

[1]DRAFT ISPM: *REQUIREMENTS FOR THE USE OF FUMIGATION AS A PHYTOSANITARY MEASURE* (2014-004)

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[27]CONTENTS [TO BE INSERTED LATER]

[28]Adoption

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

[30]INTRODUCTION

[31]Scope

[32]This standard provides technical guidance for NPPOs on the specific procedures for the application of fumigation 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, and other essential aspects for effective fumigation are covered in ISPM 28 (*Phytosanitary treatments for regulated pests*).

[33]This standard does not describe use of modified atmospheres as a phytosanitary treatment.

[34]References

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

[36]**CPM R-03**. 2017. Replacement or reduction of the use of methyl bromide as a phytosanitary measure. CPM Recommendation. Rome, IPPC, FAO. Available at <https://www.ippc.int/en/publications/84230/> (last accessed 15 May 2017).

[37]**Definitions**

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

[39]**Outline of Requirements**

[40]This standard provides a description of the main types of fumigation and provides guidance on the main operational requirements needed in order to ensure that the treatments are applied effectively, consistently and in a manner that minimizes economic and environmental impacts.

[41]The standard describes how fumigation should be carried out to achieve the stated efficacy as given in ISPM 28 for the regulated pests of concern. This standard also provides guidance for NPPOs on the procedural requirements for fumigation entities authorized to perform fumigation as a phytosanitary measure.

[42]**BACKGROUND**

[43]Fumigation is a form of treatment in which a toxic gas is applied to a commodity to kill a sufficient proportion of the target pests and may be used in pest management.

[44]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 for, 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.

[45]The change in concentration of carbon dioxide and oxygen in air as used in modified atmosphere treatments is not considered to be a fumigation treatment.

[46]**IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT**

[47]Historically, fumigation has been widely applied to prevent the introduction and spread of target pests into a regulated area and has, therefore, been beneficial to biodiversity and the environment. However, fumigant gases, such as methyl bromide, sulphuryl fluoride, phosphine and ethyl formate, may 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 sulphuryl fluoride is a recognized greenhouse gas. The IPPC Recommendation on the replacement or reduction of the use of methyl bromide as a phytosanitary measure (CPM R-03, 2017) has been adopted in relation to this issue. Environmental impacts of fumigants can be proportionally mitigated through the use of recapture technology to reduce emissions.

[48]**REQUIREMENTS**

[49]The purpose of this ISPM is to provide requirements for the application of phytosanitary fumigation, specifically those treatments adopted under ISPM 28.

[50]**1. Treatment Objective**

[51]The objective of using fumigation as a phytosanitary measure, alone or in combination with another phytosanitary measure is to manage pest risk by achieving a specified level of pest mortality (either immediately or eventually).

[52]2. Fumigation entities

[53]Fumigation is undertaken by entities (e.g. fumigation companies or individuals) either in a fumigation facility or at other locations (e.g. cargo ship hold) (hereafter, fumigation facilities and fumigation operators are referred to as fumigation entities).

[54]3. Treatment Application

[55]Fumigation may be applied at any point along the supply chain, for example:

- [56]as an integral part of packing operations
- [57]just before dispatch (e.g. at centralized locations at the port)
- [58]after packaging (e.g. once the commodity is packaged for dispatch)
- [59]during storage
- [60]during transport
- [61]after unloading.

[62]The minimum requirement of fumigation is to ensure that the scheduled parameters (e.g. concentration–time product (CT)) are attained at the required level throughout the commodity for the scheduled treatment minimum temperature and duration, allowing the required efficacy to be achieved. Appendix 1 provides guidance for fumigation efficacy studies.

[63]Parameters to consider when applying fumigation are the minimum dose, temperature and duration of the treatment, and where applicable the humidity of the treatment environment or moisture content of the commodity, all of which should be compatible with officially approved schedules or ISPM 28. Modified atmospheres created by packaging or by the commodity itself may alter treatment efficacy.

[64]The treatment protocol should describe the process of pre- and post-conditioning to reach the required dose, where these processes are critical to the treatment achieving the required efficacy. The protocol should also include contingency procedures and guidance on corrective actions for treatment failures.

[65]4. Treatment Types

[66]The following are the main groups of fumigant treatment types used.

