



Animal and Plant Health Inspection Service  
U.S. DEPARTMENT OF AGRICULTURE

# **ReFreSH**

## **Regulatory Framework for Seed Health**

Accreditation Standard / March 8, 2021

Draft

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## Scope

This Standard describes the essential elements of the Regulatory Framework for Seed Health (ReFreSH), a risk-based systems approach alternative to individual consignment inspection as the basis for phytosanitary certification for the international movement of seed, including its importation into the United States. ISPM 38 recognizes that certain seed production practices when used in combination may be sufficient to reduce or prevent pest introductions and distributions through the seed supply chain. ReFreSH combines elements of these seed production best management practices, phytosanitary systems approach and quality management systems. ReFreSH is a voluntary program conducted under the authority of national plant protection organizations (NPPOs) that accept it as a valid system for phytosanitary certification of seed moving internationally. The ReFreSH Standard outlines the basic requirements for a seed entity implementing ReFreSH and the responsibilities of NPPOs accepting the ReFreSH Program.

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## Definitions

The definitions listed here have been taken directly from the references identified in parentheses, adapted for ReFreSH from those references, or, where no reference is cited, they have been developed for the purpose of this standard.

**Accreditation audit-** The accreditation audit is a specific type of systems audit (see **Systems audit**) that is conducted after a facility’s ReFreSH application package has been reviewed and accepted by the authorizing NPPO and prior to enrollment in ReFreSH. The purpose of the accreditation audit is to demonstrate that all components of the ReFreSH Standard have been implemented at the entity. Any non-compliance identified during the accreditation audit must be resolved before the NPPO signs the ReFreSH compliance agreement with the entity. (GCP)

**Audit-** Systematic, independent and documented process for obtaining evidence to objectively evaluate that the requirements of the ReFreSH Standard are met.

**Best management practices (BMPs) -** A combination of seed supply system practices that facilitate seed quality and can be an effective and practicable means to prevent, eliminate or reduce the likelihood of pest introduction or spread to an acceptable level of phytosanitary protection.

**Brokers-** Entities that purchase or take possession of seeds from an approved ReFreSH entity for the purpose of exporting those seeds without further growing prior to export/re-export/sale. (RSPM 24)

**Critical control point (CCP) –** The identified points, steps or procedures in a process where controls can be applied and a phytosanitary hazard prevented, eliminated or reduced to an acceptable level. (ReFreSH Concept Paper)

**Entity-** The facility, organization, party or producer responsible for given processes and practices in the ReFreSH program. (RSPM 41)

**Hazard-** Any part or process of the seed supply system that has the potential to introduce plant pests through contamination or infection or allows the entry or spread of a pest. (ReFreSH Concept Paper)

**Infestation (of a commodity)** – Presence, in a commodity, of a living pest of the plant or plant product concerned. Infestation includes infection. (ISPM 5)

**Internal audit-** An entity activity to monitor and analyze its seed supply system in order to determine how well it conforms to the procedures described in the entity’s ReFreSH Manual to meet requirements of the ReFreSH Standard (see **Audit**).

**Non-compliance-** Failure to meet official phytosanitary requirements of an importing or exporting country NPPO.

**Non-conformance-** Any failure of the entity to follow the agreed upon requirements in their ReFreSH Manual. Non-conformances are categorized by severity:

**Critical non-conformance-** Critical non-conformances are incidents that compromise the integrity and efficacy of an entity’s ReFreSH processes and procedures or increase the risk of infestation of the seed supply system. (See examples in APPENDIX).

**Non-critical non-conformance.** Minor non-conformances are incidents that on their own do not directly impact the integrity of an entity’s ReFreSH processes and procedures, provided that remedial actions are completed within an agreed upon period of time defined by the NPPO. (See examples in APPENDIX).

**Pest-** Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. (ISPM 5)

**Quality management system (QMS)** - A formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives. Components of a QMS include a quality policy, which is the commitment and goal towards which the entity is working; standard operating procedures that are executed to produce the quality seed; a system for training, auditing and issuing corrective actions; continuous improvement; and risk evaluation and mitigation. (ReFreSH Concept Paper)

**Quarantine pest-** A pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. (ISPM 5).

**Reaccreditation audit-** Audit conducted by the authorizing NPPO or its designee prior to the end of the ReFreSH accreditation period/audit cycle. The purpose is to verify that an entity



continues to conform to processes and procedures described in their ReFreSH Manual to meet the requirements of the ReFreSH Standard. The reaccreditation audit is a **systems audit**. Entities that are in conformance shall maintain their accreditation and listing in the authorizing NPPO's registry of accredited ReFreSH entities.

