ReFreSH

Regulatory Framework for Seed Health Participant Manual

Table of Contents

Intro	oduction	3
	eSH Manual Essential Elements	
A.	Staff and Facilities	4
В.	Seed Health Management Plan	8
C.	Internal Audits and System Improvements	14
D.	Records and Documents	15
E.	Change Management	17
F.	Reporting and compliance	18
APP	ENDIX I: ReFreSH Seed Health Management Plan (SHMP) spreadsheet	19
Tal	ble 1. Examples of risk management measures for different pest types	20
Tal	ble 2. Risk Evaluation/Hazard Analysis Instructions	22
Tal	hle 3. Example Risk Evaluation/Hazard Analysis	23

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 by using 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 Heath (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.

ReFreSH Manual Essential Elements

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 Components
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.
A2	Staff training
	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 at least annually. A
	description of how often staff are trained on the different elements of the entity's
	ReFreSH program.

Section	ReFreSH Standard Components
A2	Staff training
	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
	 The entity must document that staff associated with their ReFreSH program include, or have access to, individuals with the following qualifications: An advanced degree or equivalent work experience in identification, diagnosis and management of plant pests; Technical knowledge of the identified seed health tests, plant health inspection protocols and the visual and sampling procedures relevant to the accreditation; Experience in the development and implementation of quality management systems

A.4.	Entity description
A.4.1.	Entity and commodity
	 The ReFreSH Manual must include: The name, physical location and description of the entity facility(ies) seeking approval including, as appropriate, production, operations, seed testing and/or distribution facilities. The seed species that the entity will be producing or distributing under the ReFreSH program.

B. Seed Health Management Plan

The ReFreSH Manual must include a Seed Health Management Plan (SHMP) for seed commodities that they would like accredited under ReFreSH. 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
	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 Appendix I . Entities may also incorporate the template in their Seed Health Management Plan (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. Factors to consider in developing risk management options are listed in Sections B.2B.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 1 and 3 shown in the appendix.

B.2. Pre-planting B.2.1. Site Selection and Preparation 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: Soil quality and water sources Site cropping and disease history Endemic pests • Isolation distance from other crops produced on-site or nearby • Presence of weeds in production field • Weed control in borders and adjacent fields Presence of volunteer plants and host debris from previous production cycles / earlier growing seasons • Presence of potential vectors Worker hygiene and sanitation Tool/equipment (including tractors and other field equipment) sanitation Accessibility of site, field, etc. by authorized and non-authorized persons • For protected culture crops (including transplant houses): structure integrity and sanitization prior to use or between production cycles Additional factors that should be considered for transplant houses include: • Sanitization or cleaning of seed beds Growing media used in transplant seed beds/pots/trays (new or sterilized only) Transplant containers (new or sterilized only) • Storage of growing media and containers to avoid pest contamination Tool/equipment sanitation B.2.2. **Seed and Plant Inputs** 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: Identification and tracking procedures Seed health testing / certification of parental seed lots Seed treatment applications • Inspection or testing of seedlings/transplants prior to transplanting Diagnosis of diseased or symptomatic plants Disposal of contaminated seeds, plants, growing media and containers by authorizing NPPO- approved methods

B.3.	Preharvest
B.3.1.	Production
	Describe procedures used to prevent, monitor and mitigate pests during seed production. Factors that should be considered include: Accessibility of site, field, etc. by authorized and non-authorized persons Worker hygiene and sanitation Tool/equipment (including planter or tractor) sanitation
	 Regular crop inspections of all plants including males (pollinator) plants Diagnosis of symptomatic plants by approved methods Disposal of diseased or symptomatic plants, growing media and containers (if applicable) by APHIS—approved methods Monitoring for vectors
	 Monitoring for vectors Management of pests with appropriate crop protection materials (chemical or biological) and cultural control practices (e.g., mulching, screens over access points in greenhouses) If applicable, irrigation details (e.g., source, frequency) Weed control within and surrounding the production location (field, structure, etc.) Identification and tracking procedures
B.3.2.	Seed Harvest
	Describe procedures used to minimize seed contamination during harvesting and drying at the production site(s). Factors that should be considered include: Harvest criteria (maturity, timing) for the crop Visual inspection of plants and fruit prior to harvest Weather conditions (e.g., rain, dew) permitted at harvest If applicable, pre-harvest fruit washing or sanitizing procedures Harvest/seed extraction location (e.g., within a facility, in the field) Use of new or sanitized seed containers/bags Worker hygiene and sanitation Harvest equipment and tool sanitation and/or cleaning If applicable, seed drying location Drying equipment sanitation Identification and tracking procedures

