Food and Agriculture Organization of the United Nations

International Plant Protection Convention

REPORT

Technical Panel on Phytosanitary Treatments

Virtual meetings

8-9 December 2020

2-3 February 2021

17-18 February 2021

IPPC Secretariat

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CONTENTS

[1] *Secretariat note: This is a report of three TPPT meetings that took place on the 8-9 December 2020, 2-3 February 2021 and the 17-18 February 2021, all concerning the revisions of ISPM 18 (*Requirements for the use of irradiation as a phytosanitary measure).

1. Opening of the Meeting

1.1. Welcome by the IPPC Secretariat and introductions

[2] The International Plant Protection Convention (IPPC) Secretariat (hereafter referred to as "Secretariat") lead for the Technical Panel on Phytosanitary Treatments (TPPT) chaired the meeting and welcomed the following participants:

1. Mr David OPATOWSKI (TPPT Steward)
2. Ms Andrea BEAM (USA)
3. Mr Toshiyuki DOHINO (Japan)
4. Mr Walther ENKERLIN HOEFLICH (IAEA)
5. Mr Peter LEACH (Australia)
6. Mr Scott MYERS (USA)
7. Mr Michael ORMSBY (New Zealand)
8. Mr Matthew SMYTH (Australia)
9. Mr Eduardo WILLINK (Argentina)
10. Mr Daojian YU (China)
11. Mr Guy HALLMAN (Invited expert)
12. Mr Carl BLACKBURN (Invited expert)
13. Ms Janka KISS (IPPC Secretariat, lead)
14. Mr Artur SHAMILOV (IPPC Secretariat, support)

[3] The full list of TPPT members and their contact details can be found on the International Phytosanitary Portal (IPP)[1].

1.2. Adoption of the agenda and election of the rapporteur

[4] The Secretariat introduced the agenda and it was adopted as presented in Appendix 1 to this report.

[5] Mr Peter LEACH was elected as the Rapporteur.

2. TPPT work programme

[6] The Secretariat introduced the following reference documents for the development of ISPMs, highlighting the importance of consistent terminology:

- IPPC Style Guide and annotated templates
- ISPM 5 (*Glossary of phytosanitary terms*)
- Guidelines for a consistent ISPM terminology (in the Procedure Manual for Standard Setting)

2.1 Requirements for the use of irradiation as a phytosanitary measure (Revision to ISPM 18) (2014-007) – priority 1

[7] Mr David OPATOWSKI and Mr Guy HALLMAN, the Steward and Assistant Steward introduced the Draft Revision to ISPM 18[2] based on Specification 62: Requirements for the use of phytosanitary treatments as phytosanitary measures[3].

[8] The Assistant Steward explained that this ISPM was revised to include recent technological developments and also to align with the structure and content of the recently adopted ISPM 42

[1] TPPT membership list: https://www.ippc.int/en/publications/81655/

[2] 2014-007

[3] Specification 62: https://www.ippc.int/en/publications/81066/

(*Requirements for the use of temperature treatments as phytosanitary measures*) and 43 (*Requirements for the use of fumigation as a phytosanitary measure*).

[9] The TPPT reviewed the revised ISPM and discussed the following changes.

[10] **Footnote.** The TPPT discussed whether the footnote in the Scope is needed, discussing the specificities of regulating irradiation treatments that concern food but agreed that as the other requirement ISPMs does not contain such a statement and all PTs have statements to this effect "There is no obligation for a contracting party to approve, register or adopt the treatments for use in its territory.", the footnote could be removed.

[11] **References.** The reference section was updated with documents of the Codex Alimentarius and ISO. The TPPT also included references to the Asia Pacific Plant Protection Commission (APPPC) regional standard (RSPM No 9) and the International Atomic Energy Agency (IAEA) Manual of good practice in food irradiation: Sanitary, phytosanitary and other applications. Both documents provide detailed examples on issues regarding the audit and accreditation of irradiation facilities as well as providing definitions that are irradiation specific and not currently included in ISPM No 5.

