

Template for comments - Draft ISPMs for country consultation, 2010

DRAFT APPENDIX to ISPM 15:2009  
SUBMISSION OF NEW TREATMENTS FOR INCLUSION IN ISPM 15

See [instructions](#) on how to use this template at the end of the document. Following these will greatly facilitate the compilation of comments and the work of the Standards Committee.

1. Section	2. Para nber	3. sentence/ row/indent, etc.	4. Type of comment (Substantive,Editorial, Translation)	5. Proposed rewording	6. Explanation	7. Country
<i>GENERAL COMMENTS</i>					<ul style="list-style-type: none"> <li>The U.S. is concerned that the testing standards proposed in this Appendix to ISPM 15 are so rigorous that they will effectively prevent the development of new treatments. The major difficulty lies in assembling the required number of experimental units of wood infested with forest pests to achieve Probit 9. Probit 9 is a standard developed for dose response of fruit flies, and it requires 99.9968% mortality in a sample of at least 100,000 individuals with a probability (p-value) of &lt;0.05. For many of the pests on the proposed list, it would be virtually impossible to assemble populations of this size for testing. The larvae of these pests are 100 times larger than fruit flies and only occur sparsely in infested logs, so a whole forest would have to be infested and cut to test for efficacy at Probit 9. It has been suggested that this is too stringent for commodities that are rarely infested or are poor hosts (see Follet, P.A. and G.T. McQuate, 2001). The currently approved treatments were never tested with this level of rigor, and they might very well not pass muster if they were tested today.</li> </ul>	USA

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					<p>If we discourage new treatment development we will maintain the status quo, relying on current, less effective treatments. For example, Myers <i>et al</i> showed only 90% of emerald ash borer pre-pupae are killed by 56/30. Ramsfield, T.D. and Dick, M.A, 2010, recently reported that only two of 11 wood-inhabiting fungi tested were reliably killed by 56/30 (with 99.99% confidence). While ISPM 24 calls for equivalency of phytosanitary measures, we would hope to see better efficacy in ISPM 15 treatments than this. But to establish criteria as restrictive as those proposed in this draft Appendix will make this unlikely.</p> <ul style="list-style-type: none"> <li>• The scope of this draft appendix to ISPM 15 has been expanded to include fungi and fungi-like organisms which were not considered as quarantine pests at the time ISPM 15 was developed. The appendix should reflect the same scope as the standard. Contaminating pests or other organisms that enter the wood packaging material after treatment are outside the scope of ISPM 15. Is there sufficient scientific justification to state these organisms can be transported in WPM and impact the health of a forest?</li> <li>• An agreement of the scope of quarantine pests associated with WPM has become the road block to current attempts to develop new treatments. Countries</li> </ul>	

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					cannot agree on what quarantine pests need to be tested. To compound the problem, new quarantine pests are identified in different parts of the world which can extend this research work for a long period of time.	
TITLE	[1]					
Introduction	[2]					
Introduction	[3]					
Introduction	[4]	First sentence	substantive	Treatment developers are encouraged to consult with experts (e.g. statisticians and pest biologists) at an early stage in the process in order to select candidate pests <a href="#">for treatment development</a> and design any required experiments appropriately.	For clarification.	USA
		Last sentence		Delete	This sentence is unnecessary and adds confusion to the document.	USA
Introduction	[5]	1st sentence	substantive	Delete	This statement may be interpreted if a member country thinks there is not enough information, they can stop the evaluation process. It could be trade restrictive.	USA
		2nd sentence	substantive	delete	This is an ambiguous sentence and inconsistent with the SPS agreement and the IPPC.	USA
Introduction	[6]	third indent	Substantive	<ul style="list-style-type: none"> <li>- Effect on treatment efficacy of wood types (e.g. hardwood vs softwood, <del>timber vs logs</del>) and dimensions likely to be encountered at the time of treating wood packaging material for subsequent use in international trade</li> </ul>	This gives the impression that countries are going to use the same treatments for these examples and that is not necessarily the case.	USA
		Last indent	editorial	<ul style="list-style-type: none"> <li>- Effect <del>on</del> <del>of</del> environmental conditions (e.g. temperatures,</li> </ul>		USA

