NAPPO
North American Plant Protection Organization
Organización Norteamericana de Protección a las Plantas
MEXICO - USA - CANADA

Proceedings

"Americas focused"

International Standard for Phytosanitary Measures (ISPM) 38:

International Movement of Seeds

Implementation Workshop

San José, Costa Rica

March 5-7, 2019

Photo courtesy of Ignacio Baez (USDA-APHIS-PPQ)

Table of Contents

Preface

Stephanie Bloem

Executive Director
North American Plant Protection Organization (NAPPO)

The "Americas focused" International Standard for Phytosanitary Measures (ISPM) 38: *International Movement of Seeds* Implementation Workshop – was extremely successful because of teamwork!

A dedicated group of government and industry seed subject matter experts, working on behalf of the North American Plant Protection Organization, designed the content of the workshop that was held at the headquarters of the Inter-American Institute for Cooperation in Agriculture (IICA) in San José, Costa Rica in early March, 2019. For information, the final workshop Agenda is included as *Appendix 1* to these Proceedings. The NAPPO Secretariat was responsible for organizing the logistics for the workshop in collaboration with IICA and we gratefully acknowledge their cooperation.

Supplementary funding to cover workshop expenditures was generously provided by two groups within the USDA-APHIS: the International Phytosanitary Standards (IPS) group which is part of Plant Protection and Quarantine, and the International Technical and Regulatory Capacity Building (ITRCB) group; and by our seed industry partners, including the Canadian Seed Trade Association (CSTA), the American Seed Trade Association (ASTA), and the Asociación Mexicana de Semilleros (AMSAC).

The workshop lecturers and discussion leaders included plant health regulatory officials, and representatives from industry and academia from five countries in the Americas (Canada, United States, Mexico, Argentina and Uruguay) and one country in Europe (Switzerland).

The fifty-three workshop participants represented the National Plant Protection Organizations (NPPOs) of 13 countries in the Americas (Argentina, Bolivia, Brazil, Canada, Costa Rica, El Salvador, Guatemala, Honduras, Jamaica, México, Nicaragua, Perú, United States); four Regional Plant Protection Organizations (Comunidad Andina [CAN], Comité de Sanidad Vegetal del Cono Sur [COSAVE], Organismo Internacional Regional de Sanidad Agropecuaria [OIRSA] and NAPPO); the International Seed Federation (ISF); six regional and national seed associations (Seed Association of the Americas [SAA], CSTA, ASTA, AMSAC, Asociación Ecuatoriana de Semillas [ECUASEM], and APISEMILLAS Perú); seven seed industry-related companies (Bayer Crop Science, Semillas Basso SA, Rijk Zwaan Mexico and the Netherlands, Corteva Agriscience, VoloAgri, Germains Seed Technology Inc. and HM Clause); and two members from academia (Universidad Nacional Agraria La Molina in Perú and Iowa State University in the United States).

The participants unanimously endorsed the statement below on full implementation of ISPM 38, agreed and took action on tangible next steps towards implementation, and prepared a realistic list of medium-term and long-term next steps.

"Complete and successful implementation of ISPM 38 means that …

Seed is moved between countries

- With managed risk
- With technically justified and predictable phytosanitary requirements, and
- Without undue phytosanitary restrictions and delays."

Action items identified include the development of "common terminology" to effectively communicate between regulatory officials and seed industry partners, two-way sharing of information including seed production systems and processes, diagnostic validation protocols, successful examples of systems approaches around the world, relevant regulations for seeds, pest interception records, etc. To this end, two ad-hoc groups were formed to initiate the work on terminology and information gathering.

This extremely successful implementation workshop complements the efforts of the Secretariat of the International Plant Protection Convention (IPPC) towards implementation of ISPM 38 during the 2018 IPPC Regional workshops using training materials developed by the ISF. Other seed summits and meetings – in Australia, Europe, Mexico, Uruguay and Argentina – also underscore the global interest in implementing this standard for the safe global movement of seeds.

