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IPPC Secretariat

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1. Opening of the Meeting

- [1] The meeting was opened Ms Janka KISS (IPPC Secretariat) who welcomed all participants to the Expert Working Group (EWG) on *Audit in the phytosanitary context (2015-014)* on behalf of the International Plant Protection Convention (IPPC) Secretariat. She also thanked Canada for their financial contribution to organize the EWG meeting, and for their support in hosting and co-organizing the meeting.
- [2] Mr Steve CÔTÉ, the National Manager of the International Phytosanitary Standards Section of the national plant protection organization (NPPO) of Canada, the Canadian Food Inspection Agency, also welcomed all participants to Toronto, Canada. He wished a fruitful meeting to the EWG members.
- [3] The participants introduced themselves briefly.
- [4] The Secretariat made a presentation on the IPPC and the Standard setting process. The Secretariat outlined the functions of the Standards Committee (SC) and the EWG, specifically explaining the roles of EWG participants. The Secretariat also facilitated a group exercise to underpin the importance of terminology in the development of the text of the Standard.

2. Meeting Arrangements

2.1 Selection of the Chairperson

- [5] Mr Steve CÔTÉ (Canada) was selected as Chairperson.

2.2 Selection of Rapporteur

- [6] Mr Jason POLLOCK (UK) was selected as Rapporteur.

2.3 Adoption of the agenda

- [7] The EWG adopted the agenda as presented in Appendix 1 to this report.

3. Administrative Matters

- [8] The Secretariat introduced the documents list (Appendix 2), the participants list (Appendix 3) and the local information¹. The meeting organizers explained logistic arrangements.

4. Review of Specification

- [9] The Steward of the ISPM, Mr Alvaro SEPULVEDA LUQUE introduced Specification 66², recalling the reason and scope for the standard as well as the tasks that should be addressed by the EWG during the meeting.
- [10] The Steward also informed the EWG of the issues around the concept of authorization of entities to perform phytosanitary activities and the discussion of the Strategic Planning Group (SPG), the CPM-14 (2019), the SC in May 2019 and the SC-7. He invited the EWG to ensure that the draft ISPM reflects the outcome of these discussions, including that the NPPO is ultimately responsible for any phytosanitary activity undertaken under its authorization, whether it is the conduct of an audit or the activity that the authorized entity audits.
- [11] He also introduced a summary paper³ for the development of the draft ISPM on Audit in the phytosanitary context (2015-014) discussing the definition of audits and the use of the concept in different ISPMs. It was highlighted that the concept of audit is mentioned often and in various contexts throughout the adopted ISPMs. It is an overarching concept and the standard to be developed should

¹ 04_EWG_Audit_2019_Jun

² Specification 66 - Audit in the phytosanitary context: <https://www.ippc.int/en/publications/85297/>

³ 05_EWG_Audit_2019_Jun

match the other ISPMs. As a reference, he also presented the regional standard on the Authorization of Entities to Perform Phytosanitary Services (RSPM 28)⁴ that provides relevant elements of audit systems.

5. Review of Discussion Papers

5.1 The use of audit in the phytosanitary context: A New Zealand perspective.

- [12] Mr Damian CLARKE introduced the discussion paper⁵ on the guidelines of the New Zealand NPPO for audits of plant export and import pathways.
- [13] He highlighted that the intention of the audit process, whether it is performed on an aspect of the plant export or import system, is to ensure that activities are undertaken in accordance with NPPO standards, and to determine whether individuals or organizations (domestic or overseas) are meeting phytosanitary requirements imposed through legislation, standards and agreements and, in some instances, international standards. The paper also provided a step-by-step description of the audit processes for phytosanitary purposes.
- [14] He explained that New Zealand's phytosanitary export system is set up according to ISPMs, in particular ISPM 7 (*Phytosanitary certification system*) and uses authorized, non-NPPO personnel to deliver services. New Zealand authorizes Independent Verification Agencies (IVAs) that carry out inspection and verification (terminology used for considered audit activities).
- [15] An IVA conducts an annual "system audit" of the approved entities, and additionally have 1-6 audits of their system outputs ("surveillance audit"). This system allows the MPI to be the regulator and not the auditor, however the responsibility remains with the NPPO.
- [16] He also introduced the imports system of NZ to audit the import pathway and that could be offshore or onshore audits (in the importing or exporting country). He explained the planning of audits and the processes involved in the delivery of the audit activity and highlighted that it is recommended to express if there is an issue during the audit, rather than only present it in the final report. It is also part of the audit process to provide an opportunity to comment on the audit report before closing out. Closing out of the audit report happens once all corrective actions are implemented.

