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[1]DRAFT ISPM: Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions (2014-002)

[2]**Status box**

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| [3]This is not an official part of the standard and it will be modified by the IPPC Secretariat after adoption. |
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| [8]**Current document stage** | [9]*To* second consultation |
| [10]**Major stages** | [11]2013-11 Standards Committee (SC) recommended topic *Authorization of non-NPPO entities to perform phytosanitary actions* to be added to the work programme.[12]2014-04 CPM-9 added the topic *Authorization of non-NPPO entities to perform phytosanitary actions* (2014-002) to the work programme with priority 3 (subsequently changed to priority 2 by CPM-10).[13]2016-05 SC approved Specification 65 (*Authorization of entities to perform phytosanitary actions*).[14]2017-06 Expert working group (EWG) drafted ISPM.[15]2018-05 SC revised and approved draft for first consultation.[16]2018-07 First consultation.[17]2019-05 SC-7 revised and approved draft for second consultation. |
| [18]**Steward history** | [19]2016-05 SC Mr Rajesh RAMARATHNAM (CA, Lead Steward)[20]2016-05 SC Ms Marina ZLOTINA (US, Assistant Steward)[21]2014-05 SC Ms Marie-Claude FOREST (CA, Lead Steward) |
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[27]CONTENTS [to be inserted later]

[28]Adoption

[29][To be inserted following adoption]

[30]Introduction

[31]Scope

[32]This standard provides requirements for national plant protection organizations (NPPOs) if they decide to authorize entities to perform specific phytosanitary actions on their behalf.

[33]In accordance with Article V.2(a) of the IPPC, this standard does not cover the issuance of phytosanitary certificates.

[34]References

[35]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>.

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

[37]Definitions

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

[39]Outline of Requirements

[40]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 suspension and revocation of authorization.

[41]Background

[42]Article IV of the IPPC lays down the roles and responsibilities for NPPOs. It is becoming common practice, however, for many NPPOs to authorize entities to perform specific phytosanitary actions such as inspection, monitoring, sampling, testing, surveillance and treatment. In order to foster confidence between NPPOs there is a need to harmonize the requirements for such authorizations and to ensure that the practice aligns with the principles of the IPPC. The NPPO remains responsible for phytosanitary actions performed by entities on their behalf.

[43]IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

[44]Prevention of the introduction and spread of quarantine pests is beneficial to biodiversity through the protection of plant health and the decrease in the use of treatments having a negative environmental impact.

[45]Requirements

[46]Article V.2(a) of the IPPC provides for the possibility for NPPOs to authorize entities to perform phytosanitary actions. However, there is no obligation for NPPOs to do so.

[47]1. Basic Understanding of Authorization

[48]Authorization may be used by NPPOs to recognize entities to perform specific phytosanitary actions. When an NPPO decides to authorize entities, it has sole responsibility for deciding which entity is authorized and for which specific phytosanitary actions.

[49]With the authorization, the phytosanitary action is performed by the entity but the responsibility remains with the NPPO. Authorization may be given only to carry out phytosanitary actions to implement phytosanitary measures that are decided by the NPPO. Examples of phytosanitary actions that an NPPO may authorize an entity to perform include monitoring, sampling, inspection, testing, surveillance, treatment, post-entry quarantine and destruction. Individuals assisting personnel of the NPPO in the presence and direct oversight of the NPPO need not be authorized. Authorization for phytosanitary actions does not include NPPO core activities such as issuance of phytosanitary certificates or development and establishment of phytosanitary measures because these are not phytosanitary actions. The NPPO should have sufficient staff with the necessary expertise to carry out oversight of authorized entities.

[50]In this standard, “entities” include the providers of phytosanitary action (e.g. individuals, organizations, enterprises) 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. The NPPO and the entity should determine the nature of the authorization agreement.

[51]1.1 Authorization programme

[52]Under its phytosanitary regulatory system, an NPPOs wishing to authorize entities to perform specific phytosanitary actions should establish an authorization programme.

[53]Prior to deciding to authorize entities to perform phytosanitary actions, NPPOs should ensure that their country’s legal framework enables them to authorize, suspend, revoke and reinstate authorizations. NPPOs should only set up authorization programmes that result in effective phytosanitary actions that are delivered with integrity and transparency. The authorization programme should ensure that the authorized entities are accountable to the NPPO for these actions and that phytosanitary security is maintained, consistent with the provisions of the IPPC and ISPMs.

