INTERNATIONAL STANDARDS FOR PHYTOSANITARY MEASURES

ISPM No. 28

PHYTOSANITARY TREATMENTS FOR REGULATED PESTS

(2007)

Produced by the Secretariat of the International Plant Protection Convention

CONTENTS

ENDORSEMENT

This standard was endorsed by the Commission on Phytosanitary Measures in March 2007.

INTRODUCTION

SCOPE

This standard presents in Annex 1 phytosanitary treatments evaluated and adopted by the Commission on Phytosanitary Measures (CPM). It also describes the requirements for submission and evaluation of the efficacy data and other relevant information on a phytosanitary treatment that can be used as a phytosanitary measure and that will be included in Annex 1 after its adoption.

The treatments are for the control of regulated pests on regulated articles, primarily those moving in international trade. The adopted treatments provide the minimum requirements necessary to control a regulated pest at a stated efficacy.

The scope of this standard does not include issues related to pesticide registration or other domestic requirements for approval of treatments (e.g. irradiation)[1].

REFERENCES

Glossary of phytosanitary terms, 2007. ISPM No. 5, FAO, Rome.
International Plant Protection Convention, 1997. FAO, Rome.
Pest risk analysis for quarantine pests, including analysis of environmental risks and living modified organisms, 2004. ISPM No. 11, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISPM No. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

Harmonized phytosanitary treatments support efficient phytosanitary measures in a wide range of circumstances and enhance the mutual recognition of treatment efficacy. Annex 1 to this standard contains those phytosanitary treatments which have been adopted by the CPM.

National Plant Protection Organizations (NPPOs) and Regional Plant Protection Organizations (RPPOs) may submit data and other information for the evaluation of efficacy, feasibility and applicability of treatments. The information should include a detailed description of the treatment, including efficacy data, the name of a contact person and the reason for the submission. Treatments that are eligible for evaluation include mechanical, chemical, irradiation, physical and controlled atmosphere treatments. The efficacy data should be clear and should preferably include data on the treatment under laboratory or controlled conditions as well as under operational conditions. Information on feasibility and applicability of the proposed treatment(s) should include items on cost, commercial relevance, level of expertise required to apply the treatment and versatility.

Submissions with complete information will be considered by the Technical Panel on Phytosanitary Treatments (TPPT), and if the treatment is found acceptable, it will be recommended to the CPM for adoption.

[1] The inclusion of a phytosanitary treatment in this ISPM does not create any obligation for a contracting party to approve the treatment or register or adopt it for use in its territory.

BACKGROUND

The purpose of the IPPC is "*to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control*" (Article I.1 of the IPPC, 1997). The requirement or application of phytosanitary treatments to regulated articles is a phytosanitary measure used by contracting parties to prevent the introduction and spread of regulated pests.

Article VII.1 of the IPPC 1997 states:
"*contracting parties shall have sovereign authority to regulate, in accordance with applicable international agreements, the entry of plants and plant products and other regulated articles and, to this end, may:*
a) prescribe and adopt phytosanitary measures concerning the importation of plants, plant products and other regulated articles, including, for example, inspection, prohibition on importation, and treatment".

Phytosanitary measures required by a contracting party shall be technically justified (Article VII.2a of the IPPC, 1997).

Phytosanitary treatments are used by NPPOs to prevent the introduction and spread of regulated pests. Many of these treatments are supported by extensive research data, and others are used based on historical evidence supporting their efficacy. In practice, many countries use the same treatments or similar treatments for specified pests; however, mutual recognition is often a complex and difficult process. Furthermore, there has previously been neither an internationally recognized organization or process to evaluate treatments for their efficacy nor a central repository for listing such treatments. The Interim Commission on Phytosanitary Measures, at its sixth session in 2004, recognized the need for international recognition of phytosanitary treatments of major importance and approved the formation of the TPPT for that purpose.

REQUIREMENTS

1. Purpose and Use

The purpose of harmonizing phytosanitary treatments is to support sufficient phytosanitary measures in a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may also facilitate trade. Furthermore, these treatment schedules should aid the development of expertise and technical cooperation. NPPOs are not obliged to use these treatments and may use other phytosanitary treatments for treating the same regulated pests or regulated articles.

