U.S. SEED INDUSTRY EXPERIENCES WITH SPS/IPPC PRINCIPLES

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NAPPO Training Session

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Merida, Mexico

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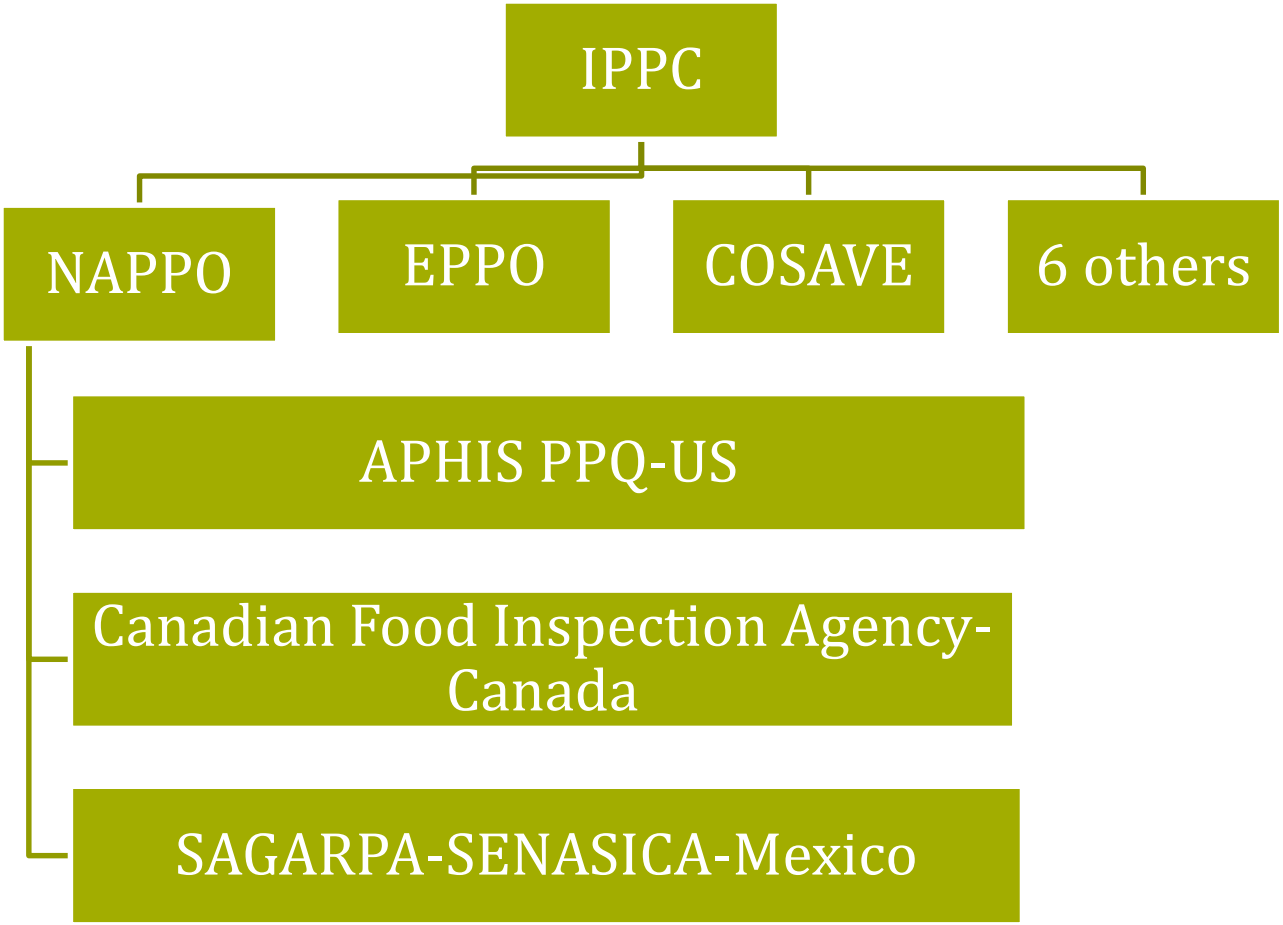
Behind the Scenes
Global Phytosanitary Framework



Why Phytosanitary Security for Seeds?

