AMERICAN SEED TRADE ASSOCIATION

American Seed Trade Association

Appendices to Comments for:

Food and Drug Administration Docket No. FDA-2011-N-0921 (RIN 0910-AG35); Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; 78 Fed. Reg. 3504 (Jan. 16, 2013)

Appendix I: Guide to Seed Quality Management Practices

Appendix II: ASTA Comments for Docket No. FDA-2010-N-0085; Preventive Controls for Fresh produce

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Guide to Seed Quality Management Practices

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The Guide to Seed Quality Management Practices is intended solely as an educational tool and as general guidance to assist companies in voluntarily developing and implementing quality management programs for maintaining seed product integrity from incorporation of a trait into a breeding program through commercial seed production and sale. It is not intended as, and should not be construed as, legal advice or a substitute for a user's own individual understanding of applicable legal requirements. The Guide does not define or create legal rights or obligations, and the American Seed Trade Association (ASTA) specifically disclaims any such rights or obligations. ASTA and its members do not make any warranties or representations, either expressed or implied, with respect to the accuracy or completeness of the information contained in this Guide; nor do they assume any liability of any kind whatsoever resulting from the use of or reliance upon any information, procedures, conclusions or opinions contained in this Guide.

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INTRODUCTION

Purpose

This document provides general guidance for the development of quality management practices for use in the development and production of seed products intended for food, feed, fiber or fuel use. The scope of this document encompasses guidance for the maintenance of product integrity and purity of both biotechnology-derived seed and non-biotechnology seed. Product integrity and product purity are defined, for the purposes of this Guide, in the Terms and Acronyms section. Due to its importance in seed quality management, the Guide also includes quality management processes that address plant pests and pathogens. The term "phytosanitary" is used throughout the Guide in regard to all measures and processes that prevent or control plant pests and pathogens which may affect seed quality, seed movement, and/or their introduction into new geographies.

This Guide is intended to serve as a reference document for companies developing individual quality management practices, operating procedures and disciplines consistent with the respective research, development and seed production systems of the entities involved. In determining how best to use this Guide, companies should consider the needs of the market place and customer demands so that the appropriate practices and procedures become a normal part of the business process. This Guide is structured to be interactive. Companies may choose to refer to the entire Guide or specific sections of the Guide (see section on Guide Organization below).

Tracking, recordkeeping, testing and other measures with appropriate oversight management systems are essential parts of product development and commercial life cycle for purposes of quality control and seed purity. Since maintaining a seed variety's trueness to type is critical for market acceptance and use, robust quality management practices are needed for both biotechnology or non-biotechnology derived crops. The practices outlined in this Guide are based on general quality management principles. Quality management systems, such as ISO 9001, provide structure and rigor to business practices by way of managing key process variables, thereby establishing routine and consistent output from their processes. In addition, these systems facilitate coexistence among growers, meeting customer expectations and mechanisms for continually improving the quality management system. An underlying consideration throughout this Guide is the importance of communication with neighboring seed growers, farms and residences as appropriate.

As advances in seed technology occur and developers gain additional insights into quality management practices through practical implementation, the provisions of the Guide will be reviewed and improved upon, as needed. This Guide contains the principles and key elements reflected in individual quality management programs, standard operating procedures (SOPs) or other appropriate operational documents.

Scope

This Guide covers those stages of the plant product life cycle from the point of incorporation of a trait into a breeding program through commercial seed production and

sale. This Guide does not cover the stages of trait discovery, product phase-out, product discontinuation or product retrieval.[1] It is also not intended to address issues associated with product performance after sale.

Guide Organization

This Guide is organized in such a way to accommodate different seed business models and practices. This approach is intended to allow an organization to utilize the guidance for the respective areas in the seed life cycle which they perform. The life cycle within the scope of this document is represented in the Work Flow Diagram (figures 1 and 2 below).

For each stage of the life cycle there is a standard set of information presented that serves as step-wise guidance for developing the quality management practices. This standard set of information follows Hazard Analysis and Critical Control Points (HACCP) principles. Please note that the information presented in the Guide is not intended to be all inclusive, but instead represents a basic set of information which is generally applicable to most seed development and commercialization activities. It is recommended that companies utilize the guidance with consideration given to their specific products, activities, infrastructure, and customer and neighbor expectations.

The set of information is as follows:

1. *Analysis of Product Integrity and Control Concerns*
   The identification of potential risk at the respective life cycle stage which if left uncontrolled could affect product integrity
2. *Determine Control Points*
   Steps in the process identified as points to control the potential risk
3. *Establish Preventative Measures*
   Specific activities to be performed at the control points to manage the risk
4. *Establish Monitoring Procedures*
   Measures taken to verify the preventive measures are performed
5. *Establish Corrective Measures*
   In-process activities taken to address a failure to follow the preventive measures or to address a product determined to be out of specification
6. *Establish Verification Procedures*
   Activities taken to verify compliance with the quality management practices
7. *Establish Record Keeping and Documentation Procedures*
   Appropriate recorded information which allows one to verify compliance and reconstruction of all relevant activities after the fact

[1] *Quality Management Program Guide to Maintaining Plant Product Integrity of Biotechnology-Derived Plants*, published by BIO Excellence Through Stewardship. Excellence Through Stewardship and the stylized *Bio* are registered service and trade marks, respectively, of the Biotechnology Industry Organization.

Hazard Analysis and Critical Control Points (HACCP)

HACCP is an internationally accepted approach to ensure food safety that is applied throughout the food chain from primary production through to consumption of the food product. This Guide uses as its basis the approach used in HACCP.

HACCP is science-based and systematic and is used as a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing[2]. According to the *Codex Alimenarius* "the application of HACCP is compatible with the implementation of quality management systems, such as the ISO 9000 series, and is the system of choice in the management of food safety within such systems."[3]

The HACCP system consists of seven principles, listed below, that are applied in a logical sequence.

Principle 1: Conduct a hazard analysis.
Principle 2: Determine the Critical Control Points.
Principle 3: Establish critical limit(s).
Principle 4: Establish a system to monitor control of the Critical Control Points.
Principle 5: Establish the corrective action to be taken when monitoring indicates that a particular Critical Control Point is not under control.
Principle 6: Establish procedures for verification to confirm that the HACCP system is working effectively.
Principle 7: Establish documentation concerning all procedures and records appropriate to these principles and their application.

General Considerations

There are general quality assurance considerations that are applicable to all of the processes covered in this Guide. Compliance with regulatory requirements is fundamental to all of the modules in this Guide, including those regulations directly related to seed labeling, to phytosanitary requirements and to the use of biotechnology. Therefore, use of this Guide will be complemented by a thorough understanding of the regulatory requirements that pertain to a company's product.[4] This Guide does not describe the details of compliance with these requirements.

In addition, training of personnel is relevant to all of the systems described in this Guide. Within the context of the Guide, it is assumed that appropriate training of personnel will be in place for the systems described.

