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

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[19]**Steward history**	[20]2014-05 SC Mr Eduardo WILLINK (AR, Steward) [21]2014-05 SC Mr Glenn BOWMAN (AU, Assistant Steward) [22]201611 SC Mr Ezequiel FERRO (AR, Steward) [23]2016-11 SC Mr Eduardo WILLINK (AR, Assistant Steward)
[24]**Notes**	[25]2016-01 Edited [26]2017-05 Edited

[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[1] provides technical guidance on the application of various types of temperature treatment as phytosanitary measures for regulated pests on regulated articles. This standard does not provide details on specific treatments.

[34]Temperature treatments using steam, quick freezing and Joule (ohmic) heating are not addressed in this standard.

[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.

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[33][1] NPPOs should take into account other factors when considering the application of phytosanitary treatments, such as the effects on human health and safety, the effects on animal health and the impact on the environment (as described in the preamble and Article I.1 of the IPPC and in Article III of the IPPC regarding relationship with other international agreements). Effects on the quality and intended use of the regulated article should also be considered.

[37]Definitions

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

[39]Outline of Requirements

[40]Temperature treatments may be used for pest management to comply with phytosanitary import requirements.

[41]This standard provides guidance on the main operational requirements for each type of temperature treatment in order to ensure that the treatments are applied effectively.

[42]This standard also provides guidance on monitoring and recording systems and temperature mapping of facilities to ensure that the specific facility–commodity configuration will enable the treatment to be effective.

[43]Furthermore, guidance is provided to NPPOs on approval of facilities that apply temperature treatments as phytosanitary measures. Guidance is also given on measures that prevent contamination or reinfestation of commodities after treatment, and on record keeping.

[44]BACKGROUND

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

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

[47]ISPM 28 provides requirements for submission and evaluation of efficacy data and other relevant information on phytosanitary treatments, and Annexes with specific temperature treatments that have been evaluated and adopted by the Commission on Phytosanitary Measures.

[48]Phytosanitary treatments based on temperature are considered to be effective when the specific temperature–time combination required for the stated efficacy to be achieved is attained throughout the commodity being treated.

[49]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[50]The use of temperature treatments as phytosanitary measures has a direct impact on biodiversity and the environment by preventing the introduction of regulated pests with the trade of plants and plant products.

[51]REQUIREMENTS

[52]1. Treatment Objective

[53]The objective of using a temperature treatment as a phytosanitary measure is to achieve pest mortality (including devitalization of seeds) at a specified efficacy. Appendix 1 provides guidance for temperature treatment efficacy studies.

[54]2. Treatment Application

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

- [56]as an integral part of production or packaging 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 requirement of a temperature treatment is that the scheduled temperature is attained throughout the commodity for the specified treatment duration, allowing the required efficacy to be achieved.

[63]Parameters to consider when implementing a temperature treatment are the temperature and duration of the treatment and, where applicable, the humidity of the treatment environment or moisture content of the commodity. The specified level for each parameter should be met to achieve the required efficacy.

[64]Packaging size and controlled atmospheres or modified atmospheres created by packaging may alter treatment efficacy.

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

[66]Where the treatment specifies a minimum humidity level, impervious packaging must be removed, opened or adequately punctured to allow the humidity to reach the requirement of the treatment.

[67]Depending on the type of the treatment, temperature treatments can readily penetrate to the interior of the commodity being treated, and can be applied to plant products of any size or shape.

[68]3. Treatment Types

[69]3.1 Cold treatment

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

[71]Cold treatment may be applied during transport to the importing country (e.g. in sea containers). The treatment may start before dispatch and be completed prior to or at the point of entry. The commodity may be precooled to the temperature at which the commodity will be treated prior to beginning treatment. Where applicable, mixed consignments (e.g. fresh lemon and orange fruits loaded in the same facility) may also be treated pre-dispatch or during transport. In all cases, the commodities should be protected from contamination and infestation throughout treatment and transport.

[72]3.2 Heat treatment

[73]Heat treatment raises the temperature of the commodity to the minimum required temperature or higher throughout a specific period of time.

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

[75]Heat treatment may be used in combination with chemical treatment (e.g. fumigation).

