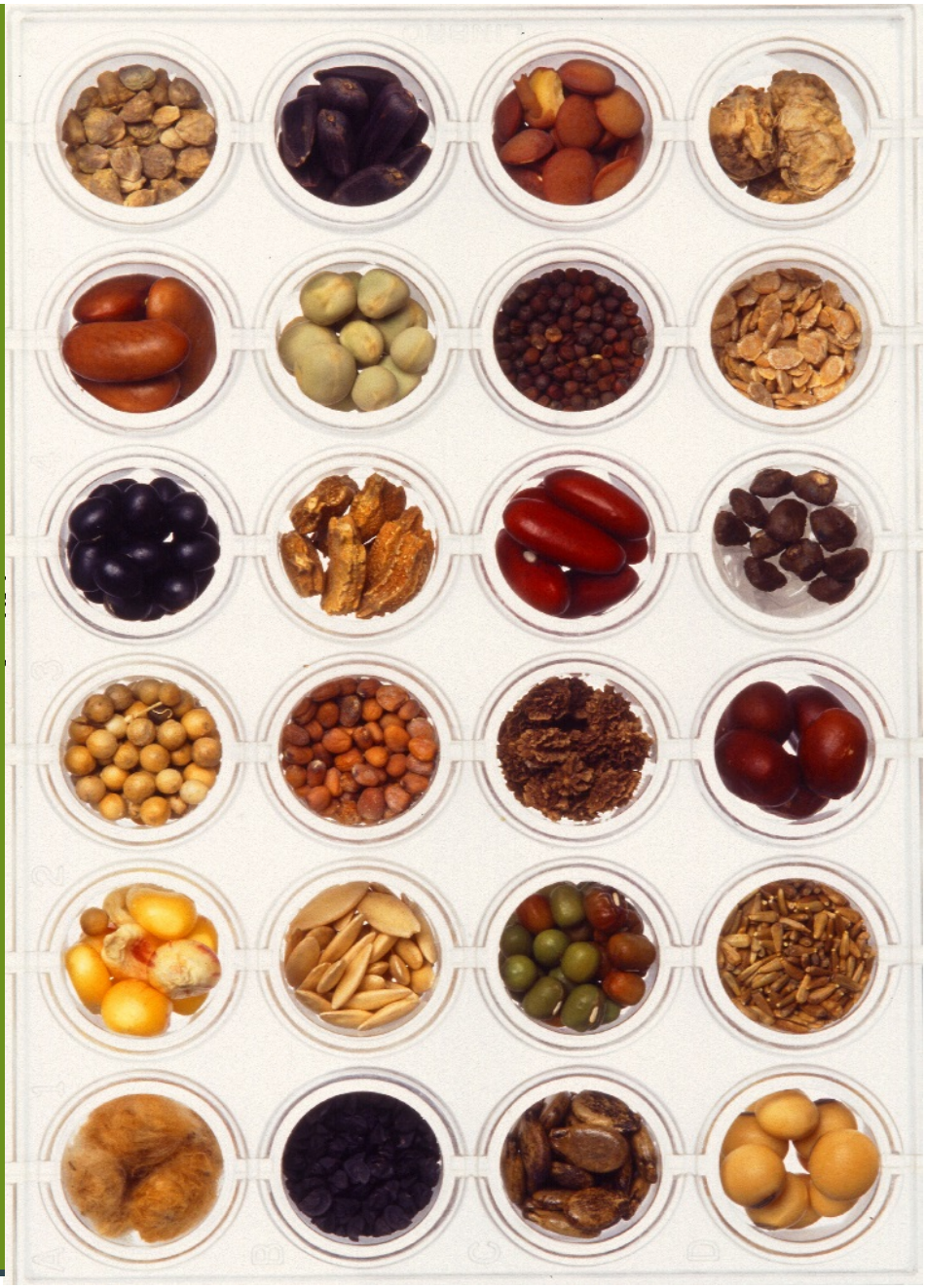
ReFreSH

A Regulatory Framework for Seed Health

Ver. 4.0



Executive Summary

In the United States, seed has traditionally, been regarded by regulators as a relatively low risk pathway for pest introduction. As a result, seed moved in trade with minimal import requirements. Recent outbreaks of seed transmitted diseases, the increasingly global nature of the seed trade and the increasing volume and complexity of the international seed trade prompted the development of a new approach to managing the phytosanitary challenges and risks of the movement of seeds. That new approach, ReFreSH (Regulatory Framework for Seed Health), is being developed jointly by the United States Department of Agriculture– Animal and Plant Health Inspection Service– Plant Protection and Quarantine, the American Seed Trade Association, the National Plant Board, United States National Seed Health System and individual members of the seed industry.

The recently adopted International Standard for Phytosanitary Measures 38- International Movement of Seeds (ISPM 38) provides guidance to National Plant Protection Organizations (NPPOs) to identify, assess and manage pest risk associated with the international movement of seeds. ISPM 38 incorporates principles for the use of integrated measures in a systems approach for pest risk management. ReFreSH is a risk-based systems approach focused on identifying the risks that exist in the seed production process, the critical control points in the process where each hazard can be managed and the measures that can be applied at those critical control points to manage the risk posed by the hazards. The ReFreSH approach was designed using principles of hazard analysis and critical control points (HACCP). This approach identifies hazards (i.e., any part or process of seed production with the potential to introduce plant pests through contamination or infection), the control points in seed production where these hazards can be controlled and the measures applied to control them. ReFreSH draws from the design of similar existing systems approaches in the seed and nursery sectors (e.g., American Seed Trade Association Guide to Quality Seed Production, Systems Approach for Nursery Certification). ReFreSH incorporates existing seed industry best management practices and quality management systems as part of the systems approach integrated measures and couples them with regulatory and oversight activities by National Plant Protection Organizations (NPPOs). Eight critical control points were identified in the ReFreSH approach: **1)** Pre-planting: Site selection and preparation; **2)** Pre-planting: Seed and plant inputs; **3)** Production: Pre-harvest; **4)** Production: Seed harvest; **5)** Post-harvest: Conditioning and treatment; **6)** Post-harvest: Handling and storage; **7)** Post-harvest: Seed quality testing; and **8)** Distribution and transport.

ReFreSH represents a significant paradigm shift in phytosanitary certification by offering an alternative to the current system of consignment by consignment phytosanitary certification. Under the ReFreSH approach, phytosanitary certification will be based instead on accreditation of seed production processes and producers. When completed, the ReFreSH approach described in this document will be a general framework for the requirements of accreditation. An accreditation manual currently being developed will provide detailed requirements including any commodity/producer specific requirements and the components of an audit system. The approach requires auditing of the components of the system approach. Primary responsibility for the audit of the system and the participating entities falls to the NPPO of the producing country. The NPPOs of the importing countries may audit the overall accreditation process and production system through reviews of documentation including audit reports and may audit selected entities if deemed necessary to ensure compliance with ReFreSH or in response to documented system failures.

The success of ReFreSH and similar approaches requires multilateral acceptance of the components of the systems approach and accreditation of the systems approach as the basis for phytosanitary certification. Trust in the systems will take time to develop and will be built by engaging in pilot programs with like-minded trading partners.

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I. Introduction

Traditionally, seed has been regarded by regulators as a relatively low risk pathway for pest introduction. As a result, seed moved in trade with minimal import requirements. For many seeds, these minimal import requirements were based on visual inspection, which may be ineffective for detecting seed transmitted pathogens like viruses, viroids or bacteria. Rapid growth in international trade has resulted in acceleration of the global spread of plant pests and seed movement is recognized as an important component of pest spread (Bebber et al., 2014). Recently, outbreaks of seed transmitted diseases like *Cucumber green mottle mosaic virus* (CGMMV) raised the profile of seed as a potential pathway for pathogens. The detection of CGMMV in a California melon field in 2013 and its putative introduction via imported seed (Tian et al., 2014) prompted APHIS to review imported seed as a pathway for the introduction of pests into the United States and the state of current regulations to prevent such introductions. This review ultimately resulted in a new seed health initiative described in this document. This new initiative, ReFreSH (Regulatory Framework for Seed Health), is being developed jointly by the United States Department of Agriculture (USDA)– Animal and Plant Health Inspection Service (APHIS)– Plant Protection and Quarantine, the American Seed Trade Association (ASTA), the National Plant Board (NPB), United States National Seed Health System (NSHS) and individual members of the seed industry. ReFreSH aims to develop a more effective and efficient approach to manage phytosanitary risk associated with international movement of seed. It will do that by identifying and leveraging current seed industry production practices and quality management systems that reduce overall phytosanitary risk and recognizing these measures within the context of an APHIS-approved systems approach. The goal of ReFreSH is to shift the current focus of consignment by consignment inspection and testing for phytosanitary certification to a system where accreditation of producers and production processes forms the basis for phytosanitary certification.