**ReFreSH Manual-** A document produced by a participating entity that specifies procedures and processes undertaken by the entity and applied to their seed supply system as part of a systems approach to meet the requirements of the ReFreSH Standard. It describes key staff resources; staff training; a physical description of the entity's facilities; their Seed Health Management Plan (see below); records and document management; and reporting, monitoring and corrective measures including internal audit procedures.

**Regulated non-quarantine pest-** A non-quarantine pest whose presence in plants for planting (including seed for planting) affects the intended use of those plants with an economically unacceptable impact and which is therefore regulated within the territory of the contracting party. (ISPM 5)

**Regulated pest-** A quarantine pest or a regulated non-quarantine pest. (ISPM 5)

**Risk Evaluation/Hazard Analysis-** A process of identifying risks or hazards, critical control points and best management practices to mitigate introduction and movement of regulated pests within an entity's seed supply system. The process identifies and prioritizes the hazards that must be monitored and controlled throughout all steps described in the seed supply system but concentrates on the steps where pest risk management could be applied. (SANC)

**Seedborne pest-** A pest carried by seeds externally or internally that may or may not be transmitted to plants growing from these seeds and cause their infestation. (ISPM 38)

**Seeds-** Seeds for planting or intended for planting and not for consumption or processing. (ISPM 5)

**Seed Health Management Plan (SHMP) -** A document written by the entity to describe plant pest risk management at the critical control points identified during the entity's risk evaluation/hazard analysis of the seed supply system. This SHMP includes, but is not limited to, procedures for scouting, record keeping, and reporting regulated pest detections.

**Seed transmitted pest-** A seedborne pest that is transmitted via seeds directly to plants growing from these seeds and causes their infestation. (ISPM 38)

**Surveillance Audit-** Verification by the authorizing NPPO of the ongoing conformance of the entity to activities described in its ReFreSH Manual to meet by conducting audits on specific portions of its seed supply system. (GCP)

**Systems approach-** A pest risk management option that integrates different measures, at least two of which act independently, with cumulative effect. (ISPM 14)

**Systems audit-** A systematic and independent examination of the complete organizational structure, procedures, processes and resources of an entity to determine whether they and related results comply with the ReFreSH Standard and are implemented effectively. (GCP, RSPM 28)

## 1. GENERAL REQUIREMENTS

ReFreSH is designed to enable entities to produce seed free of regulated pests and meet the phytosanitary requirements of the importing and exporting country or countries.

### 1.1. U.S. Legislative Authority

- [Plant Protection Act of 2000, SEC. 401. 7 U.S.C. 7701](#)
- [Title 7 Code of Federal Regulations, Part 319 Subpart H: Plants for Planting](#)
- USDA [Plants for Planting Manual](#)
- [Title 7 Code of Federal Regulations, Part 353 Export Certification](#)
- [Title 7 Code of Federal Regulations, Part 360 Noxious Weed Regulations](#)
- [Title 7 Code of Federal Regulations, Part 361 Importation of Seed and Screenings under the Federal Seed Act](#)

**1.2. Eligible Commodities.** All seeds currently admissible with phytosanitary certification and not specifically restricted by participating NPPOs along the seed supply system are eligible under the ReFreSH Standard.

**1.3. Eligible Entity.** Any entity that agrees to produce or distribute seed using best management practices as documented in a quality management system that meets the ReFreSH Standard is eligible to participate in ReFreSH.

**1.4. Fees.** Applicable fees shall be determined by the NPPO authorizing an entity's participation in ReFreSH. Fees may include charges for audits, inspections, or document review, etc.

## 2. APPLICATION AND ENROLLMENT IN THE REFRESH PROGRAM

- 2.1. Application.** The entity must apply for ReFreSH enrollment to the authorizing NPPO(s) or official designees (henceforth, authorizing NPPO) in the country where the seed supply system activity or activities to be authorized under ReFreSH occur(s), (e.g., seed is grown, conditioning, packaging, etc.). In the case of brokers, the entity must apply to the authorizing NPPO of the country from which the seed is exported or re-exported. The entity will submit a ReFreSH Manual (see Section 3.1) or equivalent documentation to the authorizing NPPO. The authorizing NPPO will review the documentation to ensure that it contains all the required elements and that it is sufficient to meet the requirements of the ReFreSH Standard.
- 2.2. Accreditation Audit.** The authorizing NPPO(s) will complete an audit to verify the entity has successfully implemented the system as described in their ReFreSH Manual.
- 2.3. Enrollment.** The entity and the authorizing NPPO will sign a ReFreSH agreement indicating the authorizing NPPO's acceptance of the entity into the ReFreSH program, and the entity's understanding and agreement to comply with the ReFreSH Standard.