[76]*3.2.1Hot water immersion treatment*

[77]Hot water immersion treatment (also known as hydrothermal treatment) uses heated water at a required 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 plants for planting (e.g. ornamental bulbs) to control pests, and generally may be used for pests present on the surface of plants.

[78]***3.2.2 Vapour heat treatment***

[79]Vapour heat treatment (VHT), including high temperature forced air (HTFA)[2], uses water vapour-saturated air to heat the commodity throughout a specific period of time. The high heat energy of hot moist air means that vapour heat is capable of raising the commodity temperature faster than dry air.

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

[82]Variable humidity heat treatment is a type of VHT or HTFA. Hot and relatively dry fan-driven air is used initially, avoiding condensation, to heat the entire commodity from ambient temperature to the required temperature, which is then maintained in humid air, just below dew point, for a specific period of time.

[83]***3.2.3 Dry heat treatment***

[84]Dry heat treatment uses heated air at the required temperature to heat the surface of the commodity or raise the entire commodity to the required temperature for a specific period of time. This treatment is used primarily for commodities with low moisture content such as seeds, grain and wood that should not be exposed to moisture.

[85]***3.2.4 Dielectric heat treatment***

[86]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.

[87]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.

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

[89]4. Temperature and Humidity Calibration, Monitoring and Recording

[90]Monitoring and recording equipment for temperature and humidity, when required, should be appropriate for the selected temperature treatment. The equipment should be evaluated for accuracy and consistency for the temperature, humidity and duration of treatment.

[91]To ensure that the required temperature, humidity and duration of treatment are achieved for a particular commodity, the temperature monitoring equipment should be calibrated in accordance with the manufacturer's instructions and international standards or appropriate national standards at the temperature and humidity specified in the treatment schedule for heat treatments or in an ice slurry for cold treatments.

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[80][2] The main distinction between VHT and HTFA relates to the moisture content of the heated air and the consequential heating. VHT typically uses air near saturation, which results in condensation of water on the fruit surface until the fruit surface temperature increases to near the air temperature, while during HTFA the dew point is typically always kept below the surface temperature of the commodity being heated resulting in no condensation.

[92]Temperature monitoring methods should consider the following factors in the commodity being treated: (1) density and composition (including insulative property of the commodity); (2) shape, size and volume; (3) orientation in the facility (e.g. stacking and spacing); and (4) packaging.

[93]The NPPO should ensure that the approved treatment for a commodity allows for accurate monitoring and recording of temperature and humidity, and thus verification that the treatment has been properly applied to a commodity. The monitoring and recording system, number and location of sensors, and frequency of monitoring (i.e. temperature and humidity readings) or recording should be appropriate for the specific treatment equipment, commodities, relevant technical standards and phytosanitary import requirements.

[94]4.1 Temperature mapping

[95]The NPPO of the exporting country should ensure that temperature mapping is conducted by an authorized person or organization and follows approved procedures. The temperature mapping should cover the use of different packaging types, each packing configuration to be used, and the arrangement and density of the commodity, as well as the type of treatment facility used.

[96]Temperature mapping studies should be conducted to characterize the temperature distribution within the temperature treatment facility and the commodity (in relation to the 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 facility and commodity configuration. Temperature mapping should not be required for each consignment, as it is designed for each facility. Temperature mapping may rely on historical use of treatments for information on the configuration, arrangement and density of a facility or commodity. In other cases, the positions of the sensors are fixed as determined by the country and based on recognized research. Temperature mapping may also be conducted regularly to check possible changes of temperature distribution over time. Independent temperature mapping for a partially filled treatment facility is required to determine whether the temperature distribution is significantly different from a routine commodity and therefore whether the treatment needs to be adjusted accordingly.

[97]Temperature mapping should be carried out following modifications or adjustments in equipment or processes that affect attainment of the required temperature for the treatment. Mapping should also be carried out following changes in packaging or pack configuration.

[98]4.2 Sensor placement for temperature monitoring

[99]When the core temperature of the commodity needs to be monitored during treatment, sensors should be inserted into appropriate units of the commodity. In mixed commodities, sensors should be placed appropriately to allow monitoring of the different commodities to ensure that they have all reached the required temperature and met the temperature conditions throughout the treatment cycle.

