# [1]DRAFT ISPM: REQUIREMENTS FOR THE USE OF MODIFIED ATMOSPHERE TREATMENTS AS PHYTOSANITARY MEASURES (2014-006)

# [2]Status box

[3]This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
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[22]Steward history	[23]2019-05 SC Mr Alvaro SEPULVEDA LUQUE (CL, Steward) [24]2017-11 SC Mr Nico HORN (NL, Steward) [25]2016-11 SC Mr Scott MYERS (US, Assistant Steward) [26]2016-11 SC Ms Marina ZLOTINA (US, Steward) [27]2014-05 SC Mr Scott MYERS (US, Steward)
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# [33] CONTENTS [to be inserted later]

# [34]Adoption

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

#### [36]INTRODUCTION

#### [37]**Scope**

[38] This standard provides technical guidance for national plant protection organizations (NPPOs) on the application of modified atmosphere treatments as phytosanitary measures, including authorization, monitoring and auditing of treatment providers.

[39]This standard does not provide details on specific modified atmosphere treatments, such as specific schedules for specific regulated pests on specific commodities, and does not include use of modified atmosphere for non-phytosanitary purposes, such as minimizing the perishability of foodstuffs or other quality related uses of modified atmosphere.

#### [40]References

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

#### [42] Definitions

[43]Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

# [44]Outline of Requirements

[45]This standard provides guidance on modified atmosphere treatments and their application as phytosanitary measures. It identifies parameters to be considered when applying modified atmosphere treatments. Operational requirements for treatment application, including enclosures, treatment procedures and treatment systems, are described.

[46]Guidance is provided to NPPOs on authorizing, monitoring and auditing treatment providers. The roles and responsibilities of NPPOs and treatment providers are described.

#### [47]BACKGROUND

[48] This standard provides generic requirements for the application of modified atmosphere treatments as phytosanitary measures, specifically those adopted under ISPM 28 (*Phytosanitary treatments for regulated pests*). The purpose of this standard is to enhance harmonization of such measures within and between different countries in different countries.

[49]Modified atmosphere treatments involve altering gas concentrations in ambient air, which is achieved by increasing the carbon dioxide  $(CO_2)$  content (hypercarbia) or reducing the oxygen  $(O_2)$  content (hypoxia or anoxia) of the treatment environment, or both, to create an atmosphere lethal to target pests. Controlled atmosphere treatment is a type of modified atmosphere treatment and is covered by this standard.

[50]Modified atmosphere treatments are frequently used in conjunction with modification of other parameters, such as temperature and humidity.

## [51] IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[52]Modified atmosphere treatments may be used to prevent the introduction and spread of regulated pests and hence may be beneficial to biodiversity. The use of modified atmosphere treatments as an alternative to methyl bromide fumigation provides an additional benefit to the environment by reducing methyl bromide emissions, which deplete ozone. While an atmosphere with a high  $CO_2$  or a low  $O_2$  concentration may be harmful, in this application there are negligible environmental impacts.

#### [53] REQUIREMENTS

# [54]1. Treatment Objective

[55] The objective of using a modified atmosphere treatment as a phytosanitary measure is to achieve pest mortality at a specified efficacy.

#### [56]2. Treatment Application

[57]Modified atmosphere treatments are undertaken by treatment providers or the NPPO in a treatment facility. Modified atmosphere treatments may be applied before export, during transport, or at the point of entry under suitable conditions of confinement.

[58] The gas concentrations may be modified in the following ways:

- [59]changing the proportion of O<sub>2</sub> and CO<sub>2</sub> in the atmosphere by adding a gas (such as CO<sub>2</sub> or nitrogen) and maintaining this atmosphere
- [60] converting  $O_2$  to  $CO_2$  by combustion of a hydrocarbon
- [61]holding the commodity in hermetic or semi-hermetic storage, in which the respiration of the commodity and pests infesting it depletes the level of  $O_2$  and increases the level of  $CO_2$
- [62]creating a partial vacuum, which lowers concentrations of all atmospheric gases proportionally.

# [63]2.1Treatment parameters

[64]Parameters to consider when implementing modified atmosphere treatments include:

- [65]atmospheric gas concentrations
- [66]duration of the treatment
- [67]temperature (of the air and the commodity)
- [68]humidity.

[69]Modified atmosphere treatments are conducted in an enclosure. The lethal condition of the atmosphere should be achieved and maintained throughout the enclosure for a specified length of time as required by the treatment schedule.

[70]Respiration, sorption of atmospheric gases and the packaging of the commodity may result in differential gas concentrations within the enclosure and influence the efficacy of a modified atmosphere treatment. This should be taken into account when applying treatments.