5.2 Audits in the phytosanitary context (Australia)

- [17] Mr Craig SCHEIBEL introduced the discussion paper⁶ on the Australian system of audits.
- [18] Australia focuses the audits on the system which may include elements of ISO and HACCP standards. They audit against phytosanitary requirements.
- [19] Commodity pathway and verification audit are important elements in new market access negotiations, and when auditing export certifications systems, especially for new pathways. Non NPPO entities may also be audited if they are on the pathways, along with packing houses, treatment facilities and producers. First, a desk audit is conducted, before the on-site audit – to verify that the documentation provided, is accurate.
- [20] PRAs may result in a review or initiate an audit process. "Assurance" is the ultimate goal of audits. Reoccurring non-compliance may trigger a desk and then an on-site audit.
- [21] From an NPPO perspective the auditors are also audited to ensure their competence and that their skill set is best matched to the topic of the audit. They have found that if training is applied after people have participated in a few audits already, it provides more context and is more productive. The training is

⁴ 12_EWG_Audit_2019_Jun

⁵ 06_EWG_Audit_2019_Jun

⁶ 07_EWG_Audit_2019_Jun

structured in several stages that may include training on ISO and HACCP standards. A pool of experts are established to have access to supplementary skills.

5.3 Reflections on Audits in the phytosanitary context and its scope in relation to ISO 9001: 2015 (Chile)

- [22] Ms Ruth Alicia ARÉVALO MACÍAS introduced the discussion papers⁷ on the Chilean NPPO's quality management system.
- [23] A quality management manual was developed for the quality management system for exporting activities for Chile. Auditing in the importing country is geared towards the facilitation of business processes. It also provides the element of standardising the process, in term of the principles and strategic directions and legal frameworks.
- [24] The benefits having a quality management system was highlighted. The personal relationships, courtesy and human interaction are important quality factors. The system also provides guidance on managing the deviations. The training of personnel is also emphasized, and detailed in the quality management system. Supervising of the certification process is also described.
- [25] Chile also authorises third parties to deliver treatments and diagnostic activities. Elements to consider when auditing were provided, and discussed. The framework and description of the processes were also described in the paper. One member queried whether yearly visits to treatment facilities (that are authorized) would fall under audit or supervision. It was explained that if it is conducted against the standards, it is audit, and if not, it is supervision. It was discussed that overseeing something in a continuous manner could be monitoring or supervision and the phrases were used interchangeably.

5.4 Specification 66: Audits in the phytosanitary context (Canada)

- [26] Ms Nancy FURNESS introduced the discussion paper⁸ on the Canadian NPPOs audit system.
- [27] There are many audit based systems in Canada, the NPPO's auditors audit the accredited agencies in the framework of a legal arrangement. The accredited agency audits the facilities (e.g. treatment facilities). There are around 11 000 facilities for wood processing and treatment (forestry certification programme), it cannot be overseen all by the NPPO, and this audit system works well in managing the task.
- [28] Proposals were made on the terminology to be used when drafting the ISPM. System audit would be conducted on the phytosanitary management system (e.g. before authorization) and surveillance audit is considered a routine monitoring. The importance to review the use of terminology around non-compliance and non-conformance was highlighted.
- [29] It was suggested that the frequency of audits should be determined based on the history of non-compliance and the risk of the pathway/commodity. Major non-conformances would trigger further audits and increased frequency. If there is a big change in the processes or a policy change (e.g. in import requirements) this could lead to additional audits.
- [30] Clear definition of roles (e.g. who oversees the programme, and who audits) is necessary. As the NPPO remains responsible, the authority should be retained with the NPPO. It's important to maintain capacity to be able to deliver audits but also maintain the subject matter expertise. Once a third party is unable to fulfil their obligations in relation to audits, a contingency plan should be implemented by the NPPO.
- [31] Auditees need to be trained and capable. Traceability of the facility, documentation procedures should also be requirements.

⁷ 08_EWG_Audit_2019_Jun, 09_EWG_Audit_2019_Jun (En/Sp)

⁸ 10_EWG_Audit_2019_Jun

- [32] There should be legal agreement between the parties and a clear code of conduct and requirement that they are free of conflict of interest. The auditors should also demonstrate that they possess the required expertise and skills, but also keep records that can be accessed by the
- [33] The paper also provided a summary of the audit activities (step by step) and the audit plan. The questions included in checklists are kept broad to allow more flexibility and input from the auditor's side. The audit closes with a full audit report. The closing report includes all information, including the activities that are satisfactory and the ones that aren't.
- [34] New facilities are frequently audited, but the frequency of any further visits can be determined later and be based on the record of non-compliance.
- [35] Disputes should be attempted to be resolved at the lowest possible level (e.g. at the facility) but if not possible, there has to be a process in place, and the NPPO should have the final authority.

5.5 Compliance to EU Directive 2000/29/EC with regard to plants for planting guideline (Kenya)

- [36] Ms Hilda MIRANYI provided an introduction to the paper⁹ presenting the perspective of the auditee. The example of Kenya was used as there is a large volume of export and is often audited for compliance for their procedures in regulating inspections, field visits, and documentation processes.

