Technical Panel on Phytosanitary Treatments
September, 2015
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1. Opening of the meeting

The International Plant Protection Convention (IPPC) Secretariat (hereafter “Secretariat”) opened the meeting and thanked Mr Ichiro NAKAGAWA and the Plant Quarantine Office, Plant Protection Division, Food Safety and Consumers Affairs Bureau of the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) for hosting the meeting and welcomed the participants. In addition, Japan was thanked for also providing financial resources to support this meeting and the work of the Technical Panel on Phytosanitary Treatments (TPPT).

The panel members and Secretariat staff introduced themselves.

The Director of the Plant Quarantine Office, Mr Ichiro NAKAGAWA, welcomed the participants to Fukushima. He thanked the members of the TPPT for their important work in helping to harmonize standards on such a vital issue as phytosanitary treatments that help facilitate international trade while protection the world’s plant resources.

He expressed his sincere appreciation to the many countries in the world that helped Japan following the tsunami and nuclear disaster in Fukushima in 2011. Noting the hardships that Japan faced in the aftermath and the tremendous efforts needed to restore things to normal, he was thankful for the TPPT to being able to meet in Fukushima this year.

He explained the organization for the Wednesday afternoon field trip. First the panel would be taken to a fruit orchard, then to the Fukushima Agricultural Technology Centre where a presentation on important pests in Fukushima region would be made and where the panel would get the opportunity to see the lab where radiation tests are carried out. He noted that the Centre carries out a remarkable high number of radiation tests to ensure that the agricultural and fishery products from this region are safe. Lastly, the panel would be taken to the traditional sake distillery “Niida-Honke Co.”, founded in 1711, that had won several prizes for their sake.

Election of the Chairperson

The panel elected Mr Patrick GOMES (USA) as Chairperson.

Election of the Rapporteur

The panel elected Mr Michael ORMSBY (New Zealand) as Rapporteur.

Adoption of the Agenda

The panel reviewed, modified slightly and adopted the agenda (Appendix 1).

2. Administrative Matters

Documents List

The panel reviewed the documents list (Appendix 2).

Participants List

Panel members reviewed their contact information (Appendix 3) and agreed to update it on the IPP.

Local Information

The meeting organizer, Mr Manabu SUZUKI, provided further information regarding the local arrangements and logistics1.

1 04_TPPT_2015_Sep
3. Updates from Relevant Bodies

[12] The Secretariat gave a brief presentation outlining the IPPC standard setting procedure to help panel members understand the process and associated deadlines that affect the work of the panel.

3.1 2015 May Standards Committee decision: ink amendments to Annexes to ISPM 28

[13] The Secretariat introduced the paper containing proposed ink amendments to annexes to ISPM 28 (Phytosanitary treatments for regulated pests) to describe the level of efficacy achieved by a treatment schedule instead of using “effective dose” or “ED”.

[14] The panel discussed the specific amendments, to ensure the wording correctly reflected the efficacy needed and provided rationale for each ink amendment (Appendix 4).

[15] The TPPT:

(1) Agreed to forward ink amendments for the 19 currently adopted phytosanitary treatments to the SC November 2015 meeting for their consideration (Appendix 4).

3.2 Report on PTTEG meeting 2015-08

[16] Mr Guy HALLMAN (USA/IAEA), who is acting as liaison between the TPPT and the Phytosanitary Temperature Treatment Expert Group (PTTEG), informed the panel of the main outcomes of the PTTEG meeting that took place in Nelspruit, South Africa, in August 2015.

[17] He noted that the group had discussed phytosanitary measures more broadly than only post-harvest treatments, such as treatments in the context of a systems approach, and that the group, based on this, had decided to change the scope and name of the group to “Phytosanitary Measures Research Group (PMRG)” (the previous name is maintained in this report for clarity). Some TPPT members queried the need for a change in scope, as it could cause confusion among IPPC contracting parties regarding the role of this group and the TPPT. Mr HALLMAN clarified that the group was clear on the fact that its mandate is to focus on research and should be able to provide responses to technical questions that would help support the development of international phytosanitary treatments.

[18] The PTTEG had also reviewed literature on cold treatments, currently there are over 200 entries contained in a database. It is hoped that this database could be made available online. It was noted that the Secretariat is exploring the possibility of setting up a database on the IPP for adopted treatments and the group thought there might be a benefit of expanding this database to also include nationally approved treatments.

[19] Mr HALLMAN noted that the PTTEG had agreed to publish a newsletter on Phytosanitary treatments research. The group had been enthusiastic about this as a possible first step towards the creation of a scientific journal in light of the current lack of a journal that published information on phytosanitary treatment research.

[20] Lastly, he informed the panel that the group had discussed the cultivar/varietal effects on treatment efficacy and found that the literature is confusing on this point. The group did agree, however, that there is not much evidence to demonstrate that differences do actually exist (differences may be due to other factors such as differences in testing systems, labs or research groups). Currently only one study (De Lima et al. (2007)) suggested there were some differences whereas other studies demonstrate that there are no differences. In the De Lima et al. (2007) study, Citrus sinensis varieties Valencia and Navel had been tested and the results demonstrated that there were no differences at 2°C but some

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2 16_TPTEG_2015_Sep; see the 2015 May TPPT Virtual Meeting Report for a full update from the SC May 2015 meeting.
3 Report of the PTTEG August 2015 meeting will be available here.
minor differences at 3 °C. A similar study carried out in Egypt (Hashem et al 2004) demonstrated no differences at 2°C or 3°C treatment schedules that achieve a level of efficacy suitable for international trade, and a third study from Argentina that tested five different cultivars also found no significant statistical differences at various temperatures. Another study on the efficacy of cold treatment on fruit flies in different varieties of oranges was conducted in Spain (see draft cold treatment for *Ceratitis capitata* on *Citrus sinensis* var. Navel and Valencia - 2010-103). This also failed to identify any differences in varietal response at different phytosanitary treatment dose levels.

The TPPT considered the report from the PTTE meeting, the papers from Egypt and Argentina, re-examined the De Lima et al. 2007 and analyzed the raw data provided. The panel agreed that although the probit analyses of the data on *Ceratitis capitata* by De Lima et al. (2007) found statistically significant differences between the two orange cultivars at estimated lethal doses of 50% and 95%, no analyses were done at levels near those required of phytosanitary treatments (>99.9%). Therefore, it is not known if there are estimated differences at levels of control required for phytosanitary cold treatments. The averages of the raw data supplied by De Lima et al. (2007) do not show apparent differences in efficacy at high levels of control. For instance, at 2 °C for 14 days average mortality of the most tolerant stage (2nd instar) was 98.95% and 99.58%, respectively for *Ceratitis capitata* in Valencia and Navel oranges, while at the next highest treatment time (16 days) mortality in both cultivars was 100%.

Taking this into consideration, the TPPT concluded that there is no evidence supporting different responses for *Ceratitis capitata* in *Citrus sinensis* var. Navel and Valencia. The TPPT therefore concluded that at this time there was no evidence to suggest different orange varieties may produce different responses in fruit flies to cold treatments at dose levels required for phytosanitary treatments.

The TPPT:

2. Expressed their appreciation for the work carried out by the Phytosanitary measures research group (previously the “Phytosanitary temperature treatments expert group”).

3. Based on the conclusion reached in this meeting on the lack of evidence supporting different responses for *Ceratitis capitata* in *Citrus sinensis* var. Navel and Valencia, agreed to modify Section 10.7 of the TPPT Working criteria.

4. **Review of Member Consultation 2014 Comments on Draft Phytosanitary Treatments (PTs)**

4.1 **Finalization of TPPT responses to member comments on draft PT High temperature forced air treatment for Bactrocera melanotus and B. xanthodes on Carica papaya (2009-105)**

The treatment lead introduced the documents and the panel reviewed and revised the treatment lead’s proposed responses to the comments (comments from the 2014 member consultation). Reference was also made to a number of supporting documents. Lastly, a TPPT member shared a recent study from Japan.

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7 2009-105_Draft Treatment; 2009-105_Treatment Portfolio; 2009-105_Draft Responses to MC; Compiled member comments on IPP: https://www.ippc.int/en/publications/2657/

8 06_TPPT_2015_Sep; 07_TPPT_2015_Sep; 08_TPPT_2015_Sep

9 18_TPPT_2015_Sep
The following points were discussed.

The panel agreed to change the title from “High temperature forced air treatment” to “Vapour heat treatment” in accordance with discussions under Section 5.1 of this report. Text in the draft PT was modified to reflect this change.

The panel noted that for consistency with previously adopted PTs, common names would be given in brackets at first mention and did not accept member comments suggesting otherwise.

The panel discussed whether to include consideration of cultivar differences in the draft because different varieties have different shapes, some which may require longer cool-down periods or potentially quicker heat-up times (like smaller fruit). This was supported by the papers published by Japanese researchers\(^{10}\) and\(^{11}\) who found that the length of heat treatment required to treat larger fruit is longer than for smaller fruit (as temperature is recorded at the core of fruit), therefore surface pests get higher heat doses on larger fruit than on smaller fruit. As this treatment was developed based on egg mortality, and eggs are on the surface of the fruit, fruit size would be critical for treatment efficacy. Also, it was noted that it is important to take the temperature reading at the core to ensure that any third instar larvae at the center of the fruit would also be killed. Based on this, the TPPT considered whether to specify a minimum fruit size as a requirement to address this issue but found that this may be a too restrictive of a requirement for international trade. Instead, the panel agreed to include a minimum length of time the fruit has to be held in the target air temperature in order to achieve the targeted core temperature. They considered that this new schedule with minimum overall exposure periods would overcome any potential differences between fruit varieties or fruit sizes.

When reviewing the member comments, and re-examining the literature, the TPPT agreed to add to the References section of the draft treatment, the paper containing the actual study (Waddell et al. 1993\(^{12}\) study) underpinning the data for the treatment, which had not been published. The TPPT recognized that the published Waddell et al. 1997\(^{13}\) publication explained the Waddell et al. 1993 study but that it modified the results somewhat, without due explanation. For this reason, the TPPT found that it was more appropriate to refer to the actual study from 1993 and agreed that this paper should be made available to interested parties.

These points considered, and after a review of the original research paper (Waddell et al. 1993) the TPPT adjusted the treatment schedule.

Regarding hydro-cooling, the TPPT felt that it was important to retain text in the treatment to state that this is an option for countries because some countries may not normally allow hydro-cooling as they believe it may result in the treatment failing to achieve the desired level of efficacy, whereas the efficacy of this treatment was determined with hydro-cooling included. The panel agreed that this text should be a note under “other relevant information” and not included in the schedule. The panel noted that if hydro-cooling is not done it may result in a more stringent treatment. In this respect, the panel felt that it was not necessary to specify how the fruit was cooled but to specify that the core

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temperature must not go below 30 °C and may not be cooled to this core temperature over a period of less than 70 minutes.

[32] One member queried whether the schedule should state “all fruit within the chamber” because concern was expressed that it would mean that all fruit would need to be tested. Another member explained that this would relate to the verification, not the schedule.

**Environmental & implementation issues**

[33] The panel considered implementation issues.

[34] Some IPPC member comments during the member consultation suggested adding guidance on what constitutes treatment failure or which pretreatment activities should be carried out. The TPPT found that the points raised could not be part of the treatment schedule but that they were important for the correct implementation of the treatment.

[35] Another IPPC member comment suggested adding “certified” to the requirements for the chamber. The TPPT agreed that normally a chamber would always have to be certified or approved, however, to ensure consistency with previously adopted PTs and because the schedules cannot specify all the equipment needed to have NPPO approval, the panel agreed not to include this term. The panel recognized that there could be operational implementation challenges connected to the air chamber and that these would be addressed in the draft standard *Requirements for the use of temperature treatments* (2014-005).

[36] The TPPT also recognized that there could be some implementation challenges to ensure the quality of smaller fruit is maintained, especially if the treatment time is increased for these fruit.