[54]2. Development of Authorization Programme

[55]The NPPO should develop an authorization programme that is appropriate for its purposes, first defining the programme’s scope and objectives. When developing an authorization programme, the NPPO should:

* [56]set the requirements that must be met by an entity to be authorized
* [57]develop procedures for receiving, maintaining and delivering information, including its confidentiality
* [58]develop a process, from the time of receipt of the required information and its subsequent evaluation to the decision on whether to grant authorization to the entity
* [59]develop a training plan to ensure that NPPO personnel have the expertise to manage the authorization programme
* [60]develop training or identify minimum training, equipment, competency and skills requirements for entities to perform phytosanitary actions; these requirements should be equivalent to those required for the NPPO if it were to undertake the same phytosanitary actions
* [61]develop a template agreement that can be used to formalize the authorization of entities and make the authorization legally binding
* [62]determine a validity period for authorization agreement, including review and prolongation if appropriate
* [63]develop specific performance criteria, guidelines, and performance-based verification processes for the actions performed by the entities
* [64]develop an audit or monitoring process and supporting tools, including audit or monitoring checklists and templates for audit or monitoring reports, and templates for preventive and corrective action reports
* [65]develop criteria to determine nonconformities
* [66]develop a process to address nonconformity, this including, where appropriate, suspending or revoking authorization
* [67]develop a process for the authorized entity to voluntarily withdraw from the authorization agreement with the NPPO
* [68]identify risks which may arise from authorization and which need to be managed through the authorization programme
* [69]develop contingency plans for continuity of action in the event that an authorized entity has its authorization suspended or revoked or has withdrawn from the authorization programme
* [70]develop a process to ensure efficient and effective communication between the NPPO and the authorized entity
* [71]develop a process to maintain an up-to-date list of authorized entities.

[72]3. Criteria for Eligibility of Entities

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

* [74]it has legal status to operate in the country of authorization
* [75]it has the ability to enter into an agreement with the NPPO
* [76]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
* [77]it agrees to conform with the requirements set by the NPPO
* [78]it has documentation describing the process by which it will consistently meet the requirements set by the NPPO for the phytosanitary actions to be performed
* [79]it is impartial and declares any possible conflicts of interest, identifying how these would be managed as regards the specific phytosanitary actions to be performed
* [80]it has a clear statement of liability for damages if these result from actions it performs in its role as an authorized entity
* [81]it has a process to ensure efficient and effective resolution of conflicts between the authorized entity and the client, including a process for escalation of issues to the NPPO.

[82]4. Roles and Responsibilities for Implementing the Authorization Programme

[83]4.1 Roles and responsibilities of the NPPO

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

* [85]to assess the entity against the criteria for eligibility for authorization set in this standard and those established by the NPPO
* [86]to evaluate the entity against the requirements set by the NPPO regarding its documented procedures and their implementation on-site, and propose suggestions for improvement as necessary
* [87]to clearly define the phytosanitary actions the entity is authorized to perform and the performance criteria
* [88]to enter into an agreement which authorizes the entity to perform specific phytosanitary actions, and review and update the agreement as necessary
* [89]to notify entities that do not meet the criteria for eligibility and provide the rationale for the decision
* [90]to train NPPO and, if needed, authorized entities personnel and ensure that their skills and competencies are maintained at an adequate level to consistently implement the authorization programme
* [91]to carry out regular audits or monitoring of the authorized entity to verify that it conforms with the requirements of the NPPO’s authorization programme
* [92]to carry out internal audits of its own procedures and processes to verify that the objectives of its authorization programme continue to be met
* [93]to implement processes for addressing identified nonconformities, including determining the corrective actions and, where appropriate, suspending or revoking authorization, which may include regulatory enforcement
* [94]to implement processes for the entity to voluntarily withdraw from the authorization programme, when needed
* [95]to maintain documentation, including records and published lists of authorized entities, corresponding authorized phytosanitary action, authorization period, and authorization code, if applicable
* [96]to implement and maintain transparent, efficient and effective communication on the authorization programme, in particular between the NPPO and the authorized entities
* [97]to ensure that NPPO personnel involved in authorization of entities maintain impartiality and are free of any conflicts of interest.

