

[1]**Draft ISPM: Requirements for the use of temperature treatments as phytosanitary measures (2014-005)**

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[22]**CONTENTS [to be inserted later]**

[23]**Adoption**

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

[25]**INTRODUCTION**

[26]**Scope**

[27]This standard provides harmonized technical guidance on the application of temperature treatments as phytosanitary measures for regulated pests or regulated articles. Target temperature, duration of treatment, commodity tolerance, equipment required, verification and other essential aspects of the application of temperature treatments are covered in ISPM 28 (*Phytosanitary treatments for regulated pests*).

[28]Some temperature treatments are recognized but are not addressed in this standard. These include treatments using steam, quick freezing and Joule (ohmic) heating.

[29]**References**

[30]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>.

[31]**Definitions**

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

### **[33]Outline of Requirements**

[34]Treatment schedules based on temperature treatments may be used for pest risk management. National plant protection organizations (NPPOs) should be satisfied that the efficacy of a treatment has been demonstrated according to ISPM 28 for the regulated pest of concern and the required result.

[35]The application of a temperature treatment requires calibration of temperature monitoring and recording systems and temperature mapping of the chamber to ensure that the specific chamber–commodity configuration will enable the treatment to be effective.

[36]Phytosanitary treatments based on temperature are considered effective when a specific temperature–time combination prescribed for the stated level of efficacy to be achieved is attained throughout the consignment being treated.

[37]The NPPO is responsible for ensuring that ships' holds, containers or other facilities are appropriate for phytosanitary treatments based on temperature. Procedures should be in place to ensure that the treatment can be conducted properly and commodity lots are handled, stored and identified in a manner that maintains the phytosanitary security of the consignment. Records should be kept and should include a compliance agreement between the operator of the facility where the treatment is conducted and the NPPO, stipulating in particular the specific requirements for phytosanitary measures.

### **[38]BACKGROUND**

[39]ISPM 28 was adopted to harmonize efficient phytosanitary treatments in a wide range of circumstances and to enhance the mutual recognition of treatment efficacy by NPPOs, which may facilitate trade.

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

### **[41]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT**

[42]The use of temperature treatments as phytosanitary measures has no direct impact on biodiversity and the environment. The application of temperature treatments may be an alternative to other treatments that may impact the environment negatively (e.g. fumigation with methyl bromide). Temperature treatments do not directly use chemicals in their application, although energy and chemicals may be used to generate heat or cold.

### **[43]REQUIREMENTS**

#### **[44]1. Treatment Objective**

[45]The objective of using a temperature treatment as a phytosanitary measure is to achieve pest mortality at a specified level.

#### **[46]2. Treatment Application**

[47]Temperature treatments may be applied:

- [48]as an integral part of packing operations
- [49]at centralized locations such as the port of embarkation
- [50]during transport, including completion of the treatment on arrival.

[51]The minimum requirement of a temperature treatment is that the scheduled target temperature is attained throughout the commodity for the scheduled treatment duration, allowing the prescribed level of efficacy to be achieved.

[52]Variables to consider when implementing a temperature treatment are the 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 may alter treatment efficacy.

[53]The treatment schedule should describe the process of pre- and post-conditioning to reach the target temperature, 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.

### [54]3. Treatment Types

#### [55]3.1 Cold treatment

[56]Cold treatment uses refrigerated air to lower the temperature of the commodity to or below the specific temperature for a specific period of time. Cold treatment is used primarily for commodities that are hosts of internally feeding pests.

[57]Cold treatment is the only temperature treatment that can be applied during transport. Treatment may be started before transport of the shipment and completed on its arrival. Where effective, mixed consignments may also be treated pre-shipment or during transport. In all cases, the phytosanitary security of the consignment should be maintained throughout treatment and transport.

#### [58]3.2 Heat treatment

[59]Heat treatment raises the temperature of the commodity to or higher than the required temperature for a specific period of time. Heat treatment is usually much faster than cold treatment, typically being efficacious within a few hours.

[60]Following the completion of a heat treatment, rapid cooling to preserve commodity quality should be carried out only if this has been shown not to reduce the treatment efficacy.

