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[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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[19]Steward history	[20]2017-11 SC Mr Nico HORN (NL, Steward) [21]2016-11 SC MsMarina ZLOTINA (US, Steward) [22]2016-11 SC Mr Scott MYERS (US, Assistant Steward) [23]2014-05 SC Mr Scott MYERS (US, Steward)
[24]Notes	[25]This is a draft document [26]2018-02 Edited [27]2018-05 Edited

[28]

[29]CONTENTS [to be inserted later]

[30]Adoption

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

[32]INTRODUCTION

[33]Scope

[34]This standard provides technical guidance for national plant protection organizations (NPPOs) on the application of modified atmosphere treatments as phytosanitary measures. The purpose of this standard is to enhance harmonization of such measures in different countries. This standard specifically does not include use of modified atmospheres for other purposes, such as minimizing the perishability of foodstuffs or other quality related uses of modified atmospheres. This standard does not provide details on specific modified atmosphere treatments.

[35]References

[36]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>.

[37]Heather, N.W. & Hallman, G.J. 2008. Disinfestation with modified (controlled) atmosphere storage, In: N.W. Heather & G.J. Hallman. *Pest management and phytosanitary trade barriers*, pp. 171–185. Wallingford, UK, CABI. 272 pp.

[38]Definitions

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

[40]Outline of Requirements

[41]NPPOs should ensure that the application of modified atmosphere treatment is carried out effectively so that critical parameters are met at the required level to achieve the stated efficacy.

[42]The main requirements for enclosures used for the treatments, application of modified atmosphere treatment, measuring of treatment parameters, and treatment procedures should be followed. Treatment facilities should implement systems which includes preventing the contamination of the treated commodity. Record keeping and documentation requirements should be followed to enable auditing, verification or trace back.

[43]The roles and responsibilities of parties involved in the modified atmosphere treatments are described. Guidance is provided to NPPOs on authorizing, monitoring and auditing entities involved in modified atmosphere treatments.

[44]BACKGROUND

[45]The purpose of this standard is to provide generic requirements for the application of modified atmosphere phytosanitary treatments, specifically those adopted under ISPM 28 (*Phytosanitary treatments for regulated pests*).

[46]Modified atmosphere phytosanitary treatments involve altering ambient atmospheric gas concentrations without the introduction of a toxic agent. They are typically based on achieving an increase in the carbon dioxide content (hypercarbia) or reducing the oxygen content (hypoxia or anoxia) of the treatment environment, or both, to create an atmosphere lethal to target pests.

[47]The term “modified atmosphere” is often used interchangeably with the term “controlled atmosphere”. However, a controlled atmosphere is a modified atmosphere in which the atmospheric components are actively maintained within prescribed parameters.

[48]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[49]Modified atmospheres may be used to prevent the introduction and spread of target pests into a regulated area and hence may be beneficial to biodiversity and the environment. The use of modified atmosphere treatments as a replacement for methyl bromide fumigation provides an additional benefit to the environment by reducing methyl bromide emissions. While high CO₂ or low O₂ atmospheres may be harmful, in this application they have negligible impacts on biodiversity and the environment.

[50]REQUIREMENTS

[51]1. Treatment Objective

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

[53]2. Treatment Application

[54]Modified atmosphere treatments for phytosanitary use may be applied before export, or during transport, or at the point of entry under suitable conditions of confinement.

[55]Parameters to consider when implementing treatments include:

- [56]atmospheric gas concentrations, as influenced by the conditions of the enclosure and the commodity being treated (i.e. load factor, leakage, sorption, respiration)
- [57]air and commodity temperature
- [58]humidity
- [59]pressure under which the treatment is applied.

[60]In a modified atmosphere treatment, the lethal atmosphere should be maintained for an adequate length of time, typically for more than a day. An enclosure is therefore required to achieve and maintain the lethal atmospheric conditions over the duration of the treatment. Enclosures can be designed as a continuous gas flow system or a static system.

[61]Maintenance of the atmosphere at the required gas composition levels depends on being able to compensate for the gas loss from the enclosure. This is influenced by the permeability of the structural fabric and the effectiveness of seals at joins and entry points, where surface to volume ratio has a major influence.

[62]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.

[63]Temperature is a factor in achieving the required efficacy of modified atmosphere treatments, in particular because it affects 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 duration of exposure needed to achieve the required efficacy.

[64]2.1 Methods for modifying atmospheres

[65]Treatment atmospheres may be modified in the following ways:

- [66]changing the proportion of O₂ and CO₂ in the atmosphere by adding CO₂ or an inert gas (such as nitrogen) and maintaining this atmosphere
- [67]converting O₂ to CO₂ by combustion of a hydrocarbon
- [68]hermetic or semi-hermetic storage in which the respiration of the commodity and organisms infesting it deplete the level of O₂ and increase the level of CO₂
- [69]partial vacuum, which lowers concentrations of all atmospheric gases proportionally.

[70]3. Enclosures Used for Modified Atmosphere Treatments

[71]The enclosure may consist of modified atmosphere packaging, or a portable or fixed structure.

[72]Enclosures that are fixed structures (e.g. vacuum chambers, freight containers, warehouses, cargo ship holds) are specifically designed and constructed to maintain the parameters of the treatment. Features of specifically designed and constructed enclosures include:

- [73]gas tight doors

- [74]pressure control
- [75]temperature control
- [76]gas concentration control
- [77]systems to alert operators when there is a treatment failure
- [78]recirculation of atmospheric gases within the enclosure
- [79]exhaust systems.

[80]Modified atmosphere treatments that rely on positive pressure of inert gases to achieve anoxic conditions may use non-gas-tight chambers or use enclosures that were not specifically designed for modified atmosphere treatments. Particular attention to pressure should be made when using enclosures that were not specifically designed for modified atmosphere treatment use.

