

# **DRAFT ISPM: Requirements for NPPOs if authorizing entities to perform phytosanitary actions (2014-002)**

**IPPC second consultation  
1 July to 30 September 2019**

**IPPC Secretariat  
2019 IPPC Regional Workshop**



# Major Stages

**Call for topics  
2013**

- Topic submitted: *Authorization of non-NPPO entities to perform phytosanitary actions*

**SC Nov  
2013**

- Recommended adding to List of Topics

**CPM-9  
(2014)**

- Added to List of Topics with priority 3 (CPM-10 upgraded to priority 2)

**SC May  
2016**

- Approved **Specification 65:**  
*Authorization of entities to perform phytosanitary actions.*

**EWG  
2017**

- Draft ISPM

**SC May  
2018**

- Approval of the draft ISPM for first consultation period

**SC-7  
May  
2019**

- Approval of the draft ISPM for second consultation period

# General Considerations

**During the first consultation period 977 comments were received**

Concern: The delegation of phytosanitary actions to private entities would compromise phytosanitary security, and also feared to weaken the position of the NPPO and the relevance of its work.

Support: Standard is necessary as it provides guidance to NPPOs, particularly in light of the increased volume of trade and the often limited resources of the NPPO, while maintaining phytosanitary integrity.

The concept of the draft ISPM and the comments received were further discussed at: SPG, CPM and Standards Committee.

The SC-7 considered the discussions at various IPPC bodies, further reviewed the comments and the stewards response, revised the draft, and approved it for second consultation.

# Discussions at IPPC bodies

- SPG 2018:
  - Discussed the issue from the perspective of the Strategic Framework 2020-2030.
  - Development Agenda - “Developing Guidance on the Use of Third Party Entities”: Was rewritten to clarify that the IPPC Strategic Framework is not promoting authorization, but highlighting that authorization is a viable alternative for NPPOs.
- CPM 14:
  - Support for and concerns on the draft ISPM were expressed.
  - FAO Legal Division confirmed that Article V.2 (a) of the IPPC provides for the possibility to NPPOs to authorize entities to perform phytosanitary actions with the exception of phytosanitary certificates, and indicated that the responsibility for the phytosanitary action remained with the NPPO.
- FAO Legal also confirmed that activities such as auditing can be authorized.



# Standards Committee

- Emphasized that it is clear that the standard is neither mandating nor endorsing authorization.
- Stressed that NPPOs should not authorize without an appropriate oversight system in place.
- Indicated that the list of phytosanitary actions in this standard is not exhaustive.
- Focus on import, domestic and export: Expressed the functions of an NPPO are clearly set out in the Convention, and the focus should be on those functions.
- Agreed that the section on auditing should be retained in the draft standard and would not overlap with the new draft ISPM to be developed on Audit.

# SC-7: Revision of the draft

- **Title:** “*Requirements for NPPOs if authorizing entities to perform phytosanitary actions*” – Modified to clearly articulate that the NPPO decides whether to authorize, who to authorize and for which phytosanitary actions, and sets the requirements.
- **Scope:** Simplified to emphasize that the requirements of the standard are applicable “only when” the NPPO choses to authorize.
- Modified draft clearly highlights that **ONLY** the NPPO can decide to authorize, and to emphasizes that it is not mandatory to authorize.
- **Basic understanding of Authorization:** A new sub-section is added to highlight that the NPPO responsible for any authorization, the actions that may be authorized and the ones that may not, as well as the need for oversight by the NPPO.

## SC-7: Revision of the draft

- **Definition of entity:** TPG suggested that Glossary definition was not necessary and should be understood in the common sense of the term.
- **Phytosanitary actions that can be authorized:** As advised by SC, the SC-7 noted that using the wording “examples include” implies that the examples listed are not exhaustive. Also, in line with ISPM 5 definition.
- **Domestic, import and export systems:** As per SC discussions, the SC-7 agreed to delete from the draft reference to the specific systems.
- **Authorization system vs programme:** A new sub-section on “Authorization programme” added to provide clarity. Outlines hierarchy (similar to ISPM 6) to clarify that authorization programmes should be set up under an NPPO’s phytosanitary regulatory system and allow the NPPO to authorize entities to perform phytosanitary actions. NPPOs should ensure their legal framework allows them to authorize.

