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## [1] **DRAFT ISPM: Authorization of entities to perform phytosanitary actions (2014-002)**

### [2] **Status box**

[3] This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption.	
[4] <b>Date of this document</b>	[5] 2018-05-22
[6] <b>Document category</b>	[7] Draft ISPM
[8] <b>Current document stage</b>	[9] To First consultation
[10] <b>Major stages</b>	[11] 2013-11 Standards Committee (SC) recommended topic <i>Authorization of non-NPPO entities to perform phytosanitary actions</i> to be added to the work programme. [12] 2014-04 CPM-9 added the topic <i>Authorization of non-NPPO entities to perform phytosanitary actions</i> (2014-002) to the work programme with priority 3 (subsequently changed to priority 2 by CPM-10). [13] 2016-05 SC approved Specification 65 ( <i>Authorization of entities to perform phytosanitary actions</i> ). [14] 2017-06 Expert working group (EWG) drafted ISPM. [15] 2018-05 SC revised draft and approved for first consultation.
[16] <b>Steward history</b>	[17] 2016-05 SC Mr Rajesh RAMARATHNAM (CA, Lead Steward) [18] 2016-05 SC Ms Marina ZLOTINA (US, Assistant Steward) [19] 2014-05 SC Ms Marie-Claude FOREST (CA, Lead Steward)
[20] <b>Notes</b>	[21] 2017-09 Edited [22] 2018-05 Edited

## [23] **CONTENTS [TO BE INSERTED LATER]**

### [24] **Adoption**

[25] [To be inserted following adoption]

## [26] **INTRODUCTION**

### [27] **Scope**

[28] This standard provides a framework that enables national plant protection organizations (NPPOs) to authorize private entities to perform specific phytosanitary actions associated with import, domestic and export systems on behalf of the NPPO. Elements of this standard may also apply when authorizing public entities.

[29] This standard does not cover the issuance of phytosanitary certificates; these are issued by authorized public officers only (Article V.2(a) of the IPPC).

### [30] **References**

[31] The present standard refers to ISPMs. ISPMs are available on the International Phytosanitary Portal (IPP) at <https://www.ippc.int/core-activities/standards-setting/ispms>.

[32] **IPPC**. 1997. *International Plant Protection Convention*. Rome, IPPC, FAO.

### **[33]Definitions**

[34]Definitions of phytosanitary terms used in this standard can be found in ISPM 5 (*Glossary of phytosanitary terms*).

### **[35]Outline of Requirements**

[36]This standard outlines the key requirements for the development of an authorization programme and the eligibility criteria for entities to become authorized. The standard identifies the roles and responsibilities of the parties involved in the implementation of an authorization programme. It also describes processes for audits, types of nonconformities, and types of authorization status that may apply to entities.

### **[37]BACKGROUND**

[38]It is becoming common in various countries throughout the world for national plant protection organizations to authorize entities to perform specific phytosanitary actions such as inspection, testing, surveillance and treatment. Concepts of quality management systems applied in the manufacturing sector are increasingly being applied to the delivery of a wide range of phytosanitary actions, including those undertaken by such authorized entities. However, there is a need to ensure the credibility of such authorizations and that the practice aligns with the principles of the IPPC.

[39]The need for harmonization when considering, developing and implementing authorization programmes has led to the development of this standard.

### **[40]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT**

[41]Standardized authorization programmes may have a positive impact on biodiversity and the environment because they may result in more effective and consistent delivery of phytosanitary actions, helping to enhance the integrity (i.e. the overall effectiveness and reliability) of the NPPO's phytosanitary system.

### **[42]REQUIREMENTS**

[43]Authorization is a process that may be used by NPPOs to formally recognize entities to undertake specific NPPO phytosanitary actions. An NPPO's authorization programme operates within its phytosanitary system.

[44]An NPPO should determine whether to authorize entities to perform phytosanitary actions. Examples of phytosanitary actions that an NPPO may authorize an entity to perform on its behalf include monitoring, sampling, inspection, testing, surveillance, treatment, post-entry quarantine, destruction, supervision and auditing. Under an authorization programme, entities may perform phytosanitary actions within a phytosanitary regulatory system (import, domestic or export).

[45]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. NPPOs should apply this standard when authorizing private entities. NPPOs may also decide to apply elements of this standard when authorizing public entities, such as other government departments. In such cases, the NPPO and the public entity will determine the nature of the authorization arrangement.