5.6 Audit in the phytosanitary context – background information and relevant IPPC implementation guides

- [37] The IPPC Secretariat introduced the background document¹⁰ on the development of the Specification, highlighted the links with the draft ISPM on Authorization of entities to perform phytosanitary actions and informed the EWG of the eagerness of both the SC and the IC to coordinate the implementation issues on standards, including the input of EWGs. The paper also highlighted those IPPC guides that discuss audits.

6. Development of text for the draft ISPM

- [38] The IPPC Secretariat highlighted the IPPC Style guide and the annotated template for ISPMs¹¹ as useful resources to develop the text of the ISPM.

6.1 Brainstorming session to develop the outline of the ISPM

- [39] The EWG reviewed Specification 66 and included its elements as headings where appropriate and agreed on the outline of the standard.

6.2 Elaboration of the text of draft ISPM

6.2.1. Scope

- [40] It was clarified that the standard should be applicable to the audit of authorized entities and audits that are conducted by the importing NPPO, exporting NPPO and authorized entities e.g. as described in ISPM 20 (*Guidelines for a phytosanitary import regulatory system*).
- [41] **Supervision and import verification.** The EWG discussed whether to include in the scope that supervision and import verification are distinct from auditing and are not covered by the standard. They decided however that the text of the scope is sufficiently clear: "The standard covers audit in phytosanitary context conducted by the NPPO of the exporting country, importing country and by the

⁹ 11_EWG_Audit_2019_Jun

¹⁰ 13_EWG_Audit_2019_Jun

¹¹ For reference: IPPC Style Guide and annotated templates: <https://www.ippc.int/en/core-activities/standards-setting/development-standards/>; [ISPM 5 \(Glossary of phytosanitary terms\)](#); Guidelines for a consistent ISPM terminology (14_EWG_Audit_2019_Jun)

entities that have been authorized by an NPPO to perform audit” and the definition in the background section provides a distinction between audit and supervision.

[42] **Non-compliance and non-conformity.** The EWG considered whether to provide explanation in the scope to distinguish between non-compliance and non-conformity. In most cases audit findings are non-conformities, where the audited entity is not aligned with the pre-established audit criteria (these could be a detail of the system or the ability of the whole system to comply with import requirements), but in some cases audits could discover non-compliance with the phytosanitary import requirements.

[43] The EWG agreed that it is not necessary to discuss these terms in the scope as they are used consistently in adopted ISPMs. The EWG included references to non-conformity and non-compliance accordingly throughout the text of the draft ISPM.

6.2.2. Definitions

[44] According to task 1 of Specification 66 the EWG considered whether a definition was needed for audit. The EWG agreed that the definition provided in the Background section is sufficiently clear and a definition in ISPM 5 (*Glossary of phytosanitary terms*) would be unnecessary as audit is not used with any specific phytosanitary meaning but in the common sense.

[45] **Consistent use of audit.** The EWG considered the use of “audit” and similar terms in ISPMs, and agreed to request the SC to consider a consistency review of the term “audit” used in other standards by the TPG – to ensure that it is used in accordance with the standard and to review if there is any confusion with inspection or supervision. It was noted that the Steward of the ISPM presented a list of all the mentions of audit in other ISPMs in his discussion paper¹² that may provide a starting point for this task (see also agenda item 4.).

6.2.3 Outline of requirements.

[46] The EWG noted that, as per the *IPPC style guide*, the outline of requirements is a summary of the substance of the standard, and they agreed that it would be finalized by the Steward for the draft ISPM and the Secretariat after the meeting, based on the text developed during the meeting.

6.2.4. Background

[47] The EWG considered the ISO definition of audit (task 2 of Specification 66) and decided to use “systematic evaluation” to reflect that audit is an in-depth analyses.

[48] It was highlighted that an audit has to be information based, objective and documented and that the current definition provides sufficient distinction from inspection and supervision. It was noted that inspection is defined in ISPM 5. It was considered that audits have a discreet time frame, as opposed to supervision that is a continuous activity. The audit provides an assessment of a phytosanitary system at a given time.

6.2.5. Impacts on biodiversity and the environment

[49] According to task 9 of Specification 66, the EWG considered whether the ISPM could affect in a specific way (positively or negatively) the protection of biodiversity and the environment. They included a generic statement on how a well-structured and implemented audit system would provide better oversight on the phytosanitary system and in turn reduce the risk of a negative environmental impact.

6.2.6. Purpose of Audit

[50] The EWG discussed whether the ISPM should be covering audits conducted by non-authorized entities, and it was clarified that the ISPM provides requirements for NPPO, and thus should only cover NPPO audits, or entities that are authorized by the NPPO.