ReFreSH will be designed to accommodate all seed sectors (vegetable, cereal, row crop, farm and lawn, flower) and all sizes of companies. Whether or not to participate in ReFreSH will be a business decision for a given company. Companies for whom international seed movements are the key to their business model would likely benefit from the program. Conversely, companies that have limited international activity may choose to continue to be regulated under the current system. Ultimately, the goal is to work with global trading partners to use ReFreSH to harmonize phytosanitary requirements for international seed movement.

Creating predictability in the international regulatory system through harmonized import/export requirements based on accreditation of a process rather than certification of individual consignments potentially benefits industry and regulators. For regulators, ReFreSH will provide equivalent or better phytosanitary security and an increased understanding of industry practices. Industry benefits from the possibility for faster release of the product to its destination and reduced operational costs.

II. Background

This section describes some of the unique characteristics of the seed industry that present challenges for regulators and producers and also the nature and examples of seed as a means for the international movement of pests. In addition, phytosanitary approaches for managing pest risk within the seed trade are discussed.

A. Seed as a pathway

In recent years there has been an increasing awareness of the potential for seed to serve as a pathway for the global movement of pests. The association of plant pests with seeds has been recognized for millennia, but scientific evidence for transmission of disease agents through seeds was not recorded until the 18th century for fungi and nematodes, and the 20th century for bacteria and viruses. It is now firmly established that seeds can serve as a pathway for the introduction and spread of a wide range of pests. The association of microbial pests with seeds can be categorized according to the location of the pest: 1) infection of the seed embryo, 2) presence in seed parts other than the embryo and 3) external contamination of seeds. Specific examples of these scenarios are listed in **Appendix 1**. Seed transmission may occur through systemic or local infection of the seedling arising from a contaminated seed, or the pest may survive in the soil to infect subsequent crops.

The significance of seed as a pathway for pest introduction depends on the specific host/pest combination. Pests with a wide host range may be seed-transmitted on some hosts while seeds of other hosts do not act as a pathway.

Definitions [ISPM 5,38; (IPPC, 2016a, 2017c)]:

Pest- Any species, strain or biotype of plant, animal or pathogenic agent injurious to plants or plant products. Note: In the IPPC, plant pest is sometimes used for the term pest

Pathway- Any means that allows the entry or spread of a pest

Seed-borne pest- A pest carried by seeds externally or internally that may or may not be transmitted to plants growing from these seeds and cause their infestation

Seed-transmitted pest- A seed-borne pest that is transmitted via seeds directly to plants growing from these seeds and causes their infestation

Introduction (of a pest) - The entry of a pest resulting in its establishment

Seeds can act as a pathway for the introduction of all types of pests, including fungi, bacteria, viruses, viroids, nematodes, weeds, and insects. Fungi can be associated with seeds as internal infection of the embryo or other seed parts, as external contamination on the seed surface, or as fungal structures that can be mixed with seeds. These structures or contaminated seed parts may also enable fungi to survive in soil after planting. Seed-associated bacteria also infect embryos or other seed parts, or can be transported as external contaminants. Viruses and viroids can be mechanically transmitted from seed parts to infect seedling tissues during germination, but for a large number of viruses, infection of the embryo is the mechanism for efficient seed transmission (Sastry, 2013). Seed-associated nematodes typically infest seed lots as galls that form in place of seeds on infested mother plants. Weeds and some nematodes can be external contaminants if the seed is not thoroughly cleaned. Insects can be associated with seed internally or externally as eggs, larvae, or adults.

Seed can serve as a pathway for the long range dispersal of certain pests, while other mechanisms such as wind water or vectors, more commonly effect local or regional spread of pests. It has been estimated that 90 percent of the world's food crops are grown from seed and that plant diseases account for a 12 percent loss in global production equating to a $50 billion loss in 1996 dollars (Agarwal and Sinclair, 1996). It is difficult to know what proportion of disease losses can be attributed to seed transmitted pathogens.

CGMMV provides a recent example of the potential losses caused by seed transmitted pathogens. An analysis conducted by APHIS shortly after the confirmation of CGMMV in California, concluded that the seed transmitted virus posed a substantial threat to U.S. cucumber and melon fresh market crops valued at over a $1 billion as well as the estimated $99 million vegetable seed market (USDA, 2013). The conclusion was based on

published reports of CGMMV causing yield losses of 15 percent in cucurbit crops (Fletcher, 1969; Ling et al., 2013).

B. The global nature of the seed trade

Most trade is based on a simple model where a product is produced in one country and exported to another. The global seed trade is a complex model that involves the movement of seed between and through various geographies worldwide (**Figure 1**). The global seed industry has rapidly increased over the past 15 to 20 years to the point where hundreds of thousands of seed shipments occur around the world annually. The global nature of seed movement allows companies to take advantage of geographies or climates to produce seed year-round permitting several cycles of seed increase within a single calendar year. Many seed shipments are moved internationally in pre-commercial stages (breeder seed, stock seed, parent seed, etc.), and seed is frequently re-

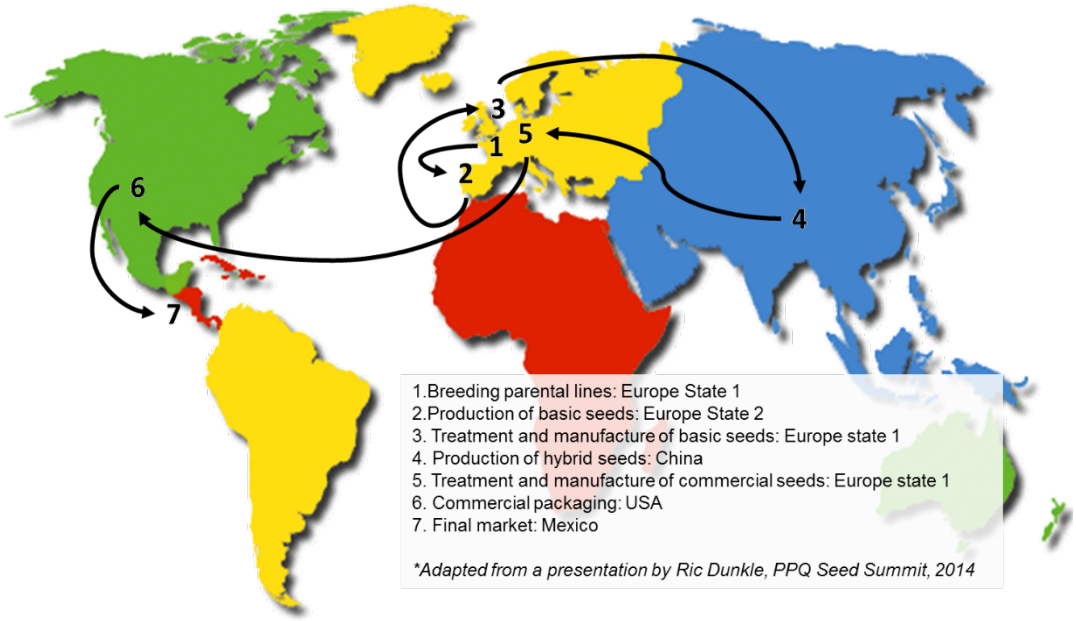


***Figure 1*. Example of seed movement associated with the development, production and commercial launch of a new seed product**

exported several times before it is moved in commercial quantities. As seed moves through these stages from breeder seed to commercial production, it is not uncommon for seed to pass through multiple countries before it ends up with the final consumer. This global production system shortens the time to market for new seed hybrids and varieties but it also exposes seed products to the multiple pest complexes in each country through which it passes.

C. Regulating seed

As noted in the preceding section, it is common for a seed company to have breeding programs and produce seed in multiple countries in different hemispheres, then send that seed to operations centers in still more countries for cleaning, treatment, testing and packaging. Commercial seed is then distributed worldwide to many more countries. There is also a temporal aspect as seed companies may use seed lots of parental lines for multiplication for ten years or more. The global and temporal aspects of seed trade affect how seed is regulated.

