



REPORT

Standards Committee Working Group (SC-7)

Virtual meeting

16–19 May 2022

IPPC Secretariat

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1. Opening of the meeting

1.1 Welcome by the IPPC secretariat

- [1] The secretariat lead, Avetik NERSISYAN, opened this meeting of the Standards Committee Working Group (SC-7) and welcomed all participants.

2. Meeting arrangements

2.1 Election of the chairperson

- [2] The SC-7 elected Hernando Morera GONZÁLEZ (Costa Rica) as chairperson.

2.2 Election of the rapporteur

- [3] The SC-7 elected Masahiro SAI (Japan) as rapporteur.

2.3 Adoption of the agenda

- [4] The SC-7 adopted the agenda but agreed to address agenda item 4.3 first.

3. Administrative matters

- [5] The documents list (Appendix 2) and the participants list (Appendix 3) had been made available to SC-7 members before the meeting.

4. Draft ISPMs for approval for second consultation

- [6] The SC-7 reviewed the draft ISPMs that had been submitted for first consultation in July–September 2021. The compiled consultation comments for all draft ISPMs are available on the International Phytosanitary Portal (IPP).¹ The draft ISPMs had been modified by the respective stewards and assistant stewards in response to the consultation comments and the modified versions had then been submitted for review by the SC-7 through the Online Comment System (OCS) before this meeting.

4.1 Draft 2021 amendments to ISPM 5 (*Glossary of phytosanitary terms*) (1994-001), priority 1

- [7] The Assistant Steward, Ebbe NORDBO (Denmark), introduced the draft amendments to ISPM 5 and supporting documentation.² He commented that, of the 14 terms and associated definitions under consideration, the Technical Panel for the Glossary (TPG) had recommended changes to seven as a result of consultation comments.
- [8] The SC-7 considered these terms, noting that 13 of them could be considered as “packages” of inter-linked definitions:
- the terms *identity (of a consignment)*, *integrity (of a consignment)* and *phytosanitary security (of a consignment)*;
 - the terms *inspection*, *test*, *compliance procedure (for a consignment)*, *clearance (of a consignment)* and *release (of a consignment)*;
 - the terms *general surveillance*, *specific surveillance* and *surveillance*;
 - the terms *emergency measure* and *provisional measure*.
- [9] **“identity (of a consignment)” (2011-001) (addition).** The assistant steward confirmed that the TPG had made no changes to the proposed term and definition as a result of the consultation comments.

¹ Compiled comments from first consultation are available at: <https://www.ippc.int/en/core-activities/standards-setting/member-consultation-draft-ispms/>

² 1994-001; 1994-001_OCS; 10_SC7_Tel_2022_May; 12_SC7_Tel_2022_May.

- [10] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [11] **“integrity (of a consignment)” (consequential revision) (2021-008) (revision).** The assistant steward explained that one consultation comment had pointed out that seals may be legitimately broken before handling by the national plant protection organization (NPPO). Acknowledging this issue, the TPG had therefore suggested that the wording of the definition be changed from “when its identity is unchanged and any seals or packaging are undamaged” to “when its identity is unchanged, packaging undamaged and any seals intact until broken by the relevant authority”.
- [12] The SC-7 acknowledged the concern raised in the consultation comment but noted that the use of the term “seal” could, in itself, give rise to confusion as there is not a general understanding about its meaning: it would not be clear, for example, whether it was referring to physical seals, electronic seals, or both. They also noted that the term “relevant authority” was ambiguous. They considered whether to omit any reference to seals, leaving the definition as simply “state of a consignment when its identity is unchanged and packaging undamaged”, but recognized that this would not address the concern expressed in the consultation comment. Instead, they noted that the reason for referring to unbroken seals is that this is a sign that the consignment has not been tampered with, and so agreed to change the proposed definition to say this explicitly.
- [13] **“phytosanitary security (of a consignment)” (2013-008) (revision).** The assistant steward confirmed that the TPG had made no changes to the proposed term and definition as a result of the consultation comments.
- [14] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [15] **“inspection” (2017-005) (revision).** The assistant steward confirmed that the TPG had made no changes to the proposed term and definition as a result of the consultation comments.
- [16] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [17] **“test” (2021-005) (revision).** The assistant steward explained that, as a result of a consultation comment, the TPG had suggested that “other than visual” be moved earlier in the definition and be changed to “non-visual” to improve the flow of the definition.
- [18] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [19] **“compliance procedure (for a consignment)” (2021-006) (revision).** The assistant steward explained that, as a result of consultation comments, the TPG had suggested that “check” be changed back to “verify” in “to verify if a consignment complies”, as “verify” implied a decisive outcome, and that the wording related to transit be simplified to clarify the meaning. He explained that “phytosanitary measures related to transit” could be confusing, because it could be interpreted as referring to the measures that a country of transit is entitled to apply within its territory and for which a compliance procedure is irrelevant (which is the main use of “phytosanitary measure” in ISPM 25 (*Consignments in transit*)), whereas it was intended to refer to the measures that the country of transit may require of the exporting country and for which a compliance procedure would be relevant. The TPG had suggested, therefore, that “phytosanitary requirements related to transit” be used, this that was analogous to “phytosanitary import requirements” and may not be as readily confused with the main usage of “phytosanitary measures” in ISPM 25.
- [20] The SC-7 noted that the use of “phytosanitary requirements” rather than “phytosanitary measures” in the definition may also give rise to confusion among contracting parties, given that “phytosanitary measures” is the term used in ISPM 25. They acknowledged, however, the difficulties in finding a suitable wording for the transit situation in the definition of “compliance procedure” and understood the rationale for the TPG’s suggestion. The assistant steward clarified that in the Glossary definition of “consignment in transit”, he understood the term “phytosanitary measure” to be referring to the measures applied within the country of transit, as per the majority use of this term in ISPM 25, although he acknowledged that the text of ISPM 25 is confusing in itself, as it uses “phytosanitary measure” to refer

to both measures that the country of transit applies and those that the country of transit requires the exporting country to apply. He suggested that the terminology used in ISPM 25 should be reviewed when the ISPM is next opened for revision, but that using the most appropriate terminology in the definition of “compliance procedure” was a first step. The SC-7 therefore agreed to use “phytosanitary requirements” and await the comments from the second consultation.

- [21] The assistant steward raised two potential simplifications to the rest of the definition. The first was to delete “and” from the list of activities mentioned to avoid the definition being interpreted as meaning that a compliance procedure had to include all the activities in the list. The second was to delete “of plants, plant products or other regulated articles” in relation to inspection and testing, because the Glossary definitions of inspection and testing include these. The SC-7 agreed to these simplifications.
- [22] **“release (of a consignment)” (2021-007) (revision).** The assistant steward explained that, as a result of consultation comments, the TPG had suggested that “of a consignment” be inserted after “entry” in the definition, because although this may seem redundant given that the qualifier for the term was “of a consignment”, its inclusion would give greater clarity.
- [23] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [24] **“clearance (of a consignment)” (2018-045) (deletion).** The assistant steward explained that no specific comments had been received on the proposed deletion of this term and definition from the glossary, and the usual practice in such situation would therefore be to submit the proposed deletion directly to the Commission on Phytosanitary Measures (CPM) rather than submitting for a second consultation. He suggested, however, that as the term and definition had been processed so far as one element of a larger “package” of related terms and definitions, the text about the proposed deletion could be retained in the draft amendments submitted for consultation but set in grey and with a remark that the proposed deletion was not open for second consultation.
- [25] The SC-7 noted that omitting the term from second consultation would not result in it being submitted to CPM any sooner. They also recognized that contracting parties had not been given advanced notice that the term would not be submitted for second consultation. The SC-7 therefore agreed with the TPG proposal for deletion and agreed to submit the term for second consultation in case there were any comments from contracting parties.
- [26] **“general surveillance” (2018-046) (addition).** The assistant steward explained that, as a result of one consultation comment, the TPG had suggested a slight revision to the proposed definition to allow for the collection of data by parties other than NPPOs.
- [27] One SC-7 member commented that the proposed definition did not appear to tally with the description of general surveillance in the revised ISPM 6 (*Surveillance*) adopted in 2018, as that did not say that general surveillance excluded surveys. The member suggested that the phrase “surveillance may not need to be restricted to a defined period” in section 2.1.1 of ISPM 6 could be interpreted as indicating that general surveillance could include surveys. However, the member acknowledged that no contracting parties had commented on this during the first consultation on this term, so this interpretation of ISPM 6 might not be widely held.
- [28] The SC-7 agreed that the proposed definition did address the main concern that it is the analysis and verification of data that need to be official, rather than the collection of data. They therefore agreed with the TPG’s revised definition and did not make any changes.
- [29] **“specific surveillance” (2018-047) (addition).** The assistant steward confirmed that the TPG had made no changes to the proposed term and definition as a result of the consultation comments.
- [30] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [31] **“surveillance” (2020-009) (revision).** The assistant steward explained that, as a result of a consultation comment, the TPG had suggested that the proposed definition be expanded to give a fuller description

while limiting redundancy and using the same structure as the definitions of the terms “general surveillance” and “specific surveillance”.

- [32] One SC-7 member reported concerns from the member’s region about the loss of “pest presence or absence” from this definition. The assistant steward clarified that if this were to be retained, either directly or by referring to “survey” (as the definition of “survey” referred to pest presence or absence), the definition would also need to mention other reasons for undertaking surveillance, as it would be too restrictive if it just referred to pest presence and absence.
- [33] The SC-7 agreed with the term and definition proposed by the TPG and did not make any changes.
- [34] **“emergency measure” (2020-004) (revision).** The assistant steward explained that, as a result of a consultation comment, the TPG had suggested that the proposed definition be changed to replace “introduced” with “set up” for consistency with the proposed revision of the definition of the term “provisional measure” (the current Glossary definition using “established”, which might sound too permanent). The TPG had also recommended that the qualifier “promptly” be added before “set up” to emphasize the urgency in setting up an emergency measure and for consistency with the definition of “emergency action”.
- [35] The SC-7 considered that “set up” was too informal and that “established” might better convey the importance of an emergency measure. They considered “implemented” as an alternative, but the assistant steward pointed out that ISPMs generally refer to phytosanitary legislation being established first and then implemented, so using implemented here could be confusing as it would imply that the emergency measure had already been established and was now being implemented. The SC-7 recognized that if “established” were to be used, there would be two instances of “established” or “establishment” in the definition, each with a different meaning: the first referring to setting up the emergency measure and the second referring to perpetuation of a pest. The SC-7 considered whether the Glossary term “introduction” could replace reference to entry and establishment in the definition to avoid this situation, but the assistant steward recalled that the definition needed to refer to entry and establishment separately, as the emergency measure might only apply to one of these. The SC-7 noted, however, that even if the definition did contain both “established” and “establishment”, the latter would be distinguished from the former by being in bold, because it was a Glossary term.
- [36] The SC-7 considered how the various possible terms would be translated into other languages and noted that neither “set up”, “established” nor “implemented” would present a problem in Spanish.
- [37] On the basis of their discussion, the SC-7 agreed to modify the proposed definition to use “established” rather than “set up”, but otherwise agreed with the rest of the definition.
- [38] **“provisional measure” (2020-008) (revision).** The assistant steward confirmed that the TPG had made no changes to the proposed term and definition as a result of the consultation comments.
- [39] The SC-7 agreed to change “set up” to “established” for consistency with the definition they had agreed for “emergency measure”.
- [40] One SC-7 member referred to the phrase “an emergency measure may or may not be a provisional measure” in the proposed definition of “emergency measure”, and sought clarity on the types of situations in which an emergency measure would not be a provisional measure. The assistant steward explained that an emergency measure would be a provisional measure if there was no technical justification for it, but would not be a provisional measure if there was technical justification (for instance if technical justification existed but an emergency measure was required because legislation could not be changed quickly enough). He added that, in almost all cases, provisional measures are a subset of emergency measures, although in theory there could be a provisional measure without an emergency.

- [41] The SC-7 noted that guidance about the use of the terms “emergency measure” and “provisional measure” was already included in Note 10 of the *Explanatory document on ISPM 5* (the Annotated Glossary), but this would be updated once the 2021 amendments to ISPM 5 have been adopted.
- [42] The SC-7 noted that one of the problems with the implementation of emergency and provisional measures is that they may continue in force long after they should, despite the obligations set out in the IPPC and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) for contracting parties to review such measures as soon as possible or within a reasonable period of time. However, the assistant steward pointed out that this sort of question needed to be addressed in a standard rather than in a definition.
- [43] On another point, the assistant steward explained that the secretariat had suggested that “owing to” be changed to “because of” in the proposed definition to conform with the new FAO style. The SC-7 agreed.
- [44] **“germplasm” (2020-005) (revision).** The assistant steward confirmed that the TPG had made no changes to the proposed term and definition as a result of the consultation comments. One consultation comment had suggested deletion of the term altogether, because it is seldom used in ISPMs. However, the TPG had recommended that it be retained with the proposed revised definition, because the revision – which made it clear that germplasm was a subset of “plants for planting” – made the term relevant and specific to the IPPC context, where “plants for planting” is a core term in several ISPMs and are perceived to pose a higher pest risk than other plants.
- [45] The SC-7 noted that the term “germplasm” is generally used to refer to plant genetic resources. One SC-7 member commented, however, that germplasm was not necessarily plants for planting, as the definition of the latter was “plants, intended to remain planted, to be planted or replanted” but germplasm could include plant cells grown in tissue culture intended for purposes other than planting (e.g. for conservation in a seed bank). Another SC-7 member recalled that the definition of “plant” does include germplasm and so wondered whether a circular argument was being created. The assistant steward replied that having germplasm as a subset of plants for planting, which in turn is a subset of plants, did not affect the relationship between “germplasm” and “plants” but suggested that, if the proposed definition was going to cause confusion, then it would be better to delete the term altogether from the Glossary, as the current definition was not specific to the IPPC at all. Given the potential for confusion with the proposed definition and the limited use of the term “germplasm” in ISPMs, the SC-7 therefore agreed to recommend that the term be deleted from the Glossary rather than revised. They agreed that this proposal should go forward as part of the second consultation on the 2021 draft amendments rather than withdrawing it and submitting for first consultation as part of the 2022 draft amendments.
- [46] The SC-7:
- (1) *approved* the draft 2021 amendments to ISPM 5 (Glossary of phytosanitary terms) (1994-001) as modified at this meeting for submission to second consultation (Appendix 4).

4.2 Draft annex to ISPM 20 (*Guidelines for a phytosanitary import regulatory system*): Use of specific import authorizations (2008-006), priority 4

- [47] The Steward, Ezequiel FERRO (Argentina), introduced the draft annex and supporting documentation.³ He highlighted two general comments that had been made during the consultation for the SC-7 to consider and proposed that the SC-7 consider the more specific comments at the appropriate points during their review of the text.
- [48] **Range of application of specific import authorizations.** The steward explained that one consultation comment had sought clarification on the range of application of specific import authorizations (SIAs) for phytosanitary purposes, saying that otherwise the ISPM would result in guaranteeing “import restrictions”. The comment had also referred to the need to “further research and organize the cases of

³ 2008-006; 2008-006_OCS; 11_SC7_Tel_2022_May; 09_SC7_Tel_2022_May; 14_SC7_Tel_2022_May.

each country and carefully consider them, including revision of the contents of section 4.2.2 ... of ISPM 20". The steward commented that the purpose of the annex was to provide further guidance than the current text of ISPM 20: recognizing that the purpose for which countries implement an SIA may be different, the draft annex expanded the range of examples provided for the use of SIAs. The steward added that rather than SIAs becoming an "import restriction" under the current text of this draft, the draft was intended to harmonize the use of SIAs, minimizing any discretion that can happen when countries implement an SIA with no standards in place. The SC-7 made no further comment on this issue.

[49] **General import authorizations.** The steward explained that one consultation comment had expressed concern that the draft annex seemed to be proposing a "second way for the establishment of phytosanitary requirements" as it lacked requirements on the process for requesting, evaluating and establishing SIAs, including how to provide technical justification for SIAs, which could allow importers to submit import requests as exceptional situations merely to expedite their requests. As such, this would run counter to the operating principles of the IPPC, including the pest risk analysis framework. The comment called for this issue to be addressed or, if not, for the annex not to be progressed further.

[50] The steward explained to the SC-7 that, according to his understanding of how SIAs operate, SIAs should not require technical justification (in contrast to phytosanitary import requirements, which do) and that the processes for requesting, evaluating and establishing SIAs are domestic procedures and may differ between countries, making harmonization very difficult. He added that SIAs should be just an administrative communication tool and not a replacement or a justification for changing phytosanitary requirements, so they should not result in an alternative mechanism by which importers bypass the regular process relating to phytosanitary import requirements.

[51] The SC-7 considered the issue. They noted that many countries use import permits, which are a form of SIA, and this would continue regardless of the annex, but the annex aimed to harmonize the use of such SIAs by clarifying what was already in place through ISPM 20. By providing more guidance on what an SIA should contain, the annex should also help improve transparency. Regardless of these benefits, however, the SC-7 recognized that countries had the sovereign right to choose not to use the annex. With this in mind, the SC-7 agreed that the development of the annex should continue but noted that it would not be possible to provide a framework for the establishment of requirements that are not subject to technical justification or being least trade restrictive, and so could not develop the annex along the lines proposed in the consultation comment.

