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

[2]Status box

[3]This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
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[25]CONTENTS [to be inserted]

[26]Adoption

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

[28]INTRODUCTION

[29]Scope

[30]This standard describes the requirements for initiating, establishing and maintaining pest free areas (PFAs) as a phytosanitary measure to attain or maintain the pest freedom of an area, support the phytosanitary certification of plants, plant products and other regulated articles exported from the PFA, or support the scientific justification for phytosanitary measures required by an importing country for protection of an endangered area.

[31]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*).

[32]References

[33]The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at <https://www.ippc.int/core-activities/standards-setting/ispm>.

[34]Definitions

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

[36]Outline of requirements

[37]A PFA is a phytosanitary measure that may be used to facilitate safe trade and protect plant resources. National plant protection organizations (NPPOs) should consider a PFA to be a phytosanitary measure that, when used alone, is sufficient for managing pest risk and meeting an importing country's appropriate level of protection.

[38]When initiating, establishing or maintaining a PFA, NPPOs should follow the requirements outlined in this standard. Requirements include systems to establish pest freedom, systems to maintain pest freedom, verification that pest freedom has been attained or maintained, appropriate corrective actions for pest detections, proper documentation of these systems and appropriate record keeping, and transparency and stakeholder communication. The phytosanitary measures used to establish or maintain the PFA should be based on an assessment of pest risk.

[39]BACKGROUND

[40]A PFA is recognized as one of the phytosanitary measures that may be used to facilitate safe trade and protect the plant resources of an area for agricultural, forestry or ecological conservation purposes.

[41]This establishes the linkage of PFAs to pest risk management and is outlined as one of the operational principles in ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*). Where economically beneficial, PFAs can also offer a cost-effective risk mitigation option for NPPOs and industry in both importing and exporting countries. One of the responsibilities of NPPOs, according to Article IV.2(e) of the IPPC, is the designation, maintenance and surveillance of PFAs.

[42]A PFA may be established as a phytosanitary measure for various purposes, including:

- [43]protecting areas of plant production or ecological conservation in importing or exporting countries;
- [44]increasing the market-access opportunities for exporting countries.

[45]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.

[46]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".

[47]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[48]This standard may contribute to the protection of biodiversity and the environment by preventing the introduction of regulated pests into an area (either a whole country or part of a country). When establishing and maintaining PFAs, countries are encouraged to consider phytosanitary procedures that minimize impact on the environment.

[49]REQUIREMENTS

[50]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 in full conformity with this standard, additional phytosanitary measures in relation to the specified pest should not be required.

[51]There are several requirements that should be met for a PFA to be established and to be used as a phytosanitary measure for trade, as detailed below. Depending on the pest concerned, an individual or

a combination of phytosanitary measures may be used to meet each requirement. The selection of these phytosanitary measures should be risk-based and in accordance with the principles of the IPPC.

[52]Requirements for the establishment and maintenance of a PFA as a phytosanitary measure by an NPPO include:

- [53]systems to establish pest freedom;
- [54]systems to maintain pest freedom;
- [55]verification that pest freedom has been attained or maintained;
- [56]corrective actions for detections of the pest;
- [57]documentation of these systems and appropriate record keeping;
- [58]transparency and stakeholder communication.

[59]Pest free areas may take significant time and resources to establish and maintain. To ensure that a PFA achieves its objectives, the following elements should be considered:

- [60]the requirement that measures used to establish and maintain a PFA should be based on the biology of the pest of concern, the relevant pathways and the characteristics of the PFA;
- [61]the existence of an appropriate legislative framework to support the establishment and maintenance of the PFA;
- [62]the feasibility of the PFA in terms of resources:
 - [63]economic considerations based on a cost-benefit analysis,
 - [64]the availability of human resources and technical expertise;
- [65]the availability of stable funding over the long term;
- [66]the support from relevant stakeholders, such as domestic industries and local regulatory bodies;
- [67]the importance of communicating with and raising awareness among other NPPOs, stakeholders and the general public.

