



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

# **ReFreSH**

## **Regulatory Framework for Seed Health**

Participant Manual / July 1, 2021

Draft

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## Introduction

The Regulatory Framework for Seed Health (ReFreSH) is a pest risk-based systems approach alternative to consignment-by-consignment inspection. It will serve as the basis for phytosanitary certification for the international movement of seeds, including seed importation into the United States. Any entity that agrees to produce or distribute seeds best management practices as documented in a quality management system that meets the ReFreSH Standard is eligible to participate in ReFreSH. Public or private entities that seek to be accredited to participate in ReFreSH are required to have a ReFreSH Manual, which describes the processes and procedures required to meet the ReFreSH Standard (USDA. 2020. *Regulatory Framework for Seed Health (ReFreSH) Standard*).

This document is intended to assist an entity in developing a ReFreSH Manual that meets the requirements of the ReFreSH Standard. An alternative, phytosanitary plan or equivalent documents may be utilized in lieu of to ReFreSH manual. The equivalent documentation could include a manual documenting equivalent, applicable accreditation, for example [International Organization for Standardization](#) (ISO) or [Good Seed and Plant Practices](#) (GSPP) accreditation documents. The ReFreSH Manual, or equivalent authorization standards or phytosanitary plan, must describe the processes and procedures used to exclude pests from the entity's seed supply system.

The components listed below are required for authorization and must be described in the entity's ReFreSH Manual:

- A. Staff and facilities
  - Management and organization
  - Staff training and qualifications
  - Entity description
- B. Seed health management plan
  - Pre-planting
  - Pre-harvest
  - Post-harvest
- C. Identification and Tracking
- D. Internal audits and system improvements
- E. Records and related documents
  - Control of the Manual and documents
  - Record requirements
  - Traceability
  - Audits
  - Pest management plan records
  - Training records
- F. Change management
- G. Reporting and compliance

Requirements for each of these sections are listed below. The entity’s ReFreSH manual must be submitted along with their ReFreSH application to the authorizing National Plant Protection Organization (NPPO) or its designee for review and approval prior to an accreditation (or reaccreditation) audit (refer to the ReFreSH Standard for definitions) to determine whether an entity is authorized (or reauthorized) to participate in ReFreSH. All documents and procedures referenced in the Manual are subject to official audits.

**Template**

**A. Staff and Facilities**

Participating entities must provide a description of the organizational structure including responsibilities and qualifications of the relevant personnel responsible for meeting the requirements of the ReFreSH Standard. The entity must assign a point of contact and maintain a list of key staff and their ReFreSH-related responsibilities.

The entity must have a training plan for all employees involved in ReFreSH. The training must impart a general understanding of the ReFreSH Standard and the entity’s specific seed health management plan, 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 the ReFreSH Standard and the Seed Health Management Plan must be provided to employees at least annually or upon hiring or reassignment to a ReFreSH-related position.

The entity must include in their ReFreSH Manual, a physical description of all entity facilities covered by their ReFreSH application. This includes, but is not limited to, relevant production, operation and seed testing locations. As appropriate, the entity must include a description of their requirements for contract vendors.

Section	ReFreSH Standard Component
A.1.	Management and Organization
A.1.1.	Policy and Entity Commitment
	The ReFreSH Manual must contain a statement by the entity’s leadership of their commitment to participate in and maintain the integrity of systems to meet the ReFreSH Standard.
A.1.2.	Resource Commitment
	The ReFreSH Manual must contain a statement of the entity’s commitment to assign the necessary resources to meet the requirements of the ReFreSH Standard.
A.1.3.	Organization
	The ReFreSH Manual must contain an organizational chart or description showing staff positions assigned to manage the components of the entity’s ReFreSH Program, including its Seed Health Management Plan (SHMP); key positions and their responsibilities as they relate to all components of the entity’s ReFreSH Program should be described; and the name and contact information for the entity’s designated ReFreSH point of contact should be provided.
A.2.	Staff training

Section	ReFreSH Standard Component
	The ReFreSH Manual must provide descriptions of the training required for staff involved in planning, implementing and maintaining the entity’s ReFreSH Program, including the following:
A.2.1.	General
	A general description of how the entity orients/trains employees on the ReFreSH Standard and the entity’s policy and commitment toward the program.
A.2.2.	Key personnel training
	A description of the specific training required for personnel (including contract vendors, if used) responsible for implementing and managing all parts of the ReFreSH Program including the SHMP. Training for these positions should provide a thorough understanding of the ReFreSH program; systems approach concepts; risk evaluation/hazard analysis and identification of critical control points; pest management; audits; recordkeeping; document control; and other topics as are relevant.
A.2.3.	Basic training
	A general description of the training and responsibilities of other positions associated with the ReFreSH program. These staff may be responsible for a single element of the entity’s ReFreSH Program or SHMP, such as traceability of seed lots or seed health testing. These employees are required to have a basic understanding of the ReFreSH Program overall, including its requirements and purpose.
A.2.4.	Frequency of training
	Training on elements of ReFreSH shall be provided to employees <u>at least</u> annually. A description of how often staff are trained on the different elements of the entity’s ReFreSH program.
A.3.	Qualifications
	<p>The entity must document that staff associated with their ReFreSH program include, or have access to, individuals with the following qualifications:</p> <ul style="list-style-type: none"> <li>• An advanced degree or equivalent work experience in identification, diagnosis and management of plant pests;</li> <li>• Technical knowledge of the identified seed health tests, plant health inspection protocols and the visual and sampling procedures relevant to the accreditation;</li> <li>• Experience in the development and implementation of quality management systems</li> </ul>
A.4.	Entity description
A.4.1.	Entity and commodity
	<p>The ReFreSH Manual must include:</p> <ul style="list-style-type: none"> <li>• The name, physical location and description of the entity facility(ies) seeking approval including, as appropriate, production, operations, seed testing and/or distribution facilities.</li> <li>• The seed species that the entity will be producing or distributing under the ReFreSH program.</li> </ul>
A.4.2.	Contractor facilities
	The ReFreSH Manual must include, as appropriate, criteria used to ensure its vendors meet the requirements of the ReFreSH Standard and the entity’s ReFreSH Program. This may include portions of production, operations, or seed health evaluation that are contracted out by the entity.

**B. Seed Health Management Plan**

The ReFreSH Manual must include a Seed Health Management Plan (SHMP). The SHMP includes the procedures entities use to reduce pest risk during all stages of the seed supply system. A risk evaluation (i.e., hazard analysis) must be conducted that analyzes the following critical control points in the seed supply system where pests may be introduced:

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

Section	ReFreSH Standard Component
B.1.	Risk Evaluation/Hazard Analysis
	<p>Based on their risk evaluation/hazard analysis, the entity should describe the target pests identified, methods of monitoring and potential management practices. A hazard analysis template is provided in <b>Appendix I</b>. Entities may also incorporate the template in their SHMP. The pest risks (hazards) identified by the analysis and the measures or practices applied at each critical control point to manage those risks must be described in the SHMP.</p> <p>Factors to consider in developing risk management options are listed in Sections B.2.-B.4. Examples of potential risk management options that may be implemented at each critical control point are described in ISPMs 14 and 38 and are listed in Tables 2 and 3 shown below.</p>
B.2.	Pre-planting
B.2.1.	Site Selection and Preparation