Regulatory challenges

From a phytosanitary perspective, the global seed production system presents a number of challenges for producers and regulators. As a result, seed companies and regulators have to handle many phytosanitary variables:

- Destination countries may have different import requirements that need to be taken into account at the time of seed production. For example, one country may require a field inspection and the other country a laboratory test for the same pest for a given seed lot.
- Importing countries' National Plant Protection Organizations (NPPOs) may have requirements that are not recognized as valid by the NPPO of the exporting country, complicating the phytosanitary certification process. For example, if one NPPO requires a field inspection, another NPPO requires a lab test and a third NPPO requires a seed treatment, the company will be forced to do all three in order to ship to all three countries.
- Import requirements of destination countries change over time as the phytosanitary status of a country changes or new pests are reported. Because of the temporal aspect of seed production, changes to import requirements may happen after the seed has left the country of origin (or production) precluding the ability to obtain the necessary phytosanitary certifications.

U.S. seed regulations

Currently, most seed for planting imported into the United States requires only a phytosanitary certificate from the country of origin and port of entry inspection. Field crop and vegetable seeds are subject to the import provisions of the Federal Seed Act (FSA) which requires each lot is accurately labeled as to kind, variety, origin, lot designation and a declaration if the seed is treated. Inspectors sample and inspect each field crop and vegetable seed lot at its port of entry. If noxious weeds or other pests are found, the consignment may be rejected and are subject to destruction, re-export or cleaned or processed under supervision.

Small lots of seed may be imported without a phytosanitary certificate provided the importation of the seed is:

- Authorized by a written permit;
- The seed is not of any prohibited genus or a Federal Noxious Weed;
- Does not require an additional declaration on a phytosanitary certificate;
- Does not require treatment;
- Is not a parasitic plant;
- Is not genetically modified; and
- If a field crop or vegetable seed, it meets the requirements of the FSA.
- Each seed packet must be clearly labeled and free from pesticides and other contaminants. The packets are limited to a maximum of 50 seeds of one taxon per packet or a maximum weight of 10 grams of seed of one taxon and a maximum of 50 seed packets per shipment.
- Small lot shipments are sent to either to the APHIS Plant Germplasm Quarantine Center in Beltsville, MD, or an approved port of entry listed in the permit.

Seed that is coated or pelleted, or embedded in a manner that obscures visibility (e.g. seed tape, seed mats) is prohibited because it cannot be inspected. Commercial seed imports of obscured seed require a permit and must be accompanied by an official seed sample from each lot taken before the seed was processed in the country of origin.

Except for small lots of seed, most flower and other herbaceous plant seeds are admissible without a written permit, subject to inspection and must be accompanied by a phytosanitary certificate. However some herbaceous seeds are subject to prohibitions and special requirements.

Some seeds are regulated by the Endangered Species Act (ESA) and the Convention on International Trade in Endangered Species (CITES), and require specific permits. Similarly, the importation, interstate movement and environmental release of genetically engineered seeds require specific permits.

For additional resources and information see **Appendix 2: U.S. regulations governing seed imports**.

D. International phytosanitary standards

Ideally, phytosanitary measures, including seed regulations, have their basis in the Sanitary and Phytosanitary Agreement (SPS) of the World Trade Organization (WTO) (WTO, 2018). The International Plant Protection Convention (IPPC) is the body designated by the SPS Agreement to set international standards for phytosanitary measures (ISPMs). The IPPC provides several ISPMs that serve as guidelines and principles for countries to implement phytosanitary measures. Under this guideline each country has the sovereign authority to use phytosanitary measures to regulate the entry of plants and plant products and other objects capable of harboring plant pests. Countries can refuse entry, require treatment or specify other requirements for regulated material. .Several ISPMs are of particular relevance in regulating seed and in the development of ReFreSH.

ISPM 38- *International Movement of Seeds* (IPPC, 2017c) provides specific guidance to assist NPPOs in the process of "identifying, assessing, and managing pest risk associated with the international movement of seeds" as a distinct commodity class. The standard also provides guidance on procedures to establish phytosanitary import requirements, inspection, sampling and testing, and overall phytosanitary certification for export and re-export purposes. ISPM 38 introduces definitions for seed borne and seed transmitted pests (see definitions above in section II. A. Seed as a Pathway).

Definitions [ISPM 5; (IPPC, 2016a)]:

Phytosanitary measure- Any legislation, regulation or official procedure having the purpose to prevent the introduction or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests

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

Systems approach- pest risk management option that integrates different measures, at least two of which act independently, with cumulative effect

ISPM 38 emphasizes the importance of pest risk analysis (PRA) [as described in ISPM 11- *Pest Risk Analysis for Quarantine Pests* (IPPC, 2017a)] to identify the regulated pests potentially associated with seeds and with seeds as pests. The PRA should consider the purpose for which seeds are imported, the probability of regulated pests establishing and spreading and economic consequences resulting from introduction. The role of IPPC standards in the development and design of ReFreSH is described below.

III. Designing ReFreSH

ReFreSH is a risk-based system focused on identifying the hazards that exist in the seed production process, the critical control points in the process where each hazard can be managed and the measures that can be applied at those critical control points to manage the risk posed by the hazards. This approach is referred to as a Phytosanitary Hazard Analysis and Critical Control Points or *P-HACCP* approach (Sequeira et al., 2006). This is not a new concept; the ASTA Guide to Quality Management Practices (ASTA, 2016) and SANC- Systems Approach to Nursery Certification (NPB, 2016) are examples of this type of approach.

Definitions (NPB, 2016):

Hazard- Any part or process of seed production that has the potential to introduce plant pests through contamination or infection and allows the entry or spread of a pest.

Critical Control Point (CCP) – The identified points, steps or procedures in a process where controls can be applied and the hazard prevented, eliminated or reduced to an acceptable level.

Best management practices (BMP) effective and practicable measures implemented to prevent, eliminate or reduce the risk associated with the specific hazard.

The design of the ReFreSH model is accomplished through a series of steps as shown in **Figure 2.** Existing systems approaches for seeds and other commodities provide insights into the components of successful approaches to managing plant pest risks.

Inventory current systems approaches

Contributors to the ReFreSH project conducted a review of quality management systems (QMS) and accreditation programs to mitigate phytosanitary risk (García-Figuera and McRoberts, 2017). The authors compared QMS [e.g., ASTA Guide to Quality Management Practices (ASTA, 2016)], accreditation systems [e.g., GSPP- Good Seed and Plant Practices (GSPP, 2018); SANC- Systems Approach to Nursery Certification (NPB, 2016)] and certification programs [e.g., GCP- United States - Canada Greenhouse-Grown Plant Certification Program (USDA, 2017b); Offshore Greenhouse Certification Program for Vegetative Cuttings (USDA, 2017a)]. Additional information on these programs is found in **Appendix 3**. The review developed a list of common "themes" that run through these various programs (García-Figuera and McRoberts, 2017):

- Quality management
- Facilities design
- Plant material
- Soil or growing media
- Irrigation water, humidity, leaf wetness
- Sanitation (tools, equipment, clothing, personal hygiene)
- Inspections, scouting, monitoring for pests, and rogueing
- Pest control program
- Seed testing

- Seed treatment
- Waste disposal
- Containment and storage

Many of these same themes are also found in the guidance provided by international standards, particularly, as noted in the preceding section ISPM 38- *International Movement of Seeds* (IPPC, 2017c). The standard describes "specific phytosanitary measures that may be used to reduce the pest risk associated with the international movement of seeds, including phytosanitary measures that may be applied before planting, during growth, at seed harvest, post-harvest, during seed processing, storage and transportation, and on arrival in the importing country". ISPM 38 incorporates principles from ISPM 14- *The use of integrated measures in a systems approach for pest risk management* (IPPC, 2017b) and ISPM 36- *Integrated measures for plants for planting* (IPPC, 2016b), by recognizing that the use of various measures during seed production, pre-harvest, and post-harvest can significantly reduce and manage phytosanitary risk. North American Plant Protection Organization (NAPPO) Regional Standard for Phytosanitary Measures, RSPM 40- *Principles of Pest Risk Management for the Import of Commodities* (NAPPO, 2017) provides similar guidance. Depending on the target pest, phytosanitary measures may be used alone or in combination to manage the pest risk. ISPM 38 proposes that phytosanitary import requirements may be met by applying equivalent phytosanitary measures when available. ISPM 14 and 38 provide the option of a systems approach when a single measure may be too restrictive or does not provide sufficient phytosanitary security.

Figure 2. **Designing ReFreSH**

Quality management systems (QMS) are frequently used by seed companies to ensure consistency in seed production quality and regulatory compliance. According to the American Society for Quality, a QMS is a formalized system that documents processes, procedures and responsibilities for achieving quality policies and objectives (http://asq.org/learn-about-quality/quality-management-system/).

