[PleaseReview document review. Review title: 2023 First consultation: Reorganization and revision of pest risk analysis standards (2020-001) . Document title: 2020-001\_Draft ISPM\_PRA\_en.docx]

***[1]***Introduction to the reorganization and revision of PRA standards (not an official part of the standard)

***[2]***Pest risk analysis (PRA) is a core process within the scope of the IPPC. Guidance for national plant protection organizations (NPPOs) is currently provided in ISPM 2 (*Framework for pest risk analysis*, adopted in 1995, revised in 2007) and ISPM 11 (*Pest risk analysis for quarantine pests*, adopted in 2001, revised in 2003, 2004, and 2013).

***[3]***The purpose of the revision is to:

* ***[4]***include all the requirements of the stages in PRA in one standard; and
* ***[5]***provide revised guidance on the pest risk management stage.

***[6]***The reorganization and revision were achieved in line with Specification 72 (*Reorganization and revision of pest risk analysis standards*) by combining, and revising where relevant, ISPM 2, ISPM 11, and the draft ISPM on *Pest risk management for quarantine pests* (2014-001) (originally drafted as a stand-alone standard) into one standard. The redundant and repetitive text was removed but the substantive guidance remained. Information on environmental risks, living modified organisms (LMOs), and PRA for plants as pests are gathered into further annexes.

***[7]***Main changes from existing PRA ISPMs

***[8]*Structure of revised PRA ISPM:**

* ***[9]***Core text of the standard
* ***[10]***ANNEX 1: Initiation (PRA Stage 1)
* ***[11]***ANNEX 2: Pest risk assessment (PRA Stage 2)
* ***[12]***ANNEX 3: Pest risk management (PRA Stage 3)
* ***[13]***ANNEX 4: Environmental risks
* ***[14]***ANNEX 5: Living modified organisms as pests
* ***[15]***ANNEX 6: Pest risk analysis for plants as quarantine pests
* ***[16]***APPENDIX 1: Pest risk analysis flow chart

***[17]***

***[18]*Supplements on the environmental impacts (S1) and LMOs (S2).** The supplemental text on environmental impacts (S1) and the section addressing plants as quarantine pests were moved to Annexes 4 and 6, respectively. The supplemental text on LMOs (S2) was moved to Annex 5 except where it was necessary to retain it in the text.

***[19]*Probability of transfer to a suitable host.** This subsection was moved from the end of the probability of entry section to the section on the probability of establishment. This was because, according to ISPM 5 (*Glossary of phytosanitary terms*), “entry” is complete when a pest enters the area, whereas, in ISPM 11, entry is complete when a pest is transferred to another host. This change was aimed at improving the logical flow of the process and achieving consistency across ISPMs.

***[20]*Consequences.** The expert working group (EWG) agreed that consequences to be considered include environmental, economic, social and other consequences, and economic consequences do not need to be mentioned specifically. The word “consequences” (without the qualifier of “economic” or “environmental”) is used, except where a special focus on “environmental” or “economical” consequences is indicated.

***[21]*NOTE:** Reviewers are encouraged to focus their review on new and revised text (specifically focusing on black text). General comments are encouraged on red and blue text at this stage of consultation, considering that the scope of the revision is limited by Specification 72 ([www.ippc.int/en/publications/90498](https://www.ippc.int/en/publications/90498/)). Reviewers are also invited to identify implementation issues, if any.

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| ***[22]*Remarks/Colour code**   * ***[23]***Text in black colour is new and revised text – all comments encouraged * ***[24]***Text in blue colour is transcribed from ISPM 2 – general comments encouraged * ***[25]***Text in red colour is transcribed from ISPM 11 – general comments encouraged   ***[26]*** |

***[27]***Additional information is included in the report of the EWG ([www.ippc.int/en/publications/91944](https://www.ippc.int/en/publications/91944/)), and the discussion of the SC in May 2023 [www.ippc.int/en/publications/92194](https://www.ippc.int/en/publications/92194/)).

***[28]***

***[30]*****DRAFT Reorganization and revision of pest risk analysis standards: Pest risk analysis for quarantine pests (2020-001)**

***[31]*Status box**

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| --- | --- |
| ***[32]***This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption. | |
| ***[33]*Date of this document** | ***[34]***2022-05-17 |
| ***[35]*Document category** | ***[36]***Draft ISPM |
| ***[37]*Current document stage** | ***[38]****To* first consultation |
| ***[39]*Major stages** | ***[40]***2020-07 CPM Bureau added topic *Reorganization of pest risk analysis standards* (2020-001) to the *List of topics for IPPC standards* (subsequently confirmed by CPM-15 (2021), with SC 2021/04 recommending priority 1).  ***[41]***2021-11 SC approved Specification 72.  ***[42]***2022-11 Expert working group met and drafted the standard.  ***[43]***2023-05 SC revised the draft and approved it for consultation. |
| ***[44]*Steward history** | ***[45]***2020-09 SC Masahiro SAI (JP, Lead Steward)  ***[46]***2020-09 SC Joanne WILSON (NZ, Assistant Steward)  ***[47]***2020-09 SC Hernando Moreira GONZÁZALES (CR, Assistant Steward) |
| ***[48]*Notes** | ***[49]***2018-03 Annex 3 edited (draft ISPM on *Guidance on pest risk management* (2014-001))  ***[50]***2023-01 Edited (*Reorganization and revision of pest risk analysis standards* (2020-001))  ***[51]***2023-05 Light edit |

***[52]***

***[53]***Adoption

***[54]***[Text in this section will be added following adoption.]

***[55]***INTRODUCTION

***[56]***Scope

***[58]***This standard describes the overall structure and concepts underlying the process of pest risk analysis (PRA) for quarantine pests within the scope of the IPPC. It covers the integrated processes of the three stages of PRA – initiation, pest risk assessment and pest risk management. Uncertainty, information gathering, documentation, pest risk communication, consistency and avoidance of undue delay are addressed. Specific guidance is also provided on the analysis of risks posed by pests to the environment and biological diversity, risks posed by plants that are living modified organisms (LMOs), and PRA for plants as quarantine pests.

***[59]***This standard does not cover PRA for regulated non-quarantine pests, guidance for which is provided in ISPM 21 (*Pest risk analysis for regulated non-quarantine pests*).

***[61]***References

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

***[63]*CBD**. 2000*. Cartagena Protocol on Biosafety to the Convention on Biological Diversity*. Montreal, Secretariat of the Convention on Biological Diversity.

***[64]*ICPM**. 2001. *Report of the Third Interim Commission on Phytosanitary Measures*, Rome, 2–6 April 2001. Rome, IPPC Secretariat, FAO. [www.ippc.int/en/publications/144](https://www.ippc.int/en/publications/144/)

***[65]*ICPM**. 2005. *Report of the Seventh Interim Commission on Phytosanitary Measures*, Rome, 4–7 April 2005. Rome, IPPC Secretariat, FAO. [www.ippc.int/en/publications/442](https://www.ippc.int/en/publications/442/)

***[66]*IPPC Secretariat**. 1997. *International Plant Protection Convention*. Rome, IPPC Secretariat, FAO. [www.ippc.int/en/core-activities/governance/convention-text](https://www.ippc.int/en/core-activities/governance/convention-text/)

***[67]*WTO (World Trade Organization)**. 1994. *Agreement on the Application of Sanitary and Phytosanitary Measures*. Geneva.

***[68]***Definitions

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

***[70]***Outline of requirements

***[71]***The PRA is an appropriate tool to: identify pests and pathways of potential phytosanitary concern for a specified area and evaluate their pest risk; identify endangered areas; and, if appropriate, identify pest risk management options and determine the most appropriate phytosanitary measures, commensurate with the identified risk, to reduce the risk of introduction and spread of the pests concerned. Pest risk analysis for quarantine pests consists of three stages: 1: Initiation; 2: Pest risk assessment; and 3: Pest risk management.

***[72]***BACKGROUND

***[74]***Pest risk analysis provides the rationale for phytosanitary measures for a specified PRA area. In a PRA, scientific evidence is evaluated to determine whether an organism is a pest. If it is a pest, the analysis evaluates the probability of introduction and spread of the pest and the magnitude of potential economic consequences in a defined area, using biological or other scientific and economic evidence. For some organisms, it is known beforehand that they are pests, but for others, the question of whether or not they are pests should initially be resolved. If the pest risk is deemed unacceptable, the analysis may continue by suggesting pest risk management options that could reduce the pest risk to an acceptable level. Subsequently, these pest risk management options may be used to establish phytosanitary regulations.

***[75]***The pest risk posed by the introduction of organisms associated with a particular pathway, such as a commodity, should also be considered in a PRA. The commodity itself may not pose a pest risk but may harbour organisms that are pests. Lists of such organisms are compiled during the initiation stage. Specific organisms may then be analysed individually, or in groups where individual species share common biological characteristics.

***[76]***Less commonly, the commodity itself may pose a pest risk. When organisms imported as commodities (such as plants for planting, biological control agents and other beneficial organisms, and LMOs) are deliberately introduced and established in intended habitats in new areas, there is a risk that they may accidentally spread to unintended habitats, causing injury to plants or plant products. Such risks may also be analysed using the PRA process.

***[77]***The PRA process is applied to pests of cultivated plants and wild flora, in accordance with the scope of the IPPC. It does not cover the analysis of risks beyond the scope of the IPPC.

***[78]***Provisions of other international agreements may address risk assessment (e.g. the Convention on Biological Diversity and the Cartagena Protocol on Biosafety to that convention (CBD, 2000)).

***[79]***The principles of necessity, managed risk, minimal impact, transparency harmonization, non-discrimination, technical justification, cooperation, and equivalence, as described in ISPM 1 (*Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*) and the World Trade Organization Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (WTO, 1994), are all essential considerations in pest risk analysis.

***[81]***IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

***[82]***The standard provides guidance on how to determine whether a pest satisfies the criteria to be considered a quarantine pest and pest risk management options to manage the associated pest risk. The identification of these options takes account of the degree of uncertainty and the options are designed in proportion to the risk. The process includes analysis of risks to biodiversity and the environment posed by pests. The resulting phytosanitary measures may help protect the environment and preserve biodiversity by managing the pest risk posed by commodities that are moved internationally, while avoiding phytosanitary actions that are not technically justified.

***[84]***REQUIREMENTS

***[85]***1. Framework for PRA

***[86]***The PRA process may be used for organisms not previously recognized as pests (such as plants, biological control agents and other beneficial organisms, and LMOs), recognized pests, pathways, and review of phytosanitary policy. The process can be summarized as follows:

* ***[88]***The PRA process is initiated in Stage 1, which involves identifying the pest (or pests) and pathways that are of potential concern and that should be considered for pest risk assessment in relation to the identified PRA area. If no pests are identified in this stage, the analysis may stop.
* ***[89]***Stage 2 (pest risk assessment) begins with the categorization of individual pests to determine whether the criteria for a quarantine pest are satisfied. If no pests meet the criteria, the analysis may stop. Pest risk assessment continues with an evaluation of the probability of pest entry, establishment and spread, and of their potential consequences.
* ***[90]***Stage 3 (pest risk management) involves identification, evaluation and selection of appropriate phytosanitary measures to reduce the pest risk posed by the quarantine pests identified at Stage 2.

***[91]***Pest risk analysis, however, is not necessarily a linear process because, in conducting the entire analysis, it may be necessary to go back and forth between various stages. Information gathering, documentation and pest risk communication are carried out throughout the PRA process.

***[93]***General requirements for the PRA process and aspects common to all PRA stages (e.g. information, gathering, documentation, pest risk communication) are provided in the core text of this standard and detailed guidance on each stage of PRA is given in Annexes 1, 2 and 3, respectively. Detailed guidance on environmental risks, LMOs and plants as pests is given in Annexes 4, 5 and 6, respectively.

***[95]***An overview of the full PRA process is illustrated in Appendix 1.

***[97]***This standard is not a detailed operational or methodological guide for assessors.

***[99]***2. Aspects common to all PRA stages

***[100]***2.1 Information gathering

***[101]***Throughout the process, information should be gathered and analysed as required to reach recommendations and conclusions. Scientific publications as well as technical information such as data from surveys and interceptions may be relevant. As the analysis progresses, information gaps may be identified necessitating further enquiries or research. Where information is insufficient or inconclusive, expert judgement may be used if appropriate.

***[103]***Cooperation in the provision of information and responding to requests for information made via the official contact point are IPPC obligations (Articles VIII.1(c) and VIII.2). When requesting information from other contracting parties, requests should be as specific as possible and limited to information essential to the analysis. Other agencies may be approached for information appropriate to the analysis.

***[105]***2.2 Uncertainty

***[106]***Uncertainty is a component of risk and therefore it is important to recognize and document uncertainty when performing PRAs. Sources of uncertainty with a particular PRA may include missing, incomplete, inconsistent or conflicting data; natural variability of biological systems; subjectiveness of analysis; and sampling randomness. Symptoms of uncertain causes and origin and asymptomatic carriers of pests may pose particular challenges.

***[108]***The nature and degree of uncertainty in the analysis should be documented and communicated, and the use of expert judgement should be clearly indicated. If adding or strengthening of phytosanitary measures is recommended to compensate for uncertainty, this should be recorded. Documentation of uncertainty contributes to transparency and may also be useful for the identification of research needs or priorities.

***[110]***As uncertainty is an inherent part of PRA, it is appropriate to monitor the phytosanitary situation resulting from the regulation based on any particular PRA and to re-evaluate previous decisions.

***[112]***2.3 Documentation

***[113]***The principle of transparency requires that contracting parties should, on request, make available the technical justification for phytosanitary import requirements. Thus, the PRA should be sufficiently documented. This may be achieved by documenting PRA at two levels:

* ***[115]***documenting the general PRA process; and
* ***[116]***documenting each analysis made.

***[117]***2.3.1 Documenting the general PRA process

***[118]***Each national plant protection organization (NPPO) may document the procedures and criteria of its general PRA process.

***[120]***2.3.2 Documenting each specific PRA

***[121]***For each particular analysis, the entire process from initiation to pest risk management should be sufficiently documented so that the sources of information and the rationale for management decisions can be clearly demonstrated. However, a PRA does not necessarily need to be long and complex. A short and concise PRA may be sufficient provided justified conclusions can be reached after completing only a limited number of steps in the PRA process.

