DRAFT SPECIFICATION FOR ISPM: Requirements for the use of diagnostic testing laboratories

Status box

This is not an official part of the specification and it will be modified by the IPPC Secretariat after approval	
Date of this document	
Document category	
Current document stage	
Major stages	
Steward history	
Notes	

Title

[1] Requirements for the use of diagnostic testing laboratories

Reason for the standard

[2] Recently, NPPOs are often required to conduct diagnostic laboratory tests in implementing phytosanitary activities such as phytosanitary certification, import inspection and surveillance because of technology advancement. In addition, some NPPOs authorize third parties to conduct laboratory tests, and the amount of such authorization may likely increase in light of the adoption of ISPM 45 "Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions" in March 2021. The result of the laboratory test is directly linked to phytosanitary certification or decision of the pest status, so it is critically important that the diagnostic test is conducted by reliable and competent laboratories.

[3] There is, however, no existing ISPM on requirements for the use of testing laboratories at the moment while Codex and OIE have international standards on testing laboratories. Although IPPC "Guide to Delivering Phytosanitary Diagnostic Services (2018)" provides useful information as a implementation material, this is not an international standard with specific requirements. Thus, the use of testing laboratories for phytosanitary purpose is currently depending on the discretion of each country, and it is not implemented in an internationally harmonized manner. The diagnostic tests including genetic diagnosis and serological diagnosis should require adequate facilities, reliable system, competent staff and advanced technology. Development of ISPM on diagnostic testing laboratories will encourage contracting parties to carry out appropriate laboratory tests, leading to the reliable and consistent test results, which will contribute to safe international trade of plants and plant products.

[4] The proposed ISPM for the use of testing laboratories will describe requirements such as management, responsibilities, facilities, equipment, personnel, quality system, diagnostic methods, criteria for authorization and audit. It is intended that the proposed ISPM does not cover all diagnostic laboratories but focuses on testing laboratories as they require more international harmonization.

Scope

[5] The ISPM should cover requirements for the laboratories which conduct diagnostic tests for phytosanitary purpose such as phytosanitary certification, import inspection, surveillance. The laboratories may be owned by NPPOs for themselves or authorized by NPPOs to conduct diagnostic tests on their behalf.

Purpose

[6] The ISPM will provide guidance to NPPOs on the use of diagnostic testing laboratories, including management of their own laboratories and authorization to other laboratories to perform diagnostic tests. It will enable a common understanding on the use of diagnostic testing laboratories among contracting parties and will encourage them to carry out appropriate laboratory tests, leading to the reliable and consistent test results, which will contribute to safe international trade of plants and plant products.

Tasks

[7] The expert drafting group (EDG) should undertake the following tasks:

(1) Review descriptions about testing laboratories in existing ISPMs, clarify the difference between testing laboratories and diagnostic laboratories in ISPMs, and specify the concept of the testing laboratories in the phytosanitary context.

(2) Review existing standards and guidelines for the use of testing laboratories developed by NPPOs, regional plant protection organizations and other international organizations (e.g. International Organization for Standardization (ISO), the World Organisation for Animal Health (OIE), the Codex Alimentarius Commission, OECD).

(3) Review example of actual use of testing laboratories by NPPOs, including management of their own laboratories and authorization to other laboratories to perform diagnostic tests.

(4) Identify the purposes and scopes of the testing laboratories and the cases where testing laboratories are used in the phytosanitary context.

(5) Consider and describe the general requirements for the use of testing laboratories including administrative and operational management and responsibilities.

(6) Consider and describe specific requirements for the use of testing laboratories including facilities, equipment, personnel, quality system, diagnostic methods and other relevant elements.

(7) Describe authorization programme to testing laboratories to perform diagnostic tests, such as criteria for eligibility of authorized laboratories and, as appropriate, other components other than the requirements of ISPM 45 "Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions".

(8) Consider whether the ISPM could affect in a specific way (positively or negatively) the protection of biodiversity and the environment. If this is the case, the impact should be identified, addressed and clarified in the draft ISPM.

(9) Consider implementation of the standard by contracting parties and identify potential operational and technical implementation issues. Provide information and possible recommendations on these issues to the Standards Committee (SC).

Provision of resources

[8] Funding for the meeting may be provided from sources other than the regular programme of the IPPC (FAO). As recommended by ICPM-2 (1999), whenever possible, those participating in standard setting activities voluntarily fund their travel and subsistence to attend meetings. Participants may request financial assistance, with the understanding that resources are limited and the priority for financial assistance is given to developing country participants. Please refer to the *Criteria used for prioritizing participants to receive travel assistance to attend meetings organized by the IPPC Secretariat* posted on the International Phytosanitary Portal (IPP) (see https://www.ippc.int/en/core-activities/).

Collaborator

[9] To be determined.

Steward

[10] Please refer to the *List of topics for IPPC standards* posted on the International Phytosanitary Portal (IPP) (see https://www.ippc.int/core-activities/standards-setting/list-topics-ippc-standards).

Expertise

[11] Six to eight experts with a wide knowledge and experience in using diagnostic testing laboratories in the phytosanitary context and conducting diagnostic laboratory tests, including at least one person knowledgeable in phytopathology and at least one person knowledgeable in authorization programmes to testing laboratories.

Participants

[12] [To be determined.]

References

[13] The IPPC, relevant ISPMs and other national, regional and international standards and agreements as may be applicable to the tasks, and discussion papers submitted in relation to this work.

Discussion papers

[14] Participants and interested parties are encouraged to submit discussion papers to the IPPC Secretariat (ippc@fao.org) for consideration by the EDG.