**Draft ISPM: Requirements for the use of fumigation as a phytosanitary measure (2014-004)**

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CONTENTS [to be inserted later]

Adoption

[Text to this paragraph will be added following adoption.]

INTRODUCTION

Scope

This standard[[1]](#footnote-1) provides harmonized technical guidance on the specific procedures for the application of fumigation treatment as a phytosanitary measure for regulated pests or articles. This includes treatments based on the application of chemicals in a gaseous form within enclosed environments. Requirements of temperature, dosage, duration, minimum concentration readings at time intervals, commodity tolerance, verification and other essential aspects for effective fumigation treatment are covered in ISPM 28 (*Phytosanitary treatments for regulated pests*).

References

The present standard refers to International Standards for Phytosanitary Measures (ISPMs). ISPMs are available on the International Phytosanitary Portal (IPP) at <https://www.ippc.int/core-activities/standards-setting/ispms>.

**APPPC RSPM No. 10** Approval of fumigation facilities.

**USDA-APHIS**. 2014. Treatment Manual. http://www.aphis.usda.gov/import\_export/plants/manuals/ports/downloads/treatment.pdf

Definitions

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

Outline of Requirements

Fumigation is a form of treatment in which a toxic chemical gas is applied to a commodity to kill or inactivate in a sufficient proportion of the target contaminating pests to reduce the risk to a quarantine area to an acceptable level.

National plant protection organizations (NPPOs) should be assured that the efficacy of the fumigation treatment is scientifically demonstrated for the regulated pest(s) of concern and the required response. Application of a fumigation treatment requires appropriately trained and certified operators, a pre-prepared fumigation site, specialized equipment, and the fumigant.

Fumigation procedures should be in place and monitored to ensure that the treatment can be conducted properly and commodity lots are handled, stored and identified to ensure that phytosanitary security is maintained. Record-keeping should be completed to comply with the requirements of the NPPO.

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). 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.

The purpose of this ISPM is to provide harmonized requirements for the application of phytosanitary fumigation treatments, specifically those adopted under ISPM 28. This standard provides guidance on the main operational requirements for each type of fumigation treatment in order to ensure the treatments are applied effectively, consistently and in a manner that minimizes economic and environmental impacts..

IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

Fumigation treatment is widely and historically applied as a cost effective phytosanitary measure to prevent the introduction or spread of target pests in a quarantine area. However, fumigant gases, such as methyl bromide, sulfuryl fluoride, phosphine and ethyl format, may above certain doses be toxic to people and have negative impacts on the environment. For example the emission of methyl bromide into the atmosphere is known to deplete the ozone layer and sulfuryl fluoride is a recognized greenhouse gas. The human health or environmental impacts of fumigants can be proportionally mitigated if through the use of recapture technology the emissions are reduced.

REQUIREMENTS

1. Treatment Objective

The objective of using a fumigation treatment as a phytosanitary measure is to achieve pest mortality at a specified level.

2. Treatment Application

Fumigation treatments may be applied:

* as an integral part of packing operations
* at centralized locations such as the port of embarkation
* to the commodity once it is packaged for shipment
* on the transport or after unloading.

The minimum requirement of a fumigation treatment is that the scheduled target concentration over time (C/T) is attained throughout the commodity for the scheduled treatment minimum temperature and duration, allowing the prescribed level of efficacy to be achieved.

Variables to consider when implementing a fumigation treatment are the minimum dose, temperature and duration of the treatment, and the humidity of the treatment environment or moisture content of the commodity, where applicable. These variables should be compatible with the treatment achieving the required level of efficacy. Controlled atmospheres or modified atmospheres created by packaging or the commodity may alter treatment efficacy.

The treatment schedule should describe the process of pre- and post-conditioning to reach the target dose, where these processes are critical to the treatment achieving the required level of efficacy. The schedule should also include contingency procedures and guidance on remedial actions for treatment failures.

3. Treatment Types

There are over 50 active chemicals that could be used in phytosanitary fumigant treatments (Foot note: For a review see Balock 1951). The following are the main groups of fumigant treatment types available.