¹² Annex 1 of document 05_EWG_Audit_2019_Jun

- [51] The EWG considered that the audit could be focused on an NPPO's system (importing or exporting) and on an entity carrying out activities on behalf of the NPPO. The EWG also discussed how audits could be focused or more general, possibly on systems or on specific pathways and commodities. The EWG agreed that audits should "objectively evaluate systems and procedures against the requirements set by an NPPO" thus the NPPO of an importing country may conduct an audit to verify the systems and procedures of the NPPO of an exporting country. It was discussed that the audit in the territory of the exporting NPPO should be focused on the exporting systems.
- [52] The EWG agreed that that in some cases an entity may even be authorized to audit a section of their own NPPO's phytosanitary activity such as laboratories of the NPPO, which would be considered part of the system of the NPPO. They considered to restrict the activities of authorized entities to auditing other authorized entities (not the NPPO's systems) both in the exporting and importing countries. However the EWG decided to leave the text open for the NPPO to decide if they wish to authorize entities to perform phytosanitary actions in its territory and to emphasize the authority of the NPPO over the auditing entities.
- [53] The EWG considered that in the case of an internal audit, the NPPO of the exporting country could audit their own employees. The EWG included that the NPPO may conduct an audit to verify their own systems and procedures and those of their authorized entities (that perform phytosanitary actions including audits) or other elements of their phytosanitary system (e.g. producers).

6.2.7. Roles and Responsibilities

- [54] According to task 4 of Specification 66, the roles of auditors and auditee are addressed including the description of different entities that could take the role of auditor or auditee. A separate subsection is dedicated to the additional specific responsibilities of entities, when authorized to conduct an audit. Roles were discussed as part of the EWG and it was felt that the roles of an auditor and auditee were self-explanatory and that identifying the responsibilities was more appropriate. In light of this EWG provided a generic definition.
- [55] The EWG discussed how to describe the roles of the auditor and auditee, as in this section the roles are the roles of the organisation and not the person conducting the audit. The EWG considered to use "auditing party" but deferred to review the document for consistency of the use of "auditor" for the IPPC editor. The EWG concluded that the most important roles in an audit are the role of the auditor and the auditee. The responsibilities may differ slightly, depending on whether it is an entity or an NPPO.
- [56] The EWG discussed that when an exporting NPPO is audited the roles change, and considered that the auditees roles could be articulated in a generic terms (as in allowing access to documentation, etc.). It was considered that there is no difference between this and when the auditee is an authorized entity and thus a generic section was established on the auditees' responsibilities.

6.2.8. Triggers

- [57] According to task 3 of Specification 66, the EWG discussed the potential triggers for performing audits and included elements that may trigger audits.
- [58] **Scheduled.** It was considered that routine audits that are required in the order to verify or ensure the ongoing conformity with the system requirements could be scheduled at certain intervals.
- [59] **Changed conditions.** Review of existing trade as a result of changed conditions could also trigger audits. Additionally changes in the exporting country (e.g. a new pest emerges, outbreak, new treatments required in the pathway) could be a trigger – initiation potentially coming from the trading partner. This point was focused on the exporting country and examples were included.
- [60] **Import requirement changes.** The changes in regulations in the importing country e.g. NPPO policy, resulting requirements or how the legislation is implemented could also be a trigger for audits.

- [61] **New import pathway.** An audit could be considered when requested by a party in the phytosanitary system to acquire recognition.
- [62] **New export programme.** Before the finalization of a PRA often a country visit happens, and it could apply both to new trade or changed conditions.
- [63] **Non-compliance.** The EWG agreed that notification of non-compliance could trigger audits such as pest interceptions..
- [64] **Non-conformity.** A potential issue that could be classified as a non-conformity may trigger a later follow up audit.

6.2.9. Types of Audit

- [65] The EWG addressed the specificities of different kinds of audits, before describing the processes. The EWG agreed that in general there are 2 types of audits:
- [66] **System audit,** that would cover a whole system and could be done regularly (e.g. yearly) or initially before authorizing an entity or a new process. The EWG discussed that system audit could be focused on a whole system from production to export (including another NPPO's system), a system of a particular entity, or particular processes and procedures relevant to a pathway or commodity.
- [67] **Verification audit.** Verification audit is focused on specific elements of a system to verify particular requirements and may be conducted periodically or randomly, or as a result of certain triggers. It could also include regular visits of an established phytosanitary system to verify the ongoing conformity of critical elements.

6.2.10. Steps in the Audit Process - Planning

- [68] According to task 5 of the Specification 66, the EWG described the procedures, for audit activities in the phytosanitary context, including planning audits. The EWG considered the elements of this task to be part of the section on the process of audit but decided to focus on this from both an auditor and auditees perspective to create one single list.
- [69] **Purpose scope and objectives of audit.** It was discussed that the first step of the audit process is to plan the purpose, scope and the objectives of the audit. This may include determining the type of audit (system or verification, and how these will take place e.g. desk or site audit) and also the critical elements to be reviewed. It was also considered important to identify the criteria and requirements to audit against. The NPPO should also determine the consequences and what constitutes critical non-conformity.
- [70] **Roles and responsibilities.** Roles and responsibilities of the auditors and the auditee should also be defined in the planning phase. It should be established that the NPPO is responsible for maintaining oversight over the audit process and the audit reports, which is especially important when the audit is conducted by an authorized entity.

