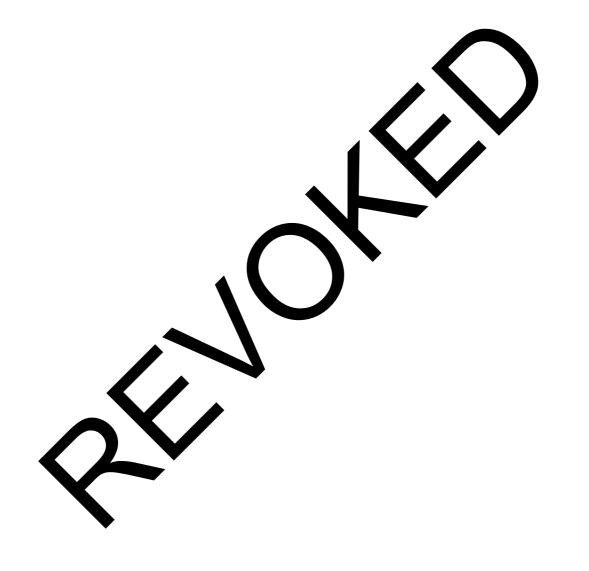




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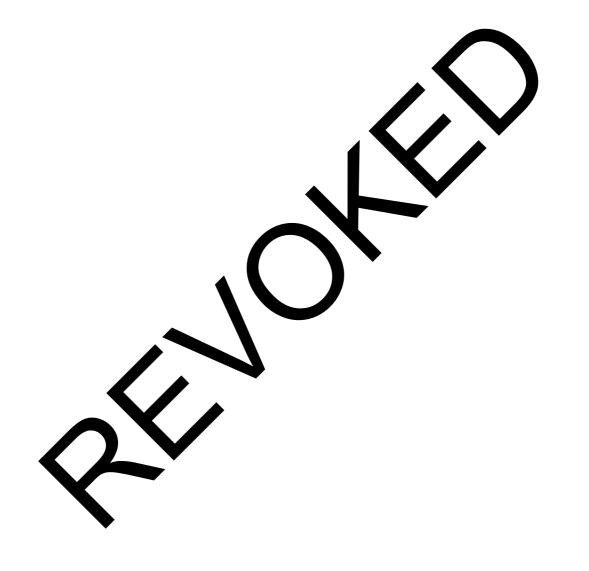
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ANNEX 1

Adopted phytosanitary treatments



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 sks and bying in View organisms, 2004. ISPM No. 11, FAO, Rome.

DEFINITIONS

Definitions of phytosanitary terms used in the present standard can be found in ISR 406. 5 (*Glossary of phytosanitary terms*).

OUTLINE OF REQUIREMENTS

Harmonized phytosanitary treatments support efficient phytosa tary casures in a wide range of circumstances and enhance the mutual recognition of treatment efficant. Annex 1 to his standard contains those phytosanitary treatments which have been adopted by the CPM.

National Plant Protection Organizations (NP Plant Protection Organizations (RPPOs) may submit s) an data and other information for the evaluation efficacy, feasibility and applicability of treatments. The information ent, including efficacy data, the name of a contact person and the should include a detailed description he trea reason for the submission. Trea ents that e for evaluation include mechanical, chemical, irradiation, physical and controlled atmosphere data should be clear and should preferably include data on the atments. The efficiency treatment under laborato or contr d conditions as well as under operational conditions. Information on feasibility and applicability of the p eatment(s) should include items on cost, commercial relevance, level of expertise required to apply th d versat

Submissions your complete information will be considered by the Technical Panel on Phytosanitary Treatments (TPPT), and if the treatment is a submission process that the 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 reests. Many of these treatments are supported by extensive research data, and others are used based on hist supporting their al evid efficacy. In practice, many countries use the same treatments or similar treatments for pecified pest owever, mutual recognition is often a complex and difficult process. Furthermore, there has previous en neither internationally recognized organization or process to evaluate treatments for their efficacy for listing such eposito a cent treatments. The Interim Commission on Phytosanitary Measures, at its sixt ession nized the need for 200 international recognition of phytosanitary treatments of major importance ation of the TPPT for ad appr d the for that purpose.

REQUIREMENTS

1. Purpose and Use

The purpose of harmonizing phytosanitary treatments is to support a cient phytosanitary measures in a wide range of circumstances and to enhance the mutual recognition a treat of the bey 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 over phytosanitary treatments for treating the same regulated pests or regulated articles.

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

When requiring phytosan by treat ants for imports, contracting parties should take into account the following points:

- Phytosanitary measurequired but contracting party shall be technically justified.
- Phytosardary patment contained in Annex 1 of this standard have the status of an ISPM and therefore should be considered a lordingly
- Registery residue of exporting contracting parties may prevent certain treatments from being approved for use we in territories. Therefore efforts should be made to accept equivalent treatments where possible.