B.4.	Post-harvest
B.4.1.	Conditioning and Treatment
	Describe the procedures used to reduce the presence of seedborne pests during seed cleaning, conditioning, sizing and packaging.
	 Factors that should be considered include: Seed sampling and testing Seed washing and/or disinfection Seed treatments Seed operations equipment and tool sanitization and/or cleaning Proper disposal of all remnant and unusable seeds and debris Disposal of all seeds found to be contaminated with regulated pests in accordance to regulatory guidelines Worker sanitation and hygiene Identification and tracking procedures
B.4.2.	Handling and Storage
	Describe procedures to prevent the introduction and spread of seedborne 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. Factors that should be considered include:
	 Segregation and physical separation of untested and tested seed inventories Seeds stored in closed containers under monitored warehouse conditions of controlled temperature and humidity Warehouse sanitation including regular cleaning, immediate clean-up of seed spills, removal of waste or unused seeds Equipment and tool sanitization and/or cleaning
	 Worker hygiene and sanitation Identification and tracking procedures

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. 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 National Seed Health System (NSHS), Naktuinbouw Authorized Laboratory (NAL) program or the International Seed Testing Association (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). Factors that should be considered include: Identification and tracking procedures Accreditation or authorization status of seed health testing laboratories Authorization status of methods used for seed health testing Use of seed sampling methods described by the International Seed Testing Association (ISTA) or the Association of Seed Control Officials (AASCO) Use of official seed samplers, if applicable Seed sampling equipment cleaning, sanitization and calibration Use of new sample collection bags Training of laboratory staff on appropriate testing methodologies and good laboratory practices Laboratory and greenhouse sanitation Laboratory equipment and tool cleaning, sanitization, calibration and maintenance Standard data interpretation for authorized methods Remnant seeds and debris properly disposed of in accordance with local regulations and good laboratory practices B.5. **Distribution and Transport** Describe procedures used to mitigate seedborne pests in seeds that are distributed outside of the accredited entity facility. Procedures used to meet international phytosanitary regulatory requirements must be included. Factors that should be considered include: Identification and tracking procedures Entity's compliance with seed quality release criteria for customer,

market and country import requirements

Safeguarding measures to maintain shipment integrity

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 Components
C.1.	Responsible Party
62	The ReFreSH Manual must include the title and position of the person responsible for the audits and system improvements program.
C.2.	Auditing
	Procedures establishing a timeline, scope, reporting, and retention of the audit results and other applicable documentation must be demonstrated. During the period between certification and the recertification audit, the manual should:
	 Establish a schedule of internal audits over the course of each year The internal audits must be sufficient to ensure all processes and procedures conform with those described in the ReFreSH Manual
	 Ensure the internal audits encompass all aspects of the Manual including the SHMP
C.3.	Corrective Actions and System Improvements
	Procedures for implementing corrective actions when non-conformances are detected including: • for conducting root cause analysis to prevent recurrence, and
	 for proactively developing system improvements must be
	described. These may occur both within and outside of the audit
6.4	process.
C.4.	NPPO Notification
	Procedures used to notify the NPPO of non-conformances that were detected while conducting internal audits and of corrective actions taken must be demonstrated. • 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.
	 Procedure to notify the authorizing NPPO of any non-critical non- conformances at least sixty (60) days prior to a scheduled external audit.