[46]NPPOs should ensure that their legal framework enables them to authorize entities to perform phytosanitary actions on their behalf. The NPPO's legal framework should allow it to suspend, revoke

and reinstate authorizations, and should also enable an authorized entity to withdraw from the authorization programme.

### **[47]1. Development of Authorization Programme**

[48]The NPPO should define its objectives for, and develop, an authorization programme that is appropriate for its purposes. When developing an authorization programme, the NPPO should:

- [49]develop and establish the requirements that must be met in order for an entity to be authorized to carry out specific phytosanitary actions on behalf of the NPPO
- [50]develop an initiation and approval process for authorizing entities
- [51]develop a training plan to ensure that NPPO personnel are trained and obtain the expertise to manage the authorization programme
- [52]identify minimum training, skills and competency requirements for entities to perform phytosanitary actions, these requirements being at least equivalent to those required for NPPO personnel to undertake the same phytosanitary actions
- [53]develop a template arrangement, such as a contract or a memorandum of understanding, that can be used to formalize the authorization of entities
- [54]develop performance criteria
- [55]develop an audit process and supporting tools, including audit checklists and corrective action reports
- [56]develop criteria to determine nonconformities
- [57]develop a process to address nonconformity, this including, where appropriate, suspending or revoking authorization
- [58]develop a process for the entity to voluntarily withdraw from the authorization programme
- [59]develop a contingency plan for business continuity in the event that an authorized entity has withdrawn from the authorization programme or had its authorization suspended or revoked
- [60]develop a process to ensure efficient and effective communication between the NPPO and the authorized entity.

### **[61]2. Criteria for Eligibility of Entities**

[62]The NPPO should ensure that the entity meets the following criteria:

- [63]it has legal status to operate in the country of authorization
- [64]it has the ability to enter into a formal arrangement with the NPPO
- [65]it has sufficient resources (financial and human), including the expertise, equipment and infrastructure required, to undertake the specific phytosanitary actions and to ensure continuity of service
- [66]it agrees to conform with the requirements set by the NPPO, including submitting to the NPPO its documented quality management system, this including a documented quality manual and standard operating procedures (an NPPO may determine that a quality manual is not required, and that other documentation may be sufficient, hereafter referred to as “documentation in lieu of a quality manual”; standard operating procedures need to describe how specific phytosanitary actions are undertaken (i.e. who does what, when, where and how))
- [67]it declares any possible conflict of interest and identifies how this would be managed to ensure that it acts impartially as regards the specific phytosanitary actions it undertakes.

### **[68]3. Roles and Responsibilities for Implementing the Authorization Programme**

#### **[69]3.1 Roles and responsibilities of the NPPO**

[70]The roles and responsibilities of the NPPO should include the following:

- [71]to assess the entity against the criteria for eligibility established by the NPPO

- [72]to define clearly the phytosanitary actions the entity is authorized to perform, the performance criteria and corrective actions
- [73]to evaluate the entity against the requirements set by the NPPO regarding its documented quality manual (or documentation sufficient to address the specific phytosanitary actions)and implementation of standard operating procedures on-site, and propose suggestions for improvement as necessary
- [74]to enter into an arrangement which authorizes the entity to perform specific phytosanitary actions, and review and update the arrangement as necessary
- [75]to train NPPO personnel and ensure that their skills and competencies are maintained at an adequate level to consistently implement the authorization programme
- [76]to carry out regular audits of the authorized entity to verify that it conforms with the requirements of the NPPO's authorization programme
- [77]to carry out internal audits of its own procedures and processes to verify that the objectives of its authorization programme continue to be met
- [78]to implement processes for addressing identified nonconformities, including, where appropriate, suspending or revoking authorization, which may include regulatory enforcement
- [79]to maintain documentation, including records and lists of authorized entities
- [80]to implement and maintain transparent, efficient and effective communication on the authorization programme, in particular between the NPPO and the authorized entities.

### **[81]3.2Roles and responsibilities of the authorized entity**

[82]The roles and responsibilities of the authorized entity should include the following:

- [83]to provide necessary information to the NPPO when applying for authorization to perform specific phytosanitary actions on behalf of the NPPO
- [84]to enter into an arrangement to perform the specific phytosanitary actions on behalf of the NPPO
- [85]to implement a documented quality management system to conform with the requirements set by the NPPO, which may cover:
  - [86]standard operating procedures
  - [87]competency of personnel
  - [88]training of personnel
  - [89]document control
  - [90]revision of documents
  - [91]records, in particular of the activities undertaken in relation to the specific phytosanitary actions
  - [92]internal audit
  - [93]management of nonconformity
- [94]to maintain infrastructure, where applicable, and resources to consistently carry out the actions necessary to conform with the requirements set by the NPPO
- [95]to ensure personnel have the relevant education and experience to perform the specific phytosanitary actions
- [96]to train personnel and ensure that their skills and competencies are maintained at an adequate level to consistently carry out the actions necessary to conform with the requirements set by the NPPO
- [97]to maintain and provide quality management system documents (including records) to the NPPO as required
- [98]to undergo audits by the NPPO (or its authorized entity) as described in the requirements set by the NPPO.