Adopted phytosanitary treatments provide a means for the killing, inactivation or removal of pests, for rendering pests infertile or for devitalization, at a stated efficacy, and are relevant primarily to international trade. The level of efficacy, specificity and applicability of each treatment is indicated where possible. NPPOs may use these criteria to select the treatment or combination of treatments that are appropriate for the relevant circumstances.

When requiring phytosanitary treatments for imports, contracting parties should take into account the following points:

- Phytosanitary measures required by a contracting party shall be technically justified.
- Phytosanitary treatments contained in Annex 1 of this standard have the status of an ISPM and therefore should be considered accordingly.
- Regulatory requirements of exporting contracting parties may prevent certain treatments from being approved for use within their territories. Therefore efforts should be made to accept equivalent treatments where possible.

2. Process for Treatment Submission and Adoption

The submission process is initiated by a call for topics for standards (including topics for treatments) according to the "IPPC standard setting procedure" and the "Procedure and criteria for identifying topics for inclusion in the IPPC standard setting work programme". These procedures are provided on the International Phytosanitary Portal (https://www.ippc.int).

In particular, the following points apply to treatments:

- Once a topic for treatments (e.g. treatments for fruit flies or for pests on wood) has been added to the IPPC standard-setting work programme, the IPPC Secretariat, under direction of the Standards Committee (with recommendations from the TPPT), will call for the submissions and data on treatments on that topic.
- NPPOs or RPPOs submit treatments (accompanied by relevant information as requested in section 3) to the Secretariat.
- Only submissions of treatments that are deemed by the NPPO or RPPO to meet the requirements listed in this standard should be submitted, and it is recommended that these treatments have been approved for national use before their submission. Treatments include, but are not limited to, mechanical, chemical, irradiation, physical

(heat, cold) and controlled atmosphere treatments. NPPOs and RPPOs should take into account other factors when considering phytosanitary treatments for submission, such as the effects on human health and safety, animal health and the impact on the environment (as described in the preamble and Article I.1 of the IPPC, 1997 and in Article III of the IPPC, 1997 regarding relationship with other international agreements). Effects on the quality and intended use of the regulated article should also be considered.

- Treatment submissions will be evaluated based on the requirements listed in section 3. If large numbers of submissions are received, the TPPT will work with the Standards Committee to determine the priority for reviewing submissions.
- Treatments that meet the requirements listed in section 3 will be recommended and the treatment submitted, along with a report and a summary of the information evaluated, to the Standards Committee and in turn to the IPPC standard setting process. The report of the technical panel with the summary information and the SC report will be available to contracting parties. Further detailed information (as long as it is not confidential) will be available on request from the Secretariat.
- The CPM will adopt or reject a treatment. If adopted, the treatment is annexed to this standard.

3. Requirements for Phytosanitary Treatments

For the purpose of this standard, phytosanitary treatments should fulfil the following requirements:

- be effective in killing, inactivating or removing pests, or rendering pests infertile or devitalization associated with a regulated article. The level of efficacy of the treatment should be stated (quantified or expressed statistically). Where experimental data is unavailable or insufficient, other evidence that supports the efficacy (i.e. historical and/or practical information/experience) should be provided.
- be well documented to show that the efficacy data has been generated using appropriate scientific procedures, including where relevant an appropriate experimental design. The data supporting the treatment should be verifiable, reproducible, and based on statistical methods and/or on established and accepted international practice; preferably the research should have been published in a peer-reviewed journal.
- be feasible and applicable for use primarily in international trade or for other purposes (e.g. to protect endangered areas domestically, or for research).
- not be phytotoxic or have other adverse effects.

Submissions of phytosanitary treatments should include the following:

- summary information
- efficacy data in support of the phytosanitary treatment
- information on feasibility and applicability.