***[123]***The main elements that should be documented are:

* ***[125]***purpose of the PRA;
* ***[126]***identity of the organism;
* ***[127]***PRA area;
* ***[128]***biological attributes of the organism and evidence of ability to cause injury;
* ***[129]***pest, pathways, endangered area;
* ***[130]***sources of information;
* ***[131]***nature and degree of uncertainty and measures envisaged to compensate for uncertainty;
* ***[132]***commodity description and categorized pest list (in the case of pathway-initiated analysis);
* ***[133]***evidence of economic impact, which includes environmental impact;
* ***[134]***conclusions of pest risk assessment (probabilities and consequences);
* ***[135]***decisions and justifications to stop the PRA process;
* ***[136]***phytosanitary measures identified, evaluated and recommended from pest risk management; and
* ***[137]***date of completion and the NPPO responsible for the analysis, including (if appropriate) names of authors, contributors and reviewers.

***[138]***Other aspects to be documented may include:

* ***[140]***any particular need for monitoring the efficacy or effectiveness of proposed phytosanitary measures; and
* ***[141]***potential dangers identified that are outside the scope of the IPPC and are to be communicated to other authorities (e.g. biological control agents).[[1]](#footnote-2)

***[143]***2.4 Pest risk communication

***[144]***Pest risk communication is important throughout each stage of PRA. It is generally recognized as an interactive process allowing exchange of information between the NPPO that has conducted the PRA and stakeholders. It is not simply a one-way movement of information or about making stakeholders understand the risk situation, but is meant to reconcile the views of scientists, stakeholders, politicians and so on, in order to:

* ***[146]***achieve a common understanding of the pest risk;
* ***[147]***develop credible pest risk management options;
* ***[148]***develop credible and consistent regulations and policies to deal with pest risk; and
* ***[149]***promote awareness of the phytosanitary issues under consideration.

***[150]***At the end of the PRA, evidence supporting the PRA, the proposed mitigations and the uncertainties should be communicated to the affected NPPOs and may be communicated to other interested parties, including other contracting parties, regional plant protection organizations and NPPOs, as appropriate.

***[152]***If, subsequent to the PRA, phytosanitary import requirements or prohibitions are adopted, the contracting party shall immediately publish these and notify contracting parties that it believes may be directly affected (according to IPPC Article VII.2(b)) and on request make the rationale available to any contracting party (according to IPPC Article VII.2(c)).

***[154]***If, subsequent to the PRA, phytosanitary import requirements or prohibitions are not adopted, contracting parties may make this information available.

***[156]***National plant protection organizations are encouraged to communicate evidence of dangers other than pest risk (such as to animals or human health) to the appropriate authorities.

***[158]***2.5 Consistency in PRA

***[159]***National plant protection organizations should strive for consistency in their conduct of PRAs. Consistency offers numerous benefits, including:

* ***[161]***promotion of the principles of non-discrimination and transparency;
* ***[162]***improved familiarity with the PRA process;
* ***[163]***increased efficiency in completing PRAs and managing related data; and
* ***[164]***improved comparability between PRAs conducted on similar products or pests, which in turn aids the development and application of similar or equivalent management measures.

***[165]***Consistency may be assured through, for example, the elaboration of generic decision criteria and procedural steps, training of individuals conducting PRA, and review of draft PRAs.

***[167]***2.6 Avoidance of undue delay

***[168]***Where other contracting parties are directly affected by the outcome of an individual PRA, the NPPO conducting the PRA should, on request, supply information about the completion of it, and if possible the anticipated time frame, taking into account avoidance of undue delay (see ISPM 1).

***[170]***3. Scope of PRA

***[171]***The range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. Pests may also include pests indirectly affecting cultivated plants, pests affecting non-cultivated plants, LMOs, and plants as pests.

***[173]***3.1 Environmental risks

***[174]***The IPPC applies to the protection of wild and cultivated plants. Therefore, pests affecting all types of plants, directly or indirectly, are within the scope of the IPPC. Information on the scope of the IPPC with regard to environmental risks is provided in Annex 4.

***[176]***3.2 Living modified organisms

***[177]***This standard is generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the pest risk posed by an LMO. Information on the scope of the IPPC with regard to PRA for LMOs, together with the factors to consider when determining the potential for an LMO to be a pest, are provided in Annex 5.

***[180]***3.3 Plants as pests

***[181]***The number and diversity of plants being moved between and within countries is increasing as opportunities for trade increase and markets develop for new plants. Movements of plants may imply two types of pest risk: the plant (as a pathway) may carry pests, or the plant itself may be a pest. The risk of introducing pests with plants as a pathway has long been recognized and widely regulated. However, the pest risk posed by plants as pests requires specific consideration. Information on the scope of the IPPC with regard to PRA for plants as pests is provided in Annex 6.

***[183]***

***[184]***

***[187]***This annex is a prescriptive part of the standard.

***[188]***ANNEX 1: Initiation (PRA Stage 1)

***[189]***1. Introduction

***[190]***The purpose of the PRA initiation is to identify pests and pathways that may potentially be considered quarantine pests or pathways for quarantine pests in relation to the identified PRA area.

***[192]***A PRA process may be triggered in the following situations:

* ***[194]***a request is made to consider a pathway that may require phytosanitary measures;
* ***[195]***a pest is identified that may justify phytosanitary measures;
* ***[196]***a decision is made to review or revise phytosanitary measures or policies; or
* ***[197]***a request is made to determine whether an organism is a pest.

***[198]***The initiation stage involves four steps:

* ***[200]***determining whether an organism is a pest (section 3 of this annex);
* ***[201]***defining the PRA area (section 4 of this annex);
* ***[202]***evaluating any previous PRA (section 6 of this annex); and
* ***[203]***conclusion (section 7 of this annex).

***[204]***When the PRA process has been triggered by a request to consider a pathway, the above steps are preceded by assembling a list of organisms of possible regulatory concern because they are likely to be associated with the pathway.

***[206]***At this stage, information is necessary to identify the organism and its potential economic impact, which includes environmental impact.[[2]](#footnote-3) Other useful information on the organism may include its geographical distribution, host plants, habitats and association with commodities. For pathways, information about the commodity, including modes of transport, and its intended use, is essential.

***[209]***2. Initiation points

***[210]***2.1 PRA initiated by the identification of a pathway

***[211]***The need for a new or revised PRA for a specific pathway may arise in situations such as when:

* ***[213]***import is proposed of a commodity not previously imported or a commodity from a new area of origin;
* ***[214]***there is an intention to import for selective breeding or scientific research a plant species or cultivar not yet introduced that could potentially be a host of pests;
* ***[215]***a pathway other than commodity import is identified (natural spread, packing material, mail, garbage, compost, passenger baggage, etc.);
* ***[216]***a change in the susceptibility of a plant to a pest is identified; or
* ***[217]***there is a change in the virulence (i.e. the aggressiveness) or host range of a pest.

***[218]***These are situations where the commodity itself is not a pest. When the commodity itself may be a pest, it should also be considered under section 2.4 of this annex.

***[220]***A list of organisms likely to be associated with the pathway should be assembled, including organisms

***[222]***that have not yet been clearly identified as pests. When a PRA is carried out for a commodity for which trade already exists, records of actual pest interceptions should be used as the basis for the listing of associated pests.

***[223]***2.2 PRA initiated by the identification of a pest

***[224]***The need for a new or revised PRA on a specific recognized pest may arise in situations such as when:

* ***[226]***an infestation or an outbreak of a new pest is discovered within an area (which may be in the exporting country or in another country or countries);
* ***[227]***an emergency arises on discovery of an established infestation or an outbreak of a new pest within a PRA area (see ISPM 1);
* ***[229]***a pest is newly identified by scientific research;
* ***[230]***a pest is reported to be more injurious than previously known;
* ***[231]***an organism is identified as a vector for other recognized pests;
* ***[232]***a pest is introduced into a PRA area;
* ***[234]***there is a change in the status or incidence of a pest in a PRA area;
* ***[235]***a pest that is new to a PRA area is intercepted on an imported commodity;
* ***[236]***a pest is repeatedly intercepted at import;
* ***[237]***a pest is proposed to be imported for research or other purpose; or
* ***[238]***an organism is genetically altered in a way which clearly identifies its potential as a pest (LMO).[[3]](#footnote-4)

***[241]***In these situations, the fact that the organism is known to be a pest should be recorded in preparation for PRA Stage 2.

***[243]***2.3 Review of phytosanitary policies

***[244]***The need for a new or revised PRA may arise from situations such as when:

* ***[246]***a national review of phytosanitary regulations, requirements or operations is undertaken;
* ***[247]***a proposal made by another country or by an international organization (e.g. a regional plant protection organization, the Food and Agriculture Organization of the United Nations) is reviewed;
* ***[249]***an evaluation of a regulatory proposal of another country or international organization is undertaken;
* ***[250]***a new system, process or procedure is introduced or new information made available that could influence a previous decision (e.g. results of monitoring; a new treatment or withdrawal of a treatment; new diagnostic methods);
* ***[251]***a dispute arises concerning phytosanitary measures; or
* ***[253]***the phytosanitary situation in a country changes, a new country is created, or political boundaries are changed.

***[255]***In these situations, pests will already have been identified and this fact should be recorded in preparation for PRA Stage 2.

***[257]***For existing trade, no new phytosanitary measures should be applied until the revision or new PRA has been completed, unless this is warranted by new or unexpected phytosanitary situations that may necessitate emergency measures.

***[259]***2.4 Identification of an organism not previously known to be a pest

***[260]***An organism may be considered for PRA in situations such as when:

* ***[262]***a proposal is made to import a new plant species or variety for cropping, amenity or environmental purposes;
* ***[263]***a proposal is made to import or release a biological control agent or other beneficial organism;
* ***[264]***an emergency arises on interception of a new organism on an imported commodity;
* ***[266]***an organism is found that has not yet been fully named or described or is difficult to identify;
* ***[267]***a proposal is made to import an organism for research, analysis or other purpose; or
* ***[268]***a proposal is made to import or release an LMO.

***[269]***In these situations, it is necessary to determine if the organism is a pest and thus subject to PRA Stage 2. Section 3 of this annex provides further guidance on this matter.

***[271]***3. Determining whether an organism is a pest

***[272]***The initiation points frequently refer to “pests”. The IPPC defines a pest as “any species, strain or biotype of plant, animal or pathogenic agent, injurious to plants or plant products”. When applying these initiation points to the specific case of plants as pests, it is important to note that the plants concerned should satisfy this definition. Pests directly affecting plants satisfy this definition. In addition, many organisms indirectly affecting plants also satisfy this definition (e.g. plants as pests, such as weeds or non-indigenous plants). The fact that they are injurious to plants may be based on evidence of their impact obtained in an area in which they are present. In cases where there is insufficient evidence that they affect plants indirectly, it may nevertheless be appropriate to assess – on the basis of available pertinent information – whether they are potentially injurious in the PRA area by using a clearly documented, consistently applied and transparent system. This is particularly important for plant species or cultivars that are imported for planting.

***[274]***“Preselection” or “screening” are terms sometimes used to cover the early step of determining whether an organism is a pest or not.

***[276]***The taxonomic identity of the organism should be defined because any biological and other information used should be relevant to the organism in question. If the organism has not yet been fully named or described, then, to be determined as a pest, it should at least have been shown to be identifiable, consistently to produce injury to plants or plant products (e.g. symptoms, reduced growth rate, yield loss or any other damage) and to be transmissible or able to disperse.

***[278]***The taxonomic level for organisms considered in PRA is generally the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In cases where the level used is below the species, this rationale should include evidence of reported significant variation in factors such as virulence, pesticide resistance, environmental adaptability, host range or its role as a vector.

***[280]***Predictive indicators of an organism are characteristics that, if found, would suggest the organism may be a pest. The information on the organism should be checked against such indicators, and if none are found, it may be concluded that the organism is not a pest, and the analysis may be ended by recording the basis of that decision.

***[282]***The following are examples of indicators that may be considered:

* ***[284]***previous history of successful establishment in new areas;
* ***[285]***phytopathogenic characteristics;
* ***[286]***phytophagous characteristics;
* ***[287]***presence detected in connection with observations of injury to plants or to beneficial organisms before any clear causal link has been established;
* ***[288]***belonging to taxa (family or genus) commonly containing known pests;
* ***[289]***capability to act as a vector for known pests; and
* ***[290]***adverse effects on non-target organisms beneficial to plants (such as pollinators or predators of pests).

***[291]***Particular cases for analysis include plant species, biological control agents and other beneficial organisms (see ISPM 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*)), organisms which have not yet been fully named or described, or are difficult to identify, intentionally imported organisms and LMOs. The potential of plants as pests should be determined as outlined in Annex 6. The potential of LMOs as pests should be determined as outlined in Annex 5.

***[293]***3.1 Biological control agents and other beneficial organisms

***[294]***Biological control agents and other beneficial organisms are intended to be beneficial to plants. Thus, when performing a PRA, the main concern is to look for potential injury to non-target organisms.[[4]](#footnote-5) Other concerns may include:

* ***[297]***presence of other species as contaminants of cultures of beneficial organisms, the culture thereby acting as a pathway for pests; and
* ***[298]***reliability of containment facilities when such are required.

***[299]***3.2 Organisms not yet fully described or difficult to identify

***[300]***Organisms that have not yet been fully named or described or are difficult to identify (e.g. damaged specimen, unidentifiable life stages) may be detected in imported consignments or during surveillance, in which case a decision as to whether phytosanitary action is justified and recommendations for phytosanitary measures may need to be made. These should be based on a PRA using the information available, even if very limited. It is recommended that, in such cases, specimens are deposited in an accessible reference collection for future further examination.

***[302]***3.3 Import of organisms for specific uses

***[303]***When a request is made to import an organism that may be a pest for use in scientific research, education, industry or other purposes, the identity of the organism should be clearly defined. Information on the organism or closely related organisms may be assessed to identify indicators that it may be a pest. For organisms determined to be pests, pest risk assessment may be carried out.

***[305]***4. Defining the PRA area

***[306]***The area to which the PRA refers should be clearly defined. It may be the whole or part of a country or several countries. Whereas information may be gathered from a wider geographical area, the analysis of establishment, spread and economic impact should relate only to the defined PRA area.

***[308]***In PRA Stage 2, the endangered area is identified. In PRA Stage 3, the regulated area may, however, be designated as wider than the endangered area if technically justified and not in conflict with the principle of non-discrimination.