- **Seeds, like any other raw agricultural commodity, can be a pathway for introducing unwanted exotic pests into new environments**
  - Weed seed contaminants
  - Insect pests (mainly in storage situations)
  - Soil/nematodes
  - Plant pathogens

- **Many companies serve global markets; seeds are frequently moved internationally many times during the life cycle and pests that are associated with the seed move too, without precautions**
- **Pathogens and other pests can significantly reduce seed quality in all stages of the life cycle**

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Major Issues with International Seed Movement

- Value of global seed industry: >$48 Billion
- For just the U.S., over $1 Billion of seed is exported annually, and $1 Billion of seed is imported.
- A tremendous number of consignments are **pre-commercial:** small lots for R&D, breeding lines, trial seed; stock seed, parental lines
- Every time a seed consignment is exported (or re-exported) to a country, it must comply with that country's phytosanitary requirements

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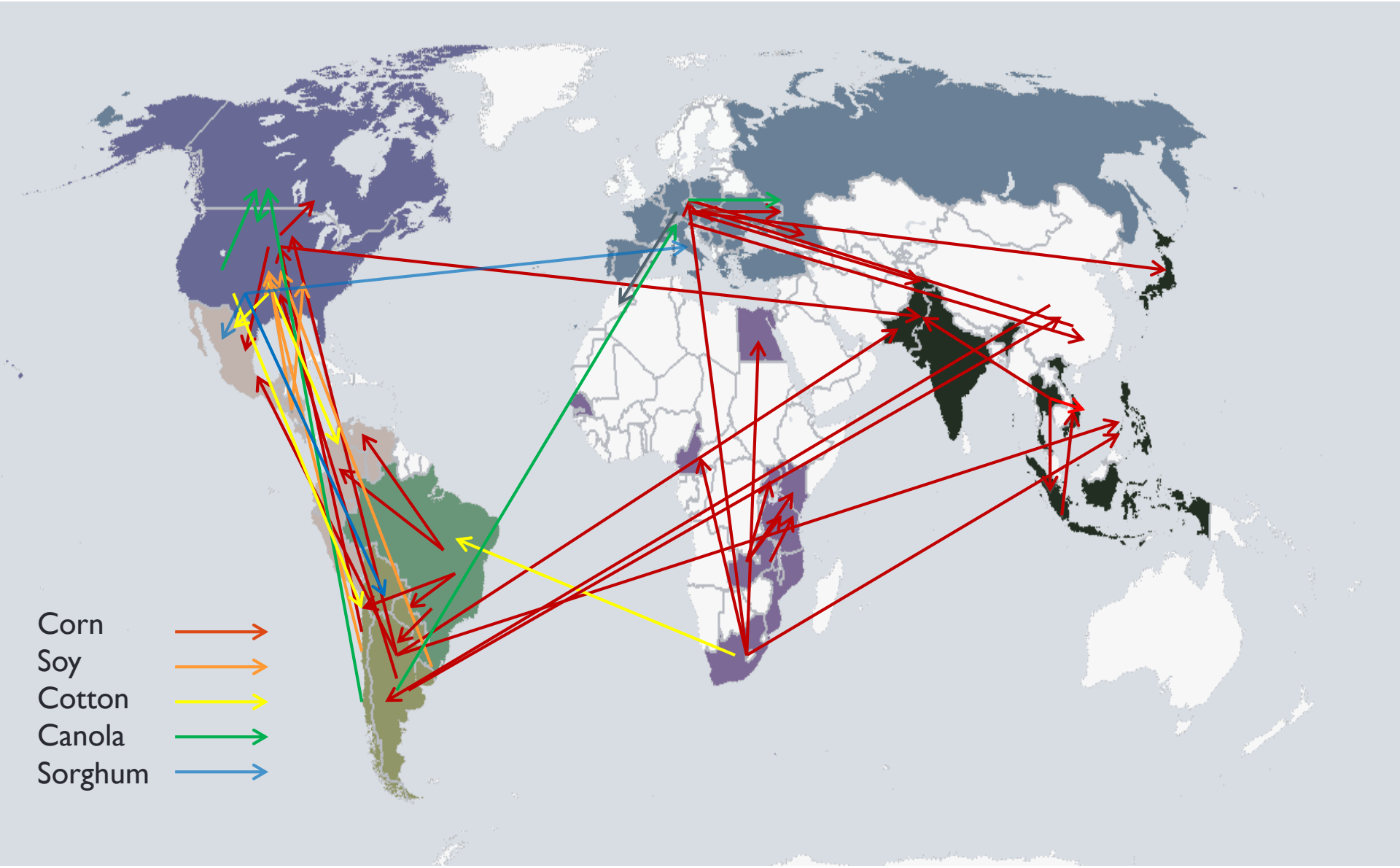
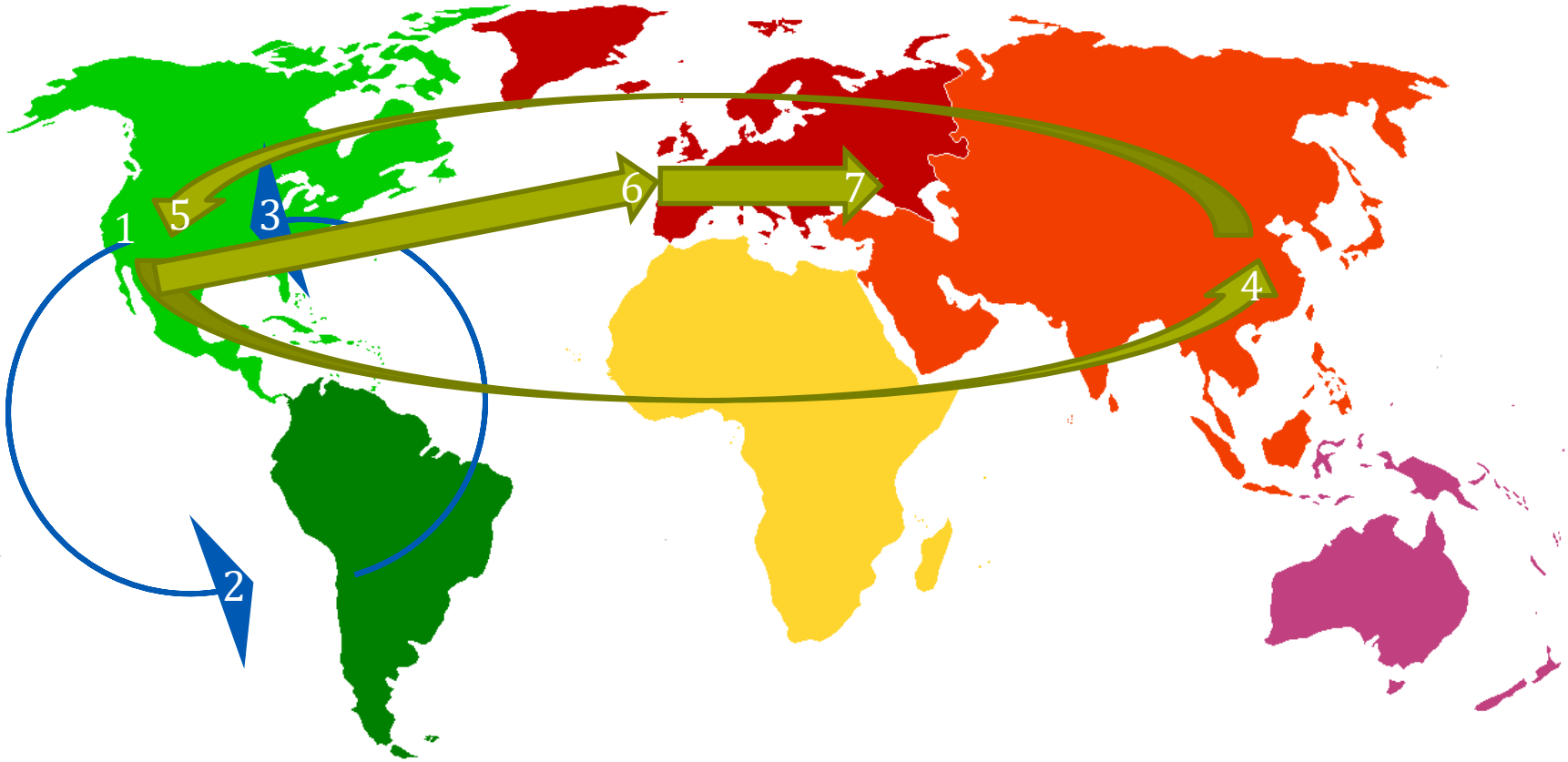
The Dilemma with Regulating Seeds