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 Components
D.1.	Control of the Manual and documents
	 The entity must establish a procedure to review the Manual on a regular basis. The Manual should include: The position/title of person(s) with authority to approve changes to the Manual The process for making and documenting those changes Details of how the document is controlled to assure that it is secure and that only the current version is available 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)
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
	All records must be maintained for a minimum of four (4) years, or other retention period, and be made available to the NPPO upon request.
D.2.2.	Traceability Records
	 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. Records include seed import and transplant crop records (trace forward/trace back) Records will be maintained and available for review by the NPPO Records can include certificates or invoices which substantiate the origin and phytosanitary status of incoming propagative material
D.2.3.	Systems Improvement Records
	The Manual shall describe procedures to maintain records of internal and external audit documents. Systems improvement records maintained and made available for review by the NPPO include: All internal/external audit reports Non-conformance records Corrective action and system improvement records Root cause analyses records.

D.2.4.	Seed Health Management Plan (SHMP) Records
	The Manual shall describe procedures that shall ensure all SHMP records are maintained and available for review by the NPPO.
	 Examples include: Soil and growing medium sterilization records Soil and water test results Transplant and production facility sanitation/disinfection records Production site inspection data Records of symptomatic plants observed, and plants removed Records of pest detections and corrective actions Records of regulated pests found and of notification(s) sent to the authorizing NPPO Records of pesticide applications Seed health test results Seed treatment records Storage facility environmental monitoring data
D.2.5.	 Disposal records for remnant or contaminated seeds Training Records
	Describe procedures that ensure all training records, training materials and a list of employees trained are maintained and available for review by the NPPO. Records must be maintained for training activities specific to the entity's ReFreSH program.
	 Examples include: Records of training dates/frequency, content and format Records of staff participants (trainers and trainees) Records of reviews and updates of training materials

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
	 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
E.2.	Minor changes to the ReFreSH Manual
	 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.
E.3.	Scheduled external audit / applying for re-accreditation
	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.

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 Components
F.1.	Point of contact
	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.).
F.2.	Notification of critical non-conformances
	 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.
F.3.	Detection of a regulated pest
	 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. 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.
F.4.	Non-critical non-conformances
	 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.

APPENDIX I: ReFreSH Seed Health Management Plan (SHMP) spreadsheet

The template shown in the fillable ReFreSH Seed Health Management Plan (SHMP) spreadsheet is included to assist entities with their risk evaluation/hazard analysis (see section B.1 Risk Evaluation/Hazard Analysis). The template is adapted from the 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 applies 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 include:

- **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

This appendix contains information that may be helpful in the development of a Seed Health Management Plan (SHMP). This includes information here or in the SHMP spreadsheet. The "instructions" tab of the fillable SHMP provides general instructions for using the risk evaluation/hazard analysis tool. The "example" sheet describes generic hazards and risks, as well as example 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 that are not included in the example. The entity should add or delete entries as appropriate for their seed supply system proposed for ReFreSH authorization. There are also examples of training and knowledge requirements and records requirements that may be useful in developing the entity's ReFreSH Manual and SHMP. A "fillable" tab can be used by an entity to create their own SHMP with this template if they so choose. Finally, the appendix includes a list of selected categories of pests and corresponding risk management measures for those pests.

Table 1. Examples of risk management measures for different pest types

Pest type	Risk Management Measure
various pest	 Use crop rotation and / or fallow periods Production in pest free areas, pest free places of production, pest free production sites, areas of low pest prevalence Field management: pest monitoring, pesticide treatment, biological control Ensure production site is sufficiently isolated from other crops produced on-site or nearby Maintain a host-free buffer around the production site to prevent infestation from other crops produced on-site or nearby Workers trained on proper sanitation and hygiene protocols Use of disinfectant footbaths and handwashing stations All tools and equipment including tractors and field equipment are properly washed and sanitized prior to entering production site Site is gated and/or fenced or access otherwise physically limited Use signs to indicate access is limited to authorized personnel; maintain authorized access to production site All surfaces are cleaned/sanitized prior to use or between growing cycles/seasons; all weeds and plant debris removed Inspection and destruction / removal of volunteers with herbicide treatment or physical destruction (e.g., plowing) Identification and tracking procedures Seed health testing / certification of seed lots Appropriate seed treatment applications Inspection or testing of seedlings/transplants prior to transplanting Regular crop inspections of production plants Diagnosis of diseased or symptomatic plants, and disposal of contaminated seeds, plants, growing media and containers by APHIS—approved methods Manage irrigation frequency to reduce moisture conditions favorable to pest populations Harvest criteria (maturity, timing) for the crop
soilborne pests	 Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence Soilless growing media Soil treatments Soil sampling / testing / inspection for soilborne pests
waterborne pests	 Use clean water source (e.g., sealed deep well, municipal water) Treat water to sterilize (e.g., boil, UV, chlorine, etc.) Sample / test water for waterborne pests of concern

