



Seed Systems Approaches: An NPPO Case Study- ReFreSH

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Regulating Seed Trade in the United States

- Seed was long regarded by regulators as a relatively low risk pathway so seed moved in trade with minimal import requirements
- 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
- Phytosanitary certification on consignment by consignment basis





Changing perception

- 2013
 - Detection of CGMMV in California
- 2014
 - **National Seed Health Summit**
- 2016

Regulatory Framework for Seed Health (ReFreSH)



Source: CDFA





Challenges of Regulating Seed Trade

- Thousands of pests potentially involved
- For given pest, is seed a pathway? What is the appropriate phytosanitary measure?
- Trend to increasing demand for documents and declarations that specific pests are absent in imported seed
- Providing those certifications on a consignment basis straining NPPO resources





A New Approach

Regulatory Framework for Seed Health (ReFreSH)

- Risk-, science-based systems approach
- Aims for an effective and more efficient program to manage phytosanitary risk of international seed movement
- Leverage industry best practices
- Voluntary system





ISPM 38 and Systems Approaches

ISPM 38 Section 2.5:

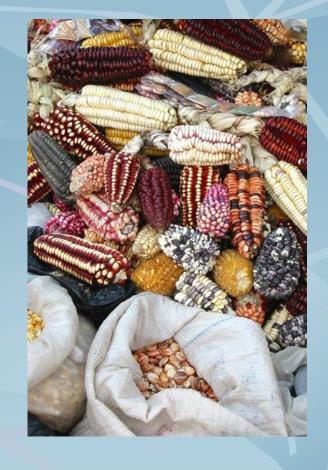
- Opportunity to consider both pre-harvest and post-harvest procedures
- May contribute to effective pest risk management
- Pest management practices throughout the seed production process [industry practices] may be integrated in a systems approach
- ISPM 14 provides guidance





Goals

- Shift current focus on consignment by consignment inspection and testing to a system where accreditation of producers and production processes is the basis for phytosanitary certification
- Accommodate all seed sectors (vegetable, cereal, row crop, farm and lawn, flower) and all sizes of companies
- Promote a harmonized global system





ReFreSH- How It Could Work

- Seed production system approved/accredited by NPPO of exporting country
- NPPO of importing country accepts accreditations as equivalent to phytosanitary certification of individual seed consignments
- Accreditation is basis for issuing phytosanitary certificates
- Compliance assured by quality management systems/audits





Benefits

Systems approaches create the opportunity for innovation and flexibility in managing pest risk

- For industry:
 - Faster release of product at import
 - Reduced operational cost
 - Harmonized import requirements
- For regulators:
 - Better overall understanding of the phytosanitary status of seed production
 - Greater efficiency and transparency







Challenges of New Model

- How do we develop a truly global seed trade regulatory system?
- How do we as an NPPO setup a system outside of our control?
- How will we build a system based on trust, but with verification built in?





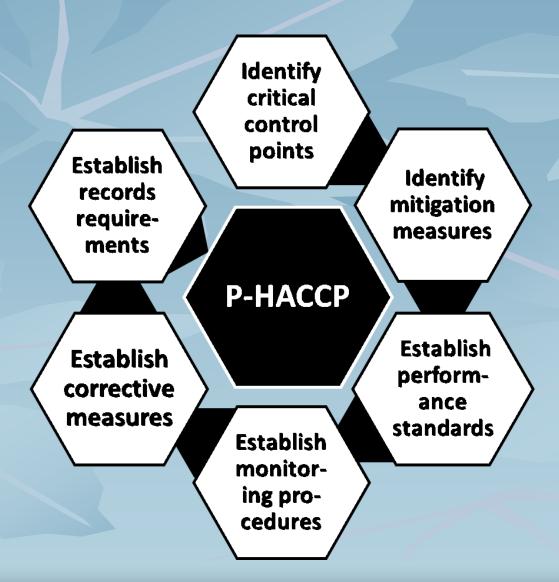
Constructing Systems Approaches

- Combination measures
 - Combine existing measures to achieve a qualitative ALP; throw measures together until we're comfortable
- Control point systems
 - Define control points and the efficacy of measures; apply measures to identified control points