##### [61]3.2.1 Hot water immersion treatment

[62]Hot water immersion treatment (also known as hydrothermal treatment) uses heated water at a prescribed temperature to heat the surface of the commodity for a specific period of time or to raise the entire commodity to the required temperature for a specific period of time. This treatment is used primarily for certain fruits that are hosts of fruit flies, but may also be used for nursery stock to control a variety of pests (e.g. nematodes in general and *Merodon equestris* (Diptera: Syrphidae)), and more generally may be used for surface pests such as mites and thrips.

[63]Application of this treatment requires a simple infrastructure.

##### [64]3.2.2 Vapour heat treatment

[65]Vapour heat treatment uses vapour-saturated air to heat the commodity for a specific period of time. Because of the high heat energy of hot moist air, vapour heat is capable of raising the commodity temperature faster than dry air can. As vapour heat can readily penetrate to the interior of the commodity being treated, it can be applied to plant products of any shape or size.

[66]This treatment is suitable for those plant products that are resistant to high moisture but are vulnerable to drying out, such as fruits, vegetables, flower bulbs, bamboo products and wood materials.

[67]Variable humidity heat treatment (e.g. high temperature forced air treatment) is a type of vapour heat treatment. Hot and relatively dry fan-driven air is used initially, avoiding condensation, to heat the entire commodity from ambient temperature to the target temperature, which is then held in humid air, just below dew point, for a specific period of time. The advantage that high temperature forced air treatment has over vapour heat treatment or hot water immersion treatment is that hot saturated air or hot water may be more likely to damage the commodity through their more rapid heating and wetting of it, respectively.

### [68]3.2.3 Dry heat treatment

[69]Dry heat treatment uses heated air at a prescribed temperature to heat the surface of the commodity for a specific period of time or raise the entire commodity to the required temperature for a specific period of time. This treatment is used primarily for seeds, grain, cereals and wood commodities.

### [70]3.2.4 Dielectric heat treatment

[71]Dielectric heating raises the temperature of the commodity by subjecting it to high frequency electromagnetic waves that cause heating by molecular dipole rotation of polar molecules, especially water. Dielectric heating may be provided by the application of electromagnetic radiation over a range of frequencies, including microwaves and radio waves.

[72]Unlike traditional heating techniques, where heat moves from the surface to the inside of the commodity, dielectric heating generates heat throughout the material, including the internal part, and the heat propagates by convection and conduction outwards, reducing treatment time.

[73]Dielectric heating has the potential advantage of selectively heating moist substances, such as pests, within relatively drier commodities, such as wood, resulting in a shorter treatment time than if the entire commodity were heated with water or air until it reached a uniform temperature throughout.

[74]Dielectric heating is applied in specialized ovens that operate through either a static system or a dynamic continuous system for heating.

## [75]4. Temperature and Humidity Calibration, Monitoring and Recording

[76]Temperature and, when appropriate, humidity, monitoring and recording equipment should be appropriate for the selected temperature treatment. The equipment should be evaluated for stability against the effects of variables such as temperature, humidity and duration of treatment. It should be accurate to  $\pm 0.5$  °C of the target treatment temperature.

[77]To ensure that the required temperature, humidity and duration of treatment are achieved for a particular commodity, the temperature monitoring and recording equipment should be calibrated in accordance with international standards or appropriate national standards within the entire range of temperature or relative humidity specified in the treatment schedule.

[78]Temperature monitoring methods should consider the following variations in the commodity being treated: (1) density and composition; (2) shape, size and volume; (3) orientation in the chamber (e.g. stacking); and (4) packaging.

[79]The NPPO should ensure that the approved treatment for a commodity allows for accurate temperature and humidity monitoring and recording and thus verification that the treatment has been applied to a consignment. The system type, number of probes required, location of probes and frequency of monitoring should be prescribed on the basis of the specific equipment, commodities, relevant standards and phytosanitary import requirements.

### [80]4.1 Temperature mapping

[81]The NPPO of the exporting country should ensure that temperature mapping by a person or an organization approved by the NPPO is undertaken, following approved procedures, for each

geometric packing configuration, arrangement and density of the commodity, and for each treatment chamber that will be used during the selected temperature treatment.

[82]Temperature mapping studies should be conducted to fully characterize the temperature distribution within the temperature treatment chamber and the load (volume and arrangement of the commodity). Such information should be used to identify where the temperature monitoring and recording devices should be placed during the application of a temperature treatment using the same chamber type and load configuration. Temperature mapping should not need to be repeated for each load. Alternatively, temperature mapping may rely on historical use of treatments for information on the configuration, arrangement and density of a chamber, container or load. Independent temperature mapping for a partially filled treatment chamber is required to determine whether the temperature distribution is significantly different from a routine load and therefore whether the treatment needs to be adjusted accordingly.

