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منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

COMMISSION ON PHYTOSANITARY MEASURES

Second Session

Rome, 26 – 30 March 2007

Comments on draft standards (CPM 2007/2 - Annex II)
Revision of ISPM No. 2 (*Framework for pest risk analysis*)

Agenda Item 9.2 of the Provisional Agenda

Document by the IPPC Secretariat

1. The Secretariat compiled comments received in advance of the CPM on the draft revision of ISPM No. 2 (*Framework for pest risk analysis*) from the following members and RPPO:

- Argentina
- Australia
- Bolivia
- Brazil
- Canada
- Chile
- COSAVE
- EC and its 27 member states
- Japan
- Korea (Republic)
- New Zealand
- Norway
- Paraguay
- Uruguay
- USA.

Draft ISPMs for adoption at CPM-2 (2007)

ANNEX II OF DOCUMENT CPM 2007/2

DRAFT ISPM - REVISION OF ISPM NO. 2: FRAMEWORK FOR PEST RISK ANALYSIS

The following are comments received as of 14 March 2007 according to guidelines given in the document CPM 2007/2. They are provided for information and the final document will be provided at the CPM meeting.

The Secretariat has compiled in the order of the text the comments received in advance of the CPM meeting, exactly as provided by countries.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
1.	***GENERAL COMMENTS***	Australia	editorial	through out	Consistency of reference to other ISPMs needs to be ensured (not just in this draft ISPM but in others released for consideration of CPM2). That is, in referring to other ISPMs is it ISPM # (name, date) or ISPM # (name), etc. Now that all ISPM is a published in a single reference document consistency needs to be ensured.	
2.	***GENERAL COMMENTS***	Australia	editorial	through out	Consistent use of ":"at the beginning of lists. Some use: and others don't.	
3.	***GENERAL COMMENTS***	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE			1) Hazard is used in item 3.3.2 and must be defined to be clearly differentiated from risk.	
4.	REFERENCES	Australia	Editorial	3rd reference	*…in environmental considerations ~~(in Glossary of phytosanitary terms, 2006)~~,*	confusing. See ISPM 11 for consistency to reference
5.	REFERENCES	Norway	Tecnical		Add Convention on Biological Diversity, 1992. CBD, Montreal Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000. CBD, Montreal	Relevant to LMO. Also referred to in ISPM 3 and ISPM 11
6.	DEFINITIONS	Canada	Editorial	Definition for "pest risk assessment (for quarantine pests)"	Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences (further described in ~~see~~ Glossary Supplement No. 2)	As per Standards Committee agreements, direct instructions to the reader to "see" another text or section will not be used. Instead, such references should be indirect.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
7.	DEFINITIONS	Canada	Editorial	Definition for "pest risk (for quarantine pests)"	The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences (further described in~~see~~ Glossary Supplement No. 2)	As per Standards Committee agreements, direct instructions to the reader to "see" another text or section will not be used. Instead, such references should be indirect.
8.	DEFINITIONS	Canada	Editorial	Definition for "pest risk (for regulated nonquarantine pests)"	The probability that a pest in plants for planting affects the intended use of those plants with an economically unacceptable impact (further described in~~see~~ Glossary Supplement No. 2)	As per Standards Committee agreements, direct instructions to the reader to "see" another text or section will not be used. Instead, such references should be indirect.
9.	OUTLINE OF REQUIREMENTS	Australia	**substantive**	Para 1 sentence 1	delete ~~Pest risk analysis (PRA) provides a basis for determining appropriate phytosanitary measures~~	**In definitions section - Pest risk analysis is interpreted as "**The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it"(underlining added) BUT in **OUTLINE OF REQUIREMENTS section,** PRA "provides a basis for determining appropriate phytosanitary measures" Suggest an inconsistency here – the need for and strength of any phytosanitary measures is part of the first definition of PRA while the second description suggests that determining phytosanitary measures is separate to PRA
10.	OUTLINE OF REQUIREMENTS	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	1st para	Pest risk analysis (PRA) ~~provides a basis~~ is a technical tool used for determining appropriate phytosanitary measures.	
11.	OUTLINE OF REQUIREMENTS	Australia	Editorial	para 2 sentence 2	…appearing in ISPM**s** No.3, No. 11 and No.21	make ISPM plural
12.	**BACKGROUND**	Australia	Editorial	para 1 sentence 1	Pest risk analysis (PRA) is a science-**based** and economics consequences ~~based~~ process that provides the rationale for phytosanitary measures for a specified PRA area.	The use of the term "economic based" implies more than just the consequences.