[67]4.1Single fumigant treatments

[68]The most common forms of fumigation are those that apply a single fumigant. General use fumigants such as methyl bromide, phosphine or sulphuryl fluoride rely on a mode of action that is effective against all pest groups or against one particular group (e.g. arthropods, fungi, nematodes) 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. A list of commonly used fumigants and their chemical properties is provided in Appendix 2.

[69]4.2Combinations with other fumigants or treatments

[70]Where a single fumigant may not achieve the required efficacy without rendering the commodity unmarketable, or for reasons of economy or logistics, another fumigant or treatment may be included in the treatment schedule.

[71]4.2.1 Sequential combination treatments

[72]Another treatment may be applied immediately before or after fumigation to increase the effectiveness of the entire treatment. For example, temperature and fumigant treatments applied sequentially may be necessary where the host commodity is vulnerable to damage from the increased severity required of either treatment alone, or where the most tolerant life stage of the target pest is different for the different treatments. An example of a temperature and fumigant combination treatment is fumigation with methyl bromide followed by a cold treatment.

[73]4.2.2 Concurrent combination treatments

[74]Concurrent combinations of a fumigant with other fumigants or treatments may be superior in efficacy, commodity tolerance, economics or logistics to treatment with a single fumigant alone.

[75]4.2.2.1 *Fumigant and modified atmosphere combination treatments*

[76]Increasing atmospheric carbon dioxide in the fumigation enclosure, either alone or in combination with increasing nitrogen and decreasing oxygen levels, may be used to increase fumigation treatment efficacy. Changing the atmosphere in this way may directly enhance target pest mortality or may increase target pest respiration thereby increasing the efficacy of fumigants such as phosphine. Reducing levels of oxygen in the atmosphere may also be necessary where the fumigant is flammable, such as is the case with ethyl formate.

[77]4.2.2.2 *Fumigation under vacuum*

[78]Applying a fumigant under a partial atmospheric vacuum can significantly increase the rate of fumigant penetration into a commodity, resulting in increased efficacy or the ability to reduce fumigant quantity or duration of treatment. Such treatments should be carried out in purpose-built vacuum chambers that allow minimal vacuum loss during the fumigation, and using a vacuum pump capable of attaining the atmospheric pressure required within the time frame required.

[79]5. Fumigation Enclosures and Equipment

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

[81]5.1 Fumigation enclosure

[82]A fumigation enclosure should be a space that can be enclosed in a manner that ensures that appropriate fumigation conditions are maintained throughout the duration of the fumigation. Examples of enclosures include purpose-built fumigation chambers, silos, freight containers, warehouses or tarpaulin “tents”. The enclosure should be constructed from materials that maintain adequate fumigant concentrations over the fumigation period (e.g. materials that are not porous or absorbent to the fumigant). Surfaces such as soil, sand, base rock and paving (stones or blocks) are unlikely to provide a suitable floor for a tent fumigation enclosure.

[83]All enclosures should be designed to allow adequate access for the equipment that is required to verify that the fumigation has been applied appropriately.

[84]5.1.1 Pressure testing the enclosure

[85]Where the gas tightness of an enclosure may not be sufficient to ensure adequate gas concentrations are maintained throughout the fumigation period, the gas tightness should be determined by measuring the 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). For example, an enclosure having a half pressure decay time of ten seconds or more (air pressure decaying from 200 Pa to 100 Pa) should be considered suitably gas tight for methyl bromide fumigations.

[86]5.2 Fumigation equipment

[87]All equipment used for measuring fumigation parameters (e.g. measuring devices) should be calibrated according to the manufacturer’s instructions.

[88]5.2.1 Dosing devices

[89]Dosing equipment should enable the quantitative introduction of fumigant gas into an enclosure. Dosing equipment includes an appropriately safe and secure storage vessel for the fumigant, and lines that allow the fumigant to be delivered to the enclosure, and should include a device that can either measure the rate or volume of gas flow into an enclosure (e.g. a gas mass flow-meter) or measure the volume or weight loss from the gas storage supplying the enclosure (e.g. a scale or balance). In some cases, gas cylinders may be opened within the enclosure applying a known volume or weight of gas into the enclosure to achieve the required fumigant dose.