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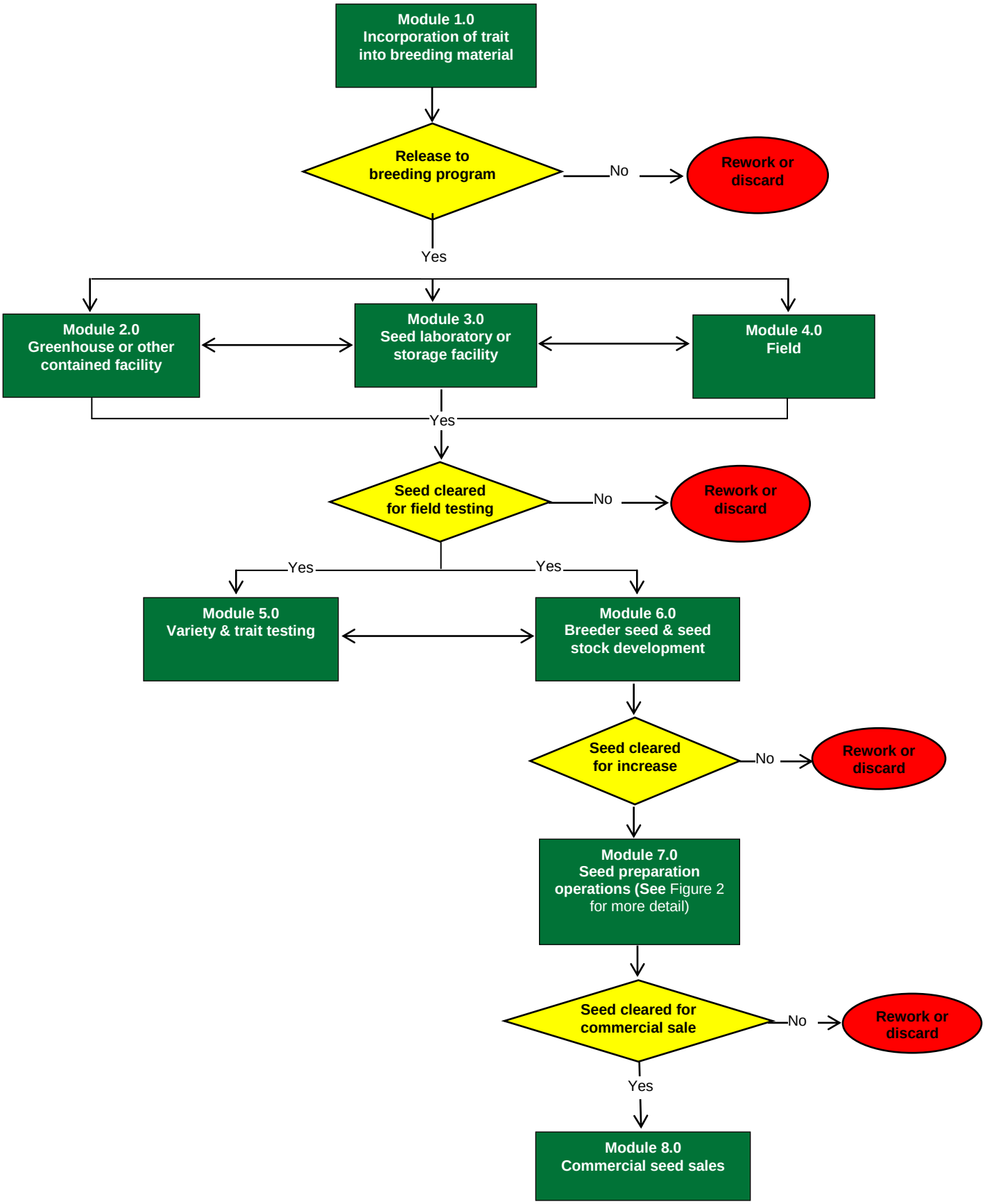
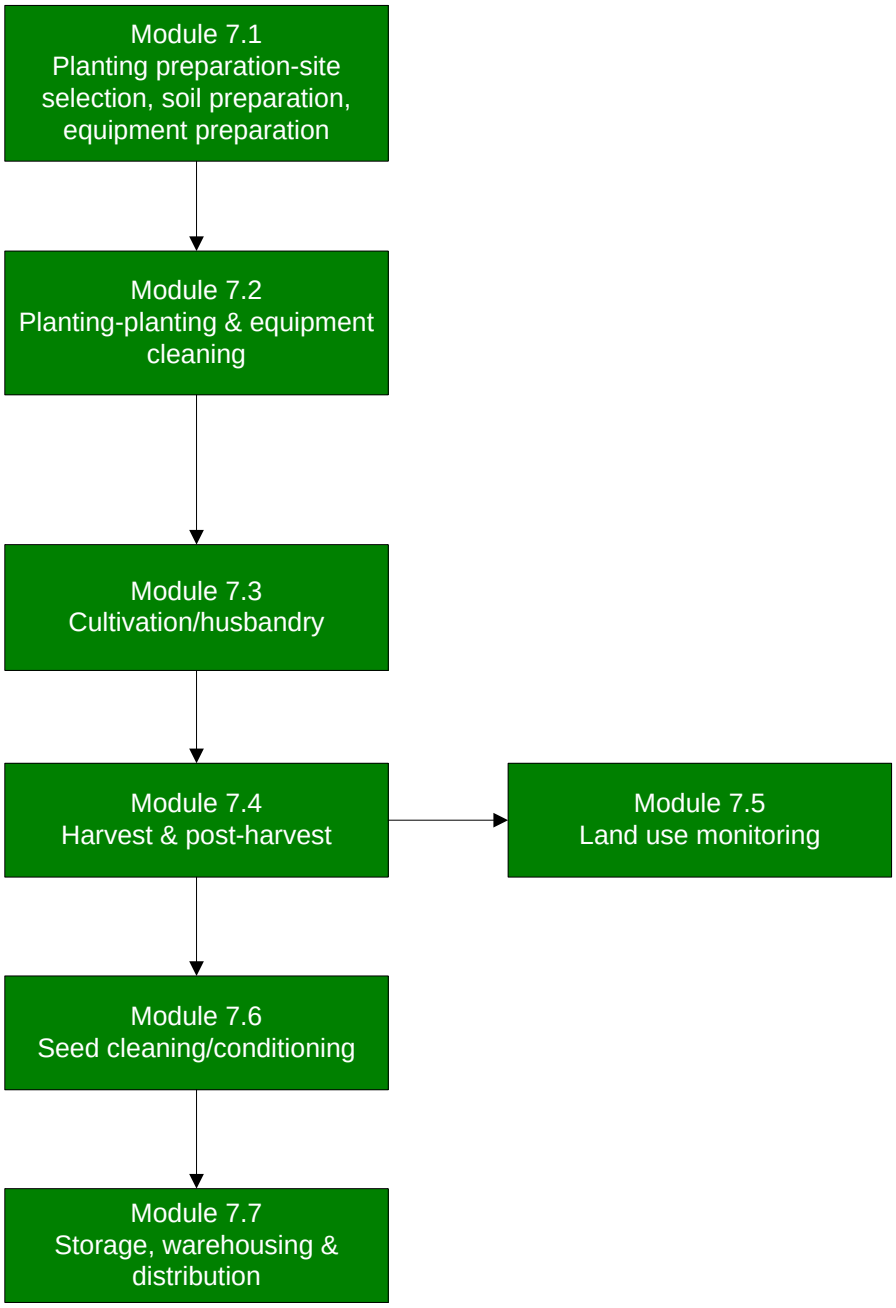
[2] *Recommended International Code of Practice-General Principles of Food Hygiene including Annex on Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application (CAC/RCP 1-1969, Rev..4 - 2003)* (Geneva: Codex Alimentarius Commission, 1997) 21-31.
[3] *Ibid. 21.*
[4] e.g., *Federal Seed Act; Plant Protection Act; Federal Insecticide, Fungicide and Rodenticide Act;* and *Federal Food, Drug, and Cosmetic Act.*

WORK FLOW DIAGRAM (FIGURE 1)



WORK FLOW DIAGRAM (FIGURE 2)



MODULE 1

1.0 Incorporation of Trait into Breeding Material: Purity of Parent and/or Donor Material

Plant breeding involves the creation of new allelic combinations, fixing of specific combinations of alleles and selection of superior combinations of alleles resulting in superior varieties or parents for hybrid seed production. Donor or source material used for breeding crosses should be determined to be of appropriate quality with regard to genetic purity and seed borne and seed transmitted pathogens. In addition, this work may occur in a contained environment such as greenhouses, laboratories, storage facilities or in the field. Each of these approaches carries a different set of product integrity issues.

1.1 Analysis of Product Integrity and Control Concerns

- Presence of unintended traits at unacceptable levels that could be carried into progeny
- Material lacks the intended trait at the level required
- Material improperly identified
- Use of incorrect material
- Determination of possible pathogen and pest risks that may impact the production and movement of donor material

1.2 Determine Control Points

- Receipt of seed if received from third party
- Selection of seed from in-house program
- Transfer of material prior to any type of planting
- Greenhouse and field facilities designed to avoid infection and spread of pathogens and other pests

1.3 Establish Preventive Measures

- Establish sourcing and seed integrity procedures
- Establish purity standards for seed entering a breeding program
- Establish phytosanitary standards and prevention procedures for seed entering a breeding program
- Establish understanding and/or agreements with third party providers of seed on purity and phytosanitary standards for material entering program, including needed data
- Establish appropriate protocols for pathogen and pest detection
- Test material using appropriate methodology to establish or confirm integrity and phytosanitary status of seed used in breeding program
- Establish pre and post entry protocols to maintain phytosanitary status
- Handling, control, and proper disposal of packaging materials

1.4 Establish Monitoring Procedures

- Upon receipt of material, confirm by documentation or verify using diagnostic methods where appropriate that material meets specification
- Utilize a checklist to establish that all needed information is present
- Implement phytosanitary monitoring after planting

1.5 Establish Corrective Measures

- If material does not meet purity specifications, review use and disposition of the material
- If material does not meet phytosanitary specifications, utilize appropriate methods to manage material
- If sourced material does not meet established purity standard, review procurement practices with supplier
- If seed is contaminated, review seed production conditions and establish or revise pathogen control measures with supplier

1.6 Establish Verification Procedures

- Confirm and establish appropriate sign-off and administrative approval of verification procedures
- Verify procedures for periodic auditing, assessments through a checklist and inspection
- Verify adequate feed-back to the supplier of the material

1.7 Establish Record Keeping and Documentation Procedures

- Establish that information accompanying the material is accessible, secure and retained as appropriate, both internal and/or as provided by third party
- Establish that documentation of identity, including test results, of the material is accessible, secure and is retained as appropriate
- Keep records of administrative approval
- Establish document retention policy for phytosanitary certificates, import permits, seed analysis reports, and related documents
- Document presence or absence of pathogens and pests

MODULE 2

2.0 Breeding or Evaluation in Greenhouse or Other Contained Facility

2.1 Analysis of Product Integrity and Control Concerns

- Purity of original material (see Module 1.0)
- Loss of containment during movement - escape of pollen, seed or other reproductive tissue
- Loss of containment through vandalism or natural disaster
- Planting errors
- Proximity to other regulated materials resulting in improper isolation
- Improper pollination
- Misidentification of plant material or seed
- Improper disposition of plant material
- Phytosanitary conditions for planting material (soil, water, environment)

