NAPPO
North American Plant Protection Organization
Organización Norteamericana de Protección a las Plantas
MEXICO - USA - CANADA

NAPPO Regional Standards for Phytosanitary Measures (RSPM)

RSPM 9
Authorization of Laboratories for Performing Phytosanitary Testing

The Secretariat of the North American Plant Protection Organization
1730 Varsity Drive, Suite 145
Raleigh, NC 27606-5202
United States of America

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Review

NAPPO Regional Standards for Phytosanitary Measures (RSPMs) are subject to periodic review and amendment. This standard was last reviewed in 2020-2021. A review of a NAPPO standard may be initiated at any time upon request of a NAPPO member country. The next review of RSPM 9 is scheduled for 2026.

Approval

This standard was approved by the North American Plant Protection Organization (NAPPO) Executive Committee on March 19, 2021 and is effective from this date.

Virtual approval of NAPPO Products

Given the current travel restrictions brought about by the COVID-19 pandemic, the NAPPO Management Team unanimously endorsed a temporary process for virtual approval of its products.

Beginning in January 2021 and until further notice, this statement will be included with each approved NAPPO product in lieu of the Executive Committee original signature page.

Regional standard for phytosanitary measures 9 – ***Authorization of Laboratories for Performing Phytosanitary Testing*** **and its associated Audit Checklist** – were approved by the North American Plant Protection Organization (NAPPO) Executive Committee – see approval dates below each signature - and is effective from the latest date below.

Approved by:

Greg Wolff

Greg Wolff
Executive Committee Member
Canada
Date March 12, 2021

Osama El-Lissy

Osama El-Lissy
Executive Committee Member
United States
Date March 15, 2021

Francisco Ramírez y Ramírez

Francisco Ramírez y Ramírez
Executive Committee Member
Mexico
Date March 19, 2021

RE: NRMF 9 + lista de control / aprobacion virtual por parte del CE de la NAPPO - RSPM 9 + audit checklist / virtual approval by the NAPPO EC

Reply | Reply All | Forward

WG Wolff, Greg (CFIA/ACIA) <greg.wolff@canada.ca>

To Stephanie Bloem; El-Lissy, Osama A - APHIS; John Greifer; francisco.ramirez@senasica.gob.mx

Cc Cote, Steve (CFIA/ACIA); Abad, Patricia V - APHIS; Dubon, Stephanie M - APHIS; Ana Lilia Montealegre; Alonso Suazo; Nedelka Marin-Martinez; Sofia Baez; Maribel Hurtado; Craig Regelbrugge; Mario Puente; Andrew Morse

Fri 3/12/2021 2:32 PM

You replied to this message on 3/13/2021 10:20 AM.

Afternoon all,

I am trying to catch up with e-mails s have only opened this one. Happy to support this and well done to all

Regards

Greg

RE: NRMF 9 + lista de control / aprobacion virtual por parte del CE de la NAPPO - RSPM 9 + audit checklist / virtual approval by the NAPPO EC

Reply | Reply All | Forward

OE El-Lissy, Osama A - APHIS <osama.a.el-lissy@usda.gov>

To Stephanie Bloem; Wolff, Greg (CFIA/ACIA); Greifer, John K - APHIS; francisco.ramirez@senasica.gob.mx

Cc Cote, Steve (CFIA/ACIA); Abad, Patricia V - APHIS; Dubon, Stephanie M - APHIS; Ana Lilia Montealegre; Alonso Suazo; Nedelka Marin-Martinez; Sofia Baez; Maribel Hurtado; Craig Regelbrugge; Mario Puente; Andrew Morse

Mon 3/15/2021 9:51 AM

Good morning, Stephanie-

The U.S. team concurs and appreciates the good work by the Secretariat and all involved.