[83]Temperature mapping should be carried out following modifications or adjustments in equipment or processes that affect attainment of the target temperature for the treatment.

#### [84]**4.2 Probe placement for temperature monitoring**

[85]When the core temperature of the commodity needs to be monitored during treatment, probes should be inserted into appropriate examples of the commodity. In mixed consignments, probes should be placed appropriately to allow monitoring of the different commodities to ensure they have all reached the target temperature.

[86]The probe should be appropriately secured to the commodity so that it does not become dislodged and in a manner that does not interfere with heat transfer in and out of the commodity.

[87]For small commodities such as cherries and grapes, the probe should be inserted through enough of the fruit to ensure that it monitors pulp temperature and not ambient air temperature.

##### [88]**4.2.1 Cold treatment**

[89]Cold treatment requires:

- [90]monitoring of the core temperature of the commodity throughout the consignment
- [91]adequate air circulation to ensure the target temperature is uniformly maintained.

[92]The number of probes will depend on factors such as treatment schedule, commodity size, the ratio of different commodities in mixed consignments and the type of treatment facility (e.g. ship's cargo hold or container used).

[93]For facility-based pre-shipment and post-shipment cold treatment, at least five probes are required to monitor the temperature of the commodity; more probes may be required in accordance with temperature mapping studies or the size of the treatment facility.

[94]Monitoring of air temperature may provide useful information for the verification of the treatment commodity.

[95]Self-refrigerated containers for in-transit cold treatment require at least three probes per container to monitor the temperature of the commodity. Monitoring of the outlet air temperature also may be required.

[96]It is highly recommended that additional probes be installed to compensate for possible sensor malfunction in one or more of the minimum required probes.

##### [97]**4.2.2 Hot water immersion treatment**

[98]Hot water immersion treatment requires:

- [99]monitoring of the water temperature or monitoring of the core temperature of the commodity

- [100]adequate water circulation to ensure the target temperature is uniformly maintained
- [101]a means to ensure that the commodity is fully submerged.

[102]Probes should be positioned in the water to ensure they can monitor the uniformity of the treatment temperature. Depending on the requirements of the treatment (e.g. whether the core temperature of the commodity or the water temperature needs to be maintained at a specific target for a given time), commodity probes may or may not be required. If they are required, the largest examples of the commodity should be selected for probe placement.

### [103]4.2.3 Vapour heat treatment

[104]Vapour heat treatment requires:

- [105]monitoring of the air temperature and humidity within the chamber
- [106]monitoring of the core temperature of the commodity
- [107]adequate circulation of vapour heated air to ensure uniformity of temperature and relative humidity in the chamber.

[108]The number of probes will depend on factors such as commodity size and configuration and the type of treatment chamber. The largest examples of the commodity should be selected for probe placement and the probes should be placed in the coldest part of the commodity, as identified by temperature mapping.

[109]The treatment schedule should include:

- (1) [110]heat-up time or run-up time: the minimum time allowed for all the temperature probes to reach the prescribed minimum temperature in the commodity
- (2) [111]minimum air temperature and heating time: the maximum time to raise the room temperature to the minimum temperature required for the air in the chamber
- (3) [112]minimum commodity temperature at the end of heat-up time: the minimum temperature required for all commodity core temperature probes
- (4) [113]dwell time: the length of time all commodity temperature probes must maintain the minimum pulp temperature
- (5) [114]total heat treatment time: total time from the start of heating of the commodity to the end of dwell time (instead of (1) or in the case of insufficient conditions in (1) (i.e. all commodity temperature probes reach the prescribed minimum commodity temperature in less than the minimum time))
- (6) [115]humidity control parameters during treatment.

### [116]4.2.4 Dry heat treatment

[117]In dry heat treatment schedules that specify air temperature and moisture requirements, air temperature should be monitored by a wet bulb thermometer.

[118]Wet and dry bulb sensors should be located within the airstream entering a chamber running a one-way airflow. Bulb sensors should be located as far from the wall as possible and away from any heat source. If transverse control or fan reversal is used, additional bulb sensors may be required.