2.2 Determine Control Points

- Facility design including containment and secured access such as fencing and walls
- Seed preparation, including the handling, packaging and identification of the seed
- Planting, isolation and pest prevention strategies
- Plant identification
- Roguing - methods, timing, disposition
- Pollination - methods, timing
- Harvesting - method, timing, containment
- Contained facility maintenance
- Planting in pathogen and pest-free media
- Seed/plant treatment with chemical/non chemical agents to maintain a quality product

2.3 Establish Preventive Measures

- Establish system to monitor proper work flow and SOPs, such as staff training, accurate identification, signage and tracking of seeds and plants including diagnostic procedures
- Determine pests and pathogens of concern in the growing area
- Determine appropriate sanitation and monitoring measures to prevent introduction of pests into the greenhouse or containment facility
- Establish methods and controls for containment, including the facility such as building designs and maintenance, methods of vector, pathogen, or other pest control, air flow, appropriate maintenance and cleaning of facility and equipment
- Establish appropriate devitalization and disposition procedures
- Establish procedures to maintain phytosanitary conditions

2.4 Establish Monitoring Procedures

- Establish inspection at regular intervals with confirmation of inspection including for pests and pathogens from seedling through harvest
- Establish supervision and oversight procedures for personnel
- Establish appropriate documentation of records, work instructions and SOPs
- Establish mechanisms so that that facility design and maintenance result in appropriate containment
- Establish appropriate training program for phytosanitary inspections

2.5 Establish Corrective Measures

- Repair deficiencies in facility integrity
- Identify exposure and eliminate cause
- Institute recovery, devitalization and disposition of any material escaping from the facility
- Rework any deficient procedures or SOPs
- Identify and mitigate any potential sources of pests and pathogens
- Establish pest and pathogen control procedures

2.6 Establish Verification Procedures

- Verify audit, inspection, and monitoring procedures
- Verify appropriate procedures for testing of trait purity
- Verify appropriate procedures for analysis of the low level presence of unintended traits (LLP)
- Verify records and work instructions
- Verify procedures for facility inspection
- Verify phytosanitary status of plants from seedling through harvest

2.7 Establish Record Keeping and Documentation Procedures

- Establish procedures so that documentation of material identity and tracking is secure, accessible and retained as appropriate
- Establish procedures for documentation of inventory control and transfer
- Maintain records of any special instructions or procedures
- Maintain records of project progress
- Maintain logs of activities
- Maintain records of compliance with specific work instructions
- Establish appropriate procedures for retention of records
- Maintain records of pests and diseases found associated with seeds or observed on planted material
- Maintain records of control measures implemented

MODULE 3

3.0 Working in Seed Laboratories or Storage Facilities

Seed laboratories and/or storage facilities are significant places of activity, including but not limited to development, identification, sorting, packaging and shipping of seed**.** If inoculating with pathogens or infesting with pests, obtain permits and follow regulations. Proper storage conditions (temperature, moisture content, humidity) for each crop or variety must be maintained to avoid infections.

3.1 Analysis of Product Integrity and Control Concerns

- Mixing of genetic material
- Identification of seed, including demarcation, tags, handwritten notation and labels as appropriate
- Loss of genetic material
- Disposition of genetic material, including plant material contaminated or inoculated with pathogens or infested with pests
- Observation of phytosanitary status when handling material

3.2 Determine Control Points

- Sorting, identifying and packaging of material
- Personnel access to facilities and/or processes
- Movement of material in and out of facility
- Disposition of material
- Permit and containment procedures

3.3 Establish Preventive Measures

- Establish work flow processes and SOPs
- Establish adequate staff training and supervisory oversight
- Establish procedures for accurate sample and product identity
- Establish timely and appropriate restocking and disposition procedures
- Establish defined work spaces or work flow where facility space and equipment is shared to allow appropriate internal isolation
- Design facility to promote and maintain product integrity
- Establish defined procedures for equipment maintenance and cleaning
- Establish procedures for conducting quality assurance analysis including, but not limited to, germination, physical purity, genetic purity, trait purity confirmation and LLP
- Establish procedures for proper sample/product disposition
- Establish procedures to control vectors, such as air, clothing, equipment, personnel and insects/mites
- Establish procedures for observation and documentation of phytosanitary status

3.4 Establish Monitoring Procedures

- Establish regular inspections of the facility
- Establish appropriate supervision and oversight procedures for facility personnel
- Establish appropriate documentation of records, work instructions and SOPs

3.5 Establish Corrective Measures

- If incorrect identity or demarcation of seed is found or if material is lost or disposed of improperly, evaluate deficiencies in SOPs and personnel training and revise
- If genetic material is inappropriately mixed, lost or disposed of improperly, evaluate deficiencies in facility inspections and/or design
- Establish disposal or applicable seed treatment procedures to be implemented when phytosanitary status is inadequate

3.6 Establish Verification Procedures

- Verify audit, inspection and monitoring procedures
- Verify appropriate testing of germination, physical purity, genetic purity, trait purity confirmation and unintended LLP, in addition to other tests as appropriate
- Verify proper analysis for the LLP of an unintended trait
- Verify adequate records and work instructions
- Verify regular facility inspection
- Verify phytosanitary status using established procedures

3.7 Establish Record Keeping and Documentation Procedures

- Establish adequate documentation of inventory control and transfer
- Establish a record of any special instructions or procedures
- Maintain records of project progress
- Maintain logs of activities
- Maintain records of compliance with specific work instructions
- Establish a record of sample and product disposition
- Establish appropriate procedures for retention of records
- Maintain records of pathogens and other pests detected and corrective measures taken

MODULE 4

4.0 Breeding in the Field

4.1 Analysis of Product Integrity and Control Concerns

- Loss of containment during movement to or from field
- Errors in identification of material to be planted
- Errors in planting
- Errors in pollination
- Insufficient isolation of plants to control outcrossing
- Volunteers or off-types found in containment area
- Errors in identification of material to be harvested and retained
- Errors in rotation or land management
- Loss of containment through vandalism or natural disaster
- Improper equipment cleanout
- Improper disposition of plant material
- Neighboring plantings/activities
- Shared production crews/personnel transferring pollen between fields
- Planting in pathogen and pest infected soils
- Irrigation water contaminated with plant pathogens or pests

4.2 Determine Control Points

- Seed preparation or seed handling in preparation for planting in the field
- Transfer of seed or other plant material to the field site for planting
- Transfer of seed or other plant material from the field site
- Field/Plot selection and identification
- Roguing
- Pollination or deliberate transfer of pollen between plants
- Harvesting
- Field and trial design, including access and movement
- Planting in correct field plot and/or farm
- Personnel movement
- Mapping/understanding neighbor activities
- Inspection of plants for pests and pathogens from seedling through harvest

4.3 Establish Preventive Measures

- Establish internal work processes and SOPs
- Establish procedures for identification, tracking and appropriate disposition of plant material
- Establish procedures for proper training of all field workers
- Establish procedures to control vectors, such as air, clothing, equipment, personnel and insects
- Establish methods, criteria and controls for appropriate confinement such as site selection, reproductive isolation measures, equipment cleaning prior to leaving the trial site,

appropriate disposition of plant material after harvest, post-harvest land use restrictions
- Establish appropriate inspection, devitalization and disposition procedures including phytosanitary aspects
- Preventive measures for pathogens and other pests
- Establish procedures for pathogen and pest observation and identification

4.4 Establish Monitoring Procedures

- Documentation and/or diagnostic testing of plant identity prior to transfer of seed or plant materials to or from the breeding nursery
- Monitor field at regular intervals through the plant life cycle so that management practices in place to confine the field trial site are implemented in accordance with internal operational requirements and, if appropriate, regulatory requirements
- Provide supervision of personnel and oversight of the field
- Conduct appropriate phytosanitary field inspections (Official inspections may be necessary if seed is to be moved interstate or internationally)
- Monitoring and documenting the development of pathogens and pests

4.5 Establish Corrective Measures

- Correction of any deficiencies identified that could affect confinement of the nursery site
- In the event that seed or plants are incorrectly identified or where identity cannot be confirmed, review and dispose of seed or plants as appropriate
- Incorporate any corrective measures or procedural changes into SOPs including pathogen and pest control measures

4.6 Establish Verification Procedures

- Verify plant identity and assessment of seed or plant purity prior to transfer of plant material from the field site
- Verify appropriate confinement measures through assessment, field inspection and monitoring after harvest
- Verify phytosanitary status before and at harvesting time

4.7 Establish Record Keeping and Documentation Procedures

- Establish procedures so that documentation of material identity and tracking is secure, accessible and retained as appropriate
- Maintain records of nursery locations and Global Positioning System (GPS) coordinates
- Maintain records of equipment use and clean-out
- Establish documentation procedures of harvest activities
- Establish documentation procedures for inventory control and transfer
- Maintain records of any special instructions and procedures

- Maintain records of project progress
- Maintain records of documentation used to identify plants so that pertinent identification is recoverable
- Maintain record of pests and pathogens present during different plant growth stages and any control measures

MODULE 5

5.0 Variety and Trait Testing

When testing occurs in the greenhouse or field, modules 2 and 4 should also be considered as appropriate.