Section	ReFreSH Standard Component
	<p>Describe pre-plant field or growing facilities assessment and procedures that prevent or mitigate pest introduction from the environment into the production site(s). Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Soil quality and water sources</li> <li>• Site cropping and disease history</li> <li>• Endemic pests</li> <li>• Isolation distance from other crops produced on-site or nearby</li> <li>• Presence of weeds in production field</li> <li>• Weed control in borders and adjacent fields</li> <li>• Presence of volunteer plants and host debris from previous production cycles / earlier growing seasons</li> <li>• Presence of potential vectors</li> <li>• Worker hygiene and sanitation</li> <li>• Tool/equipment (including tractors and other field equipment) sanitation</li> <li>• Accessibility of site, field, etc. by authorized and non-authorized persons</li> <li>• For protected culture crops (including transplant houses): structure integrity and sanitization prior to use or between production cycles</li> </ul> <p>Additional factors that should be considered for transplant houses include:</p> <ul style="list-style-type: none"> <li>• Sanitization or cleaning of seed beds</li> <li>• Growing media used in transplant seed beds/pots/trays (new or sterilized only)</li> <li>• Transplant containers (new or sterilized only)</li> <li>• Storage of growing media and containers to avoid pest contamination</li> <li>• Tool/equipment sanitation</li> </ul>
B.2.2.	<b>Seed and Plant Inputs</b>
	<p>Describe procedures used to prevent the introduction of pests from seeds, transplants, other plant material, growing media and containers used in seed production. Describe mitigation procedures used to prevent the spread of pests from materials sourced from and to vendors. Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Identification and tracking procedures</li> <li>• Seed health testing / certification of parental seed lots</li> <li>• Seed treatment applications</li> <li>• Inspection or testing of seedlings/transplants prior to transplanting</li> <li>• Diagnosis of diseased or symptomatic plants</li> <li>• Disposal of contaminated seeds, plants, growing media and containers by APHIS–approved methods</li> </ul>
B.3.	Preharvest
B.3.1.	Production

Section	ReFreSH Standard Component
	<p>Describe procedures used to prevent, monitor and mitigate pests during seed production.</p> <p>Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Accessibility of site, field, etc. by authorized and non-authorized persons</li> <li>• Worker hygiene and sanitation</li> <li>• Tool/equipment (including planter or tractor) sanitation</li> <li>• Regular crop inspections of all plants including males (pollinator) plants</li> <li>• Diagnosis of symptomatic plants by approved methods</li> <li>• Disposal of diseased or symptomatic plants, growing media and containers (if applicable) by APHIS–approved methods</li> <li>• Monitoring for vectors</li> <li>• Management of pests with appropriate crop protection materials (chemical or biological) and cultural control practices (e.g., mulching, screens over access points in greenhouses)</li> <li>• If applicable, irrigation details (e.g., source, frequency)</li> <li>• Weed control within and surrounding the production location (field, structure, etc.)</li> <li>• Identification and tracking procedures</li> </ul>
B.3.2.	Seed Harvest
	<p>Describe procedures used to minimize seed contamination during harvesting and drying at the production site(s).</p> <p>Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Harvest criteria (maturity, timing) for the crop</li> <li>• Visual inspection of plants and fruit prior to harvest</li> <li>• Weather conditions (e.g., rain, dew) permitted at harvest</li> <li>• If applicable, pre-harvest fruit washing or sanitizing procedures</li> <li>• Harvest/seed extraction location (e.g., within a facility, in the field)</li> <li>• Use of new or sanitized seed containers/bags</li> <li>• Worker hygiene and sanitation</li> <li>• Harvest equipment and tool sanitation and/or cleaning</li> <li>• If applicable, seed drying location</li> <li>• Drying equipment sanitation</li> <li>• Identification and tracking procedures</li> </ul>
B.4.	Post-harvest
B.4.1.	Conditioning and Treatment



Section	ReFreSH Standard Component
	<p>Describe the procedures used to reduce the presence of seed-associated pests during seed cleaning, conditioning, sizing and packaging.</p> <p>Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Seed sampling and testing</li> <li>• Seed washing and/or disinfection</li> <li>• Seed treatments</li> <li>• Seed operations equipment and tool sanitization and/or cleaning</li> <li>• Proper disposal of all remnant and unusable seeds and debris</li> <li>• Disposal of all seeds found to be contaminated with regulated pests in accordance to regulatory guidelines</li> <li>• Worker sanitation and hygiene</li> <li>• Identification and tracking procedures</li> </ul>
B.4.2.	<b>Handling and Storage</b>
	<p>Describe procedures to prevent the introduction and spread of seed-associated pests during postharvest handling and storage. The measures should address all stages in the process, i.e., filling, handling, storage, and distribution of containers between the entity’s facilities or from a vendor to the entity’s facilities.</p> <p>Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Segregation and physical separation of untested and tested seed inventories</li> <li>• Seeds stored in closed containers under monitored warehouse conditions of controlled temperature and humidity</li> <li>• Warehouse sanitation including regular cleaning, immediate clean-up of seed spills, removal of waste or unused seeds</li> <li>• Equipment and tool sanitization and/or cleaning</li> <li>• Worker hygiene and sanitation</li> <li>• Identification and tracking procedures</li> </ul>
B.4.3.	<b>Seed Testing</b>

Section	ReFreSH Standard Component
	<p>Describe the seed health testing procedures and methods used to ensure that the entity’s seed supply system is free of regulated pests. ReFreSH generally follows the PPQ policy that all sampling, inspection, and testing for seed health certification be conducted by government officials or accredited non-government entities. ReFreSH requires that all seed health testing uses methods that have been standardized or validated through the <a href="#">National Seed Health System</a> (NSHS), <a href="#">Naktuinbouw Authorized Laboratory</a> (NAL) program or the <a href="#">International Seed Testing Association</a> (ISTA), if available, or by other methods accepted by the authorizing NPPO. Likewise, ReFreSH requires the use of seed sampling methods described by the International Seed Testing Association (ISTA) or the Association of American Seed Control Officials (AASCO).</p> <p>Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Identification and tracking procedures</li> <li>• Accreditation or authorization status of seed health testing laboratories</li> <li>• Authorization status of methods used for seed health testing</li> <li>• Use of seed sampling methods described by the <a href="#">International Seed Testing Association</a> (ISTA) or the <a href="#">Association of Seed Control Officials</a> (AASCO)</li> <li>• Use of official seed samplers, if applicable</li> <li>• Seed sampling equipment cleaning, sanitization and calibration</li> <li>• Use of new sample collection bags</li> <li>• Training of laboratory staff on appropriate testing methodologies and good laboratory practices</li> <li>• Laboratory and greenhouse sanitation</li> <li>• Laboratory equipment and tool cleaning, sanitization, calibration and maintenance</li> <li>• Standard data interpretation for authorized methods</li> <li>• Remnant seeds and debris properly disposed of in accordance with local regulations and good laboratory practices</li> </ul>
B.5.	Distribution and Transport
	<p>Describe procedures used to mitigate seed-associated pests in seeds that are distributed outside of the accredited entity facility. Procedures used to meet international phytosanitary regulatory requirements must be included.</p> <p>Factors that should be considered include:</p> <ul style="list-style-type: none"> <li>• Identification and tracking procedures</li> <li>• Entity’s compliance with seed quality release criteria for customer, market and country import requirements</li> <li>• Safeguarding measures to maintain shipment integrity</li> </ul>

**C. Internal Audits and System Improvements**

The ReFreSH Manual must include procedures for system improvements. In other words, the ReFreSH Manual must describe a quality management system employing internal audits conducted on a regular basis. The audits must confirm that the requirements specified in the ReFreSH Standard are met and

identify elements that contribute to any non-compliance. These audits will also facilitate the continuous improvement of the ReFreSH program at the authorized entity.

