Consolidated reconciliation report for review "2017 First Consultation: Draft Specification Supplement to ISPM 11"

**T** (Type) - B = Bullet, C = Comment, P = Proposed Change, R = Rating

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| --- | --- | --- | --- | --- |
| Sequential number | Para | Text | T | Comment |
| 1 | G | (General Comment) | C | **Canada** Currently, sufficient guidance exists in ISPMs on PRA and on the evaluation of establishment. However, valuable direction is required to avoid the inconsistency in the interpretation and implementation of the guidance that is available in existing standards. The Expert Working Group should consider this and determine if further guidance in the form of an ISPM material is required or an explanatory document/manual on interpretation of the existing guidance is required.   Specific comments and changes to text are provided for relevant tasks.  *Category : SUBSTANTIVE* |
| 2 | G | (General Comment) | C | **Guyana** Guyana accepts this draft specification in its entirety.  *Category : SUBSTANTIVE* |
| 3 | G | (General Comment) | C | **Japan** 1. This supplement should cover not only the likelihood of establishment but also probability of entry of a pest, especially probability of transfer to a suitable host to ensure consistency of the requirements of ISPM11. Reason for standard refers “certain pests” and “specific pathways”. Considering Task(3), they are considered as low mobility pests and low risk pathways respectively in this specification. However, according to ISPM11, pathways and mobility of pests are factors which should be assessed mainly in “Probability of entry of a pest”. Likewise, “intended use of the commodity” in Task(2) and “the transfer to a suitable host” in Task(5) are also factors which should be assessed in the “Probability of entry of a pest”. Meanwhile, climatic requirements in Task(2) and set of conditions necessary for an organism to establish in Task(4) are factors which should be assessed in “Probability of establishment”. Therefore, this supplement should cover both entry and establishment.  2. This supplement should focus on low mobility pests and low risk pathways in order to clarify points of discussion. If ISPM11 is not sufficient for detailed conceptual guidance on the likelihood of establishment on all kinds of pests, the requirements of ISPM11 should be revised. However, this specification is expected to deal with limited cases such as low mobility pests and low risk pathways considering Task(3). Therefore the revision of ISPM11 is not needed for now and it is reasonable to develop a supplement dealing with specific cases.  *Category : SUBSTANTIVE* |
| 4 | G | (General Comment) | C | **European Union** Some of the tasks go beyond the likelihood of establishment component (2.2.2 of ISPM11) and seem to have become more general than needed to meet the needs set out in the submission form. More precision on the purpose of the proposed supplement would be helpful to the Expert Drafting Group.  *Category : SUBSTANTIVE* |
| 5 | G | (General Comment) | C | **Lao People's Democratic Republic** Lao PDR has no comment on DRAFT SPECIFICATION FOR ISPM: Supplement on Guidance on the concept of the likelihood of establishment component of a pest risk analysis for quarantine pests (2015-010) to ISPM 11 (Pest risk analysis for quarantine pests)  *Category : SUBSTANTIVE* |
| 6 | G | (General Comment) | C | **EPPO** Some of the tasks go beyond the likelihood of establishment component (2.2.2 of ISPM11) and seem to have become more general than needed to meet the needs set out in the submission form. More precision on the purpose of the proposed supplement would be helpful to the Expert Drafting Group.  *Category : SUBSTANTIVE* |
| 7 | G | (General Comment) | C | **Tajikistan** I support the document as it is and I have no comments  *Category : SUBSTANTIVE* |
| 8 | G | (General Comment) | C | **China** Add references including all the PRA method in operation.   There are 10 different PRA methods which can be used to assessment the likelihood of establishment component of a pest. The methods are listed in the table below:  Country; S/N; Standard, method and guideline  China   Method 1 GB/T 20879-2007 Technical Requirementb of Pest Risk Analysis for Import and Export Plant and Plant Product [ ]  SN/T 1893-2007 Weed-Initiated Pest Risk Analysis Requirement [ ]  Method 2 Evaluation Index System of Pest Risk (Jiang Qing, 1995) [ ]  Method 3 Index System for Risk Assessment of Alien Species (Yin Liping, 2006) [ ]  Method 4 Safety Evaluation System of Invasive Alien Species (Wan Fanghao) [ ]  Method 5 Practical Judgment Method of Imported Fruits (Sun Nan, 2008) [ ]  Method 6 Risk Assessment System for Invasive Pest of Crop (Fan Jingan & Zhao Xueqian, 1997) [ ]   The USA   Method 7 Guidelines for Plant Pest Risk Assessment of Imported Fruit & Vegetable Commodities, USDA , 2012  Weed-Initiated Pest Risk Assessment Guidelines for Qualitative Assessments, USDA, 2004   EPPO  Method 8 Decision-support Scheme for an Express Pest Risk Analysis, EPPO, 2012   Australia   Method 9 Guidelines for Import Risk Analysis, 2016   Canada   Method 10 Pest Risk Assessment Guidelines in Canada  *Category : SUBSTANTIVE* |
| 9 | G | (General Comment) | C | **Singapore** Singapore is agreeable to the proposed specifications.  *Category : EDITORIAL* |
| 10 | G | (General Comment) | C | **United States of America** Examine the NAPPO document on implementation of guidance for Likelihood of Establishment. Currently draft but should be finalized shortly  *Category : SUBSTANTIVE* |
| 11 | G | (General Comment) | C | **Samoa** no further comments on this specification  *Category : SUBSTANTIVE* |
| 12 | G | (General Comment) | C | **Algeria** NO comment  *Category : TECHNICAL* |