5.1 Analysis Of Product Integrity and Control Concerns

- Loss of containment during movement to or from field
- Errors in identification of material to be planted
- Errors in planting
- Insufficient isolation of plants to minimize outcrossing
- Volunteers or off-types found in area of confinement
- Errors in identification of material to be harvested and retained
- Errors in rotation or land management
- Loss of confinement through vandalism or natural disaster
- Improper equipment cleanout
- Improper disposition of plant material
- Shared production crews/personnel transferring pollen between fields
- Planting in pathogen or pest infested soils or media

5.2 Determine Control Points

- Seed preparation or seed handling in preparation for planting in the field
- Transfer of seed or other plant material to and from the field trial
- Field/plot selection and identification
- Harvesting
- Seed handling
- Planting operations, such as appropriate isolation
- Personnel movement
- Mapping/understanding neighbor activities
- Adequate land preparation to offer good conditions for plant growth preventing pathogen infection and pest infestation

5.3 Establish Preventive Measures

- Establish internal work processes and SOPs
- Establish procedures for identification, tracking and appropriate disposition of plant material
- Establish procedures for proper training of all field workers
- Establish procedures to control vectors, such as air, clothing, equipment, personnel and insects
- Establish methods and controls for appropriate confinement such as reproductive isolation measures, equipment cleaning prior to leaving the trial site, appropriate disposition of plant material after harvest, post-harvest land use restrictions
- Roguing, if appropriate
- Establish exposure criteria

- Establish procedures for site selection
- Establish appropriate inspection, devitalization and disposition procedures including roguing and proper disposal of infected/infested material
- Establish seed treatment practices for pathogen control

5.4 Establish Monitoring Procedures

- Documentation and/or diagnostic testing of plant identity prior to transfer of seed or plant materials to or from the breeding nursery
- Monitor field at regular intervals so that confinement of the site is in accordance with internal and, if appropriate, regulatory requirements
- Provide supervision of personnel and oversight of the field
- Establish plant disease monitoring procedures
- Training of personnel on plant pest and pathogen identification

5.5 Establish Corrective Measures

- Correction of any deficiencies identified that could affect confinement of the nursery site
- In the event that seed or plants are incorrectly identified or where identity cannot be confirmed, review and dispose of plants material as appropriate
- Incorporate any corrective measures or procedural changes into SOPs
- Implement control measures for pathogens and pests as appropriate to protect final product at harvest

5.6 Establish Verification Procedures

- Verify identity and assessment of product purity
- Verify appropriate confinement measures through assessment, field inspection and monitoring after harvest
- Verify volunteer management practices
- Verify equipment clean-out
- Verify personnel practices
- Verify phytosanitary status of plant products at harvest

5.7 Establish Record Keeping and Documentation Procedures

- Establish procedures so that documentation of material identity and tracking is secure, accessible and retained as appropriate

- Maintain records of nursery locations and GPS coordinates
- Establish documentation procedures of harvest activities
- Establish documentation procedures for inventory control and transfer
- Maintain records of any special instructions and procedures
- Maintain records of project progress
- Maintain records of documentation used to identify plants so that pertinent identification is recoverable
- Maintain records of equipment use and clean-out
- Maintain records of personnel practices
- Maintain record of neighboring practices/activities
- Maintain records of pathogens and pests detected, and utilize preventive and control measures

MODULE 6

6.0 Breeder Seed and Seed Stock Development

The goal seed crop production is to obtain the maximum number of highly viable, genetically pure seeds. During this stage, roguing is an important and effective quality control component. With proper roguing, the field should contain plants with the desired varietal and physical purity by removing off-types (e.g. from cross-pollination, or by accidental self pollination in hybrid crops) as well as mechanical contaminants (e.g. volunteers, mixed seed in prior production fields or seed lots, or seeds brought to the field by water, animals, birds, etc.). Roguing may also help in control of unwanted pests and pathogens. Also at this stage, procedures for clean seed production, isolation, monitoring, prevention, and sanitation need to be in place. At this point in the life cycle of seed production, many companies will be moving seed internationally, which may require phytosanitary certification. See Module 7 for process elements where seed is prepared, planted, harvested, conditioned, or stored..

6.1 Analysis of Product Integrity and Control Concerns

- Loss of containment during movement to or from field
- Errors in identification of material to be planted
- Errors in planting
- Errors in pollination
- Insufficient isolation of plants to minimize outcrossing
- Volunteers or off-types found in area of confinement
- Errors in identification of material to be harvested and retained
- Errors in rotation or land management
- Loss of confinement through vandalism or natural disaster
- Improper equipment cleanout
- Improper disposition of plant material
- Contamination by pests or pathogens
- Losses due to disease or pest outbreak
- Errors in planting pathogen-infected seed or plant material

6.2 Determine Control Points

- Seed preparation or seed handling in preparation for planting in the field
- Transfer of seed or other plant material to or from the field site for planting
- Field/plot identification
- Roguing
- Pollination or deliberate transfer of pollen between plants
- Harvesting
- Field and trial design, including access and movement
- Planting in correct field plot and/or farm
- Plant operations
- Phytosanitary inspection/observation before planting
- Disease and pest observation at different plant growth stages

6.3 Establish Preventive Measures

- Establish internal work processes and SOPs
- Establish procedures for identification, tracking and appropriate disposition of plant material
- Establish procedures for proper training of all field workers
- Establish procedures for vector control, such as control through air, clothing, equipment, personnel, insects
- Establish methods and controls for appropriate confinement such as reproductive isolation measures, equipment cleaning prior to leaving the trial site, appropriate disposition of plant material after harvest and post-harvest land use restrictions
- Establish appropriate inspection, devitalization and disposition procedures
- Establish appropriate pest and pathogen management procedures
- Establish procedures for seed phytosanitary analysis and treatment

6.4 Establish Monitoring Procedures

- Documentation and/or diagnostic testing of plant identity prior to transfer of seed or plant materials to or from the breeding nursery
- Monitor field at regular intervals so that confinement of the site is in accordance with internal and, if appropriate, regulatory including phytosanitary requirements
- Provide supervision of personnel and oversight of the field
- Establish monitoring procedures for pests and pathogens

6.5 Establish Corrective Measures

- Correction of any identified deficiencies that could affect confinement of the production site
- In the event that seed or plants are incorrectly identified or where identity cannot be confirmed, review and dispose of seed or plants as appropriate
- Incorporate any corrective measures or procedural changes into SOPs
- Implement procedures for pest and pathogen control in situations where problems are detected, including fungicide or other seed treatment actions

6.6 Establish Verification Procedures

- Verify identity and assessment of purity prior to transfer of plant material from the field site
- Verify appropriate confinement measures through assessment, field inspection and monitoring after harvest
- Verify phytosanitary status of plants and seeds produced, including diagnostic tests

6.7 Establish Record Keeping and Documentation Procedures

- Establish procedures so that documentation of material identity and tracking is secure, accessible and retained as appropriate
- Maintain records of nursery locations and GPS coordinates
- Establish documentation procedures of planting and harvest activities
- Establish documentation procedures for inventory control and transfer
- Maintain records of any special instructions and procedures
- Maintain records of project progress
- Maintain records of documentation used to identify plants so that pertinent identification is recoverable
- Maintain records of pathogens and other pests present
- Document control measures used

MODULE 7

7.0 Seed Production Operations

This section describes operations that are applicable to all modules covering process elements where seed is prepared, planted, harvested, conditioned, or stored.

7.1 Planting Preparation: Site Selection, Soil Preparation, Equipment Preparation

7.1.1 Analysis of Product Integrity and Control Concerns

- Appropriate isolation not established or maintained
- Producer unexpectedly plants the same crop within the area of isolation
- Planter not properly cleaned and contains seed of a different product
- Natural disaster and vandalism vulnerability of site
- Presence of sexually compatible plants in the area of isolation
- Improper removal of volunteer plants from earlier growing seasons
- Crop rotation is not adequate
- Seed source is infected with pathogens or pests
- Proximity to plants harboring pests or pathogens of concern
- Weed control in borders and adjacent fields is not adequate
- Inspection or testing for pathogens and pests in transplants, if used

7.1.2 Determine Control Points

- Site/field/producer selection and method of isolation
- Proper planter and equipment cleanout and management
- Movement of seed in and out of isolation area
- Presence of sexually compatible plants in the area of isolation
- Observation of weeds in and adjacent to the field to prevent weed seed contaminants
- Seed inspection for foreign material and evidence of improper storage during seed preparation

7.1.3 Establish Preventive Measures

- Establish parameters of isolation from other crops of the same species as required by applicable regulations[5] and/or company standards[6]
- Establish isolation maintenance plan and timing

[5] For example, U.S. Department of Agriculture, Association of American Seed Control Officials, Association of Official Seed Certifying Agencies

[6] For example utilization, as appropriate, of third party services for field location information and coordination, such as pinning and mapping

