Submissions for topics for Standards and Implementation

1. General information

Submission number	2021-004
Title of Proposal	Requirements for the use of testing laboratories
Submitted by	IPPC Contracting Party Japan

2. Contact information

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3. Summary of proposal

Summary of justification for the proposal	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. 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. 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.
Expected outcome of standard / implementation resource	The new standard will encourage contracting parties to carry out adequate laboratory tests, leading to the reliable and consistent test results, which will contribute to safe international trade of plants and plant products.
Contribution to filling gaps in the Framework for Standards	Key result area A2: All NPPOs have strong capacities to monitor, detect, diagnose, report, and prepare rapid responses to pest outbreaks, so that these pests do not have major impacts on food supplies and they do not spread and thereby threaten other regions and trading partners.

and Implementation	"Requirements for diagnostics" Key result area C2: Detections of pests in trade pathways are declining as exporting countries take more responsibility for managing the pest risk associated with exports, and importing countries report detections more quickly and consistently.

4. Type of proposed material

Proposed material	Standards
Type	New ISPM or component to an existing ISPM ISPM

5. Literature review

Literature review	There are several relevant guidelines on testing/diagnostic laboratories already available as follows, including international, regional and national ones. These materials should provide the basis for developing ISPM on phytosanitary testing laboratories. - IPPC Guide to Delivering Phytosanitary Diagnostic Services 2018 - ISO/IEC standard 17025, 'General Requirements for the Competence of Testing and Calibration Laboratories' - OIE Manual of Diagnostic tests and Vaccines for Terrestrial Animals 2021 Chapter 1.1.1. Management of veterinary diagnostic laboratories Chapter 1.1.5. Quality management in veterinary testing laboratories - CODEX Alimentarius Guidelines CXG 27-1997 Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food CXG 28-1995 Food Control Laboratory Management: Recommendations - OECD：Good Laboratory Practice (GLP) https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm - NAPPO RSPM9 Authorization of Laboratories for Performing Phytosanitary Testing - USA Plant Protection Act, Code of Federal Regulations PART 3.3.8 Accreditation of non-government facilities PART 353.9 Standards for accreditation of non-governmental facilities to perform laoratory seed health testing and seed crop phytosanitary inspection.

6. Criteria for justification and prioritization of proposed topics

6.1. Core criteria

Core Criteria	Information provided by Submitter
1. Contribution to the purpose of the IPPC as described in article I.1	The proposed ISPM on testing laboratory will facilitate adequate diagnostic test conducted by NPPOs or authorized entities. It is expected to secure common and effective action for NPPOs to prevent the spread and introduction of pests of plants and plant products as described in article I.1.
2. Linkage to IPPC SOs and Organizational results demonstrated	The proposed ISPM is to provide guidance on phytosanitary testing laboratories. It will contribute to Strategic objective A: Enhance Global Food Security and Increase Sustainable Agricultural Productivity, "Key result area A2: All NPPOs have strong capacities to monitor, detect, diagnose, report, and prepare rapid responses to pest outbreaks, so that these pests do not have major impacts on food supplies and they do not spread and thereby threaten other regions and trading partners", and Strategic objective C: Facilitate Safe Trade, Development and Economic Growth "Key result area C2: Detections of pests in trade pathways are declining as exporting countries take more responsibility for managing the pest risk associated with exports, and importing countries report detections more quickly and more consistently". It will also promote an IPPC development agenda "Diagnostic laboratory networking".
3. Feasibility of implementation	The diagnostic laboratory test is an essential phytosanitary activity to detect and identify plant pests, so it is already widely implemented by contracting parties.

Core Criteria	Information provided by Submitter
at the global level	
4. Clear identification of the problems that need to be resolved through the development of the standard or implementation resource	There is no existing international standard for phytosanitary testing laboratories, while the result of the laboratory test is critical in the phytosanitary context. The laboratory test should be conducted by reliable and competent laboratories in a consistent manner, but currently what kind of laboratories should be used depends on the discretion of each contracting party. The problems can be solved by the development of the proposed standard.
5. Availability of, or possibility to collect, information in support of the proposed standard or implementation resource	As described in the section of Literature review, there are several relevant guidelines on testing/diagnostic laboratories already available, including international, regional and national ones. These materials should provide useful information for development of the proposed standard.

6.2.Supporting criteria

Supporting Criteria	Information provided by Submitter
Practical	(1) IPPC Guide to Delivering Phytosanitary Diagnostic Services 2018 (2) ISO/IEC standard 17025, 'General Requirements for the Competence of Testing and Calibration Laboratories' (3) OIE Manual of Diagnostic tests and Vaccines for Terrestrial Animals 2021 Chapter 1.1.1. Management of veterinary diagnostic laboratories and Chapter 1.1.5. Quality management in veterinary testing laboratories (4) CODEX Alimentarius Guidelines CXG 27-1997 Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food and CXG 28-1995 Food Control Laboratory Management: Recommendations (5) OECD：Good Laboratory Practice (GLP) https://www.oecd.org/chemicalsafety/testing/good-laboratory-practiceglp.htm (6) NAPPO RSPM 9 Authorization of Laboratories for Performing Phytosanitary Testing (7) USA Plant Protection Act, Code of Federal Regulations PART 3.3.8 Accreditation of non-government facilities PART 353.9 Standards for accreditation of non-governmental facilities to perform laboratory seed health testing and seed crop phytosanitary inspection.
Economic	The laboratory diagnostic test is a effective phytosanitary measure especially for plants for planting such as seeds. In recent decades, the volume of trade of plants for planting has been significantly increased. The economic value of the trade of plants for planting is currently USD 11.4 billion (2016, ISF).
Environmental	The laboratory test is an effective and environmental-friendly method to verify that plants are free from such as plant diseases. It is useful phytosanitary measure not only for plants of economic importance but also for plants in wild flora and ecosystems.
Strategic	1) IPPC Guide to Delivering Phytosanitary Diagnostic Services was developed in 2018. 2) Laboratory diagnostic tests are frequently carried out by contracting parties for various phytosanitary activities. 3) It is also essential for developing countries to conduct diagnostic tests by competent laboratories to export plants for planting and to prevent introduction of plant disease through import.

Supporting Criteria	Information provided by Submitter
	4) The proposed ISPM can be applied to wide range of countries (both developed and developing countries), pests (especially plant disease) and commodities (especially plants for planting).) 5) The proposed ISPM may complement ISPM 27 “Diagnostic protocols for regulated pests” and other ISPMs (e.g. ISPM 6, 7, 36, 38, 45). 6) The proposed standard address fundamental concept on diagnostic testing laboratories 7) Recently, diagnostic tests have been increasingly required for phytosanitary purpose in many countries, so there is an urgent need for development of the proposed standard.

7. Financial/in-kind resources

Commitment for financial/in-kind resources to support the development of the proposed standards or implementation resource	Japan is willing to provide the in-kind resource (expert) to contribute to the discussion in the experts working group in developing the draft standard.