

Purpose

Presently the phytosanitary import requirements for many seeds for propagation into the US are limited to a visual inspection. In response to domestic detections of foreign pathogens in domestic production areas from imported seed, the National Seed Health Accreditation Pilot Program (NSHAPP) has been created. USDA-APHIS is partnering with the US seed industry to screen imported seed with diagnostic testing to detect the introduction of seed-transmitted pathogens.

Scope

The recognition of facilities that are accredited by a USDA-APHIS recognized accreditation body (see appendix 1), for the testing of foreign origin seed for propagation, in order to monitor for, and prevent the introduction of, foreign pathogens (see appendix 2) into the United States.

Who May participate in the NSHAPP

- Those companies utilizing their own laboratory for seed health testing accredited by a body listed in appendix 1 for pests listed in appendix 2 of this document
- Companies who do not utilize their own laboratory for seed health testing but utilize an laboratory recognized under the NSHAPP for pests listed under appendix 2 of this document

Document Evaluation

USDA-APHIS will verify proof of seed testing accreditation documentation of facilities to be recognized under NSHAPP. USDA-APHIS may require additional information before approval. Any recommended changes to any reviewed documents will be provided after the document evaluation.

Requirements

To participate in the NSHAPP, the entity must agree:

1. To complete and submit a "Compliance Agreement" signed by a management representative who will be responsible for ensuring that all facilities covered under this agreement are fully aware of the requirements of the program.
2. To submit a copy of facility accreditation for recognition in the NSHAPP, from an entity in appendix 1 or utilize a USDA-APHIS NSHAPP recognized laboratory (see appendix 4) to be considered eligible for participation¹.

¹ For entities without an accreditation system, but are interested in joining the NSHAPP, they may gain accreditation by applying for accreditation to the National Seed Health System (NSHS) or one of the entities in appendix 1 of this document.

Any person who knowingly violates the Plant Protection Act (PPA) (7U.S.C. §§ 7701 et. Seq.) and/or the Animal Health Protection Act (AHPA) (7U.S.C. §§ 8301 et. Seq.) may be criminally prosecuted and found guilty of a misdemeanor which can result in penalties, and one year prison term, or both. Additionally, any person violating the PPA and/or the AHPA may be assessed civil penalties of up to \$250,000 per violation or twice the gross gain or gross loss for any violation that results in the person deriving pecuniary gain or causing pecuniary loss to another, whichever is greater.

3. To demonstrate that all the components of the Compliance Agreement have been implemented at the facility.
4. To publish their name on APHIS website of "approved facilities" for the National Seed Health Accreditation Pilot (NSHAPP).
5. To allow USDA-APHIS to collect and report testing data.
6. To be free from conflicts-of-interest, that could impair their ability to objectively perform duties, and responsibilities.
7. To designate qualified personnel or contractors that are vested with the authority and the necessary knowledge, skills and training to ensure the requirements of the NSHAPP compliance agreement are met.
8. To have a robust system to ensure that diagnostic samples maintain their identity and remain segregated. Robust system principle components include but are not limited to:
 - a. Quality manual
 - b. Documented system of document and record control (integrity and traceability)
 - c. Documented system of internal audits
 - d. Documented process of handling customer feedback, corrective and preventive actions
 - e. Documented training program
 - f. Documented system for Instrument/equipment controls and calibration
 - g. Documented laboratory processes, Standard Operating Procedures (SOP), and verification SOPS are followed.
9. To assist with a trace back investigation in the event of a positive pest detection.
10. The USDA reserves the right to modify the conditions of this agreement in order to meet any changes in phytosanitary requirements of foreign countries or the United States.
11. USDA-APHIS will consider all information submitted through the National Seed Health Accreditation Pilot Program (NSHAPP) by a participating company to be confidential business information for purposes of the Freedom of Information Act (FOIA).
12. USDA-APHIS may audit any approved facility to ensure that the facility meets the standards of the recognized accreditation body. Results of an audit will be provided to the management representative and will include recommendations or necessary corrective actions.
13. Activities at facilities that are found to be in contravention of the USDA-APHIS recognized accreditation program body listed in appendix 1 are considered as non-conformances. These shall be identified during the audit and the facility will provide an action plan and time line that describes in detail the measures that the facility will implement to prevent future non-

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conformance. Failure to follow the requirements of the NSHAP compliance agreement may result in the suspension of the facility from the NSHAPP.

