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Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions

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International Plant Protection Convention (IPPC)

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INTERNATIONAL STANDARDS FOR
PHYTOSANITARY MEASURES

ISPM 45

**Requirements for national plant protection
organizations if authorizing entities to perform
phytosanitary actions**

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Adoption

This standard was adopted by the Fifteenth Session of the Commission on Phytosanitary Measures in March 2021.

INTRODUCTION

Scope

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

In accordance with Article V.2(a) of the IPPC, this standard does not cover the issuance of phytosanitary certificates. Also, this standard does not cover the development and establishment of phytosanitary measures.

References

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>.

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

Definitions

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

Outline of requirements

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.

BACKGROUND

Article IV of the IPPC sets out the responsibilities for NPPOs. Article V.2(a) of the IPPC provides for the possibility of NPPOs authorizing entities to perform phytosanitary actions. The concept of authorization is referred to in several ISPMs, such as ISPM 3 (*Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*), ISPM 6 (*Surveillance*), ISPM 7 (*Phytosanitary certification system*), ISPM 12 (*Phytosanitary certificates*), ISPM 20 (*Guidelines for a phytosanitary import regulatory system*), ISPM 23 (*Guidelines for inspection*), ISPM 42 (*Requirements for the use of temperature treatments as phytosanitary measures*) and ISPM 43 (*Requirements for the use of fumigation as a phytosanitary measure*). In order to foster confidence between NPPOs, there is a need to harmonize the requirements for authorizations of specific phytosanitary actions and to ensure that the practice aligns with the principles of the IPPC. If an NPPO decides to authorize entities, it remains responsible for the phytosanitary actions performed by the entities on its behalf.

IMPACTS ON BIODIVERSITY AND THE ENVIRONMENT

Authorization programmes may have a positive impact on biodiversity and the environment because they may contribute to the delivery of phytosanitary actions.

REQUIREMENTS

There is no obligation for NPPOs to authorize entities to perform phytosanitary actions. However, if an NPPO decides to authorize entities, the following requirements apply.

1. Basic understanding of authorization

An NPPO decides whether to use authorization of entities to perform phytosanitary actions. Authorization may be used by NPPOs to authorize entities to perform specific phytosanitary actions, to audit other authorized entities, or to supervise phytosanitary actions. Examples of phytosanitary actions that an NPPO may decide to authorize an entity to perform include monitoring, sampling, inspection, testing, surveillance, treatment, post-entry quarantine and destruction. If an NPPO decides to authorize entities, it should have sole responsibility for deciding which entity is authorized and for which specific phytosanitary actions. Audits may be conducted by an authorized entity in order to assess the eligibility of another entity to perform a specific phytosanitary action; however, the decision to authorize should be the responsibility of the NPPO alone.

The NPPO is responsible for ensuring that the authorized entity performs the phytosanitary actions according to the NPPO's requirements. With the authorization, the phytosanitary action is performed by the entity but the responsibility remains with the NPPO. Authorization may be given only to perform phytosanitary actions to implement phytosanitary measures that are decided by the NPPO. Authorization to perform 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, including auditing, of authorized entities.

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, facilities, or any combination of these. The NPPO and the entity should determine the nature of the authorization agreement.

2. Authorization programme

Under its phytosanitary system, an NPPO deciding to authorize entities to perform specific phytosanitary actions should establish an authorization programme.

Before deciding to authorize entities to perform phytosanitary actions and developing an authorization programme, 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.

2.1 Development of authorization programme

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:

- set the requirements that must be met by an entity to be authorized;
- develop procedures for receiving, maintaining and delivering information, including procedures to ensure confidentiality;

- develop procedures to process the information received, from the time of receipt of the information required by the NPPO and its subsequent evaluation to the decision on whether to grant authorization to the entity;
- develop a training plan to ensure that NPPO personnel have the expertise to manage the authorization programme;
- 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);
- develop a template agreement that can be used to formalize the authorization of entities and make the authorization legally binding;
- determine a validity period for the authorization agreement, including the timing of any review and the length of any extension if appropriate;
- develop specific performance criteria, guidelines and performance-based verification processes for the actions performed by the entities;
- develop an audit or monitoring process and supporting tools, which may include audit or monitoring checklists and templates for audit or monitoring reports, and templates for corrective action reports;
- develop criteria to determine nonconformities;
- develop a process to address nonconformity, this including, where appropriate, suspending, reinstating or revoking authorization;
- develop a process for the authorized entity to voluntarily withdraw from the authorization agreement with the NPPO;
- identify risks which may arise from authorization and which need to be managed through the authorization programme;
- develop contingency plans for ensuring continuity of action in the event that an authorized entity has its authorization suspended or revoked or voluntarily withdraws from the authorization programme;
- develop a process to ensure efficient and effective communication between the NPPO and the authorized entity;
- develop a process to maintain an up-to-date list of authorized entities;
- develop a framework to assess the impartiality and independence of entities, and to assess and identify any potential conflicts of interest and address them appropriately (e.g. by requiring entities to be free of any conflict of interest or by allowing entities to manage conflicts of interest).