***[310]***5. Information

***[311]***Information gathering is an essential element of all stages of PRA. It should be carried out at the initiation stage in order to clarify the identity of the pest (or pests), its present distribution and association with host plants or commodities, and so on. Other information should be gathered as required to reach necessary decisions as the PRA continues.

***[313]***Information for PRA may come from a variety of sources. The provision of official information necessary for PRA, to the extent that is possible, is an obligation on contracting parties under the IPPC (Article VIII.1(c)), facilitated by official contact points (Article VIII.2).

***[315]***6. Previous pest risk analyses

***[316]***Before performing a new PRA, a check should be made to determine if the organism, pest or pathway has ever been subjected to a previous PRA. The validity of any existing analysis should be verified because circumstances and information may have changed. Its relevance to the PRA area should be confirmed.

***[318]***The possibility of using a PRA of a similar organism, pest or pathway may also be investigated, particularly when information on the specific organism is absent or incomplete. Information assembled for other purposes, such as environmental impact assessments of the same or a closely related organism, may be useful but cannot substitute for a PRA.

***[320]***7. Conclusion of initiation

***[321]***At the end of PRA Stage 1, pests and pathways of concern will have been identified and the PRA area defined. Relevant information will have been collected and pests identified as candidates for further assessment, either individually or in association with a pathway.

***[323]***Organisms determined not to be pests and pathways not carrying pests need not be further assessed. The decision and rationale should be recorded and communicated, as appropriate.

***[325]***Where an organism has been determined to be a pest, the process may continue to PRA Stage 2. Where a list of pests has been identified for a pathway, pests may be assessed as groups, if biologically similar, or separately.

***[327]***Where the PRA is specifically aimed at determining if the pest should be regulated as a quarantine pest, the process may proceed immediately to the pest categorization step of pest risk assessment (PRA Stage 2), described in Annex 2 of this standard.

***[329]***

***[336]***This annex is a prescriptive part of the standard.

***[337]***ANNEX 2: Pest risk assessment (PRA Stage 2)

***[338]***1. Introduction

***[339]***The process for pest risk assessment can be broadly divided into three interrelated steps:

* ***[341]***pest categorization;
* ***[342]***assessment of the probability of introduction and spread; and
* ***[343]***assessment of potential consequences.

***[344]***In most cases, these steps will be applied sequentially in a PRA, but it is not essential to follow a particular sequence. Pest risk assessment needs to be only as complex as is technically justified by the circumstances.

***[346]***2. Pest categorization

***[347]***At the outset, it may not be clear which pest or pests identified in Stage 1 require a PRA. The categorization process examines, for each pest, whether the criteria in the definition of a quarantine pest are satisfied, namely that the pest:

* ***[349]***is not present in the PRA area or, if present, is of limited distribution and subject to official control or being considered for official control;
* ***[351]***has the potential to cause injury to plants or plant products in the PRA area; and
* ***[352]***has the potential to establish and spread in the PRA area.

***[353]***In the evaluation of a pathway associated with a commodity, multiple individual PRAs may be necessary for the various pests potentially associated with the pathway. The opportunity to eliminate an organism or organisms from consideration before in-depth examination is undertaken is a valuable characteristic of the categorization process.

***[355]***An advantage of pest categorization is that it can be done with relatively little information; however, information should be sufficient to adequately carry out the categorization.

***[357]***2.1 Elements of categorization

***[358]***The criteria for categorization of a pest as a quarantine pest consist of the following primary elements:

* ***[360]***identity of the pest;
* ***[361]***presence or absence in the PRA area;
* ***[362]***regulatory status;
* ***[363]***potential for establishment and spread in PRA area; and
* ***[364]***potential for consequences in the PRA area.

***[365]***2.1.1 Identity of pest

***[366]***The identity of the pest should be clearly defined to ensure that the assessment is being performed on a distinct organism, and that biological and other information used in the assessment is relevant to the organism in question. If this is not possible because the causal agent of particular symptoms has not yet been fully identified, then the organism should have been shown to produce consistent symptoms and to be transmissible or able to disperse.

***[368]***The taxonomic unit for the pest is generally the species. The use of a higher or lower taxonomic level should be supported by a scientifically sound rationale. In cases where the level used is below the species, this rationale should include evidence demonstrating that factors such as differences in virulence, pesticide resistance, environmental adaptability, host range or vector relationships are significant enough to affect pest risk.

***[370]***In cases where a vector is involved, the vector may also be considered a pest to the extent that it is associated with the causal organism and is required for transmission of the pest.

***[372]***Specific guidance on the consideration of LMOs and the identity of plants as pests is provided in Annexes 5 and 6.

***[374]***2.1.2 Presence or absence in PRA area

***[375]***The pest should be absent from all or a defined part of the PRA area.

***[377]***Specific guidance on determining the presence or absence of plants as pests is provided in Annex 6.

***[379]***2.1.3 Regulatory status

***[380]***A pest may be regulated if it is present but not widely distributed in the PRA area. However, it should be under official control or expected to be under official control in the near future.

***[382]***2.1.4 Potential for establishment and spread in PRA area

***[383]***Evidence should be available to support the conclusion that the pest could become established or spread in the PRA area. The PRA area (taking account also of protected environments such as greenhouses) should have ecological and climatic conditions suitable for the establishment and spread of the pest. Where relevant, host species (or near relatives), alternate hosts and vectors should be present in the PRA area.

***[385]***2.1.5 Potential consequences in PRA area

***[388]***There should be clear indications that the pest is likely to have an unacceptable impact in the PRA area.

***[390]***Unacceptable economic impact is described in Supplement 2 (Guidelines on the understanding of “potential economic importance” and related terms including reference to environmental considerations) to ISPM 5.

***[392]***2.2 Conclusion of pest categorization

***[393]***If it has been determined that the pest has the potential to be a quarantine pest, the PRA process should continue. If a pest does not fulfil all of the criteria for a quarantine pest, the PRA process for that pest may stop. In the absence of sufficient information, the uncertainties should be identified and the PRA process should continue.

***[395]***3. Assessment of the probability of introduction and spread

***[396]***Pest introduction comprises both entry and establishment. To assess the probability of introduction, an analysis should be conducted of each of the pathways with which a pest may be associated from its origin to its establishment in the PRA area. In a PRA initiated by a specific pathway (usually an imported commodity), the probability of pest entry should be evaluated for the pathway in question. The probabilities for pest entry associated with other pathways should be investigated as well.

***[398]***For PRAs that have been initiated for a specific pest, with no particular commodity or pathway under consideration, the potential of all probable pathways should be considered.

***[400]***The assessment of probability of spread should be based primarily on biological considerations similar to those for entry and establishment.

***[402]***3.1 Probability of entry of a pest

***[404]***The probability of entry of a pest depends on the pathways from the exporting country to the destination, and the frequency and quantity of pests associated with them. The higher the number of pathways, the greater the probability of the pest entering the PRA area.

***[405]***Documented pathways for the pest to enter new areas should be noted. Potential pathways, which may not currently exist, should be assessed. Pest interception data may provide evidence of the ability of a pest to be associated with a pathway and to survive in transport or storage.

***[406]***Specific guidance on assessing the probability of entry for plants as pests is provided in Annex 6.

***[407]***3.1.1 Identification of pathways for a PRA initiated by a pest

***[408]***All relevant pathways should be considered. They can be identified principally in relation to the geographical distribution and host range of the pest. Consignments of plants and plant products moving in international trade are the principal pathways of concern and existing patterns of such trade will, to a substantial extent, determine which pathways are relevant. Other pathways, such as other types of commodities, packing materials, persons, baggage, mail, conveyances and the exchange of scientific material, should be considered where appropriate. Entry by natural means should also be assessed, as natural spread is likely to reduce the effectiveness of phytosanitary measures.

***[410]***3.1.2 Probability of the pest being associated with the pathway at origin

***[411]***The probability of the pest being associated, spatially or temporally, with the pathway at origin should be estimated. Factors that should be considered are:

* ***[413]***prevalence of the pest in the source area;
* ***[414]***presence of the pest in a life stage that would be associated with commodities, containers or conveyances;
* ***[415]***volume and frequency of movement along the pathway;
* ***[416]***seasonal timing; and
* ***[417]***pest-management, cultural and commercial procedures applied at the place of origin (application of plant-protection products, handling, culling, roguing, grading).

***[418]***3.1.3 Probability of survival during transport or storage

***[419]***Examples of factors that may be considered are:

* ***[421]***speed and conditions of transport and duration of the life cycle of the pest in relation to time in transport and storage;
* ***[422]***vulnerability of the life stages during transport or storage;
* ***[423]***prevalence of the pest likely to be associated with a consignment; and
* ***[424]***commercial procedures (e.g. refrigeration) applied to consignments in the country of origin, country of destination, or in transport or storage.

***[425]***3.1.4 Probability of pest surviving existing pest-management procedures

***[426]***Existing pest-management procedures (including phytosanitary procedures) applied to consignments against other pests from origin to end use, should be evaluated for effectiveness against the pest in question. The probability that the pest will go undetected during inspection or survive other existing phytosanitary procedures should be estimated.

***[428]***3.2 Probability of establishment

***[429]***To estimate the probability of establishment of a pest, reliable biological information (life cycle, host range, epidemiology, survival, etc.) should be obtained from the areas where the pest is currently present. The situation in the PRA area may then be compared with that in the areas where the pest is currently present (taking account also of protected environments such as greenhouses) and expert judgement used to assess the probability of establishment. Case histories concerning comparable pests can usefully be considered. Examples of factors that may be considered are:

* ***[431]***availability, quantity and distribution of hosts in the PRA area;
* ***[433]***probability of transfer to a suitable host;
* ***[434]***environmental suitability in the PRA area; and
* ***[435]***cultural practices and control measures.

***[436]***Other characteristics of the pest may also affect the probability of establishment. In considering probability of establishment, it should be noted that a pest with the status “present: transient” (see ISPM 8 (*Determination of pest status in an area*)) may not be able to establish in the PRA area (e.g. because of unsuitable climatic conditions) but could still have unacceptable economic consequences (see IPPC Article VII.3).

***[438]***Specific guidance on assessing the probability of establishment of plants as pests is provided in Annex 6.

***[440]***3.2.1 Availability of suitable hosts, alternate hosts and vectors in the PRA area

***[441]***Factors that should be considered are:

* ***[443]***whether hosts and alternate hosts are present and how abundant or widely distributed they may be;
* ***[444]***whether hosts and alternate hosts are present within sufficient geographical proximity to allow the pest to complete its life cycle;
* ***[445]***whether there are other plant species that could prove to be suitable hosts in the absence of the usual host species;
* ***[446]***whether a vector, if needed for dispersal of the pest, is already present in the PRA area or likely to be introduced; and
* ***[447]***whether another vector species is present in the PRA area.

***[448]***The taxonomic level at which hosts are considered should normally be the species. The use of a higher or lower taxonomic level should be justified by a scientifically sound rationale.

***[450]***3.2.2 Probability of transfer to a suitable host

***[452]***Factors that should be considered are:

* ***[453]***dispersal mechanisms, including vectors to allow movement from the pathway to a suitable host;
* ***[454]***whether the imported commodity is to be sent to a few or many destination points in the PRA area;
* ***[455]***proximity of entry, transit and destination points to suitable hosts;
* ***[456]***time of year at which import takes place;
* ***[457]***intended use of the commodity (e.g. for planting, processing, consumption); and
* ***[458]***risks from by-products and waste.

***[459]***Some uses are associated with a much higher probability of introduction (e.g. planting) than others (e.g. processing). The probability associated with any growth, processing or disposal of the commodity in the vicinity of suitable hosts should also be considered.

***[460]***3.2.3 Suitability of environment

***[461]***Factors in the environment (e.g. suitability of climate, soil, pest–host competition) that are critical to the development of the pest, its host and if applicable its vector, and to their ability to survive periods of climatic stress and complete their life cycles, should be identified. It should be noted that the environment is likely to have different effects on the pest, its host and its vector. This needs to be recognized in determining whether the interaction between these organisms in the area of origin is maintained in the PRA area to the benefit or detriment of the pest. The probability of establishment in a protected environment, such as in greenhouses, should also be considered.

***[463]***Climatic modelling systems may be used to compare climatic data on the known distribution of a pest with that for the PRA area.

***[465]***3.2.4 Cultural practices and control measures

***[466]***Where applicable, practices employed during the production (including cultivation) of the host crops should be compared to determine if there are differences in such practices between the PRA area and the origin of the pest that may influence its ability to establish.

***[468]***Pest control programmes or natural enemies already in the PRA area that reduce the probability of establishment may be considered. Pests for which control is not feasible should be considered to pose a greater pest risk than those for which treatment is easily accomplished. The availability (or lack) of suitable methods for eradication should also be considered.

***[470]***3.2.5 Other characteristics

***[471]***Other characteristics of the pest affecting the probability of establishment include the following:

* ***[473]****Reproductive strategy of the pests and method of pest survival*. Characteristics that enable the pest to reproduce effectively in the new environment, such as parthenogenesis (i.e. self-crossing), duration of the life cycle, number of generations per year, and resting stage, should be identified.
* ***[474]****Genetic adaptability*. Whether the species is polymorphic and the degree to which the pest has demonstrated the ability to adapt to conditions like those in the PRA area should be considered (e.g. host-specific races or races adapted to a wider range of habitats or to new hosts). This genotypic (and phenotypic) variability facilitates a pest’s ability to withstand environmental fluctuations, to adapt to a wider range of habitats, to develop pesticide resistance and to overcome host resistance.
* ***[475]****Minimum population needed for establishment*. If possible, the threshold population that is required for establishment should be estimated.

***[476]***3.3 Probability of spread after establishment

***[477]***A pest with a high potential for spread may also have a high potential for establishment, and possibilities for its successful containment or eradication are more limited. To estimate the probability of spread of the pest, reliable biological information should be obtained from areas where the pest is currently present. The situation in the PRA area may then be carefully compared with that in the areas where the pest is currently present (taking account also of protected environments such as greenhouses) and expert judgement may be used to assess the probability of spread. Case histories concerning comparable pests can usefully be considered. Examples of factors that may be considered are:

* ***[479]***suitability of the natural or managed environment for natural spread of the pest;
* ***[480]***presence of natural barriers;
* ***[481]***the potential for movement with commodities or conveyances;
* ***[482]***intended use of the commodity;
* ***[483]***potential vectors of the pest in the PRA area; and
* ***[484]***potential natural enemies of the pest in the PRA area.