Section	ReFreSH Standard Component
C.1.	Responsible Party
	The ReFreSH Manual must include the title and position of the person responsible for the audits and system improvements program.
C.2.	Auditing
	<p>Procedures establishing a timeline, scope, reporting, and retention of the audit results and other applicable documentation must be demonstrated.</p> <p>The manual should:</p> <ul style="list-style-type: none"> <li>• Establish a schedule of internal audits over the course of each year</li> <li>• The internal audits must be sufficient to ensure all processes and procedures conform with those described in the ReFreSH Manual</li> <li>• Ensure the internal audits encompass all aspects of the Manual including the SHMP during the period between certification and the recertification audit</li> </ul>
C.3.	Corrective Actions and System Improvements
	<p>Procedures for implementing corrective actions when non-conformances are detected including:</p> <ul style="list-style-type: none"> <li>• for conducting root cause analysis to prevent recurrence, and</li> <li>• for proactively developing system improvements must be described.</li> </ul> <p>These may occur both within and outside of the audit process.</p>
C.4.	NPPO Notification
	<p>Procedures used to notify the NPPO of non-conformances that were detected while conducting internal audits and of corrective actions taken must be demonstrated.</p> <ul style="list-style-type: none"> <li>• The authorizing NPPO and local officials are notified of any critical non-conformance, e.g., suspected regulated pest detection, within 48 hours followed by official confirmation of the pest identity and determination of the regulatory response.</li> <li>• Procedure to notify the authorizing NPPO of any non-critical non-conformances at least sixty (60) days prior to a scheduled external audit.</li> </ul>

#### **D. Records and Documents**

Records provide evidence that seeds produced by the entity comply with the requirements of the ReFreSH Standard. Records must be made available during audits or upon request of the NPPO. The entity must describe its process to maintain and control the Manual, documents and records required by the ReFreSH Standard. This process must include procedures for superseding and archiving obsolete documents.

Section	ReFreSH Standard Component
D.1.	Control of the Manual and documents
	<p>The entity must establish a procedure to review the Manual on a regular basis. The Manual should include:</p> <ul style="list-style-type: none"> <li>• The position/title of person(s) with authority to approve changes to the Manual</li> <li>• The process for making and documenting those changes</li> <li>• Details of how the document is controlled to assure that it is secure and that only the current version is available</li> <li>• The timeline for Manual review ensuring that all sections of the Manual are reviewed within a maximum three (3) year cycle (individual sections may be reviewed more frequently, as needed)</li> </ul>
D.2.	Record requirements
	The Manual must include procedures to maintain the following records and must include position/title of person(s) responsible for maintaining records.
D.2.1.	Record retention
	<ul style="list-style-type: none"> <li>• All records must be maintained for a minimum of four (4) years and be made available to the NPPO upon request.</li> </ul>
D.2.2.	Traceability Records
	<p>The Manual will describe procedures and records to be retained that ensure traceability of seed lots from the point it enters the seed supply production system until final disposition.</p> <ul style="list-style-type: none"> <li>• Records include seed import and transplant crop records (trace forward/trace back)</li> <li>• Records will be maintained and available for review by the NPPO</li> <li>• Records can include certificates or invoices which substantiate the origin and phytosanitary status of incoming propagative material</li> </ul>
D.2.3.	Systems Improvement Records
	<p>The Manual shall describe procedures to maintain records of internal and external audit documents.</p> <p>Systems improvement records maintained and made available for review by the NPPO include:</p> <ul style="list-style-type: none"> <li>• All internal/external audit reports</li> <li>• Non-conformance records</li> <li>• Corrective action and system improvement records</li> <li>• Root cause analyses records.</li> </ul>
D.2.4.	Seed Health Management Plan (SHMP) Records

Section	ReFreSH Standard Component
	<p>The Manual shall describe procedures that shall ensure all SHMP records are maintained and available for review by the NPPO.</p> <p>Examples of SHMP records maintained include:</p> <ul style="list-style-type: none"> <li>• Soil and growing medium sterilization records</li> <li>• Soil and water test results</li> <li>• Transplant and production facility sanitation/disinfection records</li> <li>• Production site inspection data</li> <li>• Records of symptomatic plants observed, and plants removed</li> <li>• Records of pest detections and corrective actions</li> <li>• Records of regulated pests found and of notification(s) sent to the authorizing NPPO</li> <li>• Records of pesticide applications</li> <li>• Seed health test results</li> <li>• Seed treatment records</li> <li>• Storage facility environmental monitoring data</li> <li>• Disposal records for remnant or contaminated seeds</li> </ul>
D.2.5.	<b>Training Records</b>
	<p>Describe procedures that ensure all training records, training materials and a list of employees trained are maintained and available for review by the NPPO.</p> <p>Records must be maintained for training activities specific to the entity’s ReFreSH program. Examples include:</p> <ul style="list-style-type: none"> <li>• Records of training dates/frequency, content and format</li> <li>• Records of staff participants (trainers and trainees)</li> <li>• Records of reviews and updates of training materials</li> </ul>

**E. Change Management**

Changes resulting from regular reviews of the Manual, internal audits, changes in phytosanitary status, changes in technology, changes in business models or system improvement efforts may create a need to modify the Manual. The Manual must describe the mechanisms for managing any changes. This requirement applies to all aspects of the entity’s ReFreSH program.

Section	ReFreSH Standard Component
E.1.	Changes to the ReFreSH Manual that may affect phytosanitary risk within the seed supply system
	<ul style="list-style-type: none"> <li>• Changes must be communicated with and approved by the authorizing NPPO prior to adoption. Such communication shall be done by the point of contact for the entity’s ReFreSH program</li> </ul>
E.2.	Minor changes to the ReFreSH Manual
	<ul style="list-style-type: none"> <li>• Minor changes to the ReFreSH Manual that will not affect the phytosanitary risk within the seed supply system shall be communicated to the authorizing NPPO as part of the external audit noted in E.3. below.</li> </ul>
E.3.	Scheduled external audit / applying for re-accreditation

Section	ReFreSH Standard Component
	<ul style="list-style-type: none"> <li>The point of contact for the ReFreSH Manual shall provide the authorizing NPPO the most recent version of the entity’s ReFreSH Manual at least 60-days prior to a scheduled external audit and when applying for re-accreditation.</li> </ul>

**F. Reporting and compliance**

The Manual must include a description of the standard procedure for maintaining contact with the NPPO and must include the title and contact information of the NPPO official (or authorized designee) responsible for overseeing authorization of the entity’s ReFreSH program and Manual.

Section	ReFreSH Standard Component
F.1.	Point of contact
	<ul style="list-style-type: none"> <li>All inquiries and reports of non-conformances with the ReFreSH Standard should be directed to the authorizing NPPO’s designated ReFreSH point of contact (see section C.4.)</li> </ul>
F.2.	Notification of critical non-conformances
	<ul style="list-style-type: none"> <li>Any incident that may compromise the efficacy of the entity’s ReFreSH program or has increased the risk of infestation of the entity’s seed supply system by a regulated pest (i.e., a critical non-conformance) must be reported to the authorizing NPPO within 48-hours</li> </ul>
F.3.	Detection of a regulated pest
	<ul style="list-style-type: none"> <li>Any entity detection of a regulated pest that indicates a critical non-conformance within its seed supply system must be reported to the authorizing NPPO within 48 hours and the proposed corrective action must be enacted within a mutually agreed-upon time frame.</li> <li>Notification of a non-compliance (i.e., detection of a regulated pest) by the NPPO of a destination country will result in a proposed corrective action within a mutually agreed upon time frame.</li> </ul>
F.4.	Non-critical non-conformances
	<ul style="list-style-type: none"> <li>Incidents that do not immediately compromise the ReFreSH Program or increase the risk of infestation of the seed supply system by a quarantine pest (i.e., minor non-conformances) shall be reported to the authorizing NPPO at least 60-days prior to a scheduled external audit, or may be reported more frequently as determined by the entity’s quality management process.</li> </ul>

