ISPM 38 on the International Movement of Seeds – Update and Next Steps

Dennis Johnson
ISF Seed Health Manager
Bangkok, 29 June 2017
Agenda

1. Pest Risk Analysis (PRA)
2. Systems Approach Towards Phytosanitary Management
3. Seed Testing
4. Re-Exports
5. Outreach and Next Steps
Pest Risk Analysis
Pest Risk Analysis - Process

What are the pests potentially associated with the seed?

Can seed be a pathway for the introduction and spread of those pests?

No phytosanitary measures needed.
New in ISPM on seeds – seed as a pathway

Basis should be **scientific evidence.**

ISTA-annotated list - publications on seed-borne diseases. However:
• Not necessarily linked to transmission of the pathogen via the seed
• No critical review of literature cited
• Studies under experimental conditions
• No update since 1990

CABI Compendium
• Need to review references to determine if seed is a pathway

**Best resource to utilize: ISF Regulated Pest List**
### ISF Regulated Pest List – science based information about seed as a pathway

<table>
<thead>
<tr>
<th>Crop Species (9)</th>
<th>Regulated pests (no.)</th>
<th>Is seed a pathway? (in percentages)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TOTAL 666</td>
<td>Yes</td>
<td>Pathway not proven</td>
</tr>
<tr>
<td>Carrot</td>
<td>92</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Cucumber</td>
<td>90</td>
<td>4</td>
<td>9</td>
</tr>
<tr>
<td>Lettuce</td>
<td>64</td>
<td>5</td>
<td>16</td>
</tr>
<tr>
<td>Melon</td>
<td>69</td>
<td>12</td>
<td>20</td>
</tr>
<tr>
<td>Onion</td>
<td>94</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Pepper</td>
<td>107</td>
<td>8</td>
<td>17</td>
</tr>
<tr>
<td>Spinach</td>
<td>38</td>
<td>21</td>
<td>8</td>
</tr>
<tr>
<td>Squash &amp; pumpkin</td>
<td>54</td>
<td>9</td>
<td>17</td>
</tr>
<tr>
<td>Watermelon</td>
<td>58</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td><strong>Average (%)</strong></td>
<td><strong>9</strong></td>
<td><strong>13</strong></td>
<td></td>
</tr>
</tbody>
</table>

In preparation:
- Tomato
- Brassica
- Bean
- Corn

80% do not warrant to be regulated!
Stage 2 – Risk assessment

1. Pest categorisation (Q, RNQP, non-regulated)
2. Assessment of the probability of introduction and spread
3. Assessment of potential economic consequences (including environmental impacts)

• An expert judgement of information
• The amount of information available per pest will vary
• An iterative process, science-based, technical justification for decisions, transparency, consistency
• Uncertainty - documentation
Stage 3 - Pest Risk Management

NPPO decision
• Proportionate
• Zero-risk is not possible
• Required degree of protection
• Not more stringent than measures for seeds produced in the country

New in ISPM on Seeds - Risk management measures for specific types of intended use
• No planting or use in the environment – no measures may be needed
• Lab testing or destructive analysis – confinement/ destruction
• Seeds for planting under restricted conditions – phytosanitary measures relevant to the assessed pest risk
• Seeds for field planting – phytosanitary measures proportionate with assessed pest risk
Systems Approach Towards Phytosanitary Management
ISPM 14 defines a Systems Approach as two or more pest risk management measures that when combined, contribute to the effective management of the pest risk. Systems approaches provide the opportunity to consider both pre-harvest and post-harvest procedures within a Quality Management systems as pest risk mitigation measures.

Current Phytosanitary documents are mainly based on Field Inspection and Seed Health Testing only.

The advantage of a systems approach is that preventative controls or risk reduction measures are put in place during the entire seed supply chain process.

It is important to remember that appropriate risk measures within a Quality Management system differs per situation (Crop/Pest/Location).
Quantify risk reduction associated with company QM practices at each stage of seed production

*From breeding to sale*

The seed goes through a pathway which has several components. Some components introduce risk and some others are mitigation measures of that risk. Such models can estimate synergistic effects of components of a production system in reducing phytosanitary risk.
Systems Approach Towards Phytosanitary Management

A Model to estimate risk of a systems approach
As you can see there are many points along the production chain where risk can be evaluated. Some have a greater risk, than others.