[52] The SC-7 considered the other issues raised as they reviewed the text of the draft annex.

Review of the draft annex and outstanding issues

[53] **Introductory text.** The SC-7 agreed that although it should be clear from the wording of the draft annex and of ISPM 20 itself that the use of SIAs was optional, it would be a good idea to be explicit about this from the outset. They therefore added some text to this effect at the start of the annex to make it clear that it was not a requirement for countries to use SIAs.

[54] **Minimum information requirements: treatment provider.** The steward explained that one consultation comment had suggested that a new bullet point for "treatment provider registration number" be added to the list of the minimum information that should be included in SIAs, to allow consignments to be tracked. The steward expressed his view that this was too specific, as not all NPPOs may use registration numbers for treatment providers, and it was not appropriate as a requirement for the importing country, who issue the SIA, as tracking is the responsibility of the exporting country not the importing country. The SC-7 discussed the issue. They noted that the consultation comment related to those situations where an importing country requires consignments to be treated by a treatment facility that has been approved by the importing country (or sometimes by the exporting country), but that in these situations it may be helpful to both the importing country and the exporting country if the requirements regarding treatment providers are specified on the SIA: this provides assurance to the importing country and avoids the exporting country inadvertently using a non-approved treatment

provider. The SC-7 therefore agreed to add a bullet point for “treatment provider” to the list, but avoided “details of any treatment provider” as it would not be clear to which details this referred.

[55] **Minimum information requirements: issuing officer.** The SC-7 considered a consultation comment suggesting that the name of the issuing official be included under the list of minimum information required on an SIA, rather than the list of optional additional information, to ensure that there is a contact point to verify the SIA if needed. The SC-7 noted that in some cases validation may be by electronic means (e.g. by a quick-response (QR) code) rather than by an NPPO officer, so agreed to leave “issuing officer” in the list of additional information rather than the list of minimum information. However, recognizing the importance of having valid contact details, they agreed to insert “contact information for verification purposes” in the first bullet point of the list.

[56] **Minimum information requirements: phytosanitary import requirements.** The SC-7 acknowledged that including “phytosanitary import requirements” in the list of minimum information could be confusing, as it might prompt the question of why an SIA would be needed if phytosanitary import requirements were already in place. The SC-7 noted that this item referred to the phytosanitary actions (e.g. treatments) that needed to be conducted by the exporting country in those situations where an SIA was required even though phytosanitary import requirements existed. They referred to the opening sentence of the draft annex, which described three cases of when SIAs may be used: when official consent for import is necessary; when phytosanitary import requirements for the particular purpose, articles or situations have not yet been established; or when import would otherwise be prohibited for phytosanitary reasons. In the first and last of these, phytosanitary import requirements may exist but only apply if an application is made for an SIA (i.e. on a short term, case-by-case basis). The SC-7 agreed to clarify the text by amending the order in which these three cases were presented, so that the two cases where phytosanitary import requirements exist came first. One SC-7 suggested that as the case “when import would otherwise be prohibited for phytosanitary reasons” is an example of the first case, “when official consent for import is necessary”, it could be deleted completely; the SC-7 retained it, however, to make it clear to NPPOs that SIAs may be issued in certain cases of prohibition. Returning to the list of minimum information, the SC-7 amended the bullet point on phytosanitary import requirements to refer to “phytosanitary import requirements when established”.

[57] **Additional information requirements.** In response to a query from the secretariat, the SC-7 confirmed that the additional information items listed were intended as options – as opposed to the items in the minimum information list, which should always apply – but the list was not intended to be a definitive list and a country could include other types of information on their SIA, in addition to any of these or instead of them. The SC-7 therefore amended the draft annex text to make it clear that the list items were examples.

[58] **Additional information requirements: facility to which consignments are directed.** The steward explained that one consultation comment had proposed that the following bullet point be added to the list of additional information that may be included in SIAs: “facility that goods are to be directed to after arrival at the port of entry (e.g. post-entry quarantine facility)”. The steward expressed his view that this was too specific and could be requested anyway by the importing country when issuing an SIA, without being a requirement in this draft. The SC-7 noted that, if it were to be included, it should refer to “consignments” and “point of entry” (Glossary terms) rather than “goods” and “port of entry”, respectively. They discussed whether it was the type of facility that was the critical information, or more specifically the level of containment, but noted that the level of containment would not apply to all facilities, as the facility might be a processing facility rather than a quarantine facility, and it would be irrelevant in those countries that direct all consignments to the same facility after entry. Eventually, the SC-7 agreed that the most important aspect was for the importer to simply specify which facility it was (i.e. the location). They also added two examples to illustrate the types of facilities.

[59] **Uses of specific import authorizations.** The steward explained that one consultation comment had suggested a rearrangement of the list of examples of purposes, articles and situations where use of SIAs may be appropriate. In the rearranged list, the three items that were conceptual would be retained as bullet points, with the other items, which were concrete purposes or articles, as examples under these

three bullet points. The steward expressed his view that although some of the bullet points could indeed be moved to be given as an example within another bullet point, others could be examples under more than one bullet point, so he preferred to keep the items as separate bullet points rather than merging into three bullet points. He also noted that it was not intended to be an exhaustive list. The SC-7 agreed to keep the items as separate bullet points.

[60] **Responsibilities of exporters.** The SC-7 considered a suggestion from the consultation comments that the following bullet points be added to the list of responsibilities of exporters: “complying with the requirements of the SIA” and “safeguarding transport according to the requirements of the importing country”. The steward expressed his view that the responsibilities of exporters under this annex should be related only to SIAs and that safeguarding transport according to the requirements of the importing country seemed to be beyond the scope of this draft. The SC-7 agreed and did not add this.

[61] The SC-7 also considered another consultation comment, which suggested that applying for a phytosanitary certificate from the NPPO of the exporting country was a regular procedure regardless of SIAs, so should not be part of this annex and hence should be removed from the list of responsibilities of exporters. The SC-7 noted that there were occasions when a phytosanitary certificate is not required (e.g. a phytosanitary certificate may not be required when prohibited material is imported for research purposes under a SIA), so this bullet point served to draw attention to the fact that if a phytosanitary certificate were required, it was the responsibility of the exporter to apply for one. The SC-7 concluded, however, that it was not necessary to refer to this in the annex and so deleted it.

[62] **General import authorizations.** The SC-7 considered a consultation comment suggesting that the annex should specify the types of cases where general import authorizations (GIAs) are applicable, as the difference between GIAs and section 4.2.1 of ISPM 20 (on phytosanitary measures for consignment to be imported) was not clear. The steward commented that section 4.2.1 of ISPM 20 described various options for phytosanitary measures that may be applied, including both general measures that apply to all types of commodities and specific measures that apply to specified commodities from a particular origin; section 4.2.2 outlined the situations where import authorization would be provided as a GIA and as a SIA; but it was true that the annex did not provide much information about GIAs. He therefore wondered whether it was worth keeping this section on GIAs, even though it was short, or whether it was better to delete it as it did not add much and the scope of the annex was SIAs.

[63] The SC-7 agreed that, on balance, it was better to delete the whole section on GIAs, as the issuance of GIAs was already covered under ISPM 20 section 4.2.2 and so it was not necessary to provide extra information in this annex. The SC-7 noted that Specification 64 (*Use of specific import authorizations*) included a task for the expert working group (EWG) to “provide guidance on the circumstances under which specific import authorization could be developed into general import authorization”, which was why the section on GIAs had been drafted by the EWG, but agreed that such guidance, if needed, could be given in implementation material rather than in this annex. The SC-7 amended the introductory text of the annex to make it clear that the annex did not provide guidance on GIA.

Potential implementation issues

[64] The steward confirmed that there had been only one comment on potential implementation issues, which had highlighted a need for “SOPs and [a] requisite legal framework” but with no detail provided. The steward understood this to be referring to the domestic procedures of each contracting party, in which case these were unlikely to be harmonized.

[65] The SC-7 agreed that the implementation issue should be forwarded to the Implementation and Capacity Development Committee (IC) for consideration, but not until after the second consultation, in case further implementation issues were identified. They also noted that the IC may wish to discuss whether there is a need for an IPPC guide.

[66] The SC-7 noted that not all potential implementation issues need to be forwarded to the IC, as sometimes insufficient information has been provided with the comment, but the Standards Committee (SC) may wish to discuss generically how to deal with such comments.

[67] The SC-7:

- (2) *approved* the draft annex *Use of specific import authorizations* (2008-006) to ISPM 20 (*Guidelines for a phytosanitary import regulatory system*) as modified in this meeting for submission to the second consultation (Appendix 5); and
- (3) *requested* that the secretariat archive the potential implementation issues on the draft annex *Use of specific import authorizations* (2008-006) to ISPM 20 (*Guidelines for a phytosanitary import regulatory system*) identified during first consultation for review by the SC after the second consultation.

4.3 Revision of ISPM 4 (*Requirements for the establishment of pest free areas*) (2009-002), priority 4

[68] The Steward, Marina ZLOTINA (United States of America), introduced the draft ISPM and supporting documentation.⁴ She highlighted the following issues that remained for the SC-7 to consider, the first four of which were discussed by the SC-7 in more detail during their subsequent review of the text:

- use of the term “measure” versus “phytosanitary measure”;
- whether to refer to “low pest prevalence” or “tolerance” in relation to buffer zones;
- whether additional guidance was needed to clarify the situations in which a pest free area (PFA) may be required versus simply stating that the pest status is “pest absent”;
- a suggestion to use “delimitation” rather than “identification” in the heading of the section concerning the area to be considered as a PFA;
- a suggestion that the revised ISPM 4 be an overarching standard on PFAs to which other related standards, such as ISPM 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*), are annexed;
- whether to expand specific guidance on outbreaks for cases where a PFA consists of multiple countries or there is more than one PFA in the same country (which the steward did not think was necessary as the same general principles would apply to various situations and the IPPC guide already contained relevant examples);
- a suggestion to use “import requirements” instead of “appropriate level of protection” (which the steward had taken account of in modifying the text);
- a suggestion to move some text in the Background section about the geographical extent of a PFA (which the steward had not incorporated because she could not see how this would improve the flow of the text);
- a suggestion to add explanatory text on detailed communication (which the steward had not incorporated because such details are already addressed in the IPPC guide on PFAs (*Guide for establishing and maintaining pest free areas*));
- a suggestion to change the requirement for the length of time that records should be kept from a minimum of 24 months to “sufficient time”; and
- a few issues concerning multilateral recognition (which the steward had taken account of in modifying the text).

[69] With regard to the general question about amalgamating all PFA standards into one standard, the steward commented that it was not clear how to approach this comment, now that the revision of ISPM 26 had been added to the work programme, but suggested that perhaps the best approach was to continue with the current revision of ISPM 4 and review the situation once ISPM 26 had been revised.

[70] The SC-7 considered the issues raised as they reviewed the text of the draft ISPM.

⁴ 2009-002; 2009-002_OCS; 04_SC7_Tel_2022_May; 05_SC7_Tel_2022_May; 13_SC7_Tel_2022_May.

Review of the draft ISPM and outstanding issues

- [71] **“Delimitation” vs “identification” of the area.** The steward explained that one suggestion made during consultation was that “identification” be used instead of “delimitation” for the heading of this section. The SC-7 agreed with this change. Later in the section, where the text said that PFAs “may be delimited by natural barriers”, the SC-7 considered whether to use “defined” rather than “delimited”, but agreed that “delimited” was the most appropriate given that the Glossary definition of “delimiting survey” related to the boundaries of an area being established, which was the focus of this piece of text in the draft ISPM.
- [72] **Establishment of buffer zones.** The steward explained that one consultation comment had suggested that the population of the target pest in the buffer zone should be maintained at or below a low pest *prevalence* level rather than a low pest *tolerance* level. The steward commented that unless buffer zones were always to be areas of low pest prevalence (as per the Glossary term), the term “tolerance” should be used, in accordance with the “General recommendations on use of terms in ISPMs” agreed by the TPG and included in the *IPPC style guide*. Recognizing, however, that the level of the pest population would be different for different pests, the SC-7 agreed to amend the text to simply refer to the pest population being “at or below a specified level”.
- [73] **Implementation of control measures.** The SC-7 noted that the paragraph on eradication measures had been amended as a result of a consultation comment. Reviewing the amended text, they considered whether to delete reference to products when referring to treatments and control measures specified in ISPM 9 (*Guidelines for pest eradication programmes*), but agreed instead to simplify the paragraph by simply saying “measures to eradicate the pest should be implemented according to ISPM 9”.
- [74] **“Measure” vs “phytosanitary measure”.** The steward explained that some contracting parties had commented on the respective use of these terms in the draft ISPM. As a result, the steward had modified the language, using “measure” when referring to the internal pest management procedures applied by the NPPO when establishing a PFA and “phytosanitary measure” when referring to the procedures applied subsequently by the NPPO to keep the pest out of the area and hence to maintain the PFA. In this situation, the target pest would become a quarantine pest for the PFA when the PFA was used as a phytosanitary measure for trade. The steward added, however, that the TPG had considered the use of the terms in the draft ISPM to be adequate, as measures applied to set up a PFA are also phytosanitary measures if contributing to the overall objective of the PFA.
- [75] The SC-7 considered the steward’s proposal and the TPG comments. They noted that the consultation comment had arisen because of the potential confusion caused when using “phytosanitary measure” to refer to both a component measure of a PFA and to the PFA itself. To avoid this confusion, they therefore agreed to follow the approach suggested by the steward: to use “phytosanitary measure” for measures to keep the target pest out of a PFA and “measure” for internal pest management procedures when establishing a PFA.
- [76] **Pest absence vs PFA.** The steward explained that one consultation comment had suggested that additional text be added to the draft ISPM to clarify that a country may be able to claim a PFA (in accordance with this ISPM) as well as a pest status of “absent” (in accordance with ISPM 8 (*Determination of pest status in an area*)). It was the steward’s view, however, that the current text in the draft was adequate, this explaining that if the pest status is “absent: pest not recorded”, and this was supported by current scientific evidence, then establishing a PFA should not be required by the importing country.
- [77] The SC-7 discussed the various ISPM 8 “pest absent” categories in the context of importing countries requiring the establishment of a PFA in an exporting country. They agreed that the phytosanitary measures applied would be different in an area where a pest had never been present to those applied in an area where the pest had once been present but had since been eradicated: the intensity of surveillance, for example, would be lower in the area where the pest had never been present. For areas where the pest had never been present, a phytosanitary import requirement to establish a PFA would not be technically justified. By the same token, a phytosanitary import requirement for a PFA may be technically justified

where the pest status is “absent: pest eradicated”. The SC-7 acknowledged, however, that the situation was not as straightforward for some of the other ISPM 8 “pest absent” categories that shared some similarities with “absent: pest not recorded”. For example, a status of “absent: pest no longer present” could relate to situations where the pest was no longer present because of changes in climate, cultivated host species or production practices, and in those situations the pest would not be present in the future and yet an importing country may still require a PFA to be established according to the current text of the draft. The steward explained that in the case of “absent: pest records invalid”, surveillance would need to be conducted to confirm the situation, but that the general intention of the guidance in the draft ISPM was to make it clear that a PFA is an undue burden for a country that has never had the pest. The SC-7 therefore agreed to keep the text as already drafted, to say that a PFA is not required for “absent: pest not recorded”.

- [78] **Verification of pest freedom.** The SC-7 considered the following sentence that had been added to the section on verification in response to a consultation comment: “Normally, pest freedom is attained or maintained based on verification from specific surveillance”. They noted that pest freedom is attained or maintained as a result of the measures applied, and that it is the *recognition* of pest freedom that is attained or maintained based on verification from specific surveillance, but agreed that the sentence did not suit the context of this section and so deleted it.

Potential implementation issues

- [79] The SC-7 noted that although there had been some potential implementation issues raised during the consultation, none were specific to this standard as they related to issues such as the lack of sufficient resources in developing countries and the need for more guidelines for contracting parties. The SC-7 noted that comprehensive implementation material was already available in the form of the IPPC guide on pest free areas, but this would need updating to take account of the changes to ISPM 4 once the revised ISPM was adopted.

- [80] The SC-7:

- (4) *approved* the draft revision of ISPM 4 (*Requirements for the establishment of pest free areas*) (2009-002) as modified in this meeting for submission to the second consultation (Appendix 6); and
- (5) *requested* that the secretariat archive the potential implementation issues on the draft revision of ISPM 4 (*Requirements for the establishment of pest free areas*) (2009-002) identified during first consultation and in this meeting for review by the SC after the second consultation.

4.4 Revision of ISPM 18 (*Requirements for the use of irradiation as a phytosanitary measure*) (2014-007), priority 1

- [81] The Steward, David OPATOWSKI (Israel), introduced the draft ISPM and supporting documentation.⁵ He summarized the changes that had been made to the draft in response to the consultation comments and highlighted the issues that remained for the SC-7 to consider. These included a request to avoid the use of the terms “requirements”, “guidelines” and “recommendations” in the titles of all ISPMs, questions about specific references, a suggestion to add a definition of “loading configuration”, a comment about whether the draft needed to say “as defined in ISPM 5” after a specific term, the use of “validation” versus “verification”, whether the draft should refer to quarantine pests rather than regulated pests, and two minor editorial questions.