14. Violation of any of the provisions of this compliance agreement may be cause for its termination or suspension of the facility from the NSHAPP. The agreement may be withdrawn by a USDA-APHIS official orally or in writing; if the cancellation is oral, the decision and the reasons for the withdrawal shall be confirmed in writing as promptly as circumstances allow. The holder of the agreement may likewise terminate it voluntarily by providing written notice to that effect to USDA-APHIS.
15. An applicant to, or, a participant of, the NSHAPP shall be responsible for and shall attach no liability to the United States Department of Agriculture or to any officer or representative of the USDA, from and against all manners of actions, causes of action, claims, demands, losses, costs, damages, actions, or other proceedings whomsoever made, sustained, brought, or prosecuted in any manner based upon, caused by, arising out of, attributable to, or with respect to any failure, inadvertent or otherwise, by act or omission, to fully comply with the stated conditions and requirements.

Pest Detection

In the event of a positive detection of a pest in appendix 2 of this document,

1. Prior to entry into the NSHAPP, companies must provide a written protocol for disposal of infected seed material according to an APHIS approved method.
2. USDA-APHIS will be notified immediately of the positive find and provide the information as per the NSHAPP website (<http://www.seedhealth.org/imported-seed-pilot-program-nshapp>).
3. The affected lot(s) will be reexported from the U.S. or destroyed according to the method identified in 1 above.

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Appendix 1

List of USDA-APHIS Recognized Accreditation Entities

1. USDA National Seed Health System (NSHS)
2. Naktuinbouw (NAL)

Appendix 2

Pests Recognized by this compliance agreement

Cucumber Green Mottle Mosaic Virus (CGMMV) in seed

Hosts: For the purposes of the NSHAPP shall be defined as seeds of cucumbers, melons, and watermelons.

Recognized Methods:

PATHOGEN: Cucumber Green Mottle Mosaic Virus (CGMMV)

HOST: Cucurbits

METHOD: Cb 3.1 ISTA Assay 7-026

METHOD CLASS: TEMPORARY STANDARD (B)

SAMPLE: Minimum 2000 seeds

PROCEDURE: <https://www.seedtest.org/upload/cms/user/SH-07-026-2014.pdf>

REFERENCES: International Rules for Seed Testing. Annex to Chapter 7: Seed Health Testing Methods. 2014. 7-026: Detection of Squash Mosaic Virus, Cucumber Green Mottle Mosaic Virus and Melon Necrotic Spot Virus in cucurbits.

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Appendix 3

U.S. Laboratories Recognized for NSHAPP Participation

- USDA National Seed Health System (NSHS) Accredited Entities
http://www.aphis.usda.gov/plant_health/acns/downloads/SeedHealthProgram/Entities/EntitiesAccredited.pdf
- Bayer CropScience Vegetable Seeds (Naktuinbouw (NAL))
Attn: Regional Head of Quality Assurance
1200 Anderson Corner Road
Parma, Idaho 83660
Phone: (800) 733-9505

Foreign Laboratories Recognized for NSHAPP Participation

- Bayer CropScience Vegetable Seeds (Naktuinbouw (NAL))
Attn: Regional Head of Quality Assurance
P.O. Box 4005
6080 AA Haelen
The Netherlands
Phone: +31 475 599 222
Fax: +31 475 595104
- Enza Zaden Seed Operations B.V. (Naktuinbouw (NAL))
Haling 1E 1602DB Enkhuizen
The Netherlands
- Naktuinbouw (NAL)
Sotaweg 22, 2371 GD Roelofarendsveen
The Netherlands
Phone: +31 (0)71 332 62 62
Fax: +31 (0)71 332 63 63
info@naktuinbouw.nl

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