[90]5.2.2 Gas vaporizer

[91]Some fumigants are stored as a compressed liquid in a metal cylinder. Release and vaporization of a significant quantity of the liquid as required for fumigation will absorb a significant amount of energy. A vaporizer should be used to provide energy (as heat) during the vaporization of the liquid to a gas to ensure that the required amount of gas is provided to the enclosure.

[92]5.2.3 Heating equipment

[93]When it is necessary to raise the temperature of the commodity and the air within the enclosure, exposed heating sources should not be used with flammable fumigants or fumigants that decompose at high temperatures (see Appendix 2 for fumigant chemical properties).

[94]5.2.4 Gas circulation equipment

[95]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 is 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 a volume of three to ten times that of the enclosure per hour should be used to ensure gas circulation.

[96]5.2.5 Instruments to measure moisture content

[97]A moisture meter gives a reading of the approximate moisture content of the commodity (e.g. wood). Moisture content can be measured as a dry or wet weight, where the wet weight is the weight of the original “wet” sample and the dry weight is the weight of the sample after drying in an oven. As moisture content will usually vary within and between the commodities within the same lot, moisture meters need only measure within 5% of the actual moisture content. Available moisture meters include those that measure electrical resistance (pin meters) or use electrometric wave technology (pinless meters).

[98]5.2.6 Instruments to measure vacuum

[99]A suitable vacuum gauge, of appropriate accuracy and sensitivity, should be used to measure and record the air pressure or vacuum drawn and maintained during the exposure or testing period. Suitable vacuum gauges may include a simple U-tube manometer or a Bourdon gauge, although specialized electronic measuring devices are also available, and should measure within 10 Pa of the actual pressure.

[100]5.2.7 Instruments to measure temperatures

[101]Sufficiently reliable thermometers should be used to measure either continuously or at suitable intervals the temperature in the enclosure space and, as appropriate, the external surfaces and inside the commodity before and during fumigation. The number of temperature sensors required will depend on the size of the treatment enclosure (see section 6.4). The accuracy of the temperature measurement should be within 0.5 °C of the actual temperature.

[102]5.2.8 Instruments to monitor gas concentration

[103]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 $\pm 5\%$ of the fumigant concentration to be achieved throughout the fumigation. The monitoring equipment (e.g. lines) exposed to the fumigant

should be constructed from materials that do not absorb the fumigant. Fumigant monitoring lines should be placed as far as possible from fumigant supply lines or dispensers, and in the area or areas of the enclosure likely to have the lowest concentration of fumigant.

[104]5.2.9 Safety equipment

[105]Equipment suitable for ensuring the safety of those potentially exposed to the fumigant should be available at all times and in appropriate working order. Depending on the fumigant being used, protective clothing, respirators and suitably sensitive monitoring equipment may need to be made available to those handling the fumigant or undertaking or monitoring the fumigation.

[106]5.2.10 Equipment to capture or recycle fumigant emissions

[107]The use of equipment that can capture the fumigant gas for recycling, reuse or safe disposal is encouraged for safety and environmental reasons. Release of fumigant gas (e.g. methyl bromide) to the atmosphere should be minimised where it is possible to do so.

[108]6. Fumigation Procedures

[109]Many factors may affect fumigation efficacy. Fumigant concentration, exposure time, commodity temperature and atmospheric temperature are crucial factors. Gas tightness of the enclosure, commodity load pattern and load factor directly influence gas distribution and gas concentration during fumigation. The fumigant supply and circulation equipment should be arranged within the fumigation enclosure in a way that ensures that the fumigant concentrations required by the treatment schedule are achieved and maintained within the enclosure during fumigation. Some commodities, such as oil, fats or porous or finely ground materials, may absorb a large quantity of fumigant and lead to a reduction in gas concentration. Packaging materials should be of a composition and construction that does not preclude fumigant gas penetration to the commodity and prevent fumigant concentrations achieving required levels. In summary, it is essential that the fumigation enclosure and equipment are well prepared prior to fumigation in order to achieve the required efficacy.

[110]6.1 Commodity loading

[111]Before fumigation, the commodity should be loaded into the fumigation enclosure in a manner that ensures sufficient space for adequate circulation of the fumigant. To ensure fumigant penetration into the commodity, separators such as pieces of wood should be used. As a guide, and depending on the fumigant used, for container fumigations there should be 200 mm free air space above the commodity, 50 mm below, and 100 mm at the sides and between the commodities.