[71]When the gas concentrations are not maintained at the required level for the specified duration, the treatment may not have been effective and should be restarted.

[72]Temperature and humidity are factors in achieving the required efficacy of modified atmosphere treatments, in particular because they affect the respiration rate of the target pest, and should be maintained according to the treatment schedule.

# [73]3. Enclosures Used for Modified Atmosphere Treatments

[74]The enclosure used for modified atmosphere treatments may consist either of packaging or of a portable or fixed structure that is designed either as a continuous gas flow system or a static system.

[75] The ability to maintain the specified gas concentrations for the duration of the treatment is influenced by the permeability of the material and the surface-to-volume ratio of the enclosure, and the effectiveness of seals at structural conjunctions or joins and openings of the enclosure.

[76]Enclosures (e.g. vacuum chambers, freight containers, warehouses, cargo ship holds) should be designed and constructed to maintain the parameters of the treatment. Features of specifically designed and constructed enclosures, both fixed and portable, include:

- [77]gas-tight doors or gas-tight valves
- [78]pressure control
- [79]temperature control
- [80]gas concentration control
- [81]humidity control
- [82] systems to alert operators when there is a treatment failure
- [83]recirculation of atmospheric gases within the enclosure
- [84]exhaust systems.

[85]Modified atmosphere treatments that rely on the introduction of inert gases to reduce  $O_2$  levels and hence achieve anoxic conditions may use non-gas-tight enclosures or use enclosures that are not specifically designed for modified atmosphere treatments. When using enclosures that are not specifically designed for modified atmosphere treatment use, particular attention should be paid to the pressure required to maintain the treatment parameters as specified in the treatment schedule.

## [86]4. Measuring Treatment Parameters

[87]Parameters specified in the treatment schedule should be measured and recorded at appropriate intervals to ensure that the required treatment parameters have been achieved and maintained throughout the treatment period to manage the risk of target pests in regulated articles. The crucial parameters for modified atmosphere treatments are typically  $O_2$  and  $CO_2$  concentrations, temperature and duration of exposure of the commodity.

[88]In some cases, humidity is considered an important treatment parameter and should then also be measured and recorded during the treatment period.

[89]Pressure does not affect the efficacy of the treatment but may be important to ensure that the required treatment conditions are achieved, either when negative pressure is used to remove  $O_2$  or when positive pressure is used to flush the enclosure of  $O_2$ . If pressure is important to achieve the required treatment conditions, it should also be measured and recorded.

[90]All equipment used for measuring and recording treatment parameters should be calibrated according to the manufacturer's instructions and, where applicable, NPPO specifications.

#### [91]4.1Measuring gas concentrations

[92] The equipment used to measure gas concentrations should have an adequate accuracy (e.g.  $\pm 5\%$  of the gas concentrations to be achieved throughout the treatment).

# [93]4.2Measuring and mapping temperature

[94]Temperature mapping of the enclosure should be performed to identify temperature variation under normal operating conditions (e.g. loads and packaging) to determine the best locations for placing temperature sensors.

[95]The temperature of the commodity and the atmosphere within the enclosure should be measured to ensure that the required temperature is achieved.

## [96]5. Adequate Systems for Treatment Facilities

[97]Confidence in the adequacy of a modified atmosphere treatment as a phytosanitary measure is primarily based on assurance that the treatment is effective against the target pest under specific conditions and that the treatment has been properly applied. Systems for such a treatment should be

designed, used and monitored to ensure that treatments are properly conducted and commodities are protected from infestation and contamination after treatment.

[98] The NPPO of the country in which the treatment is conducted or initiated (the latter when treatment takes place during transport) is responsible for ensuring that the system requirements are met.

# [99]5.1Authorization of treatment providers

[100]Treatment providers should be authorized by the NPPO in the country in which the treatment is conducted or initiated. This authorization normally includes approval of both treatment facilities and treatment providers. The NPPO should set requirements for treatment provider authorization, including training of personnel, treatment procedures, adequate equipment and storage conditions. Specific procedures appropriate for each facility, provider and commodity treatment should also be approved by the NPPO.

[101]NPPOs should maintain a list of authorized treatment providers for modified atmosphere treatment, including, where appropriate, approved facilities.

# [102]5.2 Monitoring and auditing

[103] The NPPO of the country in which the treatment is conducted or initiated is responsible for monitoring and auditing the treatment, facilities and providers. Continuous supervision of treatments should not be necessary, provided treatment procedures are properly designed and can be verified to ensure a high degree of system integrity for the facility, process and commodity in question. The monitoring and auditing should be sufficient to detect and correct deficiencies promptly.