- [82] The SC-7 considered the issues raised as they reviewed the text of the draft ISPM.

Review of the draft ISPM and outstanding issues

- [83] **Title: use of “requirements”, “guidelines” and “recommendations”.** The steward explained that one general consultation comment had suggested that the titles of all ISPMs be revised to eliminate the words

⁵ 2014-007; 2014-007_OCS; 06_SC7_Tel_2022_May; 07_SC7_Tel_2022_May; 08_SC7_Tel_2022_May.

“requirements”, “guidelines” and “recommendations”, as the use of these terms in some ISPMs can cause confusion in World Trade Organization disputes. The SC-7 agreed, however, to retain “requirements” in the title of this draft ISPM, for consistency with other ISPMs.

- [84] **References.** The steward explained that a few consultation comments had suggested that the draft annex should not cite the Asia and Pacific Plant Protection Commission (APPPC) standard on the approval of irradiation facilities, as NPPOs should follow the guidelines of ISPM 18 and not those of a regional standard consistent with ISPM 18. The secretariat recalled that the TPG had supported this comment. One SC-7 member commented that it would be strange to allow standards of other international bodies such as the International Organization for Standardization to be cited but not regional standards for phytosanitary measures. Another suggested that the SC be invited to consider the generic issue of whether regional standards can be cited in ISPMs, given that this was likely to be pertinent to the commodity standards being developed, and that the usage in adopted standards be established beforehand. The secretariat offered to research the latter. One SC-7 member suggested that the SC could use its discretion on a case-by-case basis as to whether to cite regional standards in ISPMs.
- [85] Returning to the matter later in the meeting, the secretariat confirmed that out of ISPMs 1–47 (excluding diagnostic protocols and phytosanitary treatments), regional standards were cited in two: ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) and ISPM 37 (*Determination of host status of fruit to fruit flies (Tephritidae)*). With regard to the draft revision of ISPM 18, the SC-7 considered whether to delete the APPPC reference, as it was only cited once and it was not essential to that paragraph. The SC-7 noted that references listed under the References section were not always cited in the body text of ISPMs, but there should be a consistent practice. The secretariat confirmed that the current style was to cite references in the body text, with the exception of the IPPC itself. The SC-7 agreed, however, to delete the citation from the body text, keep the reference in the References section (because the document could provide additional information for contracting parties), and wait to see whether this generated any further comments during second consultation.
- [86] **Definitions: loading configuration.** The steward explained that one consultation comment had suggested that a definition for “loading configuration” be added to the draft ISPM, but the TPG had expressed the view that “loading configuration” was a common industrial term used in ISPMs without a specific IPPC meaning and therefore need not be defined. The TPG had pointed out, however, that three terms were currently used in the draft – “load configuration”, “commodity configuration” and “commercial-product configuration” – and had recommended that the steward strive for consistency or provide sufficient explanation of the meaning if different terms were to be used. The TPG had recalled that the Glossary definition of “process load” used “loading configuration”.
- [87] The SC-7 agreed to use “loading configuration” and apply this throughout the draft ISPM, but not to include a definition.
- [88] **Outline of requirements.** Further to a comment from the TPG, the SC-7 amended the first sentence of this section to align with the text of the other treatment standards (ISPM 42 (*Requirements for the use of temperature treatments as phytosanitary measures*), ISPM 43 (*Requirements for the use of fumigation as a phytosanitary measure*) and ISPM 44 (*Requirements for the use of temperature treatments as phytosanitary measures*)).
- [89] **Background.** The SC-7 considered a suggestion made during consultation that “(as defined in ISPM 5)” should be deleted from the Background section, where it was given after the term “process load”. The steward explained that some countries had commented that there was no need to cite ISPM 5 as there was a general reference to ISPM 5 in all ISPMs, but others thought that it should be mentioned with specific reference to “process load”. The secretariat confirmed that the usual style in ISPMs is not to cite ISPM 5 in relation to specific terms, both for the reason explained by the steward and because to do so could imply that other Glossary terms used in the ISPM were not being used in their Glossary sense. The SC-7 therefore agreed, for consistency, not to cite ISPM 5 other than in the References section.

- [90] **Irradiation application.** Further to a comment from the TPG, the SC-7 amended the beginning of the first sentence in this section to refer to “at the specified efficacy” not “at a specified efficacy” (i.e. to use the definitive article).
- [91] **Dosimetry systems.** The steward explained that a consultation comment had suggested that “technically agreed upon” be inserted before “procedures” in the following sentence: “A dosimetry system consists of dosimeters, instruments that read dosimeters and procedures”. The rationale provided for this change was that it would clarify that “the parameters around the procedures to be used are to be agreed upon on technical grounds”. The secretariat highlighted two ambiguities with the sentence as amended: what the procedures are for (presumably the operation of the dosimeters and the instruments that read dosimeters) and who agrees the procedures. The answer to the latter question was not clear to the SC-7. They noted that other standards refer to following the manufacturer’s guidelines on equipment but also acknowledged that if this was the intended meaning, it might not be necessary to say it explicitly as the presumption would always be that manufacturer’s guidelines are followed. The SC-7 therefore agreed to omit the suggested insertion from the draft ISPM.
- [92] **Validation.** The steward explained that one consultation comment had queried whether the text should refer to “verification” rather than “validation”. The SC-7 agreed to retain the latter.
- [93] **Prevention of infestation and contamination after treatment.** The steward explained that the TPG had suggested that the wording of the following bullet point be amended to align with that used in ISPM 42 and ISPM 43: “identifying irradiated commodities to prevent mixing with non-irradiated commodities”. The SC-7 agreed to this suggestion and modified the bullet to read “segregating and identifying treated commodities”.
- [94] **Typography for variables.** The secretariat explained that the variables used in the draft ISPM (D_{\max} , D_{\min} , etc.) had been set with the variable in italics and the descriptive subscript in roman type in line with standard scientific notation, although this differed from the style in the Glossary term “minimum absorbed dose (D_{\min})”. The secretariat noted that no consultation comments had been received requesting that this style be changed in the draft ISPM, and so sought clarification from the SC-7 that the new text in Appendix 1 should also follow this style. The SC-7 agreed that it should. With reference to the Glossary term, the SC agreed to ask the TPG to consider the need for an ink amendment.

Potential implementation issues

- [95] No implementation issues were raised by the SC-7, although some comments had been submitted during the first consultation.
- [96] The SC-7:
- (6) *approved* the draft revision of ISPM 18 (*Requirements for the use of irradiation as a phytosanitary measure*) (2014-007) as modified in this meeting for submission to the second consultation (Appendix 7);
 - (7) *requested* that the secretariat archive the potential implementation issues on the draft revision of ISPM 18 (*Requirements for the use of irradiation as a phytosanitary measure*) (2014-007) identified during first consultation for review by the SC after the second consultation;
 - (8) *suggested* that the SC consider the appropriateness or otherwise of citing regional standards in ISPMs; and
 - (9) *invited* the Technical Panel for the Glossary to consider whether an ink amendment is necessary to the term “minimum absorbed dose (D_{\min})” to apply italics to the variable “D” and subscript roman type to the subscript “min”.

5. Review of the standard setting calendar

[97] The secretariat invited SC-7 members to regularly check the standard setting calendar on the IPP.⁶ The SC-7 was informed of forthcoming standard setting activities.

6. Any other business

[98] There was no other business.

7. Date and type of the next SC-7 meeting

[99] The next SC-7 meeting is scheduled to take place after the SC May 2023 meeting.

8. Evaluation of the meeting process

[100] The secretariat encouraged all SC-7 members to complete the evaluation of the meeting, via the link provided on the agenda for this meeting.

9. Close of the meeting

[101] Although originally scheduled to finish on 20 May 2022, the SC-7 completed the agenda early, allowing the meeting to be closed at the end of the session on 19 May.

[102] The chairperson and secretariat thanked all participants for their contributions.

[103] The chairperson closed the meeting.

⁶ IPP calendar: <https://www.ippc.int/en/year/calendar/>

Appendix 1: Agenda

1.	Opening of the Meeting	Document number / link	Presenter / IPPC Secretariat support
1.1.	Welcome by the IPPC Secretariat		NERSISYAN
2.	Meeting Arrangements		
2.1.	Election of the Chairperson	–	IPPC Secretariat
2.2.	Election of the Rapporteur	–	Chairperson
2.3.	Adoption of the Agenda	01_SC7_Tel_2022_May	Chairperson
3.	Administrative Matters		
3.1.	Documents list	02_SC7_Tel_2022_May	Chairperson
3.2.	Participants list	03_SC7_Tel_2022_May SC membership list	Chairperson
4.	Draft ISPMs for approval for the second consultation		
4.1.	2021 Amendments to ISPM 5: Glossary of phytosanitary terms (1994-001), Priority 1 <ul style="list-style-type: none"> - Steward: Ms Laurence BOUHOT-DELDUC Assistant steward: Mr Ebbe NORDBO <ul style="list-style-type: none"> o TPG responses to comments from 2021 Consultation (1994-001) o Additional note from the TPG Assistant Steward 	1994-001 1994-001_OCS_Rev1 10_SC7_Tel_2022_May 12_SC7_Tel_2022_May	NORDBO / SHAMILOV
4.2.	Annex to ISPM 20: Use of Specific Import Authorizations (2008-006), Priority 4 <ul style="list-style-type: none"> - Steward: Mr Ezequiel FERRO - Assistant steward: - <ul style="list-style-type: none"> o Steward's responses to Comments from 2021 Consultation (2008-006) o TPG response on comments on terminology and consistency (2008-006) Steward's additional notes and potential implementation issues (2008-006)	2008-006 2008-006_OCS 11_SC7_Tel_2022_May 09_SC7_Tel_2022_May 14_SC7_Tel_2022_May	FERRO / SHAMILOV

4.3.	<p>Revision of ISPM 4 (<i>Requirements for the establishment of pest free areas</i>) (2009-002), Priority 4</p> <ul style="list-style-type: none"> - Steward: Ms Marina ZLOTINA - Assistant stewards: Mr David KAMANGIRA <ul style="list-style-type: none"> o Steward's responses to Comments from 2021 Consultation (2009-002) o TPG response on comments on terminology and consistency (2009-002) o Steward's additional notes and potential implementation issues (2009-002) 	<p>2009-002 2009-002_OCS</p> <p>04_SC7_Tel_2022_May</p> <p>05_SC7_Tel_2022_May</p> <p>13_SC7_Tel_2022_May</p>	<p>ZLOTINA / MOREIRA</p>
4.4.	<p>Revision of ISPM 18 (<i>Requirements for the use of irradiation as a phytosanitary measure</i>) (2014-007), Priority 1</p> <ul style="list-style-type: none"> - Steward: Mr David OPATOWSKI - Assistant steward: Mr Guy HALLMAN <ul style="list-style-type: none"> o Steward's responses to Comments from 2021 Consultation (2014-007) o TPG response on comments on terminology and consistency (2014-007) o Steward's additional notes and potential implementation issues (2014-007) 	<p>2014-007 2014-007_OCS</p> <p>06_SC7_Tel_2022_May</p> <p>07_SC7_Tel_2022_May</p> <p>08_SC7_Tel_2022_May</p>	<p>OPATOWSKI / KISS</p>
5.	<p>Review of the standard setting calendar</p>	<p>Link to the IPP calendar</p>	<p>MUSHEGIAN</p>
6.	<p>Any other business</p>		<p>Chairperson</p>
7.	<p>Date and type of the next SC-7 Meeting</p>		<p>Chairperson</p>
8.	<p>Evaluation of the meeting process</p>	<p>Link to survey</p>	<p>Chairperson</p>
9.	<p>Close of the meeting</p>		<p>Chairperson</p>

Appendix 2: Documents list

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE	DATE POSTED / UPDATED
Draft ISPMs for approval for the second consultation (“_OCS” – out of OCS)			
1994-001 1994-001_OCS_Rev1	4.1	2021 Amendments to ISPM 5 (<i>Glossary of phytosanitary terms</i>) (1994-001), Priority 1	2022-04-15 2022-05-02 2022-05-10
2008-006 2008-006_OCS	4.2	Annex to ISPM 20: Use of Specific Import Authorizations (2008-006), Priority 4	2022-04-15 2022-05-02
2009-002 2009-002_OCS	4.3	Revision of ISPM 4 (<i>Requirements for the establishment of pest free areas</i>) (2009-002), Priority 4	2022-04-15 2022-05-02
2014-007 2014-007_OCS	4.4	Revision of ISPM 18 (<i>Requirements for the use of irradiation as a phytosanitary measure</i>) (2014-007), Priority 1	2022-04-15 2022-05-02
Meeting documents			
01_SC7_Tel_2022_May_Rev1	2.3	Provisional agenda	2022-04-15 2022-04-19 2022-05-02 2022-05-11
02_SC7_Tel_2022_May	3.1	Documents list	2022-04-15 2022-04-19 2022-05-02 2022-05-11
03_SC7_Tel_2022_May	3.2	Participants list	2022-04-15 2022-05-11
04_SC7_Tel_2022_May	4.3	Steward’s responses to Comments from 2021 Consultation (2009-002)	2022-04-15 2022-04-19 2022-05-11
05_SC7_Tel_2022_May	4.3	TPG response on comments on terminology and consistency (2009- 002)	2022-04-15 2022-04-19 2022-05-11
06_SC7_Tel_2022_May	4.4	Steward’s responses to Comments from 2021 Consultation (2014-007)	2022-04-15 2022-04-19 2022-05-11
07_SC7_Tel_2022_May	4.4	TPG response on comments on terminology and consistency (2014- 007)	2022-04-15 2022-04-19 2022-05-11
08_SC7_Tel_2022_May	4.4	Steward’s additional notes and potential implementation issues (2014- 007)	2022-04-15 2022-04-19 2022-05-11
09_SC7_Tel_2022_May	4.2	TPG response on comments on terminology and consistency (2008- 006)	2022-04-15 2022-04-19 2022-05-11
10_SC7_Tel_2022_May	4.1	TPG responses to comments from 2021 Consultation (1994-001)	2022-04-15 2022-04-19 2022-05-11
11_SC7_Tel_2022_May	4.2	Steward’s responses to Comments from 2021 Consultation (2008-006)	2022-04-15 2022-04-19 2022-05-11
12_SC7_Tel_2022_May	4.1	Additional note from the TPG Assistant Steward	2022-04-15 2022-04-19 2022-05-11

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE	DATE POSTED / UPDATED
13_SC7_Tel_2022_May	4.3	Steward's additional notes and potential implementation issues (2009-002)	2022-04-15 2022-04-19 2022-05-11
14_SC7_Tel_2022_May	4.2	Steward's additional notes and potential implementation issues (2008-006)	2022-04-15 2022-04-19 2022-05-11

Documents links (presented in the order of the agenda items)

Links	Agenda item	Document link
SC membership list	3.2	SC membership list
Review of the standard setting calendar	5	Link to the IPP calendar
Evaluation of the meeting process	8	Link to survey

Appendix 3: Participants list

✓	Region / Role	Name, mailing address, telephone	Email address	Membership Confirmed	Term expires
✓	Africa Member SC-7	Mr David KAMANGIRA Senior Deputy Director and IPPC Focal Point Department of Agricultural Research Services Headquarters, P.O. Box 30779, Lilongwe 3 MALAWI Tel: +265 888 342 712 Tel: +265 999 122 199	davidkamangira1@gmail.com	CPM-11 (2016) CPM-14 (2019) 2 nd term / 3 years	2022
✓	Asia Member SC-7	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	CPM-13 (2018) CPM-15 (2021) 2 nd term / 3 years	2024
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Appendix 4: Draft 2021 amendments to ISPM 5 (*Glossary of phytosanitary terms*) (1994-001), priority 1

DRAFT 2021 AMENDMENTS TO ISPM 5: *GLOSSARY OF PHYTOSANITARY TERMS* (1994-001)

Publication history

(This is not an official part of the standard)

Date of this document	2022-05-20
Document category	Draft 2021 Amendments to ISPM 5 (<i>Glossary of phytosanitary terms</i>) (1994-001)
Current document stage	To second consultation
Major stages	<p>CEPM (1994) added topic: 1994-001, Amendments to ISPM 5: Glossary of phytosanitary terms</p> <p>2006-05 Standards Committee (SC) approved specification TP5</p> <p>2012-10 Technical Panel for the Glossary (TPG) revised specification</p> <p>2012-11 SC revised and approved revised specification, revoking Specification 1</p> <p>2021-01 TPG proposed 2021 amendments below</p> <p>2021-05 SC revised the 2021 amendments via the Online Comment System and approved the 2021 amendments for the first consultation via e-decision (2021_eSC_MayXX)/virtual meeting</p> <p>2021-12 TPG revised the 2021 amendments</p> <p>2022-05 SC-7 revised the 2021 amendments via the Online Comment System and approved the 2021 amendments for the first consultation at the virtual meeting</p>
Notes	Note to Secretariat formatting this paper: formatting in definitions and explanations (strikethrough, bold, italics) needs to remain.

