

DRAFT ISPM: Authorization of entities to perform phytosanitary actions (2014-002)

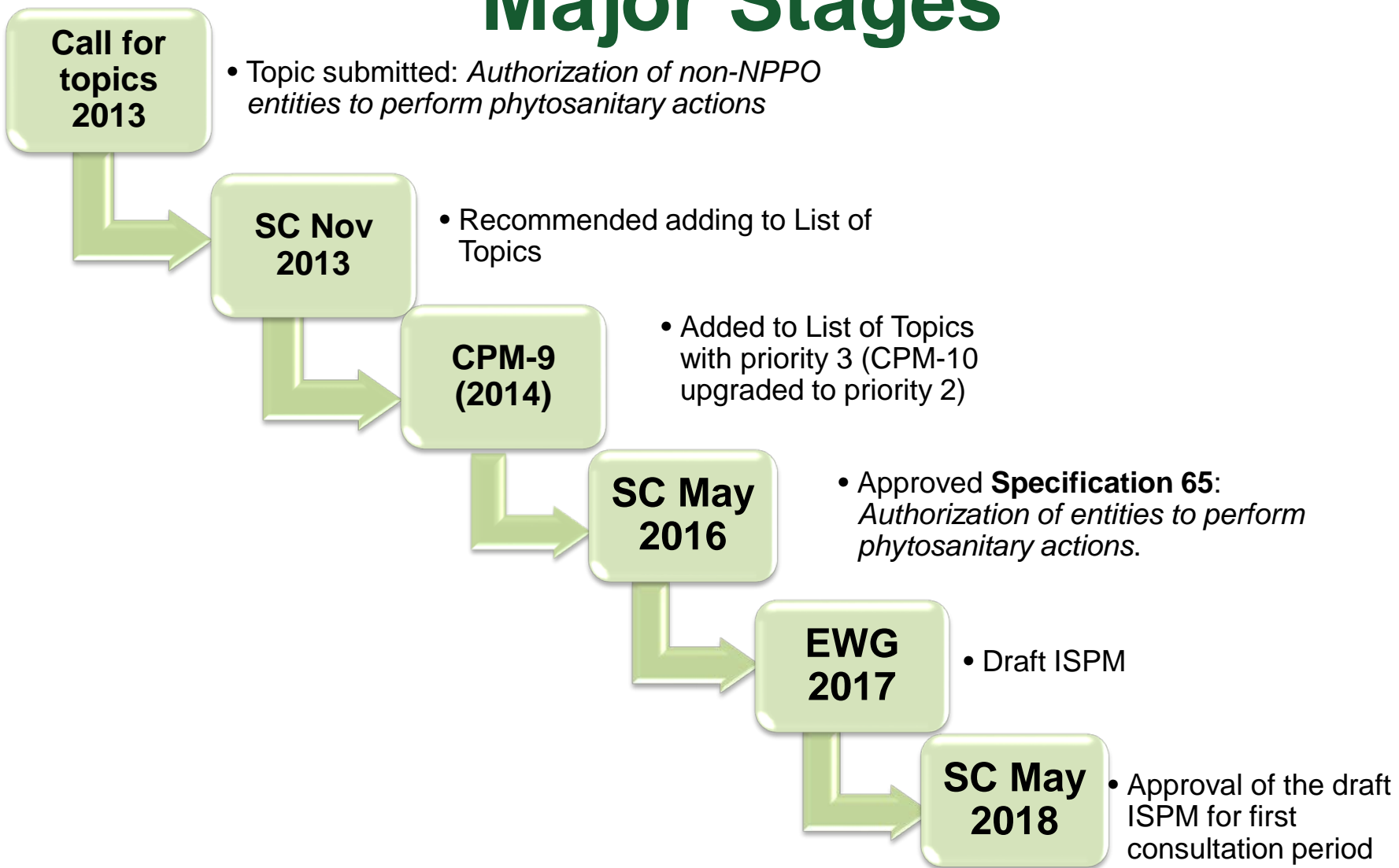
IPPC first consultation

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Major Stages



General Considerations

Reason for the ISPM

It is becoming common in various countries for national plant protection organizations (NPPO) to authorize entities to perform specific phytosanitary actions.