The Seed Standard, “ISPM 38” references many of these:

**Pre-Planting**
- Use healthy seed; free of regulated quarantine pests, or meets the tolerance level set for regulated non-quarantined pests.
- Seed is treated; Fungicides, insecticides, nematicides, bactericides.
- Seed is sanitized; Hot water, steam, deep freeze, disinfectants, etc.
Systems Approach Towards Phytosanitary Management

Pre-Harvesting

- Hygiene measures; Disinfection of workers hands, shoes, farm equipment, tools, etc.
Systems Approach Towards Phytosanitary Management

- Field Inspections; conducted by an official NPPO representative or company representative. Testing of mother plants if symptoms occur.
Systems Approach Towards Phytosanitary Management

Harvest and Post-harvest handling

- Hygiene measures; disinfection of workers hands, tools, farm equipment, and fruit.
Systems Approach Towards Phytosanitary Management

• Timely harvest. Not too soon or too late.
Systems Approach Towards Phytosanitary Management

- Seed washing, drying, and cleaning.
Systems Approach Towards Phytosanitary Management

- Seed Purity analysis for Noxious and Restricted weeds

Using a Quality Management process to reduce risk along the Seed Supply Chain could reduce the need for additional seed testing.
Systems Approach Towards Phytosanitary Management

One of the most stringent examples of a Systems Approach in Seed Production today is the “Good Seed and Plant Practices” program used with Tomato to prevent Clavibacter michiganensis subsp. michiganensis (Cmm) infection. This process was developed by Industry.

Four Main Threats:
Water – Disinfect
People – Training & Protective Clothes
Propagation Material – Compliant
Materials & Equipment - Disinfect
Systems Approach Towards Phytosanitary Management

- Training Aides and Precautions
- State of the Art Greenhouses
Systems Approach Towards Phytosanitary Management

- Attention to detail on sanitation and registration of all personnel.
Systems Approach Towards Phytosanitary Management

• Stringent Greenhouse Sanitation and Management to reduce the risk of Cmm infection during the entire Seed Production Process.
A New APHIS Approach

Regulatory Framework for Seed Health (ReFreSH)

• Risk-, science-based systems approach
• Work within current seed trade model
• Leverage industry best practices, by using established Company Quality Management Systems.
• Promote global adoption of seed trade framework
Seed Testing
International Seed Health Initiative

• In 1993, ISF supported the establishment of a cross-industry group to address seed health issues on vegetable seeds

• They are collectively referred to as ISHI-Vegetables
  • seed companies, private laboratories and public sector institutions

• They have a **Single Goal**: to develop and validate seed health assays which enable the delivery of sufficiently healthy seeds to customers globally

• Currently 55 active scientists (plant pathologists, molecular biologists) from 11 countries

• Represents ~75% of the vegetable seed traded internationally (measured in USD)
ISHI-Veg

- The development of Seed Health tests are NON-COMPETITIVE
  - Participants share data, methods, seed sources, microbial isolates, and experience
  - They actively monitor new or emerging diseases and work to develop methods timely


- Methods may also be shared and validated with other organizations:
  - International Seed Testing Association
  - National Seed Health System (US)

- More recently, governments have adopted some of the methods as part of import requirements
  - Example, Australia has stated that the ISHI-Veg method for Pepino Mosaic Virus should be used to meet import testing declarations
## Overview of ISHI-Veg Method Types

<table>
<thead>
<tr>
<th>Assay Type</th>
<th>Presence of pathogen given</th>
<th>Pathogenicity confirmed</th>
<th>Direct or Indirect Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grow-Out</td>
<td>Yes</td>
<td>Yes</td>
<td>Direct</td>
</tr>
<tr>
<td>Bio-assay</td>
<td>Yes</td>
<td>Yes</td>
<td>Direct</td>
</tr>
<tr>
<td>Blotter/Microscopy</td>
<td>Yes</td>
<td>Yes (via bioassay)</td>
<td>Direct</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Indirect</td>
</tr>
<tr>
<td>Dilution Plating</td>
<td>Yes</td>
<td>Yes (via bioassay)</td>
<td>Direct</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>No</td>
<td>Indirect</td>
</tr>
<tr>
<td>Bio-PCR</td>
<td>Yes</td>
<td>No</td>
<td>Indirect</td>
</tr>
<tr>
<td>ELISA</td>
<td>Yes</td>
<td>No</td>
<td>Indirect</td>
</tr>
<tr>
<td>Seed or Seed Extract PCR</td>
<td>Yes</td>
<td>No</td>
<td>Indirect</td>
</tr>
</tbody>
</table>

Direct Methods permit the recovery and full characterization of the pathogen. Indirect methods do not.
Direct Methods

• These are more traditional methods: Grow out, seed plating, dilution plating

• They permit the pathogen to be confirmed: recovered, characterized by other methods such as biochemical or PCR tests, and pathogenicity shown