Introduction

- [1] Terms and definitions in this document went for *first* consultation from 1 July to 30 September 2021, the outcome of which had been considered by the Technical Panel for the Glossary (TPG) in its December 2021 meeting. The TPG recommendations have been considered by the SC-7 in May 2022, and the resulting proposals for amendments are hereby submitted for the second consultation.
- [2] IPPC Official Contact Points are asked to consider the following proposals for revision of terms and definitions to ISPM 5 (*Glossary of Phytosanitary Terms*). A brief explanation is given for each proposal. For revision of terms and definitions, only the proposed changes are open for comments. For full details on the discussions related to the specific terms, please refer to [the TPG meeting reports on the IPP](#) and [to the Table providing detailed TPG replies to comments from the first consultation](#).
- [3] Guiding note: In this draft 2021 Amendments to the Glossary, certain terms and definitions are being proposed as a ‘package’ in the sense that the proposals are interlinked. Therefore, it is suggested that proposals within each ‘package’ be read in conjunction. ‘Packages’ are:
- The inter-linked definitions of the terms *identity (of a consignment)*, *integrity (of a consignment)* and *phytosanitary security (of a consignment)*;
 - The inter-linked definitions of the terms *inspection*, *test*, *compliance procedure (for a consignment)*, *clearance (of a consignment)* and *release (of a consignment)*;
 - The inter-linked definitions of the terms *general surveillance*, *specific surveillance* and *surveillance*;

- The inter-linked definitions of the terms *emergency measure* and *provisional measure*.

1. ADDITION

1.1. “identity (of a consignment)” (2011-001)

- [4] The term ‘*identity (of a consignment)*’ has been used frequently in ISPMs, notably in the context of the so-called ‘*identity check*’ performed at export, import or transit. However, the use and meaning of this term and ‘*integrity (of a consignment)*’, often used together, has been inconsistent, unclear and seemingly overlapping. At the request from the CPM-6 in 2011, the SC in 2012 had added the term to the List of topics for IPPC standards.
- [5] An approach to defining the term had been submitted by the TPG and approved by the SC in 2013, implying that a consignment’s identity is equivalent to information on the phytosanitary certificate. However, it remained unresolved which particular aspects of the phytosanitary certificate should be emphasized in a definition of ‘identity’. The SC agreed to combine the work on definitions for the inter-related terms ‘*identity (of a consignment)*’, ‘*integrity (of a consignment)*’ and ‘*phytosanitary security (of a consignment)*’.
- [6] A first TPG draft ‘package’ of those definitions had been discussed by the SC in 2014, but the further development process put on hold, awaiting the output from the Expert Drafting Group on “*Focused revision of ISPM 12 (Phytosanitary certificates) in relation to re-export*” that met in December 2019. Subsequently, the TPG in January 2021 had submitted a new proposal, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending the revised definition unchanged for the second consultation.
- [7] The following explanatory points may be considered when reviewing the proposal:
- (1) The identity of a consignment relates to certain consignment characteristics attested in its accompanying phytosanitary certificate, namely those characteristics that are not supposed to change from the time of phytosanitary certification in a country until import into another country. When considering whether simply the *number* of the phytosanitary certificate is the same as the consignment’s identity, it had been concluded that not all elements of the phytosanitary certificate could reasonably be considered part of the consignment’s identity. Then, to decide which elements are relevant for the identity and which not, the line of logic has been to reply to the question: what is the core phytosanitary concern of the importing NPPO when performing an ‘identity check’? The reply is: to reassure that *exactly those specimens* of plants, plant products or other articles (i.e. *components from a particular place of origin*) that are about to be imported are *exclusively those that had been certified*;
 - (2) Thus, the *identity* of a consignment is: its components (being the core *material* content) and its origin (being the core *immaterial* characteristic);
 - (3) In broad terms, the ‘*components*’ corresponds to the sections in phytosanitary certificates on ‘*Name of produce and quantity declared*’ and ‘*Botanical name of plants*’, as expressed in the definition;
 - (4) In contrast, descriptions provided in the phytosanitary certificate sections on ‘*Number and description of packages*’ and ‘*Distinguishing marks*’ may certainly be helpful for the practical spotting of one particular consignment among others, but are not considered part of the consignment’s identity. It is noted that the “identification” of a consignment is a different concept from the “identity” of a consignment. It is recalled that the Glossary definition of ‘consignment’ is “*A quantity of plants, plant products or other articles being moved from one country to another and covered, when required, by a single phytosanitary certificate (a consignment may be composed of one or more commodities or lots)*”. Thus, packaging, seals etc. are not elements of the consignment proper and not elements of the consignment’s identity. While packaging and its distinguishing marks could change along the chain of delivery, that would not change the identity of the consignment;

- (5) The quantity of items in the consignment is referred to in the definition. Obviously, the identity would have changed if any item was *added* to a consignment after phytosanitary certification, corresponding to the fact that the certifying statement of the phytosanitary certificate would then no longer cover all components of the consignment. In contrast, it cannot be generalized whether any (unintentional) *loss* or (intentional) *subtraction* of items from the consignment after phytosanitary certification would change the consignment’s identity. The SC, therefore, has concluded that the issue of quantity cannot possibly be explained to all detail in a definition. Referring to *‘the components’* is sufficient to indicate that any quantity *above* the declared quantity would certainly be deemed a change of identity;
- (6) As any phytosanitary certificate has been issued to exclusively cover the particular collection of plants, plant products or other regulated articles that had been inspected, the consignment’s origin is also an important part of consignment’s identity, and it corresponds to the section in phytosanitary certificates on *‘Place of origin’*, as expressed in the definition and explained in ISPM 12 (*Phytosanitary certificates*), section 5 (I);
- (7) The number of the phytosanitary certificate is implicit in the definition and need not be explicitly mentioned, as the identity refers to the specific phytosanitary certificate accompanying the consignment (cf. “...its phytosanitary certificate...”);
- (8) The sections of phytosanitary certificates on *‘Name and address of exporter’*, *‘Declared name and address of consignee’*, *‘Declared means of conveyance’* and *‘Declared point of entry’* are not considered part of the consignment’s identity;
- (9) The proposed definition of *‘identity (of a consignment)’* does not conflict with current uses of the term *‘identity’* (in relation to a consignment) in adopted ISPMs;
- (10) Defining *‘identity (of a consignment)’* facilitates the revision of the definitions of *‘integrity (of a consignment)’* and *‘phytosanitary security (of a consignment)’*.

Proposed addition

identity (of a consignment)	The components of a consignment as covered by its phytosanitary certificate and described in the sections “name of produce and quantity declared”, “botanical name of plants ” and “place of origin”
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1.2. “general surveillance” (2018-046)

- [8] In 2018, the TPG had noted that the revised ISPM 6 (*Surveillance*) had resulted in a slight change in the meaning of general and specific surveillance, with the previous version of ISPM 6 referring to “specific surveys” for what is now called “specific surveillance”. The SC meeting in May 2019 added the terms “*general surveillance*” and “*specific surveillance*” to the TPG work programme for inclusion in the Glossary, to provide clarity without having to read ISPM 6.
- [9] During their November 2019 meeting, the TPG discussed the definitions of both terms “*general surveillance*” and “*specific surveillance*” together with an analysis of the use of these terms in adopted ISPMs. The TPG considered various options for a definition for “*general surveillance*”.
- [10] In their January 2021 meeting, the TPG had submitted a definition proposal, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.
- [11] The following explanatory points may be considered when reviewing the proposal:
- It is useful to add the term and definition in the Glossary to clarify its meaning in ISPM 6 and other adopted ISPMs;
 - It is noted that in the current definition of *surveillance*, “*survey*” and “*monitoring*” implicitly refer to specific surveillance and “*other procedures*” to general surveillance;

- The proposed definition refers to “*various sources*” rather than “*procedures*” to allow for sources of data that are not procedures. Those various sources of data can be official or unofficial, as explained in ISPM 6;
- “*Pests*” is used rather than “*pest presence or absence*” to allow for surveillance of other characteristics of pests;
- With reference to the “*data*” or “*information*” resulting from the surveillance, “*data*” refers to the raw collected material, which then becomes “*information*” once it has been analysed and verified. The word “*data*” is therefore appropriate in the context of *general surveillance*;
- Whereas the overall surveillance process is official (i.e. exclusively an NPPO responsibility), data may be collected from various, also non-official sources. Data resulting from general surveillance are not official until they have been endorsed by the NPPO; therefore, the process does not stop with the collection of data, as analysis and verification are key important parts of the process when non-official data-sources are being used;
- As described in ISPM 6, general surveillance and specific surveillance are disjunctive concepts. They may be used in combination, as provided for in the revised definition of “*surveillance*” (Section 2.1).

Proposed addition

general surveillance	An official process whereby data on pests in an area , collected from various sources other than surveys , are analysed and verified.
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1.3. “*specific surveillance*” (2018-047)

[12] In 2018, the TPG had noted that the revised ISPM 6 (*Surveillance*) had resulted in a slight change in the meaning of general and specific surveillance, with the previous version of ISPM 6 referring to “specific surveys” for what is now called “specific surveillance”. The SC meeting in May 2019 added the terms “*general surveillance*” and “*specific surveillance*” to the TPG work programme for inclusion in the Glossary, to provide clarity without having to read ISPM 6. The TPG in its January 2021 meeting had submitted a proposal, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending the revised definition unchanged for second consultation.

[13] The following explanatory points may be considered when reviewing the proposal:

- The only distinction between general and specific surveillance is the source of the data, as both types of surveillance can be directed to specific pests;
- Specific surveillance is achieved through surveys;
- With reference to the “*data*” or “*information*” resulting from the surveillance, “*data*” refers to the raw collected material, which then becomes “*information*” once it has been processed; data are not official until endorsed by the NPPO. The word “*information*” is therefore appropriate in the context of *specific surveillance*;
- Reference to “*presence or absence*” of a pest in the definition would be too restrictive as it would exclude seeking information on other characteristics of a pest population, such as pest biology or distribution, as allowed by the Glossary definitions of “*survey (of pests)*” and “*monitoring survey*”.

Proposed addition

specific surveillance	An official process whereby information on pests in an area is obtained through surveys .
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2. REVISION

2.1. “surveillance” (2020-009)

- [14] In 2018, the TPG had noted that the revised ISPM 6 (*Surveillance*) had resulted in a slight change in the meaning of general and specific surveillance, with the previous version of ISPM 6 referring to “specific surveys” for what is now called “specific surveillance”. The SC meeting in May 2019 added the terms “*general surveillance*” and “*specific surveillance*” to the TPG work programme for inclusion in the Glossary, to provide clarity without having to read ISPM 6.
- [15] In 2019, the TPG also discussed the definition of “*surveillance*” and, upon TPG’s recommendation, the SC in November 2020 added the term to the TPG work programme. The TPG in its January 2021 meeting had submitted a proposal, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.
- [16] The following explanatory point may be considered when reviewing the proposal:
- Whilst the current definition of “*surveillance*” rather indistinctly mixes various methods from the two surveillance types, and unnecessarily restricts the surveillance objective to only ‘presence or absence of pests’, the proposed definitions of the new Glossary terms “*general surveillance*” (cf. section 1.2) and “*specific surveillance*” (cf. section 1.3) provides the details for distinguishing those two disjunctive surveillance types. Subsequently, the generic characteristics of “*surveillance*” remain as “*an official process whereby information on pests in an area is obtained...*” (as outlined with the first part of the definition). The possible surveillance methodologies and the conceptual relationship between the terms are then outlined in the second part of the definition as “*...through general surveillance, specific surveillance or a combination of both*”.

Current definition

Surveillance	An official process which collects and records data on pest presence or absence by survey, monitoring or other procedures [CEPM, 1996; revised CPM, 2015]
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Proposed revision

Surveillance	An official process <u>whereby information on pests in an area is obtained through general surveillance, specific surveillance or a combination of both</u> which collects and records data on pest presence or absence by survey, monitoring or other procedures
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2.2. “integrity (of a consignment)” (consequential) (2021-008)

- [17] The SC in 2013 agreed to combine the work on definitions for the inter-related terms ‘*identity (of a consignment)*’, ‘*integrity (of a consignment)*’ and ‘*phytosanitary security (of a consignment)*’, and added *integrity (of a consignment)* to the TPG work programme.
- [18] While the use and meaning of the terms ‘*identity*’ and ‘*integrity*’ in adopted ISPMs have been inconsistent, unclear and seemingly overlapping, the matter could be appropriately clarified by defining *identity (of a consignment)* and revising the definition of *integrity (of a consignment)*, relating it to the term *identity*.
- [19] A first TPG draft ‘package’ of definitions including ‘*integrity (of a consignment)*’ had been discussed by the SC in 2014, but the further development process put on hold, awaiting the output from the Expert Drafting Group on “*Focused revision of ISPM 12 (Phytosanitary certificates) in relation to re-export*” that met in December 2019. Subsequently, the TPG in January 2021 had submitted a new proposal, reviewed by the SC in May 2021 and sent for first consultation. The TPG in December 2021 and the

SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.

[20] The following explanatory points may be considered when reviewing the proposal:

- (1) By referring to the proposed definition of *identity (of a consignment)* (cf. section 1.1), the relationship between the two concepts is clarified and the definition of *integrity (of a consignment)* simplified;
- (2) Consequently, the wording ‘*composition...as described by its phytosanitary certificate*’ is deleted as redundant because that aspect is already included in the proposed definition of the term ‘*identity*’, which is inserted instead;
- (3) The wording ‘*maintained without loss, addition or substitution*’ is substituted by the wording ‘*is unchanged*’, with the intent that such simplification more strongly emphasizes the core phytosanitary concern, namely: that the identity has remained unchanged, i.e. that exactly those specimens of plants, plant products or other articles (i.e. *components from a particular place of origin*) that are about to be imported are exclusively those that had been certified (cf. the deliberation in section 1.1 regarding the proposed definition of *identity (of a consignment)*, in particular, the SC conclusion regarding *loss or subtraction*);
- (4) While the unchanged *identity* is one major element of the consignment’s integrity, ‘*its packaging undamaged*’ and ‘*it shows no other signs of tampering*’ are also considered important elements of integrity and are therefore added to the definition;
- (5) The introductory wording ‘*State of*’ is added to emphasize that integrity is a (desirable) state of a consignment, not an action to the consignment, and also added with the intent to provide a simple sentence;
- (6) The wording ‘*or other officially accepted document*’ is deleted because ISPMs deal with the harmonization of phytosanitary measures (in this case: as regards phytosanitary certification), whereas any other, bilateral arrangement is irrelevant for the definition;
- (7) The proposed definition of *integrity (of a consignment)* does not conflict with current uses of the term in adopted ISPMs.

Current definition

Integrity (of a consignment)	Composition of a consignment as described by its phytosanitary certificate or other officially acceptable document, maintained without loss, addition or substitution [CPM, 2007]
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Proposed revision

Integrity (of a consignment)	Composition State of a consignment when its identity is unchanged, its packaging undamaged and it shows no other signs of tampering as described by its phytosanitary certificate or other officially acceptable document, maintained without loss, addition or substitution
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2.3. “phytosanitary security (of a consignment)” (2013-008)

[21] The SC in 2013 agreed to combine the work on definitions for the inter-related terms ‘*identity (of a consignment)*’, ‘*integrity (of a consignment)*’ and ‘*phytosanitary security (of a consignment)*’, and added ‘*phytosanitary security (of a consignment)*’ to the TPG work programme.

[22] A first TPG draft ‘package’ of definitions including *phytosanitary security (of a consignment)* had been discussed by the SC in 2014, but the further development process put on hold, awaiting the output from the Expert Drafting Group on “*Focused revision of ISPM 12 (Phytosanitary certificates) in relation to re-export*” that met in December 2019. Subsequently, the TPG in January 2021 had submitted a new proposal, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021

and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending the revised definition unchanged for second consultation.

[23] The following explanatory points may be considered when reviewing the proposal:

- (1) *Phytosanitary security* is the term used for the (desirable) state of a consignment for which the *integrity* (cf. section 2.2) has been maintained and its infestation and contamination prevented.
- (2) The proposed revision does not change the substantial meaning of the term but aims at providing correct grammar, simplification, and consistency with the proposed definitions of *identity (of a consignment)* and *integrity (of a consignment)*.

[24] ‘*Maintenance of integrity*’ has been substituted to ‘*State...when...integrity has been maintained*’ to correctly reflect that phytosanitary security, as the term is being used in ISPMs, is a *state*, not an action (in analogy to the original and revised definition of ‘*integrity (of a consignment)*’);

- (1) Similarly, ‘*prevention of its infestation and contamination...*’ has been substituted to ‘*infestation and contamination...prevented*’;
- (2) The word ‘*appropriate*’ qualifying the ‘*phytosanitary measures*’ in the original definition is considered unnecessary and inappropriate for a definition and is therefore deleted;

Current definition

Phytosanitary security (of a consignment)	Maintenance of the integrity of a consignment and prevention of its infestation and contamination by regulated pests , through the application of appropriate phytosanitary measures [CPM, 2009]
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Proposed revision

Phytosanitary security (of a consignment)	Maintenance of the integrity State of a consignment when its integrity has been maintained and prevention of its infestation and contamination by regulated pests , prevented through the application of appropriate phytosanitary measures
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2.4. “emergency measure” (2020-004)

[25] In 2019, the TPG had proposed the revision of “*emergency action*” in the draft 2020 Amendments to the Glossary and had invited the SC to add the terms “*emergency measure*” and “*provisional measure*” to the TPG work programme. In November 2020, the SC added both terms to the List of topics for IPPC standards.

