Draft International Standards for Phytosanitary Measures

Consultation 2010

Submission of New Treatments for inclusion in ISPM 15

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Outline

- Background
- The need for new treatments for ISPM 15
- Outline of the draft appendix
- Considerations during consultation

Background

- Proposed new appendix to ISPM No. 15, *Guidelines for regulating wood packaging material in international trade*, providing criteria for submission of new treatments

- Drafted by the Technical Panel on Forest Quarantine (TPFQ) over the course of four-to-five years

- Presented to the Standards Committee (SC) in 2009, but returned to TPFQ – based on concerns on efficacy and data requirements, and for general improvements

- Resubmitted to the SC in April 2010 and approved for consultations – still some concerns on required level of efficacy

The need for new treatments for ISPM 15

- Clear and urgent need to find alternative treatments to methyl bromide:
  - Currently heat treatment and methyl bromide are the only two approved treatments for ISPM 15
  - Methyl bromide is damaging to the environment
  - Contracting parties to the IPPC may also have obligations under the Montreal Protocol
  - For parties to the Montreal Protocol, methyl bromide usage is already restricted and will eventually be phased out
- Commission on Phytosanitary Measures (CPM) has encouraged the use of alternative treatments:
  - IPPC Recommendation (2008): *Replacement or reduction of the use of methyl bromide as a phytosanitary measure*

Outline of draft appendix

- New treatments for ISPM 15 must be evaluated in accordance with ISPM 28, *Phytosanitary treatments for regulated pests*
- This appendix provides specific criteria relevant to developing submissions for new treatments of wood packaging intended to eliminate quarantine pests
- Criteria are presented as sequential steps, all of which must be followed – based on two broad and fundamental requirements:
  - Identification of most treatment-resistant test organism (from later table) and life stage, and its demonstrated susceptibility to proposed treatment
  - Detailed efficacy testing of this most resistant species to provide confidence that treatment is effective against all pests
- All relevant sources of information may be considered, therefore new primary research may or not be needed

Key factors to be considered for proposed new treatments

- Effect on quarantine pests associated with wood packaging material
- Effect on the pest life stages associated with wood packaging material
- Limitations on treatment efficacy caused by different wood types (e.g., hardwood, softwood) and dimensions
- Effect of environmental conditions (e.g. temperatures, moisture content) at the time of treatment

Most important quarantine pest groups for wood packaging

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
Nematodes	*Bursaphelenchus xylophilus*

Step 1: Determination of response of quarantine pest species to treatment

- Information to be gathered on differences in treatment responses between quarantine pest species for the pest groups listed in the previous table
- The pest species listed may have fundamentally different responses to the proposed treatment:
  - If so, more detailed information is required in the subsequent steps to ensure that each independent response for each pest group is considered
  - Examples of prospective differential responses are provided in the text

Step 2: Determination of most treatment-resistant species; selection of testing method

- Identification of pest groups that react differentially to the treatment and that species selected is/are representative of group
- Determination of resistance to the proposed treatment for each identified pest group:
  - If species and life stage most resistant to the proposed treatment are conclusively known for each group, it is assumed that all other species and life stages within that group will be at least equally susceptible to the treatment
- Essential to consider resistance of: *Anoplophora glabripennis*, *Bursaphelenchus xylophilus*, *Monochamus* sp., *Dendroctonus* sp., *Fusarium circinatum* and *Heterobasidion annosum*
  - These pests have particular relevance for wood packaging material
- If most resistant life stage is not known then all life stages associated with wood packaging must be considered

Step 2: Determination of most resistant species and testing method, cont'd.

- If testing to identify the most resistant species and life stage within a pest group, a statistically valid approach that takes into account natural variability must be pursued:
  - at least five test units per species and life stage should be used
  - sample size of controls should be the same as the number of test organisms, 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
- Test species used should be in a condition reflecting naturally occurring virulence, pathogenicity and fitness

Step 3: Determination of whether a substitute test species may be used

- If available, can use substitute test species with similar characteristics to the most resistant quarantine pest species and life stage – if it has an equivalent response to the treatment:
  - use of a substitute species may allow for less complex, less costly, and safer efficacy testing to be undertaken
  - also allows testing to be carried out in regions where the quarantine species is not present and cannot be assessed
  - justification and scientific information must be presented to support the use of substitute test species

Step 4: Determination of efficacy against target test species

- Efficacy testing can be conducted directly or through extrapolation of dose-response data and theoretical dose-response curves:
  - the number of replicates required for extrapolation testing depends on the fit of response data to the theoretical dose-response curve
  - it is recommended that at least 10 replicates are initially included
  - efficacy data provided should specify the statistical level of confidence supporting efficacy claims

- The level of efficacy required is 99.99683% (Probit 9) at a 95% confidence level for all organisms selected for testing
  - some species may not provide sufficient population numbers for this testing. For these, testing may be based upon statistically valid extrapolation or the use of substitute species

Step 5: Equivalency of efficacy during testing and under operational conditions

- A treatment schedule must be developed to ensure that the required efficacy is consistently achieved during practical production and treatment of wood packaging:
  - treatment efficacy has to be demonstrated in the type(s) and dimensions of wood packaging material and environmental conditions most challenging for the treatment in question
  - schedule should identify limitations on efficacy of treatment applications or any restrictive conditions in use of the treatment

Considerations – 1: Efficacy level

- Consensus on the required efficacy level was very difficult to achieve during drafting and review:
  - Current level is 99.99683% (Probit 9) for all species
  - Concerns exist that this efficacy level may create impracticable or even impossible conditions for researchers because of the number of replicates required, even with extrapolation as an option
  - A balance is necessary between the requirement to ensure minimal chance of treatment failure, and ensuring that requirements are sufficiently practicable and feasible to encourage submissions
  - One option considered was of different efficacy levels for different pest types
  - Existing treatments for ISPM 15 may not have had to go through such rigorous processes or had such copious supporting data requirements
- Decision to proceed with consultation was made with these concerns in mind, in order to elicit member comments on efficacy level

Considerations – 2: Data & confidence

- Concerns also exist that requirements relating to supporting data and information are perhaps so strict that they may limit submissions of treatments or their subsequent approval:
  - However, the CPM must be fully confident that adopted treatments will be consistently efficacious
  - ISPM 15 is very widely implemented and effectively provides a *de facto* "appropriate level of protection" for all contracting parties
  - Prevention of the international spread of pests via wood packaging is dependent on the effectiveness of the standard (great success to date!)
- **Viewpoints from the scientific community – via NPPOs or RPPOs during member consultation – on these two considerations are especially encouraged**

Considerations – 3: Pressing need for criteria

- Urgent need to find more alternatives to methyl bromide in addition to the existing single alternative of heat treatment
- Some alternative treatment submissions were submitted three or more years ago but have not yet been approved
- Cannot actively seek submissions of more prospective candidates for alternative treatments until these ISPM 15 criteria are adopted
- Can’t develop criteria for the draft standard on international movement of wood until the criteria for ISPM 15 treatments are adopted