***[485]***Specific guidance on assessing the probability of spread of plants as pests is provided in Annex 6.

***[487]***The information on probability of spread is used to estimate how rapidly a pest’s potential economic importance may be expressed within the PRA area. This also has significance if the pest is liable to enter and establish in an area where it may be of low potential economic importance and then spread to an area where it may be of high potential economic importance. In addition, it may be important in the risk management stage when considering the feasibility of containment or eradication of an introduced pest.

***[489]***Certain pests may not cause injurious effects on plants immediately after they establish, and in particular may only spread after a certain time. In assessing the probability of spread, this should be considered, based on evidence of such behaviour.

***[491]***3.4 Conclusion on the probability of introduction and spread

***[492]***The overall probability of introduction and spread should be expressed in terms most suitable for the data, the methods used for analysis, and the intended audience. This may be quantitative or qualitative, since either output is in any case the result of a combination of both quantitative and qualitative information. The probability of introduction and spread may be expressed as a comparison with that obtained from PRAs on other pests.

***[494]***The part of the PRA area where ecological factors favour the establishment of the pest should be identified in order to help define the endangered area. This may be the whole of the PRA area or a part of the area.

***[496]***4. Assessment of potential consequences

***[497]***In PRA, consequences should not be interpreted to be only economic market effects. Goods and services not sold in commercial markets can have economic value, and economic analysis encompasses much more than the study of market goods and services. The use of the term “economic effects” provides a framework in which a wide variety of effects (including environmental and social effects) may be analysed. Economic analysis uses a monetary value as a measure to allow policy makers to compare costs and benefits from different types of goods and services. This does not preclude the use of other tools, such as qualitative and environmental analyses, that may not use monetary terms. Economic impact is described in Supplement 2 to ISPM 5.

***[499]***4.1 Consequences

***[501]***Requirements described in this step indicate what information relative to the pest and its potential host plants should be assembled, and suggest levels of economic analysis that may be carried out using that information in order to assess all the effects of the pest (i.e. the potential economic consequences). Wherever appropriate, quantitative data that will provide monetary values should be obtained. Qualitative data may also be used. Consultation with an economist may be useful.

***[503]***In many instances, detailed analysis of the estimated economic consequences is not necessary if there is sufficient evidence or it is widely agreed that the introduction of a pest will have unacceptable economic consequences (including environmental consequences). In such cases, pest risk assessment may primarily focus on the probability of introduction and spread. Economic factors should, however, be examined in greater detail when the level of economic consequences is in question, or when the level of economic consequences needs to be known to evaluate the strength of measures used to manage pest risk or in assessing the cost-benefit of exclusion or control.

***[505]***Specific guidance on assessing the potential economic consequences of plants as pests is provided in Annex 6.

***[507]***4.1.1 Pest effects

***[508]***To estimate the potential economic importance of the pest, information should be obtained from areas where the pest is present naturally or has been introduced. This information should be compared with the situation in the PRA area. Case histories concerning comparable pests can usefully be considered. The effects considered may be direct or indirect.

***[510]***The basic method for estimating the potential economic importance of pests described in this section also applies to:

* ***[512]***pests affecting uncultivated or unmanaged plants;
* ***[513]***plants as pests; and
* ***[514]***pests affecting plants through effects on other organisms.

***[515]***The environmental effects and consequences considered should be those that result from the effects of the pest on plants. Such effects on plants, however, may be less significant than the effects or consequences on other organisms or systems. For example, a plant as a pest that has only a minor impact on other plants may be significantly allergenic for humans or a minor plant pathogen may produce toxins that seriously affect livestock. However, the regulation of plants solely on the basis of their effects on other organisms or systems (e.g. on human or animal health) is outside the scope of this standard. If the PRA process reveals evidence of a potential danger to other organisms or systems, this should be communicated to the appropriate authorities that have the legal responsibility to deal with the issue.

***[517]***4.1.2 Direct pest effects

***[518]***For identification and characterization of the direct effects of the pest on each potential host in the PRA area, or those effects that are host-specific, the following are examples of factors that may be considered:

* ***[520]***known or potential host plants (in fields, under protected cultivation, or in the wild);
* ***[521]***types, amount and frequency of damage;
* ***[522]***crop losses, in yield and quality;
* ***[523]***biotic factors (e.g. adaptability and virulence of the pest) affecting damage and losses;
* ***[524]***abiotic factors (e.g. climate) affecting damage and losses;
* ***[525]***rate of spread of the pest;
* ***[526]***rate of reproduction of the pest;
* ***[527]***control measures (including existing measures), their efficacy or effectiveness and their cost;
* ***[528]***effect of the pest on existing production practices for the host plants; and
* ***[529]***environmental effects.

***[530]***For each of the potential hosts, the total area of the crop and area potentially endangered should be estimated in relation to the elements given above.

***[532]***4.1.3 Indirect pest effects

***[533]***For identification and characterization of the indirect effects of the pest in the PRA area, or those effects that are not host-specific, the following are examples of factors that may be considered:

* ***[535]***effects on domestic and export markets, including in particular effects on export-market access;
* ***[536]***changes to producer costs or input demands, including control costs;
* ***[537]***changes to domestic or foreign consumer demand for a product resulting from quality changes;
* ***[538]***environmental and other undesired effects of control measures;
* ***[539]***feasibility and cost of eradication or containment;
* ***[540]***capacity to act as a vector for other pests;
* ***[541]***resources needed for additional research and advice; and
* ***[542]***social and other effects (e.g. on tourism).

***[543]***When considering effects on domestic and export markets, the potential consequences for market access that may result if the pest becomes established should be estimated. This involves considering the extent of any phytosanitary regulations imposed (or likely to be imposed) by importing countries.

***[545]***Effects on human and animal health (e.g. toxicity, allergenicity), water tables, tourism and so on could also be considered, as appropriate, by other agencies or authorities.

***[547]***4.1.4 Assessment of non-commercial and environmental consequences

***[548]***Some of the direct and indirect effects of the introduction of a pest determined in section 4.1.2 and section 4.1.3 will be of an economic nature, or affect some type of value, but not have an existing market which can be easily identified. As a result, the effects may not be adequately measured in terms of prices in established product or service markets. Examples include, in particular, environmental effects (such as ecosystem stability, biodiversity) and social effects (such as mental well-being or spiritual, religious and cultural connections) arising from a pest introduction. These impacts may be approximated with an appropriate non-market valuation method. More details on environmental effects are given below.

***[550]***If quantitative measurement of such consequences is not feasible, qualitative information about the consequences may be provided. An explanation of how this information has been incorporated into decisions should also be provided.

***[552]***4.2 Analysis of economic consequences

***[553]***4.2.1 Time and place factors

***[554]***Estimations made in the previous section could relate to a hypothetical situation where the pest is supposed to have been introduced and to be fully expressing its potential economic consequences (per year) in the PRA area. In practice, however, economic consequences are expressed with time and may concern one year, several years or an indeterminate period. Various scenarios should be considered. The total economic consequences over more than one year may be expressed as net present value of annual economic consequences, and an appropriate discount rate selected to calculate net present value.

***[556]***Other scenarios could concern whether the pest is present at one, few or many points in the PRA area and the expression of potential economic consequences will depend on the rate and manner of spread in the PRA area. The rate of spread may be envisaged to be slow or rapid; in some cases, it may be supposed that spread can be prevented. Appropriate analysis may be used to estimate potential economic consequences over the period of time when a pest is spreading in the PRA area. In addition, many of the factors or effects considered above could be expected to change over time, with the consequent effects of potential economic consequences. Expert judgement and estimations may be used if appropriate.

***[558]***4.2.2 Analysis of commercial consequences

***[559]***As determined above, most of the direct effects of a pest, and some of the indirect effects, will be of a commercial nature or have consequences for an identified market. These effects, which may be positive or negative, should be identified and quantified where possible. The following may usefully be considered:

* ***[561]***effect of pest-induced changes to producer profits that result from changes in production costs, yields or prices; and
* ***[562]***effect of pest-induced changes in quantities demanded or prices paid for commodities by domestic and international consumers (which could include quality changes in products or quarantine-related trade restrictions resulting from a pest introduction).

***[563]***4.2.3 Analytical techniques

***[564]***There are analytical techniques that may be used, in consultation with experts in economics, to analyse in more detail the potential economic effects of a quarantine pest. The analysis should incorporate all of the effects that have been identified. The following are examples of such techniques:

* ***[566]****Partial budgeting.* This may be used if the economic effects, induced by the action of the pest, are generally limited to producers and are considered relatively minor.
* ***[567]****Partial equilibrium.* This may be used if, under section 4.2.2, there is a significant change in producer profits, or if there is a significant change in consumer demand. Partial equilibrium analysis is necessary to measure welfare changes, or the net changes arising from the pest impacts on producers and consumers.
* ***[568]****General equilibrium.* If the economic changes are significant to a national economy, and could cause changes to factors such as wages, interest rates or exchange rates, then general equilibrium analysis may be used to establish the full range of economic effects.

***[569]***The use of analytical techniques is often limited by lack of data, by uncertainties in the data, and by the fact that for certain effects only qualitative information can be provided.

***[571]***4.2.4 Analysis of non-commercial and environmental consequences

***[572]***Application of this standard to environmental consequences requires clear categorization of environmental values and the methodologies used to assess them. The environment may be valued using various methodologies, but these methodologies are best used in consultation with experts in economics. Methodologies may include consideration of “use” and “non-use” values. “Use” values arise from consumption of an element of the environment, such as accessing clean water or fishing in a lake, and also those that are non-consumptive, such as use of forests for leisure activities. “Non-use” values may be subdivided into:

* ***[574]***“option values” (values for use at a later date);
* ***[575]***“existence values” (knowledge that an element of the environment exists); and
* ***[576]***“bequest values” (knowledge that an element of the environment is available for future generations).

***[577]***Whether the element of the environment is being assessed in terms of use or non-use values, methodologies exist for their valuation, such as market-based approaches, surrogate markets, simulated markets, and benefit transfer. Each has advantages, disadvantages and situations where it is particularly useful.

***[579]***The assessment of consequences may be either quantitative or qualitative; in many cases, qualitative data are sufficient. A quantitative method may not exist to address a situation (e.g. catastrophic effects on a keystone species), or a quantitative analysis may not be possible (no methods available). Useful analyses can be based on non-monetary valuations (number of species affected, water quality), or expert judgement, if the analyses follow documented, consistent and transparent procedures.

***[581]***4.3 Conclusion of the assessment of consequences

***[582]***Wherever appropriate, the output of the assessment of consequences described in this step should be in terms of a monetary value. The consequences may also be expressed qualitatively or using quantitative measures without monetary terms. Sources of information, assumptions, uncertainty and methods of analysis should be clearly specified.

***[585]***4.3.1 Identifying the endangered area

***[586]***The part of the PRA area where presence of the pest will result in economically important loss should be identified.

***[589]***5. Degree of uncertainty

***[590]***Estimation of the probability of introduction of a pest and of its consequences involves many uncertainties. In particular, this estimation is an extrapolation from the situation where the pest is present to the hypothetical situation in the PRA area. The areas of uncertainty and the degree of uncertainty in the assessment should be documented, as should any use of expert judgement. This is important for the purposes of transparency and may also be useful for the identification and prioritization of research needs.

***[593]***6. Conclusion of the pest risk assessment stage

***[594]***As a result of the pest risk assessment, all or some of the categorized pests may be considered appropriate for pest risk management. For each pest, all or part of the PRA area may be identified as an endangered area. A quantitative or qualitative estimate of the probability of introduction and spread of a pest or pests, and a corresponding quantitative or qualitative estimate of consequences, have been obtained and documented or an overall rating could have been assigned. These estimates, with associated uncertainties, are used in the pest risk management stage of the PRA.

***[597]***

***[602]***This annex is a prescriptive part of the standard.

***[603]***ANNEX 3: Pest risk management (PRA Stage 3)

***[606]***1. Introduction

***[607]***Stage 3 involves the identification and evaluation of pest risk management options, and their subsequent selection to be implemented as phytosanitary measures that alone, or in combination, reduce the risk of introduction and spread of a pest to an acceptable level.

***[608]***The conclusions from pest risk assessment are used to decide whether a pest risk is acceptable or not. Since zero risk is not a reasonable option, pest risk should be managed following the guiding principle of managed risk (see ISPM 1) to achieve the appropriate level of protection that can be justified and is feasible within the limits of available options and resources.[[5]](#footnote-6) The uncertainty noted in the pest risk assessments should be taken into account in the selection of a pest risk management option.

***[610]***Phytosanitary measures are not justified if the pest risk is deemed to be acceptable or if they are not feasible, such as in the case of natural spread. Even in such cases, however, contracting parties may decide to maintain some monitoring or audit regarding the pest risk to detect future changes in that risk.

***[611]***2. Level of pest risk

***[612]***In implementing the principle of managed risk, it is recognized that contracting parties have the sovereign right to decide the level of pest risk they deem to be acceptable and they can use phytosanitary measures to provide an appropriate level of protection. Equally, contracting parties should follow the principle of minimal impact when applying phytosanitary measures (see IPPC Article VII.2(g)).

***[613]***The level of pest risk deemed to be acceptable may be expressed in various ways. It may, for example:

* ***[614]***refer to existing phytosanitary import requirements;
* ***[615]***be indexed to estimated economic losses; or
* ***[616]***be expressed on a scale of risk tolerance.

***[617]***Specific guidance on pest risk management for plants as pests is provided in Annex 6.

***[618]***3. Sources of information

***[619]***A variety of sources of information may be used to support the identification and subsequent selection of pest risk management options, including pest risk assessments, historical records and history of use.

***[620]***Pest risk assessments identify quarantine pests that may require phytosanitary measures on the assessed pathway. For the formulation of pest risk management options, the pest risk assessment provides relevant information, such as:

* ***[621]***the pathway;
* ***[622]***quarantine pests likely to follow the pathway;
* ***[623]***potential control points along the pathway;
* ***[624]***intended use of the commodity;
* ***[625]***historical records on pest management;
* ***[626]***potential negative effects of measures on commodity quality; and
* ***[627]***any uncertainty associated with the pest (or pests) and the pathway.