## 3. NPPO RESPONSIBILITIES

### 3.1. ReFreSH Authorizing NPPO

- 3.1.1. Program Administration.** The authorizing NPPO(s) will establish and maintain a ReFreSH program, using the ReFreSH Standard. The NPPO may authorize an official designee(s) to perform aspects of the ReFreSH program. Such official designees are required to establish and maintain the ReFreSH program in accordance with applicable sections of the ReFreSH Standard and any additional requirements set forth by the authorizing NPPO.
- 3.1.2. Program Review.** The authorizing NPPO will periodically review the ReFreSH program performance and identify issues and potential improvement. The review should cover non-compliance information, including suspension, cancellation and notices of non-compliance, non-conformance, evaluation of the program components and any relevant new information.
- 3.1.3. Program Enrollment.** The authorizing NPPO will review an entity's application, including initiating meetings as needed (see Section 2). The authorizing NPPO shall deny participation to any entity that cannot meet the requirements of the ReFreSH Standard. Participating NPPOs have the sovereign right and responsibility to determine if the entity's SHMP provides an adequate level of phytosanitary protection.

**3.1.4. Registration.** The authorizing NPPO will maintain a registry of accredited ReFreSH entities. When a ReFreSH accreditation is suspended or an entity voluntarily withdraws from the ReFreSH program the entity will be removed from the registry of accredited ReFreSH entities.

**3.1.5. Records.** The authorizing NPPO will maintain the following information for each accredited entity:

- The original application package that was submitted to the authorizing NPPO;
- Copies of all signed ReFreSH agreements;
- Copy of the Seed Health Management Plan;
- Copies of all audit reports;
- Copies of all corrective action requests;
- Any written statements of corrective actions taken by the entity;
- Copies of any notifications of suspension and/or reinstatement; and
- Copies of any correspondence between the entity and the authorizing NPPO.

The authorizing NPPO will maintain such records in accordance with government record retention policy

**3.1.6. Audits.** The authorizing NPPO will conduct regular audits of all enrolled entities and will prepare reports that summarize their findings. Should audits identify any critical or minor non-conformance, the authorizing NPPO will ensure the non-conformance has been addressed by the entity within the specified time frame (see Section 5). The authorizing NPPO should review the SHMP as part of each audit.

**3.1.6.1. Audit Frequency.** At a minimum, audits by the authorizing NPPO will be conducted on a three (3) year cycle. The number of audits and whether they are announced or unannounced may change based on the entity's compliance and any imposed or proposed changes to the entity's ReFreSH Manual.

**3.1.6.2. Accreditation audit.** (Year 0) The Accreditation audit is a specific type of systems audit that is conducted after a facility's ReFreSH application package has been reviewed and accepted by the authorizing NPPO and prior to enrollment into the ReFreSH program. The objective of the accreditation audit is to verify that the entity has the necessary procedures, processes, systems, tools and a SHMP that result in consistently meeting the requirements of the ReFreSH Standard. This audit will allow the entity to make any corrections, if needed, for initial certification. Entities that are in compliance will be

authorized and added to the authorizing NPPO's registry of accredited ReFreSH entities. The intervals for subsequent surveillance and reaccreditation audits are set by the authorization date.

**3.1.6.3. Surveillance audit(s).** (Years 1-2) The authorizing NPPO should conduct one or more surveillance audits of the entity prior to reviewing their certification in the third year. Surveillance audits verify the ongoing compliance of the accredited entity with the requirements of the ReFreSH Standard by conducting audits on specific portions of the seed supply system. The audits should encompass the complete organizational structure over time.

**3.1.6.4. Reaccreditation audit.** (Year 3) The authorizing NPPO or its designee shall review all aspects of the entity's necessary procedures, processes, systems, tools and a SHMP that result in consistently meeting the requirements of the ReFreSH Standard. Entities that are complying shall maintain their accreditation and listing in the authorizing NPPO's registry of accredited ReFreSH entities. The cycle of audits described above is repeated.

**3.1.7. Suspension/reinstatement of entity.** The authorizing NPPO has the authority to suspend an entity from participation in the ReFreSH program based on non-compliance and may reinstate it as appropriate (see Section 4.7).