[119]A minimum of one dry bulb and one wet bulb or two dry bulb temperature sensors should be used. The use of multiple sensors ensures that mechanical failure in a sensor during a treatment is detected. This applies to both heat treatments without moisture reduction and kiln-drying processes included in treatments adopted under ISPM 15 (*Regulation of wood packaging material in international trade*).

[120]Dry heat treatment for nuts and seeds should have a minimum of three temperature sensors placed in cold spots determined by temperature mapping studies.

[121]Where the treatment temperature is monitored using probes inserted into the commodity, at least two are recommended, and they should be suitable for measuring commodity core temperature. The

overall number of probes will depend on the treatment type, commodity type, commodity size and configuration, and the type of treatment chamber. Monitoring the core temperature of the commodity, when appropriate, may provide additional information on the verification of dry heat treatment.

#### [122]4.2.5 Dielectric heat treatment

[123]Because of the nature of dielectric heating, appropriate systems for monitoring and recording temperature that are compatible with this technology are required. Examples include infrared cameras, temperature probes not affected by the electromagnetic fields generated, thermocouples and fibre-optic probes.

[124]Depending on the specific treatment to be applied to a particular commodity (e.g. whether the core or the surface of the commodity is the coolest region identified by temperature mapping), internal temperature probes may or may not be required.

[125]Probes should be positioned appropriately to monitor the uniformity of the treatment temperature in the largest examples of the commodity.

### [126]5. Phytosanitary System Integrity

[127]Confidence in the adequacy of a temperature 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.

[128]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.

#### [129]5.1 Approval of Facilities

[130]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.

#### [131]5.2 Phytosanitary security measures at the treatment facility

[132]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:

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

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

#### [138]5.3 Labelling

[139]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.

## [140]5.4 Monitoring and auditing

[141]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.

## [142]5.5 Compliance agreement

[143]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:

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

## [149]6. Documentation

[150]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.

### [151]6.1 Documentation of procedures

[152]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:

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

### [160]6.2 Record keeping

[161]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.

[162]Appropriate records for temperature 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:

- [163]identification of facility
- [164]commodity treated
- [165]purpose of treatment
- [166]target regulated pest

- [167]packer, grower and place of production of the commodity
- [168]lot size and volume, including number of articles or packages
- [169]identifying markings or characteristics
- [170]date of treatment
- [171]any observed deviation from the treatment schedule.

### [172]6.3 Documentation by the NPPO

[173]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.

## [174]7. Inspection and Phytosanitary Certification

### [175]7.1 Export inspection

[176]The NPPO of the exporting country should ensure the consignment meets the phytosanitary import requirements of the importing country.

[177]Documentation – the basis for certifying the treatment – is verified by checking for completeness and accuracy.

[178]Inspection is done to detect any non-target pests. This inspection may be done before or after the treatment. Where non-target pests are found, the NPPO should verify whether these are regulated by the importing country.

### [179]7.2 Phytosanitary certification

[180]Phytosanitary certification in accordance with the IPPC validates the successful completion of a treatment that is required by the importing country. The phytosanitary certificate or its associated documentation should as a minimum specify the treated lot, date of treatment and treatment schedule.

[181]The NPPO may issue a phytosanitary certificate based on treatment information provided to it by an entity approved by the NPPO. In this case, it should be recognized that the phytosanitary certificate may require other information to be supplied to verify that additional phytosanitary requirements have been met (see ISPM 7 (*Phytosanitary certification system*) and ISPM 12 (*Phytosanitary certificates*)).

### [182]7.3 Import inspection

[183]The detection during import inspection of a pest other than the target pest should be assessed for the risk posed, and appropriate action should be taken by the NPPO of the importing country (e.g. detainment of the consignment), considering in particular the effect the treatment may have had on the non-target pest.

[184]NPPOs should clearly identify contingency actions to be taken if live pests are found, which may be as follows:

- [185]target pests: no action, unless the required treatment response was not achieved
- [186]non-target regulated pests:
  - [187]no action if the treatment is believed to have been effective
  - [188]action if there are insufficient data on efficacy or the treatment is not known to have been effective
- [189]non-target non-regulated pests: no action, or emergency action for new pests.