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				moisture content) likely to be encountered at the time of treating wood packaging material for subsequent use in international trade.		
Introduction	[7]	para	substantive	<del>Table 1</del> <a href="#">ISPM 15 Annex 1</a> provides a listing of the most <del>important quarantine significant</del> pest groups associated with wood packaging material. Candidate <del>pests for treatment can be</del> selected from the pest groups indicated in <del>Table 1</del> <a href="#">ISPM 15 Annex 1</a> <del>should be used for evaluation purposes</del> . Steps 1-3 below provide guidance for determining selection of an appropriate pest(s), or an appropriate substitute organism(s), for testing.	The information on Table 1 is already listed in ISPM 15, Annex 1. Global change. Fungi and fungi-like organisms are secondary pests and should not be included in the Appendix. “Significant pest groups” wording aligned with ISPM 15 Annex 1. Agreement on the scope of “important quarantine pests” has become a road block to current attempts to develop new treatments.	USA
TABLE 1	[8]	Table 1	Substantive	delete	This information is already provided in ISPM 15 Annex 1. Fungi and fungi-like organisms are secondary pests. ISPM 15 was not designed for secondary pests. Including them in the Table will expand the scope of ISPM 15. Treated material that adsorbs moisture can become infested with fungi at a later date. A recent Canadian study shows our current treatments do not work against fungi. The original purpose of ISPM 15 was to reduce the risk, not to eliminate it. In addition, bark beetles are no longer relevant since the revision of ISPM 15 includes debarking wood. Bark beetles in debarked wood would not survive. Wood flies are primarily found in decaying wood, so are they really a serious pest of WPM, likely to be encountered in trade?	USA
Introduction	[9]	1st sentence	substantive	The following criteria provide a step-wise process that the submitter should follow in the testing or development of <del>justification for a new phytosanitary</del>	This is not necessary. Justification would	USA

1. Section	2. Paragraph number	3. sentence/row/indent, etc.	4. Type of comment (Substantive, Editorial, Translation)	5. Proposed rewording	6. Explanation	7. Country
				treatment for potential inclusion in ISPM 15.	be described/supported in the testing.	
Introduction	[10]	para	Substantive and editorials	This step-wise process is broadly organized into two parts. <b>First; Initially</b> , submitters of <b>new</b> treatments for evaluation should confirm that the <b>most significant pests</b> groups of organisms associated with wood packaging material presented in <b>ISPM 15 Annex 1 Table 1</b> are susceptible to the proposed treatment and that the <b>target</b> organism most resistant to the treatment is identified. <b>Second; a <u>More</u></b> detailed efficacy testing of this most resistant species <b>associated with wood packaging material</b> is then used to provide confidence that the treatment is effective against all <del>organisms</del> <b>the most significant pests</b> associated with wood packaging material <del>from all origins</del> .	Wording aligned with ISPM 15, Annex 1.  Should not have to treat to kill all or the most resistant species unless it is a significant pest associated with WPM, as identified in Annex 1.	USA
Step 1	[11]	title	substantive	Step 1: <del>Determination of r</del> Response of quarantine pest species to proposed treatment	This step is all about or focused on the response.	USA
Step 1	[12]	para	substantive	Information should be gathered regarding the differences in treatment responses between quarantine <b>the most significant</b> pest species associated with wood <b>packaging material</b> for the pest groups listed in <del>Table 1</del> <b>ISPM 15 Annex 1</b> . <del>Pest species from these groups may have fundamentally different responses to the proposed treatment. If this is the case, then Steps 2-5 will require information to be presented on independent responses for each of the pest groups.</del>	What is a quarantine pest for some countries may be indigenous somewhere else. The term “quarantine pest” is not universal for each pest.  The last two sentences will make research difficult. It makes it sound like a researcher has to have all the pests tested to Probit 9. This would be extremely hard to do.	USA
Step 1	[13]	sentence	substantive	delete	Examples are vague and not very informative.	USA
Step 1	[14]	para	substantive	delete	Examples are vague and not very informative.	USA