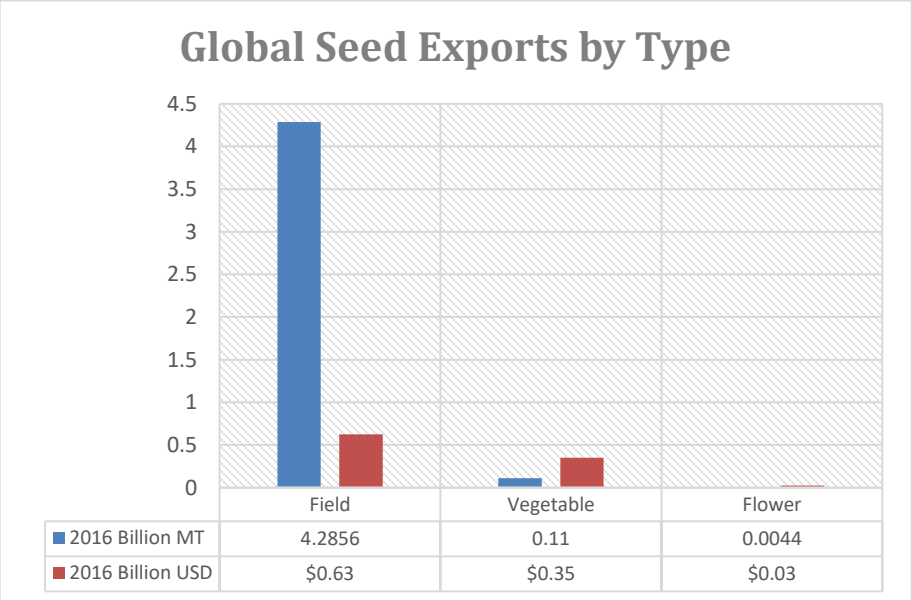
Overview of the Global Seed Industry

Ric Dunkle

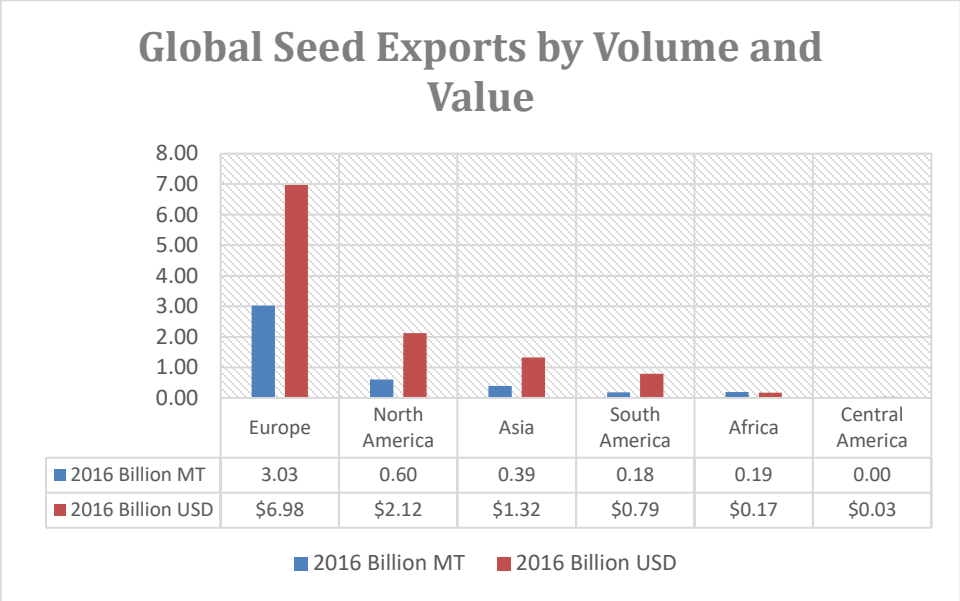
Senior Director, Seed Health and Trade
American Seed Trade Association

The seed industry is a global enterprise. On an annual basis, nearly 5 billion metric tons (MT) of seed (valued at nearly $11 billion USD) are imported, and over 4.4 billion MT (valued at 11.4 billion USD) are exported throughout the world (International Seed Federation (ISF) 2016 data).