weed pests and pests with weed hosts	 Inspection and field management through herbicide treatment or physical destruction (e.g., plowing) Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence
Vector transmitted pathogens	 Monitoring for vectors Pesticide treatment, biological control
pests with airborne or rain-splashed spores; arthropod pests; pests with arthropod vectors	Structure is inspected prior to use, during production and between growing cycles/seasons and any broken glass or tears are repaired immediately
soilborne pests capable of surviving as surface contaminants, growing media contaminants or saprophytes	 Beds cleaned to remove debris and growing medium is sterilized Beds cleaned and sanitized; growing medium is replaced with new or sterilized growing medium Use only new, unused and/or sterilized growing media in beds/pots/trays Use only new, unused and/or sterilized transplant containers Store media and containers to safeguard them from contamination/infestation by pests, soil, contaminated water, etc. All tools and equipment are properly washed and sanitized prior to entering production site

Table 2. Risk Evaluation/Hazard Analysis Instructions

	Seed	Health Management Plan	Information		R	eFreSH Manual Info	ormation	
	Information	from these entries is incorpor SHMP	ated into the entity's		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 Table 3 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 3. Example Risk Evaluation/Hazard Analysis. The table serves as a guidance and example for how key information can be presented. Potential risk/hazard and corresponding mitigation measures and information needed to develop the Seed Health Management can be presented in a table format by altering the cells.

		Seed I	Health Management Plan I	nformation		Rel	ReFreSH Manual Information		
Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records	
	B.2.	Pre-planting							
		Describe pre-plant fa	cilities assessment and pro	ocedures that prevent or miti	gate pest introduction fron	n the environme	nt into the production	site(s).	
	B. 2.1.	Site Selection and Preparation	Add any additional factors a commodity / pest combinate	and select any of the following astion.	s appropriate for the				
			Contaminated or infested soil (field grown crops)	 Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence 	 Surveys/inspection/ monitoring (e.g., trapping) 	Name / Title of responsible person	Knowledge of IPPC standards for pest- free concepts	• Survey / Inspection records	
				Soil treatments	 Soil sampling / testing / inspection for soilborne pests 		 Pesticide application; soilborne pest control 	Pesticide application records	
				Soil sampling / testing / inspection for soilborne pests	• Inspection/test results		Soil sampling; results interpretation	• Inspection / test results	
			Contaminated water sources	Use clean water source (e.g., sealed deep well, municipal water)	Verify source as part of audits				
				Treat water to sterilize (e.g., boil, UV, chlorine, etc.)	Review treatment records		Water treatment methods and equipment training	• Water treatment records	

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
	B. 2.1. Site Selection and Preparation		Sample / test water for waterborne pests of concern	Review test results		 Water sampling; results interpretation 	Water test results	
			• Site has a history of host crops and/or pests	Use crop rotation and / or fallow periods	Review cropping records			• Cropping history
			Endemic pests present	 Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence 	Surveys / inspection / monitoring (e.g., trapping)		 Survey / inspection methodology; IPM; pesticide application; knowledge of IPPC 	 Survey / Inspection records Pesticide / treatment
				Field management: pest monitoring, pesticide treatment, biological control			standards for pest- free concepts.	application records
			Regulated pests present	 Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence 				
				Field management: pest monitoring, pesticide treatment, biological control				
			Inadequate isolation distance from other crops produced on-site or nearby	Ensure production site is sufficiently isolated from other crops produced on- site or nearby				
				Maintain a host-free buffer around the production site				