[12] **Pest control vs management.** The TPPT agreed to use the wording that aligns with ISPM 42 and 43.

[13] **Operational vs Performance Qualification.** These are non IPPC terms, and they need clarification and definition. Operational Qualification is about the irradiation facility being capable of delivering the right dose, and performance qualification concerns the application of the irradiation for particular commodities. The TPPT agreed to provide clarification in the text later in the application section, rather in the Outline of Requirements. RSPM No 9 has definitions to both of these terms, so the TPPT agreed to review these definitions.

[14] **Contamination.** TPPT revised the section discussing the phytosanitary security of the treated commodity (e.g. to not to mingle treated with untreated commodities). And aligned the wording from ISPM 43 including the sentence: Systems should be implemented to prevent the infestation or contamination of the irradiated commodity.

[15] **Background**. This section was missing from the original ISPM 18, the TPPT drafted the new background section in alignment with the adopted ISPM 43 on fumigation and adapted the last paragraph to the specifics of irradiation. The TPPT decided to use commodity load.

[16] **Authority**. The original ISPM contained a section on authority that was removed in order to align with the structure of adopted ISPMs 42 and 43.

[17] **Treatment objective**. The section on treatment objective specifies what potential outcomes for irradiation treatments may be (mortality, preventing successful development (e.g. non-emergence of adults), inability to reproduce (e.g. sterility), or inactivation), and although it is later considered in detail, the TPPT thought that it is important to explain specifically that mortality is not the only acceptable outcome for irradiation treatments. They also considered the original ISPM 18 wording to be very clear and reflective of the possible options.

[18] **Efficacy**. The section on efficacy was removed as it is outlined in ISPM 28 in detail and is redundant here.

[19] **Vectors**. One member thought that the concept of using the treatment on vectors (e.g. treating thrips to prevent spreading viruses) is an important concept and is worth retaining. However the TPPT thought it was an example only and so although it is a relevant issue, it is too specific for an ISPM, but it may be part of an explanatory document or implementation guide.

[20] **Increase the Maximum Energy for X-ray irradiation of Commodities**. Mr Carl BLACKBURN introduced the discussion paper[4] suggesting to increase the maximum energy of x-ray irradiation of

[4] 04_TPPT_2020_Dec

commodities from 5 MeV to 7.5 MeV. The original text of ISPM 18 mirrors the standards[5] of Codex Alimentarius Commission in defining a maximum energy of 5 MeV[6]. The secretariat of the Codex Committee on Food Hygiene (CCFH) has forwarded a proposal to adopt 7.5 MeV energy for x-ray irradiation of food to the Chair of the CCFH Priorities Working Group to add to the list of proposals to be considered when they next meet at the fifty second CCFH.

[21] Since the Codex standards (CXC 19-1979 and CXS 106-1983) were developed the technology relating to the generation of x-ray radiation has improved considerably. Modern x-ray sources are more reliable and can operate at energies above a maximum energy of 5 MeV. Such technological developments and the growing commercial availability of technology related to food irradiation are making x-ray irradiation more commercially favourable than irradiation using gamma rays. There are currently at least five countries that allow food irradiation up to 7.5 MeV in their legislation.

[22] Increasing the maximum permitted x-ray energy for food irradiation from 5 MeV to 7.5 MeV will approximately double the efficiency with which an electron beam is converted into X-rays. This increased conversion efficiency provides a higher and more economical commodity throughput at irradiation facilities and reduces processing costs, making x-ray more sustainable, without compromising efficacy nor food safety.

[23] Electron beam and x-ray irradiation is generated by electrical machines and do not rely on radioactive sources (cobalt-60) and therefore avoid the costs of safeguarding radioactive material, is viewed as a means of diversification so as not to become too reliant on one mode of ionizing radiation. Modern electron beam and x-ray approaches offer some additional advantages (they can be turned off when not in use for example).