3.1 Single Fumigant Treatments

The most common form of fumigation treatment is those that apply a single chemical fumigant. General use fumigants such as methyl bromide, phosphine or sulfuryl fluoride etc. rely on a mode of action that is generally effective against all pest groups (e.g. insects, arthropods, fungi etc) or against one particular group (e.g. insects) and all or most life stages. Treatment schedules for single fumigants are generally simple, requiring a single application to achieve a required minimum dose over a specified duration.

3.2 Combination Fumigant Treatments

Where a single fumigant may not achieve the required efficacy in a cost effective manner, another fumigant may be included in the treatment schedule to enhance effectiveness. Combination fumigants may be necessary where the host commodity is vulnerable to damage from the main fumigant, or where a single life stage of the target pest (e.g. eggs) is tolerant to the main fumigant. Examples of combination fumigant treatments include methyl isothiocyanate with sulfuryl fluoride or methyl bromide.

3.3 Fumigant and Temperature Treatments

Excessive heat or cold may be included immediately before or after a fumigation treatment to enhance the effectiveness of the overall treatment. A combination temperature and fumigant treatment may be necessary where the host commodity is vulnerable to damage from the main fumigant, or where a single life stage of the target pest (e.g. eggs) is tolerant to the main fumigant. Examples of combination temperature and fumigant treatments include a fumigation with a sulfur dioxide and carbon dioxide mixture, followed by a cold treatment.

3.3 Fumigant and Atmosphere Treatments

Increasing atmospheric carbon dioxide, nitrogen or oxygen levels in the fumigation chamber may be used to enhance fumigation treatment efficacy where the host commodity is vulnerable to damage from the fumigant, or where a single life stage of the target pest (e.g. eggs) is tolerant to the fumigant. Changing the atmosphere in this way may directly enhance target pest mortality or may increase target pest respiration increasing the efficacy of the fumigant. Reducing levels of oxygen in the atmosphere may also be necessary where the fumigant is dangerously flammable, such is the case with Ethyl formate.

4. Fumigation equipment and enclosures

There are many potential forms and designs for equipment and enclosures used in fumigation treatments. These will vary depending on the type of fumigant used, the nature of the commodity, and the conditions of the surrounding environment. The following equipment may be necessary to ensure a fumigation achieves the required level of efficacy:

4.1 Fumigation enclosure

A fumigation enclosure is simply any space that can be enclosed in a manner that ensures the appropriate fumigation conditions are maintained throughout the duration of the fumigation. Examples of enclosures include purpose-built fumigation chambers, freight containers, warehouses or tarpaulin ‘tents’. All enclosures should be designed to allow adequate access for the equipment required to ensure the fumigation is completed appropriately.

4.2 Fumigation Equipment

**4.2.1 Dosing devices**

Dosing equipment enables the quantitative introduction of fumigant gas into an enclosure. Dosing equipment includes an appropriate storage vessel for the fumigant, lines or tubes that allow the fumigant to be delivered to the enclosure, and a device that can either measure the rate or volume of gas flow into an enclosure (e.g. a gas mass flow-meter) or the volume or weight loss from the gas storage supplying the enclosure (e.g. a scale or balance). In some cases gas cylinders can be opened within the enclosure applying a known volume or weight of gas into the enclosure.

**4.2.2 Gas Vaporizer**

Some fumigants, such as methyl bromide, are stored as a compressed liquid in a metal cylinder. Release and vaporization of a significant quantity of the liquid as is required for fumigation will absorb a significant amount of energy. A vaporizer is used to provide energy (as heat) during the vaporization of the liquid to a gas to ensure a steady supply of gas is provided to the enclosure.

**4.2.3 Heating equipment**

When temperature falls close to the boiling point of the fumigant (e.g. around 4 ºC for methyl bromide) a heater should be used to raise the temperature of the commodity and the air within the enclosure. Exposed heating sources should not be used when fumigating with potentially flammable chemicals. Enhanced gas circulation in the enclosure will speed up the gas heating rate.