- Over 300 different seed species, over 65,000 different varieties representing all seed types (vegetable, flower, forage and row crop, grasses)
- Thousands of pests potentially involved; mainly plant/seed pathogens
- Hundreds of thousands, if not millions of shipments per year!
- For a given pest, is seed a pathway? If so, what is the appropriate phytosanitary measure?
- Movements often based on “just in time” concept

Global Seed Flows

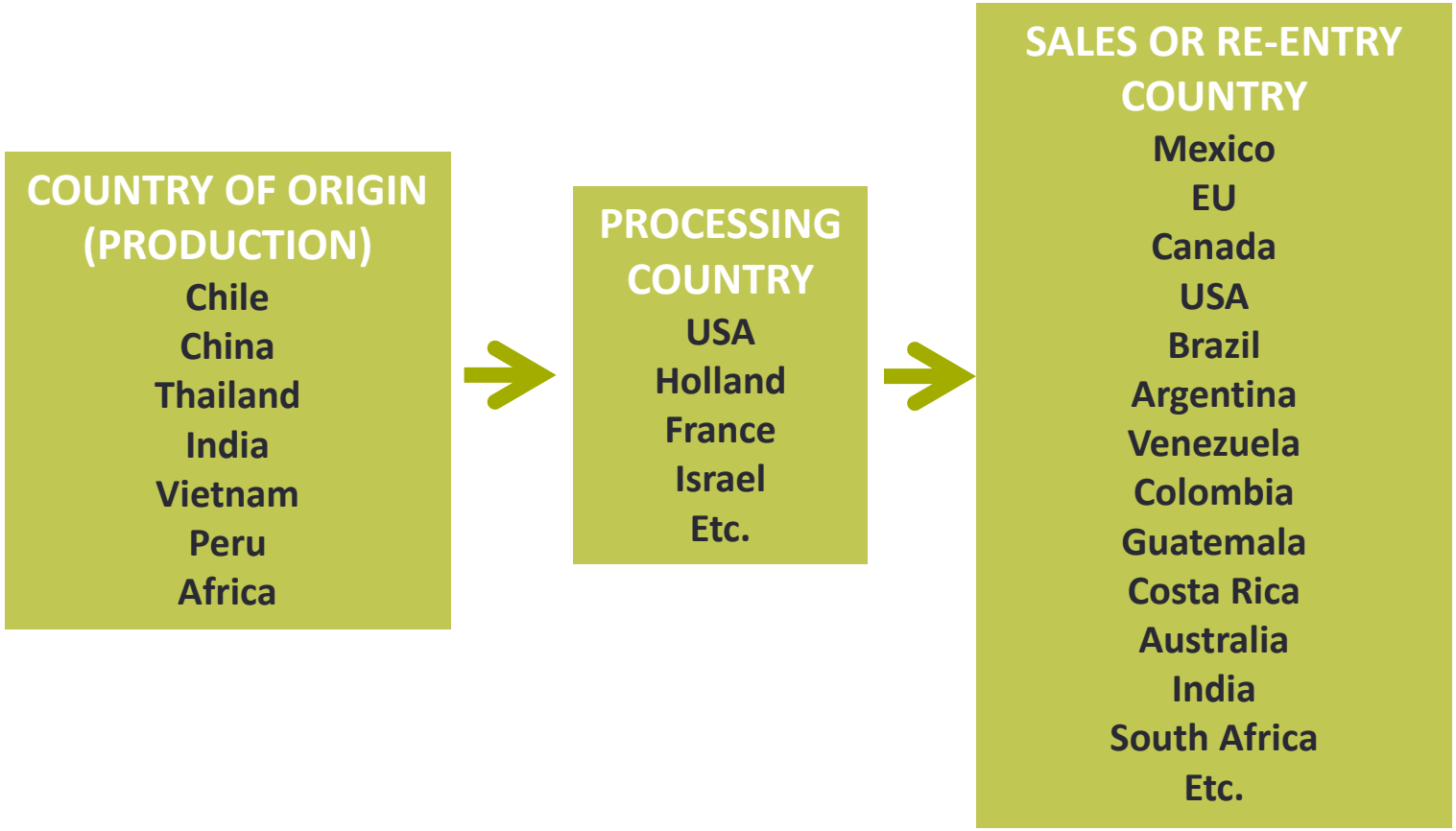


Tomato Example (1)



Seed Industry Preparation:

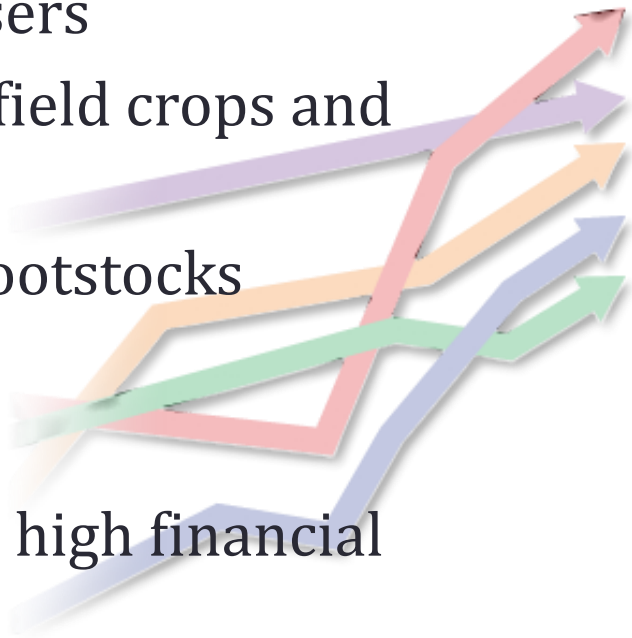
How Tomato Seed Moves Around the World



Challenges Facing the Seed Industry:

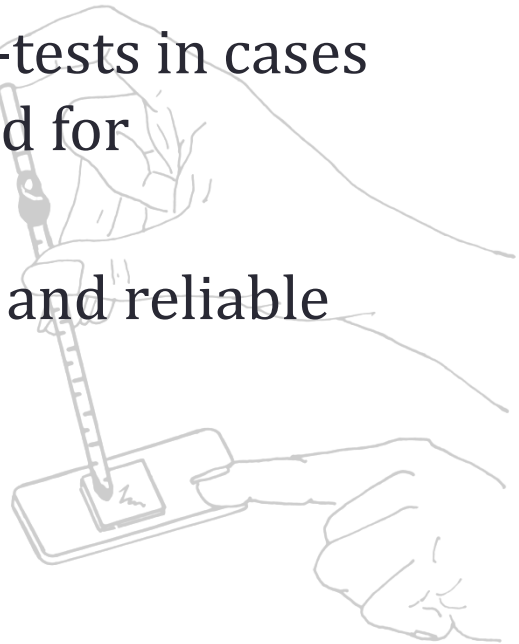
1. Industry Practices and Trends

- **Increased risk of diseases**
  - Concentration of activities by plant raisers
  - Size of horticultural enterprises (open field crops and protected cultures)
  - Use of techniques such as grafting on rootstocks (Solanaceous crops, Cucurbits)
- **Higher costs and liability**
  - Intensification of production leading to high financial risks for growers and plant raisers
  - Infected seed the first suspect in case of a disease outbreak
  - Tests demanded for pathogens for which seed is not pathway