1. Section	2. Paragraph number	3. sentence/row/indent, etc.	4. Type of comment (Substantive, Editorial, Translation)	5. Proposed rewording	6. Explanation	7. Country
Step 1	[15]	para	substantive	Delete	Examples are vague and not very informative. It focuses on heat treatment and not on developing new treatments.	USA
Step 2	[16]	title	substantive	Determination of the <del>most treatment-resistant species and life stage</del> <u>level of efficacy</u> within each pest group, and selection of appropriate testing conditions	Efficacy is a more appropriate term. It is more practical to achieve and consistent with what was previously stated in the Introduction section (level of efficacy, not level of resistance).	USA
Step 2	[17]	para	substantive	Add paragraphs 17 and 18:  <del>Once the pest groups that react differently to the treatment process have been identified, treatment submitters should determine resistance to the proposed treatment for each of the identified pest groups.</del> <u>Treatment submitters should carefully consider the various species that form the pest groups presented in Table 1- ISPM 15 Annex 1 to ensure that the candidate pest species selected for testing is available and representative of the group. Appropriate scientific justification or information should be provided for such decisions. Available data on resistance or tolerance to specific treatments should be used to guide or support this decision as described in Step 1. In cases where there is considerable variability expected in the treatment responses within the group, more candidate pest species may need to be tested to determine the most treatment-resistant species. Of the candidate pest species selected, if the most resistant life stage is not known, then all life stages that are likely to be associated with wood packaging material in international trade must be considered. In addition, where different life stages exhibit a different response to the proposed treatment, this must be</u>	The way this paragraph is worded is confusing. Reorganize paragraphs 17 and 18 for a more logical flow.  Changes consistent with para 4, 7, and the rest of the text. Global change. Test on species that are available in your country. You should be able to extrapolate to other species.  New treatments are specifically for WPM.	USA

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				<p>taken into account. <b>However</b>, if the <b>candidate</b> species and life stage most resistant to the proposed treatment are conclusively known for each group <b>associated with wood packaging material</b> then it can be assumed that all other species and life stages within that group will be at least equally susceptible to the treatment, and most likely more susceptible. <del>Consideration of the resistance of the following species to the treatment is essential in all cases because they hold particular relevance in relation to wood packaging material used in international trade: <i>Anoplophora glabripennis</i>, <i>Bursaphelenchus xylophilus</i>, a species from the genus <i>Monoctonus</i>, a species from the genus <i>Dendroctonus</i>, <i>Fusarium circinatum</i> and <i>Heterobasidion annosum</i>.</del></p>	<p>It does not make sense to treat the most resistant life stage if it is not associated with wood packaging material.</p> <p>Last sentence is arbitrary and not relevant. If kept, add Emerald Ash Borer, as this organism is slightly thermophilic, it should be listed as required test.</p>	
Step 2	[18]	Para	substantive	Combine with para 17, as above.		USA
Step 2	[19]	sentence	substantive	delete	The information is not relevant.	USA
Step 2	[20]	Para	Substantive	Delete	The information is not relevant. It refers to irradiation treatments.	USA
Step 2	[21]	para	substantive	delete	The information is not relevant.	USA
Step 2	[22]	para	Substantive and editorial	If testing is required in order to identify the most resistant <b>candidate pest</b> species	Changes consistent with comments in the rest of the text.	USA