| 13 | G | (General Comment) | C | **Australia** Australia requests that this specification be returned to the Standards Committee to consider whether this topic is guidance on entry or establishment.   This specification appears to be about providing further guidance on the distribution of a pest from specific import pathways to its host (including considerations on mobility) which is part of entry (Entry = likelihood of importation x likelihood of distribution) not establishment. ISPM 11 states that this should be considered as part of entry (Section 2.2.1 Probability of entry of a pest: Section 2.2.1.5 Probability of transfer to a suitable host) not establishment (section 2.2.2 Probability of establishment).   • Tasks 2 and 3 refer to the ‘intended end-use of the commodity’ and ‘specific pests in low risk pathways’. The import pathway, its risk status and the intended end-use of the commodity are only relevant in the consideration of entry and transfer of the pest to a suitable host. Once the pest has transferred to a suitable host, the pathway it came in on is no longer relevant.  • Tasks 3 and 4 refer to ‘management of low mobility pests’ and ‘whether a pest has low mobility’. Once a pest has transferred to a suitable host (Entry), its mobility is not relevant to the probability of establishment. Mobility is relevant in the consideration of entry and transfer of the pest to a suitable host and also relevant to the probability of spread.   • Task 5 refers to ‘the different steps after entry that are essential for establishment including, as a minimum, the transfer to a suitable host’. Transfer to a suitable host is considered as part of entry in ISPM 11 (Section 2.2.1 Probability of entry of a pest: Section 2.2.1.5 Probability of transfer to a suitable host, not establishment.   If the supplement aims to provide further guidance on the likelihood of establishment then the content of the specification needs to be substantially refocussed to be consistent with ISPM 11. Alternatively, if the aim is to provide further guidance on the items listed above in tasks 2, 3, 4 and 5 then the title should be modified to be consistent with ISPM 11 - these things are relevant to the likelihood of entry and the probability of transfer to a suitable host rather than the likelihood of establishment.  *Category : SUBSTANTIVE* |
| 14 | G | (General Comment) | C | **PPPO** No further comments. Agree with the contents.  *Category : EDITORIAL* |
| 15 | G | (General Comment) | C | **NAPPO** In 2016, the NAPPO Executive Committee approved a project for an expert group (EG) to develop additional guidance on analysis of Likelihood of Establishment (LoE) as part of pest risk analysis (PRA).    The initial project goal, similar to the present justification, was to provide harmonized conceptual guidance on assessing LoE when conducting PRA. It was thought that the guidance could be developed either as a new Regional Standard for Phytosanitary Measures (RSPM) or as an Annex to RSPM 40 (Pest Risk Management).    Similarly to this draft specification, the NAPPO EG on LoE was charged with the following tasks:   ● Consider existing standards that address concepts of pest risk assessment, risk management, classification of commodities according their risk e.g., as ISPMs 2, 11, 14, 32; RSPM 40.   ● Review and discuss existing national and regional guidance for assessing the likelihood of pest establishment. Specifically consider guidance that emphasizes the role of evidence, i.e., of pest biology or ecological requirements for assessing likelihood of establishment.   ● Review existing guidance from other regions for pest risk assessment and pest risk management of low mobility pests or for specific pests in low risk pathways.  ● Describe key criteria that can be used to evaluate likelihood of establishment (e.g. what specific information / criteria are needed to determine whether a pest has low mobility, or what set of conditions is necessary for the organism to establish).   The EG deliberated on the above-mentioned tasks during several conference calls. After reviewing the relevant standards and existing guidance on PRA and LoE, the NAPPO EG determined that existing guidance adequately and clearly describes the process. The EG noted, however, that there may be issues with inconsistent interpretation of the existing guidance, which may cause issues with over-estimation of risk, or otherwise lead to PRAs that do not fully reflect the actual risk posed by a particular pest.    Therefore, the NAPPO EG proposed an alternative approach to the project which would be to provide a discussion document on interpretation of existing guidance in standards on evaluation of the LoE in PRAs. The EG further agreed that where possible, it would be useful to provide examples that illustrate different approaches on how LoE has been evaluated.    The resulting discussion document is on the NAPPO website. While the document provides guidance for the NAPPO region, the NAPPO EG also believes that the document could be a valuable contribution to the international plant health community, so that other regions and International Plant Protection Convention (IPPC) contracting parties can benefit from the compiled information and guidance.    NAPPO suggests that perhaps, as in the case of our EG, the IPPC EWG might consider an alternate approach (instead of a supplement to ISPM 11) concerning clarity for the concept of likelihood of establishment.  *Category : SUBSTANTIVE* |
| 16 | G | (General Comment) | C | **OIRSA** Esta norma está guiada por el Análisis de Riesgo de Plagas (ARP), la cual ha orientado el ARP para plagas incluyendo cuarentenarias, por lo tanto la presente propuesta podría sesgar o malinterpretar el ARP que realiza cada ONPF del país importador, por lo tanto se puede desarrollar la propuesta pero como apéndice a la norma; es así que podría servir como referencia para la NIMF 11 y no como parte sustancial de la misma.  *Category : SUBSTANTIVE* |