Components of a QMS include:

- A quality policy which is the commitment and goal towards which the company is working
- Standard operating procedures which are the detailed methods that are executed to produce the quality product
- System for training, auditing and issuing corrective actions
- Customer feedback
- Continuous Improvement
- Risk assessment and risk mitigation

The use of a QMS formalizes processes and provides the basis for consistency in processes and approaches which can lead to the delivery of a product with predictable or reliable quality. Overlaying this with the complexity of the global seed trade model, QMS provides the system to drive alignment to process and/or product quality regardless of country or region of origin. QMS can be summarized in four steps: Plan, Do, Check, Act:

- **Plan:** Establish the objectives of the system and its processes, identify and obtain the resources needed, and identify and address any risks and opportunities that could affect the system by documenting processes, procedures, and responsibilities for achieving seed quality.

- **Do:** Ensure that documented policies and procedures are followed.
- **Check:** Monitor and measure (where applicable) processes and the resulting products or services against policies, objectives, requirements and planned activities, and report those results.
- **Act:** Take actions to improve performance, as needed. If audits detect failures, **act** to determine and correct the cause for the failure.

QMS, as defined above, documents and monitors the seed production process but the SOPs and work instructions created when a QMS is adopted include activities that mitigate phytosanitary risk if they are successfully implemented.

Identify existing industry best management practices

In addition to reviewing QMS and accreditation systems, García-Figuera and McRoberts (2017) also reviewed industry BMPs. They interviewed industry representatives and the authors of the ASTA-funded project *Model to Estimate Phytosanitary Risk Reduction Associated with Seed Quality Management Practices* (Dunkle, 2015), a probabilistic model developed by Drs. Tim Gottwald and Jose Laborde (USDA-Agricultural Research Service) to assess the efficacy of seed quality management practices in reducing phytosanitary risks. They identified some typical industry production practices that can reduce pest risk including:

- Selecting production areas where regulated pests do not occur;
- Use of containment systems such as greenhouses, screen houses, and isolation of plots or fields;
- Use of sanitation practices such as foot washes; sterilization of tools and equipment;
- Weed management practices;
- Rogueing unhealthy plants;
- Destroying infected or infested fields;
- Seed cleaning, conditioning and sorting;
- Seed treatments; and
- Seed testing.

Conduct hazard analysis and pest risk assessment

In different contexts, certain terms (e.g., hazard versus pest risk, hazard analysis versus pest risk assessment versus pest risk analysis) are sometimes used interchangeably. However, in this document and in the regulatory community these terms have specific meanings. Within this document, a **hazard** is any part or process of seed production that has the potential to introduce plant pests; a **hazard analysis** identifies anything that can cause plants harm (e.g., infested planting site, lack of pathogen testing). **Pest risk** (as defined by the IPPC) is the probability a hazard will cause plants harm and how serious the consequences will be. So a **pest risk assessment** evaluates the probability of the introduction and spread of a pest and the magnitude of the associated potential consequences (**Figure 3**). A **pest risk analysis** goes one step further than a pest risk assessment by not only evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, but also

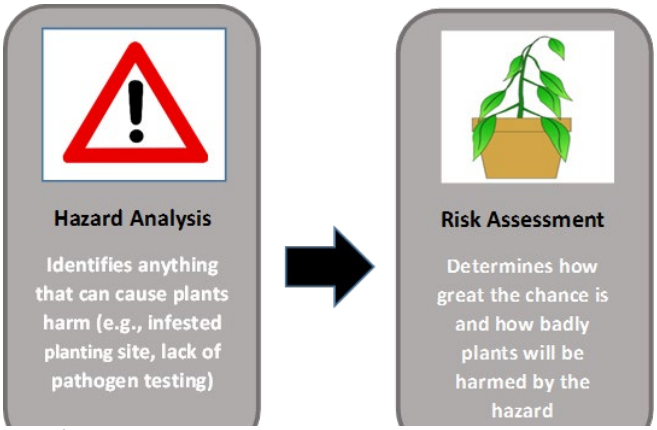


***Figure 3*. Hazard Analysis vs. Risk Assessment**

whether it should be regulated and the strength of any phytosanitary measures to be taken against it.

Conducting an assessment to identify hazards is a vital component of a systems approach. Facilities conduct a hazard analysis to identify hazards, critical control points (CCPs) and applicable BMPs. A CCP is a point or procedure in the production process at which measures (e.g., heat treatment, fumigation, area of low pest prevalence, etc.) can be applied to prevent, eliminate, or reduce a phytosanitary hazard to an acceptable level. The hazard analysis is used to develop a facility's pest management plan. Each step in the production process should be identified and the significant hazards (e.g., pest risks) associated with each step should be identified. After identifying the hazards, industry and regulatory agencies must then consider what risk reduction measures, if any, can be applied for each hazard.

In support of ReFreSH, USDA prepares pest risk assessments (PRAs) to examine the plant pest risks associated with importing seed of a specified commodity from anywhere in the world into the United States and its Territories. The PRA methodology is consistent with guidelines provided by the ISPM 11- *Pest Risk Analysis for Quarantine Pests* (IPPC, 2017a).

The most recent scientific literature and port-of-entry pest interception data are used to develop a list of all potential plant pests that are known to be associated with the specified commodity that are subject to regulatory action at U.S. ports of entry. The risk analysts then identify those organisms that have a reasonable likelihood of moving in a viable form with seed when imported into the United States (i.e., seed-borne or seed-transmitted). The PRA also determines the potential consequences should the pest organism be introduced to the United States or its Territories.

The PRA verifies which classes of pest(s) (e.g., fungi, bacteria, viruses, etc.) are of concern on the imported seed and identifies the pests that will likely require additional mitigation measures to reduce the risk of introduction to an acceptable level. The PRA serves as an aid to regulators and seed producers participating in ReFreSH by identifying the risks of specific imported seed commodities and knowledge gaps that may exist in mitigating the risk of pests identified in the PRA and those addressed by current BMPs.

Definitions [ISPM 5; (IPPC, 2016a)]:

Pest risk- The probability of introduction and spread of a pest and the magnitude of the associated potential economic consequences.

Pest risk assessment- Evaluation of the probability of the introduction and spread of a pest and the magnitude of the associated potential economic consequences.

Pest risk analysis- The process of evaluating biological or other scientific and economic evidence to determine whether an organism is a pest, whether it should be regulated, and the strength of any phytosanitary measures to be taken against it.

Seed commodity PRAs conducted by trading partners are also useful resources. For example, the Australian government has recently prepared draft analyses for seeds of the Apiaceae and Cucurbitaceae families (DAWR, 2017a, b). Also, while not a risk assessment in the same form as the USDA and Australian PRAs, the International Seed Federation has undertaken an initiative to better understand the seed pathway for pests that are regulated by some countries on imported seed (ISF, 2017). For each pest, a review of the scientific literature is conducted to determine whether conclusive evidence exists that the pest is seedborne and seed transmitted. The ISF database provides useful information for those vegetable commodities analyzed to date.

Identify potential mitigation measures

Seed transmitted pests identified in the literature and by commodity PRAs are compared with existing BMPs to determine if mitigation measures are available to reduce the risk of pest introduction into the seed production process and at what CCP in the seed production process those measures can be applied. Any gaps in the necessary mitigation measures are identified and addressed. The ReFreSH framework will contain a suite of basic mitigation measures applicable to most classes of pests. The concept is that these broad framework measures are effective across classes of pests that occupy similar ecological niches (e.g., waterborne fungi, soilborne pests, arthropod vectored pests, etc.). Additional measures may be required for given combinations of host taxa and pests (e.g., specific tests for viruses). ISPM 38 (IPPC, 2017c) encourages NPPOs "… to provide multiple options when setting phytosanitary import requirements". To maintain the flexibility of ReFreSH and its applicability to the broadest range of seed producers, ReFreSH will also recognize equivalence of measures wherever possible.

A written facility manual details the hazards of each seed species, identifies CCPs, applicable mitigation measures and procedures for CCP monitoring. The preparation and maintenance of the manual is a function of the facility and will be monitored by the NPPO(s).

Establish performance criteria that must be met to be accredited

The ReFreSH approach will provide a mechanism to certify or accredit industry pre-harvest, production and post-harvest processes and leverage industry best practices that are already in place. This step involves first establishing criteria that must be met for each measure associated with a CCP. Critical limits are the value or range of values (e.g., temperature, time, pest densities, number of bait sprays, etc.) that must be met for preventive measures to be effective. Critical limits may be derived from regulatory standards, guidelines, scientific literature, experimental studies or consultation with experts. Once the performance standards for measures are established, verification procedures are developed to track the system's operation, indicate if a failure has occurred and corrective action must be taken and provide written documentation. Although ReFreSH is intended to prevent them, failures in the system inevitably occur and a corrective action plan is necessary. The plan determines the disposition of a commodity or consignment when a noncompliance occurs at the origin, at the port of entry or beyond. Verification should be conducted at several levels. Periodic inspections (audits) and modification, as necessary, to the facility's risk management plan ensure the system is functioning effectively. NPPOs of destination and originating countries must assume responsibility to ensure that ReFreSH is functioning satisfactorily by periodically monitoring the system.