[98]4.2 Roles and responsibilities of the entity

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

* [100]to provide required information to the NPPO when being considered for authorization to perform specific phytosanitary actions
* [101]to enter into an agreement to perform the specific phytosanitary actions
* [102]to implement documented procedures to conform with the requirements set by the NPPO, which may cover:
* [103]operating procedures describing how specific phytosanitary actions are performed (i.e. who does what, when, where and how)
* [104]skills and competency of personnel
* [105]training of personnel
* [106]document control, which includes
* [107]revision of documents
* [108]records, in particular of the activities undertaken in relation to the specific phytosanitary actions
* [109]a list of equipment and their maintenance or calibration schedule, where appropriate
* [110]internal audit
* [111]management of nonconformity
* [112]to provide notification (within an agreed time frame) to the NPPO upon, a major change in management or location, or nonconformity
* [113]to maintain infrastructure and security, where applicable, and resources to consistently carry out the specific phytosanitary actions to conform with the requirements set by the NPPO
* [114]to ensure personnel have the relevant education and experience required by the NPPO to perform the specific phytosanitary actions
* [115]to train personnel and ensure that their skills and competencies are maintained at an adequate level to consistently carry out the specific phytosanitary actions to conform with the requirements set by the NPPO
* [116]to maintain and provide quality management system documents (including records of its activities) to the NPPO as required
* [117]to undergo monitoring, audits and controls by the NPPO (or its authorized entity) as described in the requirements set by the NPPO
* [118]to comply with the requirements established in the phytosanitary procedures, standards, legislation and guidelines of the NPPO
* [119]to maintain the confidentiality of the information obtained through the authorized phytosanitary actions.

[120]4.2.1 Roles and responsibilities of entities authorized to audit or supervise

[121]The roles and responsibilities of an entity that audits other authorized entities or supervises phytosanitary actions should include the following:

* [122]to 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
* [123]to maintain confidentiality of information gained through its phytosanitary actions
* [124]to maintain impartiality and independence from the entities it audits or supervises, and be free from any conflict of interest
* [125]to ensure personnel have the relevant training and experience to perform the specific audits being conducted
* [126]to undertake internal audits to provide continuous feedback and identify system gaps (if applicable).

[127]5. Process for Audits

[128]5.1 Audits to authorize an entity

[129]If an NPPO decides to consider the authorization of an entity, the NPPO (or its authorized entity) should first carry out an initial evaluation of the entity’s documented procedures.

[130]When the documented procedures are 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 documented operating procedures for each phytosanitary action.

[131]At each step of the audit, the NPPO (or its authorized entity) should provide feedback to the entity on observations or opportunities for improvement as necessary.

[132]The decision about whether to grant authorization rests solely with the NPPO. The NPPO should normally grant authorization, 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.

[133]5.2 Audits to maintain authorization

[134]The NPPO should determine the minimum frequency of the audits to maintain authorization, based on the scope of the phytosanitary actions and the associated level of pest risk and complexity, the performance of the authorized entity and the nonconformities identified, and the results of previous audits.

[135]Audits may be conducted on a specific part or parts of the entity’s system, as necessary.

[136]6. Types of Nonconformity

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

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

[139]The type and number of nonconformities identified should be used by the NPPO to determine the status of the entity (authorized, suspended or revoked) and the follow-up audit frequency.

[140]If a nonconformity is identified, the NPPO (or the entity authorized to audit or supervise) should require the authorized entity to take corrective action.

[141]Nonconformities may be considered as critical nonconformities (section 6.1) or other nonconformities (section 6.2).

[142]6.1 Critical nonconformity

[143]“Critical nonconformity” is a nonconformity that immediately impacts the integrity of and trust in the NPPO’s phytosanitary system and that requires a rapid corrective action to be identified and implemented. The NPPO may consider nonconformities to be critical in situations such as:

* [144]when there is evidence of failing to properly perform authorized phytosanitary actions
* [145]when a corrective action is not implemented to the satisfaction of the NPPO (or the entity authorized to audit or supervise)
* [146]when there is a failure to implement timely corrective actions to remedy the shortcomings identified
* [147]when the integrity or impartiality of the entity has been shown to be compromised.

[148]An entity’s authorization to perform a specific phytosanitary action should be suspended immediately if a critical nonconformity is identified.

[149]6.2 Other nonconformity

[150]“Other nonconformity” is a nonconformity that does not directly or immediately impact the integrity of and trust in the NPPO’s phytosanitary system and is not considered a critical nonconformity by the NPPO.

[151]Other nonconformity requires corrective actions to be taken within a time frame specified by the NPPO (or the entity authorized to audit or supervise).

[152]Suspension or revocation of the authorization is not needed but may be considered when this type of nonconformity is repeatedly identified or when corrective actions are not taken within the required time frame.

[153]7. Suspension and Revocation of Authorization

[154]**Suspension.** The NPPOtemporarily suspends the authorization of an entity for a specified time in order for the entity to implement corrective action.

[155]**Revocation.** The NPPOwithdraws the authorization of an entity.

[156]An entity that has had its authorization suspended and that wishes to have its authorization reinstated should apply to the NPPO for reinstatement. Entities that have had their authorization revoked should make an application for a new authorization.

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

[158]**Potential implementation issues**

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