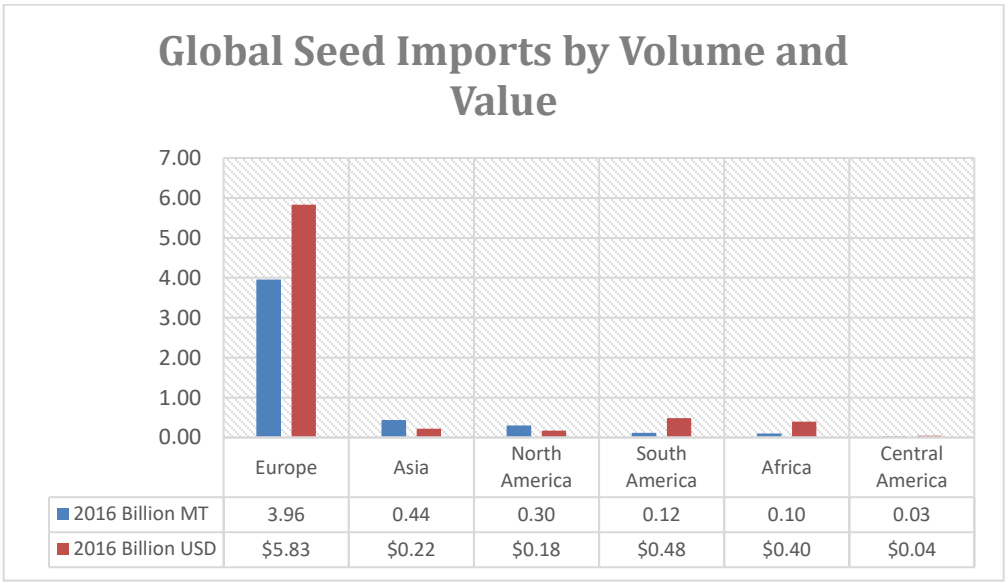
Vegetable seed represents 2.5 percent by weight and 34.9 percent by value; flower seed (seeds of herbaceous and non-herbaceous plants cultivated mainly for flowers) 0.1 percent by weight and 2.5 percent by value, and field seed (seeds from pulses, cereals, industrial crops and forages) represents 97.4 percent by weight and 62.6 percent by value.



On a continental basis, Europe is the most significant exporter of seed (68.8 percent MT; 61.2 percent total value) followed by North America (13.7; 18.6), Asia (8.9; 11.6), South America (4.2; 6.9), Africa (4.4; 1.5), and Central America/Caribbean (0.1; 0.3).



Regarding seed imports, Europe is the largest importer (79.1 percent MT; 53.0 percent total value), followed by Asia (8.7; 2.0), North America (6.0; 1.6), South America (2.4; 4.4), Africa (2.0; 3.6), and Central America/Caribbean (0.5; 0.4).



Major seed exporting countries include the United States, France, Italy, the Netherlands, Canada, Mexico, Argentina, Brazil, and Chile. Major seed importing countries include Belgium, Italy, the Netherlands, United States, Mexico, Canada, Argentina, Brazil, and Chile. The overall higher values for Europe can be attributed to the significant amount of seed moved among countries in the EU. For countries having

provinces and states such as Canada, Mexico, the United States, and many countries in South America, interstate/provincial seed movements are not captured in the ISF database.

Compared to most other agricultural commodities, managing phytosanitary risks associated with international movement of seed poses several unique challenges.

- Seed is diverse. Over 300 different seed species are moved internationally and each species has its own specific phytosanitary issues.
- Seed is routinely moved several times pre-commercially (small lots of seed for use in research and breeding programs, seed used in small trials, parental lines used for hybrid seed production, foundation seed). Often these consignments are treated similarly as large commercial lots that require import permits and phytosanitary certification.
- Pre-commercial seed lots are usually of very high value to seed companies as they represent high investments in technology, for example in genetics (for pest and disease resistance, drought tolerance, consumer traits), seed coatings and primer technologies, and in seed treatment technology.
- Most seed companies attempt to move their seed consignments on a "just in time" basis which necessitates avoidance of any unnecessary delays in the clearance processes at ports of entry (POEs).
- Practices used in the industry to produce seed to meet consumer demands for high quality and performance often significantly reduce, if not eliminate, phytosanitary risk for many seed species.

