INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

DRAFT APPENDIX to ISPM 15:2009

SUBMISSION OF NEW TREATMENTS FOR INCLUSION IN ISPM 15

(201-)

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[1] # APPENDIX 1: Submission of new treatments for inclusion in ISPM 15

[2] ## Introduction

[3] New treatments for inclusion in ISPM 15:2009 need to be evaluated in accordance with procedures outlined in ISPM 28:2007 and thus may be submitted by NPPOs and RPPOs if deemed to meet the requirements outlined in that standard. The following incremental, step-based guidance is provided for treatment developers and for NPPOs or RPPOs submitting technical efficacy data in support of phytosanitary treatments to be evaluated.

[4] 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 and design any required experiments appropriately. If additional clarification on the submission and evaluation of phytosanitary treatments is required, the IPPC Secretariat may be contacted. If necessary, secretariat staff will endeavour to provide contact details for appropriate experts.

[5] The ISPM 15 treatment evaluation process relies on the principle that all sources of existing relevant information should be considered to support each step in the process. Additional research may be required, but only where the existing information is insufficient to fulfil the criteria presented.

[6] The treatment developers and the submitting NPPO or RPPO should ensure that a range of factors are or have been tested in the development of a proposed phytosanitary treatment for IPPC evaluation. Factors may include:

- effect on quarantine pests likely to be associated with wood packaging material used in international trade
- effect on the pest life stages most likely to be associated with wood packaging material used in international trade
- effect on treatment efficacy of wood types (e.g. hardwood vs softwood, timber vs logs) and dimensions likely to be encountered at the time of treating wood packaging material for subsequent use in international trade
- effect on environmental conditions (e.g. temperatures, moisture content) likely to be encountered at the time of treating wood packaging material for subsequent use in international trade.

[7] Table 1 provides a listing of the most important quarantine pest groups associated with wood packaging material. Candidates selected from the pest groups indicated in Table 1 should be used for evaluation purposes. Steps 1–3 below provide guidance for determining selection of an appropriate pest(s), or an appropriate substitute organism(s), for testing.

[8] **Table 1**. Most important pest groups for evaluation of wood packaging material treatments

Type of organism	Pest group or individual species
Insects	bark beetles
	termites and carpenter ants
	wood-boring beetles
	wood-boring moths
	wood flies
	wood wasps
Fungi and fungi-like organisms	canker fungi
	decay fungi
	deep penetrating blue-stain fungi
	oomycetes
	rust fungi
	vascular wilt fungi
Nematode	*Bursaphelenchus xylophilus*

[9] The following criteria provide a step-wise process that the submitter should follow in the testing or development of justification for a new phytosanitary treatment for potential inclusion in ISPM 15. Included with each step is information that is intended to clarify how to interpret and respond to each criterion.

[10] This step-wise process is broadly organized into two parts. Initially, submitters of treatments for evaluation should confirm that the groups of organisms associated with wood packaging material presented in Table 1 are susceptible to the proposed treatment and that the organism most resistant to the treatment is identified. More detailed efficacy testing of this most resistant species is then used to provide confidence that the treatment is effective against all organisms associated with wood packaging material from all origins.

[11] **Step 1: Determination of response of quarantine pest species to proposed treatment**

[12] Information should be gathered regarding the differences in treatment responses between quarantine pest species associated with wood for the pest groups listed in Table 1. 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.

[13] Examples of differential pest responses to treatments:

[14] The mode of action of a pesticide may be specific to a certain pest and may have little or no effect on another (e.g. neurotoxins have a limited effect on fungi).

[15] The first effects of heat treatment on organism viability occur when intercellular proteins begin to denature and disrupt vital cellular processes. Such protein denaturation occurs in all organisms. However, some organisms or life stages have mechanisms that provide a limited tolerance to these temperature effects. In regard to pests of wood, only a very few quarantine pests of wood of concern in international trade are known to have a slightly elevated tolerance to heat treatments.

[16] **Step 2: Determination of the most treatment-resistant species and life stage within each pest group, and selection of appropriate testing conditions**

[17] Once the pest groups that react differentially to the treatment process have been identified, treatment submitters should determine resistance to the proposed treatment for each of the identified pest groups. If the species and life stage most resistant to the proposed treatment are conclusively known for each group 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. 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: *Anoplophora glabripennis*, *Bursaphelenchus xylophilus*, a species from the genus *Monochamus*, a species from the genus *Dendroctonus*, *Fusarium circinatum* and *Heterobasidion annosum*.

[18] Treatment submitters should carefully consider the various species that form the pest groups presented in Table 1 to ensure that the pest species selected for testing is 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. In cases where there is considerable variability expected in the treatment responses within the group, more species may need to be tested to determine the most treatment-resistant species. Of the species selected, if the most resistant life stage is not known then all life stages that are likely to be associated with wood in international trade must be considered. In addition, where different life stages exhibit a different response to the proposed treatment, this must be taken into account.