Challenges Facing the Seed Industry: 2. Technology Innovations

- **Rapid developments in techniques**
  - Sensitivity of tools such as bio-PCR, NGS, and real time-PCR
  - Quick development of highly sensitive PCR-tests in cases of emergency, without validating the method for suitability of use on seeds
  - Adaptation and validation to ensure sound and reliable results that have biological “relevance”
- **Adaptation of tests for treated seed**
  - Sanitation products and processes
  - Crop protection products



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Challenges Facing the Seed Industry

3. The Regulatory Environment

- **Heightened attention on seed-borne pathogens**
  - Vegetable seed produced in many countries, shipped to central facilities for processing, sanitation and upgrading, treating, testing and repacking before being re-exported
  - Import restrictions on some countries of production
  - Pest Risk Analyses
- **Greater emphasis by plant protection authorities on seed health health testing**
  - Reliability and harmonization of tests
  - Use of protocols suitable to test seed
  - **Emerging issue: testing of asymptomatic plants**
  - Laboratory capacity becoming an issue
  - Frequent re-testing by receiving NPPO at port of entry

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Seed Industry Planning
Advanced Preparation is Key!

- **Export Planning**
  - What Countries do we Sell to?
  - What is the Route of Export (Re-Export)?
  - Country of Origin Restrictions
  - Knowledge of Pests/Pathogens in Production Area
  - Country Import Requirements
    - Country Website (Brazil, Mexico)
    - PExD and PCIT
    - State and County Agencies
    - Import Permits
    - Prior Experience

Export Planning, continued

- What phytosanitary measures are available for specific pests of concern?
  - **CABI database:** available through subscription; a good start but contains incomplete and in some cases outdated and erroneous publications
  - **ISF Pest Listing Database** (www.seedworld.org) : organized by seed commodity; 10 vegetable seed species completed with 2 more nearly completed and new efforts on corn and alfalfa seed (peer reviewed)
  - **ASTA Seed Pest Database** (www.betterseeds.org): organized by pest; over 160 pests currently included; coordinated closely with ISF database (peer reviewed)

To Meet the Needs of World Food Production, the Seed Industry Needs:

- Harmonized phytosanitary import requirements
- Harmonized seed testing methods/protocols
- Seed Treatments that ensure phytosanitary security
- Standard language used in additional declarations of certificates
- Harmonized approach for seed PRAs
  - Demonstration that seed truly is a pathway!
  - Does a testing method exist for the pathogen(s) in question?