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

#### [191]7.4 Verification of treatment efficacy

[192]Methods for verification of treatment efficacy in export and import inspections, including laboratory tests or analysis to determine if the required response has been achieved, should be described by the NPPO of the exporting country at the request of the NPPO of the importing country.

[193]In some circumstances pest mortality may not be achieved immediately after application of a temperature treatment, and live but non-viable target pests may be detected on post-treatment inspection. Where this is likely to occur, the treatment schedule should specify that live but non-viable target pests may be detected if inspection is undertaken before 100 percent mortality has occurred.

#### [194]8. Authority

[195]NPPOs are responsible for the evaluation, approval and monitoring of the application of temperature treatments as phytosanitary measures, including those performed by other authorized entities. NPPOs should cooperate with national, regional and international regulatory agencies concerned with the development, approval, safety and application of temperature treatments, or with the distribution, use or consumption of temperature treated products, as required. Responsibilities should be identified to avoid overlapping, conflicting, inconsistent or unjustified requirements.

[196]The NPPO of the exporting country should have the ability and resources to evaluate, monitor and authorize temperature treatments undertaken as phytosanitary measures. Policies, procedures and requirements developed for the treatment should be consistent with those associated with other phytosanitary measures, except where the use of the treatment requires a different approach because of unique circumstances.

[197]The monitoring, certification, accreditation and approval of facilities for phytosanitary treatments is normally undertaken by the NPPO of the country in which the facility is located, but by cooperative agreement may be undertaken by the NPPO of the importing country or other national authorities.

[198]Memorandums of understanding, compliance agreements or similar documented agreements between the NPPO and the treatment facility operator or other authorized entities should specify process requirements and clarify responsibilities, liabilities and the consequences of non-compliance. Such documents strengthen the enforcement capability of the NPPO if corrective action becomes necessary. The NPPO of the importing country may establish cooperative approval and audit procedures with the NPPO of the exporting country to verify requirements.

[199]

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

## [200]APPENDIX 1: Guidance for temperature treatment efficacy studies

[201]The following guidance is provided to assist researchers in the design of temperature treatment efficacy studies for controlling pests in international trade (Heather & Hallman, 2008). Before designing such studies, ISPM 28 should be consulted for details on phytosanitary treatment requirements. The mortality level and confidence level to be achieved should be specified.

### [202]1. Experimental Pest Populations

[203]Pests used in efficacy studies should be no less tolerant to the treatment than would occur under natural conditions. If pest colonies are established for the purposes of supplying pest populations for experimental use, they should have originated from and be replenished at least annually by wild (naturally occurring) pests.

[204]The environmental conditions, most notably the temperature, in which pests are stored or reared in colonies before experimentation should be similar to those encountered by the pests in the wild. Pest mortality, morbidity, fecundity, sex ratio, and growth or development under storage or colony conditions should also be similar to those in the wild.

[205]The identity of all individuals used in an experiment should be confirmed as being taxonomically equivalent to the stated target pest. Voucher specimens of the target pest should be held in a suitable facility for later taxonomic validation should it be required.

[206]The life stages of the pest treated should correspond to those life stages likely to be found in trade and at the time of treatment application.

[207]If the treatment is being developed for more than one taxonomically related pest, small-scale dose-response testing may be undertaken to determine the pest that is most tolerant to the treatment. All subsequent testing may then be performed using this pest.

### [208]2. Host Commodity and Infestation

[209]Developmental studies, small-scale dose-response research and large-scale confirmatory trials should all be conducted using the commodity for which the treatment is being developed. If the treatment is being developed for more than one commodity, small-scale dose-response testing may be undertaken to determine the commodity in which the pest is most tolerant. All subsequent testing may then be performed using this commodity.

[210]The condition of the commodity used in the research should reflect the variability expected in trade consignments. The host commodity should be export market quality and should not have been treated previously with insecticides, fungicides or other chemicals, including soaps, dyes and waxes. If the commodity has been exposed to any of these chemicals, data that demonstrate there are no additive effects to the treatment of the exposed pests should be supplied.

[211]The host commodity should be infested with the pest in a manner consistent with that found naturally at the likely point in trade of treatment application. Natural infestation methods should be used where possible, but artificial infestation may be used where it has been demonstrated that such a population is no less tolerant to the treatment than a naturally infested population. The rate of infestation of the commodity used in testing should not result in a reduction in pest tolerance to the treatment or significant modification of the commodity from that found in trade.