[112]6.2 Fumigant impenetrable packaging

[113]Fumigant-impenetrable packing material or coatings should be removed or punctured to ensure adequate access for the fumigant. As a guide for most fumigants, otherwise impenetrable packaging can be rendered suitable for fumigation if it contains not less than four perforations of 6 mm diameter per 100 cm² (10 cm × 10 cm square) or not less than five perforations of 5 mm diameter per 100 cm². Plastic wraps containing numerous pinholes (at least six holes per cm²) may also be considered acceptable. Perforated packaging materials should not be overlapped, as holes may become blocked.

[114]6.3 Sorption

[115]Sorption is the process of chemically or physically binding free fumigant on or within the fumigated commodity, packaging or enclosure. Sorption makes the fumigant unavailable to kill the plant pest. The sorption rate is high at the start of the fumigation, then gradually reduces to a slow rate. Sorption increases the time required for aeration. Commodities or packaging known or believed to be highly sorptive should not be fumigated unless concentration readings can be taken to ensure that the required minimum concentration is achieved.

[116]6.4 Determination of fumigation temperature

[117]Temperature is a factor in achieving the efficacy of fumigation. In addition to other factors, the effectiveness of a fumigant depends on the respiration rate of the target organism. In general, the lower the temperature, the lower the respiration rate of the organism and the greater the dose of fumigant needed to achieve the required efficacy.

[118]The temperatures of the commodity and the atmosphere within the fumigation enclosure should be measured and recorded. The lowest temperature recorded in the enclosure or the commodity is deemed to be the temperature at which the fumigation is undertaken. Fumigation should not proceed if, before or during fumigation, the temperature within the enclosure or the commodity falls to within 3–5 °C of the fumigant boiling point at the atmospheric pressure used. Under such conditions, heating equipment should be used to ensure adequate fumigant activity. Appendix 2 provides boiling point temperatures for some common fumigants.

[119]The number of temperature sensors required to adequately measure the temperature throughout the enclosure will depend on the size and nature of the enclosure. The following table can be used as a guide for determining the number of sensors required under tent enclosures. Purpose-built and insulated fumigation chambers may require fewer sensors.

| [120]Size of enclosure (m ³) | [121]Number of sensors |
|--|------------------------|
| [122]Up to 300 | [123]3 |
| [124]301 to 700 | [125]6 |
| [126]701 to 1 500 | [127]9 |
| [128]Larger than 1 500 | [129]12 |

[130]6.5 Gas tightness test

[131]Prior to the fumigation (preferably immediately before), a gas tightness test should be performed. However, if the fumigation enclosure is of sufficiently resistant construction and in regular use, the testing may only be necessary at intervals of, for example, 6 or 12 months.

[132]6.6 Introduction of the fumigant gas

[133]The minimum ambient temperature that the fumigation enclosure or commodity (whichever is less) is expected to experience over the duration of the treatment should be used when determining the dosage.

[134]The total weight of fumigant to be applied is a product of the required dosage (dose rate) and the volume of the enclosure. Excess sorption or leakage from the fumigation enclosure should be taken into consideration. Correct measurement of the enclosure volume is therefore important.

[135]Once the enclosure volume has been determined, the weight of fumigant required should be calculated as follows:

$$[136]\text{Amount of fumigant (g)} = \frac{\text{Volume of enclosure (m}^3\text{)} \times \text{Target dosage (g/m}^3\text{)} \times 100}{\% \text{ Fumigant purity}}$$

[137]where the dosage should take into account fumigant loss over the duration of the treatment and the percentage fumigant release (or purity) is equal to the amount of fumigant generated from the chemical applied (e.g. aluminium phosphide generates around 33.3% of phosphine gas).

[138]The volume of the enclosure is the internal volume and should be calculated separately for each differently shaped compartment (see Appendix 3 for examples of shapes and formulae for calculations). The volume of containers (e.g. drums or boxes) within the enclosure that are airtight and non-absorbent to the fumigant can be subtracted from the enclosure volume.

[139]As the fumigant should be applied in a gaseous form, for some fumigants under cool conditions this can be achieved by applying the liquid fumigant through a vaporizer in order to fully volatilize the fumigant prior to its entry into the fumigation enclosure.