- Establish that the site or field is not adjacent to any areas prone to unauthorized access
- Implement proper crop rotation and field selection to keep pest levels as low as possible
- Establish producer access to the land through ownership, lease or grower agreement
- Establish grower contract
- Establish procedures for proper cleaning and inspection of field equipment, including for possible pest infested or pathogen infected material
- Establish communication with neighboring seed growers, farms and residences as appropriate.
- Establish procedures to detect presence of and destroy sexually compatible plants in the area of isolation
- Appropriate elimination of infected plant debris during land preparation

7.1.4 Establish Monitoring Procedures

- Prior to planting, inspect all land within the area of isolation to establish that no crops of the same species are planted.
- Communicate with neighboring producers to establish that they are not planting sexually compatible species or types within the isolation distance
- Prepare site map to identify locations of any sexually compatible wild relatives
- Inspect fields for evidence of pests and pathogens of phytosanitary concern prior to planting
- Inspect field equipment for possible sources of contamination
- Inspect field for unintended plants

7.1.5 Establish Corrective Measures

- If the isolation parameters are not met, find a different, more suitable site or field
- If a producer unexpectedly plants the same crop species within the isolation zone, negotiate to remove the conflict
- If the planter has seed in it prior to planting, thoroughly clean it and re-verify
- If infected debris or pathogen infected plants of phytosanitary concern are detected, properly dispose of or destroy them

7.1.6 Establish Verification Procedures

- Verify that the isolation parameters are met
- Verify isolation with other seed producers
- Prior to planting verify that the site/field location and acreage meets specifications
- Prior to planting, verify that the planter is clean of seed
- Verify phytosanitary condition of seed, site, and planting equipment

7.1.7 Establish Record Keeping and Documentation Procedures

- Maintain records of planter cleanout and verification.
- Create a preliminary site/field map to be finalized after planting
- Maintain a copy of the signed producer contract
- Maintain site/field inspection records
- Maintain records of phytosanitary conditions

7.2 Planting: Planting and Equipment Cleaning

7.2.1 Analysis of Product Integrity and Control Concerns

- Seed is planted at the wrong site, such as through:
  - insufficient cleanout of the planter after planting seed
  - insufficient cleanout of the tractor after planting seed
  - mistakenly planting the crop out of compliance with instructions and/or map
- Area of isolation does not satisfy minimum requirements, internal and/or external
- Mixing with more than one product occurs because of insufficient cleanout of the planter or improper loading of the planter
- Seed is planted on pathogen or pest contaminated soil or soil with pathogen infected debris of phytosanitary concern
- Movement of field equipment between sites or fields

7.2.2 Determine Control Points

- Evaluation of the site and surrounding isolation zone prior to planting
- Planter cleanout
- Disposition of planting material
- Testing or documentation to properly identify the intended seed used for planting
- Adequate land and irrigation preparation to manage possible pests and pathogens of phytosanitary concern

7.2.3 Establish Preventive Measures

- Prior to planting, verify correct location of site/field, isolation parameters and identity of seed
- Transport the seed to the field/site in a fully enclosed, secure container
- Use planters that can be cleaned and will not retain seed
- Load the seed in the planter only at the proper field/site
- Adequate control of seed, such as maintaining seed in secure location when left unattended
- Planters adequately cleaned before being transported away from the field/site
- All seed cleaned out of the planter properly disposed of, if appropriate

- All seed bags should be properly ”contained”
- All other containers used for seed should be cleaned and verified before leaving the field/site
- If field has a risk or history of pest or pathogen problems, implement sanitation/disinfestation measures

7.2.4 Establish Monitoring Procedures

- Reconciliation of intended and actual seed inventory
- Isolation parameters
- Planters and related equipment inspected after use to establish they have been cleaned
- Any other containers used are cleaned and inspected

7.2.5 Establish Corrective Measures

- If seed is planted at the wrong site, develop a remedial action plan
- If discovered that seed may have been mixed with other seed for any reason, determine appropriate remedial action
- If the isolation parameters are not correct, determine appropriate remedial action
- Have a cleaning and monitoring plan for field/site to address improper disposition of plant material
- If planting field has pest or pathogen infected debris, implement appropriate sanitation/disinfection procedures
- Manage irrigation water to minimize pathogens of phytosanitary concern

7.2.6 Establish Verification Procedures

- Verify that the field/site is correct
- Verify that the isolation parameters are correct
- Verify that the correct seed is being planted at the field/site
- Verify that the planter is clean after use
- Verify that all containers used for seed were cleaned prior to removal from the field/site
- Verify land is properly prepared and irrigation properly sourced

7.2.7 Establish Record Keeping and Documentation Procedures

- Maintain field/site maps
- Maintain records of the identity of the seed planted
- Maintain records of isolation parameters
- Maintain records of quantity of seeds or plants planted
- Maintain records of planter cleanout and verification
- Maintain records of method of disposition of any remnant seed
- Maintain records of phytosanitary conditions of planted fields

7.3 Cultivation/Husbandry

7.3.1 Analysis of Product Integrity and Control Concerns

- The isolation parameters are not met
- Volunteer plants of the same species, as well as sexually compatible plants, in the area of isolation flower concurrently with the crop causing a potential loss of confinement
- Natural disaster causes an accidental release and loss of confinement
- Site vandalized resulting in a loss of confinement
- Failure to follow internal company product integrity policy
- Volunteer plants may be hosts for pests and pathogens
- Weediness of field and adjacent areas not properly managed
- Improper crop rotations
- Sanitation practices for field equipment and personnel not followed

7.3.2 Determine Control Points

- Maintenance of the method of isolation
- Sanitation and movement of equipment and personnel into and out of the field/site
- Intensive inspection/observation for pathogen infection and pest infestation during reproductive stages

7.3.3 Establish Preventive Measures

- Establish cleaning procedures for equipment used for seed/crop production
- Standard operating procedures in place regarding personnel movement from one site or field to another
- At regular intervals until flowering of the crop is complete, establish procedure for monitoring area of isolation for volunteers and/or unexpected plantings,
- Establish natural disaster contingency plan
- Establish appropriate field management practices before planting
- Monitor development of plant diseases and other pests at different growth stages

7.3.4 Establish Monitoring Procedures

- Establish inspection procedures for plants/field, including inspections for vandalism, animal and weather damage
- Establish and follow best practices for "hand pollinations" where technique is used
- Rogue off-type plants
- Establish procedure for area of isolation to monitor for unexpected plantings and identify and eliminate unintended plants,
- If temporal isolation is used, establish procedure to verify that the isolation was effective or to correct potential problems before they occur
- Establish procedures to conduct phytosanitary field inspections

7.3.5 Establish Corrective Measures

- If crop tissue is found on or in equipment during a post-cleanout inspection, establish corrective measures, such as re-cleaning and re-inspecting the equipment
- Destroy any plants of the same species (volunteer or planted) or sexually compatible plants found within area of isolation
- If it is determined prior to, or during, flowering of the crop that the temporal isolation is likely to be ineffective, develop alternate plan with neighboring growers
- If vandalism or natural disaster occurs that results in a loss of confinement, take appropriate remedial action
- Establish sanitation procedures to mitigate pathogen infected and pest infested debris

7.3.6 Establish Verification Procedures

- Verify cleanout of all equipment
- Verify that isolation parameters are met
- Verify no plant or seed is removed without authorization
- Verify phytosanitary conditions of plants and products to be harvested

7.3.7 Establish Record Keeping and Documentation Procedures

- Maintain records documenting all equipment cleanout and verification
- Maintain routine site inspection records documenting agronomic conditions, any damage that may have occurred due to weather, animals or vandalism and monitoring of the isolation distance (physical and temporal)
- Maintain reports on any corrective or remedial actions that were taken throughout production
- Maintain records of plant pathogens and other pests detected and resulting actions

7.4 Harvest and Post-Harvest

7.4.1 Analysis of Product Integrity and Control Concerns

- Seed identity or containment is lost by:
  - accidental spill during harvest and/or transport
  - mixing with other grain/leaf tissue harvested from food/feed crop production
  - tampering with, vandalizing or removal from the site
  - spontaneous seed shedding and dispersal before or during harvest
- Seed mistakenly sent to the wrong post harvest conditioning location
- Seed infected by pathogens or infested by pests of phytosanitary concern in the field

- Seed lots not properly managed such that infested and clean lots are at risk of being co-mingled
- Procedures are not in place to prevent potential contamination during and after harvest and transportation

7.4.2 Determine Control Points

- Harvest and transport equipment inspection
- Seed harvest and transport
- Packaging for shipment to post harvest conditioning location
- Bins/containers used for seed transport

7.4.3 Establish Preventive Measures

- Training of all field operations personnel on specific job responsibilities
- Training is documented
- Cleaning of harvest, in-field conditioning and transport equipment after previous use
- Disposition of residual grain/leaf tissue in accordance with internal and/or external requirements
- Prior to next use, equipment visually inspected for cleanliness and safe operation
- Established criteria for decision to harvest
- Seed is dried or otherwise initially conditioned according to specific work process protocol
- Seed is packaged in durable container and contents of container documented
- Upon arrival at the post harvesting conditioning location, the seed is processed and stored properly
- Establish pathogen and pest preventive control measures to protect against comingling and post harvest pest infestation