**3.1.8. Authorization.** The authorizing NPPO(s) will provide approved entities a copy of the signed ReFreSH agreement. The entity will be issued a unique identifier (i.e., an accredited entity number) indicating its accreditation.

## **3.2. Importing country NPPO**

**3.2.1. Import requirements.** The importing country's NPPO must establish their import requirements and inform the exporting country or countries of the requirements.

**3.2.2. Review.** The importing country's NPPO has the right to review the authorizing NPPO's process for accrediting ReFreSH entities to ensure compliance with their import requirements. The importing NPPO may conduct audits to address specific noncompliances; during this review, they may propose additional or equivalent measures.

**3.2.3. Monitoring.** The importing country's NPPO may conduct monitoring of imported seeds.

**3.2.4. Notification of non-compliance.** The importing country's NPPO shall notify the authorizing NPPO of any non-compliance with the importing NPPO's regulatory requirements.

## **4. NON-CONFORMANCE AND CORRECTIVE MEASURES**

- 4.1. Types of Non-conformance.** A non-conformance is any failure to adhere to the procedures described in the entity's ReFreSH Manual to meet the requirements of the ReFreSH Standard. The ReFreSH program distinguishes between two types of non-conformance taking into account the severity of the non-conformance.
- 4.1.1. Critical non-conformances.** Critical non-conformances are incidents that compromise the efficacy of an entity's ReFreSH processes and procedures or increase the risk of infestation of the seed supply system. A critical non-conformance may result in immediate suspension from the program. See Appendix for examples.
- 4.1.2. Non-critical non-conformances.** Non-critical non-conformances are incidents that do not immediately compromise the ReFreSH processes and procedures or increase the risk of infestation of the seed supply system. Repeated, multiple, or failure to correct non-critical non-conformances may result in suspension of the entity's ReFreSH accreditation. See Appendix for examples.
- 4.2. Non-conformance detection and determination of status.** A non-conformance may be detected during internal audits by the entity, or during external audits conducted by the authorizing NPPO.
- 4.3. Detection by authorizing NPPO.** If detected by the authorizing NPPO, the entity will be informed in writing of the non-conformance and the need for corrective actions (See Section 4.6). The entity must make corrections promptly, and within a mutually agreed upon timeframe.
- 4.4. Detection by the entity.** If detected by the entity, the non-conformance must be documented along with any corrective actions taken. If a critical non-conformance is detected by the entity, the NPPO must be notified within 48-hours of the non-conformance and corrective actions taken. Failure to notify the NPPO of a critical non-conformance will result in immediate suspension of the entity's ReFreSH accreditation. A critical non-conformance may require a root cause analysis and subsequent changes to the ReFreSH Manual.
- 4.5. Detection by the importing country NPPO.** The detection of a ReFreSH product or process that fails to comply with the stated phytosanitary requirements of the NPPO of the importing country is a non-compliance. The importing country NPPO shall inform the authorizing NPPO of the non-compliance. The authorizing NPPO will

inform the entity if the non-compliance has caused a non-conformance or requires a change to their ReFreSH Manual.

**4.6. Corrective action requests.** Corrective Action Requests (CARs) are used by the NPPO to formally communicate and record non-conformances and their resolution. A corrective action request will be completed for each non-conformance identified, including those resulting from a non-compliance. For each CAR, the entity will propose a detailed description of the action(s) the entity will implement to prevent recurrence of the non-conformance and a timeframe for completing the action(s). CARs for critical non-conformance(s) require review by the authorizing NPPO. Failure to follow the prescribed actions may result in suspension of the entity's ReFreSH accreditation.

**4.6.1. Corrective actions for critical non-conformances.** The entity must submit CARs for critical non-conformances must be submitted to the authorizing NPPO for review and approval within 48 hours of detection. The authorizing NPPO will acknowledge receipt of the CAR and begin its review within seven (7) business days.

**4.6.2. Corrective actions for non-critical non-conformances.** The entity will submit CARs for non-critical non-conformance(s) within a mutually agreed upon time frame to the authorizing NPPO for review and approval.

**4.6.3. Implementation.** The entity may implement corrective actions immediately pending review and approval by the authorizing NPPO.