| 17 | G | (General Comment) | C | **Colombia** Estamos de acuerdo con el proyecto de especificación planteado. Sin embargo, es importante que en este suplemento se reitere que la definición de la probabilidad de establecimiento y dispersión de las plagas objeto, estén basados en estudios técnico/científicos comprobados y avalados en publicaciones indexadas. Adicionalmente, es relevante que, para la determinación de este componente, se tenga en cuenta las particularidades de las regiones biogeográficas donde se encuentran ubicados los países.  *Category : TECHNICAL* |
| 18 | G | (General Comment) | C | **Cuba**  Concordamos con los aspectos que conforman las tareas del proyecto de especificación.  *Category : SUBSTANTIVE* |
| 19 | G | (General Comment) | C | **Samoa**  agreed to the draft specification  *Category : SUBSTANTIVE* |
| DRAFT SPECIFICATION FOR ISPM: Supplement on Guidance on the concept of the likelihood of establishment component of a pest risk analysis for quarantine pests (2015-010) to ISPM 11 (Pest risk analysis for quarantine pests) | | | | |
| 20 | 1 | **DRAFT SPECIFICATION FOR ISPM: Supplement on *Guidance on the concept of the likelihood of entry and establishment component of a pest risk analysis for specific quarantine pests* such as low mobility pests (2015-010) to ISPM 11 (*Pest risk analysis for quarantine pests*)** | P | **Japan** See Japan's general comment.  *Category : SUBSTANTIVE* |
| 21 | 1 | **DRAFT SPECIFICATION FOR ISPM: Supplement on *Guidance on the concept of the ~~likelihood~~ probability of establishment component of a pest risk analysis for quarantine pests* (2015-010) to ISPM 11 (*Pest risk analysis for quarantine pests*)** | P | **Argentina** "probability" instead of "likelihood", for consistency with ISPM 11  *Category : TECHNICAL* |
| Title | | | | |
| 22 | 22 | Draft supplement *Guidance on the concept of the likelihood of entry and establishment component of a pest risk analysis for specific quarantine pests* such as low mobility pests (2015-010) to ISPM 11 (*Pest risk analysis for quarantine pests*). | P | **Japan** See Japan's general comment.  *Category : SUBSTANTIVE* |
| 23 | 22 | Draft supplement *Guidance on the concept of the ~~likelihood~~ probability of establishment component of a pest risk analysis for quarantine pests* (2015-010) to ISPM 11 (*Pest risk analysis for quarantine pests*). | P | **Brazil** Better wording for consistency with ISPM 11.  *Category : TECHNICAL* |
| 24 | 22 | Draft supplement *Guidance on the concept of the ~~likelihood~~ probability of establishment component of a pest risk analysis for quarantine pests* (2015-010) to ISPM 11 (*Pest risk analysis for quarantine pests*). | P | **Uruguay** For consistency with ISPM 11  *Category : TECHNICAL* |
| 25 | 22 | Draft supplement *Guidance on the concept of the ~~likelihood~~ probability of establishment component of a pest risk analysis for quarantine pests* (2015-010) to ISPM 11 (*Pest risk analysis for quarantine pests*). | P | **COSAVE** "probability" instead of "likelihood", for consistency with ISPM 11  *Category : TECHNICAL* |
| Reason for the standard | | | | |
| 26 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides ~~a descriptive~~ the framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk analysis, detailed conceptual guidance on the likelihood of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **European Union** 'Descriptive' is unnecessary and confusing.  *Category : TECHNICAL* |
| 27 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk analysis, detailed conceptual guidance on the ~~likelihood~~ likelihoods of entry (especially probability of transfer to a suiable host) and establishment of certain pests associated with specific pathways ~~is missing from~~ are not enough in these ~~standards~~standards when assessing specific cases like low mobility pests (including low mobility pest stages, pests with lower despersal and spread capability on the basis of biological or seasonal characteristics). This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance ~~is missing~~may be not enough. | P | **Japan** -See Japan's general comment. -Better wording for "is missing".  *Category : SUBSTANTIVE* |
| 28 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk ~~analysis~~analysis for quarantine pests, detailed conceptual guidance on the ~~likelihood~~ probability of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **Brazil** Better wording for consistency with ISPM 11.  *Category : TECHNICAL* |
| 29 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk ~~analysis~~analysis for quarantine pests, detailed conceptual guidance on the ~~likelihood~~ probability of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **Argentina** for consistency with ISPM 11  *Category : TECHNICAL* |
| 30 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides ~~a descriptive~~ the framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk analysis, detailed conceptual guidance on the likelihood of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **EPPO** 'Descriptive' is unnecessary and confusing  *Category : TECHNICAL* |
| 31 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk analysis~~, detailed conceptual guidance on the~~ . Determining likelihood of establishment ~~of certain pests associated with specific pathways~~ is ~~missing from these standards~~a critical step in PRA, but the guidance provided in ISPMs is sometimes interpreted in different ways. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **United States of America** This explains that the critical understanding of the likelihood of establishment in PRA is still missing.  *Category : TECHNICAL* |