1. Section	2. Paragraph number	3. sentence/row/indent, etc.	4. Type of comment (Substantive, Editorial, Translation)	5. Proposed rewording	6. Explanation	7. Country
				<p>and life stage within a pest group, the following approaches should be considered:</p> <ul style="list-style-type: none"> <li>The number of test units required for each <u>candidate pest</u> species should be statistically valid <u>at p&lt;0.05</u> in order to reflect the variability within the test population in an appropriate experimental design. In all cases, at least <del>five</del> <u>10</u> test units per <u>candidate pest</u> species and life stage should be used.</li> <li>The sample size of controls should be the same as the number of test organisms (e.g. <del>five controls and five treated individuals</del>), with demonstration of adequate survival of controls during treatment.</li> <li>Test units may be either individual pests or colonized pieces of wood containing the target pest. <del>When colonized pieces of wood that may contain multiple individuals are used as test units, only complete mortality, deactivation or sterilization of all individuals is considered a successful result in identifying the resistant species or life stage.</del></li> </ul>	<p>Formatting can assist with clarity. It makes a difference in perception and meaning of words.</p> <p>Consistent with Step 4.</p> <p>Five units is too few in many cases.</p> <p>NPPOs may think this is a good example to use and not appropriate for carrying out tests on treatments. ISPM 28 provides guidelines for experimental design and testing. Suggest to replace this section with wording in ISPM 28, section 3.2.1</p> <p>Imagine pieces of wood containing several life stages. Larvae are killed and pupae are not. This would still be a valid result in determining which life stage is most resistant. Complete mortality is higher than Probit 9.</p>	
Step 2	[23]	Last sentence	substantive	delete	Suggest to delete. This information is covered already in ISPM 28.	USA
Step 3	[24]	title	Substantive	<p>Delete. If kept, change to:</p> <p>Step 3: Determination of whether a <del>substitute</del> <u>surrogate</u> test species may be used</p>	<p>Steps are repetitive. Refer to ISPM 28.</p> <p>Surrogate is a more technical word and more appropriate for this document than substitute. Global change.</p>	USA
Step 3	[25]	para	substantive	Delete. If kept, change to:	Steps are repetitive. Refer to ISPM 28.	USA

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				<p><del>Having identified the most resistant quarantine pest species and life stage, there may be available a <u>A</u> substitute <u>surrogate</u> test species with similar biological characteristics to the quarantine <u>most significant</u> pest species and an equivalent response to the proposed treatment <u>may be used in Step 2 testing, with justification, to determine the most resistant candidate pest group and life stage.</u> Use of a <del>substitute</del> <u>surrogate</u> test species may allow for less complex, less costly and safer efficacy testing to be undertaken or enable testing to be carried out in regions where the quarantine species is not present and cannot be assessed. <del>Appropriate justification and scientific information must be presented to support the use of substitute test species.</del></del></p>	<p>Surrogate is a better word than substitute. Global change. Consistent with comment on para (12).</p> <p>If there is good justification, a surrogate for one of the most significant species listed in ISPM 15 Annex 1 should be allowed to be used in Step 2 and 3 testing, if it is the most or at least equally resistant to the treatment. Availability to work under quarantine conditions or to obtain quarantined species is limited and may not be possible.</p>	
Step 4	[26]	para	substantive	Delete	Steps are repetitive. Refer to ISPM 28 so the Appendix is more harmonized with the standard.	USA
Step 4	[27]	para	substantive	Delete	Steps are repetitive. Refer to ISPM 28 so the Appendix is more harmonized with the standard.	USA
Step 4	[28]	para	substantive	Delete	Steps are repetitive. Refer to ISPM 28 so the Appendix is more harmonized with the standard.	USA
Step 4	[29]	Para	substantive	<p>Delete. If kept, change to:</p> <p><u>The level of <u>treatment</u> efficacy <u>must be stipulated and justified based on the biology of the candidate pest. Higher efficacy levels will be required for pests that infest wood packaging material at high populations or present higher risk.</u> Required for treatment success is</u></p>	<p>Steps are repetitive. Refer to ISPM 28 so the Appendix is more harmonized with the standard.</p> <p>Probit 9 is prohibitively rigorous. Paragraph 28 suggests 10 replications might suffice, and this is not consistent with requiring Probit 9. There is no justification for requiring Probit 9 efficacy for all pests infesting wood. Even for fruit flies, for which Probit 9 was first</p>	USA