[37] The TPPT found that this treatment would have positive effects on the environment as it allows for a non-chemical treatment option.

[38] The TPPT:

- Agreed to submit the TPPT responses to the 2014 member consultation comments on the draft PT *Bactrocera melanotus* and *B. xanthodes* on *Carica papaya* (2009-105) to the SC.
- Asked the Secretariat to forward the translation comments to FAO translation and the editing comments to the Secretariat editor.
- Invited the SC to note the change in title of this draft PT to Vapour heat treatment for *Bactrocera melanotus* and *B. xanthodes* on *Carica papaya* (2009-105) in accordance with the conclusions reached under Section 5.1 of this report.
- Agreed to recommend the draft Vapour heat treatment for *Bactrocera melanotus* and *B. xanthodes* on *Carica papaya* (2009-105) as modified in this meeting to the SC for adoption.

### 4.2 Review of TPPT responses to member comments on draft PT Irradiation treatment for *Ostrinia nubilalis* (2012-009)

[39] The lead introduced the documents and the panel reviewed the draft responses to the comments received during the 2014 member consultation and revised the draft PT.

[40] The panel noted that for consistency with previously adopted PTs, common names would be given in brackets at first mention and did not accept member comments suggesting otherwise.

[41] The following points were discussed.

[42] **Irradiation dose.** The panel discussed whether the schedule should be modified from 289 Gy to 343 Gy at 99.9914 efficacy, as suggested by member comments and supported by Hallman &

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14 2012-009_Draft Treatment; 2012-009_Treatment Portfolio; 2012-009_Draft Responses to MC comments; Compiled member comments on IPP; [https://www.ippc.int/en/publications/2662/](https://www.ippc.int/en/publications/2662/)
Hellmich (2009) or to include both schedules in the draft treatment. The panel agreed to having two schedules in the treatment because 289 Gy still provided for a very confident treatment with prevention of F1 pupation and some countries may prefer to apply this treatment, as it may damage the commodity less than the more stringent one which prevents F1 egg hatch.

Environmental & implementation issues

[43] The panel agreed that ISPM 18 (Guidelines for the use of irradiation as a phytosanitary measure) considers general implementation issues related to irradiation.

[44] Regarding the difficulty in distinguishing contaminating adults from those emerged from treated pupae, the panel recognized that this would be an implementation challenge but also that it would be an unlikely event considering that the number of fit survivors would be very low. The panel adjusted text to the draft treatment to outline this potential implementation challenge in the section “other relevant information”.

[45] The panel also recognized that the irradiation dose may damage some commodities beyond economically acceptable levels under some conditions. As with all irradiation treatments, care should be taken to ensure the commodity being treated is presented in a form that minimizes any damage that may occur.

[46] The TPPT:

(8) **Agreed to submit** the responses to the 2014 member consultation comments for draft Irradiation treatment for *Ostrinia nubilalis* (2012-009) to the SC.

(9) **Asked the Secretariat** to forward the translation comments to FAO translation and the editing comments to the Secretariat editor.

(10) **Agreed to recommend** the draft PT Irradiation treatment for *Ostrinia nubilalis* (2012-009) as modified in this meeting to the SC for adoption.

5. Drafting of ISPMs on requirements for phytosanitary treatment use

The TPPT Steward introduced the agenda item, highlighting the tasks of Specification 62 (Requirements for the use of phytosanitary treatments as phytosanitary measures)\(^\text{15}\).

5.1 Requirements for the use of temperature treatments as a phytosanitary measure (2014-005) – Priority 1

[47] The steward introduced the draft standard\(^\text{16}\). The TPPT revised the draft and discussed the following points.

[48] **Structure.** The panel decided to incorporate information from the previously drafted explanatory documents for various temperature treatments (internal TPPT documents) into the draft standard, and to use the general IPPC draft standard template for the structure. The panel also agreed that the ISPM should state the general principles regarding the application of temperature treatments and that the specifics related to each treatment type would follow as appropriate.

[49] **Scope.** The panel felt all treatments that apply temperature (e.g. dielectric and microwave heating, steam, quick freeze) should be included in the scope, recalling for instance that ISPM 15 (title) mentions that dielectric heating is a heat treatment. Nevertheless, the panel added text to clarify that the treatments included in this draft standard would be the ones annexed to ISPM 28. Some treatments, which are not annexed to ISPM 28 but which are used in commercial contexts (e.g. steam, quick freeze or cryogenic, Joule or ohmic heating, and conducted heating), would be included only as examples of other treatments.

\(^\text{15}\) Specification 62 is available [here](#).

\(^\text{16}\) 2014-005_Draft ISPM
In this context one member queried which standard would cover mixed treatments (e.g. heated modified temperature treatment or vacuum steam treatment). The panel agreed that in these cases, the specific guidance needed should be drawn from the relevant standards (e.g. the “temperature” standard would be referred to for heat measurements). One standard alone would not be applicable; just as the treatment is mixed, so would the guidance needed be.

**Background.** The panel expanded on this section, feeling that it would be important to highlight that normally temperature treatments do not apply chemicals and therefore have less impact on the environment.

**Authority.** The panel agreed that it should be clarified throughout the draft who is responsible for the various requirements of the treatments and as such a specific separate section would not be needed.

**Compliance or treatment failure.** The panel agreed that it would useful to have brief descriptions of what would constitute treatment failure for each of the treatments.

**Requirements.** The panel discussed the level of requirements; whether they should be principles (e.g. “use probes for…”) or whether they should be more specific (e.g. “x number of probes need to be placed in…”). Regarding the number of probes and probe placement, the panel agreed to include specific requirements because they would be useful to help harmonize requirements. The panel also agreed to include requirements for mixed consignments, which is a common way of trading internationally, usually with the intention to reduce financial risk in international trade; thus, cold treatments are used to reduce risks.

**Efficacy.** The panel agreed to not include a section on efficacy as this is covered by ISPM 28.

**Types of treatments (chapeau).** “Pre- and post-shipment” treatments were mentioned under types of treatments because the panel agreed that there are different requirements for these two scenarios. “Shipment” was used as this is the normal operational term and would include export and re-export. Post-shipment in this context would also include transit.

**Heat treatments.** The panel agreed to have a general statement under “heat treatments” on rapid cooling after treatment which may be carried out to help preserve quality of the commodity. They felt it was important to provide guidance on this because it is a possibility only when the research carried out demonstrates that rapid cooling does not reduce treatment efficacy.

The panel discussed whether to distinguish kiln-drying schedules and other heat treatments because the sensor placement may vary. A kiln schedule is developed to dry [lumber] to specific conditions desirable for construction or other purposes. A heat treatment schedule is only concerned with achieving [time / temperature] conditions necessary to kill target organisms that may be present. There is some overlap where dry kiln schedules achieve necessary heat treatment standards; however, efficacy data for such treatments may be lacking. Because the temperature / time conditions for these treatments are quite severe they likely fully mitigate pest risk for phytosanitary purposes. The panel agreed that the wording in ISPM 15 when generalized could be applied for all types of dry heating

The panel discussed using the terms “dry bulb” and “wet bulb” or explaining what these terms mean. The panel agreed to explain the terms and mention them as examples, although it was noted by members that this is terminology currently used.

**Dielectric heating (DH).** The group discussed how detailed dielectric heating should be described. The panel was slightly concerned about adding details because dielectric heating is not as yet widely used. Therefore, there is still fairly little information on the application of the treatment under commercial conditions however the IPPC Secretariat is producing a manual to provide further guidance.

The panel agreed that “DH generates heat throughout the material and spreads through both convection and conduction” IT was noted that DH targets moisture, meaning that it will directly heat
the target pests (containing moisture) present in the commodity as well as the commodity. The panel did not agree to add any text on this because it would be too complicated to exhaustively explain the various scenarios (e.g. higher or lower moisture in the commodity versus higher or lower moisture in the pest).

The panel noted that temperatures should be measured at the coldest spot. If this is on the surface, the identification may be done with for example an infra-red camera. If the cold spot is internal, a probe that is not affected by the electromagnetic fields generated (thermocouples or fibre-optic probes) should be used. The panel felt that this wording adequately captured the fact that metal probes may not be able to measure the temperature correctly while the heat is being applied as the electromagnetic field waves may interfere with such probes.

Some members suggested adding guidance on interval application of the DH treatment to have pauses in the electromagnetic fields. These pauses would be needed to record the temperatures and allow heat to dissipate through the wood, whereas for other types of treatments, intervals would be recorded as interruptions and may indicate treatment failure. Other members did not wish to add it because there is limited experience with the use of this treatment, therefore the panel agreed not to add text.

Vapour heat (VH) and high temperature forced air (HTFA) treatments. The group discussed whether these two treatments should be considered one treatment with distinctions in the schedules, as they both include parameters of humidity and heat.

Some members were concerned about including HTFA under VH treatments because of possible operational challenges that a change in name could create, specifically in relation to the information needed on export certificates, and because HTFA is a recognized term for this specific treatment.

Other members felt that it would be appropriate to group HTFA under VH because HTFA is in reality a VH treatment with a lower level of humidity, and the parameters to measure are the same (temperature, relative humidity and time). A lower level of humidity means that less condensation is formed on the fruit, and the treatment is normally only applied to try to reduce damage to the fruit. To the panel members’ knowledge, no treatment schedule foresees inclusion of information on the dew point in relation to the efficacy. Furthermore, it was highlighted that it is not always possible to determine whether a treatment is VH or HTFA, as all or almost all VH treatments used forced air systems and as such could be called HTFA treatments, and all HTFA treatments used heated vapour.

Because there seems to be no differences in efficacy between VH and HTFA treatments, the panel agreed that HTFA is a variation of VH and should be mentioned under VH for explanatory purposes, not as a separate treatment. As regards the operational challenges, the panel did not think there would be problems with the differences between these two forms of vapor heat treatment. For example, methyl bromide treatments also have various parameters to consider before the treatment can be approved and that these are specified on the export certificate.

One member suggested naming all the treatments “humid heat treatment” which would include VHT, HTFA and combination treatments, but the panel felt that it would cause confusion if an additional new term was introduced and did not agree to this proposal.

The panel discussed whether to include text on the treatments being used in combination with other treatments or phytosanitary measures. One member pointed out that there are usually limits to the infestation level of the fruit before the fruit is treated; hence at least two steps are needed to reduce the pest risk e.g. one to ensure the infestation level before treatment is not above a specified level, and the second the phytosanitary treatment. Another member was concerned that the wording of the schedule could be misunderstood to allow for import requirements to state that a number of treatments have to be applied before import, and thus serve as a potential barrier to trade. The panel agreed not to mention this and felt that this type of information should rather be included in the specific PTs.

The panel also agreed that heat treatments on wood would not be termed “VH treatments” because, while humidity is often used in wood treatments, it is used to prevent the wood from warping but not...
controlled for treatment purposes or part of the schedule. For this reason, wood was not mentioned in this section.

[71] **Temperature mapping within Chambers.** The panel discussed the requirements for temperature mapping of treatment chambers and decided to clarify that mapping is done to identify where the probes should be located during treatments, and that mapping may need only be done once for routine-based treatments (when the same type of commodity and configuration in the same type of chamber is treated). It was noted that mapping is normally done once a year and the panel considered adding a requirement on recalibration annually, but did not agree to this as there is no evidence that conditions would necessarily change significantly in one year to make this necessary.

[72] **Probe placement.** The panel discussed general requirements for probe placement and whether these requirements could be used in taking measurements for all types of commodities, including wood.

[73] Regarding placing the probe in the component of the consignment being treated that has the largest dimensions (e.g. Largest block of wood, largest fruit), the panel discussed if this would always be the case. One panel member queried the situation where there are a number of pallets, one which would have all the largest components, and the rest of the pallets contained components that were smaller; and whether all the probes would be placed in only the one pallet with the largest components. The panel agreed that in all cases, probes would be placed to measure the temperature in the cold spots identified during the temperature mapping of the chamber and this would help ensure that the appropriate temperature readings were taken.