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13.	**BACKGROUND**	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical Technical	1st para 1st para	Pest risk analysis (PRA) ~~is a science and economics-based that~~ provides the rationale for phytosanitary measures for a specified PRA area. It evaluates scientific evidence to determine whether an organism is a pest. If so, 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~~, technical~~ and economic evidence. …If the risk is deemed unacceptable…….	It is not necessary to repeat a definition and the text is not on line with the definition of pest risk analysis. To be consistent with the definition of PRA
14.	**BACKGROUND**	Australia	Editorial	para 2	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~~ **determined by doing xxxx** [1].	Suggest some rewording to clarify what needs to be done to "resolve" whether they are pests and how this can be measured. It is unclear whether this is a reference to using pest indicators as described in section 1.2 Determination of an organism as a pest.
15.	**BACKGROUND**	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Footnote 1	1 The IPPC defines a pest as "*any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products*". The understanding of pests includes organisms that are pests because they directly affect either cultivated/ managed plants or uncultivated/unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms (see Annex 1 of ISPM No. 11, 2004).	The text looks like excluding cultivated/managed plants
16.	**BACKGROUND**	Canada	Editorial	Footnote to second paragraph	The IPPC defines a pest as "any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products". The understanding of pests includes organisms that are pests because they directly affect uncultivated/unmanaged plants, indirectly affect plants, or indirectly affect plants through effects on other organisms (further information is provided in~~see~~ Annex 1 of ISPM No. 11, 2004).	As per Standards Committee agreements, direct instructions to the reader to "see" another text or section will not be used. Instead, such references should be indirect

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
17.	**BACKGROUND**	Australia	Editorial	Revision of this standard 2nd dash point	…appearing in ISPMs No.3, No. 11 and No.21	make ISPM plural
18.	**BACKGROUND**	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	**Revision of this standard**, 2nd para	**Revision of this standard** This revision of ISPM No. 2 particularly addresses the issues of: - aligning the text with the 1997 revision of the IPPC - aligning the text with further conceptual developments of the PRA scope and procedures as appearing in ISPM No. 3, No. 11 and No. 21 - including regulated non-quarantine pests (RNQPs) in the description of the PRA process - including organisms not known beforehand to be pests in the description of the PRA process - including aspects common to all PRA stages in the description of the PRA. Thus, this standard provides detailed guidance on PRA Stage 1 and issues generic to all PRA stages, and refers to other ISPMs (identified in Table 1) as appropriate for further analysis through PRA Stages 2 and 3. ~~These standards are conceptual and are not~~ This standard is conceptual and is not a detailed operational or methodological guide~~s~~ for assessors. …	Adjust the text for "this standard" that is the subject of the phrase.
19.	**BACKGROUND**	Norway	Editorial	Para 9, sentence 2		Is this sentence necessary in this standard? We suggest that this information is better placed in ISPM's 3,11 and 21(if relevant)
20.	**BACKGROUND**	Australia	**substantive**	Provisions of the IPPC regarding PRA para 5 new dash point	**- sovereignty**	**the recognition of sovereignty is also applicable**
21.	**1. PRA Stage 1: Initiation**	Australia	editorial	footnote 2		italicize whole title of reference

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
22.	1.1.1 Identification of a pathway	Australia	**Substantive**	para 3 sentence 2	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.	The actual records only represent what has already been found, not what has the potential to be found, on a crop. There may be other sources of data available on which a pest list can appropriately be based. There may also be pests in exporting country, associated with commodity, that have not previously been intercepted but technical justification would exist for their assessment.
23.	1.1.1 Identification of a pathway	Norway	technical	Para 3, sentence 2		Should be rephrased to clarify that in such cases records of interceptions are important (but not the only) source of information for the establishing of the list of likely associated pests
24.	1.1.3 Review of phytosanitary policies	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	1st para	The need for a new or revised PRA may arise from situations such as when - a national review of phytosanitary regulations, requirements or operations is undertaken - an official control programme ~~(e.g. certification scheme~~) is developed to avoid unacceptable economic impact of specified RNQPs in plants for planting..	To avoid misunderstandings with certification schemes not directly addressing phytosanitary issues.
25.	1.1.3 Review of phytosanitary policies	Japan	Substantive	Para 3	~~For existing trade, no new measures should be applied until the revision or new PRA has been completed,~~ ~~unless this is warranted by new or unexpected phytosanitary situations which may necessitate emergency~~ ~~measures.~~	This paragraph is out of scope of this standard on framework for PRA