[24] Mr Blackburn explained that the x-ray radiation is produced by firing a beam of electrons into a metal target ("x-ray converter"). Most of the kinetic energy of the electron beam is lost as heat in the x-ray converter, but a small percentage of this kinetic energy is emitted as x-ray radiation. Hence electron beam irradiation facilities can use this technique to produce x-rays. The benefit is that x-rays are more penetrating than electron beams (X-rays can treat bulky pallets of food, whereas electron beams can treat small packs of food). Raising the maximum permitted x-ray energy for food irradiation from 5 MeV to 7.5 MeV will approximately double the efficiency with which an electron beam is converted into X-rays. This increased conversion efficiency provides a higher and more economical commodity throughput at irradiation facilities and reduces processing costs, making x-ray more sustainable.

[25] There are no implications for the efficacy of the process nor food safety. However, limits to the maximum energy of x-rays are necessary to minimize the risk of atoms in food becoming activated. Theoretically, very high energy x-rays can potentially induce radioactivity in food but, numerous studies have shown that 7.5 MeV x-rays do not induce measurable quantities of radionuclides (induced radioactivity is not detected in food irradiated with 7.5 MeV x-rays and modelling studies of the nuclear interactions calculate a low potential for inducing short-lived radionuclides). Hence several countries have accepted the scientific evidence that 7.5 MeV x-ray irradiation does not raise concerns for efficacy or compromise consumer safety and allow food to be irradiated with 7.5 MeV x-rays because it makes x-ray irradiation more economical and sustainable.

[26] The IAEA considered 7.5 MeV and 10 MeV x-ray interactions in food in a 2002 publication on natural and induced radioactivity in food[7]. An on-going IAEA coordinated research project includes research

[5] The Codex Code of Practice for Radiation Processing of Food (reference CXC 19-1979), at 5.2 (a) "X-rays generated from machine sources operated at or below an energy level of 5 MeV", and; The Codex General Standard for Irradiated Foods to change (reference CXS 106-1983 at 2.1(b) "X-rays generated from machine sources operated at or below an energy level of 5 MeV".

[6] An energy of 1 mega electron volt (MeV) is equivalent to 1.6×10^{-13} joules of energy and therefore 5 MeV is 8.0×10^{-13} J and 7.5 MeV is equivalent to 1.2×10^{-12} J.

[7] https://www-pub.iaea.org/MTCD/Publications/PDF/te_1287_prn.pdf

work to both model and attempt to measure nuclear activation in foods irradiated by x-rays up to 10 MeV.

[27] The TPPT agreed to the proposal and thus revised the Irradiation application section of ISPM 18.

[28] **Factors affecting treatment efficacy.** The TPPT discussed which are the factors that could influence the efficacy of the irradiation treatments. The TPPT agreed to highlight that the absorbed dose is the most important factor. They discussed the importance is to measure the minimum dose to ensure that it is reached throughout the commodity, and how the commodity configuration in the process load and the density of the product should be taken into consideration when determining the dose distribution. This is important to find the appropriate place to measure the minimum dose (dose mapping). Thus they agreed to mention commodity configuration as one of the factors that does influence efficacy. A second factor that may influence treatment efficacy is oxygen levels. TPPT has recently recommend that modified atmosphere (low oxygen) does not impact on the efficacy of treatments targeting fruit flies. For other target pests, oxygen might be an important factor (low oxygen reducing efficacy in some cases).

[29] **Dmin/Dmax.** The TPPT agreed to specify that Dmin should be equal or higher than the phytosanitary treatment dose, however they discussed that exceeding Dmax is not a phytosanitary issue**,** and although its importance from the commodity quality and the regulatory perspective is recognized, they proposed not to include it as a requirement.

[30] **Live non-viable pest.** The TPPT thought that this was a particular important concept to retain, as the required treatment response is often not acute mortality, but rather to prevent the complete development of the pest or its reproduction.

[31] **Dosimetry.** The TPPT simplified and rearranged the dosimetry section and included 3 subsections on Dosimetry systems (on instruments and equipment), Dose mapping, and Routine dosimetry.