6.2.10. Steps in the Audit Process – Preparation

- [71] It was discussed that the preparation should include the gathering of information and to request the auditee to provide their procedures and manuals. The preparation phase should also include the communication and notification of the audit to the auditee (except e.g. an unannounced verification audit). Some members thought it was important to review if there was any reported non-compliance regarding the activities of the auditee.
- [72] **Resources and audit tools.** The EWG agreed that arrangements for the necessary equipment, interpreter, and financial resources may also be needed as part of the planning phase. Resources could also include check list, manuals, and other audit tools. The EWG discussed whether checklists could be defined in the standard but thought these are variable across countries and auditors shouldn't be constrained by the checklist. The checklist is dependent on the scope and type of the audit, and could

include question prompters and other reference material. The mandatory elements of a checklist could be considered in the implementation material.

[73] **Roles during the audit.** The roles in the audit team and the responsibilities should be confirmed during the preparation phase when assembling the audit team. The EWG discussed whether this would be an overlap with the previous section on the roles of the auditor and auditee but it was clarified that the general concept refers to the auditor as an organization, and this section is distributing and clarifying the roles of the participants of the practical audit activity, such as lead auditor, team members, observers, technical experts and to identify a principal contact point of the auditee.

6.2.11. Steps in the Audit Process - Performance

[74] The performance of the audit can be divided into three stages. Depending on the scope of the audit, the elements of the stages may vary but all stages should be included.

[75] **Stage 1: Commencement.**

[76] The EWG discussed whether the auditor should share the audit criteria at the commencing of the audit. Some members thought that there would be the detailed check points that the auditor looks at, and that they usually don't share those before the audit. However it was discussed that the criteria is understood in a broader sense and a list of items to be checked can be identified, without giving the details.

[77] The EWG discussed that this stage would include confirming the way the audit process will be conducted, what to check first and later, when to meet again, and how the audit will be closed out. It was considered that this would be included in the time frame.

[78] The EWG considered that the policy around recording, photographing was an important aspect and it should be considered when starting an audit process that participants should be informed in relation to data protection and confidentiality.

[79] **Stage 2: Evaluation**

[80] This stage is the actual review of the auditee's phytosanitary system, and seeking confirmation and clarification after the review of the documentation.

[81] **Observations.** The EWG included as part of this stage, observation and how the documented procedures are practically implemented. It was discussed that that the auditor should also keep an open mind and make observations other than the ones planned, that may compromise the phytosanitary system.

[82] **Non-conformity during audit.** The EWG agreed that in case of identifying non conformities, these need to be communicated during the audit so the auditee has a chance to provide further information on the findings. It may not change the outcome of the audit but it is a chance to gather all information. In case there is a dispute, the dispute resolution process may be considered (detailed in another section).

[83] **Stage 3: Closure**

[84] The EWG clarified that this is the closing of the performance step of the audit, and not the closing of the whole audit process. The conclusion of the audit is later reviewed, feedback given and the possible corrective actions are implemented and checked before the audit is concluded.

[85] It was also agreed that if the auditor has further clarification or information, they could request it at this stage (e.g. at a closing meeting).

6.2.12. Reporting

[86] **Reporting of findings.** The structure of the audit reports were discussed and a non-exhaustive list of the elements of the report will include (any other information could include the persons present, date, etc.). The report should identify the non-conformities, recommendations for status of the auditee and the authority – as in suspension etc. The EWG discussed that corrective actions cannot be determined by

the auditor, the auditee needs to officially reply and identify how they will address the findings. It was discussed that observations could be good or bad as well. The EWG also considered whether the timeline, and outcome of audit should be specified, but the EWG thought that the conclusion of the report would cover all this. Findings could be observations and non-conformities. Additionally the conclusion would be an analysis and would include a request to identify corrective actions in a specified timeline (the auditor should not provide recommendations on specific actions).

- [87] It was clarified that if the report identifies non-conformities, a follow up visit may be needed to verify that corrective actions are implemented.

6.2.13. Types of Non-conformity

- [88] The EWG discussed that non-conformities should be recorded, and highlighted the importance of gathering and providing the supporting evidence. Non-conformities may be considered as critical non-conformities or other non-conformities. Critical nonconformities, when it immediately impacts the phytosanitary security of the system, and other non-conformities that do not impact the phytosanitary security, and for these, corrective action is identified within a specific time. It was agreed that the definition of non-conformity should be the same as the authorisation standard.

- [89] **Enforcement when critical non-conformities were not addressed.** The EWG also added that it is the responsibility of the NPPO to identify and implement corrective action in case where critical non-conformities were not addressed. The EWG considered the wording of the authorization draft and adapted it to the audit situation. The EWG considered where this could include legal action, but decided that this is dependent on each countries legislation. They considered that the enforcement would include that the audited entity would need to suspend participation in the phytosanitary system.