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
26.	1.1.4 Identification of an organism not previously known to be a pest	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical Technical	1st para	An organism may be considered for PRA in situations such as when - a proposal is made to import a new plant species or variety for cropping, amenity or environmental purposes - a proposal is made to import or release a biological control agent or other beneficial organism ~~- an organism is found which is new to science or for which there is little information available~~ - a proposal is made to import an organism for research, analysis or other purpose - a proposal is made to import or release an LMO (See Annex 3 of ISPM No. 11). In these situations it would be necessary to determine if the organism is a pest and thus subject to PRA Stage 2. Section 1.2 provides further guidance in this matter.	There is no way to perform a PRA for this kind of organisms. Organisms new for science normally don't have enough epidemiological information to perform the PRA and if they have, they are not any more new for science. To be consistent with consensus reached at the review of ISPM No. 11.
27.	1.2 Determination of an organism as a pest	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Paragraph transported from 1.2.3	Pre-selection or screening are terms sometimes used to cover the early step of determining whether an organism is a pest or not. The taxonomic identity of the organism should be specified 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. In imported consignments, organisms may be detected that are difficult to identify (e.g. damaged specimen or unidentifiable life stages). Although in such cases the information available may be very limited, a decision may need to be made as to whether phytosanitary action is justified. The taxonomic level for organisms considered in PRA is usually the species. The use of a	For coherence

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					higher or lower taxonomic level should be supported by a scientifically sound rationale. In cases where levels below the species level are being analysed, the rationale for this distinction should include evidence of reported significant variation in factors such as virulence, pesticide resistance, environmental adaptability, host range or its role as a vector. 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. The following are examples of indicators to consider: - previous history of successful establishment in new areas - phytopathogenic characteristics - phytophagous characteristics - presence detected in connection with observations of injury to plants, beneficial organisms, etc. without any clear causal link - belonging to taxa (family or genus) commonly containing known pests - capability of acting as a vector for known pests - adverse effects on non-target organisms beneficial to plants (such as pollinators or predators of plant pests).	
28.	1.2 Determination of an organism as a pest	European Commission and its 27 member states (hereafter EC + 27 MS)	Editorial	5th para, 4th indent	- presence detected in connection with observations of injury to plants, beneficial organisms, etc. ~~without any clear causal link~~ **before any clear causal link has been established.**	To express explicitly that eventually a causal link must be established for the organism to be deemed a pest

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
29.	1.2 Determination of an organism as a pest	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Last para	Particular cases for analysis include plant species, biological control agents and other beneficial organisms, ~~organisms new to science,~~ intentional import of organisms and LMOs. The pest potential of LM-plants should be determined as outlined in section 1.2.4.	There is no way to perform a PRA for this kind of organisms. Organisms new for science normally don't have enough epidemiological information to perform the PRA and if they have, they are not any more new for science
30.	1.2.1 Plants as pests	Australia	editorial	para 1 sentence 1	~~Plants have deliberately been spread among countries and continents for millennia and new species or varieties of plants cropping, amenity or environmental purposes are continually imported~~.	The next sentence in the paragraph says why plants are pests are included so this introduction is not needed.
31.	1.2.1 Plants as pests	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Editorial	4th para	The primary indicator that a plant species may become a pest in the PRA area is the existence of reports of ~~such~~ harm having occurred elsewhere. Some intrinsic attributes that may indicate that a plant species could….	Unnecessary and confusing
32.	1.2.1 Plants as pests	Australia	**substantive**	para 4 sentence 1	The primary indicator that a plant species may become a pest in the PRA area is the existence of reports ~~of such harm having occurred elsewhere~~ **that the plant species has been recorded as a pest elsewhere**.	ICPM 3 clarified that "weeds" could be included in "pests". So rather than use "harm" use pest and restructure the sentence accordingly.
33.	1.2.1 Plants as pests	Australia	**substantive**	para 4 sentence 2	Some intrinsic attributes that may indicate that a plant species could be a pest include**, but are not limited to**:	Suggest noting that intrinsic attributes are not necessarily limited to the dot points listed on this page.
34.	1.2.1 Plants as pests	EC + 27 MS	Technical	Last para	Start the para: '**However, it should be noted that plant species or cultivars without such attributes may nevertheless become pests and** that long time laps... 'etc.	As stated in the paragraph just before, the primary indicator is that the plant species has become a pest elsewhere. The other indicators listed in reality are quite weak, and therefore a general warning is appropriate that plants may become pests despite n ot displaying those attributes
35.	1.2.1 Plants as pests	USA	technical	Last sentence	Replace with "However, it should be noted that plant species without such attributes can still become plant pests."	More related to the information from previous paragraph