Validate via pilot programs

Because of the global nature of seed production, USDA is working with other like-minded countries to promote the adoption of this framework to harmonize the requirements for international seed movement. One avenue to accomplish this goal and to validate ReFreSH is via bilateral or multilateral pilot programs conducted on a small scale for a limited number of commodities and trading partners.

A second approach is to modify an existing seed health pilot program. After the 2013 detection of CGMMV in California, USDA established the National Seed Health Accreditation Pilot Program (NSHAPP). NSHAPP is being conducted in coordination with the National Seed Health System (NSHS) at Iowa State University. Under the program, seed companies voluntarily submit imported seed lots for testing at NSHS or NSHS-accredited laboratories. As a transition to ReFreSH, NSHAPP's current focus on testing seed lots of cucumbers, melons and watermelon for CGMMV will be expanded to include quality management components from ReFreSH. For this pilot, NSHAPP will still be limited to CGMMV as a target pest and to cucumbers, melons and watermelon as key crop species. These modifications to NSHAPP would serve as a transition to the more holistic ReFreSH approach.

IV. The ReFreSH Systems Approach

ReFreSH is a layered approach as illustrated in **Figure 4**. The outer ring depicts overall system requirements. This includes requirements for participating entities to define a policy that:

- Ensures the integrity of the ReFreSH approach and allocates resources to meet its standards;
- Manages entities to mitigate pest risk;
- Provides staff resources and trains them in a general understanding of the components of ReFreSH, the entity's pest management system, and the specific components for which each employee has responsibility; and,
- Establishes procedures for internal and external system audits and a process for continual improvement based on audit feedback.

The inner ring represents the various types of documentation requirements that are critical to the success of QMS and systems approaches like ReFreSH. Documents include scouting, sampling/testing and pest control records, receiving and shipping records for plants and seeds, training records and audit records.

Finally, the innermost pie chart describes key stages (i.e., critical control points) in the seed production process where the various risk mitigation measures and components of ReFreSH are applied. These include pre-planting, pre-harvest, production, harvest, post-harvest, seed quality testing and seed distribution. The mitigation measures identified in ReFreSH may be applied at appropriate CCPs within the seed production process as needed to reduce the phytosanitary risk to an acceptable level. By addressing each layer in the ReFreSH system wheel, seed shippers and regulators will accomplish a comprehensive phytosanitary risk reduction program.

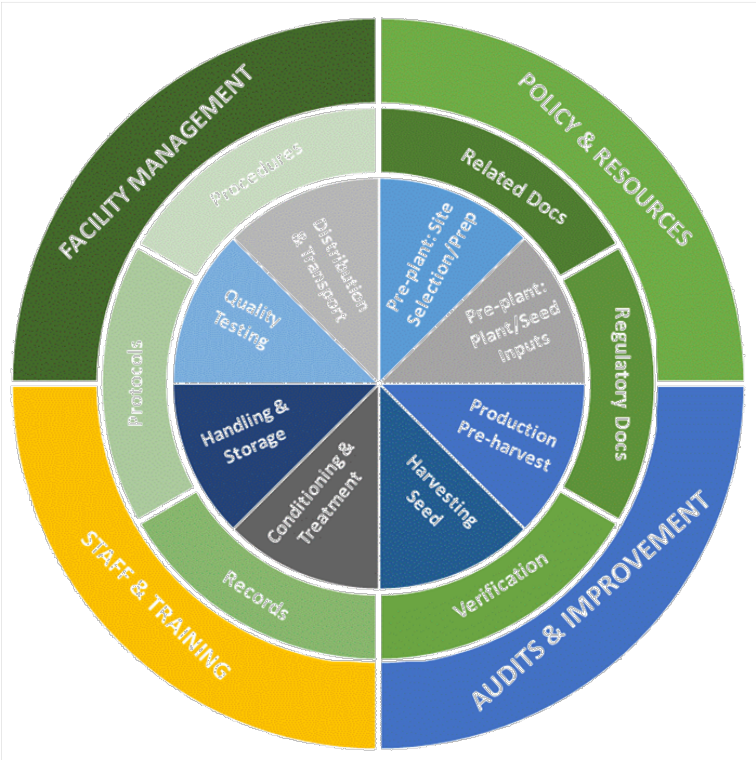


***Figure 4*. The ReFreSH System Wheel**

A. The ReFreSH Model

This section provides a summary of the current state of the ReFreSH systems approach, its components and the roles and responsibilities of the industry participants, regulators and third parties (e.g., testing laboratories). This

initial description is based on our review of existing QMS and industry BMPs and draws on the principles of risk assessment, risk management and systems approaches as described in ISPMs 11, 14, 36 and 38 (IPPC, 2016b, 2017a, b, c) as well as RSPM 40 (NAPPO, 2017). In terms of the steps described in **section III. Designing ReFreSH** and represented graphically in **Figure 2. Designing ReFreSH**, the project is currently at the stage of "Identifying mitigation measures." Activities of the preceding steps (e.g., "Conduct PRAs") are continuing in parallel. Significant work remains in development of accreditation criteria and validation via pilot programs (see **Next Steps**). Existing industry BMPs, risk mitigation measures and components of QMS are applied at critical points in the seed production process.

In the preceding section, eight stages of seed production were identified as CCPs at which hazards could be introduced into the seed production process and managed by the application of mitigation measures. Those *eight stages* are:

1. **Pre-planting:** *Site Selection and Preparation*
    - Seed Health Risk Considerations: Introduction of pests through insufficient isolation of plants; volunteers or weeds harboring pests; errors in rotation or land management; improper equipment cleanout; improper disposition of plant material; planting in pest infected soils; introduction of pests and pathogens from media (protected environment); facility (siding, floors, drainage) containment issues; irrigation water contaminated.
2. **Pre-planting:** *Seed and Plant Inputs*
    - Seed Health Risk Considerations: Seed source or transplants infected with pathogens or pests; inadequate inspection or testing for pests.
3. **Production:** *Pre-harvest*
    - Seed Health Risk Considerations: Loss of containment or insufficient isolation of plants; volunteers or weeds harboring pests and pathogens; improper equipment cleanout; improper disposition of plant material; weed control in borders and adjacent fields is not adequate; inadequate inspection or testing for pests; sanitation practices for field equipment and personnel not followed; disease or pest outbreak.
4. **Production:** *Seed Harvest*
    - Seed Health Risk Considerations: Seed lots not properly managed to prevent co-mingling of infested and clean lots; no procedures in place to prevent potential contamination during harvest; movement of contaminated field equipment between sites.
5. **Post-harvest:** *Conditioning and Treatment*
    - Seed Health Risk Considerations: Inadequate pest and pathogen control in seed cleaning, conditioning and packaging; inappropriate disposal of "discard" materials; inadequate facility and equipment cleanout and containment.
6. **Post-harvest:** *Handling and Storage*
    - Seed Health Risk Considerations: No systems in place to prevent seed exposure to pests in storage; inadequate system to maintain integrity and traceability of seed lots to meet regulatory requirements for documentation of origin, in-transit, and re-export; introduction and spread of pests and pathogens from transportation equipment and container selection.
7. **Post-harvest:** *Seed Quality Testing*
    - Seed Health Risk Considerations: Improper seed health testing techniques used; inadequate audits and controls; inadequate testing facilities.
8. **Distribution and Transport**.
    - Seed Health Risk Considerations: Inadequate system to maintain integrity and traceability of seed lots to meet regulatory requirements for documentation of origin, in-transit, and re-export;

introduction and spread of pests and pathogens from transportation equipment and container selection.

With these serving as our CCPs, we systematically assign measures or BMPs to mitigate the potential hazards associated with each of these activities. As noted above, these mitigation measures are drawn from international standards for risk management and systems approach, as well as existing industry practices and typical QMS components. To maintain flexibility and innovation in the system, producers will also be able to propose novel equivalent measures for the given CCP.