Thanks,

Osama

Dr. Osama A. El-Lissy
Deputy Administrator
USDA APHIS Plant Protection and Quarantine
Office: 202-799-7163

RE: NRMF 9 + lista de control / aprobacion virtual por parte del CE de la NAPPO - RSPM 9 + audit checklist / virtual approval by the NAPPO EC

Reply | Reply All | Forward

FR Francisco Ramirez y Ramirez <francisco.ramirez@senasica.gob.mx>

To Stephanie Bloem; Wolff, Greg (CFIA/ACIA); El-Lissy, Osama A - APHIS; John Greifer

Cc Cote, Steve (CFIA/ACIA); Abad, Patricia V - APHIS; Dubon, Stephanie M - APHIS; Ana Lilia Montealegre Lara; Alonso Suazo; Nedelka Marin-Martinez; Sofia Baez; Maribel Hurtado; Craig Regelbrugge; DC35; Andrew Morse; Gloria Carrillo Martínez

Fri 3/19/2021 7:30 PM

Dear Stephanie,

Thank you very much for sending this information, I am aware of the procedure for its adoption. From the Mexican view we are supportive of the latest version of the draft revision to RSPM 9.

Kind regards,

A t e n t a m e n t e

SENASICA
SERVICIO NACIONAL DE SANIDAD, INOCUIDAD Y CALIDAD AGROALIMENTARIA

México 2021 Año de la Independencia

Ing. Francisco Ramírez y Ramírez
Director General de Sanidad Vegetal

Insurgentes Sur, No. 489, P-7,
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Implementation

No Implementation Plans are required.

Amendment Record

Amendments to this standard will be dated and filed with the NAPPO Secretariat.

Distribution

Once approved, this standard is uploaded to the NAPPO website and is distributed by the NAPPO Secretariat to the Secretariat of the International Plant Protection Convention (IPPC) and to other Regional Plant Protection Organizations (RPPOs).

INTRODUCTION

Scope

This standard describes the criteria and guidelines used by the National plant protection organization (NPPO) for the authorization of a laboratory to perform phytosanitary testing on behalf of the NPPO.

References

Draft ISPM *Requirements for national plant protection organizations if authorizing entities to perform phytosanitary actions.* (2014-002).
FAO. 2019. *IPPC style guide.* Rome. IPPC Secretariat. FAO. 43 pp.
International Organization for Standardization. 2015. ISO 9000: 2015. *Quality Management Systems – Fundamentals and Vocabulary.* Geneva, Switzerland.
International Organization for Standardization. 2017. ISO/IEC 17025: 2017 *General requirements for the competence of testing and calibration laboratories.* Geneva, Switzerland.
ISPM 5. *Glossary of phytosanitary terms*. Rome, IPPC, FAO.
RSPM 5. 2020. NAPPO *Glossary of phytosanitary terms*. Raleigh, NAPPO.

Definitions

Definitions of phytosanitary terms used in this standard can be found in RSPM 5 (*NAPPO Glossary of phytosanitary terms)* and in ISPM 5 (*Glossary of phytosanitary terms).* Terms not defined in RSPM 5 or ISPM 5 are included below for clarity.

Appropriate uses for the terms “shall” and “should” can be found in the IPPC Style Guide.

Audit (modified from ISO 9000): Systematic, independent, and documented process for obtaining and objectively evaluating evidence to confirm established requirements are fulfilled.

OUTLINE OF REQUIREMENTS

National Plant Protection Organizations (NPPOs) may authorize public or private laboratories to conduct phytosanitary testing to enhance the delivery of programs and services that protect plant resources and facilitate safe trade.

The NPPO shall have the authority and ability to implement, maintain, and monitor a laboratory authorization program to ensure compliance and continual improvement. An NPPO’s authorization program operates within its phytosanitary system or legal framework.

Applicant laboratories shall comply with all obligations and requirements established by the NPPO to receive and maintain their status as an authorized laboratory.

General Requirements

1. National Plant Protection Organization (NPPO)

The NPPO shall ensure the integrity of its authorization programs. The NPPO shall provide the information and resources to implement and maintain the laboratory authorization program.