2. Process for reatment 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 pest sinfertile or a devitalization associated with a regulated article. The level of efficacy of the treatment should be state (quantified or expressed statistically). Where experimental data is unavailable or inconcient, other widers, 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 genered using appropriate scientific procedures, including where relevant an appropriate experimental desire. The true supporting the treatment should be verifiable, reproducible, and based on statistical methods ad/or on tablish a and accepted international practice; preferably the research should have been published a peer-review journal.
- be feasible and applicable for use primarily in interation to de or for other purposes (e.g. to protect endangered areas domestically, or for research).
- not be phytotoxic or have other adverse effect

Submissions of phytosanitary treatments should include the follow

- summary information
- efficacy data in support of the phytos sitary estment
- information on feasibility and applicab

3.1 Summary information

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

- name of the treat ont
- name of the NPPeer RPD and contact information
- name and contact detect of a percer responsible for submission of the treatment
- treatmendescaption (a vie *ing*redient(s), treatment type, target regulated article(s), target pest(s), treatment scheidte, and oper releval unformation)
- rease for sub-princluding its relevance to existing ISPMs.

Submissions should utilize a form provided by the IPPC Secretariat and available on the International Phytosanitary Portal (https://www.ip. 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, bioty, physiologica tace), 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 veriability proght, developmental time, development stage, fecundity, freedom from disease or parallys)
- method of natural or artificial infestation
- determination of most resistant species/life stage (in the regulated article where a propriate).

Regulated article information

- type of regulated article and intended use
- botanical name for plant or plant product (wb
 - type/cultivar. A requirement for varietal texing shall be based on evidence that the varietal differences impact treatment efficiely, and data shall be provided to support the requirement.

ble

- conditions of the plant or plant product, for example:
 - whether it was free from non-arget asst infestation, non-pest disorder or pesticide residue
 - size, shape, weight, stage of naturity, y
 - whether infested at a susceptible growth stage
 - storage conditions a.

Experimental parameters

- level of confidence of laboratory tests provided by the method of statistical analysis and the data supporting that calculation (e.g. wholer of subjects treated, number of replicate tests, controls)
- experiment pilities d equivalent
- experimental de gn (e.g. promized complete block design) if needed
- experimental <u>conditions</u> (e.g. temperature, relative humidity, diurnal cycle)

rvest

- monthing a critical rameters (e.g. exposure time, dose, temperature of regulated article and ambient air, relative indidity)
- methodolog, to measure the effectiveness of the treatment (e.g. whether mortality is the proper parameter, whether the expoint 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 main up the quality of the regulated article) should be included.

3.3 Feasibility and applicability

Information should be provided, where appropriate, to evaluate if the hytosa tay treatments feasible and applicable. This includes such items as:

- procedure for carrying out the phytosanitary treatment (in uding ease of use, risks to operators, technical complexity, training required, equipment required, factores in the second second

f appropriate

- cost of typical treatment facility and operational running of
- commercial relevance, including affordabilit
- extent to which other NPPOs have approve the treatment as a potosanitary measure
- availability of expertise needed to apply the phytosanitary eatment
- versatility of the phytosanitary treatment (an application) 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 appreciation or one pest or to complement treatments for other pests)
- summary of available information of optential undesirable side-effects (e.g. impacts on the environment, impacts on non-target optimization and animal health)
- applicability of treatment with respect surgific regulated article/pest combinations
- technical viability
- phytotoxicity and ther efforts on the quality of regulated articles, when appropriate
- consideration of the islast the target organism having or developing resistance to the treatment.

Treatment procedures shalld adequate describe the method for applying the treatment in a commercial setting.

4. Evaluation - Subm. a Treatments

Submissions will considered by the TPPT only when the information outlined in section 3 is fully addressed. The information provided ill 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).

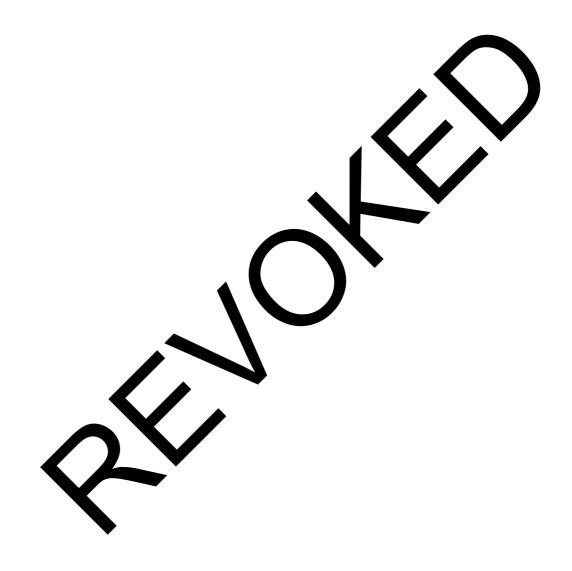
If the submission fails to meet the requirements outlined in section 3, the reason(s) will be communicated to the contact identified on the submission. There may be a recommendation to provide additional information or to initiate further work (e.g. research, field testing, analysis).

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.