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
36.	1.2.2 Biological control agents and other beneficial organisms	Canada	Technical	First paragraph, first sentence	Preferred change: Biological control agents and other beneficial organisms are intended to be beneficial to plants ~~without causing injury, except in the case where the biological control agent is used against weeds~~. Otherwise acceptable change: Biological control agents and other beneficial organisms are intended to be beneficial to plants without causing them injury, except in the case where the biological control agent is used against weeds.	All biological agents are intended to cause injury in some form or another, to some other organism – that is their general mode of operation. It is the avoidance of injury to the plant that is being protected that is the point here. Change proposed to relate the injury to the protected plants. The best approach would be to simplify significantly the sentence as suggested in the preferred change. This simplified sentence leads into the second sentence much more fluidly too.
37.	1.2.3 Organisms new to science or for which only minimal information is available	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Entire item	~~In imported consignments or during surveillance, organisms may be detected that are difficult to identify (e.g. damaged specimen or unidentifiable life stages) or are new to science. Although in such cases the information available may be very limited, a decision may need to be made as to whether phytosanitary action is justified. When organisms have been detected that are difficult to identify, recommendations for phytosanitary measures may have to be made based on incomplete identification. The PRA allows a decision to be taken based on all available information. It also enables information gaps to be identified and recommendations for further studies to be specified.~~ ~~It is recommended that specimens are deposited in an accessible reference collection for future further examination.~~	This explanation does not correspond to organisms new to science or not previously described and problems in identification are a common situation to many types of organisms. For this reason part of this paragraph has been added to item 1.2, but not considered a particular case to be listed under this ISPM.
38.	1.2.4 Living modified organisms	Australia	**substantive**	para 1 sentence 1	LMOs are organisms that possess a novel combination of genetic material, obtained through the use of modern biotechnology.~~ and are designed to express one or more new or altered traits in order to improve certain properties of the organism.~~	Delete remainder of sentence as LMOs are a defined term and the additional text may cause some problems including "improve". If this is a new definition it should be put through the technical panel for the glossary.
39.	1.2.4 Living modified organisms	USA	technical	Paragraph 1, first sentence	Delete “and are designed to express one or more new or altered traits in order to improve certain properties of the organism.”	This is adding more to what the definition says and is not totally accurate.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
40.	1.2.4 Living modified organisms	Canada	substantive	1st paragraph, 1st sentence	LMOs are organisms that possess a novel combination of genetic material, obtained through the use of modern biotechnology and are designed to express one or more new or altered traits ~~in order to improve certain properties of the organism~~.	This sentence appears to re-define LMOs unnecessarily, in a way that is inconsistent with the definition that currently exists and the way that the term is used and referred to in ISPM No. 11. Change suggested to avoid this problem.
41.	1.2.4 Living modified organisms	New Zealand	editorial	1st sentence second line	"….in order to change certain …."	LMOs do not necessarily improve the traits according to earlier docs.
42.	1.2.4 Living modified organisms	Norway	Editorial	Para 1	After sentence 1: Add [Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000]	Relevant to make this reference.
43.	1.2.4 Living modified organisms	USA	technical	Paragraph 5	Delete "and its insertion site in the recipient genome"	In the last 10 years of safe use of GMOs the insertion site has not been observed to be a critical factor in risk analysis.
44.	1.2.4 Living modified organisms	Norway	Editorial	Para 6		Would it be helpful to make a reference to ISPM 11, 1.3 (S2)?
45.	1.2.4 Living modified organisms	Norway	Editorial	Para 6	Delete sentence 3	The first and second sentence of this paragraph are helpful, but sentence 3 is covered in section 1.5, para 2
46.	1.2.4 Living modified organisms	Australia	**substantive**	para 6 sentence 3	If, subsequent to the initiation stage, it is deemed unnecessary to conduct a pest risk assessment, the basis of the decision should be recorded. ~~if appropriate.~~	Not sure what circumstances are appropriate or not for recoding a decision not to undertake a PRA.
47.	1.2.4 Living modified organisms	EC + 27 MS	Editorial	Last para , last sentence	Delete	Unnecessary and confusing repetition. The same statement is provided in Section 1.5, para 2 and covering all the subsections 1.2.1 to 1.2.5
48.	1.2.5 ~~Intentional~~ import of ~~other~~ organisms for specified uses	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Title		There is no intentional import, it ´s simply import. Also this case correspond to organisms whose end use can be variable and that is why it is preferable to talk about specified uses.
49.	1.2.5 Intentional import of other organisms	Australia	editorial	para 1 sentence 1	~~In cases w~~**W**here a request is made to import an organism that may be a pest for **use in** scientific research, educationa~~l~~, industri~~al~~**ly** or other purposes, the identity of the organism should be clearly defined.	clarity