7.4.4 Establish Monitoring Procedures

- Monitor to verify that the cleanout or equipment adjustment was done properly
- Seed sampling for characterization of lot

7.4.5 Establish Corrective Measures

- If crop tissue is found on or in equipment during a post-cleanout inspection, establish corrective measures, such as re-cleaning and re-inspection of the equipment
- If it is determined that a loss of containment has, or may have occurred, implement appropriate remedial action
- If error in shipment occurs, implement appropriate remedial action
- Establish control actions if pests or pathogens of phytosanitary concern are detected

7.4.6 Establish Verification Procedures

- Before shipment, verify that the movement is authorized
- Verify that all equipment is thoroughly cleaned before and after use and inspected
- Verify shipping containers and packages are clean, intact and sealed
- Verify that the correct seed has arrived at the post harvest conditioning location
- Verify that all appropriate samples have been taken
- Verify that the correct seed has arrived at the proper post harvest conditioning facility in a timely manner

7.4.7 Establish Record Keeping and Documentation Procedures

- Maintain records of job responsibilities for field operations personnel
- Establish documentation that equipment is cleaned or inspected for operational condition
- Establish documentation that before shipment all necessary procedures were followed
- Documentation listing shipment contents should accompany each shipment
- Documentation by receiver to show that container arrived intact and that the contents are as listed on the packing slip
- If grain/leaf tissue must be stored prior to conditioning, maintain records by the receiver indicating storage location of such materials
- Maintain records of pests and pathogens detected

7.5 Land Use Monitoring

7.5.1 Analysis of Product Integrity and Control Concerns

- Post harvest field treatment is inadequate
- Post harvest field volunteer monitoring is inadequate
- Post harvest control of plant debris is inadequate
- Monitoring/control measures for unintended plants in and adjacent to fields are inadequate

7.5.2 Determine Control Points

- Post harvest land use
- Post harvest volunteer monitoring
- Post harvest land management monitoring

7.5.3 Establish Preventive Measures

- Depending on the crop, the field may be tilled post-harvest, with volunteers allowed to emerge, in order that they be removed
- Establish schedule for the monitoring of volunteers by responsible site personnel

- Establish schedule for the monitoring of noxious and other types of weeds of concern
- Management of plant residues which may harbor pests and pathogens

7.5.4 Establish Monitoring Procedures

- Land use and volunteer monitoring, as appropriate
- Noxious and other weed species of concern
- Residues that may harbor pests or pathogens of concern

7.5.5 Establish Corrective Measures

- If determined that a loss of containment has or may have occurred, determine appropriate remedial action
- If phytosanitary risk is identified, take appropriate action

7.5.6 Establish Verification Procedures

- Verify post-harvest management of the field
- Verify the post-harvest monitoring, including duration, and removal of volunteers and sources of phytosanitary risk

7.5.7 Establish Record Keeping and Documentation Procedures

- Keep records of training for roles of field operations personnel
- Maintain documentation, including date, each time scheduled monitoring for volunteers and sources of phytosanitary risk takes place

7.6 Seed Cleaning/Conditioning

During seed conditioning and packaging, methods of identity preservation are important at all transfer points and within each process. Incorporating pest and pathogen control in seed cleaning and conditioning and appropriate disposal of “discard” materials will minimize risk of post harvest pest and pathogen contamination and spread.

7.6.1 Analysis of Product Integrity and Control Concerns

- Seed lost to environment during conveyance into or within the seed conditioning facility, around equipment, drying bins, packaging stations and personnel shoes or clothing
- Admixing due to residual seed in equipment, conveyors, drying bins or other conditioning or packaging equipment
- Misidentification of seed
- Improper identification and/or labeling of commercial product
- Potential contamination of seed with pathogens or pests from soil
- Weed seed contaminants at harvesting
- Improper seed clean out between seed lots

7.6.2 Determine Control Points

- Movement of seed into and out of the facility
- Transfer within the facility and between containers and equipment
- Facility and equipment cleanout and containment
- Disposition of discard material that may or may not contain viable seed, pathogen propagules or pest components
- Packaging and inventory entry
- Appropriate environmental and sanitary conditions during harvest/transport/cleaning/conditioning
- Seed processing (coating, pelletization, treatment)

7.6.3 Establish Preventive Measures

- Clean equipment and areas around the equipment
- Inspect equipment and containers before and after transfer
- Dispose of discard material that may or may not contain viable seed
- Establish identity verification throughout the process
- Verify product identity and the proper labeling of the commercial product
- Confirm seed lots to be of no phytosanitary risk
- Avoid high humidity conditions predisposing contamination of seed with pathogens and other pests

7.6.4 Establish Monitoring Procedures

- Document inspection of all equipment periodically for proper mechanical function and loss of seed
- Inspect seed for quality
- Verify product identity at all critical steps
- Verify product identity and the proper labeling of the commercial product
- Monitor and document as appropriate conditions at harvesting/transport/cleaning/conditioning

7.6.5 Establish Corrective Measures

- Re-adjust equipment if loss of seed or if seed does not meet specifications
- Determine that all equipment is cleaned after use and re-clean if post-cleaning inspection reveals problems
- Take appropriate remedial action to address loss of seed containment
- If misidentification or mislabeling of commercial product occurs, take appropriate steps to correct issue or properly dispose of product
- If misidentification or mislabeling of commercial product is found, take measures to determine root-cause, clarify SOPs and provide training
- If environmental conditions favor pathogen and/or pest contamination, establish control actions

7.6.6 Establish Verification Procedures

- Inspect facility and production records and conduct periodic in-progress inspections
- Verify equipment is cleaned before and after use
- Secondary audit procedures in place, as applicable
- Verify container and equipment identification is correct between each transfer of seed
- Confirm and verify commercial product identity matches product label
- Confirm phytosanitary status of harvested product

7.6.7 Establish Record Keeping and Documentation Procedures

- Establish that key activity records (e.g. cleaning checklists, conditioning records, seed locations, etc.) are maintained according to the record retention policy
- Maintain sample as required under *Federal Seed Act*[7]
- Maintain records of pathogens and other pests detected on harvested product and control measures

7.7 Viable Plant/Seed Storage, Warehousing and Distribution

From a phytosanitary standpoint, it is important that systems are in place to maintain seed quality in terms of germination and purity, prevent exposure of product to pests in storage, and to maintain integrity and traceability of seed lots to meet regulatory requirements for documentation of origin, in-transit, and re-export.

7.7.1 Analysis of Product Integrity and Control Concerns

- Seed/plant transported to an unintended destination
- Transport vehicles, packing containers and/or storage containers not properly cleaned after use
- Storage or transport containers not properly identified
- Loss of containment:
  - during material transfer from transport vehicle to storage containers via equipment malfunction
  - spillage during transfer
  - failure to properly clean transfer equipment after use
  - accident or natural disaster
  - facility or transport vehicle vandalized
- Environmental and sanitary conditions during storage not adequate to maintain product integrity and quality
- Sanitary conditions of equipment at harvesting, transporting and storage warehouse facilities

[7] See Section 202 of the Federal Seed Act and Section 201 of Title 7 of the Code of Federal Regulations

7.7.2 Determine Control Points

- Transportation equipment and container selection, filling, identification and handling during storage and shipment
- Loading and unloading of the transport vehicle
- Tracking
- Site security
- Loading for transportation of seeds/plants harvested
- Storage/warehouse facilities

7.7.3 Establish Preventive Measures

- Inspection of transport vehicles and containers prior to use to determine if there are any defects that would result in a loss of containment
- Containers properly filled, contents documented and containers securely closed
- Arrival notification procedures developed between shipper and receiver
- Upon arrival at the conditioning and/or storage facility, maintenance of proper protocols to avert unintended dispatch
- Material transferred to storage or processing in such a way as to minimize product spillage
- A regular schedule of rodent and pest control maintained during storage
- Access to facility properly controlled
- Contingency plans in place in case of natural disaster or fire
- Inspection of transport vehicles for sanitation conditions (free of dust, debris, and residual material from prior shipments)
- Identify and mitigate any areas where moisture may reside that could become environments for favoring pathogen infection and/or pest infestation

7.7.4 Establish Monitoring Procedures

- Establish inspection procedures for transport vehicles, transport containers and/or storage containers for defects
- Track inventory locations, additions and subtractions
- Track shipments to establish that they reach the intended destination and are appropriately identified
- Monitor any receiving and/or transfer areas for viable plant material
- Monitor storage facilities for signs of rodents and pests
- Monitor for moisture and temperature conditions that could increase phytosanitary risk

7.7.5 Establish Corrective Measures

- If errors in handling occur, retrain personnel in the proper procedures
- If transported to an unintended destination or if incorrect seed shipped, determine appropriate product disposition

- If material misidentified, correctly identify the container or, if identity lost, properly dispose of the material
- If loss of containment occurs, take appropriate corrective measures
- Establish corrective actions for environmental situations in which seeds/plants harvested have potential increased phytosanitary risks
- If product is found to be infected/infested, implement proper control measures to prevent “re-infestation”

7.7.6 Establish Verification Procedures

- Verify that all transportation equipment and containers are cleaned after use
- Verify that access to storage facility is restricted to authorized personnel
- Verify that storage facility is kept clean of all uncontained viable material
- Verify shipping documentation and manifest
- Verify moisture conditions of seed/plant arriving at storage facilities
- Verify temperature and humidity conditions of facility prior to storage

7.7.7 Establish Record Keeping and Documentation Procedures

- Establish procedures so that all shipments carry the proper documentation
- Establish procedures to retain records
- Maintain records of potential contaminating sites affecting seed/plant phytosanitary conditions
- Verify that appropriate phytosanitary certificates, import permits, seed analysis reports and Other official documents are in place prior to shipment

MODULE 8

8.0 Commercial Seed Sales

Most commercial seed is shipped across state borders domestically or is marketed internationally. Care must be taken to ensure that seed consignments are shipped with the appropriate documents (import permits, phytosanitary certificates, seed analysis reports) to satisfy state and Federal regulatory requirements. Some countries have post-entry requirements such as requiring that resultant crops be inspected after planting and any pests reported. Check with the appropriate plant health regulatory officials to determine entry requirements prior to movement.