| 32 | 24 | ~~While~~ ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk analysis, detailed conceptual guidance on the likelihood of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, harmonized international phytosanitary guidance is missing. | P | **United States of America** Better clarity for the reason of this supplement.  *Category : EDITORIAL* |
| 33 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk ~~analysis~~analysis for quarantine pests, detailed conceptual guidance on the ~~likelihood~~ probability of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **Uruguay** "for quarantine pests" added to refer to the specific information in ISPM 11. "Likelihood" changed by "probability" for consistency with ISPM 11  *Category : TECHNICAL* |
| 34 | 24 | While ISPM 2 (*Framework for pest risk analysis*) provides a descriptive framework for pest risk analysis and ISPM 11 (*Pest risk analysis for quarantine pests*) offers more specific information about carrying out pest risk ~~analysis~~analysis for quarantine pests, detailed conceptual guidance on the ~~likelihood~~ probability of establishment of certain pests associated with specific pathways is missing from these standards. This is particularly important for those situations where broad assumptions are made that any pest’s entry will always lead to their establishment. Some countries and regions have recognized and addressed this problem by implementing their own regulations or standards; however, international phytosanitary guidance is missing. | P | **COSAVE** for consistency with ISPM 11  *Category : TECHNICAL* |
| Scope | | | | |
| 35 | 26 | The supplement to the standard will provide guidance on requirements on how to ~~consider those organisms for which~~ evaluate in a ~~certain~~ PRA the set of conditions ~~are~~ required for the establishment of a certain organism to occur. The role of evidence in supporting the probability of establishment will be ~~emphasized over~~ emphasized, including evidence from research or observation in relation to the possibility and phytosanitary significance of rare events. | P | **European Union** Text improved to make clear that the Standard should include requirements.   Greater clarity has been introduced also to avoid opposing “the role of evidence” to the “possibility of rare events”.  *Category : SUBSTANTIVE* |
| 36 | 26 | The supplement to the standard will provide guidance on how to consider those organisms for which a certain set of conditions are required for ~~the~~ their entry, especially transferring to a suiable host, and establishment to ~~occur~~occur(including pest stages, pests with lower dispersal and spread capability on the basis of biological or seasonal characteristics). The role of evidence in supporting the probability of establishment ~~will~~ might be emphasized over the possibility of rare ~~events~~events based on scientific evidence. | P | **Japan** -See Japan's general comment. -"Rare events" might be emphasized based on scientific evidence.  *Category : SUBSTANTIVE* |
| 37 | 26 | The supplement to the standard will provide guidance ~~on how to consider~~ on the probability of establishment for those organisms for which a certain set of conditions are required for the establishment to occur. The role of evidence in supporting the probability of establishment will be emphasized over the possibility of rare events. | P | **Brazil** Text added to clarify the scope of this supplement.  *Category : TECHNICAL* |
| 38 | 26 | The supplement to the standard will provide guidance on ~~how to consider~~ the probability of establishment for those organisms for which a certain set of conditions are required for the establishment to occur. The role of evidence in supporting the probability of establishment will be emphasized over the possibility of rare events. | P | **Argentina** Text added to clarify the scope of this supplement.  *Category : TECHNICAL* |
| 39 | 26 | The supplement to the standard will provide guidance on requirements on how to ~~consider those organisms for which~~ evaluate in a ~~certain~~ PRA the set of conditions ~~are~~ required for the establishment of a certain organism to occur. The role of evidence in supporting the probability of establishment will be ~~emphasized over~~ emphasized, including evidence from research or observation in relation to the possibility and phytosanitary significance of rare events. | P | **EPPO** Text improved to make clear that the Standard should include requirements.    Greater clarity has been introduced also to avoid opposing “the role of evidence” to the “possibility of rare events”.  *Category : SUBSTANTIVE* |
| 40 | 26 | The supplement to the standard will provide guidance on how to consider ~~those organisms for which a certain set~~ elements related to determining likelihood of ~~conditions are required for the~~ establishment ~~to occur~~in more detail than is currently provided in existing ISPMs. The role of evidence in supporting the probability of establishment will be emphasized over the possibility of rare events. | P | **United States of America** This seems to unnecessarily constrain what the EG will be considering, and appears to be aimed at what we might call “low risk” pests. Suggest that the EG maintain an objective approach and consider how information is used to make determinations about LoE based on guidance in ISPMs. And regardless, ALL organisms require some kind of conditions to establish so this statement is particularly helpful. And the document is meant to consider “likelihood of establishment”, not “organisms”.  *Category : SUBSTANTIVE* |
| 41 | 26 | The supplement to the standard will provide guidance on ~~how to consider~~ the probability of establishment of those organisms for which a certain set of conditions are required for the establishment to occur. The role of evidence in supporting the probability of establishment will be emphasized over the possibility of rare events. | P | **Uruguay** Text added to clarify the scope of the supplement  *Category : TECHNICAL* |