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
		Site Selection and Preparation		to prevent infestation from other crops produced onsite or nearby				
			Weeds present in production field	 Inspection and field management through herbicide treatment or physical destruction (e.g., plowing) 	Surveys / inspection / monitoring		 Survey/inspection methodology; weed control; pesticide application 	
			Weed control in borders and adjacent fields is absent or inadequate	 Inspection and border weed management through herbicide treatment or physical destruction (e.g., plowing) 				
			 Volunteer plants and host debris from earlier growing seasons not properly removed 	 Inspection and destruction removal of volunteers with herbicide treatment or physical destruction (e.g., plowing) 				
			Potential disease vectors present	 Production in pest free areas, pest free places of production, pest free production sites, low pest prevalence 	 Surveys / inspection / monitoring (e.g., trapping) 			
				Field management: pest monitoring, pesticide treatment, biological control				
			 Worker hygiene and sanitation not properly maintained 	 Workers trained on proper sanitation and hygiene protocols 	Review training records		Sanitation and hygiene training	Training records

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
		B. 2.1. Site Selection and Preparation		Use of disinfectant footbaths and handwashing stations	 Review disinfectant logs for footbaths and handwashing stations 			 Sanitization records and disinfectant logs
			Tool/equipment (including tractors and other field equipment) sanitation not properly maintained	 All tools and equipment including tractors and field equipment are properly washed and sanitized prior to entering production site 	Review logs for cleaning and sanitization			1063
			Authorized access not properly maintained	Site is gated and/or fenced or access otherwise physically limited	Verify presence as part of audits		 Awareness of authorized access lists 	• List of authorized personnel
				Use signs to indicate access is limited to authorized personnel				
			For protected culture crop	ps (including transplant houses):				
			Structure sanitization prior to use or between growing seasons/cycles not properly maintained	All surfaces are cleaned/sanitized prior to use or between growing cycles/seasons; all weeds and plant debris removed	Review logs for cleaning and sanitization		Sanitation and hygiene training	Sanitization records and disinfectant logs
			Structure integrity prior to use or between growing seasons/cycles not properly maintained	Structure is inspected prior to use or between growing cycles/seasons and any broken glass or tears are repaired immediately	Review inspection / repair reports; inspect structure as part of audits			• Inspection reports and repair records
			Seed beds not properly cleaned / sanitized	Beds cleaned to remove debris and growing medium is sterilized	Review logs for cleaning and sanitization		Sanitation and hygiene training	Sanitization records and

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
		Site Selection and Preparation		Beds cleaned and sanitized; growing medium is replaced with new or sterilized growing medium				disinfectant logs
			 Contaminated growing media used in transplant seed beds/pots/trays 	Use only new, unused and/or sterilized growing media in beds/pots/trays	 Review records for growing media source and/or sterilization 			
			 Contaminated transplant containers used 	Use only new, unused and/or sterilized transplant containers	 Review records for transplant containers source and/or sterilization 			
			 Growing media and containers not stored properly to avoid pest contamination 	Store media and containers to safeguard them from contamination/infestation by pests, soil, contaminated water, etc.	 Inspect storage conditions as part of audits 			
			 Tool/equipment sanitation not properly completed 	 All tools and equipment are properly washed and sanitized prior to entering production site 	 Review logs for cleaning and sanitization 			
	B.2.2.	Seed and Plant Inputs	Add any additional factors a commodity / pest combinat	and select any of the following as tion	appropriate for the			
			 Non-certified/untested seeds are inadvertently planted; pest detections later in the process cannot be traced back to origin 	Identification and tracking procedures	Review seed source (import), certification records		Familiarity with and/or training in entity's inventory control system	• Seed source (import), certification and testing records