[26] At its January 2021 meeting, the TPG considered whether the definition of “*emergency measure*” needed amending because it refers to “*phytosanitary measure*” and “*provisional measure*”, which in turn relates to “*phytosanitary regulation*”, which relates to regulated pests.

[27] In 2001, the Interim Commission on Phytosanitary Measures Working Group on the Glossary of Phytosanitary Terms (GWG) noted that Article VII.6 of the Convention referred to “*emergency action*”, but no article referred to “*emergency measure*”. It was suggested that no particular distinction between “*emergency action*” and “*emergency measure*” was being made at the time the revised text was adopted. However, in hindsight, Article VII.6 should most probably refer to “*emergency measure*” and not to “*emergency action*”. It drew this point to the attention of the Interim Standards Committee. It noted further that the French text uses “mesures” and the Spanish text “medidas”.

[28] In 2004, the GWG noted the difference which was made between emergency measure / phytosanitary measure, emergency action / phytosanitary action, mostly in relation to the notification provisions. Some participants believed that emergency action is a type of phytosanitary measure, but others noted that it was not covered under the definition of phytosanitary measure, which refers to regulated pests, whereas emergency action could be taken on pests not regulated at all or regulated but not for the commodity

concerned. The GWG noted that emergency action /emergency measure and their relation to regulated pests should be considered further since it seemed that this left no place for action against pests which are not specifically regulated.

- [29] The Expert Working Group for the revision of ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) in 2004 discussed that emergency action is done on a single occasion and that an emergency measure is an established procedure of what would be done if an emergency situation arose. Therefore, emergency measures encompass emergency actions. It was indicated that the term was being used in the standard in a way not consistent with the Convention, so an explanatory note was included in section 2.11 (*Emergency measures*) of ISPM 1, stating that: “*The term emergency actions in Article VII.6 of the IPPC is interpreted to include emergency measures as defined in ISPM 5.*”
- [30] The TPG in its January 2021 meeting had submitted a proposal for a revised definition of “*emergency measure*”, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.
- [31] The following explanatory points may be considered when reviewing the proposal:
- (3) The use of “*emergency measure*” in adopted ISPMs is in relation to a new or unexpected phytosanitary situation:
 - A *new* phytosanitary situation results when a pest, not listed as a regulated pest, may require an emergency action because it has not been previously assessed. At the time of interception, it may be categorized as a regulated pest on a preliminary basis because the NPPO has a cause to believe it poses a pest risk.
 - An *unexpected* phytosanitary situation may arise when a pest, although regulated, is detected in an imported consignment and has not been listed or otherwise specified because it was not anticipated for the origin, commodity or circumstances for which the list or phytosanitary measure was developed, or is detected in an area and needs to be prevented from establishing or spreading following its recent entry;
 - (4) The use of “*phytosanitary measure*” in the current definition of “*emergency measure*” would imply that an emergency measure can only be used in relation to a regulated pest. However, this current definition contradicts the Convention text (Article VII.6), section 2.11 of ISPM 1, section 4.2 of ISPM 13 and section 5.1.6.2 of ISPM 20. In all these instances, emergency action/measure can be taken/applied on the detection of a pest, not regulated yet but that could pose a potential threat;
 - (5) “*Phytosanitary measure*” is replaced with “*official rule or procedure*” as a rule encompasses legislation, statute, etc., and procedure indicates a method or process; furthermore, the rule or procedure is official as it is established, authorized or performed by the NPPO;
 - (6) The word “*promptly*” is used to emphasize the rapid response to address the urgent situation;
 - (7) The text “*to prevent the entry, establishment or spread of a pest*” is inserted to replace “*phytosanitary*” and thus allows the deletion of “*phytosanitary measure*”; it qualifies the phytosanitary nature of the situation and the intent of the rule or procedure;
 - (8) The text “*not addressed by existing phytosanitary measures*” clarifies that the situation is critical from a phytosanitary standpoint and needs to be addressed.

Current definition

Emergency measure	A phytosanitary measure established as a matter of urgency in a new or unexpected phytosanitary situation. An emergency measure may or may not be a provisional measure [ICPM, 2001; revised ICPM, 2005]
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Proposed revision

Emergency measure	An phytosanitary measure official rule or procedure promptly established as a matter of urgency <u>to prevent the entry, establishment or spread of a pest</u> in a new or unexpected phytosanitary situation <u>not addressed by existing phytosanitary measures</u> . An emergency measure may or may not be a provisional measure
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2.5. “provisional measure” (2020-008)

- [32] In 2019, the TPG had proposed the revision of “*emergency action*” in the draft 2020 Amendments to the Glossary and had invited the SC to add the terms “*emergency measure*” and “*provisional measure*” to the TPG work programme. In November 2020, the SC added both terms to the List of topics for IPPC standards. At its January 2021 meeting, the TPG discussed the term “*provisional measure*”.
- [33] As per its current definition, a “*provisional measure*” is a phytosanitary regulation established without full technical justification. However, phytosanitary regulation is established to prevent the introduction or spread of quarantine pests or limit the economic impact of regulated non-quarantine pests.
- [34] Pest risk analysis (PRA) provides the technical justification for the regulation of a pest. Therefore the current definition of “*provisional measure*” contradicts the principle of establishing a phytosanitary regulation, which should be based on technical justification.
- [35] In reality, a provisional measure is applied following the detection of a new pest which, based on preliminary information, could be considered a potential quarantine pest. Further information in the form of completion of the PRA is required to determine the regulatory status of the pest and the appropriate phytosanitary measures. Provisional measures are established to prevent the introduction or spread of the pest for the duration it takes to complete the PRA. However, the inclusion of “*phytosanitary regulation*” in the current definition of “*provisional measure*” contradicts the use of provisional measures, which are established without full technical justification.
- [36] In order to address the discrepancy, the TPG looked into amending the definition of “*provisional measure*”. The TPG in its January 2021 meeting had submitted a proposal, reviewed by the SC in May 2021, and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending the revised definition unchanged for the second consultation.
- [37] The following explanatory points may be considered when reviewing the proposal:
- (1) The term “*phytosanitary regulation*” is replaced by “*temporary official rule*” in order to emphasize that a provisional measure is temporary in nature; rule encompasses legislation, statute, etc.; furthermore, the rule or procedure is official as it is established, authorized or performed by the NPPO;
 - (2) The text “*to prevent the entry, establishment or spread of a pest*” further enables the deletion of “*phytosanitary regulation*” and qualifies the phytosanitary nature and intent of the rule or procedure;
 - (3) Adhering to recommendations with FAO Style Guide 2021 recommendations to avoid the use of “owing to” except when used as a financial term, the wording is changed to “because of a”.

Current definition

Provisional measure	A phytosanitary regulation or procedure established without full technical justification owing to current lack of adequate information. A provisional measure is subjected to periodic review and full technical justification as soon as possible [ICPM, 2001]
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Proposed revision

Provisional measure	A phytosanitary regulation <u>temporary official rule</u> or procedure <u>to prevent the entry, establishment or spread of a pest</u> , established without full technical justification owing to because of a current lack of adequate information; and A provisional measure is subjected to periodic review and full technical justification as soon as possible
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2.6. “inspection” (2017-005)

- [38] During the revision of the definitions for ‘*test*’ and ‘*visual examination*’, the TPG in 2015 recognized that the definition of ‘*inspection*’ might be considered partly outdated due to technological advances. In 2017, the SC, therefore, added the term ‘*inspection*’ to the List of topics for IPPC standards for a possible revision. Subsequently, the TPG considered possible modifications to the definition to take into account the use of olfactory, acoustic or other types of tools that may assist inspectors in performing inspections.
- [39] A revised definition was presented to and considered by the SC in 2018. While confirming the need for retaining the distinction between the definitions of ‘*inspection*’ and ‘*test*’ (as often distinguished in ISPMs and phytosanitary legislation), the SC queried the need and feasibility of including other tools than ‘*visual examination*’ into ‘*inspection*’. Furthermore, noting that ISPM 23 (*Guidelines for inspection*) actually deals with the inspection of ‘*consignments*’ only, the SC noted two different uses of ‘*inspection*’ in ISPM 23: in some parts ‘*inspection*’ is used congruent to its current definition, in other parts explicitly stating that inspection also includes the processes of examination of documents and verification of identity and integrity of the consignment.
- [40] The SC did not reach consensus on the way forward and referred the term ‘*inspection*’ back to the TPG, to particularly evaluate the term in relation to ‘*test*’, the uses of ‘*inspection*’ in ISPM 23 and the possible future revision of that standard.
- [41] The TPG continued its discussion in its 2018, 2019 and 2021 meetings, also awaiting the parallel considerations of the consignment-related terms ‘*identity (of a consignment)*’, ‘*integrity (of a consignment)*’ and ‘*phytosanitary security (of a consignment)*’. In this process, the TPG concluded to dismiss proposed amendments to include other examination tools in the definition of “*inspection*” and reconfirmed that the distinction between ‘visual’ versus ‘other than visual’ examination in *inspection* and *test*, respectively, remains to be most important.
- [42] The TPG considered various ways to overcome the discrepancy between the current definition of ‘*inspection*’ and the broader use of the term (in less than 10 of altogether approximately 70 cases) in certain parts of ISPM 23. Considerations included:
- creating a supplementary definition of ‘*phytosanitary inspection*’ to include the processes of examination of documents and verification of the consignment’s identity and integrity,
 - broadening the definition of ‘*inspection*’ to include those processes.
- [43] However, the TPG finally concluded that, in particular given that:
- ‘*inspection*’ in its current narrow sense, i.e., referring only to the official visual examination of plants etc., is being used widely in many ISPMs, including in far the most of the cases within ISPM 23; and
 - the Glossary term ‘*compliance procedure (for a consignment)*’, already covering the verification of compliance with phytosanitary import requirements, would fit as the overarching term to be used in the particular parts of ISPM 23,
- [44] it would be appropriate to:
- retain the current, narrow definition of ‘*inspection*’; and

- adjust the very limited number of cases in ISPM 23 where ‘*inspection*’ had been used beyond its current definition by referring instead to ‘*compliance procedure (for a consignment)*’, as proposed for revision (cf. section 2.9).

[45] Following that approach, the proposed revision of ‘*inspection*’ only aims at improving the wording and consistency with other definitions. The SC reviewed the proposal at its meeting in May 2021 and sent it for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending the revised definition unchanged for the second consultation.

[46] The following explanatory points may be considered when reviewing the proposal:

- (1) Through Article VII.2f of the Convention and the definition of ‘*compliance procedure (for a consignment)*’, the terms ‘*compliance*’ and ‘*non-compliance*’ are linked with consignments, and the ‘General recommendations on use of terms in ISPMs’ stipulates ‘*conformity*’ be used in other cases. As *inspection* has a broader scope than only consignments, ‘*compliance*’ is therefore substituted by ‘*conformity*’;
- (2) The word ‘*determine*’ is substituted by ‘*check*’ to reflect the change from ‘*compliance*’ to ‘*conformity*’; it also avoids redundancy as ‘*determine*’ is used earlier in the sentence;
- (3) The term ‘*regulations*’ is substituted by ‘*requirements*’, as phytosanitary regulations are at a higher conceptual level and refer to regulated pests. However, inspection can be carried out in scenarios other than at import, like at place of production or production site or at export, and inspection in such scenarios may not always be related to regulated pests;
- (4) While the term ‘*inspection*’ needs substitution by ‘*compliance procedure*’ in a few cases in ISPM 23 (irrespective of the proposed revision), the use of the revised definition of ‘*inspection*’ does not conflict with the current uses of the term in adopted ISPMs.

Current definition

Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance with phytosanitary regulations [FAO, 1990; revised FAO, 1995; formerly “inspect”]
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Proposed revision

Inspection	Official visual examination of plants, plant products or other regulated articles to determine if pests are present or to determine compliance <u>check conformity</u> with phytosanitary <u>requirements regulations</u>
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2.7. “test” (2021-005)

[47] In January 2021, when concluding the proposed revision of ‘*inspection*’ (cf. section 2.7), the TPG recommended the consequential consistency revision of the definition of the related term ‘*test*’. The SC reviewed the proposal at its meeting in May 2021 and sent it for first consultation. *The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.*

[48] The proposed revision does not change the substance but merely aims at consistency of wording.

[49] The following explanatory points may be considered when reviewing the proposal:

- (1) Through Article VII.2f of the Convention and the definition of *compliance procedure (for a consignment)*, the terms ‘*compliance*’ and ‘*non-compliance*’ are linked with consignments, and the ‘General recommendations on use of terms in ISPMs’ stipulates ‘*conformity*’ be used in other

cases. As *test* has a broader scope than only consignments, the term ‘*compliance*’ is therefore substituted by ‘*conformity*’;

- (2) The word ‘*determine*’ is substituted by ‘*verify*’ in order to highlight that in the case of testing, the use of appropriate methods and technology would ensure that the result of the test leads to a decision. In this case, test is a decisive action, and the use of the word ‘*verify*’ to describe the action would be more appropriate.

Current definition

Test	Official examination of plants, plant products or other regulated articles , other than visual, to determine if pests are present, identify pests or determine compliance with specific phytosanitary requirements [FAO, 1990; revised CPM, 2018]
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Proposed revision

Test	Official <u>non-visual</u> examination of plants, plant products or other regulated articles , other than visual , to determine if pests are present, identify pests or determine compliance <u>verify conformity</u> with specific phytosanitary requirements
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2.8. “compliance procedure (for a consignment)” (2021-006)

[50] In May 2019, the SC added ‘*clearance (of a consignment)*’ to the List of topics for IPPC standards for a possible revision. Subsequently, a proposed revised definition to clarify that ‘*clearance (of a consignment)*’ is a process rather than a result of such a process was sent for consultation in 2020. In response to comments received, the TPG recommended to the SC that the consignment-related terms ‘*clearance (of a consignment)*’ (cf. section 3.1), ‘*compliance procedure (for a consignment)*’ and ‘*release (of a consignment)*’ (cf. section 2.10) be considered together.

[51] At the same time, in the continued TPG discussions on how to resolve the discrepancy between certain parts of ISPM 23 and the definition of ‘*inspection*’ (cf. section 2.7), the TPG concluded that the Glossary term ‘*compliance procedure (for a consignment)*’ would fit as the overarching term to be used in those parts of ISPM 23, whereby the discrepancy would be resolved through a very limited number of adjustments to ISPM 23. *The SC reviewed the proposal at its meeting in May 2021 and sent it for first consultation.* The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.

[52] The following explanatory points may be considered when reviewing the proposal:

- (1) The proposed revision in particular aims at expanding on the possible elements (as outlined in ISPM 23) of a compliance procedure by explicitly including and creating links to ‘*inspection*’, ‘*test*’, and the examination of documents and verification of the consignment’s ‘*integrity*’.

[53] The addition of ‘*of document checks, verification of consignment integrity, inspection or testing*’ serves to more specifically explain which elements a compliance procedure may consist of, and thereby creating a clear link to those concepts and definitions. It is noted that the proposed revised definition of *integrity (of a consignment)* includes the ‘*identity is unchanged*’ so that verification of integrity includes verification of identity;

- (1) ‘*Procedure*’ is substituted by ‘*process*’ in order to highlight that it is a series of steps or actions that are performed and, when completed, leads to the release of a consignment or transit through a country;
- (2) In the current phrasing ‘*...or phytosanitary measures related to transit*’, the wording ‘*phytosanitary measures*’ is potentially confusing: ‘*phytosanitary measures*’ in ISPM 25 “*Consignments in transit*” is being used mainly in referring to such measures that the country of

transit itself may apply to the transiting consignment (i.e., measures irrelevant for applying a compliance procedure), and to a lesser extent used in referring to measures that the exporter or exporting country may be required to apply prior to export (i.e., measures relevant for applying a compliance procedure). *Thus, changing ‘measures’ to ‘requirements’ clarifies that applying a compliance procedure in the transit case aims at verifying that the transiting consignment meets the set phytosanitary requirements;*

- (3) The proposed definition of ‘*compliance procedure (for a consignment)*’ does not conflict with the current uses of the term in ISPMs.

Current definition

compliance procedure (for a consignment)	Official procedure used to verify that a consignment complies with phytosanitary import requirements or phytosanitary measures related to transit [CEPM, 1999; revised CPM, 2009]
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Proposed revision

compliance procedure (for a consignment)	Official procedure used to verify that <u>process of document checks, verification of consignment integrity, inspection or testing</u> to verify if a consignment complies with phytosanitary import requirements or phytosanitary measures <u>requirements</u> related to transit
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2.9. “release (of a consignment)” (2021-007)

- [54] In January 2021, when discussing the proposed deletion of ‘*clearance (of a consignment)*’, the TPG recommended the consequential revision of the definition of ‘*release (of a consignment)*’. The SC reviewed the proposal at its meeting in May 2021 and sent it for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. The SC is now sending an amended proposal for the revised definition for second consultation.