| 42 | 26 | The supplement to the standard will provide guidance on how to consider those organisms for which a certain set of conditions are required for the establishment to occur. The role of evidence in supporting the probability of establishment will be emphasized over the possibility of rare events. | C | **COSAVE** For consistency  *Category : TECHNICAL* |
| 43 | 26 | The supplement to the standard will provide guidance on ~~how to consider~~ the probability of establishment for those organisms for which a certain set of conditions are required for the establishment to occur. The role of evidence in supporting the probability of establishment will be emphasized over the possibility of rare events. | P | **COSAVE** Text added to clarify the scope of this supplement.  *Category : TECHNICAL* |
| Purpose | | | | |
| 44 | 28 | The supplement will help to further harmonize guidance, at a global level, on pest risk ~~analysis~~analysis with emphasis on the likehood of establishment of a pest. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **Costa Rica**  *Category : SUBSTANTIVE* |
| 45 | 28 | The supplement will help to further harmonize guidance, at a global level, on requirements for pest risk analysis. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **European Union** See EU (and EPPO) comment on 'Scope'.  *Category : SUBSTANTIVE* |
| 46 | 28 | The supplement will help to further harmonize guidance, at a global level, on pest risk ~~analysis~~analysis to avoid cases of overestimated pest risk leading to the application of unjustified risk management measures. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **Japan** To clarify  *Category : SUBSTANTIVE* |
| 47 | 28 | The supplement will help to further harmonize ~~guidance, at a global level,~~ guidance on pest risk analysis. The benefits will include minimizing trade barriers by removing phytosanitary measures ~~for pest risk management~~ that are not technically justified. | P | **Brazil** Text deleted because is redundant.  *Category : EDITORIAL* |
| 48 | 28 | The supplement will help to further harmonize guidance, at a global level, on the probability of establishment component of a pest risk ~~analysis~~analysis for quarantine pests. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **Brazil**  *Category : TECHNICAL* |
| 49 | 28 | The supplement will help to further harmonize ~~guidance, at a global level,~~ guidance on pest risk analysis. The benefits will include minimizing trade barriers by removing phytosanitary measures ~~for pest risk management~~ that are not technically justified. | P | **Argentina** Text deleted because are redundant  *Category : EDITORIAL* |
| 50 | 28 | The supplement will help to further harmonize guidance, at a global level, on the probability of establishment component of a pest risk ~~analysis~~analysis for quarantine pests. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **Argentina** Added text to clarify the purpose which is not to provide guidance on PRA, but on an specific component.  *Category : TECHNICAL* |
| 51 | 28 | The supplement will help to further harmonize guidance, at a global level, on requirements for pest risk analysis. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **EPPO** See EPPO comment on Scope  *Category : SUBSTANTIVE* |
| 52 | 28 | The supplement will help to further harmonize ~~guidance, at a global level,~~ guidance on pest risk analysis. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **Uruguay** Text deleted because is redundant  *Category : EDITORIAL* |
| 53 | 28 | The supplement will help to further harmonize guidance, at a global level, on the probability of pest establishment component of pest risk ~~analysis~~analysis for quarantine pests. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **Uruguay** Text added to clarify the purpose of the supplement, which is not to provide guidance on PRA but on a specific component  *Category : TECHNICAL* |
| 54 | 28 | The supplement will help to further harmonize guidance, at a global level, on the probability of establishment component of a pest risk ~~analysis~~analysis for quarantine pests. The benefits will include minimizing trade barriers by removing phytosanitary measures for pest risk management that are not technically justified. | P | **COSAVE** Added text to clarify the purpose which is not to provide guidance on PRA, but on an specific component.  *Category : TECHNICAL* |
| 55 | 28 | The supplement will help to further harmonize guidance, ~~at a global level,~~ on pest risk analysis. The benefits will include minimizing trade barriers by removing phytosanitary measures ~~for pest risk management~~ that are not technically justified. | P | **COSAVE** Text deleted because are redundant  *Category : EDITORIAL* |
| Tasks | | | | |
| 56 | 31 | Consider existing ISPMs that address the concepts of pest risk assessment, pest risk management and classification of commodities according to their pest risk (e.g. ISPM 2, ISPM 11, ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) and ISPM 32 (*Categorization of commodities according to their pest risk*)).  (2) Consider definitions of seed borne and seed transmitted pests along with sections 1.2 'Seeds as Pathways' and 1.3 'Purpose of Import' of ISPM 38 (International Movement of Seed) to address the risk of establishment of a pest. | P | **International Seed Federation**  *Category : TECHNICAL* |