At the same time we have identified regulatory oversight activities that correspond to these CCPs and their associated pest risk mitigation measures. A graphic representation of some potential pest risk mitigation measures and regulatory oversight activities at each stage of the seed production process is shown in **Figure 5**. For example, at the second node in the diagram, **Pre-planting: Seed and Plant Inputs**, the potential pest risk mitigation measures identified include:

- Use of tested/ certified seed (or plants) for starting material
- Sanitation and hygiene practices at transplant
- Use of resistant or less susceptible cultivars
- Use of seed treatments where appropriate
- Documentation of the source, phytosanitary status, movement, treatments, destination, etc. of plant material.

Corresponding regulatory actions associated with the pre-planting activity of selecting plant and seed inputs might include:

- Accreditation of seed and plant testing facilities;
- Accreditation of seed certification programs;
- Certification of transplant facilities.

Primary oversight monitoring and auditing the accreditation system, including the accreditation of individual entities, is the responsibility of the NPPO of the producing country or its designee. The NPPO of the importing country retains the right to audit the accredited system through documentation and record review, seed sampling and testing and audits of representative entities, if deemed necessary.

The ReFreSH system as depicted in Figure 5 is a draft and is neither exhaustive nor is it complete. It is still a work in progress. Furthermore, the scheme depicted in Figure 5 comprises general measures and regulatory activities applicable across commodities, pests and facility types. The general framework of ReFreSH is meant to be flexible and performance-based. Within the general framework of the ReFreSH system, companies will develop or adapt tailored operational plans to accommodate the unique pest profiles and business plans for individual commodities. This is consistent with the overarching goal of ReFreSH to accommodate all seed sectors and all sizes of companies.

B. Next steps

The development of ReFreSH is at the stage of identifying appropriate pest risk mitigations and corresponding regulatory oversight activities. The next step is to develop the requirements and standards to be met for

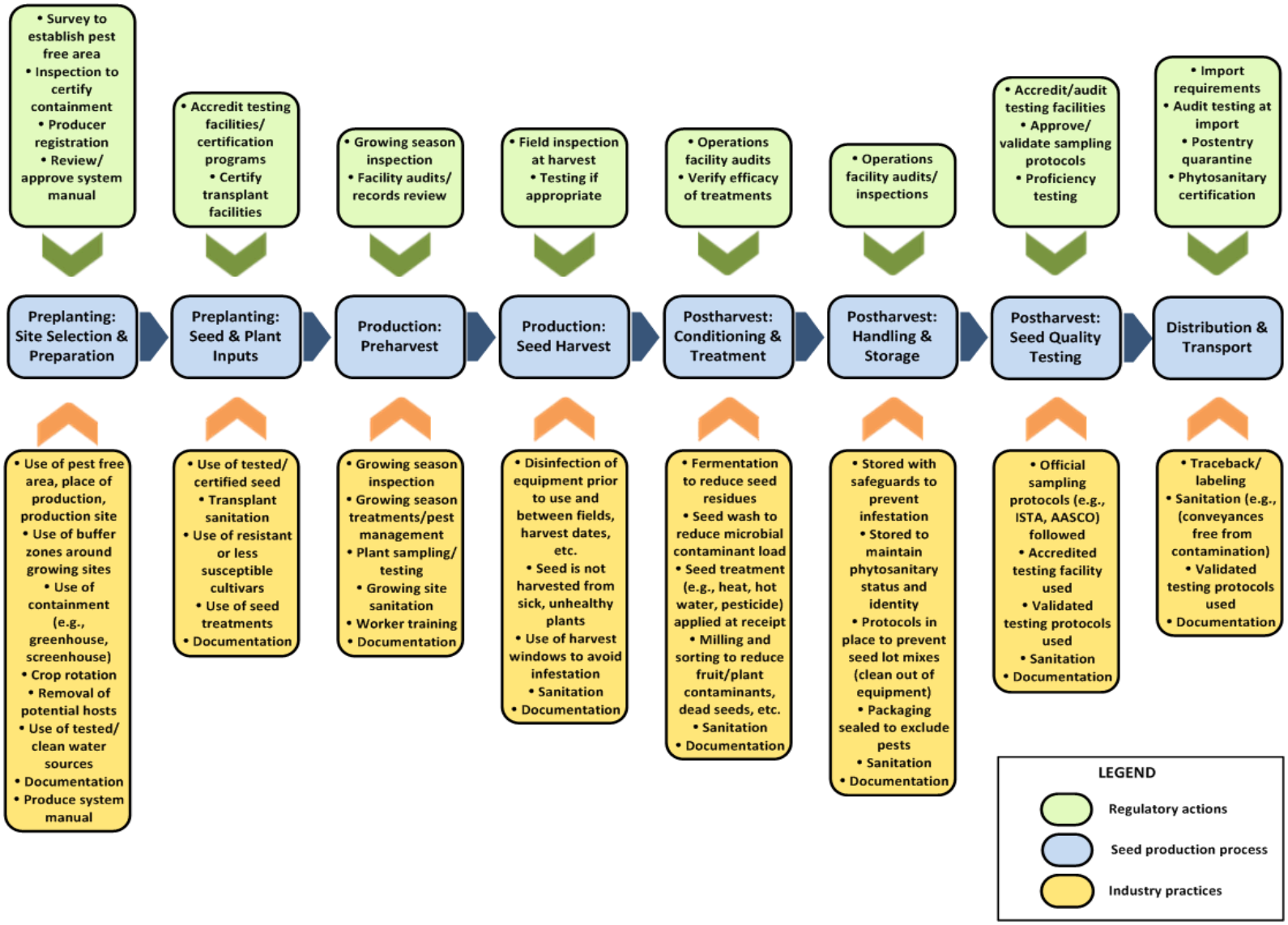
accreditation under ReFreSH. USDA will need to determine how it will accredit producers so that all CCPs are addressed, while allowing each company to determine how it will meet the requirements.

V. Conclusion

As the ReFreSH framework is developed and finalized, USDA has already entered into discussions with like-minded trading partners to share information, harmonize approaches, and explore opportunities for pilot programs. This ongoing effort is critical to the validation and acceptance of the ReFreSH approach for pest risk mitigation in seed crops.

As is evidenced in this concept paper, there is a need for a program that would simplify and harmonize the requirements for shipping seed internationally. The ReFreSH program is a collaborative effort among State and Federal regulators, academia, the seed industry and trading partners. Together, we have created an outline for a program that would provide time, cost, and resource savings while ensuring seed health for all entities involved. This program must be a collaboration, as no one entity can create the program without the input of the other and have it be successful. We anticipate this collaboration continuing as we further develop the ReFreSH framework and implement pilot programs to validate this approach, and beyond that as we formally implement the ReFreSH for international seed shipments.

Figure 5. *ReFreSH System Schematic*



References

Agarwal, V. K. and Sinclair, J. B. 1996 Principles of Seed Pathology, Second Edition. CRC Press, Boca Raton, FL. 560 pp.

ASTA. 2016. The Guide to Seed Quality Management. American Seed Trade Association, Alexandria, VA. Last accessed 12 January, 2018, https://www.betterseed.org/resources/guide-to-seed-quality-management/.

Bebber, D.P., Holmes, T. and Gurr, S. J. . 2014. The global spread of crop pests and pathogens. Global Ecol. Biogeogr. 23: 1398-1407.

DAWR. 2017a. Draft review of import conditions for apiaceous crop seeds for sowing into Australia. Australian Government Department of Agriculture and Water Resources, Canberra. 220 pp.

DAWR. 2017b. Draft review of import conditions for cucurbitaceous crop seeds for sowing into Australia. Australian Government Deapartment of Agricultural and Water Resources, Canberra. 209 pp.

Dunkle, R. 2015. Measurement of Risk Reduction Associated with Seed QM Practices. A paper presented at the NAPPO Workshop on Needs assessment for regulatory support of the North American seed industry. North American Plant Protection Organization, Ottawa,. Last accessed 12 January, 2018, https://www.nappo.org/index.php/download_file/view/377/347/.

Fletcher, J. T. 1969. Cucumber green mottle mosaic virus, its effect on yield and its control in the Lea Valley, England. Plant Pathology 18: 16-22.

García-Figuera, S. and McRoberts, N. 2017. Review of quality management systems and accreditation programs to mitigate phytosanitary risk in seed trade. Quantitative Biology and Epidemiology Laboratory, Department of Plant Pathology, UC Davis. 27 pp.

GSPP. 2018. Good Seed and Plant Practices. GSPP Good Seed and Plant Practices, Gouda. Last accessed 12 January, 2018, https://www.gspp.eu/.

IPPC. 2016a. International Standards for Phytosanitary Measures. ISPM 5: Glossary of Phytosanitary Terms. International Plant Protection Convention, FAO, Rome.