***[628]***4. Identification of appropriate pest risk management options

***[629]***4.1 Underlying principles

***[630]***The following four phytosanitary principles described in ISPM 1 should be taken into account when identifying appropriate pest risk management options:

* ***[631]****Necessity*. Phytosanitary measures should be limited to what is necessary to protect plant health.
* ***[632]****Minimal impact.* The IPPC (Article VII.2(g)) states that phytosanitary measures shall be consistent with the pest risk involved, and shall represent the least restrictive measures available that result in the minimum impediment to the international movement of people, commodities and conveyances.
* ***[633]****Equivalence*. If different phytosanitary measures providing the same level of protection are identified, they should be accepted as alternatives.
* ***[635]****Non-discrimination*. If the pest under consideration is established in the PRA area but is of limited distribution and under official control, the phytosanitary measures in relation to import should not be more stringent than those applied within the PRA area. Likewise, phytosanitary measures should not discriminate between exporting countries where the status of the relevant pest is the same.

***[637]***4.2 Requirements

***[638]***Pest risk management options should be based on the risk of the pest on a particular pathway and the intended use (further information is contained in ISPM 32 (*Categorization of commodities according to their pest risk*)). The level of risk may differ according to the pathway: for example, the presence of a pest on nursery stock may pose a very different risk from the same pest being present on fruit for consumption. Pest risk management options for the same pests may therefore vary according to the pathway. Furthermore, the types of measure identified as pest risk management options may vary according to the tolerance of the commodity to the measure.

***[639]***Depending on the intended use of the commodity, the pest risk may be sufficiently reduced to an acceptable level through basic measures including commercial production, pest-control practices and inspection.

***[640]***The major risk of introduction of pests is with imported consignments of plants and plant products, but (especially for a PRA performed on a particular pest) it is also necessary to consider the risk of introduction with other types of pathways (e.g. packing materials, conveyances, travellers and their luggage, and the natural spread of a pest).

***[641]***4.3 Pest risk management options

***[642]***Pest risk management options should be as precise as possible as to consignment type (hosts, parts of plants) and origin so as not to act as barriers to trade by limiting the import of products where this is not justified. Available measures considered as pest risk management options may be classified into broad categories relating to the pathway and the pest status in the country of origin. Measures may include those:

* ***[643]***applied to ensure the area or place of production or site of production is free from the pest;
* ***[644]***applied to prevent or reduce original infestation in the crop;
* ***[645]***applied to the consignment; or
* ***[646]***concerning the prohibition of commodities.

***[647]***Other options may arise in the PRA area, such as restrictions on the use of a commodity, introduction of a biological control agent, eradication and containment. Such options should also be evaluated and will apply in particular if the pest is already present but not widely distributed in the PRA area.

***[649]***The strength of a measure identified as a pest risk management option (i.e. its overall effectiveness) should be consistent with the pest risk that it aims to address.[[6]](#footnote-7) A stronger phytosanitary measure increases the level of confidence that the pest risk will be lowered. The level of risk reduction sought may be greater for a pest of high economic importance compared to a pest of lower economic importance.

***[651]***4.4 Specificity in relation to risk

***[652]***Pest risk management options may be identified and selected on the basis of known and specific activity against a particular pest, or they may be less specific and have a broader spectrum of activity against a group of pests.

***[653]***Examples of measures with known and specific activity against a particular pest are provided in the annexes to ISPM 28 (*Phytosanitary treatments for regulated pests*).

***[654]***4.5 Examples of pest risk management options

***[655]***The following pest risk management options are examples of the measures that are most commonly applied to regulated articles in trade. They are applied to pathways, usually consignments of a host, from a specific origin and can be stand-alone or part of a systems approach. The list of options is not exhaustive and includes measures that may already be considered as part of commercial production practices or imposed as phytosanitary measures to achieve a country’s appropriate level of protection at the conclusion of the PRA process.

***[656]***4.5.1 Pre-planting options

***[657]***Measures aimed at achieving pest freedom, either spatially or temporally, may be applied before planting.

***[658]***Requirements for pest free areas, pest free places of production and pest free production sites are described in several ISPMs (e.g. ISPM 4 (*Requirements for the establishment of pest free areas*), ISPM 10 (*Requirements for the establishment of pest free places of production and pest free production sites*), ISPM 22 (*Requirements for the establishment of areas of low pest prevalence*), ISPM 26 (*Establishment of pest free areas for fruit flies (Tephritidae)*)).

***[659]***In a pest free growing period, monitoring is carried out, based on the life cycle of the pest and the host, to verify that the pest is not detected during the growing period. Pest free growing periods are sometimes also linked to a pest-control programme.

***[660]***4.5.2 Pre-harvest options

***[661]***Measures may be applied during production to manage specific pests. These may include the application of agrochemicals, biological control agents, physical pest exclusion measures, mating disruption, surveillance and sanitation methods. Sanitation includes activities that are designed to remove materials that may attract or harbour quarantine pests, for example removing fallen fruit from orchards, destroying or ploughing-under crop residues, weed control or other similar activities.

***[662]***Physical pest-exclusion measures may include growing in protected conditions (e.g. glasshouse, fruit bagging).

***[663]***4.5.3 Options at harvest

***[664]***Examples of measures that may be applied during harvesting include:

* ***[665]***the use of harvest and dispatch “windows” (whereby harvest and dispatch are limited to the period when the pest is seasonally absent or unable to infest the commodity or when the pest and host are asynchronous);
* ***[666]***harvesting at a particular stage of ripeness or maturity;
* ***[667]***sanitation (e.g. removal of contaminating articles, waste material, infested products);
* ***[668]***defining the timing of imports (whereby the importing country defines times of the year that a particular quarantine pest cannot survive (e.g. winter) as “arrival windows”, during which the import of goods that may be infested with the pest is permitted).

***[669]***4.5.4 Post-harvest options

***[670]***A commodity may be processed and handled after harvest to reduce the pest risk posed by certain pests. Information about processing and handling of commodities and the resulting reduction in pest risk is provided in ISPM 32. Some examples include:

* ***[671]***brushing, washing, disinfection or waxing;
* ***[672]***removal of infested and damaged fruit;
* ***[673]***peeling, dicing, slicing or chopping; and
* ***[674]***removal of leaves, stems or bark.

***[675]***4.5.5 Post-entry options

***[676]***Post-entry phytosanitary measures may be applied in the importing country. Examples include:

* ***[677]***post-entry quarantine used for plants for planting (this may be the only option for certain pests not detectable on entry);
* ***[678]***limits on the intended use of the commodity (e.g. limited to processing only);
* ***[679]***entry only permitted for research purposes in containment facilities; and
* ***[680]***limited distribution of the commodity to those areas that are not endangered (use of this measure requires strict enforcement).

***[681]***4.5.6 Other options relevant for all steps

***[682]***4.5.6.1 Testing

***[683]***Some pests such as pathogens may infest a plant without producing symptoms, or symptoms may be masked, and therefore testing based on sampling may be required.

***[684]***Even when symptoms are present, testing based on sampling may be required to identify or confirm the causal organism.

***[685]***4.5.6.2 Treatments

***[686]***Treatments maybe applied at various stages in the production cycle to mitigate pest risk. Treatments maybe applied singly or in combination with other treatments or measures.

***[687]***Examples of treatments include:

* ***[688]***physical methods (e.g. brushing and washing);
* ***[689]***chemical treatments (e.g. application of fumigants, aerosols, mists, fogs, dusts, dips, granules, sprays);
* ***[690]***temperature treatments (e.g. hot water immersion, hot air treatment, vapour heat treatment, cold treatment);
* ***[691]***modified atmosphere treatments;
* ***[692]***irradiation (e.g. gamma, X-ray, microwave); and
* ***[693]***biological control.

***[694]***4.5.6.4 Inspection

***[695]***Inspection may be used as a phytosanitary measure or to verify the effectiveness of phytosanitary measures. The factors to consider when deciding to use inspection as a phytosanitary measure are described in ISPM 23 (*Guidelines for inspection*).

***[696]***4.5.7 Systems approaches

***[697]***Systems approaches offer a possible way to address the variability and uncertainty of individual measures by combining measures to meet the level of pest risk deemed to be acceptable.

***[698]***ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) provides guidance on the development and evaluation of systems approaches.

***[699]***ISPM 36 (*Integrated measures for plants for planting*) provides specific guidance on the use of integrated measures to manage the risk of plants for planting in international trade.

***[700]***4.5.8 Additional options

***[701]***Further additional phytosanitary measures may be required to provide assurance, verification, oversight, protection against infestation or contamination, or to allow for traceability.

***[702]***Examples of such measures include:

* ***[703]***certification schemes for plants for planting;
* ***[704]***registered or approved places of production or production sites;
* ***[705]***registered or approved packing houses;
* ***[706]***labelling on plants in commerce, packages and so on (e.g. identifying packing and treatment facility, dates of packing and treatment, production site and field); and
* ***[707]***segregation and secure packaging following treatment.

***[708]***4.6 Prohibition

***[709]***Prohibition should only be selected when no other alternative option is available. Other, less trade-restrictive options providing an appropriate level of protection should be considered before deciding on prohibition (see ISPM 20 (*Guidelines for a phytosanitary import regulatory system*)).

***[710]***Import prohibitions may apply to specific commodities, specific origins, specific physiological stages (e.g. dormant plants) or only during specific seasons (e.g. during the flight period of an insect).

***[711]***5. Evaluation of pest risk management options

***[712]***Measures identified as pest risk management options should be evaluated based on their effectiveness in reducing the probability of introduction and spread of the pest. To be established as phytosanitary measures, measures should not only be effective but also be feasible and have minimal impact to the international movement of commodities and conveyances.

***[713]***5.1 Effectiveness

***[714]***Effectiveness is an expression of the extent to which a given measure reduces pest risk. A description of effectiveness includes the specification of the desired response or end-point and a measurement of that response or end-point (e.g. mortality).

***[715]***When appropriate, effectiveness may be expressed in quantitative terms including the usual statistical parameters (e.g. a confidence interval). When such calculation is not possible or not feasible, effectiveness may be expressed in qualitative terms such as “high”, “medium” and “low”.

***[716]***Several factors should be considered in determining the required effectiveness of a measure. These include:

* ***[717]***the appropriate level of protection;
* ***[718]***the level of pest risk posed by a given situation;
* ***[719]***the nature of the pest risk being addressed;
* ***[720]***the biology of the pest (or pests) being managed; and
* ***[721]***the pest distribution and prevalence.

***[722]***Metrics that may be used to determine the effectiveness of a measure include:

* ***[723]***pest prevalence or frequency of pest outbreaks in the production area (e.g. from surveillance);
* ***[724]***prevalence of pests in a consignment (e.g. from inspection records); and
* ***[725]***proportion of pests removed or percent mortality (e.g. from dose–response curves).

***[726]***Certain measures may not directly affect mortality of the pest. Considerations for their evaluation include the following:

* ***[727]***for surveillance and monitoring: appropriate survey methods, intensity of monitoring, ability to detect the pest (see ISPM 6 (*Surveillance*));
* ***[728]***for pest free concepts: see ISPM 4, ISPM 10 and ISPM 26;
* ***[729]***for systems approaches: see ISPM 14 and ISPM 35 (*Systems approach for pest risk management of fruit flies (Tephritidae)*);
* ***[730]***for post-harvest processing and handling: see ISPM 32;
* ***[731]***for testing: availability and reliability of test methods, laboratory accreditation, validation of methodology (e.g. ISPM 27 (*Diagnostic protocols for regulated pests*));
* ***[732]***for irradiation treatments: see ISPM 18 (*Requirements for the use of irradiation as a phytosanitary measure*);
* ***[733]***for sampling: level of confidence of the detection of the pest for a given sample size (see ISPM 31 (*Methodologies for sampling of consignments*));
* ***[734]***for inspection: ability to detect the pest on the commodity (see ISPM 23); and
* ***[735]***for post-entry measures: see ISPM 36.

***[736]***National plant protection organizations of importing countries may identify more than one pest risk management option, consisting of one or more measures, that could be used by an exporting country.

***[737]***5.2 Treatment efficacy

***[738]***The required response or end-point for treatments should be specified, along with the required efficacy. Responses or end-points may include:

* ***[739]***mortality;
* ***[740]***sterility (including sterility of F1 generation);
* ***[741]***inactivation;
* ***[742]***devitalization; or
* ***[743]***altered behaviour.

***[744]***High-mortality treatments may not be feasible or technically justified when, for example:

* ***[745]***the testing required to establish high-mortality efficacy is not possible based on the pest biology (e.g. some organisms are difficult to rear in large enough numbers to establish the required statistical measures) but lower mortality rates can be established or lower statistical confidence can be achieved; or
* ***[746]***the commodity is only tolerant to the treatment at lower efficacies (e.g. a commodity that does not tolerate a cold treatment that achieves a high mortality rate may tolerate a cold treatment at a slightly higher temperature or shorter duration but which achieves a lower mortality rate).

***[747]***Alternative treatments may be considered when high-mortality treatments are either not available or not feasible. A combination of lower-mortality treatments may be as effective as a single high-mortality treatment.

***[748]***5.3 Potential impact of the measure

***[749]***The potential economic, social and environmental impacts of measures should be identified and considered when evaluating them as pest risk management options. The NPPO of an importing country should discuss these with the NPPOs of exporting countries.

***[750]***In general, an assessment of impacts in an exporting country may be warranted when:

* ***[751]***a particular measure may have significant unintended social or environmental impacts;
* ***[752]***the scope and magnitude of environmental impacts are unclear (as may be the case, for example, for chemical treatments);
* ***[753]***there may be public-health sensitivities or regulatory restrictions about a particular control technology; or
* ***[754]***there may be different economic impacts on different groups (producers in some areas may benefit, but producers in other areas may be disadvantaged by a particular measure).

***[755]***5.4 Uncertainty

***[756]***Pest risk management options may be difficult to evaluate if significant uncertainty is identified in the pest risk assessment. Even where uncertainty is identified, phytosanitary measures should not be applied unless information indicates that the pest risk is unacceptable.

***[757]***Uncertainty may be addressed by adjusting the strength of measures or deeming them redundant. While measures should be appropriate to the pest risk, it may be technically justifiable to require phytosanitary measures to compensate for uncertainty. In those cases, the uncertainty should be identified (in terms of the source of uncertainty and the degree of uncertainty) and, if possible, addressed. Phytosanitary measures should subsequently be adjusted once uncertainty has been reduced.