**4.2.4 Gas circulation equipment**

Even and quick distribution of fumigant gas introduced into the enclosure may be important for successful fumigation of a large quantity of commodity, especially with gases that diffuse relatively slowly. Rapid circulation of gas may also be required for the fumigation of perishable commodities or commodities that sustain damage on extended exposure to the fumigant. One or more electrical fans capable of moving gas volume 3 to 10 times that of the enclosure may be adequate for gas circulation.

**4.2.5 Instruments to measure gas tightness**

The gas tightness of an enclosure can be defined as and measured by half pressure decay time. The required gas tightness of an enclosure will depend on the fumigant being used and the environment surrounding the fumigation enclosure (e.g. proximity of sensitive equipment, commodities or people). Usually a half pressure decay time of 10 to 30 seconds (air pressure decaying from 50 Pa to 25Pa) would be considered suitably gas tight. Often a simple U tube manometer and a manually operated stop watch can be used to measure gas tightness although specialized electronic measuring devices are also available.

**4.2.6 Thermometer**

One or more thermometers may be required to measure the temperatures in the enclosure and both the external and internal surfaces of the commodity before and during fumigation. The accuracy of the temperature should be within 0.5℃ of the actual temperature.

**4.2.7 Monitoring gas concentration**

The equipment required to measure the fumigant concentration within the enclosure will depend on the type of gas used. The equipment used should have an accuracy of at least 0.1g/m3.

**4.2.8 Safety equipment**

Equipment suitable for ensuring the safety of those potentially exposed to the fumigant should be available at all times and in appropriate working order.

**4.2.9 Fumigant recycle use or disposal facility**

Equipment with the capacity to capture the fumigant gas for later recycling, reuse or safe disposal is encouraged for safety and environmental reasons.

5. Fumigation procedures

5.1 Preparation of fumigation

Many factors may affect fumigation efficacy. Fumigant concentration, exposure time and commodity/atmospheric temperature are crucial factors. Gas tightness of the enclosure, commodity load pattern and load factor are directly related to gas distribution and gas concentration during fumigation. Some commodities, such as oil, fats, porous or finely ground materials, may absorb large quantity of fumigant and lead to a reduction in gas concentration. Packaging materials may preclude fumigant gas penetration onto the commodity and prevent fumigant concentrations achieving targeted levels. Therefore, good preparation of fumigation is essential for the achievement of the target efficacy.

Before fumigation, the commodity should be loaded into the fumigation enclosure in a manner that ensures sufficient space for adequate circulation of the fumigant. Where there is limited fumigant penetration into the commodity, separators such as pieces of wood may be used to ensure adequate fumigant penetration into all items. Should fumigant-impenetrable packing material be present, this should be removed or punctured to ensure adequate access for the fumigant

The fumigant supply and circulation equipment should be arranged within the fumigation chamber to ensure appropriate fumigant concentrations within the chamber are achieved in a timely manner and maintained during fumigation.

5.2 Determination of fumigation temperature

It is necessary to measure both the temperatures of the commodity and the atmosphere within the fumigation chamber. The temperature at which the fumigation is undertaken is deemed to be the lowest temperature recorded in the chamber or the commodity. Fumigation should not proceed if at any time before during fumigation the temperature falls within 5oC of the gas boiling point.

5.3 Gas tightness test

It may be necessary to conduct gas tightness test before fumigation. Ideally testing should occur immediately prior to any fumigation. However if the fumigation chamber is of sufficiently resistant construction the testing may only be necessary at intervals, for example, monthly.

5.4 Introduction of the fumigant gas

The total weight of fumigant to be applied is a multiply of the required dosage rate and the volume of the enclosure. Consideration may also need to be made for any excess sorption or leakage from the fumigation enclosure if either of these are likely to occur to any significant degree. A correct measurement the enclosure volume is therefore important.