[74] **Temperature recording.** The panel agreed to include a general statement on the length of time for the recording intervals because they vary depending on the length of time stated in the treatment schedules.

[75] The panel considered adding requirements for probe accuracy and what the range (+/-) should be, both with reference to what is operationally feasible and what would help guarantee treatment success. One member queried if a probe that varies by +/- 0.6 °C in three readings would be considered suitably accurate for use in phytosanitary treatment application. It was explained that while such variation may not be acceptable, it did not mean the probe was inaccurate (e.g. the variation in readings may be around the correct temperature). The panel agreed to add requirements for maximum levels variation in probe readings (of +/-0.5 °C), noting that for specific treatment types the amount of variation may need to be less.

[76] The panel also had a brief discussion on the way target temperatures are measured in research (and in practical and commercial), for instance if it is done when the last probe reaches the target temperature or if it is the average temperature. One member considered it potentially beneficial to accept the mean probe temperature, but other members had concerns with this approach and there was no agreement to move from the current process of using the most conservative reading (highest or lowest probe) to determine schedule parameters.

[77] **Phytosanitary security.** The panel discussed whether to add text to clarify that phytosanitary security would normally relate to post-treatment situations only. However, the panel felt that the defined ISPM 5 (*Glossary of phytosanitary terms*) term would adequately describe the intention and did not feel it was necessary to add text.

[78] **Labeling.** The panel discussed whether it was necessary to include information on “treatment lot numbers” as several countries are trying to be more general in their requirements. The panel agreed to text that allows for flexibility in the labeling, provided it gives the necessary information for traceback purposes.

[79] **Verification.** The panel agreed that “direct treatment oversight” (as is prescribed in ISPM 18) would not be appropriate to include here, as it would imply that the importing country NPPO would need to be present every time the treatment was applied.
Inspection. The panel discussed whether to include text on live non-target pests that may be found during inspection. Some members found it would be inappropriate to include because the treatment would relate to only specific target pests, and that such a situation should be covered by other standards. They also considered that non-target pests should not be mentioned in this draft, noting that these were only relevant to ISPM 18 where live but non-viable pests may be present. Others felt that non-target pests should be mentioned, to confirm that they would not constitute a treatment failure.

Other members felt it would be appropriate to include text on non-target pests in the event where the live non-target pest could provide evidence to the fact that the treatment had failed. This evidence would need to be based on research demonstrating that those pests would have been killed by the correct application of the treatment. It was noted that if the non-target pests are not quarantine pests for the importing country, measures to prevent post-treatment infestation are not required so the presence of the pest may not indicate treatment failure even if the pest should have be killed by the treatment.

For this reason, the panel agreed to clarify that finding live non-target pests could indicate treatment failure under certain conditions, in an attempt to ensure that countries do not declare treatment failure without appropriate justification.

Regarding the use of “target” and “non-target” pests it was clarified that “target” pests would be those specified in the treatment.

Appendices. The panel agreed to include information on research protocols in appendices to help ensure research was carried out in such a way that the data produced would be useful to support treatment submissions.

Due to time constraints, the panel agreed to continue drafting this standard in a virtual meeting with the aim to finalize it and submit it to the Secretariat prior to 15 December 2015.

The TPPT:

Agreed that all TPPT members would submit comments to the steward on improvements to the draft, proposals to the research protocols and that they would consider what would constitute treatment failure for each treatment by 18 September 2015.

Agreed that the Steward would work with the Assistant-steward to prepare a revised draft to be discussed in a virtual TPPT meeting planned for December 2015 with the purpose of finalizing the draft for submission to the Secretariat by 15 December 2015.

5.2 Requirements for the use of fumigation as a phytosanitary measure (2014-004) – Priority 1

The panel agreed to defer this agenda item until the draft standard on Requirements for the use of temperature treatments as a phytosanitary measure (2014-005) has been presented to the SC and feedback from the SC could be used to help address possible concerns.

5.3 Requirements for the use of irradiation as a phytosanitary measure (Revision to ISPM 18) (2014-007) – Priority 3

The panel agreed to defer this agenda item until the draft standard on Requirements for the use of temperature treatments as a phytosanitary measure (2014-005) has been presented to the SC and feedback from the SC could be used to help address possible concerns.

5.4 Requirements for the use of modified atmosphere treatments as a phytosanitary measure (2014-006) – Priority 3

The panel agreed to defer this agenda item until the draft standard on Requirements for the use of temperature treatments as a phytosanitary measure (2014-005) has been presented to the SC and feedback from the SC could be used to help address possible concerns.
5.5 Requirements for the use of chemical treatments as a phytosanitary measure (2014-003) – Priority 3

The panel agreed to defer this agenda item until the draft standard on Requirements for the use of temperature treatments as a phytosanitary measure (2014-005) has been presented to the SC and feedback from the SC could be used to help address possible concerns.

6. TPPT working procedures and research recommendations


6.1 Requirements for experimental replication underpinning proposed PT schedules

The treatment lead for Ceratitis capitata on Citrus sinensis var. Navel and Valencia-late (2010-103) introduced the paper. He recalled that the issue of experimental replication had been discussed in the panel around the replicates carried out in collecting data for the proposed cold treatment schedule for Ceratitis capitata on Citrus sinensis var. Navel and Valencia-late (2010-103). He noted that the issue had appeared when he, after taking lead in 2015, re-examined the data submitted to support this proposed treatment. He explained that the submitter had asked the panel to consider approving the proposed schedule based on two out of three replicates (all in excess of an estimated 10 000 insects per replicate). The two replicates supported treatment for 16 days, whereas the third for 17 days. The submitter had explained that the extra day was due to the laboratory being closed for a public holiday.

The lead explained that in favor of the two replicates, in this case, was that the treatment application had been very conservative in that there had been total mortality in the dose trials after 10 days. Another TPPT member explained that when the issue had been discussed on previous occasions, the panel had found that two replicates were sufficient to determine the treatment’s efficacy (which is why it had been forwarded for member consultation). The panel discussed the issue again, and agreed that the two replicates at 16 days would suffice as validation considering the combined information received and reviewed.

The panel agreed, however, that normally a minimum of three replicates would be needed to ensure that a test may be statistically validated, and hence that a submission is valid.

For the draft PT for Ceratitis capitata on Citrus sinensis var. Navel and Valencia-late 2010-103, the panel noted that while the issue related to replications in the experimental design, the PT could not be put forward for adoption at this point due to the issues related to fruit fly population differences in cold tolerance which also affect this draft treatment (cold treatments and Ceratitis capitata (Mediterranean fruit fly)). Nevertheless, the panel agreed that member comments regarding replications should be addressed.

The TPPT:

13 Recommended that when carrying out confirmatory trials the minimum number of replicates should be three and that the three replicates should be true repeats of the basic experimental unit, and modified Section 3 of the TPPT working criteria accordingly.

14 Agreed that there was enough data and information combined to support the 16 days schedule in the draft PT on Ceratitis capitata on Citrus sinensis var. Navel and Valencia-late (2010-103) and asked the lead to draft the responses to member comments (member consultation 2014) for TPPT review.

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17 TPPT_2015_Sep
(15) Invited SC to change the status of the draft PT for Ceratitis capitata on Citrus sinensis var. Navel and Valencia-late (2010-103) to “pending” until further data on fruit fly population response differences to cold is available (PTTEG (now PMRG) and IAEA study).

(16) Agreed to review the responses to member comments inter-sessionally and then forward them to the SC for endorsement, noting that the treatment itself is currently “pending”.

6.2 Setting minimum treatment schedule parameters based on the supporting research

One panel member introduced the paper\(^{19}\) recalling that the TPPT in their virtual May 2015 meeting had agreed to discuss the issue of data requirements for testing assumptions in experimental design. The paper was prepared based on the example of Japan that had developed criteria to evaluate temperature treatment results. Results from cold treatment experiments from two sets of replicates were presented. One set of three replicates produced results around the same mean (2 °C), while the other three replicates had different means, but had a combined mean of 2 °C. The first treatment (set of replicates) had a minimum recorded temperature of 1.7 °C, while the other treatment (set of replicates) recorded a minimum temperature of 1.5 °C with the lowest recorded mean for a single replicate of 1.6 °C. The panel discussed the various interpretations of these results, as follows:

- if the treatment temperature is the average of the replicates (e.g. 2 °C for both treatments)
- if the treatment temperature is the lowest reading taken from the replicates (e.g. 1.7 °C for the first treatment, and 1.5 °C for the second)
- if the target temperature is the lowest replicate mean (e.g. 2 °C for the first treatment, and 1.6 °C for the second)

The panel felt this was a good exercise because it is not clear how the temperature of the treatment is actually agreed, and that the method could lessen the stringency of treatment schedules. Commercial operators often set the temperature in their chambers to 0.3 °C or 0.4 °C less than the schedule to be sure to meet the import requirements, although this should not be necessary when the schedule is developed based on the most conservative schedules.

The panel agreed that only treatments that meet the target temperature or are lower (for cold treatments) should be used to support the efficacy calculation, but that the mean temperature of the combined replicates should be used if the variation in or between each replicate was not too great (outside accepted variation of the treatment e.g. +/- 0.5 °C).

The TPPT:

(17) Agreed that the TPPT should use the method demonstrated in the report of this meeting when reviewing cold treatment schedules in the future.

6.3 Instructions to assist NPPOs and RPPOs in proper and complete submissions

The lead introduced the revised instructions\(^{20}\) recalling that the TPPT had discussed the paper on various occasions. The TPPT felt that there was still work that needed to be done before releasing the document (see also section 6.7) and agreed to re-discuss this issue in an e-forum.

The TPPT:

(18) Agreed to re-discuss the “Instructions to assist NPPOs and RPPOs in proper and complete submissions” in an e-forum.

6.4 Use of extrapolation to estimate phytosanitary treatment efficacy

A panel member introduced the paper\(^{21}\) and explained that historically the efficacy of some treatments had been calculated using extrapolation techniques such as probit analysis. While these techniques are

\(^{19}\) 09_TPPT_2015_Sep

\(^{20}\) 10_TPPT_2015_Sep
necessary when large numbers of the target pests are not able to be exposed to the treatment in confirmatory trials, extrapolations do add a degree of uncertainty to the treatment efficacy that may result in treatment failure or excessive damage to the treated commodity. The use of extrapolation to estimate treatment efficacy should be avoided where possible or undertaken with care when required.

[104] The TPPT reviewed and adjusted the paper slightly. There were no major comments.

[105] The TPPT:

(19) Agreed to the concepts that should be considered when using extrapolation to estimate phytosanitary treatment efficacy and modified the TPPT Working criteria\(^{18}\) accordingly (Appendix 5).

### 6.5 “Probit 9” and efficacy standards for phytosanitary treatments

[106] A panel member introduced the paper which had been reviewed by the TPPT during various e-forums\(^{22}\). There were no additional comments. This issue was considered by the TPPT to highlight the default utility of Probit 9 and that this in itself was not always particularly useful. Instead factors affecting pest survival and establishment such as the volume of trade, likely infestation levels, and levels of pest mortality during shipment and storage should be considered when requiring a particular level of efficacy.

[107] The TPPT:

(20) Agreed that Probit 9 was not always particularly useful and that other factors affecting pest survival and establishment should also be considered and modified the TPPT Working criteria\(^{20}\) accordingly (Appendix 6).

### 6.6 TPPT Working criteria for treatment evaluation

[108] The TPPT steward recalled the SC May 2015 had agreed to additions to the TPPT working criteria for treatment evaluation\(^{23}\) and summarized the changes stemming from the SC discussions.

[109] The panel noted the changes made by the SC May 2015 on the use of historical data and sought advice from the TPPT steward on how to proceed should such data be presented. The TPPT Steward noted that, if such data was submitted to support a proposed treatment, that the panel should assess such data against the requirements in ISPM 28.