[32] The Assistant Steward summarized[8] some further points brought up since the last meeting, and the TPPT discuss these, before continuing with the revision.

[33] **Process load**. The TPPT agreed to use this term to indicate the configuration of commodity that is loaded into the treatment chamber.

[34] **Routine dosimetry**. In order to properly monitor that, "routine dosimetry" should be performed, where for a certain process load, the location of the minimum and the maximum dose is determined. Then a reference dosimeter is placed in an accessible location to monitor the treatment dose adjusting the measured dose to arrive to the minimum (and the maximum) dose. They decided to include an example of the calculation of the reference dose in an Appendix of the draft.

[35] **Validation.** Validation is necessary for the approval of the facility by the relevant authorities. It requires that the facility meets the installation requirements (installation qualification), operates to its design specification (operational qualification) and will consistently deliver the required dose to a given process load within predetermined tolerances (performance qualification). Installation qualification and operational qualification are usually undertaken by the national radiation safety authority or nuclear regulatory authority. Performance qualification is usually undertaken by NPPO's.

[36] **Adequate systems for treatment facilities**. The TPPT included a separate section discussing the facilities and the requirement necessary to apply phytosanitary irradiation, similarly to the recently adopted ISPMs on treatment requirements. The TPPT agreed to rearrange the sections of ISPM 18 to align with the other ISPMs, and create a separate section for "Adequate system for treatment facilities", and moved the following sections under it as sub-section: Approval of facilities, Prevention of infestation and contamination after treatment, Labelling and Monitoring and auditing.

[8] 03_TPPT_2021_Feb

[37] **Facilities.** The TPPT discussed that in general, the establishment of an irradiation facility requires the certification of the National Nuclear Agencies. They considered that although the NPPO does not certify the installation of facilities, they need to make sure that the facility is certified by the appropriate authorities when approving its operations for phytosanitary use. They considered that any change in the setup of the irradiating facility (e.g. speed of a conveyor belt) or the process load (e.g. full pallet or half pallet) will require the NPPO to be notified and dose mapping to be repeated.

[38] **Approval of facilities**. The section was updated to include the requirement that was part of the previous version as well. The TPPT decided to revise the terminology and state that the approval should be based on clearance from competent authorities for safety (e.g. radiation safety authority, nuclear regulatory authority) where appropriate and on a set of criteria that include both criteria common to all irradiation facilities and those that are specific to the site and commodity. This section refers to a checklist to be used for the approval process in Annex 1 (previously annex 2).

[39] **Annex 1 – Checklist**. They decided to remove the restriction that the failure to receive an affirmative response to any item should result in the refusal to establish, or the termination of, an approval or certification, because although they felt that the list contains useful information, it should be left up to the NPPO to decide on the approval.

[40] The TPPT agreed that the requirement of adequate facilities for perishable commodities being available would not be a phytosanitary requirement but rather a quality issue (e.g. cooling capacity), and thus it doesn't add value and should be removed.

[41] The TPPT also considered whether to change the list from and annex into a non-prescriptive appendix, however they decided that the list contains some items that are important to check before a facility is authorized.

[42] One member noted that RSPM 9 will need some revising once the revised ISPM 18 is adapted.

[43] **Efficacy research**. The content of the section previously called Phytosanitary system integrity was moved under the new main section, Adequate systems for treatment facilities, and was slightly revised. The second paragraph was discussing efficacy research (that is not included in other ISPMs on requirements) and because ISPM 28 already addresses the issue, the TPPT thought it was unnecessary, and removed from this draft. The appendix of ISPM 18 on "Research protocol**"** was also removed in line with the other requirement ISPMs, as it is non prescriptive and better fits a guidance type of document then a standard.

[44] **System requirements.** The TPPT decided to clarify that meeting the system requirements meant to comply with the requirements described in this section, not the phytosanitary requirements of the importing country. The TPPT discussed that "under specific conditions" meant the factors to be considered discussed earlier in the draft (e.g. oxygen levels, process loads, and configuration).