The following explanatory points may be considered when reviewing the proposal:

- (1) The revision does not change the substance of the definition but merely links *release* to *compliance procedure* rather than to *clearance* (as proposed for deletion, cf. section 3.1);
- (2) Strictly speaking, the proposed insertion of ‘*of a consignment*’ is redundant, given the qualifier of the term (‘*of a consignment*’). However, the insertion makes the wording as a stand-alone definition clearer in contrast to the term and definition of ‘*release (into the environment)*’;
- (3) The revised definition of *release (of a consignment)* does not conflict with the current uses of the term in adopted ISPMs.

Current definition

release (of a consignment)	Authorization for entry after clearance [FAO, 1995]
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Proposed revision

release (of a consignment)	Authorization for entry <u>of a consignment</u> after <u>completion of the compliance procedure</u> clearance
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3. DELETIONS

3.1. “clearance (of a consignment)” (2018-045)

- [55] In 2018, the TPG had noted that the definition of ‘*clearance (of a consignment)*’ is unclear as to whether clearance is a particular *process* or the *result* of a process and recommended the definition be revised. In May 2019, the SC added ‘*clearance (of a consignment)*’ to the List of topics for IPPC standards.

Subsequently, a revised definition to clarify that clearance is a *process* rather than a result of such process and that such process is ‘official’ was sent for the first consultation in 2020. In response to comments received from several countries, the TPG recommended to the SC that the consignment-related terms ‘*clearance (of a consignment)*’, ‘*compliance procedure (for a consignment)*’ (cf. section 2.9) and ‘*release (of a consignment)*’ (cf. section 2.10) be considered together.

[56] In its meeting in December 2020 / January 2021, the TPG concluded that the Glossary terms ‘*clearance (of a consignment)*’ (in its prospective revised form) and ‘*compliance procedure (for a consignment)*’, in essence, are almost synonymous, given the general agreement at the consultation that clearance is an ‘official process’. The TPG concluded that the term ‘*clearance (of a consignment)*’ is redundant, both in its current and prospective revised form, and therefore recommended the term and definition be deleted from the Glossary. Consequential to the proposed deletion, the definition of ‘*release (of a consignment)*’ would need a slight revision (as proposed, cf. section 2.10), and some very few ink amendments in adopted ISPMs are recommendable.

[57] The SC reviewed the proposal at its meeting in May 2021 and sent it for first consultation, from which no comments were received.

Definition to be deleted

Clearance (of a consignment)	Verification of compliance with phytosanitary regulations [FAO, 1995]
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3.2. “germplasm” (2020-005)

[58] “*Plants for planting*” and “*germplasm*” had entered the Glossary independently and the distinction between the terms in practice had not been closely considered. “*Germplasm*” is considered to generally present a higher pest risk than other “*plants for planting*”, since it may originate relatively recently from wild plants, and information on its possible infestation by pests may be limited and based on a relatively short period of observation.

[59] In 2019, the TPG recognized the definition of the term “*germplasm*” as being a subset of “*plants for planting*”. At the TPG’s recommendation, the SC in 2020 added “*germplasm*” to the to the list of topics for IPPC standards.

[60] The TPG in 2021 proposed that the revised definition of “*germplasm*” should refer to “*plants for planting*” and not just “*plants*”. The proposal was reviewed by the SC in May 2021 and sent for first consultation. The TPG in December 2021 and the SC-7 in May 2022 considered the consultation comments received. Based upon consultation comments, and in particular considering that:

- (1) the term is rarely used in ISPMs;
- (2) the proposed revision may lead to confusion rather than clarity;
- (3) the current definition is not different from ordinary dictionary meaning, not specific to the IPPC and therefore not particularly needed;
- (4) the CPM has recently deleted several other terms and definitions for commodities from the Glossary.

[61] The SC-7 is now proposing the term and definition be deleted.

Definition to be deleted

Germplasm	Plants intended for use in breeding or conservation programmes [FAO, 1990]
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Appendix 5: Draft annex *Use of specific import authorizations (2008-006) to ISPM 20 (Guidelines for a phytosanitary import regulatory system)*

DRAFT ANNEX TO ISPM 20: Use of specific import authorizations (2008-006)

Status box

This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
Date of this document	2022-05-26
Document category	Draft annex to ISPM
Current document stage	To second consultation
Major stages	2008-04 CPM-3 added the topic <i>Use of specific import authorization (Annex to ISPM 20: Guidelines for a phytosanitary import regulatory system) (2008-006)</i> with priority 4. 2016-11 Standards Committee (SC) approved Specification 64 (<i>Use of specific import authorizations</i>) via e-decision (2016_eSC_May_05). 2021-02 Expert working group met virtually and drafted the annex. 2021-05 SC revised and approved for first consultation. 2021-07 First consultation. 2022-05 SC-7 revised and approved for second consultation.
Steward history	2022-05 SC Álvaro SEPÚLVEDA LUQUE (CL, Lead Steward) 2019-05 SC Ezequiel FERRO (AR, Lead Steward) 2016-05 SC Moses Adegboyega ADEWUMI (NG, Assistant Steward)
Notes	2021-03 Edited 2021-03 review by lead steward 2021-05 Edited 2022-05 Edited

This annex was adopted by the XXX Session of the Commission on Phytosanitary Measures in XXX 20XX.

This annex is a prescriptive part of the standard.

ANNEX 2: Use of specific import authorizations

[1] The national plant protection organizations (NPPOs) of importing countries may choose to use specific import authorizations (SIAs) as referred to in this standard (section 4.2.2) when official consent for import is necessary, when import would otherwise be prohibited for phytosanitary reasons, or when phytosanitary import requirements for the particular purpose, articles or situations have not yet been established. Even when using SIAs as part of their phytosanitary import regulatory system, NPPOs are still required to make their phytosanitary import requirements available as described in section 5.1.9.2 of this standard and in Article VII.2(b) of the IPPC.

[2] This annex describes situations where the use of SIAs may be required by an NPPO, the information that should be included on SIAs, and the respective responsibilities of the parties involved. Specific import authorizations are generally applied on a case-by-case basis and tailored to each specific import situation. They may be issued for individual consignments or a series of consignments. Although it is noted that some countries include non-phytosanitary requirements in their SIAs, this annex addresses only phytosanitary requirements. This annex does not cover transit authorization. This annex also does not cover information on general import authorizations, which can be found in section 4.2.2 of this standard.

1. Types of specific import authorizations

[3] Specific import authorizations may be provided in the form of import permits, licences or other types of written authorization as determined by the NPPO of the importing country, and may be in either paper or electronic format.

2. Elements of specific import authorizations

[4] When SIAs are used, they should be issued by the NPPO of the importing country to importers.

2.1 Information requirements

The following information is the minimum information that should be included in SIAs:

- name of the NPPO, contact information for verification purposes, and name of the importing country;
- identification code or SIA number;
- importer's information (e.g. name and address of importer);
- date of issuance;
- description of the consignment covered by the SIA;
- country of origin and country of export or re-export;
- intended use of the commodity or commodities that make up the consignment;
- phytosanitary import requirements (where these have been established); and
- period of validity.

[5] Other information may also be included in SIAs, such as:

- quantity of the consignment (number of units that make up the consignment, or its weight);
- whether the authorization is for an individual or a series of consignments;
- means of conveyance;
- point of entry;
- issuing officer;
- exporter;
- location to which consignments are to be directed (e.g. post-entry quarantine facility, processing facility); and
- treatment provider.

2.2 Language

[6] The NPPOs of importing countries may choose the language or languages in which their SIAs are issued but are encouraged to also use one of the official languages of the Food and Agriculture Organization of the United Nations, preferably English.

3. Uses of specific import authorizations

[7] The following examples of purposes, articles and situations related to import indicate where use of SIAs may be appropriate:

- research and scientific purposes;
- exhibition purposes;
- educational purposes;
- religious or cultural purposes (e.g. religious festivals, ancestral customs);
- articles for which the NPPO of the importing country requires the ability to trace and manage over a period of time after entry (e.g. articles subject to post-entry quarantine or processing);
- emergency or exceptional situations;
- biological control agents and other beneficial organisms;
- situations where general import authorizations have not been developed or it is not possible to develop them; and
- articles that are not routinely imported.

[8] The list above is not intended to be exhaustive and countries are not required to use SIAs for the examples provided.

4. Responsibilities

4.1 The NPPO of the importing country

[9] When using SIAs, the NPPO of the importing country should comply with the principles described in the IPPC and ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*), such as those relating to minimal impact, transparency, non-discrimination, technical justification and cooperation.

[10] The responsibilities of the NPPO of the importing country should include elements such as:

- publishing (e.g. on the NPPO website) information on the regulated articles and intended uses for which an SIA is required;
- having a process in place for assessing and identifying the information that will be needed for SIAs and setting up SIAs;
- having a process in place for amending, suspending or revoking SIAs, including a process to communicate with relevant parties when this occurs;
- publishing the process by which an importer can apply for an SIA and the application form that the importer needs to complete;
- communicating all requirements to the importer;
- issuing an SIA without undue delay if the requirements for the SIA are met;
- defining the language or languages used in SIAs;
- clearly specifying phytosanitary import requirements in SIAs (where these have been established);
- providing the NPPOs of exporting countries, on request, with information to verify the authenticity of SIAs and provide clarification as needed; and
- monitoring trade under SIAs and considering transferring SIAs to general import authorizations where appropriate.

4.2 Importers

[11] The responsibilities of importers, as determined by the NPPO of the importing country, may include:

- applying for an SIA before import in situations where an SIA is required;
- complying with the requirements of the SIA;
- providing the SIA to the exporter;
- if required, notifying the NPPO of the importing country of the timing of the import or other information; and
- when necessary, providing a translation of the SIA in a language that the NPPO of the exporting country can understand.

4.3 Exporters

[12] The responsibilities of exporters may include:

- obtaining an SIA from the importer before export if an SIA is required;
- complying with the requirements of the SIA;
- submitting a legible SIA to the NPPO of the exporting country; and
- when necessary, providing a translation of the SIA in a language that the NPPO of the exporting country can understand.

4.4 The NPPO of the exporting country

[13] The responsibilities of the NPPO of the exporting country may include:

- obtaining the SIA; and
- certifying the compliance of plants, plant products or other regulated articles with the phytosanitary import requirements when a request for phytosanitary certification is accompanied by an SIA.

Potential implementation issues

[14] This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.

Appendix 6: Draft revision of ISPM 4 (*Requirements for the establishment of pest free areas*) (2009-002)

DRAFT ISPM: Revision of ISPM 4 (*Requirements for the establishment of pest free areas*) (2009-002)

Status box

This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
Date of this document	2022-05-25
Document category	Draft revision of ISPM
Current document stage	To second consultation
Major stages	<p>2009-11 Standards Committee (SC) recommended topic <i>Revision to ISPM 4</i> (Requirements for the establishment of pest free areas) (2009-002) be added to the work programme.</p> <p>2010-03 CPM-5 added topic to the work programme with high priority (subsequently changed to priority 4 by CPM-10).</p> <p>2010-11 SC deferred.</p> <p>2013-11 SC approved Specification 58.</p> <p>2015-10 Secretariat revised Specification 58 to incorporate task on references to ISPM 4 as requested by the 2014-11 SC.</p> <p>2020-12 / 2021-01 Expert working group met virtually and drafted standard.</p> <p>2021-05 SC revised and approved for first consultation.</p> <p>2021-07 First consultation.</p> <p>2022-05 SC-7 revised and approved for second consultation.</p>
Steward history	<p>2015-11 SC Marina ZLOTINA (US, Lead Steward)</p> <p>2019-05 SC David KAMANGIRA (MW, Assistant Steward)</p>
Notes	<p>THIS IS A DRAFT DOCUMENT</p> <p>2021-02 Edited</p> <p>2021-05 Edited</p> <p>2022-05 Edited</p>

CONTENTS [to be inserted]

Adoption

- [1] Text to this paragraph will be added following adoption.

INTRODUCTION

Scope

- [2] This standard describes the requirements for initiating, establishing and maintaining pest free areas (PFAs) as a phytosanitary measure to support the phytosanitary certification of plants, plant products and other regulated articles exported from the PFA or, if technically justified, as a phytosanitary measure required by the national plant protection organization (NPPO) of an importing country for the protection of an endangered area in its territory.
- [3] This standard does not cover pest free places of production or pest free production sites, the requirements for which can be found in ISPM 10 (*Requirements for the establishment of pest free places of production and pest free production sites*).

References

- [4] The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at www.ippc.int/core-activities/standards-setting/ispms.

Definitions

- [5] Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of requirements

- [6] A PFA is a phytosanitary measure that may be used to facilitate safe trade and protect plant resources. National plant protection organizations should consider a PFA to be a phytosanitary measure that, when used alone, is sufficient for managing pest risk.
- [7] When initiating, establishing or maintaining a PFA, NPPOs should follow the requirements outlined in this standard. Requirements include systems to establish and maintain pest freedom, verification that pest freedom has been attained or maintained, appropriate corrective actions for pest detections, proper documentation of these activities and appropriate record-keeping, and transparency and stakeholder communication. The measures used to establish or maintain the PFA should be based on an assessment of pest risk.

BACKGROUND

- [8] A PFA is recognized as one of the pest risk management options that contracting parties may consider implementing as a phytosanitary measure to protect the plant resources of an area for agricultural, forestry or ecological conservation purposes, facilitate safe trade, or increase the market-access opportunities for exporting countries. Pest free areas can offer a cost-effective way for NPPOs and industry in both importing and exporting countries to manage pest risk.
- [9] According to Article IV.2(e) of the IPPC, the responsibility for the designation, maintenance and surveillance of PFAs lies with NPPOs. The operational principles outlined in ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) also require contracting parties to take into account the status of an area as a PFA when determining phytosanitary measures for imports from that area.
- [10] A PFA may be applied to an entire country or part of it. A PFA may, as appropriate, include the territory of all or parts of several countries. Within a single country, more than one PFA may be established for the same pest, depending on the geographical nature of the country, the distribution of the pest and its hosts and the biology of the pest.
- [11] When a PFA is established it is usually for one specific pest, but a PFA may also be established for a group of pests with similar biology. In this standard, “pest” is used hereafter to refer to “pest or group of pests”.

IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

- [12] This standard may contribute to the protection of biodiversity and the environment by preventing the introduction of regulated pests into an area. When establishing and maintaining PFAs, countries are encouraged to consider phytosanitary procedures that minimize impact on the environment.

REQUIREMENTS

- [13] A PFA should be considered a phytosanitary measure that, when used alone, is sufficient for managing the pest risk associated with a specific pest. Where a PFA has been established and maintained in

accordance with the requirements of this standard, additional phytosanitary measures in relation to the specified pest should not be imposed.

[14] The requirements that should be met for a PFA to be established and to be used as a phytosanitary measure for trade are detailed below. Depending on the pest concerned, an individual or a combination of measures may be used to meet each requirement.

[15] Requirements for the establishment and maintenance of a PFA by an NPPO include:

- systems to establish pest freedom;
- programmes to maintain pest freedom;
- verification that pest freedom has been attained;
- verification that pest freedom has been maintained;
- corrective actions for detections of the specified pest;
- documentation of these activities and appropriate record-keeping; and
- transparency and communication with other NPPOs and stakeholders.

[16] The following elements should be considered when establishing and maintaining a PFA:

- measures should be based on the biology of the specified pest, the relevant pathways and the characteristics of the PFA;
- the availability of appropriate surveillance tools for the specified pest (detection and identification);
- the existence of an appropriate legislative framework to support the establishment and maintenance of the PFA;
- the support from relevant stakeholders, such as domestic industries and local regulatory bodies; and
- the importance of communicating with and raising awareness among other NPPOs, stakeholders and the general public.

[17] In addition, NPPOs may wish to consider the feasibility of the PFA in terms of resource availability (economic, human and technical) over the long term as well as the cost-benefit.

1. Initiation of a pest free area

1.1 Pest to be controlled

[18] When initiating a PFA, an NPPO should first specify the pest that is to be controlled (including its scientific name) and identify valid diagnostic methods and relevant aspects of its biology. In the following sections of this standard, this pest is referred to as “the pest”.

1.2 Identification of the area

[19] The area being considered for pest freedom may be the entire country, a part of a country, or all or part of several countries. The area should be described specifically enough to allow it to be readily identified. This is important when NPPOs are providing evidence to support the claim that the area is free of the pest, but also when NPPOs are subsequently reporting the pest status of the PFA and when raising public awareness.

[20] Pest free areas may be delimited by natural barriers such as bodies of water, mountains, deserts or other geographical features that prevent pest movement from one area to another.

1.3 Suitability of ecological conditions in the area

[21] The NPPO of the country in which the area is situated should determine the presence of host plants in the area. Potential differences in host susceptibility in the specified area, the climatic suitability of the area, and the potential for entry and establishment of the pest in the area should also be considered.

