secretariat	Ms Erika MANGILI ANDRE Standard Setting Unit Specialist	Erika.MangiliAndre@fao.org;