[45] **Prevention of infestation and contamination after treatment**. The TPPT discussed the issue in connection with irradiation, and felt that it is important that the segregation of treated and untreated commodities are provided, as irradiation does not induce visible changes, and thus it is not apparent whether something was treated yet. The TPPT also noted that it is common for irradiation facilities to use pest resistant packaging (plastic wraps or fine mesh), to preventre-infestation even if the commodity is not held in a pest free enclosure**.** This section is replacing the previous "Phytosanitary security measures at the treatment facility", capturing the same points but in line with the adopted ISPMs on treatment requirements. The relevant section was kept from the previous ISPM to highlight the issue of pest-resistant packaging. They also discussed the segregating commodities could be misleading, as they don't need to be separated from each other, but from non-treated commodities. They adjusted the wording to make this clearer. They also considered to retain the concept of ensuring the phytosanitary security while moving commodities from receiving to treatment areas (pre-treatment cross-contamination) but decided that it was covered elsewhere.

[46] **Labelling.**

[47] Both ISPM 42 and 43 have dedicated sections on labelling which recommends that commodities have lot numbers or other features of identification allowing trace-back for non-compliant consignments.

[48] Labelling of lot numbers is also important for irradiated commodities but the term "labelling" may be confusing because many regulatory bodies responsible for approving food irradiation also have labelling requirements. However labelling provisions for food safety relates to information that informs consumers that the food or components of food have been treated with ionising radiation.

[49] The requirements for specific wording or labelling provisions may vary between regulatory bodies and the TPPT has made no recommendation on food safety labelling requirements.

[50] **Implementation issues.** The TPPT did not discuss specific implementation issues, but they thought that the concept of using the treatment on vectors of diseases is an important concept and is worth providing guidance on.

[51] The TPPT

(1) *recommended* the draft revision of ISPM 18 to the SC for review and approval for consultation.

(2) *recommended* to post the content of the previous Appendix 2 as a guidance document once the new ISPM is adopted

2.2 Draft PT: Cold treatment for *Thaumatotibia leucotreta* on *Citrus sinensis* (2017-029)

[52] Due to time constrains, this agenda item was deferred.

3. Close of the Meeting

[53] The Secretariat thanked the TPPT members for their participation and closed the meeting.

Appendix 1: Agenda

	AGENDA ITEM	DOCUMENT NO.	PRESENTER
1.	Opening of the meeting		
1.1	Welcome by the IPPC Secretariat		KISS / ALL
1.2	Adoption of the agenda and election of the rapporteur	01_TPPT_2020_Dec	KISS / ALL
2.	TPPT work programme Reference documents for the development of ISPMs: - IPPC Style Guide and annotated templates - ISPM 5 (*Glossary of phytosanitary terms*) - Guidelines for a consistent ISPM terminology (in the Procedure Manual for Standard Setting)	 Link to the IPPC Style Guide Link to ISPM 5 Link to Procedure Manual for Standard Setting	KISS
2.1	Requirements for the use of irradiation as a phytosanitary measure (Revision to ISPM 18) (2014-007) – priority 1		OPATOWSKI, HALLMAN
	- Specification 62: Requirements for the use of phytosanitary treatments as phytosanitary measures	https://www.ippc.int/en/publications/81066/	
	- Draft Revision to ISPM 18	2014-007	
	- Discussion paper from IAEA	04_TPPT_2020_Dec	BLACKBURN
	- Assistant Stewards notes	03_TPPT_2021_Feb2	
2.2	Draft PT: Cold treatment for *Thaumatotibia leucotreta* on *Citrus sinensis* (2017-029)		LEACH
	- Compiled comments from first consultation	02_TPPT_2020_Dec	
	- Treatment Lead summary	03_TPPT_2020_Dec	
	- Draft PT	2017-029	
3.	Close of the meeting	-	KISS