Once the enclosure volume has been determined the weight of fumigant required can be calculated as follows:

Amount of fumigant (kg) =

Where the dose rate takes into account fumigant loss over the duration of the treatment and the % fumigant released is equal to the amount of fumigant generated from the chemical applied (e.g. Aluminum phosphide generates around 33.3% phosphine gas).5.5 Monitoring of the fumigation

Fumigant concentration readings can indicate if the amount of fumigant applied is correct and if any heavy leakage or sorption of the commodity exists. Concentration readings should be taken a number of times during the treatment and in a number of locations (preferably where concentrations are likely to be the lowest) in the fumigation enclosure to ensure the fumigant is relatively evenly distributed in the enclosure over the duration of the treatment and achieves the targeted levels.

Where required to calculate achieved C/T values, concentration readings should be taken in sufficient frequency during the fumigation to provide an adequate measure of the dose curve. C/T values can be estimated using the following calculation:

C/T value achieved (g.h/m3) = where

* Tn is the time the first reading was taken in hours
* Tn+1 is the time the second reading was taken in hours
* Cn is the concentration reading at Tn in g/m3
* Cn+1 is the concentration reading at Tn+1 in g/m3
* Ctn,n+1 is the calculated Ct product between Tn and Tn+1 in g h/m3

5.6 Completion of the fumigation

Once the treatment time has been completed and the concentration and temperature readings indicate that the required minimum readings have been achieved, the fumigation can be considered completed.

Indications of fumigation success can be obtained on inspection and conformation of target pest mortality. For many fumigations an extended period post-fumigation may be required before full pest mortality is achieved. Required treatment effects should not necessarily be expected on non-target pests on the fumigated commodity.

6. Phytosanitary System Integrity

Confidence in the adequacy of a fumigation treatment as a phytosanitary measure is primarily based on assurance that the treatment is effective against the pest of concern under specific conditions, the treatment has been properly applied and the commodity has been adequately safeguarded. Efficacy research provides assurance that only effective treatments are used. (Appendix 1 provides guidance for temperature treatment efficacy studies.) Well-designed and closely monitored systems for treatment delivery and safeguarding provide assurance that treatments are properly conducted and consignments are protected from infestation, reinfestation and loss of integrity.

The NPPO of the country in which the treatment facility is located is responsible for ensuring system integrity, so that treatments meet the phytosanitary requirements of the importing country.

6.1 Approval of Facilities

Treatment facilities should be subject to approval (certification or accreditation) by the NPPO in the country in which the facility is located before phytosanitary treatments are applied there.

6.2 Phytosanitary security measures at the treatment facility

It is not usually possible to visually distinguish treated from non-treated commodities. Therefore, the following phytosanitary security measures may be required at the treatment facility:

* a means of moving the commodity from the receiving area to the treatment area without the risk of contamination or infestation
* a means to ensure commodities that are unpackaged or exposed in their packaging are not subject to infestation, reinfestation or contamination immediately following treatment
* handling of treated commodities under conditions that safeguard against contamination or infestation
* adequate segregation and clear identification of treated commodities that safeguards against misidentification of treated and non-treated commodities.

Specific procedures appropriate for each facility and commodity treatment should be approved by the NPPO of the exporting country.

6.3 Environment, health and safety

Prior to any application of a fumigant, a review of the health and safety risks should be completed to ensure that all the requirements of local regulations are fully met and the safety of applicators and those living or working in proximity to the treatment are fully considered. The fumigant used should be appropriate to the commodity being fumigated, and the equipment, facility (enclosure or chamber) are appropriate to the circumstances.

6.4 Labelling

Commodities may be labelled with treatment lot numbers or other features of identification (e.g. locations of packing and the treatment facility, dates of packing and treatment) allowing trace-back.

6.5 Monitoring and auditing

The adequacy of a treatment facility and its processes should be verified through monitoring and auditing of facility treatment records that includes, as necessary, direct oversight. Continuous supervision of treatments should not be necessary, provided treatment programmes are properly designed to ensure a high degree of system integrity for the facility, process and commodity in question. The level of oversight should be sufficient to detect and correct deficiencies promptly.