IPPC. 2016b. ISPM 36: Integrated measures for plants for planting. FAO, Rome. 22 pp.

IPPC. 2017a. International Standards for Phytosanitary Measures ISPM 11: Pest risk analysis for quarantine pests. FAO, Rome. 40 pp.

IPPC. 2017b. International Standards for Phytosanitary Measures ISPM 14: The use of integrated measures in a systems approach for pest risk management. FAO, Rome. 16 pp.

IPPC. 2017c. International Standards for Phytosanitary Measures. ISPM 38: International Movement of Seed. International Plant Protection Convention FAO, Rome. 19 pp.

ISTA. 2014. Annexe to Chapter 7: Seed Health Testing Methods: 7-026: Detection of Squash Mosaic Virus, Cucumber Green Mottle Mosaic Virus and Melon Necrotic Spot Virus in Cucurbits. International Seed Testing Association (ISTA), Bassersdorf, Switzerland. 8 pp.

Ling, K. S., Li, R. and Zhang, W. 2013. First Report of Cucumber green mottle mosaic virus Infecting Greenhouse Cucumber in Canada. Plant Disease 98(5): 701-701.

NAPPO. 2017. RSPM 40- Principles of Pest Risk Management for the Import of Commodities. North American Plant Protection Organization, Raleigh. 28 pp.

NPB. 2016. A Systems Approach to Nursery Certification. National Plant Board. Last accessed 12 January, 2018, http://sanc.nationalplantboard.org/.
Sastry, K. S. 2013. Seed-borne Plant Virus Diseases. Springer, New Delhi.
Sequeira, R. A., Takeuchi, Y. and Kalaris, T. 2006. Potential for Using a Phytosanitary Hazard Analysis and Critical Control Point (P-HACCP) System as a New Alternative for SPS Quarantine Pest Risk Management and Trade Facilitation. 2006 North American Plant Protection Organization Annual Meeting, Ft. McDowell, AZ.
Tian, T., Posis, K., Maroon-Lango, C. J., Mavrodieva, V., Haymes, S., Pitman, T. L. and Falk, B. W. 2014. First Report of Cucumber green mottle mosaic virus on Melon in the United States. Plant Disease 98: 1163.
USDA. 2013. New Pest Advisory Group Report: Cucumber green mottle mosaic virus (CGMMV). USDA, APHIS, Plant Epidemiology and Risk Analysis Laboratory, Raleigh, NC. 9 pp.
USDA. 2017a. Offshore Greenhouse Certification Program Pilot Framework. USDA, Washington, DC. Last accessed 12 January, 2018, https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/accreditation+and+certification+programs+for+plant+imports/ogcp-framework.
USDA. 2017b. United States - Canada Greenhouse-Grown Plant Certification Program (GCP) USDA-Canadian Food Inspection Agency, Washington, DC. Last accessed 12 January, 2018, https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/accreditation+and+certification+programs+for+plant+imports/gcp.
WTO. 2018. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Geneva. https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm. Last accessed 12 January, 2018.

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Appendix 1: Examples of seed-transmitted, seed-borne and contaminating pests

Source: ISPM 38- *International Movement of Seed* (IPPC, 2017c)

Seed-transmitted pests that are carried by the seed internally or externally and directly infest[1] the host plant growing from the seed

- *Acidovorax citrulli* in seeds of *Citrullus lanatus*
- *Clavibacter michiganensis* subsp. *michiganensis* in seeds of *Solanum lycopersicum*
- *Ditylenchus dipsaci* on or in seeds of *Vicia faba* and *Medicago sativa*
- *Fusarium circinatum* on or in seeds of *Pinus* spp. and *Pseudotsuga menziessii*
- *Pea seed-borne mosaic virus* in seeds of *Pisum sativum*
- *Squash mosaic virus* in seeds of *Cucumis melo*
- *Tomato mosaic virus* in seeds of *S. lycopersicum*

Non-seed transmitted pests that are carried by the seed internally or externally and are transferred to the environment (e.g. water, soil) and then infest a host plant under natural conditions

- *D. dipsaci* on or in seeds of *V. faba* and *M. sativa*
- *Fusarium oxysporum* f.sp. *lycopersici* on seeds of *S. lycopersicum*
- *Gibberella avenaceae* on seeds of *Linum usitatissimum*
- *Megastigmus* spp. in seeds of *Abies* spp.

Pests carried by the seed, internally or externally, that do not transfer to a host plant under natural conditions

- *Callosobruchus chinensis* and *C. maculatus* on seeds of Fabaceae
- *Rice yellow mottle virus* on seeds of *Oryza sativa*

Contaminating pests[2]

- *Cyperus iria* in seed lots of *Oryza sativa*
- *Mycosphaerella pini* in seed lots of *Pinus* spp. contaminated with needle debris
- Sclerotium cepivorum, sclerotia in seed lots of *Allium cepa*

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[1] **Infestation (of a commodity):** Presence in a commodity of a living pest of the plant or plant product concerned. Infestation includes infection. (IPPC, 2016a)

[2] **Contaminating pest:** A pest that is carried by a commodity and, in the case of plants and plant products, does not infest those plants or plant products.

Appendix 2: U.S. regulations governing seed imports

The United States has created regulations to protect agriculture and native flora and fauna from the introduction and establishment of exotic pests. These regulations vary and include requiring permits, phytosanitary certificates, field inspections, and inspections of plants for planting materials, including seed, at ports of entry.

Plants for Planting Regulations (Q-37)

One of the regulations governing imports into the United States is the Plants for Planting (Nursery Stock) quarantine, Title 7 Code of Federal Regulations (CFR), 7CFR Part 319 Subpart Plants for Planting (Q-37). It is the primary regulation governing the import of plants for planting. It provides the permit requirements for seeds of woody plants, inspection and phytosanitary certificate requirements, restriction of certain plant material, specific treatments for the entry of some types of plant material, and the requirements of the small lots of seed program in lieu of a phytosanitary certificate. Under Q37, some plants are listed as **Not Authorized Pending Pest Risk Analysis** (NAPPRA) and some are **Restricted** (allowed under certain conditions). Apart from these categories, most propagative material can enter the United States with only a phytosanitary certificate and port of entry inspection, unless there is a demonstrated plant risk. Taxon-specific requirements for propagative plant material, including seeds, is found in the APHIS Plants for Manual.

Not Authorized Pending Pest Risk Analysis (NAPPRA)

To ensure U.S. import regulations provide adequate protection against the risk posed by plants for planting, the APHIS created a new regulated category known as "Not Authorized Pending Pest Risk Analysis" (NAPPRA). The intent of NAPPRA is to allow APHIS to better protect U.S. agriculture from foreign pests while controlling adverse economic and trade impacts. Under NAPPRA, APHIS will publish a notice in the *Federal Register* to declare their finding that a taxon is a quarantine pest or host of a quarantine pest, cite the scientific evidence utilized in arriving at the decision, and give stakeholders the opportunity to comment on the determination. Based on the comments, APHIS may revise their determination, but if not, the taxon will be added to the NAPPRA list.

Federal Noxious Weed Regulation (7CFR 360)

Prohibits the import and interstate movement of plants determined and listed by USDA–APHIS–PPQ as Federal Noxious Weeds (FNW) unless the agency issues a permit for the movement.

Federal Plant Pest Regulation (7CFR 330)

This regulation restricts the import and interstate movement of seeds of parasitic plants except under permit.

Federal Seed Act (7CFR 201)

The Federal Seed Act regulations are listed in 7 CFR 201 (https://www.gpo.gov/fdsys/granule/CFR-2011-title7-vol3/CFR-2011-title7-vol3-part201). The Federal Seed Act requires accurate labeling and purity standards for seeds in commerce, and restricts the importation and movement of adulterated or misbranded seeds. The law works in conjunction with the Plant Protection Act of 2000 to authorize APHIS to regulate the importation of field crop, pasture and forage, or vegetable seed that may contain noxious weed seeds. USDA's Agricultural Marketing Service is responsible for enforcing the labeling and purity standard provisions. The Federal Seed Act also regulates the import of seed under 7 CFR 361 (Importation of Seed and Screenings under the Federal Seed Act). It applies specifically to agriculture and vegetable seed listed in the regulation. It includes labeling requirements, provisions regarding noxious weeds and mandates visual inspection of seed lots.

Endangered and Threatened Species

There are regulations governing Endangered and Threatened Species (50 CFR 17), which block the import of seeds of any endangered plant and require seeds of threatened plants be of "cultivated origin".