| 57 | 31 | [new (1)] Consider whether this guidance should be a supplement to ISPM 11 explaining the assessment process for this risk factor or whether it would be more useful to provide informaiton on how the existing guidance can be better implemented for determining likelihood of establishment.  [new (2)] Consider existing ISPMs that address the concepts of pest risk assessment, pest risk management and classification of commodities according to their pest risk (e.g. ISPM 2, ISPM 11, ISPM 14 (*The use of integrated measures in a systems approach for pest risk management*) and ISPM 32 (*Categorization of commodities according to their pest risk*)). | P | **United States of America** The NAPPO expert group developing the RSPM on the subject determined that the existing guidance is actually sufficient and it would be very difficult to add to the standards. What is missing is HOW to implement. Trying to simply identify risk according to pest mobility is difficult since that is not the sole determinant of risk. It is tied to commodity, vectors and a other multiple factors, so it is not very straightforward. Suggest the expert group be given the opportunity to go for developing a document/ or Supplement such as guidance on the interpretation and application of this concept (see ISPM 5) rather than a supplement to ISPM 11 outlining the details of the risk assessment process.  *Category : SUBSTANTIVE* |
| 58 | 32 | Review and discuss existing national and regional guidance for assessing the likelihood of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the ~~commodity)~~ commodity ability and means dispersion) for assessing the likelihood of establishment. | P | **Costa Rica**  *Category : SUBSTANTIVE* |
| 59 | 32 | Review and discuss existing national and regional guidance for assessing the likelihood of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the commodity) for assessing the likelihood of ~~establishment~~establishment and consider how to address uncertainty when evidence if incomplete or lacking. | P | **Canada** Suggest adding some working about how to address uncertainty when evidence is lacking or incomplete.  *Category : SUBSTANTIVE* |
| 60 | 32 | Review and discuss existing national and regional guidance for assessing the likelihood of entry of a pest and the pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the commodity) for assessing the likelihood of entry, especially transferring to a suitable host, and establishment. | P | **Japan** See Japan's general comments.  *Category : SUBSTANTIVE* |
| 61 | 32 | Review and discuss existing national and regional guidance for assessing the ~~likelihood~~ probability of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the ~~commodity) for assessing the likelihood of establishment.~~commodity). | P | **Brazil** Use "probability" instead of "likelihood", for consistency with ISPM 11. Text deleted because is redundant.  *Category : EDITORIAL* |
| 62 | 32 | Review and discuss existing national and regional guidance for assessing the ~~likelihood~~ probability of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the ~~commodity) for assessing the likelihood of establishment~~commodity). | P | **Argentina** See comment para 22.  Text deleted because is redundant.  *Category : EDITORIAL* |
| 63 | 32 | Review and discuss existing national and regional guidance for assessing the likelihood of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the commodity) for assessing the likelihood of establishment. | C | **Nicaragua** Nicaragua considera que los elementos citados son utilizados para realizar un análisis de riesgo, pero no existe una guía de referencia internacional que pueda ser adoptada por los países a su condición fitosanitaria. Así mismo se recomienda que el Comité de Normas proponga una guía homologada por los países, en la cual se tomen los elementos necesarios de evaluación del establecimiento de una plaga.  *Category : TECHNICAL* |
| 64 | 32 | Review and discuss existing national and regional guidance for assessing the likelihood of pest establishment; specifically, consider how the guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, and intended use of the commodity) ~~for~~ is implemented when assessing the likelihood of establishment. | P | **United States of America** Evidence is already emphasized in ISPMs. This is really an implementation problem, not an absence of guidance.  *Category : SUBSTANTIVE* |
| 65 | 32 | Review and discuss existing national and regional guidance for assessing the ~~likelihood~~ probability of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the ~~commodity) for assessing the likelihood of establishment~~commodity). | P | **Uruguay** Deleted text is redundant  *Category : EDITORIAL* |
| 66 | 32 | Review and discuss existing national and regional guidance for assessing the ~~likelihood~~ probability of pest establishment; specifically, consider guidance that emphasizes the role of evidence (i.e. pest biology, pest ecological or climatic requirements, intended use of the ~~commodity) for assessing the likelihood of establishment~~commodity). | P | **COSAVE** See comment para. 22 Text deleted because is redundant.  *Category : EDITORIAL* |
| 67 | 33 | Review existing national and regional guidance for pest risk assessment and pest risk ~~management of low~~ management, particularly those that consider pest mobility ~~pests~~ and ~~for specific pests in low~~ pathway risk ~~pathways~~as they relate to potential for establishment. | P | **Canada** The language is a bit specific in referring to “low mobility pests”, “pests in low risk pathways”, etc. At this stage suggest keeping the guidance more general and applicable to all pests and situations, and allow the PRA process itself to identify which pests is low vs high risk for establishment.  *Category : SUBSTANTIVE* |
| 68 | 33 | Review existing national and regional guidance for pest risk assessment and pest risk management in specific situations which have an impact on likelihood of establishment, for example pests of low ~~mobility~~ intrinsic mobility, pests ~~and~~ with low capacity for reproduction and specific pests in low risk pathways. | P | **European Union** Low mobility is just one example. Also need to distinguish intrinsic mobility from likelihood of spread by human agency.  *Category : TECHNICAL* |