[19] Examples of life stage-dependent responses to treatments:

[20] Irradiation treatments primarily affect pest viability through the creation of hydroxyl radicals that begin to break down the DNA in these organisms. Life stages that have higher levels of cell division or activity in general are likely to be more susceptible to irradiation treatments. Hence the later life stages such as adults or pupae are often found to be more resistant to the effects of irradiation than earlier life stages such as eggs or first instar larvae.

[21] Some pests are known during certain life stages to be differentially susceptible to a specific pesticide (e.g. greater tolerances are shown by adult insect life stages treated with juvenile growth hormones).

[22] If testing is required in order to identify the most resistant species and life stage within a pest group, the following approaches should be considered. The number of test units required for each species should be statistically valid in order to reflect the variability within the test population in an appropriate experimental design. In all cases, at least five test units per species and life stage should be used. The sample size of controls should be the same as the number of test organisms (e.g. five controls and five treated individuals), with demonstration of adequate survival of controls during treatment. Test units may be either individual pests or colonized pieces of wood containing the target pest. 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.

[23] Test species used should be in a condition that represents their naturally occurring virulence, pathogenicity and fitness. In using isolates, consideration should also be given to the quality, vigour and stability appropriate to the type of organism used. Some organisms, for example fungi and nematodes, should be tested only *in vivo* in wood unless evidence is provided that *in vitro* testing provides equivalent and acceptable results. In testing fungi, fungal isolates from a broad variety of locations should be used, where possible, for each species tested.

[24] **Step 3: Determination of whether a substitute test species may be used**

[25] Having identified the most resistant quarantine pest species and life stage, there may be available a substitute test species with similar biological characteristics to the quarantine pest species and an equivalent response to the proposed treatment. Use of a substitute 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. Appropriate justification and scientific information must be presented to support the use of substitute test species.

[26] **Step 4: Determination of efficacy against the target test species**

[27] Efficacy testing can be completed either directly, using the numbers of test individuals required to demonstrate statistically the efficacy level, or by extrapolation by fitting dose-response data to a known theoretical dose-response curves (e.g. normal (i.e. probit), logistic, Gompertz[1], Weibull[2]).

[28] When undertaking extrapolations, testing may be completed either on individuals *in situ* or on units comprising wood pieces that have been either naturally colonized or colonized in the laboratory to simulate natural colonization. When using the "wood unit" approach, the nature and level of colonization should be equivalent to that experienced during natural outbreak conditions to ensure that a worst-case scenario approach is tested. The number of replicates required for extrapolation testing will depend on the fit of the actual response data to the theoretical dose-response curve (and required sensitivity of the outcome at the 95% confidence level. It is recommended that at least 10 replicates are initially included, although the greater the number of replicates, the higher the confidence of the conclusions drawn. The type of test and its expected statistical limits will determine the potential responses of those individuals that are most resistant to the treatment being evaluated; the degree of variation at a determined dose and level of replication should reflect this. The efficacy data provided should also specify the statistical level of confidence supporting efficacy claims made for treatment of the specified pest and life stage.

[29] The level of efficacy required for treatment success is 99.99683% at a 95% confidence level for all organisms selected for testing. However, since some species (e.g. *Anoplophora glabripennis*) 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 appropriate pest or substitute 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.

[30] **Step 5: Determination of equivalency of efficacy during experimental testing with efficacy under operational conditions**

[31] A schedule must be developed to ensure that the required efficacy is consistently reached or exceeded during production and treatment of wood packaging material under normal operating conditions. In developing this schedule, treatment efficacy should be demonstrated in the type(s) and dimensions of wood packaging material and environmental conditions (e.g. temperature, moisture content) most challenging for the treatment in question. The schedule should clearly document the limitations on efficacy of treatment applications (e.g. penetrability, water solubility) and clearly indicate any restrictive conditions in use of the treatment (e.g. penetration limitations of some fumigants may restrict the dimensions of the wood for which successful treatment is feasible).

[32] **Assessment of treatment success**

[33] The criteria used to determine treatment success for each pest group and life stage tested must be thoroughly described. In particular, in each case the specific treatment effect(s) should be clearly indicated. For example, treatments on fungi may kill the organism or may simply inhibit growth. 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. 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.

[1] **Gompertz, B**. 1832. On the nature of the function expressive of the law of human mortality, and on a new mode of determining the value of life contingencies. *Phil. Trans. Roy. Soc. London*, 123: 513–585.

[2] **Weibull, W**. 1951. A statistical distribution function of wide applicability. *J. Appl. Mech., Trans. ASME*, 18(3): 293–297.

[34] **Submission of treatment for approval**

[35] All treatments proposed for inclusion in ISPM 15 must be submitted to the IPPC Secretariat for evaluation under the provisions of ISPM 28:2007. Submission forms are available from the IPPC Secretariat for this purpose. These forms must be completed and include all of the supporting information required to meet the criteria presented in the above steps.