***[758]***Provisional measures may be implemented when there is uncertainty, but their application should be reviewed in a timely manner to provide technical justification for their continuance or removal.

***[759]***5.5 Feasibility

***[760]***In addition to being technically justified and effective, pest risk management options selected as phytosanitary measures should also be feasible.

***[761]***The NPPO of the importing country should identify any available measures that could prevent the introduction of the pest. These should be considered for their feasibility in the exporting country or countries.

***[762]***In determining feasibility, factors including the following should be considered:

* ***[763]***negative effects of treatments on the commodity (e.g. phytotoxicity, physical damage, reduction in shelf life);
* ***[764]***negative economic, social and environmental impacts resulting from the application of the measure;
* ***[765]***cost-effectiveness;
* ***[766]***availability of facilities and equipment;
* ***[767]***whether a particular treatment is approved for use; and
* ***[768]***operational and technical considerations (e.g. practicality, timing, available technologies).

***[769]***6. Selection of appropriate phytosanitary measures

***[770]***Once potential pest risk management options have been identified and evaluated based on effectiveness, feasibility and impacts, specific phytosanitary measures may be selected from these options.

***[771]***Exporting countries should have the opportunity to provide proposals on phytosanitary measures to importing countries.

***[772]***Depending on the effectiveness of the measures, and the appropriate level of protection, one or more phytosanitary measures may be selected.

***[773]***A phytosanitary measure that is effective against one quarantine pest may also be effective against other quarantine pests. Therefore, a single phytosanitary measure may mitigate the pest risk for multiple quarantine pests.

***[774]***If the NPPO of the importing country or countries identifies more than one appropriate phytosanitary measure to manage the pest risk, all these phytosanitary measures should be considered equivalent and published as options in the country’s phytosanitary import requirements or shared with the NPPOs of exporting countries.

***[775]***The NPPO of an exporting country should identify its preferred phytosanitary measure or measures to minimize impacts.

***[776]***7. Conclusion of pest risk management

***[777]***The pest risk management process concludes either with the determination that there are no appropriate pest risk management options or with the selection of one or more pest risk management options that would lower the pest risk to a level deemed acceptable.

***[778]***The selected pest risk management options may form the basis of phytosanitary regulations or phytosanitary import requirements for the **regulated area**.

***[779]***8. Documentation and communication

***[780]***Contracting parties should be able to provide technical justification, if requested, for phytosanitary measures applied as a result of the pest risk management stage of PRA.

***[781]***The main documentation elements to be provided on request by the NPPO of the importing country to the NPPO of an exporting country may include:

* ***[782]***the list of potential pest risk management options identified and evaluated;
* ***[783]***the selected phytosanitary measures; and
* ***[784]***the justification for selecting these, and not other, measures.

***[785]***Contracting parties should be open to consultation regarding phytosanitary measures when requested and should allow the exporting country or countries a reasonable time frame for submitting comments.

***[786]***9. Monitoring and re-evaluation of phytosanitary measures

***[787]***Phytosanitary measures may be reviewed at any stage when:

* ***[788]***the NPPO of an exporting country proposes equivalent measures for evaluation by the NPPO of the importing country according to ISPM 24 (*Guidelines for the determination and recognition of equivalence of phytosanitary measures*);
* ***[789]***there is a change in the pest status in an importing or exporting country that requires management;
* ***[790]***there is significant or repeated non-compliance (see ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*)); or
* ***[791]***emergency measures are reviewed to provide technical justification for their continuance or removal.

***[792]***The importing country may carry out monitoring of pathways to determine the effectiveness of phytosanitary measures and systems audits to verify the implementation of phytosanitary measures.

***[793]***

***[800]***This annex is a prescriptive part of the standard.

***[801]***ANNEX 4: Environmental risks

***[803]***1. Introduction

***[804]***The range of pests covered by the IPPC extends beyond pests directly affecting cultivated plants. The coverage of the IPPC definition of “pests” includes plants as pests and other species that have indirect effects on plants, and the convention applies to the protection of wild flora. The scope of the IPPC also extends to organisms that are pests because they fall into one or more of the following categories:

* ***[805]****They directly affect uncultivated or unmanaged plants*. Introduction of these pests may have few commercial consequences, and therefore they have been less likely to have been evaluated, regulated or placed under official control. An example of this type of pest is Dutch elm disease (caused by *Ophiostoma novo-ulmi* Brasier, 1991).
* ***[806]****They indirectly affect plants*. In addition to pests that directly affect host plants, there are those that affect plants primarily by other processes such as competition. Examples include most plants as pests (e.g. weeds, non-indigenous plants that establish or spread rapidly).
* ***[807]****They indirectly affect plants through effects on other organisms*. Some pests may primarily affect other organisms but thereby cause deleterious effects on plant species or on plant health in habitats or ecosystems. Examples include parasites of beneficial organisms, such as biological control agents.

***[808]***To protect the environment and biodiversity without creating disguised barriers to trade, environmental risks, including risks to biological diversity, should be analysed in a PRA.

***[809]***2. Sources of information

***[810]***For environmental risks, the variety of sources of information will generally be wider than traditionally used by NPPOs. Broader inputs may be required. These sources may include environmental impact assessments, but it should be recognized that such assessments usually do not have the same purpose as PRA and cannot substitute for PRA.

***[811]***3. Regulatory status

***[812]***Official control of pests posing an environmental risk may involve agencies other than the NPPO. However, it is recognized that Supplement 1 (Guidelines on the interpretation and application of the concepts of “official control” and “not widely distributed”) to ISPM 5 applies, and in particular its provisions regarding NPPO authority and involvement in official control.

***[813]***4. Environmental consequences of pest effects

***[814]***In the case of the analysis of environmental risks, examples of **direct pest** effects on plants or their environmental consequences that may be considered include:

* ***[815]***reduction of plant species that are key to the ecological integrity of ecosystems;
* ***[816]***reduction of plant species that are major components of ecosystems (in terms of abundance or size) and endangered indigenous plant species (including effects below species level where there is evidence of such effects being significant); and
* ***[817]***significant reduction, displacement or elimination of other plant species.

***[818]***The estimation of the area potentially endangered should relate to these effects.

***[819]***In the case of the analysis of environmental risks, examples of **indirect pest** effects on plants or their environmental consequences that may be considered include:

* ***[820]***significant effects on plant communities;
* ***[821]***significant effects on designated environmentally sensitive or protected areas;
* ***[822]***significant change in ecological processes and the structure, stability or processes of an ecosystem (including further effects on plant species, increased erosion, water-table changes, increased risk of fire, changes to nutrient cycling);
* ***[823]***effects on human use of plant communities and the environment (e.g. effects on water quality, recreational uses, tourism, animal grazing, hunting, fishing); and
* ***[824]***costs of environmental restoration.

***[825]***5. Uncertainty

***[826]***It should be noted that the assessment of the probability of introduction and spread and of environmental consequences of pests of uncultivated and unmanaged plants often involves greater uncertainty than for pests of cultivated or managed plants. This is because of the lack of information, the greater complexity associated with ecosystems, and the greater variability associated with pests, hosts or habitats of uncultivated and unmanaged plants.

***[827]***In considering the management of environmental risks, NPPOs should recognize that phytosanitary measures are intended to account for uncertainty and should be designed in proportion to the pest risk. Pest risk management options should be identified, taking account of the degree of uncertainty in the assessment of economic consequences, probability of introduction, and the respective technical justification of those options. In this respect, the management of risks to the environment caused by pests does not differ from the management of other pest risk.

***[828]***6. Communication

***[829]***Phytosanitary measures taken in relation to potential environmental consequences should, as appropriate, be notified to relevant competent authorities responsible for national biodiversity policies, strategies and action plans.

***[830]***

***[831]***

***[838]***This annex is a prescriptive part of the standard.

***[839]***ANNEX 5: Living modified organisms as pests

***[841]***1. Introduction

***[842]***The pest risk that may be posed by a living modified organism is within the scope of the IPPC and should be considered using PRA to inform decisions regarding pest risk management.

***[843]***This annex includes guidance on evaluating the potential pest risk posed by an LMO. This guidance does not alter the scope of this standard but is intended to clarify issues related to the PRA of LMOs. This annex should be read in conjunction with Annexes 1, 2 and 3 of this standard.

***[844]***The analysis of LMOs includes consideration of the following:

* ***[845]***Some LMOs may pose a pest risk and therefore warrant a PRA. However, other LMOs will not pose a pest risk beyond that posed by related non-LMOs and therefore will not warrant a complete PRA. For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not change the pest risk posed by that plant. The pest risk that may be posed by an LMO is dependent on a combination of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits. It may be useful, therefore, to consider the pest risk posed by an LMO in the context of the pest risk posed by the non-modified recipient or parental organisms, or similar organisms, in the PRA area. Section 2 of this annex therefore provides guidance on how to determine if an LMO is a potential pest.
* ***[846]***Pest risk analysis may constitute only a portion of the overall risk analysis for the import and release of an LMO. For example, countries may require the assessment of risks to human or animal health, or to the environment, beyond that covered by the IPPC. This annex only relates to the assessment and management of the risks within the scope of the IPPC. As with other organisms or pathways assessed by an NPPO, LMOs may pose other risks not falling within the scope of the IPPC. When an NPPO discovers potential for risks that are not of phytosanitary concern it may be appropriate to notify the relevant authorities.
* ***[847]***The pest risk posed by an LMO may result from certain traits introduced into the organism, such as those that increase the potential for establishment and spread, or from inserted gene sequences that do not alter the pest characteristics of the organism but that might act independently of the organism or have unintended consequences.
* ***[848]***In cases of pest risk related to gene flow, the LMO is acting more as a potential vector or pathway for introduction of a genetic construct of phytosanitary concern rather than as a pest in and of itself. Therefore, the term “pest” should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a gene posing a potential pest risk.
* ***[849]***The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. However, genotypic characteristics may need to be considered when assessing the pest risk posed by an LMO.

***[850]***2. Determining the potential for a living modified organism to be a pest

***[851]***This annex is relevant for LMOs only where there is potential for the pest risk posed by an LMO to result from some characteristic or property related to the genetic modification. Other pest risk posed by the organism should be assessed under other appropriate sections or annexes of this standard or under other appropriate ISPMs.

***[852]***The information requirements outlined in section 4.2 of this annex may be needed in determining the potential for an LMO to be a pest.

***[853]***2.1 Potential characteristics or properties of living modified organisms that may affect pest risk

***[854]***Characteristics or properties of LMOs that may potentially affect the pest risk posed by the organism include the following:

1. ***[855]***changes in adaptive characteristics that may increase the potential for introduction or spread, for example alterations in:

* ***[856]***tolerance to adverse environmental conditions (e.g. drought, freezing, salinity),
* ***[857]***reproductive biology,
* ***[858]***dispersal ability of pests,
* ***[859]***growth rate or vigour,
* ***[860]***host range,
* ***[861]***pest resistance, or
* ***[862]***pesticide (including herbicide) resistance or tolerance;

1. ***[863]***changes to gene flow or gene transfer that have adverse effects, such as:

* ***[864]***transfer of pesticide or pest resistance genes to compatible species,
* ***[865]***development of the potential to overcome existing reproductive and recombination barriers, or
* ***[866]***development of the potential for hybridization with existing organisms or pathogens to result in pathogenicity or increased pathogenicity;

1. ***[867]***changes that have adverse effects on non-target organisms, such as:

* ***[868]***changes in host range of the LMO, including the cases where it is intended for use as a biological control agent or organism otherwise claimed to be beneficial,
* ***[869]***changes that have effects on other organisms, such as biological control agents, beneficial organisms, soil fauna and microflora, or nitrogen-fixing bacteria, that result in a phytosanitary impact (indirect effects),
* ***[870]***development of the capacity to vector other pests, or
* ***[871]***negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants;

1. ***[872]***genotypic and phenotypic instability, such as:

* ***[873]***reversion of an organism intended as a biocontrol agent to a virulent form; and

1. ***[874]***changes that have other injurious effects, such as:

* ***[875]***pest risk resulting from new traits in organisms that do not normally pose a pest risk,
* ***[876]***novel or enhanced capacity for virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences, or
* ***[877]***pest risk resulting from nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.

***[878]***If there is no indication that new traits resulting from genetic modifications affect the pest risk, the LMO may require no further consideration.

***[879]***It may be useful to consider the characteristics and properties contributing to the potential pest risk in the context of those associated with the non-modified recipients or parental organisms, or similar organisms, in the PRA area.

***[880]***Factors that may result in the need to subject an LMO to Stage 2 of the PRA include:

* ***[881]***lack of knowledge about a particular modification event;
* ***[882]***insufficient credibility of information if it is an unfamiliar modification event;
* ***[883]***insufficient data on the behaviour of the LMO in environments similar to the PRA area;
* ***[884]***operational experience, research trials or laboratory data indicating that the LMO may pose a pest risk (see (1)–(2) above);
* ***[885]***expression by the LMO of characteristics that are associated with pests under Annex 2 of this standard;
* ***[886]***existence of conditions in the country (or PRA area) that may result in the LMO being a pest;
* ***[887]***existence of PRAs for similar organisms (including LMOs) or risk analyses carried out for other purposes that indicate a pest potential; and
* ***[888]***experience in other countries indicating a pest potential.

***[889]***Factors that may lead to the conclusion that an LMO is not a potential pest or requires no further consideration under this standard include:

* ***[890]***evidence from a previous assessment by the NPPO (or other recognized experts or agencies) indicating that the genetic modification in similar or related organisms does not affect pest risk;
* ***[891]***the LMO is to be confined in a reliable containment facility and not be released;
* ***[892]***evidence from research trials indicating that the LMO is unlikely to be a pest under the use proposed; and
* ***[893]***experience in other countries indicating that there is no pest potential.

***[894]***4. Initiation (PRA Stage 1)

***[895]***The aim of the initiation stage is to identify LMOs that have the characteristics of a potential pest and need to be assessed further, and those which need no further assessment under this standard.

***[896]***Living modified organisms are organisms that have been modified using techniques of modern biotechnology to express one or more new or altered traits. In most cases, the parent organism is not normally considered to be a pest but an assessment may need to be performed to determine if the genetic modification (i.e. gene, new gene sequence that regulates other genes, or gene product) results in a new trait or characteristic that may pose a pest risk.