**4.7. Suspension of accreditation.** Entities, or relevant part(s) thereof, unable to maintain the requirements of the ReFreSH Standard or misrepresenting / misusing information related to ReFreSH accreditation, will be immediately notified by the authorizing NPPO of the suspension of the entity's ReFreSH accreditation. Entity participation may also be suspended if program fees are not paid. The suspended entity will be removed from the authorizing NPPO's registry of accredited ReFreSH entities until or unless its accreditation is reinstated by the authorizing NPPO. Suspended entities shall not ship seed using their official ReFreSH identifier.

**4.8. Reinstatement of suspended entities.** An entity, or relevant part(s) thereof, suspended from the ReFreSH Program may be reinstated after the authorizing NPPO has received a request for reinstatement and documentation of completed corrective actions related to the suspension. The authorizing NPPO will verify

completion of corrective actions and issue a determination regarding the request for reinstatement.

**4.9. Cancellation of the ReFreSH agreement.** An entity's ReFreSH agreement will be cancelled by the NPPO when:

- The facility is unable to maintain consistent compliance or achieve compliance within a reasonable period of time; or,
- The entity voluntarily withdraws from their ReFreSH agreement.

The NPPO will notify the accredited entity when their ReFreSH agreement has been cancelled. Entities whose ReFreSH agreement has been cancelled may reapply for designation as an accredited entity in the ReFreSH program. If so, the entire application and approval process must be reinitiated, including submitting an application form and a revised ReFreSH Manual. The NPPO may refuse to reauthorize entities at their discretion.

## 5. REFRESH PARTICIPATING ENTITY RESPONSIBILITIES

**5.1. ReFreSH Manual.** The entity must complete a ReFreSH Manual to record details about its facilities, key personnel and specific activities for healthy seed production. System components listed below are required for authorization and must be described in the entity's ReFreSH Manual or equivalent documentation, [e.g., a manual documenting equivalent, applicable accreditation such as [International Organization for Standardization](#) (ISO) or [Good Seed and Plant Practices](#) (GSPP)]. The ReFreSH Manual must describe the processes and procedures used to manage the risk of pest introduction or spread within and via the entity's seed supply system.

The entity is required to notify the authorizing NPPO of any changes to the ReFreSH Manual, facility ownership or the ReFreSH manager at their facility. The ReFreSH Manual should be amended to reflect these changes. This may trigger an evaluation of the amended document by the authorizing NPPO.

Entities must apply to request changes to the scope of an entity's ReFreSH accreditation (e.g., additional seed commodities). Applications must be submitted to the authorizing NPPO for approval. These requests may trigger an audit.



**5.1.1. Staff and Facility**

**5.1.1.2. Management and Organization.** Participating entities must provide a description of the organizational structure and responsibilities of the relevant personnel responsible for the implementation of ReFreSH processes and procedures. The management for each entity must define a policy that ensures compliance with the ReFreSH Standard and allocates the necessary resources to meet the ReFreSH Standard. The entity must assign a point of contact for ReFreSH and maintain a list of key staff and their ReFreSH-related responsibilities.

**5.1.1.3. Qualifications.** The ReFreSH point of contact may designate qualified personnel or contractors to assist with specific components of the entity's ReFreSH processes and procedures. The individuals designated to carry out tasks related to ReFreSH must have adequate knowledge, skills and training, and must be vested with the authority to ensure the requirements of the ReFreSH Standard are met.

**5.1.1.4. Staff Training.** The entity must have a training plan for all employees involved in ReFreSH processes and procedures. The training must impart a general understanding of ReFreSH and the entity's SHMP, as well as specific knowledge related to each employee's responsibilities. The training plan must be reviewed by entity management annually. Training on elements of ReFreSH shall be provided to employees at least annually.

**5.1.1.5. Entity Description.** A physical description of all entity facilities covered by their application must be incorporated in their ReFreSH Manual. This includes, but is not limited to, relevant production, operation and seed testing locations. As appropriate, include a description of the entity's requirements for contract vendors.

**5.1.2. Seed Health Management Plan.** The entity must complete a SHMP to record details about its specific processes and procedures for healthy seed production. It must describe how the plan is maintained and reviewed. The entity is required to notify the authorizing NPPO when they propose any changes to the SHMP; this must occur prior to implementing the changes. Seedborne pests, as defined in ISPM 38, and occurring in the country or countries of seed origin listed in the entity's application, must be included in the SHMP. The entity must conduct a risk evaluation / hazard analysis to assess the following critical control points in the seed supply system where pests may be introduced or spread:

- **Pre-planting**
  - *Site Selection and Preparation*
  - *Seed and Plant Inputs*
- **Pre-harvest**
  - *Production*
  - *Seed Harvest*
- **Post-harvest**
  - *Conditioning and Treatment*
  - *Handling and Storage*
  - *Seed Testing*
  - *Distribution and Transport*

The pest risks (hazards) identified by the assessment and the measures or practices applied at each critical control point to manage those risks must be specifically described in the SHMP. Examples of potential management practices that may be implemented at each critical control point are described in ISPMs 14 and 38. The SHMP must be implemented throughout the ReFreSH-accredited entity in a manner that will ensure consistent compliance with the requirements of the ReFreSH Standard.