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				<p><del>99.99683% at 95% confidence level for all organisms selected for testing. However, since some species (e.g. <i>Anoplophora glabripennis</i>) may not provide population numbers sufficient for this testing, testing may be based upon statistically valid extrapolation or the use of substitute species as described in Step 3. By using an appropriate candidate pest or substitute surrogate species tested at this level of efficacy, the test is considered to provide for the conclusion that the treatment is sufficiently effective against any pest that may be associated with wood packaging material from any origin.</del></p>	<p>proposed in the early 1930's, it was never intended to be the universal standard and it is not necessary for most pests of wood. It will be next to impossible to achieve this standard with most organisms, with the exception of <i>B. xylophilus</i>. It would be quite impossible to do for <i>A. glabripennis</i>, nor does it seem necessary given the low levels of infestation in wood by this insect. Although the use of extrapolation by modeling is permitted in the text, recent work has shown that extrapolation overestimates the dosage required to kill 100% of insects, resulting in overtreatment, added expense and potential risk of damaging the wood. It also makes no sense that it is acceptable to treat 100,000 organisms in a single piece of wood, kill them all, and call this proof of Probit 9. Statistically this makes no sense because this approach is pseudoreplication (there is no replication). Instead, proposers should be able to present a level of efficacy with justification as to why this level of efficacy is biologically relevant for the organisms of interest. In addition, Probit 9 was never demonstrated for methyl bromide, which is currently an approved treatment under ISPM-15, so why require it for any and all organisms now?</p>	
Step 5	[30]	Para	substantive	Delete	Steps are repetitive. Refer to ISPM 28 so the Appendix is more harmonized with the standard.	USA
Step 5	[31]	Para	substantive	Delete	Steps are repetitive. Refer to ISPM 28 so the Appendix is more harmonized with the standard.	USA
Assessment of treatment success	[32]					
Assessment of	[33]	Para	Substantive	The criteria used to determine treatment		USA

1. Section	2. Paragraph number	3. sentence/row/indent, etc.	4. Type of comment (Substantive, Editorial, Translation)	5. Proposed rewording	6. Explanation	7. Country
treatment success				<p>success for each <b>candidate</b> pest group and life stage tested must be thoroughly described. In particular, in each case the specific treatment effect(s) should be clearly indicated. <del>For example, treatments on fungi may kill the organism or may simply inhibit growth.</del> With insects, methods for assessing treatment success can vary widely across studies. For example, counts of living specimens immediately after a treatment may underestimate effectiveness as some apparent survivors may die subsequently and, conversely, those that may appear moribund may recover. <del>Mortality of nematodes should be confirmed by the failure of recovery of nematodes from Wood samples incubated at 25 °C using a Baermann funnel at both 6 and 21 days after treatment.</del></p>	<p>For consistency with the rest of the text.</p> <p>For consistency with previous commentary to remove fungi and fungi-like from the text.</p> <p>There are other tests than the funnel test. Information in ISPM 28 would align better here.</p>	
Submission of treatment for approval	[34]					
Submission of treatment for approval	[35]					

## INSTRUCTIONS FOR THE USE OF THE TEMPLATE

A template is provided to facilitate the submission and compilation of member comments. The instructions have been modified since last year; please review both the instructions and the examples. Paragraph numbers have been included in the draft standards, and each paragraph has a row in the template with the corresponding number. It is important to be accurate in allocating comments to paragraphs, since the compilation of comments will be done automatically and only based on paragraph numbers.

**To facilitate compilation of comments and the work of the Standards Committee, please apply the following and refer to the table of examples below:**

- do not add or delete columns, and do not change their width or formatting of the actual table.
- ensure that all comments refer to the appropriate section of the text and paragraph number.
- if proposals are made to add, delete or move paragraphs to the text of the standard, subsequent comments should continue to refer to the paragraph numbers used in the draft standard sent for consultation.
- only one type of comment should be made in each row of the template; when more than one type of comment needs to be made on the same paragraph, **insert a new row**, include all appropriate information (including paragraph number) and fill in your comment. **Do not use automatic numbering.**
- ensure that all cells of the row are completed when a comment is made.
- use formatting to indicate proposed additions (e.g. underline) and deletions (e.g. ~~strikethrough~~), and not tracked changes of the Word processor
- only include those sentences from the draft standard to display the suggested modifications. Do not include paragraphs or sentences for which no modifications are suggested.
- to provide a comment on a footnote, please enter it in a row with the number of the paragraph with which the footnote is associated.
- delete the rows of the template in which no comments are made.

### Specific guidelines for each column in the template and examples of comments

General comments apply to the entirety of the standard. Comments on specific sections of the standard can be provided as described below.