There are several trends occurring in the seed industry worldwide that affect the ability of NPPOs to manage phytosanitary risks without significantly impacting seed trade.

- For the past several years the seed industry has been undergoing consolidation, resulting in fewer but much larger companies, many of which are now international and have operations and facilities in numerous countries.
- Many markets are expanding, and more and larger seed production operations are moving to additional countries.
- Similarly, plant breeding programs are becoming more diverse and expanding into more countries where future markets are being explored and developed resulting in companies moving seed among many countries.
- Seed re-export has become a common business practice used to move seed many times pre-commercially around the world.
- With all the investments in technology, the overall value of seed continues to increase. For example, seed of some tomato varieties used in greenhouse culture is now worth up to $2.00 USD per seed.
- Systems for production of quality seed, which include development of seed that are free from pests and pathogens, are becoming much more sophisticated.
- In addition, the organic sector, which is rapidly increasing worldwide, poses new challenges for the international movement of organic seed as they cannot be treated with conventional chemical materials that, if used, would nullify their organic certifications.

The seed industry is well organized at national, regional, and international levels. Nearly all countries with a significant seed industry have a national seed association (NSA) whose responsibility is to develop and maintain an effective relationship with its respective NPPO. At the regional level there are several regional

seed associations (RSAs) that coordinate seed phytosanitary and other important issues among NSAs in their region. At the international level the International Seed Federation (ISF) coordinates activities of NSAs and RSAs. Each of these associations has its own structure of committees and working groups and annual meetings/congresses that bring together representatives to address phytosanitary and other important seed issues and to coordinate seed-related activities.

ISF as well as several RSAs participate in activities and meetings of the International Plant Protection Convention (IPPC) as NGO observers; NSA representatives can attend IPPC meetings as observers as members of ISF or RSA delegations, For example, they can attend the annual meeting of the Commission on Phytosanitary Measures (CPM) which is the governing body of the IPPC represented by all 183 contracting parties (countries) that are signatories to the Convention. Interactions of these various associations with NPPOs and RPPOs facilitates the development of regional and international standards that reflect the issues, needs, and concerns of the global seed industry.

It is very important that the global framework for managing phytosanitary security associated with the international movement of seed be predictable and, to the largest extent possible, harmonized. Factors that often disrupt international seed movements include rapidly increasing, often unharmonized, phytosanitary import requirements issued by countries; inability to use chemical phytosanitary treatment materials for seeds; problems with movement of small seed lots (breeder and foundation seed lots); increased seed health testing requirements at POEs for consignments that have already been tested by the NPPO of the country of origin; increased reliance on indirect molecular-based seed testing methods (PCR, etc.) that are often sensitive at levels that may not be biologically relevant; delays in clearing shipments at POEs, and the practice by some importing country NPPOs of using harmful organism lists to identify pests for testing at the POE for which additional declarations are not technically justified. This last practice prevents phytosanitary certification by exporting country NPPOs.

Uniform interpretation of, and adherence to, ISPM 38 by NPPOs should significantly lessen the impediments to the safe and predictable international movements of seeds. More uniform interpretation of conditions under which seed can be a pathway for introduction and spread of regulated pests by NPPOs will eliminate unnecessary regulation of many pests on seed. The development, international validation, and use of improved molecular methods and more uniform interpretation of results will significantly reduce the discrepancies in test results among exporting and importing NPPOs and thereby reduce the numbers of rejected seed shipments. ISPM 38 also provides guidance for NPPOs to use systems approaches in their pest risk assessment and other phytosanitary decision-making activities. A clearer understanding of the extent to which industry seed quality production and management practices reduce phytosanitary risk will allow NPPOs and seed companies to focus on how best to manage any remaining phytosanitary risk of significance. In the future it may be possible to design an alternative approach to consignment-by-consignment phytosanitary certification that is instead based largely on multilateral recognition of seed company quality management (QM) production and management practices by NPPOs.