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
	B.2.2. Seed and Plant Inputs	Non-certified or untested seeds are infested and planted	Seed health testing / certification of seed lots	Review certification and testing records		 Familiarity with seed certification systems 		
			Inappropriate, improperly applied or missing seed treatments result in diseased plants	Appropriate seed treatment applications	Monitor seed treatments; review seed treatment records		 Familiarity with or training in seed treatments and their application 	• Seed treatment records
		Infected/infested transplants planted in the field	Inspection or testing of seedlings/transplants prior to transplanting	Review inspection / testing records for each transplant lot prior to planting		• Familiarity / training of signs and symptoms of pests in transplants; familiarity / training in inspection / sampling /testing methodology and interpretation of results	• Inspection / testing records	
			Diseased or contaminated seeds, plants, growing media or containers infest, infect or contaminate healthy seeds or plants	Diagnosis of diseased or symptomatic plants, and disposal of contaminated seeds, plants, growing media and containers by APHIS—approved methods	Review records for diagnosis and destruction of diseased/contaminated materials		Experience / training / or access to expertise in diagnostics; familiarity /training for approved destruction/devitali zation methods	Diagnostic and destruction / devitalization records

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records			
	B.3.	Pre-harvest									
	В.3.1.	Production	•	Add any additional factors and select any of the following as appropriate for the commodity / pest combination							
			Unauthorized visitors to the production site may introduce pests	 Maintain authorized access to site; use signs to indicate access is limited to authorized personnel 	Monitor visitor /activity records for production site		Awareness of authorized access list	 List of authorized personnel 			
			Worker hygiene and sanitation not properly maintained	Workers trained on proper sanitation and hygiene protocols	Review training records; monitor hygiene and sanitation		Sanitation and hygiene training	Training records			
				Use of disinfectant footbaths and handwashing stations	Review disinfectant logs for footbaths and handwashing stations			Sanitization and cleaning records and disinfectant			
			Tool/equipment sanitation and washing not properly completed resulting in contamination	Tool/equipment (including planter or tractor) sanitation	Review logs for cleaning and sanitization			logs			
			Production sites infested / infected during growing season	Regular crop inspections of all plants including males (pollinator) plants	Review crop inspection records		 Familiarity / training in field inspection and signs / symptoms of pests 	• Crop inspection reports			
			Diseased or contaminated plants infest, infect or contaminate healthy plants	Diagnosis and disposal of symptomatic plants by approved methods	Review records for diagnosis and destruction of diseased/contaminated materials		 Experience / training or access to expertise in diagnostics; familiarity / training for approved 	Diagnostic and destruction / devitalization records			

Table 3.

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
							destruction /devitalization methods	
			Presence of vectors may result in the introduction and/or spread of pests	Monitoring for vectors	Survey / inspect/ monitor for the presence of vectors		Experience / training or access to expertise in identifying vector species; knowledge training in survey / inspection methods	• Survey / inspection records
			Production site infestation during production cycle	 Management of pests with appropriate pesticide (chemical or biological) applications and cultural control practices (e.g., mulching, screens over access points in greenhouses) 	Survey / inspect/ monitor for the presence of pests		 Survey/inspection methodology; Integrated pest management; pesticide application 	 Survey / inspection records; pesticide application records
			Contaminated water sources	Use clean water source (e.g., sealed deep well, municipal water)	Verify source as part of audits			
			Irrigation creates favorable environment for pest populations	 Manage irrigation frequency and type (e.g., drip vs. overhead) to reduce moisture conditions favorable to pest populations 	Monitor production site moisture levels		Knowledge of pest biology / moisture requirements	

Table 3.

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			Weed control in production site and borders is absent or inadequate	Weed control within and surrounding the production location (field, structure, etc.)	Surveys / inspection / monitoring		Survey/inspection methodology; weed control; pesticide application	• Survey / Inspection records; pesticide / treatment application records
			Non-certified/untested seeds are inadvertently planted; pest detections cannot be traced back to origin or traced forward to customers	Identification and tracking procedures	Review seed source records; ensure proper labelling		Familiarity with and/or training in entity's inventory control system	Inventory tracking records
	B.3.2.	Seed Harvest	Describe procedures used to at the production site(s).	o minimize seed contamination o	during harvesting and drying			
			Pests present in harvested seeds if harvested when pest population high or plants at susceptible stage for seed infestation	Harvest criteria (maturity, timing) for the crop	Monitor pest populations and crop maturity		Familiarity / training in epidemiology crop phenology	Harvest dates/ pest populations
			Harvested seeds and equipment contaminated by surface contaminants on harvested fruit	 If applicable, pre-harvest fruit washing or sanitizing procedures 	Review logs for cleaning and sanitization		Sanitation and hygiene training	Sanitization and cleaning records and disinfectant logs

Table 3.