8.1 Analyze Product Integrity and Control Concerns

- Errors in product identity
- Errors in product purity
- Inappropriate use of product
- Errors in commercial labelling
- Presence of pathogens or pest contamination in final product
- Lack of awareness of phytosanitary documentation requirements of states or countries to which product will be shipped

8.2 Determine Control Points

- Transfer of seed during cleaning, conditioning, packaging, transporting and delivery
- Identification of seed during cleaning, conditioning, packaging, transporting and delivery

8.3 Establish Preventive Measures

- Establish procedures for identification, tracking and disposition of plant material for all commercial sales
- Establish procedures so that labels, identity measures and documentation used to identify commercial seed inventory are recorded and that information pertinent to identity and production history is retrievable
- Establish procedures to communicate to customers any use and stewardship instructions
- Establish procedures to confirm that conditioning or treatment practices for final packaged product do not adversely impact seed quality

8.4 Establish Monitoring Procedures

- Identity verification before and after cleaning, packaging, transporting and delivery by documentation or by using diagnostic methods, where appropriate
- Procedures followed to monitor product germination, physical purity, genetic purity and trait purity as appropriate

- Procedures in place to capture customer feedback on product quality
- Procedures in place to determine/validate seed phytosanitary status

8.5 Establish Corrective Measures

- Product retrieval procedures in place
- In the event that material is found to be incorrectly identified or where identity cannot be confirmed, the material and any derivatives reviewed and disposition determined
- Incorporate any corrective measures or procedural changes into SOPs, including phytosanitary

8.6 Establish Verification Procedures

- Verify identity before and after cleaning, conditioning, packaging, transporting and delivery
- Verify and confirm analysis for product germination, physical purity, genetic purity and trait purity as appropriate
- Verify seed phytosanitary status before delivery

8.7 Establish Record Keeping and Documentation Procedures

- Establish procedures for secure, but accessible, documentation of product tracking
- Maintain appropriate product inventory, shipping and disposition records
- Records retained as appropriate
- Maintain copies of control measures, phytosanitary certificates, phytosanitary field inspections, seed health test results, and other documents for an appropriate time period

TERMS AND ACRONYMS

Terms

Biotechnology: The application of: a) *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles or b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Breeder Seed: Seed or vegetative propagating material, developed by the originating, sponsoring plant breeder or institution used as the source for further seed increase.

Coexistence: The practice of growing, reproducing and handling seed products with different characteristics or intended markets with the goal of successfully achieving intended product integrity and maintaining the economic value of such products.

Confinement: The control of viable seed or other vegetative propagating material planted in the field, in a manner that mitigates the spread of pollen or other propagative plant parts out of the confined trial area.

Containment: The control of viable seed or other vegetative propagating material in a manner that mitigates their release outside of their controlled development in the laboratory, greenhouse, seed conditioning, storage or other restrictive facility.

Contained Facility: Any facility designated to limit access by unauthorized personnel or substances as well as egress of controlled materials.

Devitalization: Removal or deprivation of vitality or of vital properties required to sustain life or reproduce.

Disposition: The act or means of final settlement of plant material.

Documentation: Recorded information such as specifications, quality manuals, quality plans, records, and procedure documents.

Facility: Sites that are contiguous, under common control by a company or individual and have a grouping of equipment or individuals engaged in a common process.

Isolation: Confinement tool (physical, special, temporal) that mitigates gene flow.

Noxious Weed: Any plant or plant product that can directly or indirectly injure or cause damage to crops (including nursery stock or plant products), livestock, poultry or other interests of agriculture, irrigation, navigation, the natural resources of the United States, the public health, or the environment.

Phytosanitary: Sanitary (clean, free of) with regard to plant pests and pathogens.

Product Integrity: For the purposes of this Guide, "product integrity" means establishing and maintaining the specific identity of a seed product and the purity of that seed product using appropriate quality management measures.

Product Purity (*three types of product purity*):

- **Physical Purity:** A measure of the presence of seed that is not the labeled crop kind, the amount of broken seed and any foreign material.
- **Varietal Purity:** A measure of the trueness (genotypic and/or phenotypic) to the cultivar as described by the originating breeder.
- **Trait Purity:** A measure of the extent to which the desired trait is present and unintended traits are absent in a material.

Roguing: To remove, inferior, nontypical and/ or volunteer plants.

Seed Stocks: Seed stocks are increased from breeder seed, and so handled as to closely maintain the genetic identity and purity of a variety used to render commercial seed.

Standard Operating Procedures (SOPs): A documented procedure or set of work instructions that defines how to perform a given operation.

Trait: A genetically determined characteristic.

Unintended Plant: Any plant (volunteer, weed, other crop species) that is not supposed to be where it is observed.

Variety: Subdivision of a species for taxonomic classification. Used interchangeably with the term cultivar to denote a uniform, stable group of individuals that is genetically distinct from other groups of individuals in the species.

Volunteer: Plant that is derived from a previous crop cycle.

Acronyms

ASTA	American Seed Trade Association
BIO	Biotechnology Industry Organization
GPS	Global Positioning System
HACCP	Hazard Analysis and Critical Control Points
IP	Import Permit
ISO	International Organization for Standardization
LLP	Low Level Presence of Unintended Trait
PC	Phytosanitary Certificate
QMP	Quality Management Program

SOP Standard Operating Procedure

RESOURCES

American Seed Trade Association Paper on Seed Purity. This paper provides an overview of seed purity as it relates to seed labeling information required under the *Federal Seed Act*. The paper describes what information is put on the seed labels and tags. The paper can be found at: http://www.amseed.org/newsDetail.asp?id=118.

American Seed Trade Association Paper on Standardization of Seed Testing Protocols. This paper describes the parameters that can be used to establish consistent and accurate seed testing, when testing for low levels of a specific trait. The paper can be found at: http://www.amseed.org/advpres/Standardization.pdf

Association of Official Seed Analysts, Inc. The Association of Official Seed Analysts (AOSA) is an organization of member laboratories. AOSA sets seed testing rules which are adopted by most states. More information can be found at www.aosaseed.com.

Association of Official Seed Certifying Agencies. The Association of Official Seed Certifying Agencies (AOSCA) sets out the minimum standards for seed purity and seed identity. It also recommends minimum standards for seed quality for the different classes of certified seed. More information can be found at www.aosca.org.

Association of American Seed Control Officials. The Association of American Seed Control Officials (AASCO) is an organization of seed regulatory officials from the United States and Canada. AASCO developed and updates the Recommended Uniform State Seed Law. More information can be found at www.seedcontrol.org.

Federal Food Drug and Cosmetic Act. Under the Federal Food Drug and Cosmetic Act (FFDCA), the Food and Drug Administration is responsible for ensuring the safety and proper labeling of all plant-derived foods and feeds, including those developed through biotechnology. More information can be found at http://usbiotechreg.nbii.gov/.

Federal Insecticide Fungicide and Rodenticide Act. Under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), the Environmental Protection Agency registers and regulates pesticides in the United States. Included, under FIFRA, are pesticidal substances produced by plants. More information can be found at http://usbiotechreg.nbii.gov/.

Federal Seed Act. Under the Federal Seed Act (FSA), the United States Department of Agriculture (USDA) Agriculture Marketing Service (AMS) regulates the interstate shipment of agricultural and vegetable seeds. The FSA includes several definitions of seeds by class, Breeder, Foundation, and Commercial, as well as labeling requirements. More information can be found at www.ams.usda.gov/lsg/seed/geninfo.htm.

International Seed Testing Association. The International Seed Testing Association (ISTA) develops and publishes standard procedures for sampling and testing of seeds. ISTA also runs an Accreditation Program. More information can be found at www.seedtest.org.

International Seed Federation. The International Seed Federation (ISF) represents the interests of the seed industry at a global level through interaction and dialogue with public and private institutions that have an impact on international seed trade. More information can be found at: www.worldseed.org.