The new ISPM 38 addresses many of these needs

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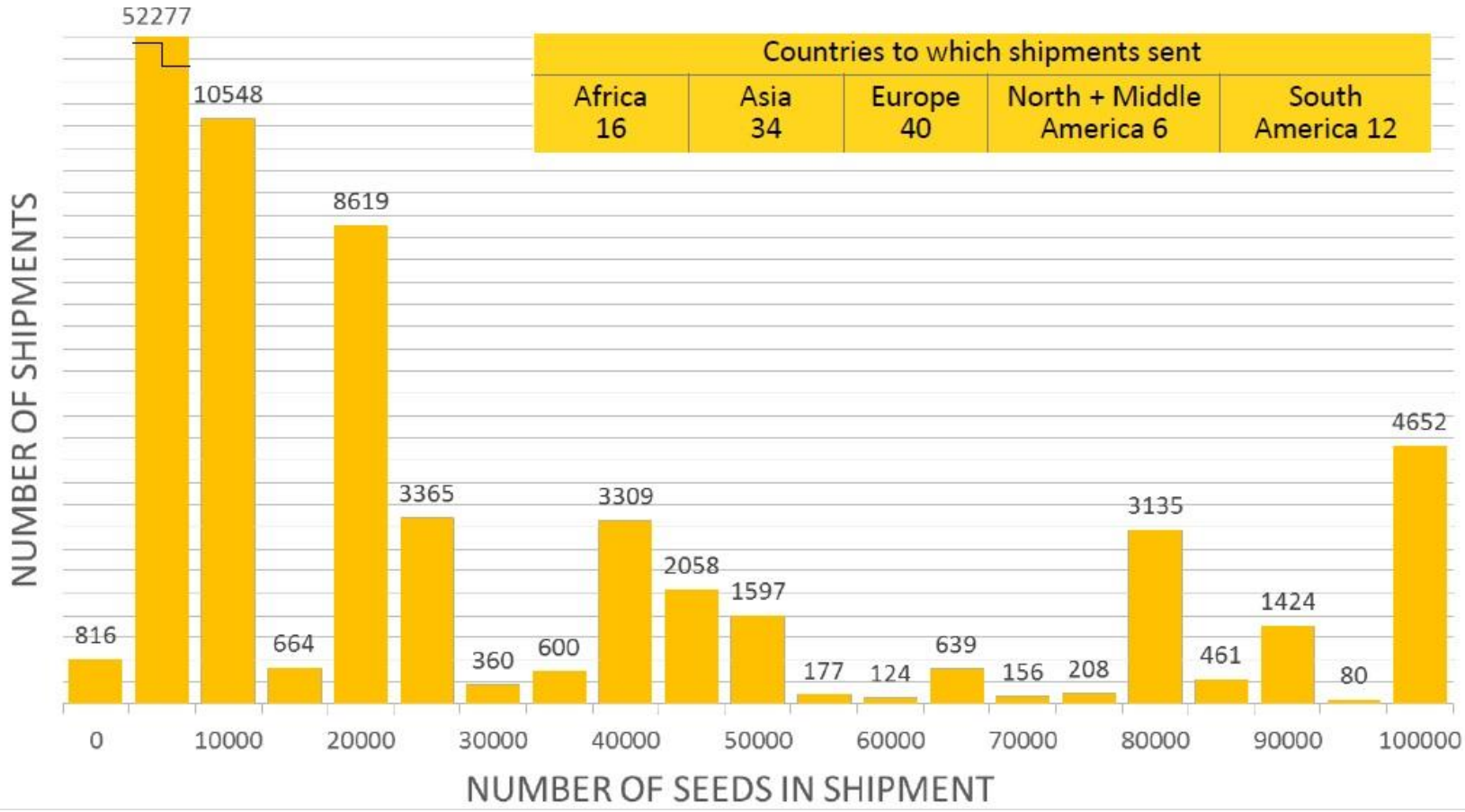
Small Lots of Seed

- This issue continues to increase as a problem globally
- Problem occurs when a seed test requires a sample size that can force destruction of most or all of the seed lot
- ISF and ASTA have proposed a new approach for calculating sample size based on “infection units”
- ASTA proposal also includes using risk assessment to avoid seed testing where possible

Example: Shipments of small lots (commercial and samples) – 2015



SEED IS LIFE
ISF
International Seed Federation

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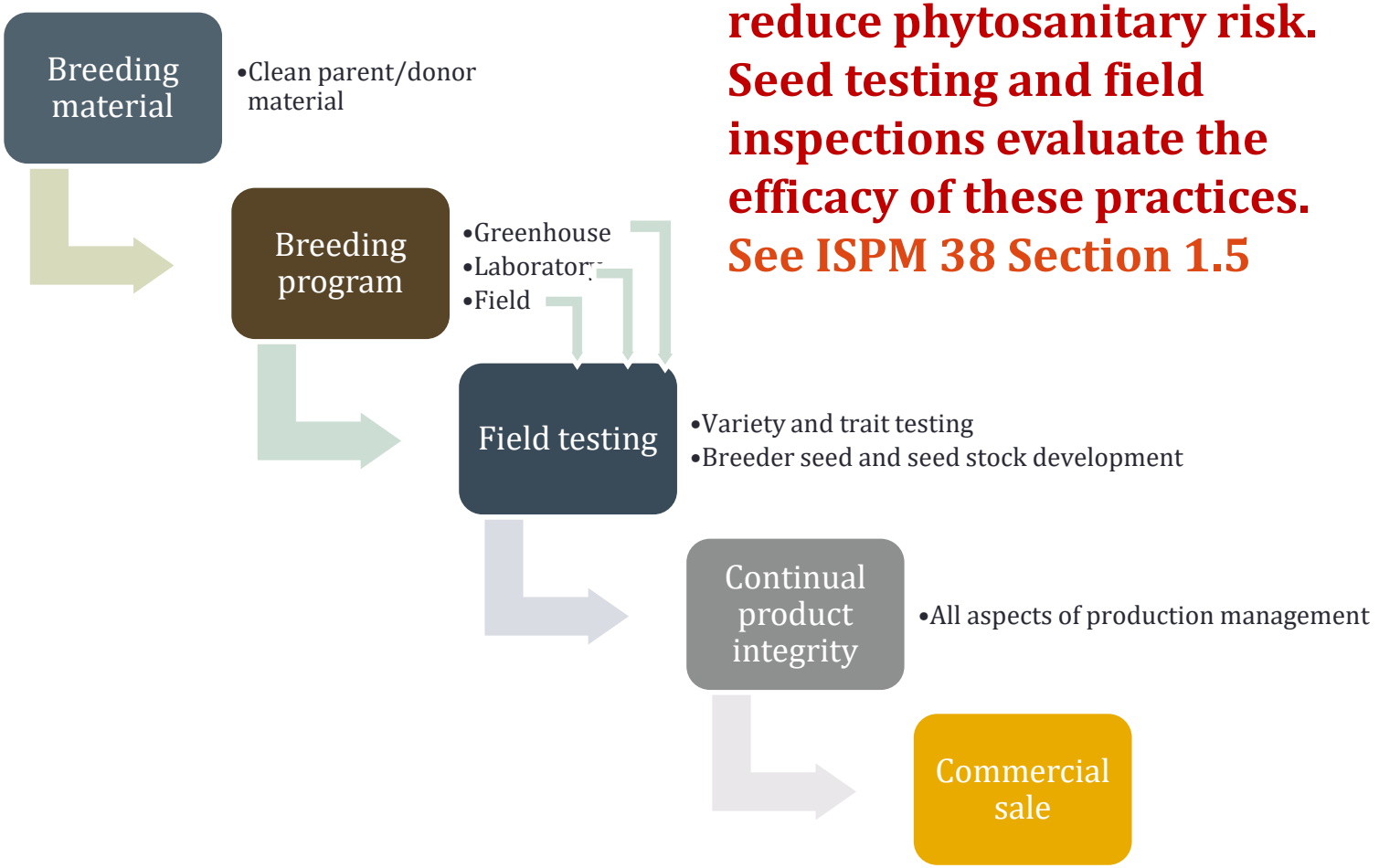
Systems Approaches