**5.1.3. Identification and tracking.** Accredited entities must have procedures and processes in place that maintain product identity (i.e., traceability) from the point it enters the entity's seed supply system until its final disposition/delivery to the customer.

**5.1.4. Internal Audits and System Improvement.** A process for regular internal audits must be established, described and implemented to verify conformance to the ReFreSH Manual, verify that systems are functioning as designed and identify opportunities for system improvement. The internal audits should be sufficient to cover all aspects of the ReFreSH Manual. Internal audits shall not be carried out by personnel who are directly responsible for the audited activity.

**5.1.5. Records and Documents.** All records must be maintained and made available to the authorizing NPPO upon request.

**5.1.5.1. Control of the ReFreSH Manual and Documents.** The entity must describe its process to maintain and control the ReFreSH Manual, documents and records required by the ReFreSH Standard. This process must include procedures for superseding and archiving obsolete documents. The entity must establish a procedure to review the ReFreSH Manual on a regular basis. At a minimum, all sections of the ReFreSH Manual must be reviewed

every three (3) years. Individual sections in the Manual may be reviewed more frequently as needed.

**5.1.5.2. Record Requirements for ReFreSH.** The entity must establish a retention policy for all records pertaining to ReFreSH. The minimum acceptable retention period is four (4) years. The retention period begins once the seed is no longer under the control of the accredited entity (i.e., has reached its final disposition). Where an entity performs different seed supply system processes at multiple locations, each location must maintain records for the accredited processes within their purview. Records subject to this requirement include but are not limited to the following:

- **Traceability.** A process to maintain traceability of seed for the entire period it is under an entity's control, including processes and procedures by contractors, must be established and documented. Records must verify the origin and phytosanitary status of the seed.
- **Audits.** Records of both internal and external audits and any corrective actions, recommendations for improvement and resulting changes to the ReFreSH Manual taken as a result of those audits.
- **Seed Health Management Plan.** Records (e.g., monitoring reports, pest detections, corrective actions, treatment records, diagnostic test results, etc.) verifying the steps of the SHMP were followed.
- **Training.** Records documenting required ReFreSH-related training. Records should include verification that training has occurred and evidence of regular review of training materials.

**5.1.6. Regulated pest reporting and response.** The ReFreSH Manual must include an agreed upon procedure for reporting regulated pest detections and corrective actions taken to the authorizing NPPO. This includes detections at the accredited entity or its contractor(s). The procedure must a root cause analysis to identify how the pest was introduced into the seed supply system, adjustments to the SHMP may be adjusted in response, and how the efficacy of those adjustments may be verified.

**APPENDIX: EXAMPLES OF NON-CONFORMANCE**

This appendix is for reference purposes only and is not a prescriptive part of this standard.

Some examples of **critical non-conformances** may include the following:

- Detection of quarantine pests or regulated non-quarantine pests (above set tolerance levels; regulated non-quarantine pests only) of concern to the importing country;
- Failure to undertake required laboratory tests or analyses or correctly follow procedures to identify pests;
- Failure to carry out control measures at the place of production for regulated pests;
- Failure to notify the authorizing NPPO of the presence of regulated pests at the entity;
- Failure to undertake ordered corrective actions within the specified time period;
- Failure to perform internal audits as required;
- Failure to maintain an effective pest management program;
- Significant modification of the ReFreSH Manual or SHMP without prior approval from the authorizing NPPO;
- Failure to maintain sanitation management practices at the place of production; or,
- Operating without adequately trained personnel, designated responsible person or plant protection specialist.
- Multiple non-critical non-conformances in a single audit.
- Repeated occurrences of the same non-critical non-conformances during different audits.

Some examples of **non-critical non-conformances** may include the following:

- Failure to keep consistent pest management records as required in the ReFreSH Manual and the SHMP;

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- Failure to maintain an up-to-date list and training records of all personnel involved in implementing ReFreSH; or,
- Failure to consistently sign and date reports or records.
- Staff members are not aware of the applicable ReFreSH requirements related to their duties.