***[897]***A pest risk from LMOs may be posed by:

* ***[898]***the organism (or organisms) with the inserted gene (or genes) (i.e. the LMO);
* ***[899]***the combination of genetic material (e.g. gene from pests such as viruses); or
* ***[900]***the consequences of the genetic material moving to another organism.

***[901]***4.1 Initiation points

***[902]***The types of LMOs that an NPPO may be asked to assess for pest risk include:

* ***[903]***plants for use (1) as agricultural crops, for food and feed, ornamental plants or managed forests; (2) in bioremediation (as an organism that cleans up pollution); (3) for industrial purposes (e.g. production of enzymes or bioplastics); (4) as therapeutic agents (e.g. pharmaceutical production);
* ***[904]***biological control agents modified to improve their performance in that role;
* ***[905]***pests modified to alter their pathogenic characteristic and thereby make them useful for biological control (see ISPM 3); and
* ***[906]***organisms genetically modified to improve their characteristics, such as for biofertilizer or other influences on soil, for bioremediation or for industrial uses.

***[907]***In order to be categorized as a pest, an LMO has to be injurious or potentially injurious to plants or plant products under conditions in the PRA area. This damage may be in the form of direct effects on plants or plant products, or indirect effects. For guidance on the process of determining whether an LMO has the potential to be a pest, see section 2 of this annex.

***[908]***4.2 Information

***[909]***For LMOs, information required for a full PRA may include:

* ***[910]***name, identity and taxonomic status of the LMO (including any relevant identifying codes) and the risk management measures applied to the LMO in the country of export;
* ***[911]***taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism;
* ***[912]***description of the nucleic acid or the modification introduced (including genetic construct) and the resulting genotypic and phenotypic characteristics of the LMO;
* ***[913]***details of the transformation process;
* ***[914]***appropriate detection and identification methods and their specificity, sensitivity and reliability;
* ***[915]***intended use, including intended containment; and
* ***[916]***quantity or volume of the LMO to be imported.

***[917]***The provision of information necessary for PRA, to the extent that is possible, is an obligation under the IPPC (Article VIII.1(c)), facilitated by official contact points (Article VIII.2). A country may have obligations to provide information about LMOs under other international agreements, such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (CBD, 2000). The Secretariat of the Convention on Biological Diversity provide an online platform, the Biosafety Clearing-House, that may contain relevant information. Information on LMOs is sometimes commercially sensitive and applicable obligations with regard to release and handling of information should be observed.

***[918]***4.3 Conclusion of initiation

***[919]***At the end of Stage 1, an NPPO may decide that the LMO is either:

* ***[920]***a potential pest and needs to be assessed further in Stage 2; or
* ***[921]***not a potential pest and needs no further analysis under this standard.

***[922]***5. Pest risk assessment (PRA Stage 2)

***[923]***For LMOs, from this point forward in PRA, it is assumed that the LMO is being assessed as a pest, and therefore “LMO” refers to an LMO that is a potential quarantine pest because of new or altered characteristics or properties resulting from the genetic modification. The risk assessment should be carried out on a case-by-case basis. Living modified organisms that have pest characteristics unrelated to the genetic modification should be assessed using the normal procedures.

***[924]***5.1 Pest categorization

***[925]***5.1.1 Identity of pest

***[926]***In the case of LMOs, identification requires information regarding characteristics of the recipient or parent organism, the donor organism, the genetic construct, the gene or transgene vector and the nature of the genetic modification. Information requirements are set out under section 4.2 of this annex.

***[927]***5.1.2 Regulatory status

***[928]***Official control should relate to the phytosanitary measures that are applied because of the pest nature of the LMO. It may be appropriate to consider any official control measures in place for the parent organism, donor organism, transgene vector or gene vector.

***[929]***5.1.3 Potential for establishment and spread in PRA area

***[930]***The following should be considered:

* ***[931]***changes in adaptive characteristics resulting from the genetic modification that may increase the potential for establishment and spread;
* ***[932]***gene transfer or gene flow that may result in the establishment and spread of pests, or the emergence of new pests; and
* ***[933]***genotypic and phenotypic instability that could result in the establishment and spread of organisms with new pest characteristics (e.g. loss of sterility genes designed to prevent outcrossing).

***[934]***5.1.4 Potential for economic consequences in PRA area

***[935]***The economic impact (including environmental impact) should relate to the pest nature (injurious to plants and plant products) of the LMO.

***[936]***5.2 Assessment of the probability of introduction and spread

***[937]***Assessing the probability of introduction of an LMO requires an analysis of both intentional or unintentional pathways of introduction, and intended use.

***[938]***5.2.1 Probability of entry of a pest

***[939]***The assessment of probability of entry is not relevant to LMOs imported for intentional release into the environment.

***[940]***5.2.1.1 Identification of pathways for a PRA initiated by a pest

***[941]***For LMOs, all relevant intentional and unintentional pathways of introduction should be considered.

***[942]***5.2.2 Probability of establishment

***[943]***The survival capacity without human intervention should be considered.

***[944]***Where gene flow is a concern in the PRA area, the probability of expression and establishment of a trait of phytosanitary concern should be considered.

***[945]***Case histories concerning comparable LMOs or other organisms carrying the same genetic construct may be considered.

***[946]***5.2.2.1 Probability of transfer to a suitable host

***[947]***When there is a trait of phytosanitary concern that may be transferred, the probability of gene flow and gene transfer should be considered.

***[948]***5.2.2.2 Cultural practices and control measures

***[949]***For plants that are LMOs, it may be appropriate to consider specific cultural, control or management practices.

***[950]***5.2.2.3 Other characteristics of the pest affecting the probability of establishment

***[951]***If there is evidence of genotypic and phenotypic instability, this should be considered.

***[952]***It may be appropriate to consider proposed production and control practices related to the LMO in the country of import.

***[953]***5.3 Assessment of potential consequences

***[954]***The impact being assessed should relate to the pest nature (injurious to plants and plant products) of the LMO.

***[955]***The following evidence should be considered:

* ***[956]***potential economic consequences that could result from adverse effects on non-target organisms that are injurious to plants or plant products; and
* ***[957]***economic consequences that could result from pest properties.

***[958]***6. Pest risk management (PRA Stage 3)

***[959]***6.1 Identification of appropriate pest risk management options

***[960]***6.1.1 Pest risk management options

***[961]***Information may have been obtained concerning the risk management measures applied to the LMO in the country of export (see section 4.2 of this annex). These measures should be assessed to determine if they are appropriate for the conditions in the PRA area and, if appropriate, the intended use.

***[962]***Measures may include procedures for the provision of information on the integrity of consignments (e.g. tracing systems, documentation systems, identity-preservation systems).

***[963]***6.1.2 Options preventing or reducing infestation in the crop

***[964]***Measures may be applied to reduce the probability that LMOs (or genetic material from LMOs) that pose a pest risk could be present in other crops. These include:

* ***[965]***management systems (e.g. buffer zones, refugia);
* ***[966]***management of trait expression;
* ***[967]***control of reproductive ability (e.g. male sterility); and
* ***[968]***control of alternative hosts.

***[969]***6.1.3 Options within the importing country

***[970]***The potential pest risk posed by LMO pests depends in part on the intended use. As for other organisms, certain intended uses (such as high-security contained use) may significantly manage pest risk.

***[971]***Options within the country include the use of emergency measures related to the potential pest risk posed by LMOs. Any emergency measures should be consistent with Article VII.6 of the IPPC.

***[972]***6.2 Phytosanitary certificates and other compliance measures

***[973]***Information on phytosanitary certificates regarding LMOs (as with any other regulated articles) should only be related to phytosanitary measures (see ISPM 12 (*Phytosanitary certificates*)).

***[974]***

***[975]***

***[982]***This annex is a prescriptive part of the standard.

***[983]***ANNEX 6: Pest risk analysis for plants as quarantine pests

***[985]***1. Introduction

***[986]***This annex provides specific guidance on conducting PRA to determine if a plant is a pest of cultivated or wild plants, whether it should be regulated, and to identify phytosanitary measures that reduce the pest risk to an acceptable level. It focuses primarily on plants proposed for import, whether as plants for planting or for other intended uses. It does not cover the unintentional introduction of plants as contaminating pests in commodities or conveyances.

***[987]***2. Plants as pests

***[988]***Plants as pests may affect other plants through competition for space and resources, such as light, nutrients and water, or through parasitism or allelopathy. Plants introduced to a new area may also become pests by hybridizing with cultivated plants or wild plants.

***[989]***Thus, the protection of plants as pursued through the IPPC may include considering certain plants as pests, and taking phytosanitary measures to prevent their introduction and spread. Determining which plants are pests is context-specific and may vary with geography, habitat, land use, time and the perceived value of the natural resources in the endangered area. Pest risk analysis should form the basis of such a determination and subsequent decisions regarding possible regulation of the plant species as a quarantine pest. It should be noted that a plant having undergone such analysis may also require assessment of its potential to be a pathway for other pests.

***[990]***The governing body of the IPPC has recognized the importance of plants as pests by underscoring that the definition of “pest” includes weeds (ICPM, 2001), and by specifically including “plants that are invasive alien species” in a range of recommendations for action for those invasive alien species that are pests of plants (ICPM, 2005). This annex provides some specific guidance on how to apply these recommendations.

***[991]***The IPPC is concerned with pests injurious to cultivated and wild plants, and therefore weeds and invasive plants that are injurious to other plants should be considered pests in the IPPC context. Henceforth in this annex, the terms “weed” and “invasive plants” are not used, but only the single term “plants as pests”.[[7]](#footnote-8)

***[993]***3. Initiation (PRA Stage 1)

***[994]***3.1 Initiation points

***[995]***The PRA process for plants as quarantine pests will most frequently arise in situations such as when:

* ***[996]***a request is made to import a plant not previously imported;
* ***[997]***a plant already available and used in a country is suspected of posing a pest risk (e.g. because of new evidence or anticipated changes in its intended use); or
* ***[998]***a decision is made to review or revise phytosanitary policies.

***[999]***3.2 Preselection

***[1000]***Annex 1 of this standard describes, as part of the initiation stage, a preselection step for determining whether or not an organism is a pest, and provides some indicators that a plant may be a pest. Particular attention is needed for plants that have proven to be pests elsewhere or that have intrinsic characteristics that are strong predictors of pest potential, such as a high propagation rate or strong competitive or propagule dispersal abilities. In most cases, consideration of these factors in Stage 1 of the PRA may not be sufficient to terminate the process; however, in cases where it is clearly determined that the plant is only suited to a specific type of habitat that does not exist in the PRA area, it may be concluded that the plant cannot become a pest in that area and the PRA process may stop at that point.

***[1001]***4. Pest risk assessment (PRA Stage 2)

***[1002]***4.1 Identity of the plant

***[1003]***The species is the taxonomic level usually considered in PRA. However, in the case of cultivated plants that may be pests, lower taxonomic levels may be used where there are scientifically sound rationales. The taxonomic level appropriate for conducting the PRA for a particular plant as a pest should be determined by the NPPO.

***[1004]***Some particular considerations regarding the identity of plants as pests may include the following:

* ***[1005]***The taxonomic identity of the plant may be unclear because it has been obscured by breeding or hybridization or is the subject of plant breeders’ rights. This is particularly relevant for horticultural plants. The NPPO should acquire the best possible information about the identity and parentage of the plant from various sources (e.g. the prospective importer, plant breeders, scientific literature).
* ***[1006]***The use of taxonomic levels below the species (i.e. subspecies, variety, cultivar) may be justified if there is scientific evidence demonstrating that differences in characteristics are stable and may significantly affect the pest risk. Examples may include differences in adaptability to environmental conditions, ability to exploit resources, ability to defend against herbivores, and methods of reproduction or propagule dispersal.
* ***[1007]***The evaluation of a hybrid should be based on information specific to that hybrid where available. Where such information does not exist, PRA may be conducted on the parent species to determine their pest risk. If either parent is determined to be a pest and the associated pest risk is deemed unacceptable, this information may form the basis of the pest risk assessment for the hybrid. However, as hybrids do not always express similar characteristics to their parent species, that approach may significantly increase the assessment uncertainty and should be used with caution.

***[1008]***4.2 Presence or absence in the PRA area

***[1009]***Determination of presence or absence in the PRA area is a particular challenge for NPPOs when plants are proposed for import because the plants may already be growing in locations (e.g. botanical gardens, home gardens) that may not be reported. Sources of information may include horticultural, agricultural, forestry and aquaculture publications and databases. The NPPO may need to carry out a survey or surveys for the plant being assessed to obtain information on its presence and distribution.

***[1010]***The presence or absence of wild or cultivated relatives in the PRA area should also be determined in the case where there is scientific evidence that the plant may hybridize with such local relatives.

***[1011]***4.3 Intended use

***[1012]***The PRA should include consideration of the intended use (see ISPM 32) of the plant being assessed, as this may affect the probability of establishment, spread and economic consequences. However, it should also be recognized that plants, once entered, may escape or be diverted from the use for which they were originally intended.

***[1013]***In the case of plants for planting, significant human effort is made to ensure their continuous survival and, in some cases, successful reproduction, because of their perceived benefits. Furthermore, the plants for planting have often been selected to be well suited for growing in the importing country. This significantly increases the likelihood of establishment and spread. Therefore, plants for planting are generally considered to pose the highest pest risk. Examples of intended uses, broadly in the order of decreasing pest risk at the time of planting, are:

* ***[1014]***planting in the open landscape without management (e.g. for soil erosion control, wastewater treatment and carbon dioxide uptake, or as aquatic plants in watercourses or ponds);
* ***[1015]***planting in the open landscape with management (e.g. in forestry, agriculture (including for biofuel), horticulture, land reclamation and golf courses, or as cover crops);
* ***[1016]***planting outdoors in urban areas (e.g. for amenity purposes in roadsides, parks or gardens); and
* ***[1017]***planting indoors only.

***[1018]***Plants for intended uses other than planting may be considered, including for human consumption or animal feed, processing, combustion for energy production, or research.

***[1019]***4.4 Habitats, locations and endangered areas

***[1020]***Plants imported for planting may be destined for a particular geographical location of a particular habitat. However, the NPPO should assess:

* ***[1021]***the probability that the plants could establish in habitats in the PRA area other than where they were intended to grow (i.e. to what degree other habitats are suitable for the plant); and
* ***[1022]***the probability that the plants could spread from the location where they were intended to grow.