[212]The condition of the treated infested commodity, including packaging or other storage conditions, should be consistent with that found in shipments at the likely point in trade of treatment application.

### [213]3. Experimental Design

[214]Treatment efficacy studies may include developmental studies, small-scale dose-response research or large-scale confirmatory trials, as required.

[215]Small-scale experiments can be used to determine the following:

- [216]the most treatment-tolerant life stage or condition of the pest
- [217]the likely temperature–time combination that will achieve the desired end-point at the target level of efficacy with a specified confidence level
- [218]the likely temperature–time combination that will maintain suitable commodity condition
- [219]the relative level of tolerance of the target pest to the treatment compared with another pest for which sufficient efficacy has already been demonstrated; if the target pest is less tolerant to the treatment than the other pest, no further work need be undertaken.

[220]Large-scale confirmatory trials or small-scale temperature–time response trials (for later statistical regression analysis) should then be completed on the temperature most likely to achieve the desired level of efficacy without causing economically significant levels of damage to the commodity (e.g. quality standards).

[221]Replicates of treated populations are necessary to allow for adequate statistical analysis. The minimum is three replicates per temperature–time combination in all cases.

[222]Untreated controls are also necessary, with one control per replicate being optimal. Untreated controls should be no less than one-tenth of the size of the treated population, and they should be held in conditions that maximize pest survival.

[223]Conditions immediately before and after the treatment (e.g. during heating up or cooling down) should be equivalent to what could be achieved under trade conditions. After treatment, but before and during the analysis of the experimental results, the treated commodity should be held in conditions equivalent to the untreated control.

### [224]4. Facilities, Equipment and Monitoring

[225]The facilities and equipment used should ensure adequate control of the environmental conditions during treatment, and be equivalent or similar to those likely to be used in trade.

[226]Treatment monitoring equipment should be able to monitor the temperature of the commodity and/or the pest with an accuracy of  $\pm 0.5$  °C over the duration of the treatment. The temperatures measured should be that of the pest, the commodity close to the pest (where the pest is), or the coolest (for heat treatment) or warmest (for cold treatment) part of the commodity.

[227]Monitoring equipment should be appropriate to accurately determine when the end-point of the treatment has been achieved. Measurements should have appropriate levels of sensitivity and specificity to avoid significant ambiguity.

### [228]5. Statistical Analysis

[229]It is recommended that statisticians are consulted on the design of treatment efficacy studies and the method of statistical analysis to be used before research is undertaken.

[230]Appropriate correction factors should be used to account for control mortality (e.g. Abbott's correction factor (Abbott, 1925)). While results where control mortality is  $\leq 5$  % need not be corrected, control mortality at  $\geq 10$  % must be explained. Results will not be considered to support treatments where control mortality is  $\geq 20$  % unless this is shown to be normal for the target pest under optimal conditions for survival.

[231]Any potential differences in treatment efficacy that may arise from the scaling up of a treatment from research-scale to trade-scale need to be explained, including those arising from differences in

pre-cooling or pre-heating times and the potential impact of these times on pest acclimation or total length of temperature exposure.

[232]In the analysis of the results, variation in the temperature within and between replicates should be examined, and a justification for the target temperature selected should be included in the treatment schedule.

## [233]6. Documentation

[234]Accurate and detailed information should be recorded on the species, variety and origin of the pest and the host commodity used in the research on temperature treatment efficacy. Information on the condition of the pest and commodity (i.e. stage of maturity, colour, size, physiological condition) at the time of the study should also be documented.

[235]The following should be submitted for evaluation in support of treatment efficacy:

- [236]“raw” or unmodified mortality or survivorship data from all temperature–time combinations studied
- [237]“raw” data from the temperature probes throughout both the pre-cooling or pre-heating period and the treatment period of each experiment
- [238]information showing the location of infested and “filler” commodities (if applicable)
- [239]information on all items outlined in ISPM 28 and in this appendix.

## [240]7. References

[241]Abbott, W.S. 1925. A method of computing the effectiveness of an insecticide. *Journal of Economic Entomology*, 18: 265–267.

[242]Heather, N.W. & Hallman, G.J. 2008. *Pest management and phytosanitary trade barriers*. Wallingford, UK, CABI. 257 pp.

## [243]Potential implementation issues

[244]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.