Overview of the Seed Industry in the Americas

Maria Inés Ares

Seed Phytosanitary Advisor
Seed Association of the Americas

The seed industry in the Americas is represented by the Seed Association of the Americas (SAA) which was created in 2005 as a non-governmental organization. SAA fosters and promotes dialogue between public and private sectors in the region to develop harmonized regulations that promote the continued growth of the seed industry and adoption of new technologies. SAA has four technical working groups, among them a phytosanitary working group.

The SAA holds a Congress every two years. The Congress includes a phytosanitary session and in 2008 and 2010 the Congress also included phytosanitary workshops. SAA is an observer of the Commission on Phytosanitary Measures (CPM) of the International Plant Protection Convention (IPPC) and has participated in Regional Plant Protection Organization (RPPO) meetings in the region (NAPPO, COSAVE).

Seed trade in the Americas is characterized by companies with facilities and operations in different countries that produce seed counter-seasonally in both northern and southern hemispheres to meet the ever-increasing demand for seed. When seed moves between countries in the region it must comply with each country's phytosanitary requirements with respect to volumes, intended use (e.g., research, analysis), and seed categories (e.g., small lots of seed for use in research and breeding programs, seed used in small trials, parental lines used for hybrid seed production, foundation seed, etc.).

Harmonized and predictable regulatory systems would allow seed companies operating in multiple countries in the region to seamlessly meet the phytosanitary requirements of each country. The most frequent phytosanitary problems experienced by industry in relation to phytosanitary requirements include the pest risk assessment process and official communications among trading partners. The strong working relationships between private and public organizations at the national (between NSAs and NPPOs) and regional levels (between SAA and RPPOs) suggest that the Americas can play a leading role in developing implementation guidance for ISPM 38.

SAA invites workshop participants to attend its 7th Congress that will be held in Buenos Aires, Argentina from September 10 to 12, 2019.

Overview of ISPM 38: International Movement of Seeds

Edward Podleckis

Senior Risk Manager
USDA-APHIS Plant Protection and Quarantine

This presentation provides a brief overview of the components of International Standard for Phytosanitary Measures (ISPM) 38: *International Movement of Seeds*. It does not go into detail on each component of ISPM 38, but it does note several elements that are particularly significant.

From start to adoption, ISPM 38 took about eight years to develop. Work began in 2009 when the topic was introduced to the IPPC Standards Committee (SC). By 2011, the specification for the standard was approved and two years later the Expert Working Group (EWG) was assembled and met in the Netherlands to write the draft standard. After a series of country consultations and revisions, the standard was adopted in April 2017.

One of the first things the EWG drafting ISPM 38 made very clear is that this international standard applies to botanical seeds but not to grain or vegetative plant parts like seed potatoes. It does, however, apply to

viable seeds, whether they are a sample of a seed lot, imported for laboratory testing or imported for destructive analysis. ISPM 38 provides guidance to national plant protection organizations (NPPOs) on:

- Identifying, assessing and managing potential pest risks associated with the international movement of seeds;
- Establishing phytosanitary requirements for seed importation;
- Inspection, sampling and testing seeds; and
- Phytosanitary certification of seeds for export or re-export.

These are the nine sections of ISPM 38:

- Introduction
- Background
- Pest risk analysis
- Phytosanitary measures
- Equivalence
- Specific requirements
- Phytosanitary certification
- Record keeping
- Appendices.