3.1 Summary information

The summary information should be submitted by NPPOs or RPPOs to the Secretariat and should include:

- name of the treatment
- name of the NPPO or RPPO and contact information
- name and contact details of a person responsible for submission of the treatment
- treatment description (active ingredient(s), treatment type, target regulated article(s), target pest(s), treatment schedule, and other relevant information)
- reasons for submission, including its relevance to existing ISPMs.

Submissions should utilize a form provided by the IPPC Secretariat and available on the International Phytosanitary Portal (https://www.ippc.int).

In addition, the NPPO or RPPO should describe the experience or expertise in the subject area of the laboratory, organization and/or scientist(s) involved in producing the data, and any quality assurance system or accreditation programme applied in the development and/or testing of the phytosanitary treatment. This information will be considered when evaluating the data submitted.

3.2 Efficacy data in support of the submission of a phytosanitary treatment

The source of all efficacy data (published or unpublished) should be provided in the submission. Supporting data should be presented clearly and systematically. Any claims on the efficacy must be substantiated by data.

3.2.1 Efficacy data under laboratory/controlled conditions

The life-cycle stage of the target pest for the treatment should be specified. Usually, the life stage(s) associated with the regulated article moving in trade is the stage for which a treatment is proposed and established. In some circumstances, e.g. where several life stages may occur on the regulated article, the most resistant life stage of the pest should be used

for testing a treatment. However, practical considerations should be taken into account, as well as pest control strategies aimed at exploiting more vulnerable or otherwise specific stages of a pest. If efficacy data is submitted for a life stage that is not considered to be the most resistant (e.g. if the most resistant life stage is not associated with the regulated article), rationale for this should be provided. The efficacy data provided should specify the statistical level of confidence supporting efficacy claims made for treatment of the specified life stage.

Where possible, data should be presented on methods used to determine the effective dose/treatment to demonstrate the range of efficacy of the treatment (e.g. dose/efficacy curves). Treatments can normally be evaluated only for the conditions under which they were tested. However, additional information can be provided to support any extrapolation if the scope of a treatment is to be extended (e.g. extension of the range of temperatures, inclusion of other cultivars or pest species). Where the information provided is adequate to demonstrate the effectiveness of the treatment, only a summary of relevant preliminary laboratory tests will be required. The materials and methods used in the experiments should be suitable for the use of the treatment at the stated efficacy.

The data provided should include detailed information on, but not limited to, the following elements:

Pest information

- identity of the pest to the appropriate level (e.g. genus, species, strain, biotype, physiological race), life stage, and if laboratory or field strain was used
- conditions under which the pests are cultured, reared or grown
- biological traits of the pest relevant to the treatment (e.g. viability, genetic variability, weight, developmental time, development stage, fecundity, freedom from disease or parasites)
- method of natural or artificial infestation
- determination of most resistant species/life stage (in the regulated article where appropriate).

Regulated article information

- type of regulated article and intended use
- botanical name for plant or plant product (where applicable)
    - type/cultivar. A requirement for varietal testing should be based on evidence that the varietal differences impact treatment efficacy, and data should be provided to support the requirement.
- conditions of the plant or plant product, for example:
    - whether it was free from non-target pest infestation, non-pest disorder or pesticide residue
    - size, shape, weight, stage of maturity, quality, etc.
    - whether infested at a susceptible growth stage
    - storage conditions after harvest.

Experimental parameters

- level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation (e.g. number of subjects treated, number of replicate tests, controls)
- experimental facilities and equipment
- experimental design (e.g. randomized complete block design) if needed
- experimental conditions (e.g. temperature, relative humidity, diurnal cycle)
- monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity)
- methodology to measure the effectiveness of the treatment (e.g. whether mortality is the proper parameter, whether the end-point mortality was assessed at the correct time, the mortality or sterility of the treated and control groups)
- determination of efficacy over a range of critical parameters, where appropriate, such as exposure time, dose, temperature, relative humidity and water content, size and density
- methodology to measure phytotoxicity, when appropriate
- dosimetry system, calibration and accuracy of measurements, if using irradiation.