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
50.	1.2.5 Intentional import of other organisms	Australia	**substantive**	para 1 sentence 3	For organisms determined to be pests, the pest risk assessment ~~may~~ **should** be carried out.	If an organism is considered to be a pest, then a risk assessment should be conducted. If phytosanitary measures are to be applied against a pest, then a risk assessment is needed.
51.	1.3 Defining the PRA area	Norway	Editorial	Para 2, sentence 1		It could be helpful to add text from the definition of the term *endangered area* to clarify the relationship with the term **PRA area**
52.	1.5 Conclusion of initiation	EC + 27 MS	Technical	3rd para, 1st indent	Add '...**or being considered for official control**'	Logically, in most cases a pest being analysed will not already be under official control, because the decision about official control is taken only after the PRA has been concluded.
53.	1.5 Conclusion of initiation	EC + 27 MS	Editorial	Last para, 1st indent	Delete brackets around 'or being considered for official control'	Brackets are superfluous and confusing
54.	1.5 Conclusion of initiation	USA	editorial	Last paragraph, first indent	Remove brackets to read "…subject to official control or being considered for official control"	
55.	1.5 Conclusion of initiation	Japan	Substantive	Para 5, indent 2	- plants for planting are the ~~main~~ pathway for the pest in the PRA area	Risks may arise when plants for planting are not the MAIN pathway. In the case that plants for planting are a pathway, the pest has the potential to be an RNQP (section 3. 1. 2 of ISPM No. 21).
56.	2.1 Linked standards	Canada	Technical	First paragraph, second sentence	As circumstances change and techniques evolve, new standards ~~will~~ may be developed and others revised.	Presuppositions like this about future ISPMs aren't really warranted. Further work is a good expectation, but is still just an expectation.
57.	2.1 Linked standards	Australia	editorial	Table 1 ISPM no 21	ISPM No. 21 **(2004)**	consistency
58.	2.3 Summary of PRA Stage 3: Pest risk management	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	2nd para	Stage 3 involves the identification of phytosanitary measures that (alone or in combination) reduce the risk to an acceptable level. Phytosanitary measures are not justified if the pest risk is considered acceptable or if they are not feasible (e.g. as may be the case with natural spread). However, even in such cases contracting parties may decide to maintain a ~~monitoring programme~~ low level of monitoring or audit regarding the pest risk to ensure that future changes in that risk are identified.	1) To adjust language to ISPM No. 11 item 3.3.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
					The conclusion of the pest risk management stage will be whether or not appropriate phytosanitary measures adequate to reduce the pest risk to an acceptable level are available, cost-effective and feasible. In addition to standards for PRA (Table 1), other standards provide specific technical guidance to pest risk management options.	
59.	2.3 Summary of PRA Stage 3: Pest risk management	Australia	**substantive**	para 3	The conclusion of the pest risk management stage will be whether or not appropriate phytosanitary measures adequate to reduce the pest risk to an acceptable level are available~~, cost-effective~~ and feasible.	Section 3 of ISPM 11 "The conclusions from pest risk assessment are used to decide whether risk managements are required and the strength of the measures to be used. Since zero risk is not a reasonable option, the guiding principle for risk management should be to manage risks to achieve the required degree of safety that can be justified and is feasible within the limits of available options and resources". The inclusion of "cost-effective" implies that if the importing country does not believe that the phytosanitary measures are going to be cost-effective for the exporting country then there are no phytosanitary measures available. Surely in determining phytosanitary measures those measures which achieve a contracting party's ALOP should be listed and the exporting party can make a decision based on "cost".
60.	2.3 Summary of PRA Stage 3: Pest risk management	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	New proposed para	Under principles of transparency and cooperation, the contracting party that performs the PRA shall communicate the phytosanitary measures to be adopted to the other contracting party, stakeholders and other relevant contracting parties. Once consultation is finished , the regulatory decision adopted shall be communicated according to international applicable rules.	2) New para proposed for : • Agreement with PRA and pest risk management definitions. • Compliance with the contracting parties obligations on transparency and cooperation. • Coherence with obligations consecrated in other international agreements(IPPC 1997, Art III) • Granting the applicability of the adopted phytosanitary measures and avoiding further controversies.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
61.	3.1 Uncertainty	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical Technical Technical	1st para	Uncertainty is a ~~n integral~~ component of risk and therefore important to recognize and document when performing PRAs. Sources of uncertainty with a particular PRA may include: missing, incomplete, inconsistent or conflicting data; ~~sampling from natural variability~~; natural variability in biology: subjective judgement; and sampling randomness. ~~Diseases~~ Symptoms ~~-~~of uncertain aetiology and asymptomatic carriers of pests may pose particular challenges.	1) Integral means that something is part of a wider universe, necessary for completeness, constituent, and it is not relevant for the first phrase. Uncertainty must be used under the framework of the transparency principle and as it is stated in item 2.4 of ISPM No. 11 2) Sampling form natural variability is not understandable. 3) Since you don´t know who or what caused a symptom, it can not be classified as a disease, it could be a harm.
62.	3.1 Uncertainty	Australia	**substantive**	para 1 sentence 2	Sources of uncertainty with a particular PRA may include: ….~~sampling from natural variability~~ **variability of biological systems**	better terminology
63.	3.1 Uncertainty	Canada	substantive	1st paragraph, 2nd sentence	Sources of uncertainty with a particular PRA may include: missing, incomplete, inconsistent or conflicting data; ~~sampling from~~ natural variability of biological systems; subjective judgement; and sampling randomness.	Sentence as written did not make sense.
64.	3.1 Uncertainty	EC + 27 MS	Technical	Para 1, 2nd sentence: 'sampling from natural variability'	Delete 'sampling from' to read only '**natural variability**'	Sampling randomness as a source of uncertainty is already mentioned at the end of the sentence. Natural variability (of the pest, the hosts etc.) is another source of uncertainty. It is noted that 'uncertainty' in this context is broader than in the strict statistical sense, cf. the other sources mentioned such as 'subjective judgement' etc.
65.	3.1 Uncertainty	USA	technical	First paragraph, second sentence	Delete: "sampling from natural variability; subjective judgement; and sampling randomness. Add: "natural variability of biological systems; and subjectiveness of analysis.	The last three points are not clear as to the intent.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
66.	3.1 Uncertainty	Australia	**substantive**	para 1 sentence 3	Diseases of uncertain ~~aetiology~~ **causes and origin,** and asymptomatic carriers of pests may pose particular challenges.	Simpler – common usage. aetiology (Science: study) a branch of knowledge concerned with the causes of particular phenomena, specifically a branch of medical science concerned with the causes and origins of diseases. The study of factors of causation or those associated with the causation of disease or abnormal body states. Origin: L. Aetiologia, gr. Aitiologia. (online biology dictionary)
67.	3.2 Information gathering	Norway	Editorial	Para 1, sentence 4	Move this sentence to after sentence 1	Better placed here.
68.	3.3.2 Documenting each specific PRA	Australia	**substantive**	Para 1 new dot points	insert **identity of the pest/s**	for completeness
69.	3.4 Risk communication	Australia	**substantive**	Para 1 sentence 2	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 etc~~ **all stakeholders** in order to:	Politicians and scientists are stakeholders.
70.	3.4 Risk communication	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Second para	~~At the end of the PRA, evidence supporting the PRA, the proposed mitigations and uncertainties should preferably be communicated to stakeholders and other interested parties, including other contracting parties, RPPOs and NPPOs, as appropriate.~~ The conclusion of the PRA, at any of the stages (I, II, or III), as well as the regulatory decision, shall be communicated to the other contracting party, relevant stakeholders and to other contracting parties on request. NPPOs are encouraged to communicate evidence of risks other than pest risks such as to animals or human health to the appropriate authorities	Clarifies the concept included in ISPMs No. 11 and 21, that risk communication is performed all over the PRA process.