6.2.14. Follow-Up

- [90] Follow-up may be necessary when the audit report concludes that corrective actions are needed. The most important item of the follow up is to check if the corrective action was taken. The EWG included several methods to verify that the corrective action was effective.
- [91] After audits, some countries (regions) send out questionnaires to evaluate the audit team, although the EWG considered that this is a good practice, it should not be a requirement.

6.2.15 Settlement of Disputes

- [92] The EWG discussed that most often the conflict arises either in relation to the report findings, the conduct of the audit or lack of adherence to the predetermined scope of the audit. It was considered that the resolution of the dispute should be attempted to be resolved on the lowest possible level first, between the auditor and the auditee, and could be later escalated to the agreed process. The process should be already in place before the audit commences with an agreed dispute mechanism and should consider the documentation submitted by the concerned parties.

6.2.16. Conflicts of Interest

- [93] According to task 7 of Specification 66, the EWG considered how to manage conflicts of interest and confidentiality and decided to align this section with the draft ISPM on Authorization of entities to perform phytosanitary action. They considered whether the auditee should be free from conflict of interest as well. It was discussed that most cases the auditor should be the focus of these provisions, but the auditee should also declare any conflict of interest if they have any beyond representing the entity being audited. The parties should also develop guidance in order to identify how to manage any conflict of interest otherwise it could be considered a non-conformity.

6.2.17. Confidentiality

- [94] It was agreed to include as a requirement that the parties should agree in advance on the disclosure rules and who will have access to the audit report. As customs vary across countries, the EWG thought this

cannot be specified further (e.g. European Commission publish their reports). It is also included in the responsibilities of the auditor, to maintain confidentiality of the information gained when auditing.

- [95] **Commercially sensitive information.** The EWG also discussed that an auditor may have access to several similar facilities and may be aware of good methods to resolve common problems but may not disclose the methods to auditees. Reference to commercially sensitive information was included.

6.2.18. Selection of Auditors

- [96] According to task 8 of Specification 66, the EWG considered the requirements to select auditors. Section on competencies of the auditor to be included.
- [97] The EWG discussed that auditors should have relevant skills and expertise depending on the scope of the audit (e.g. technical skills if they review a process or a pathway or expertise in legal administration if the paperwork is audited). The need for specific expertise was discussed and that it is sometimes necessary to bring along a subject matter expert when auditing a particular technical field.
- [98] The EWG discussed that even though several countries have training requirements, it's hard to define training requirements in the framework of an ISPM. It is considered as one of the implementation issues to develop guidance on this. The title was changed from competency of auditors to selection of auditors as the EWG felt that the word competency meant different things to different people.

6.2.19. Financial Arrangements

- [99] According to task 5 of Specification 66, the EWG discussed that financial obligations was a complex issue to agree on, and hard to harmonize, as there are many different scenarios. They discussed that the budget of the audit should be reasonable, however they agreed that there is no generic requirement that could be included in a standard. The EWG agreed that the financial arrangements should be discussed in advance and included this as a requirement into the draft ISPM.

6.2.20. Scheduling of Audits

- [100] The performance step of the audit may be announced or unannounced. The EWG considered that in some cases unannounced visits may be something that the auditor still makes an appointment e.g. 2 days in advance (scheduled but unannounced). An announced audit is when both parties agree on the date and time. System audits are almost always announced.

6.2.21. Frequency of Audit

- [101] Audits may occur with varying frequencies depending on risk factors identified. In some cases the audit frequency is defined at the initial setting up of the audit system. It was discussed what the frequency refers to. It was agreed that it is to be understood in the context of the system and not the particular location (e.g. 10 percent of all heat treatment facilities gets audited every year based on a random selection – not 10 times the same place).
- [102] The EWG included that triggers can be one of the factors in determining the frequency and provided a list of other possibly influencing factors. The EWG considered the compliance history or other risk that may be associated with a pathway may also influence the frequency of audits. It was discussed that if an auditee has a good history of compliance, it may be reducing the frequency of audits. It was discussed that PRA may also be a process that allows to determine the risk and thus the necessary frequency of audits.

6.2.22. Recognition of Equivalent Audit Systems

- [103] The EWG considered task 6 of Specification 66 to be a difficult issue to address, as the recognition of equivalent audit systems is mostly dependent on bilateral agreement. They thought this could be addressed in an implementation material, but is not required in the standard as prescriptive guidance.

[104] One member thought that the standard should inspire contracting parties to apply good practices, and should encourage NPPOs to use existing quality management tools for effective system management. It was discussed that in some countries the accreditation of other quality management systems are recognised and considered a factor in the assessment such as ISO accreditation. If another NPPO has an established system that functions well, that could be considered as something increasing trust in the phytosanitary system and thus influence audit frequencies. The EWG decided to add that consideration should be given to both international quality management systems and other NPPOs systems and practices.