CITES

The Convention on International Trade of Endangered Species of Flora and Fauna (CITES), 50 CFR 23, prohibits import of seed of any plant listed in Appendix I, II, or III of the convention except under permit. Most of the seed trade movement involves Appendix II.

Genetically Modified Seeds

Genetically modified seeds are regulated by 7CFR 340, which governs the import, interstate movement, and environmental release of these materials.

Resources

There are resources in place to determine the phytosanitary requirements regarding seed import:

- **APHIS-Plant-Protection and Quarantine (PPQ) permit website**. The five documents most relevant to seed import are: "Suggestions to Applicants for Permits to Import Plants for Planting," "Plant Importing Procedures and Responsibilities of Plant Importers," "Entry Status of Seeds for Planting," "Protocol for Importing Obscured Seed," and "Small Lots of Seeds Program."
- **Plants for Planting Manual**: An additional resource is the Port of Entry Manual for Plants for Planting; restraints apply to seeds if an entry in the list of regulated propagative material says "seed" or "all propagules." If the family, genus, or species is not listed in the Port of Entry Manual for Plants for Planting, then the seed is generally admissible with a phytosanitary certificate and subject to inspection. Seeds of wood plants require a written import permit

Appendix 3: Examples of successful USDA/Industry systems approaches

As seed trade has evolved, there have been collaborations between USDA and the seed industry. Some of these were born out of necessity to resolve an issue, while others were a proactive attempt to help create a framework to address a specific pest risk. Seed trade is continuing to grow and flourish. As we develop the ReFreSH program, it is important to recognize the systems already created and the parts of those systems that can be incorporated into the ReFreSH.

Minimum sanitation protocol for offshore Pelargonium production

One opportunity for collaboration was the importation of the very popular home garden plant genus *Pelargonium*, commonly called zonal geranium or geranium. However, geraniums can carry serious plant diseases. To allow safe import of these popular plants, USDA created a certification program for offshore *Pelargonium* production facilities. USDA's certifications ensure facilities and their operations meet standards and regulatory requirements based on industry best management practices (BMP). The program is primarily focused on preventing the introduction of the bacterium *Ralstonia solanacearum* race 3 biovar 2, a particularly destructive pest of potatoes and tomatoes. This certification process helps protect U.S. plant health from pests that could enter the country though high-demand, and large volume commodity imports. In developing this offshore protocol, USDA worked closely with the floriculture industry to adapt existing BMPs as well as listening to the concerns of the potato and tomato industries regarding the importance of these markets and the impacts their losses would have.

Pilot program for offshore vegetative cuttings production

A similar program is currently in the pilot phase to certify offshore facilities producing ornamental plant vegetative cuttings for export to the United States. This program was precipitated by the 2016 detection of *Ralstonia solanacearum* in plants derived from imported *Osteospermum* cuttings. The detected bacterium was ultimately determined to be a non-quarantine strain of *R. solanacearum*; nonetheless the detection served as a warning that a potential pathway for pest introduction existed. USDA again partnered with the floriculture industry to define a program concept that would create standard plant pest exclusion procedures, sanitation, and traceability protocols for cuttings produced offshore. This is a voluntary program, but it encourages participation through incentives in the form of potential reductions in the frequency of port-of-entry inspections for consignments from approved facilities. Facilities in Mexico, Guatemala, Nicaragua, El Salvador, Costa Rica, and Columbia are part of the pilot program. At the conclusion of the pilot, inspection data will be analyzed and evaluated; USDA will compare the data from non-pilot facilities to determine the efficacy of the greenhouse certification. If the data indicates that certified facilities have decreased pest risk, then these facilities will qualify for a reduced rate of inspection at Miami and Atlanta ports. If the pilot is successful, then additional countries will be included.

US-Canada greenhouse certification program

Many companies in the plant industry have locations in the United States and Canada. To facilitate movement of greenhouse-grown plant material between the two countries, USDA and the Canadian Food Inspection Agency (CFIA) developed the U.S.-Canada Greenhouse-Grown Plant Certification Program (GCP). The program allows for the movement of greenhouse-grown plants between the United States and Canada by permitting authorized facilities to use an export certification label rather than a phytosanitary certificate. The GCP is based on a systems approach that integrates different pest risk management measures to achieve the appropriate level of protection against regulated pests. The GCP consists of three phases. Phase 1 determines the eligibility of the plants. Plants that originate in either Canada or the United States are eligible. If the plants were imported from a third country, then they must enter each country under its phytosanitary guidelines. In

Phase 2, facilities producing plants for movement between the two countries must meet the procedures outlined in their Pest Management Plan to be a certified plant. In Phase 3, certified plants are available for shipping and may use the export certification label to ship materials between the two countries without a phytosanitary certificate. The national plant protection organizations (NPPOs) conduct audits at the facilities in their country to authorize facilities and verify compliance with the GCP.

To verify freedom from regulated pests, authorized facilities will 1) inspect plants entering the facility; 2) implement a crop scouting program for plants in production; 3) inspect Certified Plants when they are shipped; 4) identify unknown pests; and 5) report, to the NPPO, new pests and regulated pests found in an area where they have not previously been known to exist. A Pest Management Plan (PMP) is required and is a written description of procedures or processes designed to control, suppress or eradicate pest populations and produce plants that meet the phytosanitary requirements of the GCP. The PMP must address 1) protection from soil-borne pests; 2) protection from water-borne pests; 3) buffers/protection from unmanaged plants/areas; 4) separation from unmonitored plants; 5) pest detection and pest control; 6) incoming plants; 7) examination of production areas; and 8) shipping and inspection of certified plants. A combination of systems and surveillance audits are used to verify that the authorized facility meets all requirements.

National seed health accreditation pilot program (NSHAPP)

NSHAPP is an example of a program that was built in collaboration with the seed industry. NSHAPP was created as a framework for a voluntary system of testing seed imported in to the United States for pathogens of phytosanitary concern. The target pest for NSHAPP is *Cucumber green mottle mosaic virus* (CGMMV). Imported cucumber, melon, and watermelon seeds are tested for the pathogen using the diagnostic protocol developed and validated by the Seed Health Committee of the International Seed Testing Association (ISTA, 2014) and approved by NSHS. Companies accredited for CGMMV testing by the NSHS or the Naktuinbouw Approved Laboratory (NAL) program can perform import testing at their own seed testing facilities. Companies that are not accredited to perform testing can utilize accredited third-party laboratories that are recognized by NSHS to conduct CGMMV testing. To expedite the response to detections of contaminated seed lots, companies must also specify how they will dispose of seed that tests positive for CGMMV. Monthly reports that include the number of tested samples, production locations and crop species is compiled by each participant and is submitted to the NSHAPP program administrator at Iowa State University who then shares this report with the USDA. This report facilitates both industry and USDA monitoring of CGMMV pressures across global production locations.

Systems Approach to Nursery Certification (SANC)

The Systems Approach to Nursery Certification (SANC) is a voluntary, audit-based certification program developed by State regulatory agencies and the nursery industry with Federal input to decrease the pest risks associated with the domestic movement of nursery stock. Nurseries and greenhouses participating in the SANC program perform a risk assessment to identify hazards, critical control points (CCP) and BMPs to mitigate pests and prevent the movement of those pests with their shipments. Nurseries and greenhouses participating in SANC will be eligible to ship materials without individual consignment or annual inspections by their state regulatory agencies. The SANC Program relies on implementation of BMPs to mitigate the risk of the spread of plant pests and utilize audits to ensure the BMPs are implemented. The SANC program has created standards, which establish the minimum requirements that must be met by the nursery or greenhouse facility prior to final certification; these standards allow SANC to be customized to each facility. State regulatory agencies ensure the SANC Standards are met. At a minimum, a systems approach for the certification of the facility requires: (1) adequate facilities and personnel to implement all SANC requirements; (2) training for employees to ensure compliance with the requirements of a systems approach; (3) a pest management plan which is based on the hazards, CCPs and BMPs identified during the risk assessment; (4) accurate records and

control of the documents required for participation in SANC; and (5) audits at regular intervals. The SANC Pest Management Plan must address risk areas such as 1) plants; 2) media and containers; 3) site; 4) shipping; 5) water; 6) equipment; and 7) sanitation and disposal. Under the SANC model, expensive and resource intensive inspections are replaced with audits of established systems for the processing of plants in nursery systems. SANC relies on training of facility personnel so that they can scout for pests in the nursery, thereby eliminating the reliance on annual inspections by state regulatory personnel. Industry will also save resources through the more efficient movement of materials among states and the ability of SANC facilities to move plant material during pest outbreaks due to implementation of BMPs which prevent the pest infestation at the SANC facility.