[140]For methyl bromide, the water in the vaporizer unit should be raised to 65 °C before any liquid methyl bromide is released into it. To ensure complete vaporization, the water should be maintained at this temperature for as long as possible throughout the gas introduction process and should not be allowed to fall below 65 °C.

[141]6.7 Monitoring and recording of the fumigation

[142]Fumigant concentration readings or recordings should be used to indicate if the amount of fumigant applied is correct and if any excessive leakage or sorption of the fumigant exists. The fumigation time begins once all the gas has been introduced and has distributed throughout the enclosure. Concentration readings should be taken a number of times during the treatment and in a number of locations in the fumigation enclosure to ensure that the fumigant is evenly distributed in the enclosure over the duration of the treatment. Fumigant concentration should be monitored and recorded either continuously or in sufficient frequency to provide confidence that the required dose has been achieved and maintained or to allow adequate calculations of CT to be made (if required).

[143]6.7.1 Measuring fumigant concentration

[144]The number of sampling lines required to adequately measure the fumigant concentration throughout the enclosure will depend on the size and nature of the enclosure. The following table can be used as a guide for determining the number of sampling lines required under tent enclosures. Purpose-built fumigation chambers may require fewer sampling lines.

| [145]Size of enclosure (m ³) | [146]Number of sampling lines |
|--|---|
| [147]Up to 15 000 | [148]6 sampling lines for the first 3 000 m ³ , plus one line for each additional 1 500 m ³ |
| [149]Larger than 15 000 | [150]14 sampling lines for the first 15 000 m ³ , plus one line for each additional 5 500 m ³ |

[151]Depending on the commodity and the fumigation schedule, further sampling lines may be required to be placed within the commodities within the enclosure. As a guide, a minimum of three sampling lines should be used for the first 300 m³ of commodity, with additional lines for commodities that are tightly packed or difficult to penetrate.

[152]6.7.2 CT calculation

[153]The CT is best calculated by multiplying together two observed gas concentrations at each location, taken one after the other, then multiplying the square root of this number by the time interval (in hours) between the two readings. The CT values obtained from a contiguous series of readings may then be added together to calculate the cumulative CT for the whole exposure period for that location. The dose achieved at the location providing the lowest cumulative CT should be used as the achieved treatment dose.

[154]CT can be estimated using the following calculation:

$$[155]CT_{n,n+1} = (T_{n+1} - T_n) \times \sqrt{C_n \times C_{n+1}}$$

[156]where

[157] T_n is the time the first reading was taken, in hours

[158] T_{n+1} is the time the second reading was taken, in hours

[159] C_n is the concentration reading at T_n , in g/m^3

[160] C_{n+1} is the concentration reading at T_{n+1} , in g/m^3

[161] $CT_{n,n+1}$ is the calculated CT between T_n and T_{n+1} , in $\text{g}\cdot\text{h}/\text{m}^3$

[162] 6.8 Completion of the fumigation

[163] Once the treatment time has been completed and the concentration and temperature readings indicate that the required minimum readings have been achieved, the application of the fumigation should be considered as being in accordance with this standard and the treatment schedule.

[164] Indications of fumigation success can be obtained by inspection to verify target pest mortality. For many fumigations an extended post-fumigation period 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.

[165] 7. Phytosanitary System Security

[166] Well-designed and closely monitored systems for treatment delivery, and for safeguarding of treated commodities, provide an assurance that treatments are properly conducted.

[167] The NPPO of the country in which the treatment facility is located or where treatments are initiated should ensure that treatments are properly applied to meet the phytosanitary import requirements of the importing country and that commodities are protected from infestation and reinfestation.

[168] 7.1 Authorization of fumigation entities

[169] Fumigation entities should be authorized by the NPPO in the country in which the phytosanitary treatments are conducted (see 7.6). NPPOs should maintain a list of authorized fumigation entities capable of undertaking fumigation treatments. The NPPO of the exporting country is responsible for authorizing the entity applying the treatment during transport.

[170] 7.2 Prevention of infestation after treatment

[171] The fumigation entity should implement the necessary measures to prevent possible infestation or contamination of the commodity after fumigation. The following measures may be required:

- [172] keeping the commodity in a pest free enclosure
- [173] packing the commodity immediately after fumigation
- [174] segregating and identifying treated commodities
- [175] dispatching the commodity immediately after fumigation.