### [99]3.2.1 Roles and responsibilities of entities authorized to audit or supervise

[100]An entity that audits other authorized entities or supervises phytosanitary actions should:

- [101]develop and carry out an action plan or procedures for dealing with nonconformities that compromise the integrity of and trust in the programme, including notification of these to the authorizing NPPO
- [102]maintain confidentiality of information gained through its phytosanitary actions
- [103]maintain impartiality and independence from the entities to be audited or supervised, and be free from any conflict of interest.

## [104]4. Process for Audits

### [105]4.1 Audits to authorize an entity

[106]Before granting authorization, the NPPO (or its authorized entity) should carry out an initial evaluation of the entity's quality manual (or documentation in lieu of a quality manual).

[107]When the quality manual (or other documentation sufficient to address the specific phytosanitary actions) is acceptable, the NPPO (or its authorized entity) should carry out an audit to evaluate the entire system and the capability of the entity to implement the standard operating procedures for each phytosanitary action.

[108]At each step of the audit, the NPPO (or its authorized entity) should provide recommendations for improvement as necessary.

[109]The NPPO should normally grant authorization to the entity if the system audit conducted by the NPPO (or its authorized entity) demonstrates that the NPPO's requirements for authorization of entities have been met.

### [110]4.2 Audits to maintain authorization

[111]The NPPO should determine the ongoing frequency of the audits to maintain authorization, based on the level of risk and complexity associated with the phytosanitary actions, the performance and the conformance of the entity.

[112]Audits to maintain authorization should be conducted at least once a year on the entity's entire system. Additional audits on a specific part or parts of the entity's system may be conducted as necessary.

## [113]5. Types of Nonconformity

[114]When the authorized entity does not meet the requirements specified by the NPPO, this should be considered as a nonconformity.

[115]A nonconformity may be identified during audits, supervision, investigations, or through notification of non-compliance (ISPM 13 (*Guidelines for the notification of non-compliance and emergency action*)).

[116]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.

[117]Any nonconformity identified should result in a corrective action to be agreed between the NPPO (or the entity authorized to audit or supervise) and the authorized entity being audited.

[118]Nonconformities may be considered as critical nonconformities (section 5.1) or other nonconformities (section 5.2).

## [119] **5.1 Critical nonconformity**

[120] Critical nonconformity is nonconformity that immediately impacts the integrity of and trust in the NPPO's phytosanitary system and that requires an immediate corrective action to be identified and implemented.

[121] If the authorized entity does not immediately implement the mutually agreed corrective action or the corrective action is not implemented to the satisfaction of the NPPO (or the entity authorized to audit or supervise), the authorization of the entity should be suspended or revoked by the NPPO.

## [122] **5.2 Other nonconformity**

[123] Other nonconformity is nonconformity that does not directly or immediately impact the integrity of and trust in the NPPO's phytosanitary system but that will need corrective actions to be taken within a timeframe specified by the NPPO (or the entity authorized to audit or supervise).

## [124] **6. Suspension, Revocation and Reinstatement of Authorization**

[125] **Suspension.** An entity whose authorization is suspended may continue to operate only under the direct supervision of the NPPO (or the entity authorized to audit or supervise).

[126] **Revocation.** An entity whose authorization is revoked should no longer have its phytosanitary actions recognized by the authorizing NPPO within the NPPO's phytosanitary system.

[127] **Reinstatement.** An entity whose authorization has been suspended or revoked and that wishes to have its authorization status reinstated should apply to the NPPO for reinstatement.

[128] An entity that has voluntarily withdrawn from an authorization programme and that wishes to have its authorization status reinstated should also apply to the NPPO for reinstatement.

## [129] **Potential implementation issues**

[130] This section is not part of the standard. The Standards Committee in May 2016 requested the Secretariat to gather information on any potential implementation issues related to this draft. Please provide details and proposals on how to address these potential implementation issues.