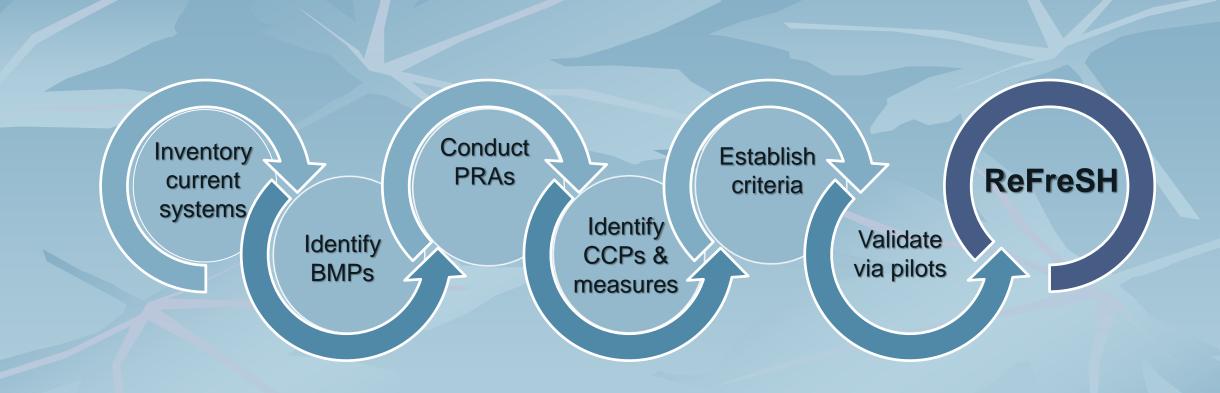
Designing a P-HACCP System





USDA

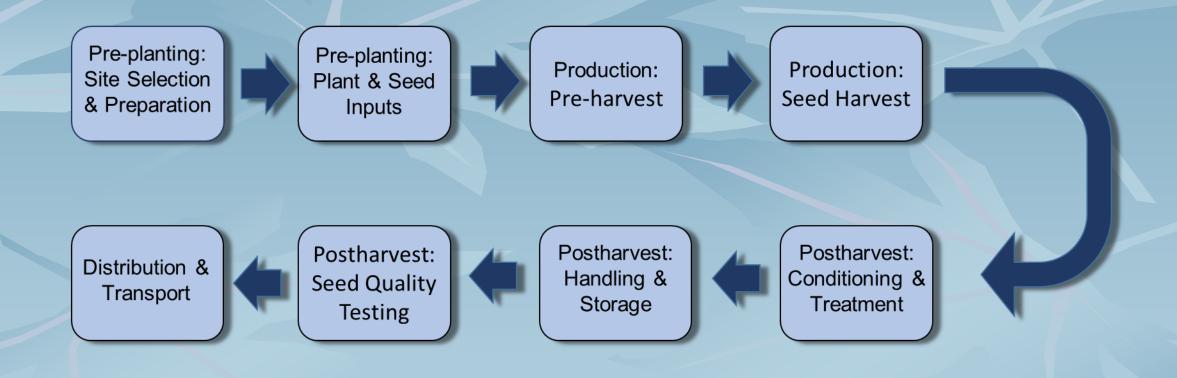
Building ReFreSH







Critical Control Points







ReFreSH Model

Survey to establish pest free area
 Inspection to certify containment
 Producer registration
 Review/
approve system manual

Accredit testing facilities/ certification programs
 Certify transplant facilities

 Growing season inspection
 Facility audits/ records review Field inspection at harvest
 Testing if appropriate Operations facility audits
 Verify efficacy of treatments

 Operations facility audits/ inspections Accredit/audit testing facilities
 Approve/ validate sampling protocols
 Proficiency testing Import requirements
 Audit testing at import
 Postentry quarantine
 Phytosanitary certification

Preplanting: Site Selection & Preparation Preplanting: Seed & Plant Inputs

Production: Preharvest Production: Seed Harvest Postharvest: Conditioning & Treatment Postharvest: Handling & Storage Postharvest: Seed Quality Testing

Distribution & Transport



Use of pest free area, place of production, production site
Use of buffer zones around growing sites
Use of containment (e.g., greenhouse, screenhouse)
Crop rotation
Removal of

Use of tested/certified seed
Transplant sanitation
Use of resistant or less susceptible cultivars
Use of seed treatments
Documentation

Growing season inspection
 Growing season treatments/pest management
 Plant sampling/testing
 Growing site sanitation
 Worker training
 Documentation

Disinfection of equipment prior to use and between fields, harvest dates, etc.
 Seed is not harvested from sick, unhealthy plants
 Use of harvest windows to avoid infestation
 Sanitation
 Documentation.