## APPENDIX I: Risk Evaluation/Hazard Analysis

The model/template shown below is included to assist entities with their risk evaluation/hazard analysis (see section **B.1. Risk Evaluation/Hazard Analysis**). The template is adapted from Systems Approach for Nursery Certification (SANC) Risk Assessment Tool (<https://sanc.nationalplantboard.org/certification/risk-assessment/>). The entity should describe the target pests included in the scope of their ReFreSH accreditation, critical control points, potential management practices and monitoring methods. Entities may also incorporate the template in their SHMP. The risk assessment identifies phases and practices of seed production where risk of pest introduction or spread may occur. The pest risks (hazards) identified by the analysis and the measures or practices applied at each critical control point to manage those risks must be described in the SHMP. The seed supply system phases addressed correspond to the SHMP **Sections B.2. through B.5.** described above:

**B.2. Pre-planting:** Site Selection and Preparation, Seed and Plant Inputs

**B.3. Pre-harvest:** Production, Seed Harvest

**B.4. Post-harvest:** Conditioning and Treatment, Handling and Storage, Seed Testing

**B.5. Distribution and Transport**

**Appendix 1** consists of three tables. **Table 1** provides general instructions for using the hazard analysis tool. **Table 2** describes generic hazards and risks and risk management measures for the identified hazard/risk at the critical control points noted above. These are intended as examples only. They may not all apply to every entity / commodity / pest / hazard combination. Conversely some combinations may require additional entries. The entity should add or delete entries as appropriate for their seed supply system proposed for ReFreSH authorization. There are also examples of training / knowledge requirements and records requirements that may be useful in developing the entity's ReFreSH Manual. Finally, **Table 3** provides a list of selected categories of pests and corresponding risk management measures for those pests.

**Table 1. Risk Evaluation/Hazard Analysis Instructions**

Seed Health Management Plan Information					ReFreSH Manual Information		
Information from these entries is incorporated into the entity's SHMP					Information from these entries is incorporated into the appropriate sections of the entity's ReFreSH Manual		
Commodity / Pest(s)	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
List the seed taxa for which the entity seeks to be ReFreSH accredited and the regulated pests associated with the listed seed taxa. The sample below lists descriptions of pest categories mitigated by the listed risk management measure(s). When part of an actual SHMP, the descriptions would be replaced by specific pest names.	Determine the Critical Control Point (CCP): Where and/or when risk management measures are applied.	A Hazard is an identified area or process that could potentially introduce a pest or pathogen. Or if a pest or pathogen is prevalent, could result in dispersal or spread of the pest or pathogen without mitigation.	Determine the steps taken to mitigate the hazard/risk at the CCP. List or describe any internal procedures used or needed for the SHMP. List any other procedures or documents used to determine appropriate risk management. Regulatory requirements, compliance agreements, internal quality management procedures, extension information are examples. Examples of pest types and possible risk management measures for them are listed in <b>Table 3</b> in this appendix.	Describe the procedures to verify that risk management measures are implemented and effective.	Define who is responsible for implementing and verifying risk management measures.	Define any training requirements or specific knowledge that may be needed to implement risk management. All workers should receive general ReFreSH principles training.	List the records used to document all SHMP requirements are met. (e.g. spraying records, trap records, etc.)



**Table 2. Risk Evaluation/Hazard Analysis Example**

Seed Health Management Plan Information						ReFreSH Manual Information			
Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records	
Commodity	B.2.	<b>Pre-planting</b>							
Describe pre-plant facilities assessment and procedures that prevent or mitigate pest introduction from the environment into the production site(s).									
Pest(s)	B. 2.1.	<b>Site Selection and Preparation</b>	Add any additional factors and select any of the following as appropriate for the commodity / pest combination.						
		<ul style="list-style-type: none"> <li>Contaminated or infested soil (field grown crops)</li> </ul>	<ul style="list-style-type: none"> <li>Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence</li> </ul>	<ul style="list-style-type: none"> <li>Surveys/inspection/ monitoring (e.g., trapping)</li> </ul>	<ul style="list-style-type: none"> <li>Name / Title of responsible person</li> </ul>	<ul style="list-style-type: none"> <li>Knowledge of IPPC standards for pest-free concepts</li> </ul>	<ul style="list-style-type: none"> <li>Survey / Inspection records</li> </ul>		
			<ul style="list-style-type: none"> <li>Soil treatments</li> </ul>	<ul style="list-style-type: none"> <li>Soil sampling / testing / inspection for soilborne pests</li> </ul>				<ul style="list-style-type: none"> <li>Pesticide application; soilborne pest control</li> </ul>	<ul style="list-style-type: none"> <li>Pesticide application records</li> </ul>
			<ul style="list-style-type: none"> <li>Soil sampling / testing / inspection for soilborne pests</li> </ul>	<ul style="list-style-type: none"> <li>Inspection/test results</li> </ul>				<ul style="list-style-type: none"> <li>Soil sampling; results interpretation</li> </ul>	<ul style="list-style-type: none"> <li>Inspection / test results</li> </ul>
		<ul style="list-style-type: none"> <li>Contaminated water sources</li> </ul>	<ul style="list-style-type: none"> <li>Use clean water source (e.g., sealed deep well, municipal water)</li> </ul>	<ul style="list-style-type: none"> <li>Verify source as part of audits</li> </ul>	<ul style="list-style-type: none"> <li>Water treatment methods and equipment training</li> </ul>	<ul style="list-style-type: none"> <li>Water treatment records</li> </ul>			
<ul style="list-style-type: none"> <li>Treat water to sterilize (e.g., boil, UV, chlorine, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Review treatment records</li> </ul>								

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
				<ul style="list-style-type: none"> <li>Sample / test water for waterborne pests of concern</li> </ul>	<ul style="list-style-type: none"> <li>Review test results</li> </ul>		<ul style="list-style-type: none"> <li>Water sampling; results interpretation</li> </ul>	<ul style="list-style-type: none"> <li>Water test results</li> </ul>
			<ul style="list-style-type: none"> <li>Site has a history of host crops and/or pests</li> </ul>	<ul style="list-style-type: none"> <li>Use crop rotation and / or fallow periods</li> </ul>	<ul style="list-style-type: none"> <li>Review cropping records</li> </ul>			<ul style="list-style-type: none"> <li>Cropping history</li> </ul>
			<ul style="list-style-type: none"> <li>Endemic pests present</li> </ul>	<ul style="list-style-type: none"> <li>Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence</li> <li>Field management: pest monitoring, pesticide treatment, biological control</li> </ul>	<ul style="list-style-type: none"> <li>Surveys / inspection / monitoring (e.g., trapping)</li> </ul>		<ul style="list-style-type: none"> <li>Survey / inspection methodology; IPM; pesticide application; knowledge of IPPC standards for pest-free concepts.</li> </ul>	<ul style="list-style-type: none"> <li>Survey / Inspection records</li> <li>Pesticide / treatment application records</li> </ul>
			<ul style="list-style-type: none"> <li>Regulated pests present</li> </ul>	<ul style="list-style-type: none"> <li>Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence</li> </ul>				
				<ul style="list-style-type: none"> <li>Field management: pest monitoring, pesticide treatment, biological control</li> </ul>				
			<ul style="list-style-type: none"> <li>Inadequate isolation distance from other crops produced on-site or nearby</li> </ul>	<ul style="list-style-type: none"> <li>Ensure production site is sufficiently isolated from other crops produced on-site or nearby</li> </ul>				
				<ul style="list-style-type: none"> <li>Maintain a host-free buffer around the production site</li> </ul>				