7. Identify Operational and Technical Implementation Issues and Possible recommendations (see task 10 of Specification 66)

[105] The EWG considered the implementation of the ISPM by contracting parties and identified the following potential operational and technical implementation issues.

[106] **Audit guidance tools.** The mandatory elements of a checklist could be considered in an implementation material – with examples provided. The ultimate goal of the checklist is to clearly indicate through the answers whether the auditee is compliant or not (critical control points) and auditors may provide their own questions and issues based on their experience. Questions should be open ended and based on audit criteria (e.g. SOPs and manuals) and referenced against the purpose of the audit. The audit questions should complement the criteria and evidence should be gathered with the purpose to support the conclusion.

[107] **To require to rotate auditors.** Good practices on audit to ensure that the auditor does not become too familiar and to avoid regulatory capture (complacency). Further advantages of rotation of auditors could be that different people pick up different issues, and it helps to maintain expertise of auditors – previous auditor should go with a new person for the first time.

[108] **Auditor training.** The EWG discussed that auditors should have relevant skills and expertise depending on the scope of the audit (e.g. technical skills if they review a process or a pathway or expertise in legal administration if the paperwork is audited). Implementation issue to consider the **minimum training** and what soft skills are required for a good auditor. The principles of auditors and audit process and the need for training. It could include details on not victimising the auditees and how it should be made clear that not the person but the organisation is audited.

[109] **Potential operational and technical implementation issues.**

- NPPOs may not have personnel knowledgeable in quality systems approaches in conducting of direct facility audits or in conducting audits and oversight of entities (other than the NPPO) overseeing programs (lack of trained personnel)
- Appropriate entities other than the NPPO may not exist
- NPPOs may not have the legal or regulatory framework necessary to support authorization of entities other than the NPPO to perform audits
- There may be potential resistance from NPPO personnel if tasks and responsibilities are delegated to third parties
- There may be lack of NPPO confidence and trust in audit-based approaches
- Desk study, success stories, IRSS
- To further increase the confidence in audit processes (and auth. And systems approaches) via training a

[110] **Note: There is a need to:**

- Acknowledge potential concerns/resistance of certain NPPOs in recognizing/accepting systems approaches which are often more effective than traditional product inspection in maintaining phytosanitary standards/requirements.

- Explore the reasons behind the resistance, e.g., lack of knowledge/experience with systems approach.
- determine ways to address each factor of resistance, i.e., develop educational material, share positive experiences, etc.

Recommendations

[111] The EWG invited the SC to:

- (1) *consider* the above information on potential operational and technical implementation issues.
- (2) *consider* the need to conduct a consistency review of the term “audit” used in other ISPMs to ensure that it is used in accordance with the standard and to review if there is any confusion with inspection or supervision

8. Any Other Business

[112] The Secretariat explained the next steps to the EWG members:

- The draft ISPM would be edited by the Secretariat before being presented to the Standards Committee. The Secretariat would be in direct contact with the Steward for any query that would arise after this meeting.
- The report of this meeting would be drafted by the Secretariat and forwarded to the Rapporteur, and Steward for their clearance. Any controversy would be decided by the Rapporteur. The report would then be posted publicly on the International Phytosanitary Portal¹³ and the EWG members informed.

[113] There was no other business.

9. Close of the Meeting

[114] The Chairperson and the Secretariat thanked the NPPO of Canada for their contribution to the organization of the meeting, as well as all participants for their fruitful contributions.

¹³ International Phytosanitary Portal – Expert Working Groups: <https://www.ippc.int/en/core-activities/standards-setting/expert-drafting-groups/expert-working-groups/>

Appendix 1: Agenda

	Agenda Item	Document No.	Presenter
1.	Opening of the Meeting		
	<ul style="list-style-type: none"> Welcome by the IPPC Secretariat Welcome by the meeting host and organizer Introductions 	--	IPPC Secretariat / Canada NPPO (CFIA)
	<ul style="list-style-type: none"> Presentation of the standard setting process Roles of the Participants Terminology game 	--	KISS
2.	Meeting Arrangements	--	
2.1	Selection of the Chairperson	--	IPPC Secretariat
2.2	Selection of the Rapporteur	--	CHAIRPERSON
2.3	Adoption of the Agenda	01_EWG_Audit_2019_Jun	CHAIRPERSON
3.	Administrative Matters	--	
3.1	Documents list	02_EWG_Audit_2019_Jun	KISS
3.2	Participants list	03_EWG_Audit_2019_Jun	HOST
3.3	Local information	04_EWG_Audit_2019_Jun	
4.	Review of Specification	Specification 66 on Audit in the phytosanitary context	SEPULVEDA (Steward)
4.1	<p>Considerations for the development of the draft ISPM on Audit in the phytosanitary context (2015-014)</p> <ul style="list-style-type: none"> RSPM 28:Authorization of Entities to Perform Phytosanitary Services 	<p>05_EWG_Audit_2019_Jun</p> <p>12_EWG_Audit_2019_Jun (En/Sp)</p>	SEPULVEDA
5.	Review of discussion papers	--	CHAIRPERSON
5.1	The use of audit in the phytosanitary context: A New Zealand perspective	06_EWG_Audit_2019_Jun	CLARKE
5.2	Audits in the phytosanitary context (Australia)	07_EWG_Audit_2019_Jun	SCHEIBEL
5.3	<p>Reflections on Audits in the phytosanitary context and its scope in relation to ISO 9001: 2015 (Chile)</p> <ul style="list-style-type: none"> Manual of Internal Audit SAG 	<p>08_EWG_Audit_2019_Jun</p> <p>09_EWG_Audit_2019_Jun (En/Sp)</p>	ARÉVALO MACÍAS
5.4	Specification 66: Audits in the phytosanitary context (Canada)	10_EWG_Audit_2019_Jun	FURNES
5.5	Compliance to EU Directive 2000/29/EC with regard to plants for planting guideline (Kenya)	11_EWG_Audit_2019_Jun	MIRANYI