- The integration of different risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of protection against regulated pests [ISPM No. 14, 2002; revised ICPM, 2005]
- **ISPM 38** references seed production and quality practices which themselves reduce or manage phytosanitary risk
- ASTA has been sponsoring a research project with USDA Agricultural Research Service scientists (Dr. Gottwald and Laborde) to develop a model to assess or estimate the amount of phytosanitary risk reduction provided by seed QM practices in a systems approach

Rationale for Systems Approaches for Seeds

- Seed trade continues to increase rapidly (especially imports into the U.S.)
- Many countries are adopting more restrictive phytosanitary requirements
- U.S. seed import regulations were not designed for such high volumes and diversity of seed imports (impossible to conduct all necessary PRAs that would be needed)
- Systems approaches provide much better overall phytosanitary risk reduction/management than shipment-by-shipment phytosanitary certification
- Seed companies already use systems approaches and HAAPC principles to produce seed

Seed Production Pathway



Best practices for production of quality seed work together within a systems approach to significantly reduce phytosanitary risk. Seed testing and field inspections evaluate the efficacy of these practices.

See ISPM 38 Section 1.5

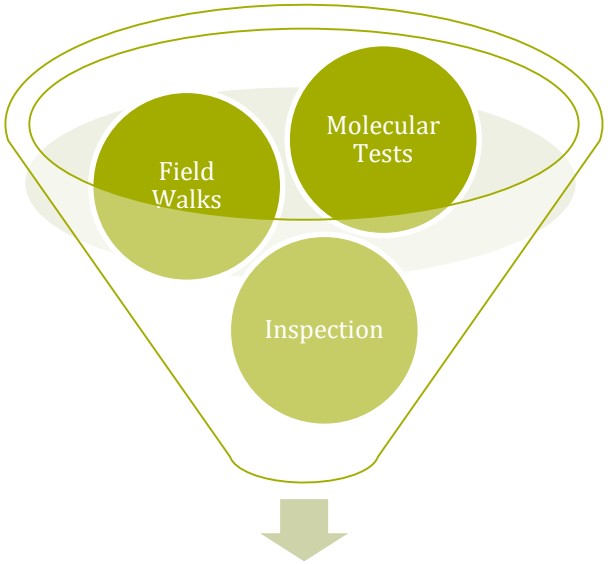
A New APHIS Approach

- **Re**gulatory **Fr**amework for **S**eed **H**ealth (ReFreSH)
- Risk-, science-based systems approach
- Work within current seed trade model
- Leverage industry best practices
- Promote global adoption of seed trade framework

ReFreSH-Clean Seed "Passport"

- Participating company will be issued a clean seed document based on an accreditation
- Company will be able to move seed among participating countries without phytosanitary certificates for each consignment
- Production process will be certified/accredited at each stage; practices will be audited
- Industry required to report pests
- Goal: Facilitate safer global movement of clean seed