3. Criteria for eligibility of entities

The NPPO should ensure that the entity meets the following criteria:

- it can legally operate in the country of authorization;
- it has the ability to enter into an agreement with the NPPO;
- it has sufficient resources (financial and human), including the expertise, equipment and infrastructure required, to undertake the specific phytosanitary actions to be performed and to ensure continuity of service;
- it appoints or identifies the individual or individuals who will be responsible for delivery of the phytosanitary actions to be performed;
- it has documentation demonstrating the process by which it will consistently meet the requirements set by the NPPO for the phytosanitary actions to be performed;
- it agrees to conform with the NPPO's requirements, including requirements on impartiality, independence and conflicts of interest (e.g. to declare whether it is free of any conflict of interest or to identify potential conflicts of interest);

- it has a clear statement of liability for damages if these result from actions it performs in its role as an authorized entity;
- it has a process to ensure efficient and effective resolution of conflicts with the client receiving delivery of the phytosanitary action (if the client is not the NPPO), including a process to elevate issues to the NPPO for a final decision.

4. Roles and responsibilities for implementing the authorization programme

4.1 Roles and responsibilities of the NPPO

The roles and responsibilities of the NPPO should include the following:

- to assess the entity against the criteria for eligibility for authorization set in this standard and those established by the NPPO;
- 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;
- to clearly define the phytosanitary actions the entity is authorized to perform and the performance criteria;
- to enter into an agreement which authorizes the entity to perform specific phytosanitary actions, and to review and update the agreement as necessary;
- to notify entities that do not meet the criteria for eligibility and provide the rationale for the decision;
- to train NPPO personnel 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;
- 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;
- to carry out internal audits of its own procedures and processes to verify that the objectives of its authorization programme continue to be met;
- to implement processes for addressing identified nonconformities, including determining the corrective actions and requiring the authorized entity to take the corrective actions, and, where appropriate, suspending or revoking authorization, which may include regulatory enforcement;
- to implement processes for reinstatement of authorization;
- to implement processes for the entity to voluntarily withdraw from the authorization agreement with the NPPO, when needed;
- to maintain documentation, including records and published lists of authorized entities, corresponding authorized phytosanitary action, and authorization period, if applicable;
- to identify for how long an entity needs to save its records, in relation to the specific phytosanitary actions performed;
- to implement and maintain transparent, efficient and effective communication on the authorization programme, in particular between the NPPO and the authorized entities;
- to ensure that NPPO personnel involved in authorization of entities maintain impartiality and are free of any conflict of interest.

4.2 Roles and responsibilities of the entity

The roles and responsibilities of the entity should include the following:

- to provide required information to the NPPO when being considered for authorization to perform specific phytosanitary actions;
- to enter into a written agreement to perform the specific phytosanitary actions;

- to implement documented procedures to conform with the requirements set by the NPPO, which may cover:
 - operating procedures describing how specific phytosanitary actions are performed (i.e. who does what, when, where and how),
 - skills and competency of personnel,
 - training of personnel,
 - document control, which includes:
 - revision of documents
 - records, in particular of the activities undertaken in relation to the specific phytosanitary actions,
 - a list of equipment and their maintenance or calibration schedule, where appropriate,
 - internal audit,
 - management of nonconformity;
- to provide notification (within an agreed time frame) to the NPPO upon a major change in management or location, a change in process, a nonconformity or any other information that has an impact on the specific phytosanitary action that has been authorized;
- 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;
- to ensure that personnel have the relevant knowledge and experience required by the NPPO to perform the specific phytosanitary actions;
- 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;
- to maintain and provide documented procedures (including records of its activities) to the NPPO as required;
- to undergo monitoring, audits and controls as described in the requirements set by the NPPO;
- to comply with the requirements set in the authorization agreement, the phytosanitary procedures, standards, legislation and guidelines of the NPPO that relate to the authorization;
- to maintain the confidentiality of the information obtained through the authorized phytosanitary actions.