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
71.	3.6 Avoidance of undue delay	Canada	Substantive	Title	~~**Avoidance of undue delay**~~ **Anticipated time frames**	Avoidance of undue delay is a principle and should not be a title for this section. The principle, together with a number of other relevant principles, is listed in the background.
		Canada	substantive	paragraph	~~In cases where other contracting parties are directly affected~~When the PRA is initiated as a result of a request by another contracting party to consider a pathway that may require phytosanitary measures, the NPPO should, on request, supply information about the anticipated time frame for completion of individual analyses~~, taking into account avoidance of undue delay (section 2.14 of ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006).~~	The principle on avoidance of undue delay is listed under background. The intent of this section is to identify that information on the anticipated time requirements to complete the PRA should be provided, if requested.
72.	3.6 Avoidance of undue delay	Korea (Rep.)	Technical	Sentence 1	~~In case where other contracting parties are directly affected the NPPO should, on request, supply information about the anticipated time frame for completion of individual analysis, taking into account avoidance of undue delay (section 2.14 of ISPM No.1~~ The importing contracting parties should endeavour to avoid undue delay (section 2.14 of ISPM No.1) for completion of individual analysis	There are many factors that affect the PRA process, which cannot be predicted at the stage of initiation. If the suggested timeframe is not followed due to irresistible reason, it can give negative effect to trade and relationship between both parties, in the contrary. Therefore, it is not recommendable to suggest timeframe for PRA.
73.	3.6 Avoidance of undue delay	USA	technical	Beginning of the sentence	Replace first sentence with "Importing contracting parties are encouraged to establish a provisional time table for the completion of individual analysis, taking into account…"	Consistent with standard on Recognition of PFA and ALPP.