[176] Specific procedures appropriate for each fumigation entity and commodity treatment should be approved by the NPPO in the country in which the fumigation is conducted.

[177] 7.3 Environment, health and safety

[178] 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 domestic regulations are met and the safety of applicators and those living or working in proximity to the fumigation site are ensured. The fumigant used should be appropriate to the commodity being fumigated, and the equipment and enclosure appropriate to the circumstances.

[179] An assessment of health and safety risks associated with handling of fumigated consignments should be completed prior to unloading or inspecting fumigated commodities.

[180]7.4 Labelling

[181]Commodities may be labelled with treatment lot numbers or other features of identification (e.g. locations of packing and the fumigation site, dates of packing and treatment, identity of operator) allowing trace-back.

[182]7.5 Monitoring and auditing

[183]The NPPO of the country in which the fumigation is conducted is responsible for the monitoring and auditing of fumigation entities. Continuous supervision of fumigations should not be necessary, provided treatment programmes are properly designed and can be verified to ensure a high degree of system integrity for the fumigation entity, process and commodity in question. Oversight should be appropriate to detect and correct deficiencies promptly.

[184]7.6 Compliance agreement

[185]A compliance agreement should be in place between the fumigation entity and the NPPO of the country in which the fumigation is conducted. Such an agreement may include the following elements:

- [186]authorization of the fumigation entity by the NPPO of the country in which the fumigation is conducted
- [187]the monitoring programme to be administered by the NPPO of the country in which the fumigation is conducted
- [188]audit provisions
- [189]access for the NPPO of the country in which the fumigation is conducted to documentation and records of the fumigation entity
- [190]corrective action to be taken in cases of non-compliance.

[191]8. Documentation

[192]The NPPO of the country in which the fumigation is conducted is responsible for monitoring the record keeping and the documentation by the fumigation entities, and for ensuring that records are available to concerned parties.

[193]8.1 Documentation of procedures

[194]Procedures should be documented to ensure that commodities are fumigated in accordance with the fumigation schedule and this standard, as required. Process controls and operational parameters should be established, documenting the details necessary for a specific authorization of a fumigation entity. Calibration and quality control procedures should be documented by the entity. As a minimum, a written procedure should include the following:

- [195]commodity handling procedures before, during and after fumigation
- [196]orientation and configuration of the commodity during fumigation
- [197]critical process parameters and the means for their monitoring
- [198]records of temperature sensor calibrations and, where appropriate, calibration records for humidity sensors or moisture meters
- [199]contingency plans and corrective actions to be taken in the event of fumigation failure or problems with critical treatment processes
- [200]procedures for handling rejected lots
- [201]staff training
- [202]record keeping and documentation requirements.

[203]8.2 Record keeping

[204]Fumigation entities should keep records. These records should be available to the NPPO of the country in which the fumigation is conducted or initiated for auditing and verification purposes or trace-back.

[205]Appropriate records for fumigation as a phytosanitary measure should be kept by the fumigation entity for at least one year to enable the trace-back of treated lots. The fumigation entity should keep all records for every treatment. Information that should be recorded includes:

- [206]identification of enclosure and fumigation entity
- [207]enclosure leakage testing records (as appropriate)
- [208]equipment calibration records
- [209]commodity fumigated
- [210]target regulated pest
- [211]packer, grower and place of production of the commodity
- [212]fumigation lot number
- [213]lot size and volume, including number of articles or packages
- [214]identifying markings or characteristics
- [215]date of fumigation
- [216]any observed deviation from the treatment schedule
- [217]air and commodity temperature records
- [218]fumigant dose and concentration records
- [219]fumigant volumes (dose rate) calculated and added throughout fumigation.

[220]8.3 Documentation by the NPPO

[221]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 (*Guidelines for the notification of non-compliance and emergency action*).

[222]9. Inspection

[223]Inspection is carried out to determine compliance with phytosanitary import requirements. Where live non-target pests are found, the NPPO should consider if their survival would indicate a treatment failure.