3.2.2 Efficacy data using operational conditions

Treatments may be submitted for evaluation without going through the processes outlined in section 3.2.1 when there is sufficient efficacy data available from the operational application of the treatment. When a treatment has been developed under laboratory conditions, it should be validated by testing under operational or simulated operational conditions. Results of these tests should confirm that the application of the treatment schedule achieves the stated efficacy under conditions in which the treatment will be used.

Where treatment specifications differ for trials under operational conditions, the test protocol modifications should be indicated. Supporting data may be presented from preliminary tests to refine the treatment schedule to establish the effective dose (e.g. temperature, chemical, irradiation) under operational conditions.

In some cases the method of achieving the effective dose will be different from the method established under laboratory conditions. Data that supports any extrapolation of laboratory results should be provided.

The same data requirements as listed in section 3.2.1 should also be provided for these tests. Other data required, depending on whether the treatments are carried out pre- or post-harvest, are listed below:

- factors that affect the efficacy of the treatment (e.g. for post-harvest treatments: packaging, packing method, stacking, timing of treatments (pre/post packaging or processing, in transit, on arrival)). The circumstances of the treatment should be stated, for example the efficacy of a treatment may be affected by packaging, and data should be provided to support all the circumstances that are applicable.
- monitoring of critical parameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative humidity). For example:
  - the number and placement of gas sampling lines (fumigation)
  - the number and placement of temperature/humidity sensors.

In addition, any special procedures that affect the success of the treatment (e.g. to maintain the quality of the regulated article) should be included.

3.3 Feasibility and applicability

Information should be provided, where appropriate, to evaluate if the phytosanitary treatment is feasible and applicable. This includes such items as:

- procedure for carrying out the phytosanitary treatment (including ease of use, risks to operators, technical complexity, training required, equipment required, facilities required)
- cost of typical treatment facility and operational running costs if appropriate
- commercial relevance, including affordability
- extent to which other NPPOs have approved the treatment as a phytosanitary measure
- availability of expertise needed to apply the phytosanitary treatment
- versatility of the phytosanitary treatment (e.g. application in a wide range of countries, pests and commodities)
- the degree to which the phytosanitary treatment complements other phytosanitary measures (e.g. potential for the treatment to be used as part of a systems approach for one pest or to complement treatments for other pests)
- summary of available information of potential undesirable side-effects (e.g. impacts on the environment, impacts on non-target organisms, human and animal health)
- applicability of treatment with respect to specific regulated article/pest combinations
- technical viability
- phytotoxicity and other effects on the quality of regulated articles, when appropriate
- consideration of the risk of the target organism having or developing resistance to the treatment.

Treatment procedures should adequately describe the method for applying the treatment in a commercial setting.

4. Evaluation of Submitted Treatments

Submissions will be considered by the TPPT only when the information outlined in section 3 is fully addressed. The information provided will be evaluated against the requirements in section 3.

Due respect for confidentiality will be exercised when the confidential nature of information is indicated. In such cases, the confidential information within the submission should be clearly identified. Where confidential information is essential for the adoption of the treatment, the submitter will be requested to release the information. If the release of the information is not granted, the adoption of the treatment may be affected.

Treatments will be adopted only for the regulated articles and target species for which they were tested and for the conditions under which they were tested, unless data is presented to support extrapolation (e.g. to apply the treatment to a range of pest species or regulated articles).

If the submission fails to meet the requirements outlined in section 3, the reason(s) will be communicated to the contact identified on the submission. There may be a recommendation to provide additional information or to initiate further work (e.g. research, field testing, analysis).

5. Publication of Phytosanitary Treatments

After adoption by the CPM, phytosanitary treatments will be annexed to this standard.

6. Treatment Review and Re-evaluations

Contracting parties should submit to the IPPC Secretariat any new information that could have an impact on the treatments currently adopted by the CPM. The TPPT will review the data and revise the treatments if necessary through the normal standard-setting process.

ANNEX 1

ADOPTED PHYTOSANITARY TREATMENTS

Phytosanitary treatments will be included in this annex after adoption by the CPM.