#### **1. Section**

- This gives the titles of sections as they appear in the draft, plus a row for general comments. To propose changes to section titles, include new wording in the "proposed rewording" column.

#### **2. Paragraph number (Para nber)**

- To propose a new paragraph, add a row and qualify the paragraph number with a letter (e.g. 12a, to indicate that the new paragraph follows paragraph 12).
- To propose to move a paragraph, indicate the new location in the "proposed rewording" column (e.g. move paragraph 51 to after paragraph 47). **Do not alter the paragraph numbers.**

#### **3. Sentence/row/indent, etc.**

- Clearly identify the specific place in the paragraph, such as sentence, row of a table, indent, etc, where the comment applies (e.g. sentence 2, indent 5, row 2, footnote 3, figure 15, etc). Table rows have been also numbered similar to the paragraphs
- The text as circulated for consultation should be used as a basis for counting sentences, bullet points, etc. Please do not refer to page or line numbers as these may vary depending on the word processor used or language version of the draft.

#### **4. Type of comment**

Indicate whether the type of comment refers to one of the three choices: substantive, editorial, or translation. Please only use these keywords: Substantive, Editorial, Translation.

- substantive comments include technical comments. They take into account conceptual changes, addition of new aspects or ideas, scientific corrections and technical adjustments.
- editorial comments clarify or simplify the text without changing the meaning. This includes spelling or grammatical corrections, suggestions of different but equivalent words, and simplification of sentence structure.
- translation comments correct points that are considered to be inaccurately translated into another language version of the text.

#### **5. Proposed rewording**

Suggestions to change the text should always include proposed rewording. Modifications to the original text should be clearly identifiable (i.e. text that is added or deleted should appear in a distinct way from unchanged text). For example, text added can be underlined and text deleted can be ~~striked through~~ (with colours as appropriate). Tracked changes should not be used.

## 6. Explanation

Detailed explanations should give justification for the comment made and should be sufficient for the Standard Committee to understand the intention of the comment and the proposed rewording.

## 7. Country

- There should be only one name in this column.
- The country name should be indicated in every row for which a comment is made. The country name should be that of the country submitting the comments.
- Comments made on behalf of an organization (such as an RPPO) should include only the organization name, and not the names of the member countries.

### Examples of comments using the template

1. Section	2. Paragraph	3. Sentence/row/indent, etc.	4. Type of comment (Substantive, Editorial, Translation) only	5. Proposed rewording	6. Explanation	7. Country
BACKGROUND	[9]	Sentence 1	Substantive	The main purpose of the IPPC is to <del>protect</del> <u>plants secure common and effective actions to prevent the spread and introduction of pests of plants and plant products</u>	To be consistent with the text of the IPPC.	COUNTRY NAME
BACKGROUND	[9]	Sentence 2	Editorial	In doing so, contracting parties undertake the promotion of appropriate measures for the control of <u>regulated</u> pests.	The scope of the IPPC addresses regulated pests.	COUNTRY NAME
BACKGROUND	[17]	Sentence 4	Editorial	<del>Thus</del> <u>Additionally</u> , while pursuing the ....	Clearer wording	COUNTRY NAME
1.4 Supervision activities	[26]	Sentence 3	Substantive	The FF-ALPP programme, including <del>regulatory control</del> <u>domestic regulation</u>	The term regulatory control is unclear and text should use specific terms clarifying what is meant.	COUNTRY NAME
1.4 Supervision activities	[32]	New 2nd indent	Substantive	- operation of surveillance procedures <del>- fruit sampling</del> - surveillance capability	Fruit sampling is necessary as part of surveillance	COUNTRY NAME
1.6 Tolerance level	[44a]	After para 44	Substantive	add new paragraph after 44: <u>For quarantine pests the tolerance level generally equals zero. Setting the level of detection to zero implies that all units of the consignment must be included in the sample. Hence, for quarantine pests, a detection level that is as small as technically possible approaches the zero tolerance level.</u>	to explain the particular situation for quarantine pests	COUNTRY NAME
3. Phytosanitary Risk Categories and Measures	[61]	Whole para	Editorial	Move para 61 to after para 47	More appropriate location.	COUNTRY NAME