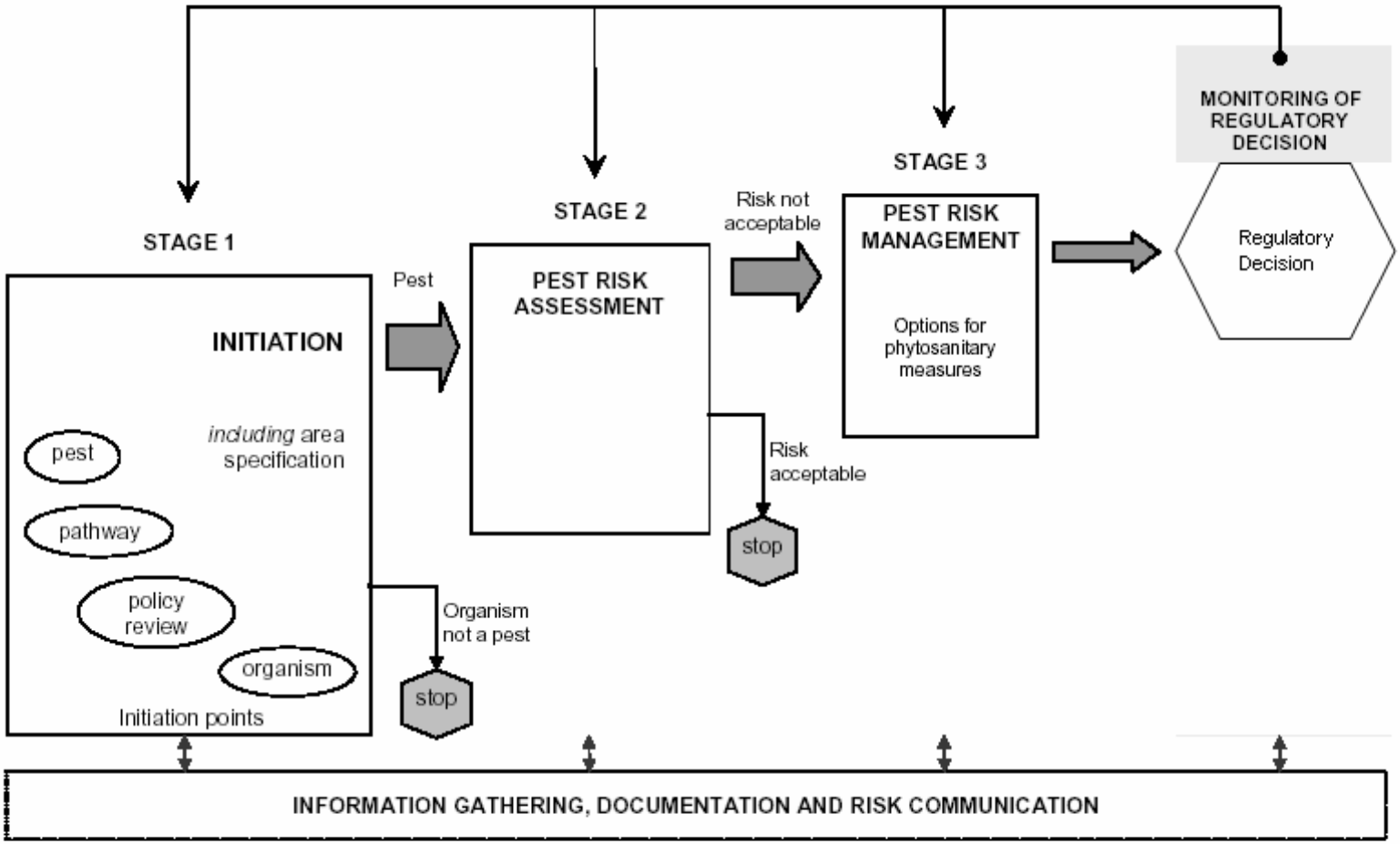
	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
74.	3.6 Avoidance of undue delay	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Single para.	~~In cases where other contracting parties are directly affected the NPPO should, on request, supply information about the anticipated time frame for completion of individual analyses, taking into account avoidance of undue delay~~ All stages of he PRA process, including the adoption of the corresponding regulatory decision ,shall be performed without undue delay.(section 2.14 of ISPM No. 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade*, 2006).	It is not a matter of which contracting party is affected or the measure of the affection. The text has been adjusted to reflect the text of the corresponding principle in ISPM no. 1.
75.	3.6 Avoidance of undue delay	Australia	**substantive**	whole section	~~Avoidance of undue delay~~ **Provisional Timeframe** In cases where other contracting parties are directly affected**, such as where PRAs are commission by third parties,** the NPPO ~~should on request,~~**is encouraged to** supply information about the anticipated timeframe for completion of individual analyses.~~, taking into account avoidance of undue delay (section 2.14 of ipam No 1: *Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006).*~~	Note: appears to be adding to the Glossary ISPM 5 meaning of 'undue delay' There should be consistency in approach If undue delay is worthy of a special inclusion surely other IPPC principles are equally as important including sovereignty, managed risk, transparency, non-discrimination, technical justification, corporation and should be included. These principles are picked up under Background: Provisions of the IPPC regarding pest risk analysis
76.	3.6 Avoidance of undue delay	Japan	Substantive		In cases where other contracting parties are directly affected and appropriate information are provided by the parties, the NPPO should perform PRA promptly~~,on request, supply information about the anticipated time frame for completion of individual analyses,~~ taking into account avoidance of undue delay (section 2.14 of ISPM No. 1: Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006).	The time to complete PRA largely depends on the quality and quantity of data provided by affected contracting parties. Furthermore, the required time for risk communication described in this draft standard is difficult to be anticipated since it is not simply a one-way movement of information. Thus, it is difficult to anticipate time frame for completion.. Description of avoidance of undue delay should be aligned with the description of ISPM No. 1, "*Associated procedures, which include, but are not limited to, pest risk analysis, recognition of pest free areas or recognition of equivalence, should also be performed promptly*."