2. Establishment of the pest free area

2.1 Determination of pest status in the area

[22] Once the pest has been specified and the area identified, the NPPO should determine the pest status in the area by conducting surveillance in accordance with the requirements outlined in ISPM 8 (*Determination of pest status in an area*) and ISPM 6 (*Surveillance*).

[23] Where more reliable evidence is needed to demonstrate pest absence in an area, specific surveillance should be conducted rather than general surveillance. The level of specific surveillance (i.e. the type and frequency of surveys) should be based on the results of an assessment of the potential for entry and establishment of the pest in the area. The specific surveillance should include a delimiting survey or a detection survey to justify the area that is being proposed as a PFA.

[24] If the pest status is “absent: pest not recorded” as defined in ISPM 8 and this is supported by current scientific evidence – such as from continued surveillance for pest absence in the area, the results of which are made available on request – then establishing a PFA should not be required by importing countries.

[25] In addition to its use in determining pest status, surveillance in the context of PFAs may also be used to:

- determine pest distribution and abundance;
- delimit a pest population;
- assess the effectiveness of eradication measures taken; or
- provide data to report to other NPPOs.

2.2 Controls on the movement of regulated articles

[26] To prevent the entry of the pest into the area, the potential pathways should be identified and appropriate controls on the movement of regulated articles should be established. The movement controls should depend on the assessed pest risk, including the probability of pest establishment. Such controls should include:

- inclusion of the pest on a list of regulated pests;
- regulation of the pathways and articles that require control;
- imposition of domestic restrictions or other measures to control the movement of regulated articles into or through the area;
- inspection of regulated articles, examination of the relevant documentation and, where necessary for cases of non-compliance, the application of appropriate measures.

2.3 Establishment of buffer zones

[27] Where the geographical isolation of the area is not adequate to prevent the natural spread of the pest into it, the establishment of a buffer zone should be considered. The population of the pest in the buffer zone should be maintained at or below a specified level, which should be verified by surveillance. The extent of the buffer zone should be determined by the NPPO, based on the distance over which the likely natural spread of the pest population to the area could not occur during the season when hosts are present. The NPPO should describe, with the use of supporting maps, the boundaries of the buffer zone.

2.4 Official declaration of pest freedom

- [28] When the pest status is determined as absent (according to ISPM 8), or eradication of the pest from the target area is achieved (according to ISPM 9 (*Guidelines for pest eradication programmes*)), the NPPO should make an official declaration that the area is free from the pest. All internal management procedures and phytosanitary measures to maintain the PFA (see section 3) should be in place before this declaration is made.

3. Maintenance of the pest free area

- [29] The NPPO of the country in which the PFA is situated should set up a programme to ensure maintenance of the PFA. This programme should be risk-based and should incorporate at least the following elements: a regulatory framework to control the movement of regulated articles; routine surveillance and collection of relevant data to inform the management of the PFA, including outbreak management; a framework for reporting pest detections; and contingency plans for corrective action in the event of an outbreak, with associated rules for suspension and reinstatement of the PFA.

3.1 Regulatory framework

- [30] The regulation of the pest through the controls of the movement of regulated articles (see section 2.2) should be sufficient to prevent its entry into the PFA. Where appropriate, buffer zones may be established with rules for intensified surveys to ensure early detection of the spread of the pest into the vicinity of the PFA. The phytosanitary measures should also allow traceability of regulated articles introduced into the PFA or moving within the PFA, so that the appropriate corrective actions can be taken in a timely manner.

3.2 Surveillance for the maintenance of the pest free area

- [31] Surveillance should be conducted on a regular basis to verify that the absence of the pest from the PFA is maintained.
- [32] The decision about whether general surveillance for the pest is sufficient or specific surveillance is needed should be based on the risk of the pest's entry and establishment in the PFA and depends on the biology of the pest, the relevant entry pathways and the characteristics of the PFA.
- [33] General surveillance may be sufficient in cases where the pest has never been introduced into the PFA, nor into the surrounding areas, and there have been no records of the pest's presence in the PFA.
- [34] Specific surveillance to detect possible outbreaks of the pest at an early stage should be the standard procedure in all other cases. The type and frequency of the surveys should be based on an assessment of the potential for pest entry and establishment in the PFA and should allow detection of the pest with an appropriate level of confidence.

3.3 Notification of detection of the pest

- [35] A reporting framework should be established to ensure that detections of the pest are immediately notified to the NPPO (or other competent authority delegated by the NPPO) and officially confirmed.

3.4 Corrective action plans, including response to an outbreak

- [36] In the event of the pest being detected in the PFA, the NPPO should determine, based on ISPM 6 and ISPM 8, the type of corrective action to be taken. An eradication programme should be initiated unless the pest can be eradicated immediately, or evidence indicates that there is no risk of the pest establishing or no risk of it being spread outside the PFA by infested or contaminated regulated articles.
- [37] Preparedness for rapid intervention may be ensured by developing a corrective action plan in advance, including plans for rapid technical assessment of the situation, availability of financial and human resources, the roles and responsibilities of decision makers, and the operational activities that are likely

to be needed (in the form of a draft action plan). To assist in preparedness, regular simulation exercises may be used to review the effectiveness of the corrective action plan.

[38] The eradication programme should follow ISPM 9 and include the following steps.

3.4.1 Delimiting survey to demarcate the outbreak area

[39] As soon as the detection of the pest has been officially confirmed in the PFA, a delimiting survey should be conducted to determine the boundary of the infested area. Based on this determination and an assessment of the pest biology, the relevant pathways and the characteristics of the PFA, an outbreak area within the PFA should be demarcated and the PFA should be temporarily suspended therein. This demarcated outbreak area should consist of the infested area surrounded by a buffer zone, the size of which should depend on the biology of the pest, the presence of host plants and the ecological conditions.

3.4.2 Implementation of control measures

[40] Control measures should be applied to prevent the pest moving out of the demarcated outbreak area by human activities (e.g. through the movement of infested host plants or plant products, or contaminated means of conveyance) or, to the extent that is reasonably achievable, by natural spread.

[41] Measures to eradicate the pest should be implemented in accordance with ISPM 9.

3.4.3 Increased surveillance in the demarcated outbreak area

[42] An intensive survey should be used in the demarcated outbreak area to determine and record the distribution of the pest and its population dynamics, and to assess the effectiveness of the eradication measures. This intensive survey should be maintained until the pest is eradicated from the outbreak area.

3.5 Provisions for suspension, reinstatement or withdrawal of the pest free area

[43] Criteria for successful eradication in accordance with ISPM 9 should be established before the start of the eradication programme, including the intensity of the survey in the demarcated outbreak area and the minimum period that the outbreak area needs to be free from the pest before lifting the suspension of the PFA.

[44] If the criteria are fulfilled, then eradication may be officially declared successful and the temporary control and eradication measures may be lifted. The full PFA may then be reinstated.

[45] If the criteria for eradication within the demarcated outbreak area cannot be fulfilled within a reasonable timeframe to be determined by the NPPO, then either the PFA should be withdrawn or the delimitation of the PFA should be reviewed.

4. Verification of pest freedom and regular review

[46] Once the PFA is established, the performance of the PFA maintenance programme should be regularly reviewed. This review should allow the NPPO to find and correct deficiencies, incorporate any new and relevant information on the pest or associated pathways, and adjust and improve the maintenance programme accordingly.

[47] The correct implementation of the maintenance programme, including the administrative activities, should be verified.

[48] Traceability procedures for the movement of regulated articles should allow the verification of their origin and conformity with the phytosanitary requirements set for the PFA.

5. Data collection, documentation and record-keeping

[49] The data from the surveillance (e.g. time of surveillance, number and type of plants inspected, number of samples taken for inspection, number of samples taken for laboratory analysis, analytical methods

used, results of the analyses, and other relevant information as required by ISPM 6) should be stored and kept available for a sufficient time to ensure the possibility of traceability and verification.

- [50] The measures used to establish and maintain the PFA should be adequately documented. The documentation should be reviewed regularly, updated as needed, and include any amendments. Records of the procedures to establish, maintain and implement corrective actions should be kept for a minimum of 24 months, or longer depending on the biology of the pest.

6. Communication and stakeholder engagement

- [51] Individuals, groups or organizations other than the NPPO of the country in which the PFA is situated can also affect, or be affected, by the actions to establish and maintain the PFA. The NPPO may establish partnerships with stakeholders, which may include seeking contributions of resources.
- [52] Information about the establishment and maintenance of the PFA, including information about the methodology, results of surveys and pest diagnostics, and other relevant information supporting the claim of pest freedom, should be made available on request to relevant stakeholders and other NPPOs.
- [53] Maps and information about the phytosanitary measures applied to maintain the PFA should be communicated to relevant stakeholders.
- [54] To achieve the support of the community, NPPOs are encouraged to raise public awareness about PFAs in their territory, including the framework for reporting sightings of the pest, the phytosanitary measures applied to establish in the PFAs, and the importance of maintaining the PFAs.

7. Recognition of pest free areas

- [55] Bilateral recognition of PFAs should take place in accordance with ISPM 29 (*Recognition of pest free areas and areas of low pest prevalence*).

Potential implementation issues

- [56] This section is not part of the standard. The Standards Committee in May 2016 requested the secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.

Appendix 7: Draft revision of ISPM 18 (*Requirements for the use of irradiation as a phytosanitary measure*) (2014-007)

DRAFT Revision of ISPM 18: Requirements for the use of irradiation as a phytosanitary measure (2014-007)

Status box

This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
Date of this document	2022-05-31
Document category	Draft revision of ISPM
Current document stage	To second consultation
Major stages	<p>2014-03 CPM-09 added topic <i>Requirements for the use of irradiation as a phytosanitary measure (Revision to ISPM 18)</i> (2014-007) to the work programme with priority 2 (subsequently changed to priority 3 by CPM-10 (2015) and to priority 1 by the Standard Committee (SC) (e-decision 2020_eSC_Nov_02)).</p> <p>2014-05 IPPC Secretariat, supported by the Technical Panel on Phytosanitary Treatments (TPPT), developed the generic specification (2014-008) for the development of five standards; SC agreed to this approach.</p> <p>2015-05 SC approved Specification 62 (<i>Requirements for the use of phytosanitary treatments as phytosanitary measures</i>).</p> <p>2020-12 TPPT started the revision.</p> <p>2021-02 (two meetings) TPPT revised the draft.</p> <p>2021-05 SC revised and approved for first consultation.</p> <p>2021-07 first consultation.</p> <p>2022-05 SC-7 revised and approved for second consultation.</p>
Steward history	<p>2016-11 David OPATOWSKI (IL, Steward)</p> <p>2020-10 Guy HALLMAN (US, Assistant Steward)</p>
Notes	<p>2021-03 Edited</p> <p>2021-05 Edited</p> <p>2022-05 Edited</p>

CONTENTS [to be inserted]

Adoption [to be revised following adoption]

- [1] This standard was first adopted by the Fifth Session of the Commission on Phytosanitary Measures in April 2003. This first revision was adopted by the [XXXX] Session of the Commission on Phytosanitary Measures in [Month YYYY].

INTRODUCTION

Scope

- [2] This standard provides technical guidance on the application of ionizing radiation as a phytosanitary measure. This standard does not provide details on specific irradiation treatments, such as specific schedules for specific regulated pests on specific commodities, or treatments used for the production of sterile organisms for pest control.

References

- [3] The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at www.ippc.int/core-activities/standards-setting/ispms.

APPPC (Asia and Pacific Plant Protection Commission). 2014. *Approval of irradiation facilities.* Regional Standard for Phytosanitary Measures (RSPM) 9. Bangkok, APPPC, FAO Regional Office for Asia and the Pacific. 20 pp.

ISO/ASTM 51261:2013. *Practice for calibration of routine dosimetry systems for radiation processing,* 2nd edn. United States of America, International Organization for Standardization and ASTM International. 18 pp.

IAEA (International Atomic Energy Agency). 2015. *Manual of good practice in food irradiation – Sanitary, phytosanitary and other applications.* Technical Reports Series No. 481. Vienna, IAEA. 85 pp.

ISO 14470:2011. *Food irradiation – Requirements for the development, validation and routine control of the process of irradiation using ionizing radiation for the treatment of food.* Geneva, International Organization for Standardization. 20 pp.

Definitions

- [4] Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

Outline of requirements

- [5] This standard provides guidance on irradiation and its application as a phytosanitary measure to comply with phytosanitary import requirements.
- [6] The roles and responsibilities of parties involved in the use of irradiation as a phytosanitary measure are described. Guidance is provided to national plant protection organizations (NPPOs) on responsibilities for approving treatment facilities, and for monitoring and auditing treatment facilities and providers.

BACKGROUND

- [7] The purpose of this standard is to provide generic requirements for the application of ionizing radiation as a phytosanitary measure, specifically for those treatments adopted under ISPM 28 (*Phytosanitary treatments for regulated pests*).
- [8] ISPM 28 was adopted to harmonize effective phytosanitary treatments over a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may facilitate safe trade. ISPM 28 provides requirements for submission and evaluation of efficacy data and other relevant information on phytosanitary treatments. The annexes of ISPM 28 contain specific irradiation treatments that have been evaluated and adopted by the Commission on Phytosanitary Measures.
- [9] Irradiation is considered to be effective when the phytosanitary treatment dose of ionizing radiation (hereafter referred to as the “phytosanitary treatment dose”) required by the treatment schedule is absorbed at the location in the process load that receives the lowest dose of radiation. Therefore, process control relies on identifying the minimum dose location for a specific loading configuration of a commodity and routinely delivering to this location a dose of ionizing radiation (a minimum dose) that is equal to or greater than the required phytosanitary treatment dose. The effectiveness of the treatment process also includes measures applied to prevent infestation or contamination after irradiation.

IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

- [10] The use of irradiation as a phytosanitary measure has a beneficial impact on biodiversity and the environment by preventing the introduction and spread of regulated pests with the trade of plants and plant products.

REQUIREMENTS

1. Irradiation objective

[11] The objective of using irradiation as a phytosanitary measure is to achieve, at a specified efficacy, certain pest responses such as:

- mortality;
- inability to develop successfully (e.g. non-emergence of adults);
- inability to reproduce (e.g. sterility);
- inactivation; or
- devitalization of plants as pests (e.g. seeds may germinate but seedlings do not grow; or tubers or bulbs do not sprout).

[12] A range of specific options may be specified where the required response is the inability of the pest to reproduce. These may include:

- complete sterility in one or both sexes;
- oviposition or hatching without further development; or
- sterility of the F₁ generation.

2. Irradiation application

[13] Ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or caesium-137), electrons (up to 10 MeV) or X-rays (up to 7.5 MeV) generated from machine sources. The unit of measurement for absorbed dose is the gray (Gy).

[14] The phytosanitary treatment dose is the minimum dose required to achieve the pest response at the specified efficacy. The treatment is dependent upon the understanding of dose distribution within the loading configuration and consistent presentation of the process load to the ionizing radiation. Factors that may alter the effectiveness of the treatment may include inconsistent loading configurations and variable levels of oxygen (O₂).

[15] To ensure that the phytosanitary treatment dose has been attained throughout the process load, treatment procedures should ensure that the minimum absorbed dose (D_{\min}) is equal to or greater than the required phytosanitary treatment dose. The intended use of the commodity should be considered. For example, although appropriate for foods and agricultural products for processing or consumption, irradiation may not be appropriate for plants for planting as it may devitalize them.

[16] It is rare that mortality is technically justified as the required response to irradiation. It is therefore possible for live, non-viable target pests to be found in correctly treated commodities. This does not imply a failure of the treatment. It does mean, however, that it is essential for the treatment to be applied correctly to ensure that any target pests that are still alive are unable to complete development or otherwise reproduce. In addition, it is preferable that such pests are unable to escape into the environment unless they can be distinguished from non-irradiated pests.

[17] Irradiation may be applied:

- as an integral part of packing operations;
- to bulk unpackaged commodities; or
- to packaged commodities.

[18] Irradiation may take place where the commodity originates. When it is operationally feasible to prevent the escape of any pests during transport of the untreated commodity, treatment may alternatively be conducted at:

- the point of entry;
- a designated location in a third country; or
- a designated location within the country of final destination.

[19] Treated commodities should be certified and released only after dosimetry measurements show that no absorbed doses were less than the required phytosanitary treatment dose and therefore that the dose requirement has been met throughout the process load.

[20] Depending on the pest risk to be managed, the tolerance of the commodity to treatment, and the availability of other pest risk management options, irradiation may be used either as a single phytosanitary measure or combined with other measures as part of a systems approach (see ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*)).

3. Dosimetry

[21] Irradiation does not deliver a uniform dose throughout a process load but a continuum of doses. The dose range may increase as the size or density of the treated material increases. Therefore, it is important that an accurate measurement of the absorbed dose in a process load can be readily determined to ensure that the required phytosanitary treatment dose has been reached throughout the load.

[22] Dosimetry provides assurance that D_{\min} is equal to or greater than the required phytosanitary treatment dose and therefore that the dose requirement has been met throughout the process load. Properly designed systems for treatment delivery and protection against infestation and contamination, together with continual checking and regular monitoring of those systems, provide assurance that treatments are properly conducted. Dosimetry is highly specialized; NPPOs unfamiliar with irradiation should therefore collaborate with technical experts from their national nuclear agencies when approving facilities to be used for irradiating commodities for phytosanitary purposes.