[100]Sensors should be placed in areas of the commodity that will take the longest to reach core temperature (e.g. centre of a bag in the centre bag of a pallet).

[101]The sensor 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.

[102]The sensor should be completely encased by the commodity to avoid heat travelling down protruding components and giving false readings. Core sensors that are not completely encased should be sealed into the holes using heat resistant, insulating filler.

[103]Probing close to metal objects such as nails should be avoided, as heat transfer along the metal objects may interfere with the integrity of the temperature recorded by the core sensor.

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

[105]For larger commodities, the sensor should be placed in the largest item, which may take the longest to reach the required temperature.

[106]*4.2.1 Cold treatment*

[107]Cold treatment requires:

- [108]monitoring of the core temperature of the commodity
- [109]adequate air circulation to ensure that the required temperature is uniformly maintained.

[110]The number of sensors will depend on factors such as the treatment schedule, commodity size, commodity type and the type of treatment facility. The number of sensors required to monitor the temperature of the commodity also depends on the temperature mapping and the size of the treatment structure.

[111]Monitoring of the air temperature provides useful information for the verification of the commodity treatment, but not as a replacement for commodity temperature.

[112]Temperature treatment facilities should have at least three sensors.The number of additional sensors may be adjusted to take into account factors such as the density and composition of the commodity, and the load configuration. Monitoring of the outlet air temperature may also be required.

[113]Additional sensors may be installed in accordance with the mapping to compensate for possible sensor malfunction of one or more of the minimum required sensors.

[114]*4.2.2 Hot water immersion treatment*

[115]Hot water immersion treatment requires:

- [116]monitoring of the water temperature
- [117]adequate water circulation to ensure that the required temperature is uniformly maintained
- [118]a means to ensure that the commodity is fully submerged.

[119]Sensors should be positioned 10 cm underwater to ensure that they can monitor the uniformity of the treatment temperature. Depending on the requirements of the treatment (e.g. whether it is the core temperature of the commodity or the water temperature that needs to be maintained at a specific temperature for a given time), commodity sensors may or may not be required. If they are required, the largest units of the commodity should be selected for sensor placement.

[120]*4.2.3 Vapour heat treatment*

[121]Vapour heat treatment requires:

- [122]monitoring of the air temperature and humidity within the facility
- [123]monitoring of the core temperature of the commodity
- [124]adequate circulation of vapour heated air to ensure uniformity of temperature and relative humidity in the facility.

[125]The number of sensors will depend on factors such as commodity size and configuration and the type of treatment facility. The largest units of the commodity should be selected for sensor placement and the sensors should be placed in the coldest part of the commodity and the heat treatment facility, as identified by temperature mapping.

[126]The treatment schedule should include:

(1) [127]heat-up time (also known as run-up or ramp-up time): the minimum time allowed for all the temperature sensors to reach the required minimum temperature in the commodity

(2) [128]minimum air temperature and heating time: the maximum time to raise the room temperature to the minimum temperature required for the air in the facility

(3) [129]minimum commodity temperature at the end of heat-up time: the minimum temperature required for all commodity core temperature sensors

(4) [130]dwell time: the length of time all commodity temperature sensors must maintain the minimum core or pulp temperature and air temperature sensors must maintain the minimum air temperature

(5) [131]total heat treatment time (instead of (1) or in the case of insufficient conditions in (1)): total time from the start of heating of the commodity to the end of dwell time

(6) [132]humidity control parameters during treatment.

[133]*4.2.4 Dry heat treatment*

[134]**Dry heat treatment requires:**

- [135]monitoring of the air temperature and humidity in the facility
- [136]monitoring of the core temperature of the commodity
- [137]adequate circulation of air to ensure uniformity of temperature and relative humidity in the facility.

[138]In dry heat treatment schedules that specify air temperature and moisture requirements, air temperature should be monitored by dry bulb thermometer and moisture should be monitored by wet and dry bulb thermometer, or by digital thermometer in combination with humidity sensors.

[139]Sensors should be located within the airstream entering a facility running a one-way airflow. Sensors should be located as far from the wall of the treatment facility as possible and away from any heat source. If transverse control or fan reversal is used, additional sensors may be required.

[140]The use of additional sensors compensates for possible sensor malfunctioning.