4.2.1 Roles and responsibilities of entities authorized to audit or supervise

The NPPO may choose to authorize entities to audit other authorized entities or to supervise phytosanitary actions. An entity that audits other authorized entities or supervises phytosanitary actions should meet the requirements in section 4.2. The roles and responsibilities of the entity should also include the following:

- to develop and carry out an action plan, including procedures or corrective actions, for dealing with nonconformities of the entities it audits that compromise the integrity of and trust in the programme, including notification (within an agreed time frame) of these to the authorizing NPPO;
- to maintain confidentiality of information gained through its auditing or supervisory activities;
- to maintain impartiality and independence from the entities it audits or supervises, and be free of any conflict of interest;
- to ensure personnel have the relevant knowledge, experience and training to carry out the specific audits or supervision being performed;
- to undertake internal audits to provide continuous feedback and identify system gaps (if applicable).

5. Process for audits

5.1 Audits to authorize an entity

If an NPPO decides to consider the authorization of an entity, the NPPO (or the entity authorized to conduct audits) should first carry out an initial evaluation of the entity's documented procedures.

When the documented procedures are acceptable, the NPPO (or the entity authorized to conduct audits) 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.

At each step of the audit, the NPPO (or the entity authorized to conduct audits) should provide feedback to the entity on observations and opportunities for improvement as necessary.

The decision about whether to grant authorization should rest solely with the NPPO. The NPPO should only authorize the entity if the audit demonstrates that the NPPO's requirements for authorization of entities have been met.

5.2 Audits to maintain authorization

The NPPO should determine the minimum frequency of the audits to maintain authorization, based on the scope and complexity of the phytosanitary actions and the associated level of pest risk, the performance of the authorized entity and the nonconformities identified, and the results of previous audits. An unscheduled audit may be conducted, for instance upon receipt of a notification of non-compliance from an importing country.

Audits may be conducted by the NPPO (or the entity authorized to conduct audits) on a specific part or parts of the entity's system, as necessary.

6. Types of nonconformity

When the authorized entity does not meet the requirements specified by the NPPO as set out in the authorization agreement, this should be considered as a nonconformity.

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

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.

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

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

6.1 Critical nonconformity

“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:

- when there is evidence of failing to properly perform authorized phytosanitary actions;
- when a corrective action is not implemented to the satisfaction of the NPPO (or the entity authorized to audit or supervise);
- when there is a failure to implement timely corrective actions to remedy the shortcomings identified;
- when the integrity or impartiality of the entity is shown to have been compromised;

- when there is evidence of fraud.

An entity's authorization to perform a specific phytosanitary action should be suspended or revoked immediately if a critical nonconformity is identified. The NPPO should have a system in place to manage the critical nonconformity.

6.2 Other nonconformity

“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.

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

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. The decision about whether to suspend or revoke authorization of the entity should rest solely with the NPPO.

7. Suspension and revocation of authorization

The decision to suspend, revoke or reinstate authorization of the entity should rest solely with the NPPO.

Suspension. The NPPO temporarily suspends the authorization of an entity for a specified time in order for the entity to implement corrective action.

Revocation. The NPPO withdraws the authorization of an entity.

An entity that has had its authorization suspended and that wishes to have its authorization reinstated should apply to the NPPO for reinstatement. When an entity's authorization has been revoked, the NPPO should evaluate if the entity is eligible for a new authorization. Affected entities should make an application for a new authorization, according to the rules set by the NPPO. The decision about whether to reinstate an entity's authorization should rest solely with the NPPO.

An entity that has voluntarily withdrawn from an authorization agreement and that wishes to have its authorization reinstated should apply to the NPPO for reinstatement.

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IPPC

The International Plant Protection Convention (IPPC) is an international plant health agreement that aims to protect global plant resources and facilitate safe trade.

The IPPC vision is that all countries have the capacity to implement harmonized measures to prevent pest introductions and spread, and minimize the impacts of pests on food security, trade, economic growth, and the environment.

Organization

- ◆ There are over 180 IPPC contracting parties.
- ◆ Each contracting party has a national plant protection organization (NPPO) and an Official IPPC contact point.
- ◆ 10 regional plant protection organizations (RPPOs) have been established to coordinate NPPOs in various regions of the world.
- ◆ IPPC liaises with relevant international organizations to help build regional and national capacities.
- ◆ The Secretariat is provided by the Food and Agriculture Organization of the United Nations (FAO).

International Plant Protection Convention Secretariat
ippc@fao.org | www.ippc.int

Food and Agriculture Organization of the United Nations
Rome, Italy