	1. Section	2. Country	3. Type of comment	4. Location	5. Proposed rewording	6. Explanation
77.	3.6 Avoidance of undue delay	New Zealand	Editoriual		The NPPO is encouraged to supply, on request, a provisional timetable for the completion of the process, taking into account ….	Reword to be aligned with the language used in section 4.3 of the draft standard on the recognition of PFAs and ALPPs.
78.	**APPENDIX 1** Pest risk analysis flow chart	USA	technical	diagram	Show clearly that it is not a linear process	Text was included to state that PRA is not a linear process; however the diagram illustrates PRA as being linear, potentially confusing, especially for those lacking experience with PRAs.
79.	**APPENDIX 1** Pest risk analysis flow chart	Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE	Technical	Flow chart	1) Take out "options for " and let only "Phytosanitary measures" in the right part of the chart. 2) Eliminate "Beyond the PRA". 3) Eliminate the words "Phytosanitary situation " of the expression " monitorig of the phytosanitary situation" 4) Include into an hexagon as any other final point of the chart, the words " Regulatory decision"	PRA definition implies the adoption of phytosanitary measures, understanding as such, legislations, regulations (as a regulatory decision) or official procedure, according article II of the Convention. See annexed version of the flow chart.

Diagram submitted by Argentina, Bolivia, Brazil, Chile, Paraguay, Uruguay, COSAVE:

APPENDIX 1

PEST RISK ANALYSIS FLOW CHART[7]



[7] This appendix is not an official part of the standard. It is provided for information only.

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