• Generally these are resource heavy
  • For example, Grow outs: requires greenhouses or growth rooms with specific environmental conditions, test duration is days to several weeks, technical expertise for plant evaluation, generally a low number of samples can be processed at one time
  • Due to time and resources, many researchers are pursuing indirect methods
Indirect Methods

- These are methods which provide an indication of pathogen presence as they react with proteins (antigens, nucleic acids) which are known to be indicative of the target pathogen
  - Molecular and Serological assays

- They tend to require fewer resources and technical expertise as compared with direct methods
  - For example, ELISA: Lab-based protocols, hours to a few days for results, robust assays that give consistent results across time, technicians, laboratories

- They provide *an indication*, not *confirmation*
  - They may detect 1) non-viable pathogens, 2) closely related species
Indirect Methods (2)

• Per ISPM 38, “Molecular and serological diagnostic methods are considered indirect protocols to detect pests in seeds”

• Additionally the ISF position paper on Indirect Methods states “A positive result of an indirect test should be considered as preliminary and should always be followed with a confirmatory test that is preferably a direct test”
  • Indirect methods can be very useful as pre-screens
  • Negative = no pathogen present
  • Positive= pathogen may be present, Need further evaluation

• Considering that regulatory or quality usage decisions can be made (that is, import permission, production use), results interpretation needs to be done carefully
Small Lots

• These represent a unique CHALLENGE

• Lifeline to a seed company is the continued development of new varieties/hybrids
  • These start as very small productions, potentially only a few plants
  • They are trialed at growers to ensure fit and if desired, they will then proceed to commercialization (scale up production)
  • Many questions arise on what is the best sampling model?

• ISPM 31 indicates that for small lots, the hypergeometric model should be used
  • When there are less than 2000 seeds in a lot, nearly all to all of the seeds would represent the appropriate sample size

• This is counterproductive to the seed industry! What to do?

• Needs to be a new approach
Small Lot Guidance from ISPM 38

• New ISPM 38 Guidance:
  • In such cases [that small lots are sampled], alternative sampling methodologies (e.g., clustering small samples of different lots for testing) or equivalent phytosanitary measures should be considered by the NPPO of the importing country, as per the guidance in ISPM 24.
  • In cases where sampling from small lots is not possible, specific post-entry quarantine requirements may be determined by the NPPO of the importing country.

• A new approach that considers pathogen biology and epidemiology will be very useful as it becomes clear that if only a few plants generate the initial lot, infection in one of them will lead to a population of infected seeds which will facilitate detection with a smaller sample size.
Seed Treatments

- One additional consideration to performing seed health methods is the starting material
- It is important to note that most ISHI-Veg methods have been validated on untreated seed
  - Often import or market requirements lead to imports of treated seed
  - The impact of the seed treatment should be evaluated prior to using a method on treated seed batches as it may impact method accuracy

- ISHI-Veg focuses on method development and validation
  - They also monitor method performance post industry adoption; if a method is found be insufficient, this drives method improvement
  - An example of this occurred with treated brassica seed as it was discovered that seed treatments could lead to false negatives.
  - Improvements were made and today there are 2 brassica methods for the detection of Xanthomonas
Re-exports
Re-exports – Seed Production

• Typically seeds are produced in several countries all over the world:
  • Breeding programs under specific climate conditions
  • Commercial seeds are produced in several countries because of
    • Climate conditions
    • Spread of risks
    • Timing of harvest (e.g. Northern and Southern Hemisphere to use counter season)
    • Specialised seed production (locations, expertise)
Re-exports: Handling, treatment and testing in central ‘Hub’

- Seeds produced in several countries are all shipped to (a) central location(s) to:
  - Ensure traceability
  - Centralize Quality Control on seed purity, true to type, germination and pests
  - Centralize seed treatment application like pesticides, disinfectants, physical and biological treatments

- Reasons for central location:
  - Expertise
  - Re-export to many countries of destination
  - Specialised facilities (seed processing/lab equipment)
Re-exports: Sales to many countries

- Varieties may be suitable for segments in several countries worldwide
- Several varieties are needed to cover different sowing/planting windows, climate conditions and markets requirements
- Delivery of seeds from the same seed lot over many years
Phytosanitary requirements

• Different phytosanitary requirements by several countries
• Some examples of required declarations for PSTVd, tomato seeds

Conclusion
Different additional declarations:
• Area / production place free
• Field inspection
• Treatment
• Tested
• Free from

Different wordings
Sometimes more than one requirement
Sometimes multiple options
Phytosanitary requirements to be fulfilled by the NPPO of the country of seed production