### 6.7 Estimating treated pest numbers from control emergence

[110] A panel member introduced the papers\(^{24}\), noting that the paper arose out of concern for the derivation of the formula for calculating the average per treated pest numbers from control samples in the panels working criteria for evaluating submissions and the instructions to assist NPPOs and RPPOs in preparing submissions (see section 6.3).

[111] The panel briefly discussed this issue and the general principle of applying an adjustment to the estimate of treated pests when the estimate is based on the means of control data. The panel agreed that the paper provided a suitable derivation for the formula to assess control emergence, but that the use of the formula will need to be discussed further in an e-forum.

[112] Some TPPT members felt that these calculations were based on a very conservative view, noting that they did not find that treatment failure was necessarily due to lack of severity but possibly due to operational errors. The conservative approach would lead to low efficacy rates meaning that countries may (for instance) add a few extra days in their import requirements to ensure treatment success.

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\(^{21}\) 11\_TPPT\_2015\_Sep
\(^{22}\) 12\_TPPT\_2015\_Sep
\(^{23}\) 15\_TPPT\_2015\_Sep
\(^{24}\) 13\_TPPT\_2015\_Sep; 14\_TPPT\_2015\_Sep (serving as reference for document 13).
The TPPT:

(21) *Noted* the paper providing the derivation of the formula for estimating treated pests numbers from control emergence, and agreed to discuss in an e-forum the justification for using the formula for this purpose.

7. **Other business**

No other business was discussed.

8. **Follow-up Actions for next TPPT Meetings**

8.1 **Status of Phytosanitary Treatments (PTs) under the TPPT work programme**

The Secretariat introduced the paper outlining the various treatments on the TPPT work programme.

8.2 **Review of List of Topics**

The Secretariat introduced the treatments and standards currently on the *List of topics for IPPC standards* and proposed additional modifications.

The TPPT noted that the panel had suggested assigning assistant-stewards to the topics 2014-004, 2014-003, 2014-005, 2014-006 and 2014-007 in their May virtual 2015 meeting.

Mr Patrick GOMES informed the panel that he would retire in December 2015, but the panel did not wish to assign new leads for his areas of responsibility at this moment.

The TPPT:

(22) *Invited the SC to consider the proposed modifications to the List of topics for IPPC standards done in this meeting and in the May 2015 virtual meeting to the topics and subject on the TPPT work programme. (See also Section 4.1 on change of title of topic 2009-105, Vapour heat treatment for *Bactrocera melanotus* and *B. xanthodes* on *Carica papaya*).*

8.3 **TPPT Work plan 2015/2016**

The TPPT reviewed the work plan for 2015-2016 as developed in this meeting (Appendix 7).

For ease of reference, a list of action points arising from the meeting is attached as Appendix 8. TPPT member were reminded to check it for any deadlines before the next meeting.

The TPPT reconfirmed the pending status of the following treatments due to indication of *Ceratitis capitata* population response differences to cold and heat treatments:

- Vapour heat treatment for *Bactrocera dorsalis* on *Carica papaya* var. Solo (2009-109)
- Vapour heat treatment for *Ceratitis capitata* on *Mangifera indica* (2010-106)
- Cold treatment for *Ceratitis capitata* on *Citrus clementina* var. Clemenules (2010-102)
- Cold treatment for *Ceratitis capitata* on *Citrus sinensis* var Navel and Valencia (2010-103)
- Cold treatment for *Ceratitis capitata* on *Citrus sinensis* 2007-206A
- Cold treatment for *Ceratitis capitata* on *Citrus reticulata* x *C. sinensis* 2007-206B
- Cold treatment for *Ceratitis capitata* on *Citrus limon* 2007-206C
- Cold treatment for *Ceratitis capitata* on *Citrus paradisi* (2007-210)
- Cold treatment for *Ceratitis capitata* on *Citrus reticulata* cultivars and hybrids (2007-212).

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25 05_TPTT_2015_Sep
26 [Link to List of topics for IPPC standards](#)
27 05_TPTT_2015_Sep
The Secretariat highlighted that the agenda for the next face-to-face meeting will be very heavy with, possibly, nine draft PTs to review in relation to the responses on the fruit fly population issue, four draft PTs to review member comments for and four draft ISPMs to review.

The TPPT:

(23) Invited the SC to note that the following draft phytosanitary treatments are pending further research in relation to Ceratitis capitata population response differences to cold and heat treatments and change the status to “pending” on the List of topics for IPPC standards:
- Cold treatment for Ceratitis capitata on Citrus sinensis (2007-206A)
- Cold treatment for Ceratitis capitata on Citrus reticulata x C. sinensis (2007-206B)
- Cold treatment for Ceratitis capitata on Citrus limon (2007-206C)
- Cold treatment for Ceratitis capitata on Citrus paradisi (2007-210)
- Cold treatment for Ceratitis capitata on Citrus reticulata cultivars and hybrids (2007-212).
- Vapour heat treatment for Bactrocera dorsalis on Carica papaya var. Solo (2009-109)
- Cold treatment for Ceratitis capitata on Citrus clementina var. Clemenules (2010-102)
- Cold treatment for Ceratitis capitata on Citrus sinensis var Navel and Valencia (2010-103)
- Vapour heat treatment for Ceratitis capitata on Mangifera indica (2010-106)

(24) Invited the SC to note that for the draft treatments 2009-109, 2010-102, 2010-103 and 2010-106, which had been submitted to member consultation 2014, TPPT responses to member comments would be finalized only after receipt of the research mentioned in the decision above.

8.4 TPPT Medium-term work plan

The TPPT developed their Medium-term work plan for 2015-2019 following discussions in this meeting (Appendix 9).

The panel noted that the current nine draft PTs that are on hold pending research findings from the PTTEG (now PRMG) and IAEA may be ready for the TPPT to recommend to the SC for adoption in late 2016. The number of PTs on the TPPT work programme would be significantly reduced leaving resources for the panel to work on the draft ISPMs on Treatment Requirements and possible review additional treatments submission. The panel strongly supported a call for treatments.

The TPPT:

(25) Invited the SC to approve the TPPT medium term work plan 2015-2017 (Appendix 9).

(26) Invited the SC and Secretariat to consider opening a call for treatments in 2016.

9. Recommendations to the SC

The following summarizes the TPPT recommendations to the SC from this meeting.

- Agreed to forward ink amendments for the 19 currently adopted phytosanitary treatments to the SC November 2015 meeting for their consideration (Appendix 4).
- Agreed to submit the TPPT responses to the 2014 member consultation comments on the draft PT Bactrocera melanotus and B. xanthodes on Carica papaya (2009-105) for SC endorsement.
- Invited the SC to note the change in title of this draft PT to Vapour heat treatment for Bactrocera melanotus and B. xanthodes on Carica papaya (2009-105) in accordance with the conclusions reached under Section 5.1 of this report.
- Agreed to recommend the draft Vapour heat treatment for Bactrocera melanotus and B. xanthodes on Carica papaya (2009-105) as modified in this meeting to the SC for adoption by CPM.
- **Agreed to submit** the responses to the 2014 member consultation comments for draft Irradiation treatment for *Ostrinia nubilalis* (2012-009) for SC approval.

- **Agreed to recommend** the draft PT Irradiation treatment for *Ostrinia nubilalis* (2012-009) as modified in this meeting to the SC for adoption.

- **Invited SC** to change the status of the draft PT for *Ceratitis capitata* on *Citrus sinensis* var. Navel and Valencia-late (2010-103) to “pending” until further data on fruit fly population response differences to cold is available.

- **Invited the SC to note** that the following draft phytosanitary treatments are pending further research in relation to *Ceratitis capitata* population response differences to cold and heat treatments and change the status to “pending” on the List of topics for IPPC standards:
  - Cold treatment for *Ceratitis capitata* on *Citrus sinensis* (2007-206A)
  - Cold treatment for *Ceratitis capitata* x *C. sinensis* (2007-206B)
  - Cold treatment for *Ceratitis capitata* on *Citrus limon* (2007-206C)
  - Cold treatment for *Ceratitis capitata* on *Citrus paradisi* (2007-210)
  - Cold treatment for *Ceratitis capitata* on *Citrus reticulata* cultivars and hybrids (2007-212)
  - Vapour heat treatment for *Bactrocera dorsalis* on *Carica papaya* var. Solo (2009-109)
  - Cold treatment for *Ceratitis capitata* on *Citrus Clementina* var. Clemenules (2010-102)
  - Cold treatment for *Ceratitis capitata* on *Citrus sinensis* var Navel and Valencia (2010-103)
  - Vapour heat treatment for *Ceratitis capitata* on *Mangifera indica* (2010-106)

- **Invited the SC to note** that for the draft treatments 2009-109, 2010-102, 2010-103 and 2010-106, which had been submitted to member consultation 2014, TPPT responses to member comments would be finalized only after receipt of the research mentioned in the decision above.

- **Invited the SC to approve** the TPPT medium term work plan 2015-2017 (Appendix 9).

- **Invited the SC to consider** opening a call for treatments in 2016.

### 10. Close of the meeting

[128] The Secretariat informed the panel that the next TPPT meeting was tentatively scheduled from 29 August to 2 September 2016 to be held in Tokyo, Japan, and the panel was reminded to check the IPP calendar for updated information.  

[129] The Secretariat noted that an e-forum for the approval of the meeting report will be opened from 21 to 25 September (tentative dates). Additionally, the following virtual meetings were tentatively scheduled:

- 2 December 2015
- 3 March 2016
- 5 July 2016
- 26 October 2016.

[130] The Secretariat thanked the NPPO of Japan for their generous offer to host and provide financial support for the next meeting and for hosting and financially supporting this meeting, for the enlightening field trip, the reception and the excellent organization of the local arrangements. The Secretariat also thanked all the panel members for their essential contributions and gave special recognition to Mr Patrick GOMES (USA) for his role as chair and wished him farewell as this was his last meeting.

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28 Link to the IPPC Secretariat calendar on the IPP.
Lastly, the Secretariat invited the panel to respond to the electronic evaluation of the meeting by 11 September 2015.

The TPPT Steward thanked the panel members for their contributions and the contracting parties who provide the experts to this panel, recognizing not only the time needed to attend the meeting but also the time and efforts needed to prepare appropriately for it. Without the support from the national agencies, the experts would not have the possibility to contribute to developing international standards that have major impact on food security and international trade.

The Chairperson also extended his gratitude to Japan for hosting and supporting the meeting in Fukushima, providing for an opportunity to understand the mitigation of the nuclear disaster, and to the TPPT steward and Secretariat for their support during the meeting. The Chairperson closed the meeting.
## Appendix 1: Agenda

2015 Meeting of the Technical Panel on Phytosanitary Treatments

31 August – 4 September 2015

Fukushima, Japan

### AGENDA

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<td>3. Updates from Relevant Bodies</td>
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<td>2015 May TPPT Virtual Meeting Report 16_TPPT_2015_Sep</td>
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<td>3.2 Report on Phytosanitary Temperature Treatments Expert Group (PTTEG) meeting 2015-08</td>
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<td>4. Review of Member Consultation 2014 Comments on Draft Phytosanitary Treatments (PTs)</td>
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<td>4.1 Finalisation of TPPT Responses to Comments from Member Consultation 2014 on draft PT:</td>
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<td>Environmental &amp; implementation issues</td>
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<td>Presentation by Mr Dohino</td>
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<td>Effects of VHT with different heating rate on fruit fly mortality &amp; Effects of heating time and total treatment time of VHT on fruit fly mortality (research presentation from MAFF)</td>
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<td>4.2 Review of TPPT Responses to Comments from Member Consultation 2014 on draft PT:</td>
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29 The PTTEG meeting report once available will be posted at: https://www.ippc.int/en/liason/organizations/phytosanitarytemperaturerealtreatmentsexpertgroup/
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<th>AGENDA ITEM</th>
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| Irradiation treatment for *Ostrinia nubilalis* (2012-009)  
(Discussion specifically on selection of treatment dose) | 2012-009_Draft Treatment  
2012-009_Treatment Portfolio  
2012-009_Draft Responses to MC comments | SMYTH |
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<p>| 8.1 Status of Phytosanitary Treatments (PTs) under the TPPT work programme | 05_TPTT_2015_Sep | MOREIRA |</p>
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<td>8.3 TPPT Work Plan 2015/2016</td>
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<td>• Date and venue of the next TPPT meeting</td>
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<td>• Close</td>
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Appendix 2: Documents list

Documents List

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Appendix 3: Participants list

A check (✓) in column 1 indicates confirmed attendance at the meeting.