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard		Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge		Records
	B.3.2.	Seed Harvest	Seeds contaminated during extraction	٠	Harvest/seed extraction location (e.g., within a facility, in the field)	Review harvest /extraction records			/	Harvest /extraction records
			Unfavorable weather results in seed contamination	•	Avoid weather conditions (e.g., rain, dew) at harvest that favor disease development / contamination	Review harvest records		Familiarity / training in epidemiology		
			Infected seeds harvested	•	Visual inspection of plants and fruit prior to harvest	Surveys / inspection / monitoring		 Familiarity / training in field inspection and signs / symptoms of pests 		Inspection records
			 Harvested seeds contaminated as a result of poor worker hygiene and sanitation 	•	Workers trained on proper sanitation and hygiene protocols	 Review training records; monitor hygiene and sanitation 		Sanitation and hygiene training		Training records
			Harvested seeds contaminated by improper equipment and tool cleaning and sanitization	•	Harvest equipment and tool sanitation and/or cleaning	Review logs for cleaning and sanitization			(Sanitization and cleaning records and disinfectant logs
			Seeds contaminated during drying	•	If applicable, seed drying location	Review harvest records				Harvest records
			 Harvested seeds contaminated by improper equipment cleaning and sanitization 	•	Drying equipment sanitation	Review logs for cleaning and sanitization		Sanitation and hygiene training	á	Sanitization and cleaning records and

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
	В. 3.2.	Seed Harvest	Contaminated seed containers used	Use of new or sanitized seed containers/bags	Review records for seed container source and/or sterilization			disinfectant logs
			Pest detections cannot be traced back to origin or traced forward to customers	Identification and tracking procedures	Review seed source records; ensure proper labelling		 Familiarity with and/or training in entity's inventory control system 	 Inventory tracking records
	B.4.	Post-harvest						
	B.4.1.	Conditioning and Treatment	Describe the procedures use cleaning, conditioning, sizin	ed to reduce the presence of see g and packaging.	dborne pests during seed			
			 Pest detections cannot be traced back to origin or traced forward to customers 	Identification and tracking procedures	Review seed source records; ensure proper labelling		 Familiarity with and/or training in entity's inventory control system 	Inventory tracking records
			Missing / misapplied / incorrect seed treatments allow infestation / infection of seeds / subsequent plants	Seed treatments	Monitor seed treatments; review seed treatment records		Familiarity with or training in seed treatments and their application	Seed treatment records
			Seeds contaminated as a result of improper equipment and tool cleaning and sanitization	Seed operations equipment and tool sanitization and/or cleaning	Review logs for cleaning and sanitization		Sanitation and hygiene training	Sanitization and cleaning records and disinfectant logs
			Potential contamination from remnant and	Proper disposal of all remnant and unusable seeds and debris	Review disposal records		Sanitation and hygiene training; familiarity /	

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
		Conditioning and Treatment	unusable seeds and debris • 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			training for approved destruction /devitalization methods	Disposal and destruction records
			Harvested seeds contaminated because of poor worker hygiene and sanitation	Worker sanitation and hygiene	Review training records; monitor hygiene and sanitation		Sanitation and hygiene training	Training records
	B.4.2.	Handling and Storage	during post-harvest handlin process, i.e., filling, handling	vent the introduction and spreading and storage. The measures shough storage, and distribution of column to the entity's facilities.	ould address all stages in the			
			 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	Seeds stored in closed containers under monitored warehouse conditions of controlled	Monitor storage conditions		Familiarity with storage protocols	Storage condition records

Table 3.