6.6 Compliance agreement

A compliance agreement should be in place between the treatment facility and the NPPO of the country in which the facility is located. Such an agreement may include the following elements:

* approval of the facility by the NPPO of the country in which the facility is located
* the monitoring programme to be administered by the NPPO of the country in which treatments are conducted
* audit provisions, including unannounced visits
* free access to documentation and records of the treatment facility
* corrective action to be taken in cases of non-compliance.

7. Documentation

The NPPO of the country in which the treatment facility is located is responsible for monitoring record keeping and documentation by the treatment facility and ensuring that records are available to concerned parties. As with any phytosanitary treatment, trace-back capability is essential.

7.1 Documentation of procedures

Documentation of procedures is necessary to ensure that commodities are consistently treated, as required. Process controls and operational parameters are usually established to provide the details necessary for a specific authorization of a treatment facility. Calibration and quality control procedures should be documented by the treatment facility operator. At a minimum, an agreed written procedure should address the following:

* consignment handling procedures before, during and after treatment
* orientation and configuration of the commodity during treatment
* critical process parameters and the means for their monitoring
* temperature calibration and recording and, where appropriate, humidity calibration and recording
* contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes
* procedures for handling rejected lots
* labelling (if required), record keeping and documentation requirements.

7.2 Record keeping

Treatment facility operators should be required to keep records. These records should be available to the NPPO when, for example, a trace-back is necessary.

Appropriate records for fumigation treatments as phytosanitary measures should be kept by the treatment facility for at least one year to enable the trace-back of treated lots. The facility operator should keep all records for every treatment. Information that may be required to be recorded includes:

* identification of facility
* commodity treated
* purpose of treatment
* target regulated pest
* packer, grower and place of production of the commodity
* lot size and volume, including number of articles or packages
* identifying markings or characteristics
* date of treatment
* any observed deviation from the treatment schedule.

7.3 Documentation by the NPPO

All NPPO procedures should be appropriately documented and records, including those of monitoring inspections made and phytosanitary certificates issued, should be maintained for at least one year. In cases of non-compliance or new or unexpected phytosanitary situations, documentation should be made available as described in ISPM 13.8. Inspection and Phytosanitary Certification

8.1 Export inspection

The NPPO of the exporting country should ensure the consignment meets the phytosanitary import requirements of the importing country by::

* documentation verification
* examination for target pests.

Documentation is checked for completeness and accuracy as the basis for certifying the treatment. Inspection is done to detect any target pests that are not adequately treated. Where non-target pests are found, the NPPO should verify whether these are regulated by the importing country.

If mortality is required, target pests that are not yet dead may be found during the period immediately following the treatment application depending on the specification for efficacy and the fumigant used (see section 5.6).

8.2 Phytosanitary certification

Certification should be issued in accordance with the IPPC to validate the successful completion of a treatment when required by the importing country. The phytosanitary certificate or its associated documentation should at least specifically identify the treated lot(s), date of treatment, fumigation temperature, fumigant name and its dosage applied, exposure duration and concentration at different intervals. It should be recognized that the phytosanitary certificate may require other information supplied to verify that additional phytosanitary requirements have also been met (see ISPM 7 and ISPM 12).

8.3 Import inspection

As mortality is the required response, this may be confirmed at inspection on arrival. The detection of pests other than target pest(s) on import should be assessed for the risk posed and appropriate measures taken, considering in particular the effect the treatment may have had on the non-target pest(s). The consignment may be detained and any other appropriate action may be taken by the NPPO of the importing country. NPPOs should clearly identify the contingency actions to be taken if live pests are found:

* target pests – no action to be taken unless the required response was not achieved
* non-target regulated pests:
* no action if the treatment is believed to have been effective
* action if there is insufficient data on efficacy or the treatment is not known to be effective
* non-target non-regulated pests – no action, or emergency action for new pests.

In case of non-compliance or emergency action, the NPPO of the importing country should notify the NPPO of the exporting country as soon as possible (see ISPM 13).

8.4 Verification of treatment efficacy

Verification methods, including laboratory tests or analysis to determine if the required response has been achieved should be described by the exporting country at the request of the importing country.