<table>
<thead>
<tr>
<th>Participant role</th>
<th>Name, mailing, address, telephone</th>
<th>Email address</th>
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</thead>
<tbody>
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<td>✓ Steward</td>
<td>Mr Jan Bart ROSSEL</td>
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<td></td>
<td>International Plant Health Program</td>
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<td></td>
<td>Office of the Australia Chief Plant Protection Officer</td>
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<td>Australian Department of Agriculture, 7 London Circuit, Canberra, ACT 2601</td>
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<td>Fax: +61 2 6272 5835</td>
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<td>N/A</td>
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<td>Mr Ezequiel FERRO</td>
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<td></td>
<td>Dirección Nacional de Protección Vegetal - SENASA</td>
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<td></td>
<td>Mr Patrick GOMES</td>
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<td></td>
<td>Fruit Fly Coordinator</td>
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<td><a href="mailto:G.Hallman@iaea.org">G.Hallman@iaea.org</a></td>
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<tr>
<td></td>
<td>Mr Guy HALLMAN</td>
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<td></td>
<td>Research Entomologist</td>
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<p>|                   | Member                          | <a href="mailto:Michael.Ormbsby@mpi.govt.nz">Michael.Ormbsby@mpi.govt.nz</a> | 2020 – 3rd Term |
|                   | Mr Michael ORMSBY              |               |             |
|                   | Senior Adviser, Plant Risk Analysis |           |             |
|                   | Ministry for Primary Industries |               |             |
|                   | P.O Box 2526, Wellington, 6011  |               |             |
|                   | NEW ZEALAND                     |               |             |
|                   | Tel: +64 4 8940486              |               |             |</p>
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<tbody>
<tr>
<td>✓ Member</td>
<td>Mr Eduardo WILLINK</td>
<td><a href="mailto:ewillink@eeaoc.org.ar">ewillink@eeaoc.org.ar</a> <a href="mailto:ewillink@arnet.com.ar">ewillink@arnet.com.ar</a></td>
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<td>Institute of Inspection Technology and Equipment Chinese Academy of Inspection and Quarantine No. 241 Huixinli, Chaoyang District, Beijing 100029 CHINA</td>
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<td>USDA APHIS Entomologist / Commodity Treatment Specialist 1398 W Truck Rd., Buzzards Bay, MA, USA</td>
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<td>Mr Matthew SMYTH</td>
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<tr>
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<tr>
<td>Host Representative</td>
<td>Mr Ichiro NAKAGAWA</td>
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<td>Organizer</td>
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Appendix 4: Summary of proposed ink amendments to Annexes to ISPM 28 (approved new wording to state efficacy)

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<td>Minimum absorbed dose of 70 Gy to prevent the emergence of adults of <em>Anastrepha ludens</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing third instar larvae that were identified as the most tolerant life stage.</td>
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<td><em>Efficacy and confidence level of the treatment is ED₉₉.₉₉₆₈ at the 95% confidence level.</em></td>
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<td>*There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9968% of adults of <em>Anastrepha ludens</em>.</td>
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<tr>
<td>PT2</td>
<td>Irradiation treatment for <em>Anastrepha obliqua</em></td>
<td>Minimum absorbed dose of 70 Gy to prevent the emergence of adults of <em>Anastrepha obliqua</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing third instar larvae that were identified as the most tolerant life stage.</td>
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<td><em>Efficacy and confidence level of the treatment is ED₉₉.₉₉₆₈ at the 95% confidence level.</em></td>
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<tr>
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<td>*There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9968% of adults of <em>Anastrepha obliqua</em>.</td>
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</tr>
<tr>
<td>PT3</td>
<td>Irradiation treatment for <em>Anastrepha serpentina</em></td>
<td>Minimum absorbed dose of 100 Gy to prevent the emergence of adults of <em>Anastrepha serpentina</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing third instar larvae that were identified as the most tolerant life stage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Efficacy and confidence level of the treatment is ED₉₉.₉₉₇₂ at the 95% confidence level.</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>*There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9972% of adults of <em>Anastrepha serpentina</em>.</td>
<td></td>
</tr>
<tr>
<td>PT4</td>
<td>Irradiation treatment for <em>Bactrocera jarvisi</em></td>
<td>Minimum absorbed dose of 100 Gy to prevent the emergence of adults of <em>Bactrocera jarvisi</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing 1-day old eggs and third instar larvae that were identified as the most tolerant life stages.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Efficacy and confidence level of the treatment is ED₉₉.₉₉₇₈ at the 95% confidence level.</em></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>*There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9981% of adults of <em>Bactrocera jarvisi</em>.</td>
<td></td>
</tr>
<tr>
<td>PT5</td>
<td>Irradiation treatment for <em>Bactrocera tryoni</em></td>
<td>Minimum absorbed dose of 100 Gy to prevent the emergence of adults of <em>Bactrocera tryoni</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing 1-day old eggs and third instar larvae that were identified as the most tolerant life stages.</td>
</tr>
<tr>
<td></td>
<td></td>
<td><em>Efficacy and confidence level of the treatment is ED₉₉.₉₉₇₈ at the 95% confidence level.</em></td>
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<tr>
<td></td>
<td></td>
<td>*There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9978% of adults of <em>Bactrocera tryoni</em>.</td>
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</tr>
<tr>
<td>PT#</td>
<td>PT Title</td>
<td>Changes in the treatment schedule</td>
<td>Rational for ink amendment to reflect end-point</td>
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<tr>
<td>PT6</td>
<td>Irradiation treatment for Cydia pomonella</td>
<td>Minimum absorbed dose of 200 Gy to prevent the emergence of adults of <em>Cydia pomonella</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing fifth instar larvae that were identified as the most tolerant life stage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy and confidence level of the treatment is ED&lt;sub&gt;99.9978&lt;/sub&gt; at the 95% confidence level.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9978% of adults of <em>Cydia pomonella</em>.</td>
<td></td>
</tr>
<tr>
<td>PT7</td>
<td>Irradiation treatment for fruit flies of the family Tephritidae (generic)</td>
<td>Minimum absorbed dose of 150 Gy to prevent the emergence of adults of fruit flies.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing the most tolerant life stage of a number of economically important species in the Tephritidae.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy and confidence level of the treatment is ED&lt;sub&gt;99.9968&lt;/sub&gt; at the 95% confidence level.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9968% of adult fruit flies.</td>
<td></td>
</tr>
<tr>
<td>PT8</td>
<td>Irradiation treatment for Rhagoletis pomonella</td>
<td>Minimum absorbed dose of 60 Gy to prevent the development of phanerocephalic pupae of <em>Rhagoletis pomonella</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented the formation of the phanerocephalic pupa in fruit that were treated containing third instar larvae that were identified as the most tolerant life stage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy and confidence level of the treatment is ED&lt;sub&gt;99.9921&lt;/sub&gt; at the 95% confidence level.</td>
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<tr>
<td></td>
<td></td>
<td>There is 95% confidence that the treatment according to this schedule prevents the development of not less than 99.9921% of phanerocephalic pupae of <em>Rhagoletis pomonella</em>.</td>
<td></td>
</tr>
<tr>
<td>PT9</td>
<td>Irradiation treatment for Conotrachelus nenuphar</td>
<td>Minimum absorbed dose of 92 Gy to prevent the reproduction in adults of <em>Conotrachelus nenuphar</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented successful reproduction (development of F1 beyond the first instar) in treated adults that were identified as the most tolerant life stage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy and confidence level of the treatment is ED&lt;sub&gt;99.8800&lt;/sub&gt; at the 95% confidence level.</td>
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<tr>
<td></td>
<td></td>
<td>There is 95% confidence that the treatment according to this schedule prevents the reproduction in not less than 99.9880% of adults of <em>Conotrachelus nenuphar</em>.</td>
<td></td>
</tr>
<tr>
<td>PT10</td>
<td>Irradiation treatment for Grapholita molesta</td>
<td>Minimum absorbed dose of 232 Gy to prevent the emergence of adults of <em>Grapholita molesta</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing fifth instar larvae that were identified as the most tolerant life stage.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Efficacy and confidence level of the treatment is ED&lt;sub&gt;99.9494&lt;/sub&gt; at the 95% confidence level.</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9494% of adults of <em>Grapholita molesta</em>.</td>
<td></td>
</tr>
<tr>
<td>PT#</td>
<td>PT Title</td>
<td>Changes in the treatment schedule</td>
<td>Rational for ink amendment to reflect end-point</td>
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</table>
| PT11 | Irradiation treatment for *Grapholita molesta* under hypoxia | Minimum absorbed dose of 232 Gy to prevent oviposition of *Grapholita molesta*.  
Efficacy and confidence level of the treatment is ED\(99.9932\) at the 95% confidence level.  
There is 95% confidence that the treatment according to this schedule prevents oviposition of not less than 99.9932% of *Grapholita molesta*. | The confirmatory trials demonstrated that the stated dose prevented egg laying (oviposition) in adults that emerged from the fruit that were treated containing fifth instar larvae that were identified as the most tolerant life stage. |
| PT12 | Irradiation treatment for *Cylas formicarius elegantulus* | Minimum absorbed dose of 165 Gy to prevent the development of F1 adults of *Cylas formicarius elegantulus*.  
Efficacy and confidence level of the treatment is ED\(99.9952\) at the 95% confidence level.  
There is 95% confidence that the treatment according to this schedule prevents the development of not less than 99.9952% of F1 adults of *Cylas formicarius elegantulus*. | The confirmatory trials demonstrated that the stated dose prevented F1 adult production from eggs laid by treated adults that were identified as the most tolerant life stage. |
| PT13 | Irradiation treatment for *Euscepes postfasciatus* | Minimum absorbed dose of 150 Gy to prevent the development of F1 adults of *Euscepes postfasciatus*.  
Efficacy and confidence level of the treatment is ED\(99.9950\) at the 95% confidence level.  
There is 95% confidence that the treatment according to this schedule prevents the development of not less than 99.9950% of F1 adults of *Euscepes postfasciatus*. | The confirmatory trials demonstrated that the stated dose prevented F1 adult production from eggs laid by treated adults that were identified as the most tolerant life stage. |
| PT14 | Irradiation treatment for *Ceratitis capitata* | Minimum absorbed dose of 100 Gy to prevent the emergence of adults of *Ceratitis capitata*.  
Efficacy and confidence level of the treatment is ED\(99.9970\) at the 95% confidence level.  
There is 95% confidence that the treatment according to this schedule prevents emergence of not less than 99.9970% of adults of *Ceratitis capitata*. | The confirmatory trials demonstrated that the stated dose prevented adult emergence from the fruit that were treated containing third instar larvae that were identified as the most tolerant life stage. |
<table>
<thead>
<tr>
<th>PT#</th>
<th>PT Title</th>
<th>Changes in the treatment schedule</th>
<th>Rational for ink amendment to reflect end-point</th>
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</thead>
</table>
| PT15 | Vapour heat treatment for *Bactrocera cucurbitae* on *Cucumis melo* var. *reticulatus* | [Scope of the treatment  
This treatment comprises the vapour heat treatment of *Cucumis melo* var. *reticulatus* (netted melon) fruit to result in the mortality of eggs and larvae of melon fly (*Bactrocera cucurbitae*) at the stated efficacy.]  
**Treatment schedule**  
The efficacy and confidence level of the treatment is effective dose (ED)\(_{99.9889}\) at the 95% confidence level.  
There is 95% confidence that the treatment according to this schedule kills not less than 99.9889% of eggs and larvae of *Bactrocera cucurbitae*.  
| The confirmatory trials demonstrated that the stated dose killed the treated eggs and third instar larvae that were identified as the most tolerant life stages. |
| PT16 | Cold treatment for *Bactrocera tryoni* on *Citrus sinensis* | [Scope of the treatment  
This treatment comprises the cold treatment of fruit of *Citrus sinensis* (orange) to result in the mortality of eggs and larvae of *Bactrocera tryoni* (Queensland fruit fly) at the stated efficacy.]  
**Treatment schedule**  
For cultivar “Navel”, the efficacy is effective dose (ED)\(_{99.9981}\) at the 95% confidence level.  
For cultivar “Valencia”, the efficacy is ED\(_{99.9973}\) at the 95% confidence level.  
For cultivar “Navel”, there is 95% confidence that the treatment according to this schedule kills not less than 99.9981% of eggs and larvae of *Bactrocera tryoni*.  
For cultivar “Valencia”, there is 95% confidence that the treatment according to this schedule kills not less than 99.9973% of eggs and larvae of *Bactrocera tryoni*.  
<p>| The confirmatory trials demonstrated that the stated dose killed the treated first instar larvae that were identified as the most tolerant life stage. |</p>
<table>
<thead>
<tr>
<th>PT#</th>
<th>PT Title</th>
<th>Changes in the treatment schedule</th>
<th>Rational for ink amendment to reflect end-point</th>
</tr>
</thead>
</table>
| PT17| Cold treatment for *Bactrocera tryoni* on *Citrus reticulata × Citrus sinensis* | **[Scope of the treatment]**  
This treatment comprises the cold treatment of fruit of *Citrus reticulata × Citrus sinensis* (tanger) to result in the mortality of eggs and larvae of *Bactrocera tryoni* (Queensland fruit fly) at the stated efficacy.  