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
			Seeds contaminated as a result of improper warehouse cleaning and sanitization or remnant and unusable seeds and debris	temperature and humidity • Warehouse sanitation including regular cleaning, immediate clean-up of seed spills, removal of waste or unused seeds	Review logs for cleaning and sanitization; review disposal records		Sanitation and hygiene training	 Sanitization and cleaning records and disinfectant logs Disposal and destruction records
			Harvested seeds contaminated by improper equipment cleaning and sanitization	Equipment and tool sanitization and/or cleaning	Review logs for cleaning and sanitization			Sanitization and cleaning records and disinfectant logs
			 Harvested seeds contaminated as a result of poor worker hygiene and sanitation 	Worker hygiene and sanitation	 Review training records; monitor hygiene and sanitation 			Training records
	B.4.3.	Seed Testing	Describe the seed health testing seed supply system is free of re	g procedures and methods used egulated pests.	to ensure that the entity's			

			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	Identification and tracking procedures	Review testing, tracking and tracing records; ensure proper labelling		Familiarity with and/or training in entity's inventory control system	Familiarity with and/or training in entity's inventory control system
Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
	B.4.3.	Seed Testing	Improper seed testing results in failure to detect pests	Accreditation or authorization status of seed health testing laboratories	Review authorization and audit records		 Familiarity with authorization/ accreditation requirements 	 Authorization and audit records
				 Authorization status of methods used for seed health testing 				
				Use of seed sampling methods described by the International Seed Testing Association (ISTA) or the Association of Seed Control Officials (AASCO)			Familiarity with approved seed sampling methods	Seed sampling records
				Use of official seed samplers, if applicable				
			Seeds contaminated by improper equipment cleaning and sanitization; test results impacted by incorrect sample size resulting from improper calibration	Seed sampling equipment cleaning, sanitization and calibration	 Review logs for cleaning and sanitization and calibration 		Sanitation and calibration training	Sanitization, cleaning and calibration records

		 Seeds contaminated by previously used sample bags Seeds contaminated as a 	 Use of new sample collection bags Laboratory and greenhouse 	Review as part of auditsReview logs for		Sanitation trainingSanitation training	Sanitization,	
			result of improper laboratory / greenhouse cleaning and sanitization	sanitation	cleaning and sanitization		3 January Halling	cleaning records
			 Seeds contaminated by improper equipment 	Laboratory equipment and tool cleaning, sanitization,	 Review logs for cleaning and 			 Sanitization, cleaning and
Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard	Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records
	B.4.3.	Seed Testing	cleaning and sanitization; test results impacted by improper equipment calibration	calibration and maintenance	sanitization and calibration			Calibration records
			 Seed test results compromised as a result of using inappropriate methods or poor laboratory practices 	Training of laboratory staff on appropriate testing methodologies and good laboratory practices	Review test methodologies and laboratory practices		Training in test methods and good laboratory practices	 Work instructions for laboratory testing
			Improper data interpretation results in incorrect test results	Standard data interpretation for authorized methods	Review data interpretation		 Training in test methods and data interpretation 	
			Potential contamination from remnant seeds and debris	Remnant seeds and debris properly disposed of in accordance with local regulations and good laboratory practices	Review logs for cleaning and sanitization; review disposal records		Sanitation and hygiene training	Sanitization and cleaning records and disinfectant logs; disposal and destruction records

Commodity/ Pest(s)	Manual section	Critical Control Point	Risk / Hazard		Risk Management Measures	Monitoring / Verification	Responsible Person	Training / Knowledge	Records	
	B.5.	 Distribution and Transport Describe procedures used to mitigate seed-associated pests in seeds that are distributed outside of the accredited entity facility. Procedinternational phytosanitary regulatory requirements must be included. 								
			 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	 Familiarity with and/or training in entity's inventory control system 	
			Noncompliant seeds are released	•	Entity's compliance with seed quality release criteria for customer, market and country import requirements	Review seed quality records		Familiarity with entity's seed quality standards	Release records	
			Seeds contaminated in transit	•	Safeguarding measures to maintain shipment integrity	Monitor packing and shipping conditions		Familiarity with safeguarding methods	Shipping records	