[224]10. Authority

[225]The NPPO of the country in which the fumigation is conducted or initiated is responsible for the evaluation, approval and monitoring of the application of fumigation as phytosanitary measures, including those performed by authorized fumigation entities. However, when treatments are conducted or completed during transport, the NPPO of the importing country is responsible for verifying if the treatment requirement has been met.

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

[227]APPENDIX 1: Guidance for fumigation efficacy studies¹

[229]1. Research Materials

[230]It is recommended that samples of the different life stages of the pests studied are archived in order to, among other reasons, resolve possible future disputes on identification (voucher specimens). The commodity to be used for confirmation tests should be of normal commercial condition.

[231]To perform research into the control of regulated pests by fumigation, it is necessary to know the basic biology of the pests as well as to 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 or with laboratory-reared pests that are used to infest the commodity preferably in a natural manner. The method of rearing, feeding and refreshing of the pest colony should be carefully detailed.

[232]Note: Studies carried out with pests *in vitro* are not recommended unless preliminary testing indicates that results from *in vitro* treatments are no different than *in situ*.

[233]2. Instrument Recording

[234]Instrument recording systems used to record fumigation parameters, such as gas concentration and enclosure and commodity temperature, should be calibrated, certified and used according to the manufacturer's instructions. Routine calibration of all measuring instruments should be conducted periodically.

[235]3. Estimation and Confirmation of Optimal Gas Concentration and its Duration for Treatment

[236]3.1 Preliminary tests

[237]The following steps should be carried out to estimate the dose required to achieve an adequate efficacy:

- (1) [238]The treatment tolerance of the different life stages of the pest in question that may be present in the commodity should 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 treatment dose is established.
- (2) [239]The treatment tolerance of different shapes, size and varieties of the commodities should be addressed to determine if they may influence the treatment outcome.
- (3) [240]The optimal fumigant concentration and treatment duration at each temperature should be determined experimentally. If pertinent data do not already exist, it is recommended that at least five dose levels and a control are used for each pest life stage, temperature, and shape or size of commodity, with a minimum of 120 individuals where possible for each of the doses and a minimum of three replicates. The relationship between optimal fumigant concentration and its duration and response for each life stage and temperature should 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 should be conducted on the most fumigant-resistant life stage in the variety or commodity type where the target pest shows the highest resistance at each temperature.
- (4) [241]During the period of post-treatment observation of the commodities and associated pests, both treated and control commodities must remain under favourable conditions for survival of the pests. The untreated controls must respond normally 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%.

[1]

[228]¹ Based primarily on insect pest treatment research.

[242]3.2 Large-scale or extrapolation (confirmatory) tests

[243]To confirm whether the estimated optimal fumigant concentration and its duration at each temperature provides the adequate efficacy, two methods are recommended: (1) treat a large number of individuals of the most resistant life stage of the pest while achieving complete mortality; or (2) treat the most resistant stage over a range of levels of efficacy that may be less than adequate and estimate the adequate efficacy using a regression analysis. The number treated will depend on the required level of confidence.

- [244]Treating a large number of individuals (usually many thousands or tens of thousands), using one set of treatment parameters (commodity, concentration, duration, temperature) and with no (or nearly no) survivors is a direct method of severely testing the efficacy of the treatment, and calculations of efficacy are straightforward.
- [245]Establishing a treatment schedule via estimation using regression analysis should be accepted only if the data closely fit the model and the upper 95% confidence interval is used to establish the treatment parameters. This method is especially useful when it is too difficult or costly to test very large numbers of individuals and the treatment for achieving the required efficacy can be more severe than may be absolutely necessary.

[246]Because the most severe fumigant concentration and duration at each temperature measured during the confirmatory part of the research will be the fumigant concentration, temperature and duration required for the approved treatment, it is recommended that fluctuations in fumigant concentration and temperature during the large scale or extrapolation tests are kept as low as possible.

[247]4. Record Keeping

[248]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.