[68]1. Initiation of a pest free area

[69]1.1Pest and area to be controlled

[70]When initiating a PFA, an NPPO should first characterize the pest – including the scientific name of the pest, valid identification methods and relevant aspects of its biology – and identify the area that is being considered for pest freedom. The area may be the entire country, a part of a country, or all or part of several countries.

[71]1.2Suitability of ecological conditions in the area

[72]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.

[73]1.3Identification of the area

[74]The area being considered for pest freedom 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.

[75]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.

[76]2. Establishment of the pest free area

[77]2.1 Surveillance activities before establishment

[78]Once the target pest has been characterized and the area identified, the NPPO should determine the pest status in the area. To do this, the NPPO should conduct surveillance in accordance with the requirements outlined in both ISPM 6 (*Surveillance*) and ISPM 8 (*Determination of pest status in an area*). These standards describe how surveillance should be conducted and how to establish the evidence necessary to determine the status of a pest in an area.

[79]In certain cases, such as for the establishment of a pest free country, general surveillance as referred to in ISPM 6 may be sufficient if the NPPO has concluded that the information is reliable and relevant.

[80]Where more reliable evidence is needed to demonstrate pest absence in an area, specific surveillance should be established. The level of surveillance should be based on the results of a pest risk assessment, and a delimiting survey conducted to justify the area that is being proposed as a PFA.

[81]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 an official PFA should not be required.

[82]In addition to determining pest presence or absence, surveillance in the context of PFAs may also be used to:

- [83]determine pest distribution and abundance;
- [84]delimit a pest population;
- [85]assess the effectiveness of pest eradication measures;
- [86]provide data to report to other NPPOs.

[87]2.2 Controls on the movement of regulated articles

[88]To prevent the entry of the pest into the PFA, the potential entry 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:

- [89]inclusion of the pest on a list of regulated pests;
- [90]regulation of the import pathways and articles that require control;
- [91]imposition of domestic restrictions or other measures to control the movement or transit of regulated articles into or through the PFA;
- [92]inspection of regulated articles, examination of the relevant documentation and, where necessary for cases of non-compliance, the application of appropriate phytosanitary measures.

[93]2.3 Establishment of buffer zones, if appropriate

[94]Where the geographical isolation of the PFA is not considered adequate to prevent the natural spread of the pest into the area, the implementation of a buffer zone should be considered. The population of the pest in the buffer zone should be maintained at or below a low pest tolerance level, which should be verified by surveillance. The extent of the zone is determined by the NPPO, based on the distance over which the likely natural spread of the pest population to the PFA could not occur during the growing season. The NPPO should describe, with the use of supporting maps, the boundaries of the buffer zone.

[95]2.4 National declaration of the pest free area

[96]When the pest status is confirmed as absent (according to ISPM 8), or eradication of the pest from the prospective PFA is achieved for the first time (according to ISPM 9 (*Guidelines for pest eradication programmes*)), the NPPO should make a national 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.

[97]3. Maintenance of the pest free area

[98]A risk-based programme to ensure maintenance of the PFA should be based on at least the following elements: a legal framework to control the movement of regulated articles; routine pest monitoring and collection of relevant data to inform the management of the PFA, including outbreak management; and contingency plans for corrective action in the event of an outbreak, with associated rules for suspension and reinstatement of the PFA.

3.1 [99] Legal framework

[100]The pest should be regulated in such a way that it may not be brought into the PFA through movement of regulated articles (see section 2.2). Where appropriate, buffer zones may be established with rules for intensified surveys to ensure early detection of natural spread of the pest into the vicinity of the PFA. The phytosanitary measures should also allow trace-back 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.

[101]Pest detections in the PFA should be immediately notified to the NPPO (or other competent authority delegated by the NPPO).

[102]3.2 Surveillance for the maintenance of the PFA

[103]Surveillance on a regular basis should be conducted to verify that the absence of the pest from the PFA is maintained.

[104]The decision about whether general surveillance for the pest is sufficient or specific surveillance is needed should be based on the results of a pest risk assessment.