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Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
				to prevent infestation from other crops produced on-site or nearby				
			<ul style="list-style-type: none"> <li>Weeds present in production field</li> </ul>	<ul style="list-style-type: none"> <li>Inspection and field management through herbicide treatment or physical destruction (e.g., plowing)</li> </ul>	<ul style="list-style-type: none"> <li>Surveys / inspection / monitoring</li> </ul>		<ul style="list-style-type: none"> <li>Survey/inspection methodology; weed control; pesticide application</li> </ul>	
		<ul style="list-style-type: none"> <li>Weed control in borders and adjacent fields is absent or inadequate</li> </ul>	<ul style="list-style-type: none"> <li>Inspection and border weed management through herbicide treatment or physical destruction (e.g., plowing)</li> </ul>					
		<ul style="list-style-type: none"> <li>Volunteer plants and host debris from earlier growing seasons not properly removed</li> </ul>	<ul style="list-style-type: none"> <li>Inspection and destruction / removal of volunteers with herbicide treatment or physical destruction (e.g., plowing)</li> </ul>					
			<ul style="list-style-type: none"> <li>Potential disease vectors present</li> </ul>	<ul style="list-style-type: none"> <li>Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence</li> <li>Field management: pest monitoring, pesticide treatment, biological control</li> </ul>	<ul style="list-style-type: none"> <li>Surveys / inspection / monitoring (e.g., trapping)</li> </ul>			
			<ul style="list-style-type: none"> <li>Worker hygiene and sanitation not properly maintained</li> </ul>	<ul style="list-style-type: none"> <li>Workers trained on proper sanitation and hygiene protocols</li> </ul>	<ul style="list-style-type: none"> <li>Review training records</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Training records</li> </ul>

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
				<ul style="list-style-type: none"> <li>Use of disinfectant footbaths and handwashing stations</li> </ul>	<ul style="list-style-type: none"> <li>Review disinfectant logs for footbaths and handwashing stations</li> </ul>			<ul style="list-style-type: none"> <li>Sanitization records and disinfectant logs</li> </ul>
			<ul style="list-style-type: none"> <li>Tool/equipment (including tractors and other field equipment) sanitation not properly maintained</li> </ul>	<ul style="list-style-type: none"> <li>All tools and equipment including tractors and field equipment are properly washed and sanitized prior to entering production site</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>			
			<ul style="list-style-type: none"> <li>Authorized access not properly maintained</li> </ul>	<ul style="list-style-type: none"> <li>Site is gated and/or fenced or access otherwise physically limited</li> <li>Use signs to indicate access is limited to authorized personnel</li> </ul>	<ul style="list-style-type: none"> <li>Verify presence as part of audits</li> </ul>			
<b>For protected culture crops (including transplant houses):</b>								
			<ul style="list-style-type: none"> <li>Structure sanitization prior to use or between growing seasons/cycles not properly maintained</li> </ul>	<ul style="list-style-type: none"> <li>All surfaces are cleaned/sanitized prior to use or between growing cycles/seasons; all weeds and plant debris removed</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization records and disinfectant logs</li> </ul>
			<ul style="list-style-type: none"> <li>Structure integrity prior to use or between growing seasons/cycles not properly maintained</li> </ul>	<ul style="list-style-type: none"> <li>Structure is inspected prior to use or between growing cycles/seasons and any broken glass or tears are repaired immediately</li> </ul>	<ul style="list-style-type: none"> <li>Review inspection / repair reports; inspect structure as part of audits</li> </ul>			<ul style="list-style-type: none"> <li>Inspection reports and repair records</li> </ul>
			<ul style="list-style-type: none"> <li>Seed beds not properly cleaned / sanitized</li> </ul>	<ul style="list-style-type: none"> <li>Beds cleaned to remove debris and growing medium is sterilized</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization records and</li> </ul>

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
				<ul style="list-style-type: none"> <li>Beds cleaned and sanitized; growing medium is replaced with new or sterilized growing medium</li> </ul>				disinfectant logs
			<ul style="list-style-type: none"> <li>Contaminated growing media used in transplant seed beds/pots/trays</li> </ul>	<ul style="list-style-type: none"> <li>Use only new, unused and/or sterilized growing media in beds/pots/trays</li> </ul>	<ul style="list-style-type: none"> <li>Review records for growing media source and/or sterilization</li> </ul>			
			<ul style="list-style-type: none"> <li>Contaminated transplant containers used</li> </ul>	<ul style="list-style-type: none"> <li>Use only new, unused and/or sterilized transplant containers</li> </ul>	<ul style="list-style-type: none"> <li>Review records for transplant containers source and/or sterilization</li> </ul>			
			<ul style="list-style-type: none"> <li>Growing media and containers not stored properly to avoid pest contamination</li> </ul>	<ul style="list-style-type: none"> <li>Store media and containers to safeguard them from contamination/infestation by pests, soil, contaminated water, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Inspect storage conditions as part of audits</li> </ul>			
			<ul style="list-style-type: none"> <li>Tool/equipment sanitation not properly completed</li> </ul>	<ul style="list-style-type: none"> <li>All tools and equipment are properly washed and sanitized prior to entering production site</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>			
	<b>B.2.2.</b>	<b>Seed and Plant Inputs</b>	Add any additional factors and select any of the following as appropriate for the commodity / pest combination					
			<ul style="list-style-type: none"> <li>Non-certified/untested seeds are inadvertently planted; pest detections later in the process cannot be traced back to origin</li> </ul>	<ul style="list-style-type: none"> <li>Identification and tracking procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review seed source (import), certification records</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>	<ul style="list-style-type: none"> <li>Seed source (import), certification and testing records</li> </ul>

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Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			<ul style="list-style-type: none"> <li>• Non-certified or untested seeds are infested and planted</li> </ul>	<ul style="list-style-type: none"> <li>• Seed health testing / certification of seed lots</li> </ul>	<ul style="list-style-type: none"> <li>• Review certification and testing records</li> </ul>		<ul style="list-style-type: none"> <li>• Familiarity with seed certification systems</li> </ul>	
			<ul style="list-style-type: none"> <li>• Inappropriate, improperly applied or missing seed treatments result in diseased plants</li> </ul>	<ul style="list-style-type: none"> <li>• Appropriate seed treatment applications</li> </ul>	<ul style="list-style-type: none"> <li>• Monitor seed treatments; review seed treatment records</li> </ul>		<ul style="list-style-type: none"> <li>• Familiarity with or training in seed treatments and their application</li> </ul>	<ul style="list-style-type: none"> <li>• Seed treatment records</li> </ul>
			<ul style="list-style-type: none"> <li>• Infected/infested transplants planted in the field</li> </ul>	<ul style="list-style-type: none"> <li>• Inspection or testing of seedlings/transplants prior to transplanting</li> </ul>	<ul style="list-style-type: none"> <li>• Review inspection / testing records for each transplant lot prior to planting</li> </ul>		<ul style="list-style-type: none"> <li>• Familiarity / training of signs and symptoms of pests in transplants; familiarity / training in inspection / sampling /testing methodology and interpretation of results</li> </ul>	<ul style="list-style-type: none"> <li>• Inspection / testing records</li> </ul>
			<ul style="list-style-type: none"> <li>• Diseased or contaminated seeds, plants, growing media or containers infest, infect or contaminate healthy seeds or plants</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnosis of diseased or symptomatic plants, and disposal of contaminated seeds, plants, growing media and containers by APHIS-approved methods</li> </ul>	<ul style="list-style-type: none"> <li>• Review records for diagnosis and destruction of diseased/contaminated materials</li> </ul>		<ul style="list-style-type: none"> <li>• Experience / training / or access to expertise in diagnostics; familiarity / training for approved destruction /devitalization methods</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnostic and destruction / devitalization records</li> </ul>
	<b>B.3.</b>	<b>Pre-harvest</b>						