**Treatment schedule**  
*The efficacy is effective dose (ED)_{99.9986} at the 95% confidence level.*  
*There is 95% confidence that the treatment according to this schedule kills not less than 99.9986% of eggs and larvae of *Bactrocera tryoni*.* | **The confirmatory trials demonstrated that the stated dose killed the treated first instar larvae that were identified as the most tolerant life stage.** |
| PT18| Cold treatment for *Bactrocera tryoni* on *Citrus limon* | **[Scope of the treatment]**  
This treatment applies to the cold treatment of fruit of *Citrus limon* (lemon) to result in the mortality of eggs and larvae of *Bactrocera tryoni* (Queensland fruit fly) at the stated efficacy.  

**Treatment schedule**  
*Schedule 1: 2 °C or below for 14 continuous days*  
*The efficacy is effective dose (ED)_{99.99} at the 95% confidence level.*  
*There is 95% confidence that the treatment according to this schedule kills not less than 99.99% of eggs and larvae of *Bactrocera tryoni*.*  
*Schedule 2: 3 °C or below for 14 continuous days*  
*The efficacy is ED_{99.9872} at the 95% confidence level.*  
*There is 95% confidence that the treatment according to this schedule kills not less than 99.9872% of eggs and larvae of *Bactrocera tryoni*.* | **The confirmatory trials demonstrated that the stated dose killed the treated first instar larvae that were identified as the most tolerant life stage.** |
<table>
<thead>
<tr>
<th>PT#</th>
<th>PT Title</th>
<th>Changes in the treatment schedule</th>
<th>Rational for ink amendment to reflect end-point</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT19</td>
<td>Irradiation treatment for <em>Dysmicoccus neobrevipes</em>, <em>Planococcus lilacinus</em> and <em>Planococcus minor</em></td>
<td>Minimum absorbed dose of 231 Gy to prevent the reproduction of adult females of <em>Dysmicoccus neobrevipes</em>, <em>Planococcus lilacinus</em> and <em>Planococcus minor</em>. Efficacy and confidence level of the treatment is (ED_{99.99023}) at the 95% confidence level. There is 95% confidence that the treatment according to this schedule prevents the reproduction of not less than 99.99023% of adult females of <em>Dysmicoccus neobrevipes</em>, <em>Planococcus lilacinus</em> and <em>Planococcus minor</em>.</td>
<td>The confirmatory trials demonstrated that the stated dose prevented F1 larval development from eggs laid by treated female adults that were identified as the most tolerant life stage.</td>
</tr>
</tbody>
</table>
Appendix 5: Use of Extrapolation to Estimate Treatment Efficacy

Use of Extrapolation to Estimate Phytosanitary Treatment Efficacy

[1] ISPM 28. (Phytosanitary treatments for regulated pests) requires that where possible the level of efficacy of a phytosanitary treatment be indicated and quantified or expressed statistically. Where experimental data are insufficient, other evidence supporting efficacy (i.e., historical experience) should be provided. Furthermore, it should be documented that the efficacy data were generated using appropriate scientific procedures, including where relevant an appropriate experimental design. The data supporting the treatment should be verifiable, reproducible, and based on statistical methods and/or on established and accepted international practice.

[2] The efficacy of a phytosanitary treatment can be determined by exposing large numbers of the most tolerant stage of the pest infesting the commodity to the treatment with the target dose extrapolated from the dose-response relationship. Treatments are often approved by national plant protection organizations of importing countries based on treatment efficacy when large numbers of pests in the most tolerant stage are treated with none or acceptably few reaching the defined survival threshold.

[3] Extrapolation has been used to estimate the dose that will provide a high level of treatment efficacy, >99.9%, and sometimes up to 99.9968% (“probit 9”), from dose-response models. Extrapolation in a statistical sense is estimation outside of the observed range, including observations within the observed range but with insufficient sample size; e.g., a sample size of 200 individuals is inadequate to serve as an observation at treatment levels that provide >99.9% control.

[4] Box and Draper (1987) famously wrote, “Essentially, all models are wrong, but some are useful.” They clarified that the practical question is how wrong they can be while still being useful. Regression analyses (most often probit analysis) are often used to analyze dose-response data and estimate doses to achieve specific levels of response. However, these dose estimates are typically in the 50% range in order to compare treatments and options, and in that range they are quite useful. These models may be not well suited to estimate extreme levels of response such as those demanded of phytosanitary treatments, and it is open to inquiry how useful it might be for this purpose. It is not so much that a more useful model might exist and should be sought but whether what is being asked of any such model might be feasible.

[5] A variety of statistical methods have been used for extrapolating phytosanitary treatment doses, such as probit analysis, other forms of regression analysis, and kinetic models. Markov chain Monte Carlo has been used, but in biology it is mainly used for computational biology, the degree of complexity of which has not been available at the same level for research into phytosanitary treatments. Probit analysis is often suggested as the preferred model for biological assay of insects. Although different probability density functions (normal, logit, Gompertz) give largely the same estimates for most of the dose-response curve, where they differ is precisely where it is important for phytosanitary treatments: at the extremes.

[6] Schortemeyer et al. (2011) reviewed many papers on phytosanitary treatment development for fresh fruits and vegetables and concluded that extrapolations based on dose-response analyses from these studies do not “generally lead to confidence in the outcomes”. They concluded that “the analysis of carefully designed dose-response experiments may be used to” extrapolate to appropriate treatment doses. Their suggestions for careful experiments that would be more successful than research they reviewed can be insinuated from problems that they identify in published studies estimating mortality, which are lack of:

(1) preliminary studies to indicate doses “necessary to achieve interpretable results”
(2) transparency is selection of numbers and levels of treatment and sample size
(3) correction for mortality in the untreated controls
(4) information on model selection or fit of data to the model
(5) role of confidence limits in dose extrapolation
(6) discussion on how far results can be meaningfully extrapolated

[7] However, many of the studies Schortemeyer et al. (2011) found lacking did, indeed, address the criticisms that they levelled, so it is not readily evident where general improvements could be made that would yield more confident extrapolations.

[8] West and Hallman (2013) examined 11 dose-response studies coupled with large-scale tests where a few survivors occurred to use those data points to compare the accuracy of different analyses in extrapolating to high-levels of control (Table 1). Large-scale studies with a few survivors are especially useful for studying the accuracy of extrapolations because the lack of 100% efficacy avoids the uncertainty of overkill associated with large-scale testing when there are no survivors. Also, it provides an estimate of accuracy that is independent of statistical fit of the data to a model; i.e., accuracy of extrapolation need not be dependent on fit to model.

[9] One pertinent observation from Table 1 is that discrepancy from the closest model extrapolation varied from -18 to +48%, which may be excessive error for supporting extrapolation of doses required for phytosanitary treatments to fresh commodities, which often have narrow tolerance ranges above doses required for efficacy. In any case, from a phytosanitary perspective over-treating is an acceptable error, because although it may result in unnecessary expense and increase the risk of damage to the commodity it would provide quarantine security, while under-treating may not. The least-close extrapolations in Table 1 had, of course, greater discrepancies. Also, no one model best predicted extrapolated doses, indicating that it might be difficult to recommend one model to support extrapolation. Of course, the studies examined might not be ideally designed for purposes of extrapolation and perhaps better experimental designs can be devised. Non-perishable commodities, such as wooden pallets and durable goods, may very well tolerate treatment severities in excess of the minimum needed to control quarantine pests, and in these cases upper range dose estimates of extrapolations may be applied as phytosanitary treatments.

[10] Unfortunately dose-response analyses might not accurately point to a confirmatory dose that should be tried and researchers are urged to pick a confirmatory dose that will result in the least severe treatment feasible taking into consideration possible detrimental effects to the commodity, the difficulty and cost of conducting the confirmatory testing, and the level of urgent need for the treatment. Detailed knowledge of the phytosanitary situation including pest and commodity reactions to the treatment, logistics of commercial application, and ramifications of overtreatment will help guide dose selection in confirmatory testing. It is also worth noting that the result of dose-response analysis should provide a high level of confidence (e.g. 95%) that the treatment will achieve the required level of protection represented by the upper dose confidence level.

References cited:
Table 1. Dose extrapolation, best-fitting model, and Pearson $X^2$ from large-scale studies that resulted in a very small percentage survival (West & Hallman, 2013)

<table>
<thead>
<tr>
<th>Dose tested</th>
<th>Observed control (%)</th>
<th>Model that fit best*</th>
<th>Dose extrapolated</th>
<th>% discrepancy</th>
<th>Pearson $X^2$</th>
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</thead>
<tbody>
<tr>
<td>65 min</td>
<td>99.9973</td>
<td>Skewed logit</td>
<td>44 min</td>
<td>+48</td>
<td>0.0</td>
</tr>
<tr>
<td>22 d</td>
<td>99.9921</td>
<td>Skewed logit</td>
<td>21 d</td>
<td>+4.8</td>
<td>4.1</td>
</tr>
<tr>
<td>14 d</td>
<td>99.9990</td>
<td>Skewed logit</td>
<td>17 d</td>
<td>-18</td>
<td>3.5</td>
</tr>
<tr>
<td>12 wk</td>
<td>99.9940</td>
<td>Probit</td>
<td>11 wk</td>
<td>+9.1</td>
<td>3.0</td>
</tr>
<tr>
<td>49 d</td>
<td>99.9993</td>
<td>Logit</td>
<td>11 d</td>
<td>-18</td>
<td>19</td>
</tr>
<tr>
<td>12 d</td>
<td>99.9991</td>
<td>Gompertz</td>
<td>13 d</td>
<td>-7.7</td>
<td>46</td>
</tr>
<tr>
<td>30 min</td>
<td>99.9994</td>
<td>Logit</td>
<td>32 min</td>
<td>-6.3</td>
<td>15</td>
</tr>
<tr>
<td>7 d</td>
<td>99.9994</td>
<td>Logit</td>
<td>6 d</td>
<td>+17</td>
<td>7.0</td>
</tr>
<tr>
<td>20 min</td>
<td>99.9988</td>
<td>Skewed logit</td>
<td>16 min</td>
<td>+25</td>
<td>8.2</td>
</tr>
<tr>
<td>14 d</td>
<td>99.9999</td>
<td>Skewed logit</td>
<td>17 d</td>
<td>-18</td>
<td>3.5</td>
</tr>
<tr>
<td>40 g/m$^2$</td>
<td>99.9990</td>
<td>Gompertz</td>
<td>38 g/m$^2$</td>
<td>+5.3</td>
<td>8.3</td>
</tr>
</tbody>
</table>

*The following models were tested: probit, logit, skewed logit, Gompertz
Appendix 6: Probit 9 and Efficacy Standards for Phytosanitary Treatments

“Probit 9” and Efficacy Standards for Phytosanitary Treatments

[11] Phytosanitary measures must assure a level of security appropriate to preventing invasive species from becoming established in new areas. The level of security of phytosanitary treatments has often been set at the irrational number ≈99.99683% since 1939. This number is “probit 9” and was chosen from a then newly developed statistical model, probit analysis, designed for transforming data from a normal, sigmoid distribution into a straight line for ease of analysis in the pre-computer age. The idea is to “stretch” both tails of the normal, bell-shaped curve until they become straight. In this scheme probits (from “probability units”) 5, 6, 7, 8, 9, 10, and 11 when expressed as percentages are 50, ≈84.14, ≈97.72, ≈99.86, ≈99.997, ≈99.99997, and ≈99.9999999 %, respectively.