There is a need to ensure the criteria for such authorizations are harmonized and that the practice aligns with the principles of the IPPC.



ISPM provides a framework that enables NPPOs to authorize private entities to perform specific phytosanitary actions associated with import, export and domestic systems on behalf of the NPPO.

Major drafting issues

Clarification of “entities”

- NPPOs authorize many different types of entities and therefore more details are provided to clarify.

- In this standard “entities” include the providers of phytosanitary action (e.g. individuals, organizations, businesses) and, where appropriate, their facilities (such as equipment, laboratories, treatment enclosures).
- In some cases, authorization of entities may require an NPPO to approve individuals within the entity (such as those responsible for specific phytosanitary actions), relevant documentation, their facilities, or any combination of these.

Major drafting issues

Private vs public entities

- Draft clarifies that NPPOs should use the standard for authorization of private entities and may use some elements of this standard when involving public entities.

- Differences exist between authorizing governmental bodies, for example Customs, and authorizing private entities such as laboratories.
- Arrangements for authorization depend on the situation in a country and it would be difficult to cover all possibilities in an ISPM.
- NPPO to decide how the authorization is undertaken and which entities should be covered by the requirements of the standard.

Major drafting issues

Development of Authorization Programme

- NPPO should define its objectives for, and develop, an authorization programme that is appropriate for its purposes.

- Authorization requires an “initiation and approval process”.
- To address the concern that NPPOs may not have the skills to perform a phytosanitary action and may use an entity, the text states that it should be “*at least equivalent to those required for the NPPO personnel*”.
- NPPO should develop a contingency plan to ensure business continuity in the event that an authorized entity no longer undertakes the phytosanitary actions.

Major drafting issues

Criteria for eligibility of entities

- NPPOs should ensure that the entity meets the criteria prior to being authorized to perform phytosanitary actions.
- The draft indicates that an entity should submit to the NPPO its documented quality management system, this including a documented quality manual and standard operating procedures, unless other documentation is deemed sufficient by the NPPO.
- Conflict of interest: it is clarified that an entity should declare the conflicts of interest and identify how they would be managed. NPPOs may not authorize if conflict of interest is unacceptable.

Major drafting issues

Roles and responsibilities

- Clarified the roles and responsibilities of NPPOs and authorized entities during the implementation of the authorization programme.

• Authorization of entities to undertake audits:

- The SC noted that the requirements for authorization of entities to undertake audits or supervision were different to authorizations of entities for other phytosanitary actions.
- A separate section was created to include all the requirements for entities that are authorized to audit or supervise, including the criteria for eligibility and roles and responsibilities.

Major drafting issues

Audits

- Reduced detail on requirements for audits to authorize an entity and to maintain authorization in view of future ISPM on audits.

- The section on Audits was simplified because the SC noted that *Audit in the phytosanitary context* (2015-014) is on the List of topics for IPPC standards and this draft should not be in conflict with or duplicate the future ISPM.
- Audits should be conducted prior to the authorization of an entity and audits of the entity's whole system should be conducted at least once a year to maintain authorization. Additional audits may be conducted as necessary.

Major drafting issues

Nonconformities and status of authorization

- Clarified the type and number of nonconformities identified that should be used by the NPPO to determine the authorization status of the entity.

- The type and number of nonconformities identified should be used by the NPPO to determine the ongoing status of the entity (authorized, suspended or revoked) and the subsequent audit frequency.
- Nonconformities may be classified as critical nonconformities or other nonconformities.

Potential Implementation Issues

- NPPOs may need to set up or adjust their **legal framework** to support the authorization of entities.
- **Capacity development material** on quality systems, quality manuals and on auditing authorized entities would be particularly important to help enhance NPPOs' ability to proficiently carry out authorization of entities.
- Some NPPOs may perceive authorization of entities as being difficult to implement because of potential resistance from NPPO personnel if their tasks and responsibilities are outsourced. **Education and confidence building** actions may therefore be needed.
- **Other??**



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