[141]Dry heat treatment for nuts and seeds should have a minimum of three temperature sensors placed in the commodity at locations determined by temperature mapping studies.

[142]Where the treatment temperature is monitored using sensors inserted into the commodity, they should be suitable for measuring commodity core temperature. The overall number of sensors should be adjusted according to the treatment type, commodity type, commodity size and configuration, and the type of treatment facility. Monitoring the core temperature of the commodity, when appropriate, may provide additional information on the verification of dry heat treatment, compared to monitoring air temperature alone.

[143]*4.2.5 Dielectric heat treatment*

[144]Dielectric heat treatment requires monitoring of the temperature at the coolest region of the commodity.

[145]The nature of dielectric heating means that systems for monitoring and recording temperature need to be compatible with this technology. Examples include infrared cameras, temperature sensors not affected by the electromagnetic fields generated, thermocouples and fibre-optic sensors.

[146]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 be required as appropriate.

[147]Sensors should be positioned, according to approved procedures, to monitor the uniformity of the treatment temperature in the largest part of the commodity.

[148]5. Adequate Systems at Treatment Facilities

[149]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

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 reinfestation.

[150]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.

[151]5.1 Approval of facilities

[152]Treatment facilities should be subject to approval by the NPPO in the country in which the facility is located before phytosanitary treatments are applied there. In cases where the treatment is applied during transport, the NPPO may approve the procedures for this application. NPPOs should maintain a list of approved facilities.

[153]5.2 Prevention of infestation after treatment

[154]The treatment facility should provide the necessary measures to prevent possible infestation or contamination of the commodity after treatment. The following measures may be required:

- [155]keeping the commodity in a pest free enclosure
- [156]packing the commodity immediately after treatment
- [157]segregating and identifying treated commodities.

[158]Specific procedures appropriate for each facility and commodity treatment should be approved by the NPPO of the exporting country or the country in which the facility is located.

[159]5.3 Labelling

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

[161]5.4 Monitoring and auditing

[162]The NPPO of the exporting country is responsible for monitoring and auditing the application of phytosanitary treatments and the facilities within which the treatments are conducted. Continuous supervision of treatments should not be necessary provided that there is a system for continuous temperature monitoring, and that 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.

[163]Requirements for treatment facilities

[164]Treatment facilities should fulfil the requirements specified by the NPPO. These may include the following elements:

- [165]approval of the facility by the NPPO of the country in which the facility is located
- [166]authorization of entities (treatment company or person)
- [167]the monitoring programme to be administered by the NPPO of the country in which treatments are conducted
- [168]audit provisions
- [169]free access to documentation and records of the treatment facility
- [170]corrective action to be taken in cases of non-compliance.

[171]6. Documentation

[172]The NPPO of the country in which the treatment facility is located is responsible for monitoring record keeping and documentation. This includes the raw data on temperature and humidity recorded during the treatment. This information should be available to concerned parties. Trace-back capability is essential.

[173]6.1 Documentation of procedures

[174]Procedures should be documented to ensure that commodities are consistently treated, as required. Process controls and operational parameters should be established to provide the details necessary for a specific approval of a treatment facility. Calibration and quality control procedures should be documented by the treatment facility operator. As a minimum, a written procedure should address the following:

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

[182]6.2 Record keeping

[183]Treatment facility operators should keep records for each treatment application. These records should be made available to the NPPO when, for example, a trace-back is necessary.

[184]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. Information that may be required to be recorded includes:

- [185]identification of facility
- [186]commodity treated
- [187]target regulated pest
- [188]packer, grower and place of production of the commodity
- [189]lot size and volume, including number of articles or packages
- [190]identifying markings or characteristics
- [191]date of treatment
- [192]any observed deviation from the treatment schedule.

[193]6.3 Documentation by the NPPO

[194]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*).

[195]7. Inspection and Phytosanitary Certification

[196]7.1 Inspection

[197]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 would indicate a treatment failure.

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

[199]7.2 Phytosanitary certification

[200]The phytosanitary certificate should, as a minimum, specify the treated lot, date of treatment and treatment schedule. The NPPO may issue a phytosanitary certificate based on treatment information provided to it by an entity authorized by the NPPO.