[12] It is not clear how Probit 9 became a de-facto efficacy standard for many phytosanitary treatments. Landolt et al. (1984) find no reason for setting the efficacy level at probit 9 or even why mortality is used as the criterion for phytosanitary treatments (except for irradiation) instead of other criteria that would closer reflect biological reality. For example, they state that in an unpublished 1938 document confirmatory testing was decided at no survivors of 10,000 insects tested, but was later raised to probit 9 and requiring 75-100 thousand or more insects treated in a subsequent unpublished document with no reasons given for either decision.

[13] Robertson et al. (1994) bemoan the fact that the probit 9 requirement, including attending assumptions of, a) complete mortality as the measurement of efficacy, and b) fit to the probit model, has undergone no revision since it was first codified in 1939 despite substantial progress in understanding pest risk potential.

[14] Authors such as Landolt et al. (1984), Baker et al. (1990), Vail et al. (1993), and Mangan et al. (1997) have argued that treatment efficacy decisions should be based on the remaining level of phytosanitary risk of the entire production system not the level of mortality achieved of the phytosanitary treatment. That proposal presents a challenge for treatments designed to be geographically broadly applicable such as those adopted by the IPPC because the level of risk may vary considerably among prospective exporting areas. For example, Mangan et al. (1997) estimate that even a phytosanitary treatment at the probit 9 level might be insufficient to prevent a mating pair of Mexican fruit fly, Anastrepha ludens, from entering the US via shipments of fruit from Mexico.

[15] The possibility that probit 9 level security for phytosanitary treatments would be insufficient to prevent infestation from invasive species gives pause to attempts to lower the efficacy requirement for treatments that apply over broad geographic areas that may include some that are highly infested with quarantine pests. Therefore, studies that show support for requiring such a high level of efficacy deserve further scrutiny. In Mangan et al. (1997), the percentage of A. ludens infested grapefruit picked off trees during the entire harvest period in orchards in Tamaulipas, Mexico, in two years was as high as 6.5% (mean puparia/infested fruit = 5.0), and it was estimated that in 4 of 9 instances a probit 9 level treatment would be insufficient to prevent the survival of two insects to the puparial stage using the maximum pest limit equations developed by Baker et al. (1990). Fruit lot size for these calculations was one truck load of 120,000 grapefruit. Furthermore, many other pests, such as mites, thrips, and mealybugs, may occur in large numbers in harvested fresh commodities and thus not be controlled to the required level of security by a probit 9 treatment.

[16] Data from Mangan et al. (1997) highlight the fact that commodities such as fresh fruits cannot be infested to levels of > 3 % before there is an unacceptable risk of pest establishment after a probit 9-level treatment. Likewise Baker et al. (1990) calculate that infestations not greater than 0.4 % may be required under some scenarios to assure quarantine security after a probit 9 level treatment. Therefore, phytosanitary treatments designed for broad application should not be “stand-alone” but be supported
by pre-treatment infestation limits. National plant protection organizations from importing countries may also require pre-harvest controls to reduce infestation levels.

[17] Caveats for the paper by Mangan et al. (1997) are that only survival to the puparial stage is used with many steps to go before an invasive species would be at risk of establishment; therefore, the risk of establishment seems higher than it actually is. It also assumes that both puparia would result in a sexual pair of adults that would end up together after the load of 120,000 grapefruits was distributed. Furthermore, it assumes that the distribution models accurately predict survival, which may have a low level of accuracy at the extreme level of security demanded of phytosanitary treatments. However, model accuracy could go either way; i.e., be less than reality or more. Also on the side of caution the data used probably underestimated infestation levels, as sampling techniques for fruit flies and likewise other pests miss some of them (Gould 1995).

[18] Regardless, the levels of infestation considered by Mangan et al. (1997) that resulted in post-treatment risk of survival greater than those normally considered acceptable for fresh commodities and tephritids and should not be considered normal for international trade, although they sometimes do occur (APHIS 2002). The TPPT concludes that phytosanitary treatment schedules should not be designed for worst-case scenarios that may be imagined, but scenarios of reasonably high risk. Furthermore, members are advised that phytosanitary treatments might not be sufficiently efficacious under all trading situations such as where infestation levels or volumes of trade are high, nor should exporters trade highly infested fresh commodities.

[19] A more pertinent question for treatment research is whether confirmatory testing at the probit 9 level with a standard confidence level of 95%, which requires that ~93,600 insects be treated with no survivors yields a more useful level of confidence than testing only 30,000 insects as is approved by an APPPC (2004) Standard. A probit 9 requirement results in an increase in confidence of 0.0068% compared with 30,000 insects treated with a cost of treatment research that is more than tripled. Although the difference in efficacy seems slight the difference in treatment severity could be significant. For example, Hallman and Martinez (2001) found that an irradiation dose to prevent adult emergence of 3rd instar A. ludens in grapefruit that satisfied 30,000 insects treated was 17 % less than the dose required for probit 9.

[20] The TPPT does not recommend any specific level of efficacy but encourages members to take into account factors that affect the risk of quarantine pests occurring in and surviving shipments, such as infestation levels, volumes traded, and other factors affecting survival and establishment, as is discussed by previous authors (Landolt et al. 1984; Baker et al. 1990, Vail et al. 1993, Mangan et al. 1997). Additionally, the TPPT does not propose to change the way efficacy is measured (mortality except for irradiation treatments) or recommend specific models for analysis of data.

References Cited


## Appendix 7: Technical Panel on Phytosanitary Treatments (TPPT) 2015-2016 work plan

### 2015-2016 Phytosanitary treatments (PTs) and draft ISPMs on “Treatment requirements” overall management

**Goals:**

a) Track, manage and ensure high quality PTs and draft ISPMs

b) Overall management of 15 draft PTs and 5 draft ISPMs

### Action 1. Draft PTs for recommendation to the Standards Committee (SC) for adoption

**Goal:** To ensure a transparent and inclusive process for the adoption of draft PTs

<table>
<thead>
<tr>
<th>Year</th>
<th>Responsible</th>
<th>Deadline to revise the draft</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td></td>
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<tr>
<td>2016</td>
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</tbody>
</table>
### Action 2: Consultation Period on draft ISPMs

**Goal:** To ensure a transparent and inclusive process for the development of high quality PTs

<table>
<thead>
<tr>
<th>Year</th>
<th>Notes</th>
<th>Responsible</th>
<th>Deadline to revise the draft</th>
<th>Tentative: Recommendation to SC for adoption by CPM-12 (2017)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>Draft ISPM on Requirements for the use of temperature treatments as a phytosanitary measure (2014-005)</td>
<td>WILLINK</td>
<td>a) 23 November 2015 (For TPPT virtual meeting) b) 01 February 2016 (For SC May 2016)</td>
<td>Tentative: Recommendation to SC for adoption in 2018</td>
</tr>
</tbody>
</table>
### Action 3: 2016 TPPT meeting (face to face meeting) tentative date: 29 August – 02 September 2016, Tokyo, Japan

**Goal:** Discuss deeply the technical content of draft PTs and draft ISPMs, TPPT working procedures, as well as challenges and strengthens of the panel and review the TPPT work programme.

- Draft PTs and draft ISPMs (+ responses to consultation comments and formal objections) to the meeting are due on 22 July 2016
- Draft papers to the meeting are due on 01 August 2016

### Draft PTs (annexes to ISPM 28) and responses to consultation comments

<table>
<thead>
<tr>
<th>Description</th>
<th>Responsible</th>
<th>Deadline to revise the draft</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sulfuryl fluoride fumigation of insects in debarked wood (2007-101A)</td>
<td>ORMSBY</td>
<td>15 February 2016</td>
<td>Possible TPPT e-decision / Virtual meeting</td>
</tr>
<tr>
<td>2. Sulfuryl fluoride fumigation of nematodes and insects in debarked wood (2007-101B)</td>
<td>ORMSBY</td>
<td>15 February 2016</td>
<td>Possible TPPT e-decision / Virtual meeting</td>
</tr>
<tr>
<td>3. Heat treatment of wood using dielectric heating (2007-114)</td>
<td>ORMSBY</td>
<td>15 February 2016</td>
<td>Possible TPPT e-decision / Virtual meeting</td>
</tr>
<tr>
<td>4. Vapour heat treatment for <em>Bactrocera tryoni</em> on <em>Mangifera indica</em> (2010-107)</td>
<td>HALLMAN</td>
<td>15 February 2016</td>
<td>Possible TPPT e-decision / Virtual meeting</td>
</tr>
</tbody>
</table>

### Draft PTs (and responses to formal objections received) pending further research in relation to *Ceratitis capitata* population response differences to cold and heat treatments

<table>
<thead>
<tr>
<th>Description</th>
<th>Responsible</th>
<th>Deadline to revise the draft</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus sinensis</em> (2007-206A)</td>
<td>WILLINK</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>6. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus reticulata</em> x <em>C. sinensis</em> (2007-206B)</td>
<td>GOMES</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>7. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus limon</em> (2007-206C)</td>
<td>WANG</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>8. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus paradisi</em> (2007-210)</td>
<td>GOMES</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>9. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus reticulata</em> cultivars and hybrids (2007-212)</td>
<td>ORMSBY</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>10. Vapour heat treatment for <em>Bactrocera dorsalis</em> on <em>Carica papaya</em> var. Solo (2009-109)</td>
<td>HALLMAN</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>11. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus clementina</em> var. Clemenules (2010-102)</td>
<td>HALLMAN</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>12. Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus sinensis</em> var Navel and Valencia (2010-103)</td>
<td>BOWMAN</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
<tr>
<td>13. Vapour heat treatment for <em>Ceratitis capitata</em> on <em>Mangifera indica</em> (2010-106)</td>
<td>HALLMAN</td>
<td>22 July 2016</td>
<td>-</td>
</tr>
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</table>

### Draft ISPMs

<table>
<thead>
<tr>
<th>Description</th>
<th>Responsible</th>
<th>Deadline to revise the draft</th>
<th>Notes</th>
</tr>
</thead>
</table>
### Action 3: 2016 TPPT meeting (face to face meeting) tentative date: 29 August – 02 September 2016, Tokyo, Japan

**Goal:** Discuss deeply the technical content of draft PTs and draft ISPMs, TPPT working procedures, as well as challenges and strengthens of the panel and review the TPPT work programme.