1.1 Authority

The NPPO has the authority to authorize and monitor authorized laboratories performing phytosanitary testing.

The NPPO has the authority to suspend or revoke the authorization of a laboratory that does not comply with agreed-upon standards or provisions.

1.2 Responsibility

The NPPO is responsible for:

- providing laboratories with the necessary information describing how to apply for and maintain authorization
- establishing the scope of testing for which a laboratory has been authorized. If permitted by the NPPO and where the laboratory has demonstrated expertise and competence, the scope of testing may include activities in addition to diagnostic testing such as visual inspection. Any additional activities shall be delineated in the agreement between the NPPO and the laboratory
- setting the minimum standards for authorization
- conducting the authorization process
- maintaining a current, publicly available list of NPPO approved laboratories, unless otherwise specified in the agreement.

The NPPO or its representative should:

- evaluate the competence of the laboratory prior to entering into the authorization agreement
- periodically monitor the competence of authorized laboratories to ensure their work continues to meet the agreement.

Evaluation and monitoring of laboratory competence may include but is not limited to:

- on-site or remote audits
- document review
- records review
- follow-up on reported results
- proficiency testing provided either by the NPPO or by an internationally recognized proficiency test provider.

Where monitoring identifies a non-conformance, the NPPO will examine the non-conformance documentation and will determine how to proceed as per the legal framework established by each NPPO.

1.3 Audit

Audits may be carried out to evaluate laboratory technical competence for performing phytosanitary testing. Appendix 1 provides an Audit checklist that may be used for this purpose.

The NPPO should determine the frequency and requirements for the audit.

An audit may be carried out on a selected part, or on the entire laboratory quality system. The audit should reflect the level of risk and complexity associated with the agreed-upon phytosanitary testing. Additionally, performance and conformance of the laboratory should be considered.

If the NPPO or its representative identifies a non-conformity, the laboratory shall promptly take action to correct the non-conformity.

The NPPO should suspend some or all phytosanitary testing activities if the non-conformity is not reasonably addressed or continues to pose a risk.

1.4 Authorization Agreement

The authorization agreement shall describe the rights, obligations, and requirements of both the NPPO and the authorized laboratory.

A record of authorization or equivalent document shall be issued to a laboratory that complies with the requirements established in the authorization agreement. This record shall identify the scope for which the authorized laboratory may perform phytosanitary testing activities.

Authorization should be renewed at a frequency established by the NPPO.

Upon authorization, a laboratory is officially recognized by the NPPO to perform the phytosanitary testing as outlined in the agreement.

1.5. Suspension, Reinstatement or Revocation

The NPPO may reject a laboratory's application, suspend, or revoke an authorization to perform phytosanitary testing activities.

The NPPO shall specify the procedures and criteria for rejection, suspension, revocation, or reinstatement of authorization.

A laboratory that wishes to have its authorization reinstated shall meet the requirements for reinstatement of authorization as specified by the NPPO.

During suspension, the laboratory can remain under the purview of the NPPO. If the laboratory remains under the purview of the NPPO, it shall continue to meet the requirements of the authorization agreement.

During suspension or upon revocation, the laboratory shall not perform any phytosanitary testing activities pertaining to suspension or revocation. The NPPO should update the publicly available list of authorized laboratories.

2. Applicant Laboratory

To be authorized, the applicant laboratories in NAPPO member countries shall:
- meet the requirements of this standard
- meet the NPPO's general and specific legal requirements
- complete the authorization process established by the NPPO.

The laboratory should promptly inform the NPPO of changes that could affect the authorization agreement, including but not limited to changes in key personnel, equipment, methods, facilities, ownership, and subcontracting.

2.1 Applications

The laboratory shall designate a representative who will be accountable to the NPPO for the

authorized activities, and if necessary, for performance evaluation of authorized activities.