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

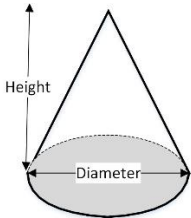
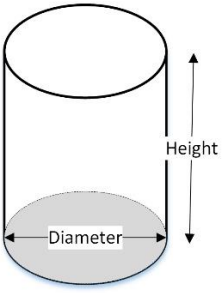
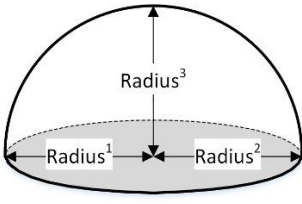
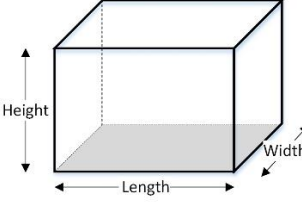
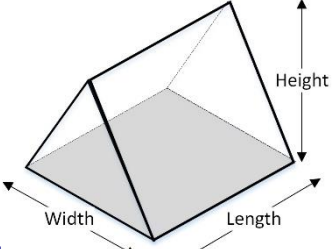
[250]APPENDIX 2: Chemical properties of some common fumigants

| [251]Fumigant name | [252]Formula | [253]Molecular weight [254](g/mol) | [255]Boiling point (°C) [256](@ 1atm) | [257]Specific gravity (gas) (air = 1.0) | [258]Flammability limits in air (v/v %) | [259]Solubility in water | [260]Conversion factor [261](mg/litre to ppm, v/v @ 1 atm) |
|-----------------------------|---|---------------------------------------|--|--|---|--------------------------|---|
| [262]Carbonyl sulphide | [263]COS | [264]60 | [265]-50.2 | [266]2.07 | [267]12-29 | [268]0.125 g/100 ml | [269]247 |
| [270]Ethane dinitrile (EDN) | [271]C ₂ N ₂ | [272]52 | [273]-21.2 | [274]1.82 | [275]6-32 | [276]Highly soluble | [277]480 |
| [278]Ethyl formate | [279]CH ₃ .CH ₂ .COOH | [280]74.08 | [281]54.5 | [282]2.55 | [283]2.7-13.5 | [284]11.8 g/100 ml | [285]330 |
| [286]Hydrogen cyanide | [287]HCN | [288]27 | [289]26 | [290]0.9 | [291]5.6-40 | [292]Miscible | [293]659 |
| [294]Methyl bromide | [295]CH ₃ Br | [296]95 | [297]3.6 | [298]3.3 | [299]10-15 | [300]3.4 [301]v/v % | [302]260 |
| [303]Methyl iodide | [304]CH ₃ I | [305]141.94 | [306]42.6 | [307]4.89 | [308]non | [309]1.4 g/100 ml | [310]580 |
| [311]Methyl isothiocyanate | [312]C ₂ H ₃ NS | [313]73.12 | [314]119 | [315]2.53 | [316]non | [317]0.82 g/100 ml | [318]300 |

| | | | | | | | |
|-------------------------|-------------------------------------|-------------|------------|-----------|-----------|-------------------------|----------|
| [319]Phosphine | [320]PH ₃ | [321]34 | [322]-87.7 | [323]1.2 | [324]>1.7 | [325]0.26 [326]v/v % | [327]730 |
| [328]Sulphur dioxide | [329]SO ₂ | [330]64.066 | [331]-10 | [332]2.26 | [333]non | [334]9.4 g/100 ml | [335]266 |
| [336]Sulphuryl fluoride | [337]SO ₂ F ₂ | [338]102 | [339]-55.2 | [340]3.72 | [341]non | [342]Slight | [343]245 |

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

[345]APPENDIX 3: Formulae for calculating volume of geometrical shapes

| [346]Type of geometrical shape | [347]Geometrical structure | [348]Formula for calculating volume |
|--------------------------------|--|---|
| [349]Cone |  <p>[350]</p> | [351] $Volume = \frac{\pi \times Radius^2 \times Height}{3}$ |
| [352]Cylinder |  <p>[353]</p> | [354] $Volume = \pi \times Radius^2 \times Height$ |
| [355]Dome [†] |  <p>[356]</p> | <p>[357]$Volume =$</p> <p>[358]$\frac{2 \times \pi \times Radius^1 \times Radius^2 \times Radius^3}{3}$</p> |
| [359]Rectangular prism |  <p>[360]</p> | [361] $Volume = Length \times Width \times Height$ |
| [362]Triangular prism |  <p>[363]</p> | [364] $Volume = \frac{Length \times Width \times Height}{2}$ |

[365][†] The formula used provides an approximate volume only.

[366]Potential implementation issues

[367]This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.