[104]Treatment providers should meet monitoring and auditing requirements set by the NPPO. These requirements may include:

- [105] access for the NPPO for audit, including either prearranged or unannounced visits or both
- [106]a system to maintain and archive treatment records and provide NPPOs, or where appropriate other government agencies, with access to these
- [107]corrective action to be taken in the event of nonconformity.

#### [108] 5.3 Prevention of infestation and contamination after treatment

[109]The consignment owner is responsible for prevention of infestation and contamination after treatment and may cooperate with the treatment provider on how to achieve this. After the treatment is successfully completed, measures should be implemented to prevent possible infestation or contamination of the treated commodity. The following measures may be required:

- [110]keeping the commodity in a pest free enclosure
- [111]packing the commodity immediately in pest-proof packaging
- [112]segregating and identifying treated commodities
- [113] dispatching the commodity as soon as possible.

# [114]5.4 Labelling

[115]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 for non-compliant consignments. When used, labels should be easily identifiable and placed on visible locations.

#### [116]6. Documentation

[117]The NPPO of the country in which the treatment is conducted or initiated is responsible for ensuring that treatment providers maintain documents of procedures and keep appropriate records, such as raw data on gas concentrations and temperature recorded during treatments. Accurate record keeping is essential to allow for trace-back capability.

#### [118]**6.1** Documentation of procedures

[119]Procedures should be documented to ensure that commodities are treated consistently in accordance with the treatment schedule. Process controls and operational parameters should be established to provide the operational details necessary for the authorization of a treatment provider. Calibration and quality control procedures should be documented by the treatment provider. The documented procedures should include the following:

- [120]commodity handling before, during and after treatment
- [121]orientation and configuration of the commodity during treatment
- [122]treatment parameters and the means for measuring and recording them
- [123]temperature and gas sensor calibration
- [124]contingency plans and corrective actions to be taken in the event of treatment failure or problems with treatment parameters
- [125]handling of rejected lots
- [126] labelling (if required), record keeping and documentation requirements
- [127]training of personnel.

# [128]6.2 Record keeping

[129]Treatment providers should keep records for each treatment application. These records should be made available to the NPPO of the country in which the treatment is conducted or initiated for auditing and verification purposes or when a trace-back is necessary.

[130]Appropriate records for modified atmosphere treatments as phytosanitary measures should be kept by the treatment provider for at least one year to enable the trace-back of treated lots. Records on individual treatments may include data on:

- [131]identification of facility and treatment provider
- [132]treatment schedule applied
- [133]commodity treated
- [134]target regulated pest
- [135]packer, grower, exporter and place of production of the commodity
- [136]lot size and volume, including number of articles or packages
- [137]treatment number or other identifying markings or characteristics of the lot
- [138]date and duration of treatment and name of individual performing the treatment
- [139]gas concentration or concentrations, temperature of commodity and (if required) other atmospheric parameters such as humidity and pressure
- [140]any observed deviation from the treatment schedule and, where appropriate, subsequent actions taken.

# [141]6.3 Documentation by the NPPO

[142]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 upon request as described in ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*).

# [143]7. Inspection

[144]Inspection should be carried out by the NPPO of the exporting country, and may be carried out by the NPPO of the importing country, to determine compliance with phytosanitary import requirements. Where live non-target pests are found after treatment, by either the NPPO of the exporting country or

the NPPO of the importing country, this NPPO should consider if their survival indicates a treatment failure and whether additional phytosanitary measures may be necessary.

[145] The NPPO of the importing country may check documentation and records for treatments conducted during transport to determine compliance with phytosanitary import requirements.

## [146]8. Responsibilities

[147]The NPPO of the country in which the treatment is conducted or initiated is responsible for the evaluation, approval and auditing of the application of modified atmosphere treatments as phytosanitary measures, including those performed by the NPPO itself or by other authorized treatment providers. When treatments are conducted or completed during transport, the NPPO of the exporting country is usually responsible for authorizing the treatment provider applying the treatment during transport, and the NPPO of the importing country is responsible for verifying if the treatment requirements have been met.

[148]To the extent necessary, the NPPO should cooperate with other national and international regulatory agencies concerned with the development, approval and safety of the modified atmosphere treatment, including the training and certification of personnel conducting the treatment, the authorization of treatment providers, and the approval of modified atmosphere facilities. The respective responsibilities of the NPPO and the other regulatory agencies, if any, should be identified to avoid requirements that are overlapping, conflicting, inconsistent or unjustified.

#### [149]Potential implementation issues

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