7. Authority

The NPPO is responsible for the phytosanitary aspects of evaluation, adoption and use of fumigation as a phytosanitary measure. To the extent necessary, it is the NPPO’s responsibility to cooperate with other national and international regulatory agencies concerned with the development, approval , safety and application of fumigation treatment, or the distribution, storage, use or consumption of fumigants . Their respective responsibilities should be identified to avoid overlapping, conflicting, inconsistent or unjustified requirements.

This appendix is for reference purposes only and is not a prescriptive part of the standard.

APPENDIX 1: Guidance for fumigation treatment efficacy studies [[2]](#footnote-2)

Research materials

It is recommended to archive samples of the different developmental stages of the pests studied in order to, among other reasons, resolve possible future disputes on identification (voucher specimens). The commodity to be used should be of normal commercial condition.

To perform treatment research to control quarantine pests it is necessary to know its basic biology as well as define how the pests used in the research will be obtained. Fumigation experiments should be carried out on the commodity infested naturally in the field and/or with laboratory-reared pests that are used to infest the commodity preferably in a natural form. The method of rearing, feeding and refreshing of the colony should be carefully detailed.

Note: Studies done with pests *in vitro* are not recommended because the results could be different from those obtained when fumigating pests in commodities unless preliminary testing indicates that results from *in vitro* treatments are no different than *in situ*.

Temperature recording

The gas concentration and temperature recording systems should be calibrated, certified and used according to recognized international standards. Temperature sensitive probes and recorders are generally calibrated against an ice/water slurry for 0ºC. Routine calibration should be conducted periodically.

Estimation and confirmation of optimal gas concentration and its duration for treatment

*Preliminary tests*

The following steps should be carried out to estimate the dose required to ensure quarantine security:

* Treatment tolerance of the different stages of development of the pest in question that may be present in the commodity that is marketed must be established with the purpose of determining the most resistant stage. The most resistant stage, even if it is not the most common one occurring in the commodity, is the stage for which the quarantine treatment dose is established.
* Treatment tolerance of different shapes, size and varieties of the commodities have to be addressed to determine if they may influence the treatment outcome.
* The optimal temperature and its duration will be determined experimentally. If pertinent data do not already exist, it is recommended to use at least five (5) dose levels and a control for each developmental stage, and variety/shape/size with a minimum of 120 individuals where possible for each of the doses and a minimum of three (3) replicates. The relationship between optimal temperature and its duration and response for each stage will be determined to identify the most resistant stage. The optimum dose to kill the pest at the most resistant stage in the variety or commodity type where the target pest shows the highest resistance needs to be determined. The remainder of the research will be conducted on the most temperature tolerant stage in the variety or commodity type where the target pest shows the highest resistance.
* During the period of post-treatment observation of the commodities and associated pests, both treated and control, must remain under favourable conditions for survival, development and reproduction of the pests so that these parameters can be measured. The untreated controls must develop and/or reproduce normally for a given replicate for the experiment to be valid. Any study where the control or check mortalities are high indicates that the organisms were held and handled under suboptimal conditions. These organisms may give misleading results if their treatment mortality is used to predict an optimum treatment dose. In general, mortality in the control or check should not exceed 10%.

*Large-scale (confirmatory) tests*

* To confirm if the estimated optimal temperature and its duration to provide quarantine security is valid, it is necessary to treat a large number of individuals of the most resistant stage of the organism while achieving mortality. The number treated will depend on the required level of confidence. The level of efficacy of the treatment should be established between the exporting and importing countries and be technically justifiable.
* Because the most severe temperature and its duration measured during the confirmatory part of the research will be the target temperature and its duration required for the approved treatment, it is recommended to keep the temperature fluctuation during the large scale tests as low as possible.

Record-keeping

Test records and data need to be kept to validate the data requirements and should upon request be presented to interested parties, for example the NPPO of the importing country, for consideration in establishing an agreed commodity treatment.

1. Nothing in this standard shall affect the rights or obligations of contracting parties under other international agreements or national legislation, including those applicable to irradiation of food. [↑](#footnote-ref-1)
2. Based primarily on insect pest treatment research. [↑](#footnote-ref-2)