[105]General surveillance may be sufficient in cases where the pest has never been introduced into the PFA, nor in the surrounding areas, and there have been no records of the pest's presence in the PFA.

[106]Specific surveillance to detect possible incursions 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 a pest risk assessment and should allow detection of the pest with an appropriate level of confidence.

[107]3.3 Data collection and record keeping

[108]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 analysis) should be stored and kept available for a sufficient time to ensure the possibility of trace-back and verification.

[109]3.4 Notification of detection of the pest

[110]A reporting framework should be established to ensure that detections of the pest, including interceptions, incursions and outbreaks, are immediately notified to the NPPO (or other competent authority delegated by the NPPO) and confirmed.

[111]3.5 Corrective action plans, including response to an outbreak

[112]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 activated, unless the pest can be eliminated immediately or evidence indicates that there is no risk of the pest establishing.

[113]Preparedness for rapid intervention may be ensured by developing a contingency plan in advance, including plans for rapid technical assessment of the situation, mobilizing financial and human resources, the roles and responsibilities of executive services, and the operational activities that are likely to be needed (in the form of a draft action plan). Regular simulation exercises may ensure that the contingency plan is effective and remains current.

[114]The eradication programme should include the following steps.

[115]3.5.1 Delimiting survey to demarcate the outbreak area

[116]As soon as the pest has been confirmed in the PFA, a delimiting survey should be conducted to determine the infested area. Based on this determination and a pest risk analysis identifying the suitability of the infested area for pest establishment, an outbreak area within the PFA should be demarcated and the PFA status 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 environmental conditions.

[117]3.5.2 Increased surveillance in the demarcated outbreak area

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

[119]3.5.3 Implementation of control measures

[120]Control measures should be applied to prevent the pest moving out of the demarcated outbreak area by human activities (movement of host plants) or, to the extent that is reasonably achievable, by natural spread.

[121]Measures to eradicate the pest should be implemented. This may include destruction of infested and possibly infested plants and plant products.

[122]3.5.4 Provisions for suspension, reinstatement or withdrawal of pest free area status

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

[124]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.

[125]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 status should be withdrawn or the delimitation of the PFA should be reviewed.

[126]4. Verification and regular review

[127]Once the PFA is established, a regular review of the performance of the PFA maintenance programme should be carried out. 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 management programmes accordingly.

[128]The correct implementation of the programme, including the administrative activities, should be verified by audit.

[129]Trace-back procedures for the movement of regulated articles should allow the verification of their origin and conformity with the phytosanitary requirements set for the PFA.

[130]5. Documentation and record keeping

[131]The phytosanitary measures used for the establishment and maintenance of the PFA should be adequately documented. The documentation should be reviewed and updated regularly, and include any

corrective actions taken. National plant protection organizations should ensure that records are kept for a minimum of 24 months, or longer depending on the biology of the pest.

[132]6. Communication and stakeholder engagement

[133]To ensure transparency, information about the establishment of the PFA should be communicated to the NPPOs of importing countries as part of the evidence provided to support the claim that the area is free from the pest. 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 interested stakeholders and NPPOs.

[134]Information about the maintenance of the PFA status should be made available on request to the NPPOs of importing countries. Maps and information about the measures applied to maintain the PFA status should be communicated to producers and stakeholders. Information about outbreaks should also be communicated to relevant stakeholders and contracting parties.

[135]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 of the NPPO. The NPPO should establish partnerships with stakeholders, which may include seeking contributions of resources.

[136]National plant protection organizations are encouraged to raise public awareness about PFAs in their territory, including the framework for reporting sightings of the pest, the phytosanitary measures established, and the importance of maintaining the PFA status, to achieve the support of the community.

[137]7. Recognition of pest free areas

[138]Recognition of PFAs based on bilateral negotiations should take place in accordance with ISPM 29 (*Recognition of pest free areas and areas of low pest prevalence*).

[139]Potential implementation issues

[140]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.