National Organic Program. The USDA National Organic Program (NOP) develops, implements, and administers national production, handling, and labeling standards for organic production. More information can be found at www.ams.usda.gov/AMSv1.0/nop

Plant Protection Act. Under the Plant Protection Act, USDA's Animal Plant Health Inspection Service (APHIS) regulates the import, handling, interstate movement and environmental release-including confined field trials, organisms produced through biotechnology. More information can be found at http://usbiotechreg.nbii.gov.

State Seed Regulations. Various state seed regulatory publications direct the intra-state movement of seed including labeling and weights and measures. A compilation of these regulations can be found at www.amseed.org/member_SeedRegs.asp.

ASTA Paper: Existing U.S. Seed Industry Production Practices that Address Coexistence. This paper discusses the tools the seed industry uses with respect to coexistence. The paper can be found at www.amseed.org.

GENERAL AUDITING PRINCIPLES

The purpose of this section is to describe the role of independent auditing related to company quality management and compliance systems. An audit should bring a systematic, disciplined approach to evaluate and improve effectiveness of risk management, control, and governance processes. This section is not meant to be a detailed "how to" guide on conducting audits. Rather, it describes the principles behind audits and provides resources for further information.

The Institute of Internal Auditors (IIA) defines audits as an independent, objective, assurance and consulting activity designed to add value and improve an organization's operations.

Audit Principles

- Independence and objectivity: The auditing activity should be independent, with an organization reporting relationship that allows it to fulfill its responsibilities. It should be free from interference and determining the audit scope, performing work and reporting. Auditors should be impartial and unbiased and should generally not be involved in auditing specific activities for which they are accountable.
- Proficiency and professional care: Internal auditors should have sufficient knowledge, skills and competencies to identify and assess the relevant audit indicators.
- Continuous improvement: The audit should include a process to monitor and assess the overall effectiveness of the corrective actions. This can include both an internal and external assessment.
- Planning and management: The auditing activity should conform to accepted management practices.
- Risk Management: The audit should assist the organization by identifying and evaluating significant exposures to risk and contributing to the improvement of risk management and control systems. It should promote effective performance management and accountability.
- Value added to organization: The audit should add value to the organization by identifying problem areas and identifying systematic organizational practices that represent possible areas of risk.

Audit Approaches

- Audits should focus on the whole process and performance of quality management systems, not on specific procedures.
- The following basic questions can be asked to evaluate effectiveness:
  - Are there appropriate and communicated standard operating procedures in place?
  - Are processes being performed according to these procedures?
  - Are the planned results (i.e., levels of compliance) being achieved?
  - Are opportunities for improvement being identified and implemented?
- Audit finding and recommendations should be presented from a risk management perspective and should be targeted to the correct part of the organization.

- The audit function may be delivered either by an independent auditing group within the organization or by a third party provider.
- The audit should include a mechanism for follow-up.
- Under some circumstances, third party auditors may provide greater transparency and credibility. If using a third party auditor, it is important that they understand the existing “quality culture” within the organization and the goals of the organization with regard to the quality management systems.

Sources of Audit Information

- Institute of Internal Auditors: www.theiia.org
- American Society for Quality: www.asq.org

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

ISO is the world's largest developer of technical standards designed to make the development, manufacturing and supply of products and services more efficient, safer and cleaner[8]. ISO has published the ISO 9000 family of standards which were developed to assist organizations to implement and operate effective quality management systems. These standards collectively provide a framework that an organization may use to develop, implement and maintain a management system that incorporates a process for continual performance improvement while addressing the needs of all interested parties.

ISO identifies eight management principles that can be used to lead an organization towards improved performance. These principles form the basis for the quality management system standards within the ISO 9000 family:

- **Customer focus:** Organizations depend on their customers, and therefore, should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

- **Leadership:** Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

- **Involvement of people:** People at all levels are the essence of an organization, and their full involvement enables their abilities to be used for the organization's benefit.

- **Process approach:** A desired result is achieved more efficiently when activities and related resources are managed as a process.

- **System approach to management:** Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives.

- **Continual improvement:** Continual improvement of the organization's overall performance should be a permanent objective of the organization.

- **Factual approach to decision making:** Effective decisions are based on the analysis of data and information.

- **Mutually beneficial supplier relationships:** An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

The requirements for quality management systems as specified in ISO 9001:2000 are purposefully generic so that they may be applied by any organization that wishes to establish a quality management system irrespective of the product or service that the organization may offer. Further information on ISO can be found at http://www.iso.org/iso/home.htm.

[8] Switzerland, ISO Secretariat, "About ISO," *International Organization for Standardization*, 17, March 2008 **<** http://www.iso.ch/iso/en/aboutiso/introduction/index.html**>.**

DISCLAIMER

This Guide to Seed Quality Management Practices is intended solely as an educational tool and as general guidance to assist companies in voluntarily developing and implementing quality management programs for maintaining seed product integrity from incorporation of a trait into a breeding program through commercial seed production sales. This Guide is intended to serve as a reference document for companies developing individual quality management practices, operating procedures and disciplines consistent with their respective research, development and seed production systems. Companies may choose to refer to the entire Guide or specific sections of the Guide as appropriate. The guidance is intended to be flexible, and its application will differ according to the size, nature and complexity of the organization and products involved. The Guide is representative and not exhaustive.

It is the responsibility of any user of this document to consider that user's specific circumstances when: 1) developing a quality management program specific to its business and 2) in meeting any applicable legal and regulatory requirements. This Guide is not intended as, and should not be construed as, legal advice or a substitute for a user's own individual understanding of applicable legal requirements. Regulatory requirements may be issued or revised by government agencies after the publication date of this Guide. Users are advised to consult with their legal counsel and/or contact the appropriate regulatory agency(ies) to ensure compliance with applicable requirements.

The Guide does not define or create legal rights or obligations, and the American Seed Trade Association (ASTA) specifically disclaims any such rights or obligations. ASTA and its members do not make any warranties or representations, either expressed or implied, with respect to the accuracy or completeness of the information contained in this Guide to Seed Quality Management Practices; nor do they assume any liability of any kind whatsoever resulting from the use of or reliance upon any information, procedures, conclusions or opinions contained in this Guide.

AMERICAN SEED TRADE ASSOCIATION

May 5, 2010

Docket No. FDA-2010-N-0085
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Rm 1061
Rockville, MD 20852

www.regulations.gov (Subject Line: Docket No. FDA-2010-N-0085)

RE: FDA-2010-N-0085 Preventive Controls for Fresh produce; Request for Comments

The American Seed Trade Association (ASTA) is pleased to provide comments on issues related to the potential role of seed in food borne human pathogen outbreaks associated with the production, harvesting, and marketing of fresh fruits and vegetables. Founded in 1883, ASTA, located in Alexandria, Virginia, is one of the oldest trade organizations in the United States. Its membership consists of more than 730 companies which are involved in seed production and distribution, plant breeding, and related industries in North America. As an authority on plant germplasm, ASTA advocates science and policy issues of industry importance. The mission of ASTA is to enhance the development and movement of quality seed worldwide.

In response to the 2006 outbreak of E.coli 0157:H7 on spinach in California, ASTA formed a Food Safety Pathogen Working Group (WG) to evaluate the possible role of seed in outbreaks of food borne human pathogens in commercial field and greenhouse vegetable production environments. The WG concluded that seed, at that point in time, was not a clear pathway and there was no significant value in testing seed lots for the presence of human pathogens. These conclusions were based on discussions with researchers, a thorough review of research literature, and a review of practices in use for the production and marketing of seed intended for fresh vegetable production. In July of 2008, ASTA articulated these conclusions with its “ASTA Statement on Field and Greenhouse Planted Seeds and Human Pathogens” position paper (available on the ASTA website at www.amseed.org/newsDetail.asp?id=167) This ASTA statement is in the process of being revised to indicate that, after continued monitoring of scientific literature and information following outbreaks of food borne human pathogens, the conclusions in the original statement remain valid. The updated statement will be formally presented to the ASTA Board of Directors for adoption on July 1, 2010.

The Food and Drug Administration (FDA) has recognized the potential risk of seed used for the production of sprouts in transmitting human pathogens, and has issued several alerts to the public recently to discontinue eating sprouts until further assessment of the specific causes and sources of inoculum can be determined. In addition, the FDA has

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released guidance documents to the sprout industry, urging implementation of properly recognized sanitation practices, testing of irrigation water and seed, traceability of products through the production chain, and documentation and recordkeeping practices. ASTA fully supports FDA's responses to food borne human pathogen outbreaks associated with sprout production and guidance to the sprouting industry for preventing outbreaks. This guidance appears to be adequate and new standards for sprout production need not be included in this ASTA initiative. ASTA urges the FDA to continue to distinguish between seeds used in fields and greenhouse vegetable production versus seeds used for the production of sprouts in the development of future policies, standards, and guidance documents.

In summary, ASTA believes that seeds used in fields and greenhouses for the production of fresh produce do not contribute to outbreaks of human pathogens. ASTA will continue to monitor the scientific literature and future outbreaks of human pathogens associated with the production of fresh produce, and provide leadership to its members to ensure that seed does not contribute to future outbreaks.