• Based on analysis: request vendor in production country to provide all needed ADs for all relevant re-export countries
• (Official) field inspection needs to be organised in time
• Not always clear to the NPPO of production country why there is a need to declare ADs for all pathogens that are for re-export purpose

→ ISPM 38 encourages NPPO’s to exchange additional declarations for the sake of re-export:

NPPOs are encouraged to exchange additional official phytosanitary information at the time of export certification with other NPPOs to enable certification for re-export of seeds, as described in ISPM 12 (Phytosanitary certificates). Additional official phytosanitary information, which is not required by the first country of import, may be included on the phytosanitary certificate issued by the country of origin when so requested by the exporter in order to facilitate future re-export to other countries (ISPM 12).
Hurdles to comply with phytosanitary requirements

- Several phytosanitary requirements are hard or even not possible to comply with:

- Additional declarations on PC in country of production:
  - Countries of final destination are not always known at time of seed production
  - Requirements may change over time
  - Seeds may be stored for several years (which is not possible to anticipate)
  - ADs by NPPO country of production cannot be obtained afterwards

- Testing in country of re-export:
  - Validated tests not always available
  - Number of seeds for test may be hurdle (e.g. small seed lots)

- Seed treatment:
  - Active ingredient may not be registered in country of re-export
  - For organic seeds, chemical treatment is not possible

- Physical treatment:
  - May negatively affect the quality of seeds
Relevance of equivalent phytosanitary measures

- ISPM 38 gives guidance on importance for equivalent measures:
  - ISPM 38 emphasizes importance of equivalent measures for seeds:

  The equivalence of phytosanitary measures (ISPM 1 (Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade)) is particularly important for the international movement of seeds as seed companies may have breeding and multiplication programmes in several countries and may export these seeds to other countries, and there may be frequent re-export from a single seed lot.

- NPPOs are encouraged to provide multiple options:

  Determination of the equivalence of phytosanitary measures may be initiated by the exporting country making a request for equivalence to the importing country, as described in ISPM 24 (Guidelines for the determination and recognition of equivalence of phytosanitary measures). It may also be initiated by the importing country. NPPOs are encouraged to provide multiple options when setting phytosanitary import requirements.

- Example of a substitution of field inspection by testing or treatment:

  Equivalent phytosanitary measures may provide NPPOs with options to achieve the required protection. An example of an equivalent phytosanitary measure is the substitution of a requirement for field inspection of the seed crop in the country of origin with appropriate seed testing or seed treatment for the regulated pest. ISPM 24 provides further guidance on the equivalence of phytosanitary measures.
Outreach and Next Steps
Outreach

• ISF Outreach messaging to the NSAs and the Seed Industry
  • Raise awareness
  • Become familiar with ISPM 38 as well as the other ISPMs
    • Download and read the ISF ISPM 38 Training Manual
    • Attend workshops
  • Partner with ISF to create regional workshops
  • Align ISPM 38 with your national procedures and regulations to identify gaps
  • Develop proposals to address those gaps and support your NPPOs implementation of ISPM 38
Preparation of Outreach Proposal

• Need to provide technical justification for proposed changes to the requirements
  • For example, include references from the ISF Regulated Pest List to justify de-regulation of a pest for which seed is not a pathway
• Refer to specific sections within the ISPMs for justification
• Partner with ISF to make recommendations on:
  • equivalent measures to be proposed to NPPOs
  • integrated pest management practices as a phytosanitary measure
  • proportional measures based on purpose of import
Outreach means collaboration with NPPOs

NPPO role: protecting a country from unwanted pests.
Seed company role: supply healthy seeds and satisfy customer needs
Seeds = only one of many plant-related commodities for a NPPO
Seed companies have very specific know-how and experience
Outreach starts with a technical discussion about why:
  a pest needs or does not need to be regulated,
or can be regulated differently,
or can be managed differently etc.
ISPM 38 and industry outreach

• Options for outreach towards science based and feasible requirements:
  • Exclude pests where seed is not a pathway from regulated lists for seeds
  • Proportional requirements for seeds not intended for uncontrolled planting
  • Practical (and uniform) sampling and testing protocols
  • Use of integrated pest management practices as phytosanitary measure
    • These may include pest resistance and seed treatments/disinfections
  • Equivalent measures to accommodate technical options of country of origin
    • E.g. area freedom, or field inspection or sampling and laboratory testing
  • Facilitate requests for Additional Official Phytosanitary Information for re-export
Outreach: use ISF resources

• ISHI protocols for seed health testing
• ISF Disease resistance definitions, pathogen codes and differential hosts
• ISF paper on testing of treated seeds for seed health
• ISF Regulated pest list
• Exchange best practices in phytosanitary requirements and measures
Seed is Life