 Fermentation to reduce seed residues Seed wash to reduce microbial contaminant load Seed treatment (e.g., heat, hot water, pesticide) applied at receipt Milling and sorting to reduce fruit/plant contaminants, dead seeds, etc. Sanitation Documentation,

 Stored with safeguards to prevent infestation Stored to maintain phytosanitary status and identity Protocols in place to prevent seed lot mixes (clean out of equipment) Packaging sealed to exclude pests

Sanitation

Documentation

Official sampling protocols (e.g., ISTA, AASCO) followed
 Accredited testing facility used
 Validated testing protocols used
 Sanitation
 Documentation

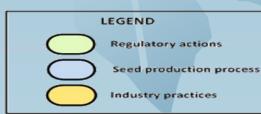
• Traceback/ labeling
• Sanitation (e.g., (conveyances free from contamination)
• Validated testing protocols used
• Documentation

Documentation
 Produce system manual

potential hosts

Use of tested/

clean water sources







A Closer Look

Accredit testing facilities/ certification programs Certify transplant facilities Preplanting: Seed & Plant Inputs Use of tested/ certified seed Transplant sanitation Use of resistant or less susceptible cultivars · Use of seed treatments Documentation Accredit testing facilities / certification programs
 Certify transplant facilities

> Pre-planting: Plant & Seed Inputs

- Use tested/ certified seed
- Transplant sanitation
- Use resistant or less susceptible cultivars
 Seed treatments
- Phytosanitary status of seed / transplants
- Audit, review of records and documentation
 Laboratory ring tested

Regulatory Activity

Critical Control Point

Mitigation/ Best Practice

Hazard

Verification

ReFreSH Accreditation Standard: Scope

- Describes essential elements of ReFreSH
- Outlines the responsibilities of all participants in the ReFreSH
 Program







ReFreSH Accreditation Standard

- Application and Enrollment in ReFreSH
- Participating Entity Responsibilities
- Authorizing NPPO Responsibilities
- Non-conformance and Corrective Measures





Next Steps

- Finalize ReFreSH accreditation standard
- Develop ReFreSH manual
- Explore ReFreSH pilots
 - Cucurbit small lots of seed/CGMMV
 - Quads countries Seed Health WG







Beyond ReFreSH

Simultaneous efforts across the globe

- U.S.:
 - ReFreSH
- Australia:
 - Global Integrated System of Seed Production
- ISF:
 - Systems Approach Working Group /
 Disease Prevention Program
- France:
 - PGRP





Beyond ReFreSH

Significant international meetings on systems approaches

- ISF Systems Approach Chatham House Rule Meeting
 - Rome, April 2018
 - Participants: One NPPO representative, one national seed association representative from each country
 - Countries: Australia, Chile, Netherlands, South Africa, U.S.

Australia DAWR International Clean Seeds Pathway

- Brisbane, June 2018
- Participants: NPPO and industry representatives from at least 10 countries from Europe, the Americas, Asia and Oceania





International "consensus"

"Consensus" opinion from these international meetings on use of systems approaches.

- Recognizing industry practices as part of a Systems Approach as an alternative to current consignment based approaches is beneficial.
- Desire to create a global, multilaterally accepted and implemented Systems Approach







International "consensus"

"Consensus" opinion from these international meetings on use of systems approaches.

- Shift current focus of consignment by consignment inspection and testing to a system where accreditation of production processes forms the basis for phytosanitary certification
- Accommodate all seed sectors (vegetable, cereal, row crop, farm and lawn, flower) and all sizes of companies







International "consensus"

Next steps:

- Most viable path to multilateral acceptance is through the IPPC probably as ISPM 38 annex
- As ReFreSH most developed, it can serve as model and NAPPO logical choice to sponsor IPPC proposal







Questions?