The **introduction** describes the scope of the standard as described above. The introduction also contains the definitions of seed-borne and seed-transmitted pests. No definitions for these terms exist in the IPPC's ISPM 5: *The Glossary of Phytosanitary Terms* and the EWG felt it was necessary to develop these definitions for the standard. This is one of the standard's key features. ISPM 38 defines a seed-borne pest as "A pest carried by seeds externally or internally that may or may not be transmitted to plants growing from these seeds and cause their infestation." A seed-transmitted pest is a subset of seed-borne pests where the pest is transmitted via seeds directly to plants growing from these seeds and causes their infestation. The standard goes further and describes several categories of seed-borne pests:

Category	Description
1a	Seed-transmitted pests carried internally or externally that directly infest host plant **Example:** *Clavibacter michiganensis*
1b	Non-seed-transmitted pests carried by the seed internally or externally, are transferred to the environment (e.g., water, soil) and then infest hosts **Example:** *Fusarium*; usually involves the contamination of the seed coat with spores that are splashed or blown about within fields, germinate and resulting hyphae infect the host.
1c	Carried internally or externally, that do not transfer to a host **Example:** Rice yellow mottle virus
2	Though not seed-borne, contaminating pests may be relevant **Example:** Weed seeds (*Cyperus*); *Scerotinia sclerotia* in soybean

The **background** section discusses the nature of international seed trade and some of the challenges it presents. The next section focuses on **Pest Risk Analysis** and the factors that should be considered in analyzing the potential pest risk of seed movements. This includes seeds as pest, or in other words, weeds;

seeds as pathways for introducing pests; the purpose of import or intended use; mixing of seeds and the potential for seed production practices to mitigate pest risk.

The **Pest Risk Analysis** (PRA) section of ISPM 38 also emphasizes the role of PRA in establishing whether seed is a pathway for any given pest. To that end the standard points out several considerations in conducting seed PRAs:

- Seed transmission reports under artificial conditions should be confirmed under natural conditions;
- Seed-transmission in one host does not mean seed transmission in all hosts; and
- Biological and epidemiological characteristics of specific pest groups can provide guidance on the likelihood of seed transmission (see Appendix 2 below).

In this section, ISPM 38 makes note of the potential for taking into account the role that production practices and normal industry practices can have in mitigating pest risk: "Certain practices used in seed production may alone or in combination be sufficient to meet phytosanitary import requirements."

The next section of the standard describes the range of **phytosanitary measures** available to NPPOs ranging from inspection to prohibition and options in between. As one of those options, ISPM 38 supports the use of systems approaches to manage pest risk in the movement of seeds: "Phytosanitary measures may be included in integrated pest management and quality control protocols applied in seed production … Many pest management practices to reduce pest risk throughout the seed production process, from planting to harvesting, may be integrated in a systems approach."

The following section of ISPM 38 discusses the WTO-SPS principle of **equivalence of measures**. For example, a country's phytosanitary import requirement for a field inspection may not be known at the time of production. Where appropriate, the NPPO of the importing country may consider equivalent phytosanitary measures (such as tests or treatments) to fulfil its phytosanitary import requirements for seeds already harvested. However, it is the responsibility of the exporting country to meet phytosanitary import requirements.

The **specific requirements** section provides guidance on inspection, sampling and testing of seeds for phytosanitary certification. The last two sections of the body of the standard cover phytosanitary certification and record keeping. The **phytosanitary certification** section focuses on two things in particular: the additional official phytosanitary information provided on a Phytosanitary Certificate (PC) and country of origin and how they relate to the nature of global seed trade. NPPOs are encouraged to exchange additional official phytosanitary information at the time of export certification. Information which is not required by the first country of import may be included on the PC issued by the country of origin, when so requested by the exporter, in order to facilitate future re-export to other countries.

There are three appendices to ISPM 38. Appendix 1: *Examples of seed-transmitted, seed-borne and contaminating pests* provides examples of each of the different seed-borne pest categories described above. Appendix 2: *Guidance on the likelihood of pest groups being carried and introduced with seeds* provides characteristics of various classes of pests and how those characteristics can impact the seed-borne potential for those pests. The third and final appendix is the bibliography.