| 69 | 33 | Review existing national and regional guidance for pest risk assessment and pest risk management of low mobility pests and for specific pests ~~in~~ associated with pathways which are considered as low pest risk ~~pathways~~(e.g. for human consumption or processing). | P | **Japan** To clarify "low risk pathways"  *Category : SUBSTANTIVE* |
| 70 | 33 | Review existing national and regional guidance for pest risk assessment and pest risk management in specific situations which have an impact on likelihood of establishment for example pests of low ~~mobility~~ intrinsic mobility, pests ~~and~~ with low capacity for reproduction and specific pests in low risk pathways. | P | **EPPO** Low mobility is just one example. Also need to distinguish intrinsic mobility from likelihood of spread by human agency.  *Category : TECHNICAL* |
| 71 | 33 | ~~Review existing national and regional guidance for pest risk assessment and pest risk management of low mobility pests and for specific pests in low risk pathways.~~ | P | **United States of America** In reality this will be very difficult to restrict discussions to ONLY low risk pests, low mobility, etc. This is a short sighted approach to handling what is really an implementation problem.  *Category : TECHNICAL* |
| 72 | 34 | Describe key criteria that can be used to evaluate the likelihood of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions outdoor or in 'protected cultivation' such as glasshouses etc. necessary for an organism to establish). | P | **European Union** Improvement to highlight, that it is fully legitimate that PRAs take threats to protected cultivation into account.  *Category : TECHNICAL* |
| 73 | 34 | Describe key criteria that can be used to evaluate probability of the ~~likelihood~~ pest being associated with the pathway at origin(e.g. sorting, grading and pest management in the exporting country), probability of transfer to a suitable host and probability of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | P | **Japan** Reason for the standard and Tasks refer pathways(e.g. specific pathways, low risk pathways) and transfer to a suitable host. In this regard, this supplement should cover at least pathway, transfer to a suitable host and establishment. Regarding pathway, the probability of the pest being associated with the pathway at origin needs to be evaluated appropriately.  *Category : SUBSTANTIVE* |
| 74 | 34 | Describe key criteria that can be used to evaluate the likelihood of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | C | **Kenya** The reviewers can consider developing and recommending a scale and parameters upon which the likelihood of establishment can be flagged as high, medium or low. This can help in eliminating subjectivity. This can also be developed for likelihood of entry and spread.  *Category : SUBSTANTIVE* |
| 75 | 34 | Describe key criteria that can be used to evaluate the likelihood (The reviewers can consider developing and recommending a scale and parameters upon which the likelihood of establishment can be flagged as high, medium or low. This can help in eliminating subjectivity. This can also be developed for likelihood of entry and spread) of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | P | **Kenya**  *Category : SUBSTANTIVE* |
| 76 | 34 | Describe key criteria that can be used to evaluate the ~~likelihood~~ probability of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | P | **Brazil** Use "probability" instead of "likelihood", for consistency with ISPM 11  *Category : TECHNICAL* |
| 77 | 34 | Describe key criteria that can be used to evaluate the ~~likelihood~~ probability of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | P | **Argentina** See comments para 22  *Category : TECHNICAL* |
| 78 | 34 | Describe key criteria that can be used to evaluate the likelihood of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions outdoor or in ‘protected cultivation’ such as glasshouses etc. necessary for an organism to establish). | P | **EPPO** Improvement to highlight, that it is fully legitimate that PRAs take threats to protected cultivation into account  *Category : TECHNICAL* |
| 79 | 34 | Describe key criteria that can be used to evaluate the likelihood of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | C | **Nicaragua** Nicaragua propone que este párrafo debe leerse así:  Describir los criterios claves que se pueden utilizar para evaluar la probabilidad de establecimiento de una plaga cuarentenaria considerando las siguientes condiciones: biología de la plaga, condiciones climáticas, hospederos principales, alternos y vectores relevantes. Para determinar los criterios de una plaga de baja movilidad además se debe considerar la naturaleza y finalidad del producto.  *Category : SUBSTANTIVE* |
| 80 | 34 | Describe key criteria that can be used to evaluate the likelihood of establishment ~~(e.g. specific information or criteria needed to determine whether a pest has low mobility~~considering, ~~set~~ where necessary, important differences between major groups of ~~conditions necessary for an organism to establish)~~pests. | P | **United States of America** In reality this will be very difficult to restrict discussions to ONLY low risk pests, low mobility, etc. This is a short sighted approach to handling what is really an implementation problem.  *Category : TECHNICAL* |
| 81 | 34 | Describe key criteria that can be used to evaluate the ~~likelihood~~ probability of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | P | **Uruguay** For consistency with ISPM 11  *Category : TECHNICAL* |