Appendix 8: Action points arising from the TPPT September 2015 meeting

<table>
<thead>
<tr>
<th>Action</th>
<th>Agenda Item</th>
<th>Responsible</th>
<th>Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. The TPPT agreed to forward ink amendments (to describe the level of efficacy achieved by a treatment schedule instead of using “effective dose” or “ED”) for the 19 currently adopted phytosanitary treatments to the SC November 2015 meeting for their consideration.</td>
<td>3.1 Secretariat</td>
<td>Next SC meeting</td>
<td></td>
</tr>
<tr>
<td>2. Draft PT “High temperature forced air treatment for <em>Bactrocera melanotus</em> and <em>B. xanthodes</em> on <em>Carica papaya</em> (2009-105)”: The TPPT agreed to submit the TPPT responses to the 2014 member consultation comments for SC endorsement, invited the SC to note the change in title of this draft PT to “Vapour heat treatment for <em>Bactrocera melanotus</em> and <em>B. xanthodes</em> on <em>Carica papaya</em> (2009-105)” and finally recommended the draft PT to the SC for adoption by CPM.</td>
<td>4.1 Secretariat</td>
<td>Next SC meeting</td>
<td></td>
</tr>
<tr>
<td>3. Draft PT “High temperature forced air treatment for <em>Bactrocera melanotus</em> and <em>B. xanthodes</em> on <em>Carica papaya</em> (2009-105)”: Treatment lead and assistant to send revised version of the responses to member comments and the draft PT, as agreed by the TPPT, back to Secretariat.</td>
<td>4.1 Treatment lead (YU)</td>
<td>14 September 2015</td>
<td></td>
</tr>
<tr>
<td>4. Asked the Secretariat to forward the translation comments received during the 2014 member consultation period on the draft PT for “High temperature forced air treatment for <em>Bactrocera melanotus</em> and <em>B. xanthodes</em> on <em>Carica papaya</em> (2009-105)” to FAO translation and the editing comments to the Secretariat editor.</td>
<td>4.1 Secretariat</td>
<td>Before next SC meeting</td>
<td></td>
</tr>
<tr>
<td>5. Draft PT for “Irradiation treatment for <em>Ostrinia nubilalis</em> (2012-009)”: The TPPT agreed to submit the TPPT responses to the 2014 member consultation comments for SC endorsement and agreed to recommend the draft PT to the SC for adoption by CPM.</td>
<td>4.2 Secretariat</td>
<td>Next SC meeting</td>
<td></td>
</tr>
<tr>
<td>6. Draft PT “Irradiation treatment for <em>Ostrinia nubilalis</em> (2012-009)”: Treatment lead and assistant to send revised version of the responses to member comments and the draft PT, as agreed by the TPPT, back to Secretariat.</td>
<td>4.2 Treatment lead (SMYTH)</td>
<td>14 September 2015</td>
<td></td>
</tr>
<tr>
<td>7. Asked the Secretariat to forward the translation comments received during the 2014 member consultation period on the draft PT for “Irradiation treatment for <em>Ostrinia nubilalis</em> (2012-009)” to FAO translation and the editing comments to the Secretariat editor.</td>
<td>4.2 Secretariat</td>
<td>Before next SC meeting</td>
<td></td>
</tr>
<tr>
<td>8. TPPT members were invited to provide comments and suggestions on the draft ISPM “Requirements for the use of temperature treatments as a phytosanitary measure (2014-005)” to the Steward and Assistant-steward.</td>
<td>5.1 TPPT members</td>
<td>18 September 2015</td>
<td></td>
</tr>
<tr>
<td>9. The TPPT agreed that the Steward would work with the Assistant-steward to prepare a revised draft ISPM “Requirements for the use of temperature treatments as a phytosanitary measure (2014-005)” to be discussed in a virtual TPPT meeting planned for December 2015 with the purpose of finalizing the draft for submission to the SC May 2016 meeting.</td>
<td>5.1 Steward and Assistant-steward (WILLINK / BOWMAN)</td>
<td>23 November 2015</td>
<td></td>
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<tr>
<td>Action</td>
<td>Agenda Item</td>
<td>Responsible</td>
<td>Deadline</td>
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<tr>
<td>10. Stewards to work closely with the Assistant-stewards, and send the revised version back to the Secretariat, on the following draft ISPMs:</td>
<td>5.2, 5.3, 5.4, 5.5</td>
<td>Stewards and Assistant-stewards (Stewards: WANG/HALLMAN/ MYERS/ORMSBY)</td>
<td>01 February 2016</td>
</tr>
<tr>
<td>- Requirements for the use of fumigation as a phytosanitary measure (2014-004)</td>
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<tr>
<td>- Requirements for the use of irradiation as a phytosanitary measure (Revision to ISPM 18) (2014-007)</td>
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<tr>
<td>- Requirements for the use of modified atmosphere treatments as a phytosanitary measure (2014-006)</td>
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<tr>
<td>- Requirements for the use of chemical treatments as a phytosanitary measure (2014-003)</td>
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<tr>
<td>11. The TPPT agreed to invite the SC to change the status of the draft PT for <em>Ceratitis capitata</em> on <em>Citrus sinensis</em> var. Navel and Valencia (2010-103) to “pending” until further data on fruit fly population response differences to cold is available</td>
<td>6.1</td>
<td>Secretariat</td>
<td>Next SC meeting</td>
</tr>
<tr>
<td>12. The TPPT agreed to review the responses to member comments of the draft PT for <em>Ceratitis capitata</em> on <em>Citrus sinensis</em> var. Navel and Valencia (2010-103) inter- sessionally and forward them to the SC for endorsement, noting that the treatment itself is currently on hold</td>
<td>6.1</td>
<td>Treatment lead (BOWMAN) / TPPT members</td>
<td>23 November 2015</td>
</tr>
<tr>
<td>13. The TPPT agreed to re-discuss the “Instructions to assist NPPOs and RPPOs in proper and complete treatment submissions” in an e-forum.</td>
<td>6.3</td>
<td>ORMSBY / Secretariat</td>
<td>TPPT e-forum (No deadline set)</td>
</tr>
<tr>
<td>14. The TPPT noted the paper “Estimating treated numbers from control emergence” and agreed to discuss the formula for calculating treatment numbers from control means in an e-forum.</td>
<td>6.7</td>
<td>ORMSBY / Secretariat</td>
<td>TPPT e-forum (No deadline set)</td>
</tr>
<tr>
<td>15. The TPPT agreed to invite the SC to change the status of the following draft PTs to “pending” until further data on fruit fly population response differences to cold is available (research conducted by conducted by the IAEA/FAO Joint Division of Nuclear Techniques in Agriculture):</td>
<td>6.1, 8.2, 8.3</td>
<td>Secretariat</td>
<td>Next SC meeting</td>
</tr>
<tr>
<td>- Vapour heat treatment for <em>Bactrocera dorsalis</em> on <em>Carica papaya</em> var. Solo (2009-109)</td>
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<tr>
<td>- Vapour heat treatment for <em>Ceratitis capitata</em> on <em>Mangifera indica</em> (2010-106)</td>
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<tr>
<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus clementina</em> var. Clemenules (2010-102)</td>
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<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus sinensis</em> var Navel and Valencia (2010-103)</td>
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<tr>
<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus sinensis</em> 2007-206A</td>
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<tr>
<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus reticulata</em> x C. sinensis 2007-206B</td>
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<tr>
<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus limon</em> 2007-206C</td>
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<tr>
<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus paradisi</em> (2007-210)</td>
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<td>- Cold treatment for <em>Ceratitis capitata</em> on <em>Citrus reticulata</em> cultivars and hybrids (2007-212)</td>
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<tr>
<td>Action</td>
<td>Agenda Item</td>
<td>Responsible</td>
<td>Deadline</td>
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<tr>
<td>16. Draft PTs currently under member consultation (2015 MC) back to Secretariat:</td>
<td>8.3</td>
<td>Treatment leads (ORMSBY / HALLMAN)</td>
<td>15 February 2016</td>
</tr>
<tr>
<td>• Heat treatment of wood using dielectric heating (2007-114)</td>
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<tr>
<td>• Sulphuryl fluoride fumigation of insects in debarked wood (2007-101A)</td>
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<tr>
<td>• Sulphuryl fluoride fumigation of nematodes and insects in debarked wood (2007-101B)</td>
<td></td>
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<tr>
<td>• Vapour heat treatment for <em>Bactrocera tryoni</em> on <em>Mangifera indica</em> (2010-107)</td>
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<tr>
<td>17. TPPT draft responses to member comments back to Secretariat (see action points 12 and 16):</td>
<td>8.3</td>
<td>Treatment leads (BOWMAN / HALLMAN) / TPPT members</td>
<td>23 November 2015</td>
</tr>
<tr>
<td>• Vapour heat treatment for <em>Bactrocera dorsalis</em> on <em>Carica papaya</em> var. Solo (2009-109)</td>
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<td>• Vapour heat treatment for <em>Ceratitis capitata</em> on <em>Mangifera indica</em> (2010-106)</td>
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<tr>
<td>18. The TPPT invited the SC to approve the TPPT medium term work plan 2015/2017. The panel also invited the SC to consider opening a call for treatments in 2016</td>
<td>8.4</td>
<td>Secretariat</td>
<td>Next SC May meeting</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Year</th>
<th>Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2015</strong></td>
<td></td>
</tr>
</tbody>
</table>
| | • Submission of 2 draft PTs for SC approval for adoption  
| | • Submission of 4 draft PTs for SC approval for member consultation  
| | • TPPT face-to-face meeting preparation: 31 August – 4 September 2015, Fukushima, Japan (Agenda: 5 draft ISPMs and 2 draft PTs (annexes to ISPM 28))  
| | • Call for expert for TPPT: Irradiation / Temperature  
| | • TPPT working procedures and research recommendations  
| | • TPPT virtual meetings as needed  
| **2016** |  
| | • Submission of 9 draft PTs for SC approval for adoption  
| | • Submission of 1 draft ISPM for SC approval for member consultation  
| | • TPPT face-to-face meeting preparation: Tentative: 29 August – 02 September 2016, Tokyo, Japan (tentative 9 draft PTs and 4 draft ISPMs on the agenda)  
| | • Call for expert for TPPT: Irradiation/ Fumigation/ Temperature/ Modified atmosphere (TBC)  
| | • TPPT working procedures and research recommendations  
| | • TPPT virtual meetings as needed  
| **2017** |  
| | • Submission of 9 draft PTs and for SC approval for adoption  
| | • Submission of 4 draft ISPMs for SC approval for second member consultation  
| | • TPPT face-to-face meeting preparation: TPPT face-to-face meeting preparation: Tentative: 04 - 08 September 2017 (tentative agenda: review of any pending draft PTs or draft ISPMs; review of PTs submissions from 2016 call for treatments )  
| | • Call for expert for TPPT: Temperature/ Fumigation (TBC)  
| | • TPPT working procedures and research recommendations  
| | • TPPT virtual meetings as needed  
| | • Review of treatments (PTs) submissions from 2016 Call for Treatments, if any  
| **2018** |  
| | • Submission of 4 ISPMs for SC approval for adoption  
| | • Submission of draft PTs and draft ISPMs for SC approval for member consultation: No forecast yet; pending Call for Treatments  
| | • TPPT face-to-face meeting preparation: (tentative agenda: no forecast yet; pending Call for Treatments)  
| | • Call for expert for TPPT: Temperature/ Irradiation/ Fumigation/ Chemical (TBC)  
| | • TPPT working procedures and research recommendations  
| | • TPPT virtual meetings as needed  
| **2019** |  
| | • Submission of draft PTs and draft ISPMs for SC approval for adoption: No forecast yet; pending Call for Treatments  
| | • Submission of draft PTs and draft ISPMs for SC approval (e-decision) for member consultation: No forecast yet; pending Call for Treatments  
| | • TPPT face-to-face meeting preparation: (tentative agenda: no forecast yet; pending Call for Treatments)  
| | • Call for expert for TPPT: Irradiation / Temperature/ Fumigation/ Chemical/ Modified atmosphere (TBC)  
| | • TPPT working procedures and research recommendations  
| | • TPPT virtual meetings as needed  

*Tentative 2016 IPPC call for treatments*