## SC-7: Revision of the draft

- **Private vs public entities:** NPPOs to decide whether to authorize and also to decide how to set requirements for private versus public entities. Reference to private and public entities removed from draft.
- **Development of authorization programme:** As per comments received, the indents were rearranged and *new indents* added regarding:
  - Procedure for receiving and maintaining information, and its confidentiality.
  - Duration of authorization
  - Identification of risk from authorization which need to be managed
  - Process to maintain list of authorized entities
- **Criteria for eligibility of entities:**
  - **Conflict of interest:** Considering comments, SC-7 modified the text to indicate, “entity “is impartial and declares any possible conflicts of interest and identifies how these would be managed as regards the specific phytosanitary actions to be performed”.
  - **QMS, quality manual, SOP:** Considering comments, the terms were removed and the draft simplified to indicate “documented procedures”.
  - **Conflict resolution:** Considering comments, a process for escalation to the NPPO has been included.
  - Statement of **liability** of damages resulting from phytosanitary actions.



## SC-7: Revision of the draft

- **Roles and responsibility of the NPPO:** As per comments received, the following indents were added:
  - Notify entities that did not meet the criteria of eligibility.
  - Implement process for an entity to voluntarily withdraw
  - NPPO personnel should maintain impartiality and should be free of any conflict of interest.
- **Roles and responsibility of the entity:** As per comments received, the following indents were added:
  - Notify NPPO regarding major changes (management, nonconformity)
  - Comply with requirements set by the NPPO
  - Maintain confidentiality of information
- **Audit vs supervise:** SC-7 considered that unlike audit, supervision requires that tasks are performed under direct oversight. However, the terms were not defined in the draft as suggested by TPG. SC-7 agreed that these terms could be considered as part of draft ISPM on audit and as implementation guidance.
- **Roles and responsibilities of entities** authorized to audit or supervise: As per comments, following indents were added:
  - Personnel have relevant training and experience
  - Undertake internal audits

## SC-7: Revision of the draft

- **Audit:** As per comments received, the following changes were made:
  - Frequency of audit was made flexible by modifying to “minimum frequency” depending on complexity of phytosanitary actions, current performance and conformance of the entity.
  - Entire “system audit” reference removed as it would be covered by the draft ISPM on Audit.
- **Types of nonconformity:** In response to a comment, SC-7 indicated that authorization is a new concept and the information on the types of nonconformities in relation to authorization would be useful. Further to address comment, the following changes were made:
  - **Critical nonconformity:** The section was adjusted to clarify the concept and to align with the aspect of conflict of interest. Examples were provided to emphasize situations in which nonconformity would be considered as critical. The text highlights that critical nonconformity would lead to *suspension*.
  - **Other nonconformity:** The text was revised to clarify that situations or criteria that do not fit critical nonconformity would be considered “other”. As per comment received, text was added to indicate that repeated other nonconformities may lead to suspension of authorization.

# SC-7: Revision of the draft

- **Suspension and revocation:** To address concerns from consultation, provided clarity and modified the text to indicate:
  - **Suspension:** should be temporary for a specified time in order to implement corrective action and should allow for a simple process for reinstatement of the authorization after the corrective action is reviewed.
  - **Revocation:** should be a permanent withdrawal of authorization and reinstatement would require the entity to submit a new application for authorization.

# Potential Implementation Issues

- **Legal framework:** Developing countries may not be able to establish the legal framework needed for the implementation of this standard or face difficulties in enacting the laws due to lack of resources.
- **Implementation guidance:** The Implementation and guidance material to supplement the ISPM will be critical for the development of systems with integrity. Such material should underscore the challenges of dealing with conflicts of interest and should also include a number of case studies to demonstrate how a delegated system and its elements can be established.
- **Capacity building:** There is need to consider the extent of implementation capacity and the availability of resources in developing countries.
- **Conflict of interest:** In implementing a system it will be important to define and articulate potential conflicts of interest and transparently explain how they are managed.



# Potential Implementation Issues

- **Costs:** Some contracting parties were concerned that private entities may push for higher profits leading to high costs of authorized services, while an NPPO may only charge a minimal (or no) fee for the service as per the relevant regulations..
- **Other issues:** In some countries there may be a lack of entities authorized to conduct audit or a lack of technical capacity within the NPPO for evaluation and audit. The role of internal phytosanitary systems and entities (not for import/export) may need to be clarified.
- The SC-7 also recalled implementation issues that were raised during the discussion of the draft, including implementation of quality management systems, implementation of complaint and feedback systems, listing of examples for nonconformities and additional guidance on audit and supervision.



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# Contact us

## IPPC Secretariat

Food and Agriculture Organization  
of the United Nations (FAO)

Tel.: +39 06 57054812

Email: [ippc@fao.org](mailto:ippc@fao.org)

Web:

[www.ippc.int](http://www.ippc.int)

[www.fao.org/plant-health-2020](http://www.fao.org/plant-health-2020)