| 82 | 34 | Describe key criteria that can be used to evaluate the ~~likelihood~~ probability of establishment (e.g. specific information or criteria needed to determine whether a pest has low mobility, set of conditions necessary for an organism to establish). | P | **COSAVE** see comments para. 22  *Category : TECHNICAL* |
| 83 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the ~~transfer to a~~ presence of suitable ~~host and then~~ hosts or habitats as well as the existence of suitable environmental conditions that ~~result in infection~~ would lead to perpetuation of ~~this host and~~ the pest in ~~establishment in~~ the longer term. | P | **Canada** The proposed change allows for the inclusion of plants as pests for which availability of a suitable habitat is important. Perpetuation of the pest allows for the inclusion of plants as pests and also the other pests, which need to infect or infest a suitable host.  *Category : SUBSTANTIVE* |
| 84 | 35 | Consider the different steps ~~after entry~~ that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in infection of this host and in establishment in the longer term. | P | **European Union** Transfer to the host should be assessed as part of entry not establishment (2.2.1.5 of ISPM11).  *Category : SUBSTANTIVE* |
| 85 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in ~~infection~~ infestation of this host and in establishment in the longer term. | P | **European Union** To be more inclusive.  *Category : TECHNICAL* |
| 86 | 35 | Consider the different steps during final stage of entry and after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in infection of this host and in establishment in the longer term. | P | **Japan** See Japan's general comments.  *Category : SUBSTANTIVE* |
| 87 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in ~~infection~~ infestation of this host and in ~~establishment in the longer term~~its establishment. | P | **Brazil** "Infestation" is a glossary term.  Text deleted is redundant  *Category : EDITORIAL* |
| 88 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in ~~infection~~ infestation of this host and in ~~establishment in the longer term~~establishment. | P | **Argentina** "Infestation" is a glossary term.  Text deleted is redundant  *Category : EDITORIAL* |
| 89 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in ~~infection~~ infestation of this host and in establishment in the longer term. | P | **EPPO** To be more inclusive  *Category : TECHNICAL* |
| 90 | 35 | Consider the different steps ~~after entry~~ that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in infection of this host and in establishment in the longer term. | P | **EPPO** Transfer to the host should be assessed as part of entry not establishment (2.2.1.5 of ISPM11).  *Category : SUBSTANTIVE* |
| 91 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host or environment and then the existence of suitable environmental conditions that result in infection of this host or environmental damage and in establishment in the longer term. | P | **China** Most of weed without host but could entry and infect the environment  *Category : SUBSTANTIVE* |
| 92 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in ~~infection~~ infestation of this host and in establishment ~~in the longer term.~~ | P | **Uruguay** Infestation is the Glossary term. "in the longer term" deleted because is redundant  *Category : TECHNICAL* |
| 93 | 35 | Consider the different steps after entry that are essential for establishment, including, as a minimum, the transfer to a suitable host and then the existence of suitable environmental conditions that result in ~~infection~~ infestation of this host and in ~~establishment in the longer term~~establishment. | P | **COSAVE** "Infestation" is a glossary term. Text deleted is redundant  *Category : EDITORIAL* |
| Expertise | | | | |
| 94 | 45 | Five to seven experts with a wide knowledge of and experience in pest risk assessment, preferably with a combined knowledge of and experience in pest risk management, entomology, plant ~~pathology~~ pathology, botany, weed science and phytosanitary regulation. | P | **Canada** PRA is regularly applied to plants as pests in addition to other pests.  *Category : SUBSTANTIVE* |
| 95 | 45 | Five to seven experts with a wide knowledge of and experience in pest risk assessment, preferably with a combined knowledge of and experience in pest risk management, entomology, plant ~~pathology~~ pathology, weed science and phytosanitary regulation. | P | **China**  *Category : SUBSTANTIVE* |
| References | | | | |
| 96 | 51 | **COSAVE** (Comité de ~~Sandid~~ Sanidad Vegetal). 2003. *Lineamientos para la evaluación y manejo riesgo de plagas cuarentenarias de baja movilidad en vías de ingreso destinadas al consumo*. Regional Standard for Phytosanitary Measures (RSPM) 3.5. Montevideo, COSAVE. | P | **Brazil**  *Category : EDITORIAL* |
| 97 | 51 | **COSAVE** (Comité de ~~Sandid~~ Sanidad Vegetal). 2003. *Lineamientos para la evaluación y manejo riesgo de plagas cuarentenarias de baja movilidad en vías de ingreso destinadas al consumo*. Regional Standard for Phytosanitary Measures (RSPM) 3.5. Montevideo, COSAVE. | P | **Argentina**  *Category : EDITORIAL* |
| 98 | 51 | **COSAVE** (Comité de ~~Sandid~~ Sanidad Vegetal). 2003. *Lineamientos para la evaluación y manejo riesgo de plagas cuarentenarias de baja movilidad en vías de ingreso destinadas al consumo*. Regional Standard for Phytosanitary Measures (RSPM) 3.5. Montevideo, COSAVE. | P | **Uruguay** Editorial error  *Category : EDITORIAL* |
| 99 | 51 | **COSAVE** (Comité de ~~Sandid~~ Sanidad Vegetal). 2003. *Lineamientos para la evaluación y manejo riesgo de plagas cuarentenarias de baja movilidad en vías de ingreso destinadas al consumo*. Regional Standard for Phytosanitary Measures (RSPM) 3.5. Montevideo, COSAVE. | P | **COSAVE**  *Category : EDITORIAL* |