***[1023]***The overall area of suitable habitats where the presence of the plant would result in economically important loss constitutes the endangered area.

***[1024]***With respect to a plant being assessed as a pest with indirect effects, wherever a reference is made to a “host” or “host range”, these terms should be understood to refer to a suitable habitat in the PRA area.

***[1025]***The analysis of suitable habitats is analogous to the analysis of host plants for other pests (in the case of parasitic plants, both host and habitat should be considered). The guidance provided in section 3.2 of Annex 2 may be applicable, substituting the terms “host” and “host range” with “suitable habitat”.

***[1026]***4.5 Probability of entry

***[1027]***For imported plants, the assessment of probability of entry is not relevant. Nevertheless, where an estimation of the volume, frequency and destinations of prospective imports is needed in order to assess the likelihood of establishment and spread, NPPOs should consider such estimations in the pest risk assessment. In addition, the probability of entry should be assessed for pests that may be carried by these plants, such as contaminating seeds carried with seeds imported for planting.

***[1028]***For plants for planting proposed for import, the plants may be planted and maintained in a particular location. A pest risk may arise if there is a possibility that the plants may spread from the location where they are intended to grow and establish in the endangered area. Accordingly, the probability of spread (section 4.8 of this annex) may be considered before the probability of establishment (section 4.7 of this annex).

***[1029]***Imported plants not intended to be planted may be used for various purposes (e.g. as bird seed, as fodder, for processing). A pest risk may arise if there is a possibility that the plants may escape or be diverted from the intended use and establish in the endangered area.

***[1030]***4.6 Historical evidence of pest behaviour

***[1031]***The most reliable predictor of establishment, spread and potential consequences of a plant as a pest is the history of that plant as a pest when introduced into new areas with similar habitats and climate. Where such a history is documented, the assessment should use this information, comparing the habitat and climate conditions with those in the PRA area to determine if they are sufficiently similar. However, a plant may never have been moved out of its native range, where it may be controlled by naturally occurring enemies or other biotic or abiotic factors. In such cases, no historical evidence will exist of establishment, spread or consequences.

***[1032]***4.7 Probability of establishment

***[1033]***In the case of plants as pests, assessment of the probability of establishment concerns their establishment in habitats other than those in which they are intended to grow.

***[1034]***The assessment of the probability of establishment should consider the suitability of the climate, other abiotic and biotic factors (see section 3.2.3 of Annex 2), and cultural practices (see section 3.2.4 of Annex 2). The assessment should compare the conditions in habitats within the PRA area to the conditions in habitats in which the plant is currently present. Depending on the information available, the following may be incorporated:

* ***[1035]****climate:* suitability of current climates and, for long-lived plants, future projected climates;
* ***[1036]****other abiotic factors:* soil characteristics, topography, hydrology, natural fires, and so on;
* ***[1037]****biotic factors:* current vegetation, degree of disturbance, presence or absence of natural enemies and competitors; and
* ***[1038]****cultural practices in crops or managed plant communities:* herbicide usage, harvesting, soil cultivation, burning, and so on (including side-effects such as aerial deposition of nitrogen or pesticides).

***[1039]***Where the history of a particular plant as a pest is not well documented, the assessment should consider intrinsic characteristics of the plant that may predict establishment (see section 3.2.5 of Annex 2). Although intrinsic characteristics have sometimes been shown to be poor predictors, the following may be considered:

* ***[1040]****reproductive characteristics:* sexual and asexual mechanisms, dioecism, duration of flowering, self-compatibility, reproduction frequency, generation time;
* ***[1041]****adaptive potential (of individuals and populations):* genotypic or phenotypic plasticity, hybridization potential;
* ***[1042]****propagule attributes:* volume and viability, dormancy; and
* ***[1043]****tolerance or resistance:* response to pests, herbicides, grazing and other cultural practices, drought, flooding, frost, salinity, climate changes.

***[1044]***Many plants as pests are opportunists with a strong potential to become established in disturbed habitats. Plants with a robust dormancy combined with a prolific reproductive ability are particularly suited for such an opportunistic strategy. Disturbed habitats are common; therefore, plants with such opportunistic adaptations may encounter many opportunities for establishment and spread.

***[1045]***4.8 Probability of spread

***[1046]***Assessment of spread concerns spread from the location where the plants are intended to grow or from the intended use to the endangered area.

***[1047]***The likelihood and extent of spread depends on natural and human-mediated factors. Natural factors may include:

* ***[1048]***intrinsic characteristics of the plant species (particularly regarding reproduction, adaptation and propagule dispersal);
* ***[1049]***existence of natural means of dispersal (e.g. birds and other animals, water, wind); or
* ***[1050]***existence and spatial pattern of suitable habitats and dispersal corridors connecting them.

***[1051]***Human-mediated factors, whether intentional or unintentional, may include:

* ***[1052]***intended use, consumer demand, economic value and ease of transport;
* ***[1053]***the movement of propagules of contaminating pests with soil or other materials (e.g. clothing, conveyances, machinery, tools, equipment);
* ***[1054]***the discarding of plants (e.g. after flowering or when private aquaria are emptied); or
* ***[1055]***disposal procedures (e.g. composting) for waste that contains plants.

***[1056]***There are often long time lags between a plant’s initial introduction and its later spread. As a consequence, even in the cases where establishment may be well documented, the potential for later spread may be less known. If evidence exists, it should be considered. This may include evidence of factors such as:

* ***[1057]***changes in abiotic factors (e.g. an increase in aerial deposition of nitrogen or sulphur);
* ***[1058]***changes in the genetic profile of the plant species (e.g. through natural selection, genetic drift);
* ***[1059]***whether the plant has a long generative time or time to maturity;
* ***[1060]***emergence of novel uses for the plant;
* ***[1061]***relatively rare dispersal events that move propagules from suboptimal to optimal habitats;
* ***[1062]***changes in land use or disturbance pattern (e.g. following natural floods, natural fires); and
* ***[1063]***changes in climate (e.g. warmer climate, changes in precipitation patterns).

***[1064]***4.9 Assessment of potential consequences

***[1065]***Plants as pests may have a variety of consequences, including yield losses in agriculture, horticulture and forestry; reduction of recreational value; or reduction of biodiversity and negative effects on other parts of the ecosystem. Assessment of consequences of plants as pests may be inherently difficult because they may have broad agricultural, environmental and social consequences that may be non-specific, not readily apparent or not easily quantified (e.g. changes in the soil’s nutrient profile).

***[1066]***The assessment should also consider the potential long-term consequences for the entire PRA area, including where the plants are intended to grow. In particular, in the case of plants for planting that may be pests, the long-term consequences for the habitat in which the plants are intended to grow may be included in the assessment because planting may affect further use of, or have a harmful effect on, that habitat.

***[1067]***The most reliable predictor of potential consequences is evidence of consequences elsewhere, particularly in areas with similar habitats. However, in some cases, plants have never been moved out of their native ranges and therefore may not have had an opportunity to express any potential consequences. In the absence of evidence of consequences elsewhere, consideration may be given to whether or not the plant possesses intrinsic characteristics that predict pest potential, such as those discussed in sections 4.7 and 4.8 of this annex and in section 3.2.5 of Annex 2 related to establishment and spread.

***[1068]***5. Pest risk management (PRA Stage 3)

***[1069]***Plants for planting will usually be introduced into habitats suitable for their establishment and growth. In such cases, most pest risk management options would be counterproductive to the intended use. In general, for plants for planting considered to be quarantine pests, the most effective pest risk management option is prohibition (see section 4.6 of Annex 3). However, those plants may at the same time have a perceived benefit that may be considered in the decision-making process following the PRA.

***[1070]***For specific situations, other pest risk management options may be pursued, such as:

* ***[1071]***requirements for growing plants under confinement;
* ***[1072]***requirements for harvesting plants at a certain stage or specified time to prevent opportunities for reproduction;
* ***[1073]***restriction of plants to particular locations, such as those that are marginally suitable;
* ***[1074]***restriction of import to specified cultivars or clones;
* ***[1075]***restrictions on the disposal of excess or waste plant material; and
* ***[1076]***other restrictions on planting, growing, sale, holding, transport or disposal.

***[1077]***In some situations, it may be appropriate for NPPOs to promote the use of codes of conduct for sale, holding, transport, planting or disposal, for example in the form of internal rules or guidelines within the plant industry to refrain from or restrict the selling of particular plants for specific intended uses.

***[1078]***For plants imported for consumption or processing, pest risk management options may include restrictions on transport, storage, locations of import and use, sale, waste disposal, time of year that import takes place, and requirements regarding processing or treatments (e.g. devitalization).

***[1079]***In identifying pest risk management options, the suitability of control measures, ease of detection, identification of and access to the plants, time needed for effective control and difficulty of eradication or containment should be considered. For example, plants in highly managed systems such as cropping systems may be more easily controlled than plants in natural or semi-natural habitats, or in private gardens. Many of the factors considered under “establishment” and “spread” also influence a plant’s response to control measures and thus the feasibility of control.

***[1080]***In cases where the assessed plants are present in collections (e.g. botanical gardens) and import regulation is considered, phytosanitary measures may have to be applied to those collections.

***[1081]***Irrespective of pest risk management options, where the import of a plant is allowed, it may be appropriate to develop post-entry systems such as surveillance in the PRA area, contingency plans, and systems to report new occurrences.

***[1082]***Potential implementation issues

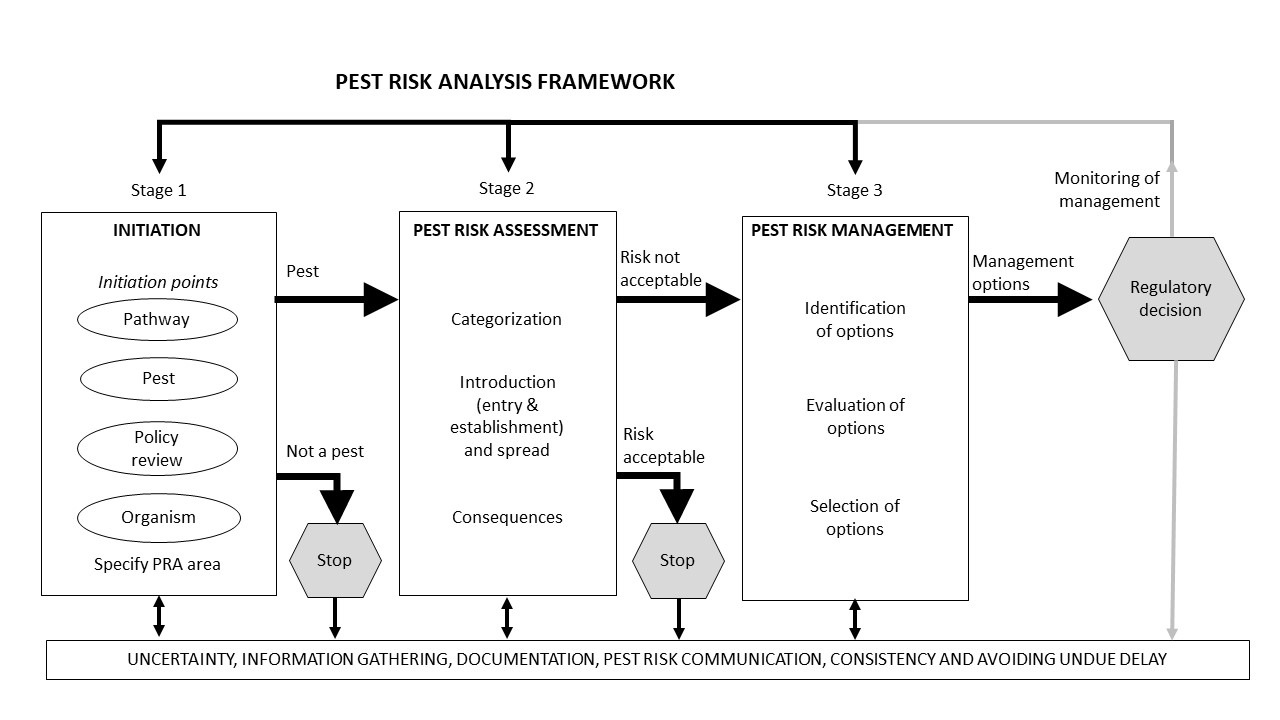
***[1083]***This section is not part of the standard. The Standards Committee in May 2023 requested the secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.

***[1084]***

***[1085]***

***[1092]***This appendix is for reference purposes only and is not a prescriptive part of the standard.

***[1093]***APPENDIX 1: Pest risk analysis flow chart

***[1095]*****

***[1096]****Note:* PRA, pest risk analysis.

1. ***[142]*** ISPM 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*) lists additional documentation requirements in relation to biological control agents and other beneficial organisms. [↑](#footnote-ref-2)
2. ***[207]*** Further information on this aspect is provided in Supplement 2 (Guidelines on the understanding of “potential economic importance” and related terms including reference to environmental considerations) to ISPM 5. [↑](#footnote-ref-3)
3. ***[239]*** “Genetically altered” organisms in this context are understood to include organisms obtained through the use of modern biotechnology. [↑](#footnote-ref-4)
4. ***[295]*** ISPM 3 recommends that NPPOs should conduct a PRA either before import or before release of biological control agents and other beneficial organisms. [↑](#footnote-ref-5)
5. ***[609]*** The appropriate level of sanitary or phytosanitary protection is a concept found in the SPS Agreement. It refers to “the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory”, which many countries refer to as the “acceptable level of risk”. [↑](#footnote-ref-6)
6. ***[650]*** The strength of measures is a concept found in the the SPS Agreement. It refers to the degree to which a measure is known to reduce the incidence of a viable, regulated pest in a commodity. [↑](#footnote-ref-7)
7. ***[992]*** “Invasive plants” are often taken to mean invasive alien species in the sense used in the Convention on Biological Diversity (see ISPM 5, Appendix 1). The term “weed” usually refers to pests of cultivated plants. However, some countries use the term “weed” irrespective of whether cultivated plants or wild flora are at risk, and other countries use the term “noxious weed”, “landscape weed”, “environmental weed” or similar terms to distinguish them from plants only affecting crops. [↑](#footnote-ref-8)