3.1 Dosimetry systems

[23] A dosimetry system consists of dosimeters, instruments that read dosimeters, and associated procedures and standards. A dosimeter is a device with a reproducible response to irradiation that can be used to measure the absorbed dose. The dosimeter responds to the radiation and the response is measured by instruments to calculate the amount of ionizing radiation that the product has absorbed (expressed as absorbed dose).

[24] The selection and use of specific dosimetry systems should be appropriate for both the dose range and the type of radiation. It should take into account the influence of factors such as dose rates, the minimum level of uncertainty deemed to be acceptable and the required spatial resolution. Examples of dosimetry systems that can be used for gamma ray, electron beam and X-ray facilities can be found in ISO/ASTM 51261:2013.

3.2 Dose mapping

[25] Dose mapping is performed by placing dosimeters throughout the process load, irradiating the process load and reading the dosimeter values. Further information on the practices used for electron beams and X-rays are described in ISO 14470:2011 and ISO/ASTM 51261:2013.

[26] The objectives of dose mapping are:

- to determine the dose distribution throughout the process load and in particular where D_{\min} and D_{\max} are found;
- to demonstrate that the required phytosanitary treatment dose can be attained for the process load (i.e. D_{\min} can be equal to or greater than the required phytosanitary treatment dose);
- to establish the process parameters that will lead to doses within the required range;
- to assess the variability of the particular process; and
- to establish how routine dose measurements will be made.

- [27] The dose distribution in a process load is specific to the irradiator, the path that the commodity takes through the irradiator, the process load and the characteristics of the commodity. If any of these factors change, dose mapping should be repeated, as such changes affect dose distribution.

3.3 Routine dosimetry

- [28] Accurate measurements of absorbed dose in a process load are critical for determining the effectiveness of the treatment. They are part of the quality control of the treatment and of the validation process. The required number, location and frequency of these measurements should be prescribed based on the specific equipment, processes, commodities, relevant standards and phytosanitary requirements.
- [29] When the position of D_{\min} or D_{\max} is inside the process load and it is not practical to place dosimeters there routinely, a dosimeter may be placed in a reference location on the surface of the process load or on the irradiation container in a location that is readily accessible and easily reproducible for the operator (see Appendix 1). For a given loading configuration, a given path through the irradiator or given machine settings, the relationship between the dose measured at the reference location (D_{ref}) and D_{\min} and D_{\max} is arithmetic and constant. The coefficient representing this relationship should be established by dose mapping and may then be used to calculate D_{\min} and D_{\max} from D_{ref} during routine dosimetry.

4. Validation

- [30] Validation encompasses a series of checks designed to verify that a treatment facility meets its installation requirements (installation qualification), operates to its design specification (operational qualification) and will consistently deliver the required dose to a given process load within predetermined tolerances (performance qualification).
- [31] Installation qualification and operational qualification validate the irradiator and may be performed by the treatment provider with the technology suppliers. National plant protection organizations are typically not involved with installation- or operational-qualification activities, but the treatment provider should inform the NPPO if major changes have been made to the facility that would require dose mapping to be repeated (e.g. replenishment of gamma sources or major changes to conveyor-belt systems or speeds).
- [32] The way in which the commodity is loaded and irradiated is based on the results of the performance qualification. Therefore, the NPPO should review the performance-qualification activities that are undertaken with the actual commodity and loading configuration (e.g. full pallet or half pallet). The objective of performance qualification is to demonstrate that the equipment, as installed and properly operated, consistently performs as expected and that the treatment schedule can be met. Dose mapping of the actual process load to define the loading configuration is a key activity to ensure that the required phytosanitary treatment dose is achieved.

5. Adequate systems for treatment facilities

- [33] Confidence in the adequacy of irradiation as a phytosanitary measure is primarily based on assurance that the treatment schedule is effective against the target pests under specific conditions and the treatment has been properly applied. Systems for treatment delivery in the facilities should be designed, used and monitored to ensure that treatments are properly conducted.
- [34] The NPPO of the country in which the treatment facility is located is responsible for ensuring that the facility system requirements are met.

5.1 Approval of treatment facilities and authorization of treatment providers

- [35] Treatment facilities should be approved by the NPPO of the country in which the facility is located before phytosanitary treatments are applied there, with such approval thereby providing authorization to the treatment provider responsible for the facility to conduct treatments according to agreed procedures. This approval should be subsequent to authorization from competent authorities for safety (e.g. radiation safety authority, nuclear regulatory authority) where appropriate and be based on a set of

criteria that include both criteria common to all irradiation facilities and those that are specific to the site and commodity (see Annex 1).

- [36] Evaluation of phytosanitary treatment facilities for re-approval should be carried out by the NPPO on a regular basis at appropriate intervals.

5.2 Prevention of infestation and contamination after treatment

- [37] The consignment owner is responsible for prevention of infestation and contamination after irradiation and may cooperate with the treatment provider on how to achieve this. At the treatment facility, the necessary measures should be implemented to prevent possible infestation or contamination of the commodity after treatment. The following measures may be required:

- keeping the commodity in a pest free enclosure under conditions that protect it from infestation and contamination;
- packing the commodity immediately after irradiation;
- segregating and identifying treated commodities; and
- dispatching the commodity as soon as possible after irradiation.

- [38] The use of pest-proof packaging before irradiation may help to prevent possible infestation or contamination after irradiation. It may also prevent the accidental escape of the target pests before treatment if irradiation is applied at the destination.

5.3 Labelling

- [39] The treatment provider is responsible for labelling commodities with treatment lot numbers or other identifying features allowing trace-back for non-compliant consignments. The labels should be easily identifiable and placed in visible locations.

5.4 Monitoring and auditing

- [40] The NPPO of the country in which the irradiation is conducted should monitor and audit treatment facilities and providers. The NPPO should maintain an audit schedule and ensure that such audits are conducted by appropriately trained personnel. Continuous supervision of irradiation by the NPPO should not be necessary, provided treatment procedures are properly designed by the treatment provider and can be verified to ensure a high degree of system integrity for the facility, process and commodity in question. The monitoring and auditing should be sufficient to detect and correct deficiencies promptly.

- [41] Treatment providers should meet monitoring and auditing requirements set by the NPPO. These requirements may include:

- access for the NPPO to conduct audits, including unannounced visits;
- a system to maintain and archive treatment records and provide the NPPO with access to these; and
- corrective action to be taken in the event of nonconformity.

- [42] The NPPO of the importing country may establish approval and audit procedures with the NPPO of the exporting country to verify conformity with requirements.

6. Documentation

- [43] The NPPO of the country in which the irradiation is conducted is responsible for ensuring that treatment providers document all operational procedures and keep appropriate records, such as raw data on dosimetry readings recorded during treatments. Accurate record-keeping is essential to enable auditing and trace-back.

6.1 Documentation of procedures

[44] Procedures should be documented by treatment providers to ensure that commodities are consistently treated as required. Process controls and operational parameters should be established to provide the details necessary for the specific approval of a treatment facility. Calibration and quality control procedures should be documented by the treatment provider. The documented procedures should include the following:

- commodity-handling procedures before, during and after irradiation;
- orientation and loading configuration of the commodity during irradiation;
- critical process parameters and the means for measuring and recording them;
- dosimetry and calibration of the dosimetry system;
- contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes;
- procedures for handling rejected lots;
- labelling, record-keeping and documentation requirements; and
- training of personnel.

6.2 Record-keeping

[45] The treatment provider should keep appropriate records for each treatment application. These records should be made available to the NPPO of the country in which the treatment facility is located for auditing and verification purposes or when a trace-back is necessary.

[46] Appropriate treatment records for irradiation as a phytosanitary measure should be retained by the treatment provider for at least one year to enable the trace-back of treated lots. Information that may be required to be recorded includes:

- identification of facility and responsible parties;
- commodity treated;
- target regulated pest;
- treatment objective (i.e. required response);
- owner, packer, grower and place of production of the commodity;
- lot size and volume, including number of articles or packages;
- identifying markings or characteristics;
- orientation and loading configuration of the commodity during irradiation;
- absorbed doses (required doses and measured doses), dosimetry calibration and dose mapping records;
- date of treatment; and
- any observed deviation from the treatment schedule and, where appropriate, subsequent actions taken.

6.3 Documentation by the NPPO

[47] All NPPO procedures should be appropriately documented. Records, including those of monitoring inspections made and phytosanitary certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available upon request as described in ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*).

7. Inspection

- [48] Inspection should be carried out by the NPPO of the exporting country and inspection at import may be carried out by the NPPO of the importing country to determine compliance with phytosanitary import requirements.
- [49] Live target pests may be found after irradiation, but this should not result in the refusal to issue a phytosanitary certificate. Where mortality is not the required response, it is more likely that live target pests may persist in the treated consignment; in such cases, phytosanitary certification should be based on confirmation from the validation programme that the required minimum dose is administered and the required response is achieved for the specific treatment conditions concerned.

8. Responsibilities

- [50] The NPPO of the country in which the irradiation is conducted is responsible for the evaluation, approval and auditing of the application of irradiation as a phytosanitary measure.
- [51] To the extent necessary, the NPPO should cooperate with other national regulatory agencies concerned with the development, approval and safety of irradiation, including the training and certification of personnel conducting the treatment and the approval of treatment facilities. The respective responsibilities of the NPPO and the other regulatory agencies should be identified to avoid requirements that are overlapping, conflicting, inconsistent or unjustified.
- [52] The treatment provider is responsible for keeping the treatment records for at least one year and making them available for auditing and verification purposes.

Potential implementation issues

- [53] This section is not part of the standard. The Standards Committee in May 2016 requested the secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.

This annex is a prescriptive part of the standard.

ANNEX 1: Checklist for facility approval

- [54] This checklist may be used when an NPPO is inspecting or monitoring an irradiation facility as part of an approval or auditing process.

Criteria	Yes	No	Comments
<p>1. Premises</p> <p>The treatment facility meets the NPPO phytosanitary requirements, and the NPPO has access to the facility and appropriate records as necessary to validate phytosanitary treatments.</p> <p>Facility buildings are designed and built to be suitable in size, materials and placement of equipment to facilitate proper maintenance and operations for the lots to be treated.</p> <p>Appropriate means, integral to the facility design, are available to maintain non-irradiated lots separate from irradiated lots.</p> <p>Buildings and equipment are maintained in a sanitary condition and in repair sufficient to prevent infestation or contamination of the lots being treated.</p> <p>Effective measures are in place to protect against the infestation or contamination of consignments or lots being stored or processed.</p>			

Criteria	Yes	No	Comments
<p>Adequate measures are in place to handle breakages, spills or other damage to lots.</p> <p>Adequate systems are in place to dispose of lots that are improperly treated or unsuitable for treatment.</p> <p>Adequate systems are in place to control non-compliant lots and when necessary to suspend facility approval.</p>			
2. Personnel			
<p>The facility is adequately staffed with trained personnel.</p> <p>Personnel are aware of requirements for the proper handling and treatment of commodities for phytosanitary purposes.</p>			
3. Commodity handling, storage and segregation			
<p>Commodities are examined upon receipt to ensure that they are suitable for irradiation.</p> <p>Commodities are handled in an environment that does not increase the risk of dangerous physical, chemical or biological contaminants.</p> <p>Commodities are appropriately stored and adequately identified.</p> <p>Procedures, equipment and structures are in place to ensure the segregation of treated and untreated lots, including physical separation between incoming and outgoing holding areas.</p>			
4. Irradiation			
<p>The facility is suitably designed and equipped to allow required treatments to be conducted in conformity with a treatment schedule.</p> <p>A process control system is in place providing criteria to assess irradiation effectiveness.</p> <p>Proper process parameters are established for each type of commodity to be treated.</p> <p>Written procedures have been submitted to the NPPO and are well known to appropriate treatment facility personnel.</p> <p>The absorbed dose delivered to each type of commodity is verified by proper dosimetric measurement practices using calibrated dosimetry, and dosimetry records are kept and made available to the NPPO as needed.</p>			
5. Packaging and labelling			
<p>Each commodity is packaged using materials suitable for the commodity and process.</p> <p>Treated lots are adequately identified or labelled and adequately documented.</p> <p>Each irradiated lot carries identification to distinguish it from all other lots.</p>			
6. Documentation			
<p>All records about each lot irradiated are retained at the facility for the period of time specified by relevant authorities and are available for inspection by the NPPO as needed.</p>			

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 1: Example of a dosimeter in a reference location

- [55] In Figure 1, the coefficients (R_{\min} and R_{\max}) representing the relationship between the minimum (D_{\min}) and maximum (D_{\max}) absorbed doses and the dose in the reference location (D_{ref}) have been calculated as 0.8 and 1.4, respectively. The calculations are as follows:

Measured values:

$$D_{\max} = 4.2 \text{ kGy}$$

$$D_{\min} = 2.4 \text{ kGy}$$

$$D_{\text{ref}} = 3.0 \text{ kGy}$$

Therefore:

$$R_{\min} = D_{\min}/D_{\text{ref}} = 2.4 \text{ kGy}/3.0 \text{ kGy} = 0.8$$

$$R_{\max} = D_{\max}/D_{\text{ref}} = 4.2 \text{ kGy}/3.0 \text{ kGy} = 1.4$$

- [56] Thus, if the target dose range is $D_{\min} = 2.0 \text{ kGy}$ and $D_{\max} = 5.0 \text{ kGy}$, one can estimate the routine values for D_{ref} to be:

$$D_{\text{ref}} = D_{\min}/R_{\min} = 2.0 \text{ kGy}/0.8 = 2.5 \text{ kGy at a minimum}$$

$$D_{\text{ref}} = D_{\max}/R_{\max} = 5.0 \text{ kGy}/1.4 = 3.57 \text{ kGy at a maximum.}$$

- [57] For further examples, please refer to IAEA (2015).

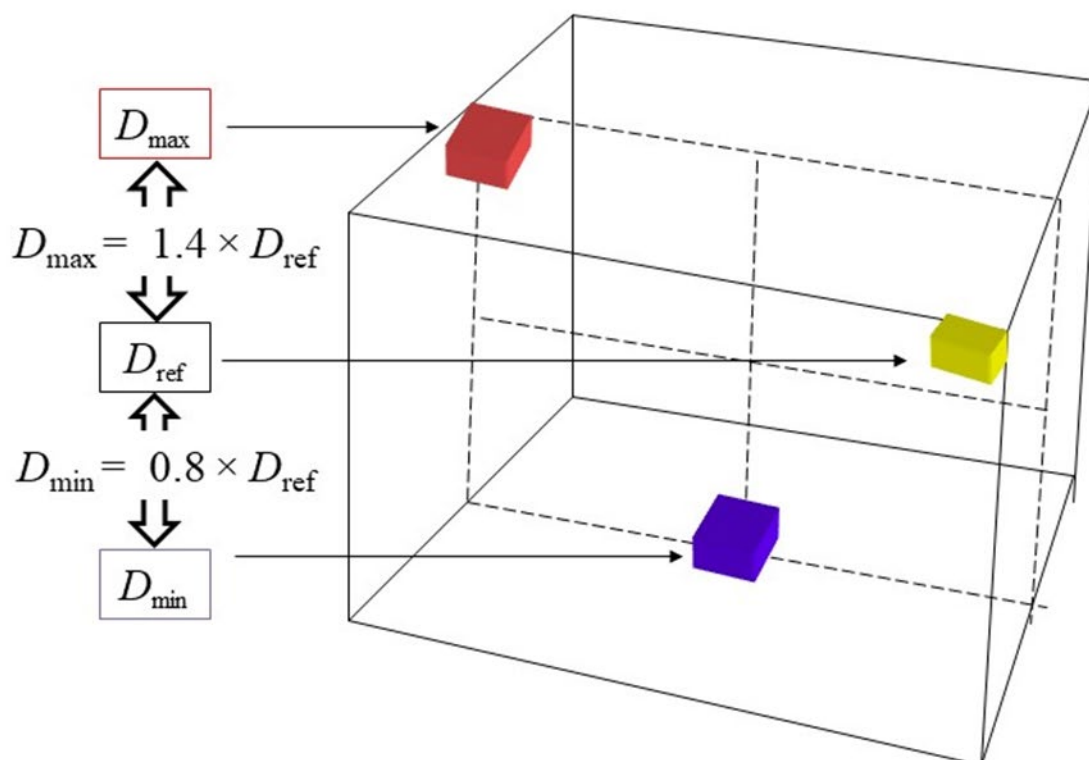


Figure 1. Example of relationship between minimum and maximum doses and the dose in the reference position. Blue box, position of minimum absorbed dose (D_{\min}); red box, position of maximum absorbed dose (D_{\max}); yellow box, position of dosimeter in the reference location (dose measured is D_{ref}).

Source: IAEA (International Atomic Energy Agency). 2015. *Manual of good practice in food irradiation – Sanitary, phytosanitary and other applications*. Technical Reports Series No. 481. Vienna, IAEA. 85 pp.