[201]8. Authority

[202]The NPPO of the country in which the temperature treatment is conducted or initiated is responsible for the evaluation, approval and monitoring of the application of temperature 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 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.

[203]

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

[204]APPENDIX 1: Guidance for temperature treatment efficacy studies

[205]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 requirements for submitting data for the evaluation of phytosanitary treatments. If the research is done as a response to a request for market access, the research protocol should be discussed with the importing country before initiating the research. The mortality level to be achieved should be specified, at a stated confidence level.

[206]1. Experimental Pest Populations

[207]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, natural infestation should be used whenever possible and colonies should be replenished regularly by wild (naturally occurring) pests.

[208]The environmental conditions, most notably the temperature, in which pests are stored or reared in colonies before experimentation should be suitable to maintain a healthy colony, this including, where appropriate, a constant temperature. Pest mortality, morbidity, fecundity, sex ratio, and growth or development under storage or colony conditions should also be in accordance with international or national standards for that particular species to ensure a healthy, vigorous colony.

[209]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.

[210]The life stages of the pest treated should correspond to the life stages associated with trade that are most tolerant to the treatment.

[211]If the treatment is being developed for more than one taxonomically related pest, small-scale temperature–time 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.

[212]2. Host Commodity and Infestation

[213]Developmental studies, small-scale temperature–time 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 temperature–time 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.

[214]The condition of the commodity used in the research should reflect the variability expected in trade commodities. 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 should be supplied that demonstrate that there are no additive effects to the treatment of the exposed pests.

[215]The host commodity should be infested with the pest in a manner consistent with that which occurs naturally when subjected to treatment application during trade. 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.

[216]The condition of the treated infested commodity, including packaging or other storage conditions, should be consistent with that found in commodities subjected to treatment during trade.

[217]3. Experimental Design

[218]Treatment efficacy studies may include developmental studies, small-scale temperature–time response research or large-scale confirmatory trials, as required.

[219]Small-scale experiments may be used to determine the following:

- [220]the most treatment-tolerant life stage or condition of the pest
- [221]the likely temperature–time combination that will achieve the desired end-point at the required level of mortality with a specified confidence level
- [222]the likely temperature–time combination that will maintain suitable commodity condition
- [223]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).

[224]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 efficacy without causing economically significant levels of damage to the commodity (e.g. without compromising quality standards).

[225]Replicates of treated populations are necessary to allow for adequate statistical analysis. The minimum is three replicates per temperature–time combination in all cases and each replicate treatment should be conducted separately.

[226]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 do not affect pest survival. Countries may have specific requirements regarding the proportion of insects that may die in the control for the control to be deemed valid, because high mortality in the control may be variable and would mean that control mortality could not be separated from the effects of the treatment.

[227]Conditions immediately before and after the treatment (e.g. during heating up or cooling down) should be equivalent to what would normally 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.

[228]4. Facilities, Equipment and Monitoring

[229]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.

[230]Treatment monitoring equipment should be able to monitor the temperature of the commodity or the facility with a stated accuracy and frequency over the duration of the treatment, determined by the importing country. The equipment should be calibrated prior to each trial. The temperatures measured should be that of 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.

[231]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.

[232]5. Data Analysis

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

[234]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 of ≥ 10% must be explained. Results will not be considered to support treatments where control mortality is ≥ 20% unless this is shown to be normal for the target pest under optimal conditions for survival.

[235]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.

[236]Variation in the temperature within and between replicates should be examined in the analysis of the results, and a justification for the required temperature selected should be included in the treatment schedule.

[237]6. Documentation

[238]Accurate and detailed information should be recorded on the pest and host species, the host variety, the 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.

[239]The following should be documented for evaluation in support of treatment efficacy:

- [240]"raw" or unmodified mortality or survivorship data from all temperature–time combinations studied.
- [241]"raw" data from the temperature sensors throughout both the pre-cooling or pre-heating period and the treatment period of each experiment with calibration data for each sensor.
- [242]information showing the location of infested and "filler" commodities (if applicable) as well as sensors to measure air and commodity temperature.
- [243]information on all items outlined in ISPM 28 and in this appendix.

[244]7. References

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

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

[247]Potential implementation issues

[248]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.