The laboratory shall designate a representative who has the authority to sign the authorization agreement with the NPPO.

Applications for authorization are approved by the NPPO.

The authorization agreement shall identify any information that is confidential. This may include, but is not limited to, results from phytosanitary testing, personnel descriptions, sampling sources and locations.

The laboratory and the NPPO shall secure and protect information designated as confidential.

2.2 Subcontracting

If subcontracting is permitted by the NPPO, the authorized laboratory:

- shall be legally responsible for the subcontracted testing results
- should subcontract to a laboratory that is accredited to an internationally recognized standard, or as agreed upon between the NPPO and the contracting laboratory
- should document subcontracting requirements in the agreement prior to commencing testing
- should indicate clearly in their reports which testing is performed by the subcontractor.

If the laboratory subcontracts work at any point after the NPPO authorizes the agreement, the NPPO shall be notified without undue delay.

2.3 Quality System

The laboratory shall define, document, and adhere to its quality system.

The quality system should be based on a nationally or internationally recognized standard.

The quality system shall meet the requirements of the NPPO.

The quality system shall be managed to safeguard impartiality to ensure conflicts of interest do not exist or are addressed to prevent undue influence on phytosanitary testing results.

The laboratory should routinely monitor and document its competency using sample checks, participation in proficiency testing programs, or other mechanisms as required by the NPPO.

The laboratory should identify and document non-conformities. Where a non-conformity is identified, the laboratory shall promptly take action to correct the non-conformity. If the non-conformity poses a risk to phytosanitary test results the laboratory shall notify the NPPO of the proposed corrective action measures.

When required by the NPPO, the laboratory shall use NPPO-approved methodologies.

If the NPPO does not specify the methodologies to be used, the laboratory shall use other validated methods (published or internally developed). The selected methodologies and validation data shall be made available to the NPPO upon request.

2.4 Personnel

Laboratory personnel shall follow the laboratory's quality system.

Laboratory personnel shall be trained and competent to perform the required phytosanitary tests.

The laboratory shall:
- document the qualifications, training, and managerial authorization of laboratory personnel
- monitor the competency of laboratory personnel.

2.5 Voluntary Termination

The laboratory may voluntarily terminate the authorization agreement with the NPPO. Upon termination:
- the laboratory shall immediately inform the NPPO
- the laboratory shall not perform any phytosanitary testing activities authorized in the original agreement
- the NPPO should update the publicly available list of authorized laboratories.

3. Facilities

The laboratory facilities and environmental conditions shall be suitable for performing phytosanitary testing. This should include:
- steps to minimize contamination
- steps to protect against pest entry
- appropriate lighting, temperature, moisture, ventilation, and noise conditions.

The laboratory facilities and environmental conditions should be monitored, controlled, and periodically reviewed by laboratory personnel in accordance with a documented schedule and meeting technical requirements where defined.

4. Equipment

The laboratory shall have the equipment necessary to conduct the authorized phytosanitary testing.

The equipment shall meet the NPPO requirements where defined and shall ensure that equipment meets the specified requirements of the methodologies used. This can be achieved through monitoring equipment performance through an established and documented preventative maintenance, calibration, and verification program.

The equipment shall conform to the laboratory's quality system.

5. Records

The laboratory shall maintain detailed records of the phytosanitary testing activities authorized by the NPPO.

Records shall confirm that phytosanitary test results are reviewed and approved by personnel authorized by laboratory management prior to reporting.

When requested by the NPPO, the laboratory shall provide all records for testing activities for which it is authorized.

Detailed records shall be maintained in a way that ensures integrity and traceability of the phytosanitary testing activities for the period specified by the NPPO.

Detailed records should include, but are not limited to, sample submission forms, worksheets, test results, equipment records, personnel training records, and all original observations to enable repetition of the laboratory activity under conditions as close as possible to the original. Detailed records ensure that errors can be identified, and corrective actions can be taken, as necessary.