	Agenda Item	Document No.	Presenter
5.6	Audit in the phytosanitary context – background information and relevant IPPC implementation guides	13_EWG_Audit_2019_Jun	KISS/ SHAMILOV
6.	Development of text for the draft ISPM <i>Reference documents:</i> <ul style="list-style-type: none"> - <i>IPPC Style Guide and annotated templates (particularly Part 1, sections 2, 3 and 5)</i> - <i>ISPM 5 (Glossary of phytosanitary terms)</i> - <i>Guidelines for a consistent ISPM terminology</i> 	Link to the IPPC Style Guide Link to ISPM 5 14_EWG_Audit_2019_Jun	CHAIRPERSON
6.1	Brainstorming session to develop the outline of the ISPM		CHAIRPERSON/ ALL
6.2	Elaboration of the text of draft ISPM	Link to the Annotated template for draft ISPMs	ALL
7.	Identify Operational and Technical Implementation Issues and Possible recommendations (see task 10 of Specification 66)	--	CHAIRPERSON
8.	Any Other Business	--	CHAIRPERSON
9.	Close of the Meeting	--	IPPC SECRETARIAT / CHAIRPERSON

Appendix 2: Documents List

DOCUMENT NO.	AGENDA ITEM	DOCUMENT TITLE (PREPARED BY)	DATE POSTED / DISTRIBUTED
01_EWG_Audit_2019_Jun	2.3	Agenda	2019-05-03 2019-05-17 2019-05-28
02_EWG_Audit_2019_Jun	3.1	Documents list	2019-05-28
03_EWG_Audit_2019_Jun	3.2	Participants list	2019-05-03
04_EWG_Audit_2019_Jun	3.3	Local information	2019-05-04
05_EWG_Audit_2019_Jun	4.1	Considerations for the development of the draft ISPM on Audit in the phytosanitary context (2015-014)	2019-05-17
06_EWG_Audit_2019_Jun	5.1	The use of audit in the phytosanitary context: A New Zealand perspective	2019-05-15
07_EWG_Audit_2019_Jun	5.2	Audits in the phytosanitary context (Australia)	2019-05-15
08_EWG_Audit_2019_Jun	5.3	Reflections on Audits in the phytosanitary context and its scope in relation to ISO 9001: 2015 (Chile)	2019-05-15
09_EWG_Audit_2019_Jun	5.3	Manual of Internal Audit SAG	2019-05-15
10_EWG_Audit_2019_Jun	5.4	Specification 66: Audits in the phytosanitary context (Canada)	2019-05-15
11_EWG_Audit_2019_Jun	5.5	Compliance to EU Directive 2000/29/EC with regard to plants for planting guideline (Kenya)	2019-05-15
12_EWG_Audit_2019_Jun (En/Sp)	4.6	RSPM 28: Authorization of Entities to Perform Phytosanitary Services	2019-05-15
13_EWG_Audit_2019_Jun	5.6	Audit in the phytosanitary context – background information and relevant IPPC implementation guides	2019-05-28
14_EWG_Audit_2019_Jun	6.0	Guidelines for a consistent ISPM terminology	2019-05-15

IPP LINKS:	Agenda item
Annotated template for draft ISPMs: https://www.ippc.int/en/publications/81325/	1 / 6
IPPC Style guide: https://www.ippc.int/en/publications/132/	1 / 6
ISPM 5 (<i>Glossary of phytosanitary terms</i>): https://www.ippc.int/en/publications/622/	1 / 6
Specification 66 – Audit in the phytosanitary context: https://www.ippc.int/en/publications/85297/	1 / 6

IPP LINKS:	Agenda item
Adopted Standards https://www.ippc.int/en/core-activities/standards-setting/ispms/	1 / 6

Appendix 3: Participants List

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

	Participant Role	Name, mailing address, telephone	Email address
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