[81]**4. Measuring Treatment Parameters**

[82]Critical parameters of the treatment should be measured at regular intervals to ensure that it is conducted properly to mitigate the risk of target pests in regulated articles. The crucial parameters for modified atmospheres are typically O₂ and CO₂ concentrations, temperature and duration of exposure.

[83]**4.1 Measuring gas concentration**

[84]Atmospheric gas concentrations should be measured at regular intervals during modified atmosphere treatments. Treatment providers (e.g. companies or individuals) should verify, before each treatment, that sensors used to measure gases are calibrated according to the manufacturer's instructions.

[85]**4.2 Measuring and mapping temperature**

[86]Treatment providers should verify that sensors used to measure temperature are calibrated according to the manufacturer's instructions.

[87]Temperature mapping of the enclosure should be performed to identify temperature variation under commercial operating conditions.

[88]Temperature mapping should be conducted according to appropriate procedures using loads and packaging equivalent to that used in commercial application. Temperature variation in the enclosure can be used to determine the best locations for placing the temperature sensors.

[89]The temperature of the commodity and the atmosphere within the enclosure should be measured at regular intervals to ensure that the required treatment parameters are achieved throughout the enclosure.

[90]**5. Adequate Systems for Treatment Facilities**

[91]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 pest of concern under specific conditions and the treatment has been properly applied. Systems for treatment delivery should be designed, used and monitored to ensure that treatments are properly conducted and commodities are protected from infestation and contamination after treatment.

[92]The NPPO of the country in which the treatment facility is located or where treatments are initiated is responsible for ensuring that the system requirements are met.

[93]**5.1 Authorization of entities**

[94]In this standard, "entities" include both treatment providers and treatment facilities. Modified atmosphere treatments are applied by treatment providers in treatment facilities.

[95]Treatment entities 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. Specific procedures appropriate for each facility, provider and commodity treatment should be approved by the NPPO.

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

[97]**5.2 Prevention of infestation and contamination after treatment**

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

- [99]keeping the commodity in a pest free enclosure
- [100]packing the commodity immediately after treatment
- [101]segregating and identifying treated commodities
- [102]dispatching the commodity immediately after treatment.

[103]**5.3 Labelling**

[104]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. The labels should be easily identifiable and placed on visible locations.

[105]**5.6 Monitoring and auditing**

[106]The NPPO of the country in which the treatment is conducted is responsible for monitoring and auditing the facilities and providers. Continuous supervision of treatments should not be necessary provided there is a system for continuous monitoring of the treatment parameters, and treatment programmes are properly designed 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.

[107]Parameters to consider when verifying treatment programmes include meeting requirements for treatment atmospheric conditions, treatment time, temperature, humidity and ventilation. A modified atmosphere treatment protocol should include the following to ensure that the treatment schedule is met:

- [108]a treatment monitoring protocol that is conducted by the NPPO at the facility where the treatment occurs
- [109]audit provisions, including unannounced visits
- [110]a system to maintain and archive treatment records and provide access to NPPOs
- [111]corrective action to be taken in the event of non-compliance.

[112]**6. Documentation**

[113]The NPPO of the country in which the facility is located is responsible for ensuring that treatment providers keep appropriate records, such as raw data on treatment parameters recorded during treatments. Accurate record keeping is essential to allow for trace-back capability.

[114]**6.1 Documentation of procedures**

[115]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 a specific approval of a treatment facility.

Calibration and quality control programmes should be documented by the treatment provider. As a minimum, they should address the following:

- [116]commodity handling procedures before, during and after treatment
- [117]orientation and configuration of the commodity during treatment
- [118]critical treatment process parameters and the means for their monitoring
- [119]contingency plans and corrective actions to be taken in the event of treatment failure or problems with critical treatment processes
- [120]procedures for handling rejected lots and treatment failures
- [121]temperature and gas sensor calibration and recordings
- [122]labelling (if required), recordkeeping, and documentation requirements
- [123]training of personnel.

[124]6.2 Record keeping

[125]Treatment providers should keep records for each treatment application. These records should be made available to the NPPO of the importing or the exporting country when, for example, a trace-back is necessary.

[126]Appropriate records for modified atmosphere treatments as phytosanitary measures should be retained by the treatment provider for at least one year to enable the trace-back of treated lots. Information that may be required to be recorded includes:

- [127]identification of facility and responsible parties
- [128]identity of commodities treated
- [129]target pest
- [130]packer, grower and identification of the place of production of the commodity
- [131]lot size, volume and identification, including number of articles or packages
- [132]identifying markings or characteristics
- [133]date of treatment
- [134]any observed deviation from the treatment specification.

[135]6.3 Documentation by the NPPO

[136]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*).

[137]7. Inspection

[138]Inspection is carried out to determine compliance with phytosanitary import requirements. Where live non-target pests are found after treatment, the NPPO should consider if their survival indicates a treatment failure and whether additional phytosanitary measures may be necessary.

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

[140]8. Responsibilities

[141]The NPPO of the country in which the treatment is initiated or conducted is responsible for the evaluation, approval and auditing of modified atmosphere treatments as phytosanitary measures, including those performed by other authorized entities. However, when treatments are conducted or completed during transport, the NPPO of the exporting country is usually responsible for authorizing

the entity applying the treatment during transport, and the NPPO of the importing country is responsible for verifying if the treatment requirements have been met. To the extent necessary, it is the NPPO's responsibility to 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 operators, and the approval of modified atmosphere facilities. Their respective responsibilities should be identified to avoid requirements that are overlapping, conflicting, inconsistent or not technically justified.

[142]Potential implementation issues

[143]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.