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
	<b>B.3.1.</b>	<b>Production</b>	Add any additional factors and select any of the following as appropriate for the commodity / pest combination					
			<ul style="list-style-type: none"> <li>Unauthorized visitors to the production site may introduce pests</li> </ul>	<ul style="list-style-type: none"> <li>Maintain authorized access to site; use signs to indicate access is limited to authorized personnel</li> </ul>	<ul style="list-style-type: none"> <li>Monitor visitor /activity records for production site</li> </ul>		<ul style="list-style-type: none"> <li>Awareness of authorized access list</li> </ul>	<ul style="list-style-type: none"> <li>List of authorized personnel</li> </ul>
			<ul style="list-style-type: none"> <li>Worker hygiene and sanitation not properly maintained</li> </ul>	<ul style="list-style-type: none"> <li>Workers trained on proper sanitation and hygiene protocols</li> </ul>	<ul style="list-style-type: none"> <li>Review training records; monitor hygiene and sanitation</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Training records</li> </ul>
				<ul style="list-style-type: none"> <li>Use of disinfectant footbaths and handwashing stations</li> </ul>	<ul style="list-style-type: none"> <li>Review disinfectant logs for footbaths and handwashing stations</li> </ul>			<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs</li> </ul>
			<ul style="list-style-type: none"> <li>Tool/equipment sanitation and washing not properly completed resulting in contamination</li> </ul>	<ul style="list-style-type: none"> <li>Tool/equipment (including planter or tractor) sanitation</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>			
			<ul style="list-style-type: none"> <li>Production sites infested / infected during growing season</li> </ul>	<ul style="list-style-type: none"> <li>Regular crop inspections of all plants including males (pollinator) plants</li> </ul>	<ul style="list-style-type: none"> <li>Review crop inspection records</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity / training in field inspection and signs / symptoms of pests</li> </ul>	<ul style="list-style-type: none"> <li>Crop inspection reports</li> </ul>
			<ul style="list-style-type: none"> <li>Diseased or contaminated plants infest, infect or contaminate healthy plants</li> </ul>	<ul style="list-style-type: none"> <li>Diagnosis and disposal of symptomatic plants by approved methods</li> </ul>	<ul style="list-style-type: none"> <li>Review records for diagnosis and destruction of diseased/contaminated materials</li> </ul>		<ul style="list-style-type: none"> <li>Experience / training or access to expertise in diagnostics; familiarity / training for approved</li> </ul>	<ul style="list-style-type: none"> <li>Diagnostic and destruction / devitalization records</li> </ul>

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Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
							destruction /devitalization methods	
			<ul style="list-style-type: none"> <li>• Presence of vectors may result in the introduction and/or spread of pests</li> </ul>	<ul style="list-style-type: none"> <li>• Monitoring for vectors</li> </ul>	<ul style="list-style-type: none"> <li>• Survey / inspect/ monitor for the presence of vectors</li> </ul>		<ul style="list-style-type: none"> <li>• Experience / training or access to expertise in identifying vector species; knowledge training in survey / inspection methods</li> </ul>	<ul style="list-style-type: none"> <li>• Survey / inspection records</li> </ul>
			<ul style="list-style-type: none"> <li>• Production site infestation during production cycle</li> </ul>	<ul style="list-style-type: none"> <li>• Management of pests with appropriate pesticide (chemical or biological) applications and cultural control practices (e.g., mulching, screens over access points in greenhouses)</li> </ul>	<ul style="list-style-type: none"> <li>• Survey / inspect/ monitor for the presence of pests</li> </ul>		<ul style="list-style-type: none"> <li>• Survey/inspection methodology; Integrated pest management; pesticide application</li> </ul>	<ul style="list-style-type: none"> <li>• Survey / inspection records; pesticide application records</li> </ul>
			<ul style="list-style-type: none"> <li>• Contaminated water sources</li> </ul>	<ul style="list-style-type: none"> <li>• Use clean water source (e.g., sealed deep well, municipal water)</li> </ul>	<ul style="list-style-type: none"> <li>• Verify source as part of audits</li> </ul>			
			<ul style="list-style-type: none"> <li>• Irrigation creates favorable environment for pest populations</li> </ul>	<ul style="list-style-type: none"> <li>• Manage irrigation frequency and type (e.g., drip vs. overhead) to reduce moisture conditions favorable to pest populations</li> </ul>	<ul style="list-style-type: none"> <li>• Monitor production site moisture levels</li> </ul>		<ul style="list-style-type: none"> <li>• Knowledge of pest biology / moisture requirements</li> </ul>	



Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			<ul style="list-style-type: none"> <li>Weed control in production site and borders is absent or inadequate</li> </ul>	<ul style="list-style-type: none"> <li>Weed control within and surrounding the production location (field, structure, etc.)</li> </ul>	<ul style="list-style-type: none"> <li>Surveys / inspection / monitoring</li> </ul>		<ul style="list-style-type: none"> <li>Survey/inspection methodology; weed control; pesticide application</li> </ul>	<ul style="list-style-type: none"> <li>Survey / Inspection records; pesticide / treatment application records</li> </ul>
			<ul style="list-style-type: none"> <li>Non-certified/untested seeds are inadvertently planted; pest detections cannot be traced back to origin or traced forward to customers</li> </ul>	<ul style="list-style-type: none"> <li>Identification and tracking procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review seed source records; ensure proper labelling</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>	<ul style="list-style-type: none"> <li>Inventory tracking records</li> </ul>
	B.3.2.	<b>Seed Harvest</b>	Describe procedures used to minimize seed contamination during harvesting and drying at the production site(s).					
			<ul style="list-style-type: none"> <li>Pests present in harvested seeds if harvested when pest population high or plants at susceptible stage for seed infestation</li> </ul>	<ul style="list-style-type: none"> <li>Harvest criteria (maturity, timing) for the crop</li> </ul>	<ul style="list-style-type: none"> <li>Monitor pest populations and crop maturity</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity / training in epidemiology crop phenology</li> </ul>	<ul style="list-style-type: none"> <li>Harvest dates/ pest populations</li> </ul>
			<ul style="list-style-type: none"> <li>Harvested seeds and equipment contaminated by surface contaminants on harvested fruit</li> </ul>	<ul style="list-style-type: none"> <li>If applicable, pre-harvest fruit washing or sanitizing procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs</li> </ul>

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Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			<ul style="list-style-type: none"> <li>Seeds contaminated during extraction</li> </ul>	<ul style="list-style-type: none"> <li>Harvest/seed extraction location (e.g., within a facility, in the field)</li> </ul>	<ul style="list-style-type: none"> <li>Review harvest /extraction records</li> </ul>			<ul style="list-style-type: none"> <li>Harvest /extraction records</li> </ul>
			<ul style="list-style-type: none"> <li>Unfavorable weather results in seed contamination</li> </ul>	<ul style="list-style-type: none"> <li>Avoid weather conditions (e.g., rain, dew) at harvest that favor disease development / contamination</li> </ul>	<ul style="list-style-type: none"> <li>Review harvest records</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity / training in epidemiology</li> </ul>	
			<ul style="list-style-type: none"> <li>Infected seeds harvested</li> </ul>	<ul style="list-style-type: none"> <li>Visual inspection of plants and fruit prior to harvest</li> </ul>	<ul style="list-style-type: none"> <li>Surveys / inspection / monitoring</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity / training in field inspection and signs / symptoms of pests</li> </ul>	<ul style="list-style-type: none"> <li>Inspection records</li> </ul>
			<ul style="list-style-type: none"> <li>Harvested seeds contaminated as a result of poor worker hygiene and sanitation</li> </ul>	<ul style="list-style-type: none"> <li>Workers trained on proper sanitation and hygiene protocols</li> </ul>	<ul style="list-style-type: none"> <li>Review training records; monitor hygiene and sanitation</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Training records</li> </ul>
			<ul style="list-style-type: none"> <li>Harvested seeds contaminated by improper equipment and tool cleaning and sanitization</li> </ul>	<ul style="list-style-type: none"> <li>Harvest equipment and tool sanitation and/or cleaning</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>			<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs</li> </ul>
			<ul style="list-style-type: none"> <li>Seeds contaminated during drying</li> </ul>	<ul style="list-style-type: none"> <li>If applicable, seed drying location</li> </ul>	<ul style="list-style-type: none"> <li>Review harvest records</li> </ul>			<ul style="list-style-type: none"> <li>Harvest records</li> </ul>
			<ul style="list-style-type: none"> <li>Harvested seeds contaminated by improper equipment cleaning and sanitization</li> </ul>	<ul style="list-style-type: none"> <li>Drying equipment sanitation</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization and cleaning records and</li> </ul>