Certification/Accreditation Process



Seed Company Application for Accreditation

Supporting Documentation

Seed Passport or Equivalent Certificate Issued

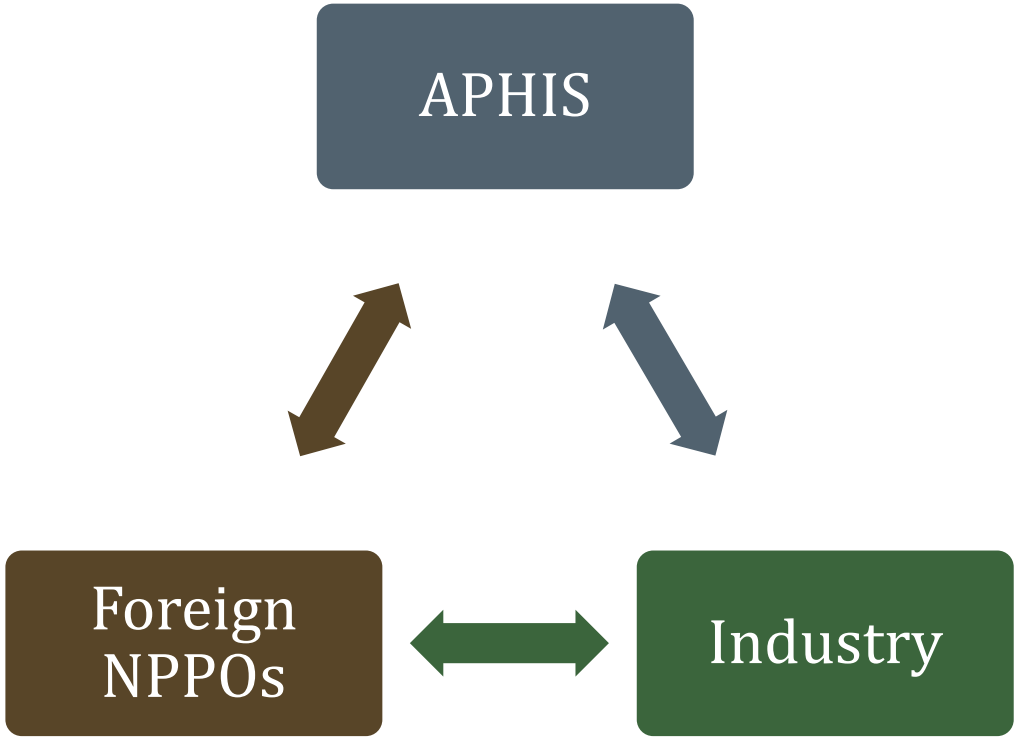
Information Needs

- Seed production practices
- Global production areas and typical movement patterns
- Pests of high concern
- Differences between small and large producers

Risk Characterization: Needed for Key Pests/Crop Species

- Pathway analysis
- Pest risk assessment of high profile crops
- Determine critical quarantine pests that follow the seed pathway
- **APHIS has started with spinach, tomato, Capsicum seed**

Collaborative Effort to Build Global System



Leading a Global Conversation

- APHIS is working with other NPPOs to establish widely accepted global seed movement system that promotes a managed risk approach
- APHIS has had initial conversations with QUADs countries (CA, AUS, NZ) and Netherlands
- **Initial discussions for a future international NPPO meeting on seeds**

Recent APHIS/Seed Industry Interactions

- NSHS PPAB (Policy and Program Advisory Board): ongoing since 2000
- NSHAPP for CGMMV: precursor to ReFreSH
- Development of ISPM 38 (2009-2017)
- APHIS/industry seed summit (2015)
- ReFreSH workshop (January 24, 2017, Orlando)
- APHIS routine participation in ASTA conventions
- Industry visit to APHIS molecular diagnostics lab (Beltsville 580 facility to explore future joint activities)
- APHIS visits to company facilities (ongoing this fall)
- Assignment of full-time APHIS national seed health coordinator (Ed Podleckis)

Next Steps

- Development of ReFreSH concept paper (draft by September 30; final in early 2018)
- Develop accreditation standard (early 2018)
- Establish pilot (September 2018)
- Longer term: new RSPM and/or ISPM on seed systems approach/accreditation(?)

Overall Strategy for Moving Forward

- Encourage NPPOs to remove pests for which seed is not a pathway from their regulatory requirements (ISPM 38)
- Encourage NPPOs to harmonize their regulatory requirements for the same pests (ISPM 38)
- Encourage NPPOs to share their seed testing methodologies to minimize testing result discrepancies
- Encourage NPPOs to use ISPM 38 guidance on seed pathway analysis and recognition of seed quality management and production practices in their PRAs (systems approach)

Summary

- The seed industry is large, diverse, and global
- The current emphasis on regulating seed shipment-by-shipment is taxing capacities of many NPPOs
- Although relatively fast and inexpensive, molecular testing methods need to be harmonized multi-laterally to minimize test result discrepancies
- International standards (ISPMs) are essential in the seed industry. RSPM 36 and ISPM 38 offer much promise to resolve fundamental seed phytosanitary problems.
- The systems approach offers much promise as an alternative to the shipment-by shipment approach for more efficiently managing phytosanitary risk in the seed industry

QUESTIONS & ANSWERS