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			<ul style="list-style-type: none"> <li>Contaminated seed containers used</li> </ul>	<ul style="list-style-type: none"> <li>Use of new or sanitized seed containers/bags</li> </ul>	<ul style="list-style-type: none"> <li>Review records for seed container source and/or sterilization</li> </ul>			disinfectant logs
			<ul style="list-style-type: none"> <li>Pest detections cannot be traced back to origin or traced forward to customers</li> </ul>	<ul style="list-style-type: none"> <li>Identification and tracking procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review seed source records; ensure proper labelling</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>	<ul style="list-style-type: none"> <li>Inventory tracking records</li> </ul>
	<b>B.4.</b>	<b>Post-harvest</b>						
	<b>B.4.1.</b>	<b>Conditioning and Treatment</b>	Describe the procedures used to reduce the presence of seed-associated pests during seed cleaning, conditioning, sizing and packaging.					
			<ul style="list-style-type: none"> <li>Pest detections cannot be traced back to origin or traced forward to customers</li> </ul>	<ul style="list-style-type: none"> <li>Identification and tracking procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review seed source records; ensure proper labelling</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>	<ul style="list-style-type: none"> <li>Inventory tracking records</li> </ul>
			<ul style="list-style-type: none"> <li>Missing / misapplied / incorrect seed treatments allow infestation / infection of seeds / subsequent plants</li> </ul>	<ul style="list-style-type: none"> <li>Seed treatments</li> </ul>	<ul style="list-style-type: none"> <li>Monitor seed treatments; review seed treatment records</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with or training in seed treatments and their application</li> </ul>	<ul style="list-style-type: none"> <li>Seed treatment records</li> </ul>
			<ul style="list-style-type: none"> <li>Seeds contaminated as a result of improper equipment and tool cleaning and sanitization</li> </ul>	<ul style="list-style-type: none"> <li>Seed operations equipment and tool sanitization and/or cleaning</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs</li> </ul>
			<ul style="list-style-type: none"> <li>Potential contamination from remnant and</li> </ul>	<ul style="list-style-type: none"> <li>Proper disposal of all remnant and unusable seeds and debris</li> </ul>	<ul style="list-style-type: none"> <li>Review disposal records</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training; familiarity /</li> </ul>	

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			unusable seeds and debris				training for approved destruction /devitalization methods	• Disposal and destruction records
			• Potential contamination of clean seed lots and equipment from contaminated seeds	• Disposal of all seeds found to be contaminated with regulated pests in accordance to regulatory guidelines				
			• Harvested seeds contaminated as a result of poor worker hygiene and sanitation	• Worker sanitation and hygiene	• Review training records; monitor hygiene and sanitation		• Sanitation and hygiene training	• Training records
	<b>B.4.2.</b>	<b>Handling and Storage</b>	Describe procedures to prevent the introduction and spread of seed-associated pests during post-harvest handling and storage. The measures should address all stages in the process, i.e., filling, handling, storage, and distribution of containers between the entity's facilities or from a vendor to the entity's facilities.					
			• Pest detections cannot be traced back to origin or traced forward to customers; phytosanitary status of seeds is not maintained	• Identification and tracking procedures	• Review tracking and tracing records; ensure proper labelling		• Familiarity with and/or training in entity's inventory control system	• Inventory tracking records
			• Infected seeds distributed in seed supply system	• Untested seeds are not commingled with tested seed inventory	• Review testing and tracking records; ensure proper labelling			• Inventory tracking / testing records
			• Storage conditions allow seeds to become contaminated / infested / infested	• Seeds stored in closed containers under monitored warehouse conditions of controlled	• Monitor storage conditions		• Familiarity with storage protocols	• Storage condition records

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
				temperature and humidity				
			<ul style="list-style-type: none"> <li>Seeds contaminated as a result of improper warehouse cleaning and sanitization or remnant and unusable seeds and debris</li> </ul>	<ul style="list-style-type: none"> <li>Warehouse sanitation including regular cleaning, immediate clean-up of seed spills, removal of waste or unused seeds</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization; review disposal records</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs</li> <li>Disposal and destruction records</li> </ul>
			<ul style="list-style-type: none"> <li>Harvested seeds contaminated by improper equipment cleaning and sanitization</li> </ul>	<ul style="list-style-type: none"> <li>Equipment and tool sanitization and/or cleaning</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>			<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs</li> </ul>
			<ul style="list-style-type: none"> <li>Harvested seeds contaminated as a result of poor worker hygiene and sanitation</li> </ul>	<ul style="list-style-type: none"> <li>Worker hygiene and sanitation</li> </ul>	<ul style="list-style-type: none"> <li>Review training records; monitor hygiene and sanitation</li> </ul>			<ul style="list-style-type: none"> <li>Training records</li> </ul>
	B.4.3.	Seed Testing	Describe the seed health testing procedures and methods used to ensure that the entity's seed supply system is free of regulated pests.					
			<ul style="list-style-type: none"> <li>Untested seeds are released into seed supply system; pest detections cannot be traced back to origin or traced forward to customers; phytosanitary status of seeds is not maintained</li> </ul>	<ul style="list-style-type: none"> <li>Identification and tracking procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review testing, tracking and tracing records; ensure proper labelling</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>	<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			<ul style="list-style-type: none"> <li>Improper seed testing results in failure to detect pests</li> </ul>	<ul style="list-style-type: none"> <li>Accreditation or authorization status of seed health testing laboratories</li> </ul>	<ul style="list-style-type: none"> <li>Review authorization and audit records</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with authorization/ accreditation requirements</li> </ul>	<ul style="list-style-type: none"> <li>Authorization and audit records</li> </ul>
		<ul style="list-style-type: none"> <li>Authorization status of methods used for seed health testing</li> </ul>						
		<ul style="list-style-type: none"> <li>Use of seed sampling methods described by the <a href="#">International Seed Testing Association</a> (ISTA) or the <a href="#">Association of Seed Control Officials</a> (AASCO)</li> </ul>				<ul style="list-style-type: none"> <li>Familiarity with approved seed sampling methods</li> </ul>	<ul style="list-style-type: none"> <li>Seed sampling records</li> </ul>	
		<ul style="list-style-type: none"> <li>Use of official seed samplers, if applicable</li> </ul>						
			<ul style="list-style-type: none"> <li>Seeds contaminated by improper equipment cleaning and sanitization; test results impacted by incorrect sample size resulting from improper calibration</li> </ul>	<ul style="list-style-type: none"> <li>Seed sampling equipment cleaning, sanitization and calibration</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization and calibration</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and calibration training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization, cleaning and calibration records</li> </ul>
			<ul style="list-style-type: none"> <li>Seeds contaminated by previously used sample bags</li> </ul>	<ul style="list-style-type: none"> <li>Use of new sample collection bags</li> </ul>	<ul style="list-style-type: none"> <li>Review as part of audits</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation training</li> </ul>	
			<ul style="list-style-type: none"> <li>Seeds contaminated as a result of improper laboratory / greenhouse cleaning and sanitization</li> </ul>	<ul style="list-style-type: none"> <li>Laboratory and greenhouse sanitation</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization, cleaning records</li> </ul>
			<ul style="list-style-type: none"> <li>Seeds contaminated by improper equipment</li> </ul>	<ul style="list-style-type: none"> <li>Laboratory equipment and tool cleaning, sanitization,</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and</li> </ul>			<ul style="list-style-type: none"> <li>Sanitization, cleaning and</li> </ul>

Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records	
			cleaning and sanitization; test results impacted by improper equipment calibration	calibration and maintenance	sanitization and calibration			calibration records	
			<ul style="list-style-type: none"> <li>Seed test results compromised as a result of using inappropriate methods or poor laboratory practices</li> </ul>	<ul style="list-style-type: none"> <li>Training of laboratory staff on appropriate testing methodologies and good laboratory practices</li> </ul>	<ul style="list-style-type: none"> <li>Review test methodologies and laboratory practices</li> </ul>		<ul style="list-style-type: none"> <li>Training in test methods and good laboratory practices</li> </ul>	<ul style="list-style-type: none"> <li>Work instructions for laboratory testing</li> </ul>	
			<ul style="list-style-type: none"> <li>Improper data interpretation results in incorrect test results</li> </ul>	<ul style="list-style-type: none"> <li>Standard data interpretation for authorized methods</li> </ul>	<ul style="list-style-type: none"> <li>Review data interpretation</li> </ul>		<ul style="list-style-type: none"> <li>Training in test methods and data interpretation</li> </ul>		
			<ul style="list-style-type: none"> <li>Potential contamination from remnant seeds and debris</li> </ul>	<ul style="list-style-type: none"> <li>Remnant seeds and debris properly disposed of in accordance with local regulations and good laboratory practices</li> </ul>	<ul style="list-style-type: none"> <li>Review logs for cleaning and sanitization; review disposal records</li> </ul>		<ul style="list-style-type: none"> <li>Sanitation and hygiene training</li> </ul>	<ul style="list-style-type: none"> <li>Sanitization and cleaning records and disinfectant logs; disposal and destruction records</li> </ul>	
	<b>B.5.</b>	<b>Distribution and Transport</b>							
		Describe procedures used to mitigate seed-associated pests in seeds that are distributed outside of the accredited entity facility. Procedures used to meet international phytosanitary regulatory requirements must be included.							
			<ul style="list-style-type: none"> <li>Pest detections cannot be traced back to origin or traced forward to customers;</li> </ul>	<ul style="list-style-type: none"> <li>Identification and tracking procedures</li> </ul>	<ul style="list-style-type: none"> <li>Review tracking and tracing records; ensure proper labelling</li> </ul>		<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory control system</li> </ul>	<ul style="list-style-type: none"> <li>Familiarity with and/or training in entity's inventory</li> </ul>	

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Commodity / Pest	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			phytosanitary status of seeds is not maintained					control system
			<ul style="list-style-type: none"><li>• Noncompliant seeds are released</li></ul>	<ul style="list-style-type: none"><li>• Entity's compliance with seed quality release criteria for customer, market and country import requirements</li></ul>	<ul style="list-style-type: none"><li>• Review seed quality records</li></ul>		<ul style="list-style-type: none"><li>• Familiarity with entity's seed quality standards</li></ul>	<ul style="list-style-type: none"><li>• Release records</li></ul>
			<ul style="list-style-type: none"><li>• Seeds contaminated in transit</li></ul>	<ul style="list-style-type: none"><li>• Safeguarding measures to maintain shipment integrity</li></ul>	<ul style="list-style-type: none"><li>• Monitor packing and shipping conditions</li></ul>		<ul style="list-style-type: none"><li>• Familiarity with safeguarding methods</li></ul>	<ul style="list-style-type: none"><li>• Shipping records</li></ul>



**Table 3. Examples of pest types and possible risk management measures for them**

Pest Type	Risk Management Measures
Multiple pest categories	<ul style="list-style-type: none"> <li>• Use crop rotation and / or fallow periods</li> <li>• Production in pest free areas, pest free places of production, pest free production sites, areas of low pest prevalence</li> <li>• Field management: pest monitoring, pesticide treatment, biological control</li> <li>• Ensure production site is sufficiently isolated from other crops produced on-site or nearby</li> <li>• Maintain a host-free buffer around the production site to prevent infestation from other crops produced on-site or nearby</li> <li>• Workers trained on proper sanitation and hygiene protocols</li> <li>• Use of disinfectant footbaths and handwashing stations</li> <li>• All tools and equipment including tractors and field equipment are properly washed and sanitized prior to entering production site</li> <li>• Site is gated and/or fenced or access otherwise physically limited</li> <li>• Use signs to indicate access is limited to authorized personnel; maintain authorized access to production site</li> <li>• All surfaces are cleaned/sanitized prior to use or between growing cycles/seasons; all weeds and plant debris removed</li> <li>• Inspection and destruction / removal of volunteers with herbicide treatment or physical destruction (e.g., plowing)</li> <li>• Identification and tracking procedures</li> <li>• Seed health testing / certification of seed lots</li> <li>• Appropriate seed treatment applications</li> <li>• Inspection or testing of seedlings/transplants prior to transplanting</li> <li>• Regular crop inspections of production plants</li> <li>• Diagnosis of diseased or symptomatic plants, and disposal of contaminated seeds, plants, growing media and containers by APHIS–approved methods</li> <li>• Manage irrigation frequency to reduce moisture conditions favorable to pest populations</li> <li>• Harvest criteria (maturity, timing) for the crop</li> </ul>
Soilborne pests	<ul style="list-style-type: none"> <li>• Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence</li> <li>• Soilless growing media</li> <li>• Soil treatments</li> <li>• Soil sampling / testing / inspection for soilborne pests</li> </ul>
Waterborne pests	<ul style="list-style-type: none"> <li>• Use clean water source (e.g., sealed deep well, municipal water)</li> <li>• Treat water to sterilize (e.g., boil, UV, chlorine, etc.)</li> <li>• Sample / test water for waterborne pests of concern</li> </ul>

Pest Type	Risk Management Measures
Weed pests and pests with weed hosts	<ul style="list-style-type: none"> <li>• Inspection and field management through herbicide treatment or physical destruction (e.g., plowing)</li> <li>• Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence</li> </ul>
Pests with vectors (e.g., arthropods, nematodes)	<ul style="list-style-type: none"> <li>• Monitoring for vectors</li> <li>• Field management: pest monitoring, pesticide treatment, biological control</li> </ul>
Pests with airborne or rain-splashed spores; arthropod pests; pests with arthropod vectors	<ul style="list-style-type: none"> <li>• Structure is inspected prior to use, during production and between growing cycles/seasons and any broken glass or tears are repaired immediately</li> </ul>
Pests capable of surviving as surface contaminants, growing media contaminants or saprophytes, soilborne pests	<ul style="list-style-type: none"> <li>• Beds cleaned to remove debris and growing medium is sterilized</li> <li>• Beds cleaned and sanitized; growing medium is replaced with new or sterilized growing medium</li> <li>• Use only new, unused and/or sterilized growing media in beds/pots/trays</li> <li>• Use only new, unused and/or sterilized transplant containers</li> <li>• Store media and containers to safeguard them from contamination/infestation by pests, soil, contaminated water, etc.</li> <li>• All tools and equipment are properly washed and sanitized prior to entering production site</li> </ul>