In summary, ISPM 38 provides a broad range of guidance on various aspects of managing seed pest risks and regulating the international movement of seeds. ISPM 38 contains several key features including creating new definitions for seed-borne and seed-transmitted pests; the emphasis on PRA to establish

seed as a pathway; recognition of the risk reduction potential of seed production practices; and support for the use of systems approaches to reduce risk of international seed movement.

Seeds as Pests and as Pathways for Pests

Marina Gutiérrez Olivares

Pest Risk Analyst
Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)

This presentation briefly discusses the elements used in Pest Risk Analysis (PRA) for the evaluation of seeds as pests and as pathways for pests. Before initiating a PRA, the following should be considered:

- Seeds are the main propagative method for plants; they carry the plant's genetic variability and food security depends on availability of seeds. However, some plants developing from seeds can behave like weeds and even as invasive species.

As stated in ISPM 2: *Guidelines for Pest Risk Analysis*, a PRA has three stages: initiation, risk assessment and pest management. A PRA for seeds usually starts with the identification of a pathway.

In Mexico, a PRA for seeds not previously imported begins with a series of questions to determine if the seed behaves like a weed and/or invasive species. If so, the PRA process ends and the import request is rejected. If the seed to be imported does not behave like a weed, the PRA process continues.

Once the PRA is initiated, pests related to seeds and the category for each pest are determined, as per guidance available in ISPM 38:

- Category 1a: Seed transmitted pests that are carried by the seed internally or externally and directly infest the host plant growing from the seed.
- Category 1b: Non-seed transmitted pests that are carried by the seed internally or externally and are transferred to the environment and then infest a host plant under natural conditions.
- Category 1c: Pests carried by the seed, internally or externally, that do not transfer to a host plant under natural conditions.
- Category 2: Contaminating pests, present in seed lots, including the plant seeds as pests (weed).

Only pests in categories 1a, 1b and 2 are considered in the pest risk assessment and pest risk management processes which are described in ISPM 11: *Pest Risk Analysis for Quarantine Pests*.

In Mexico, risk communication is done via public comments for phytosanitary requirements (MCRFI) - http://sistemas.senasica.gob.mx/mcrfi/

Intended Use as a Risk Factor

Natalia Fernandez Eraso

Seed Regulatory and CP Manager for Latin/South America

Bayer Crop Science

Intended use of the seed should be addressed, along with other variables, during the Pest Risk Analysis process. Particularly, for the movement of seed, intended use has a direct relationship with the risk of spreading a pest.

ISPM 2 defines the framework for Pest Risk Analysis, and particularly states that the process for pest risk assessment (Stage 2) can be broadly divided into three interrelated steps:

- Pest categorization (quarantine pest, regulated non quarantine pest, non-regulated);
- Assessment of the probability of introduction (entry and establishment) and spread;
- Assessment of potential economic consequences (including environmental impacts) of introduction and spread.

The probability of pest introduction and spread is directly related to the *intended use*. As stated in ISPM 38, the production of seeds typically involves several steps which may be performed in different countries. Movement/import of seed for different purposes like breeding, multiplication, destructive analysis, restricted field planting, and others will result in different quantities of seed being moved and different exposures of the seed to the environment. It follows that the purpose or intended use of imported seeds may impact the probability of establishment of quarantine pests and should be considered when conducting the PRA and determining phytosanitary measures.

The Seed Association of the Americas (SAA) developed a technical paper in 2016 entitled “International Movement of Small Lots of Seed” that addresses the above-mentioned concepts.

The purpose or intended use of imported seed may be broadly ranked from lowest to highest pest risk as follows:

- Seeds for laboratory testing or destructive analysis (lowest risk);
- Seeds for planting under restricted conditions (intermediate risk);
- Seeds for field planting (highest risk).

Seed for Laboratory Testing: A PRA may not be necessary when moving seeds for laboratory testing or destructive analysis, since no seed release into the environment will take place. The establishment of official requirements for laboratory testing, confinement, and destruction of the seeds and plants should be sufficient as a phytosanitary measure. The NPPO of the importing country should not require additional phytosanitary measures for these seeds if the pest risk is considered low or negligible.

Seed held in Restricted Conditions: Some seeds are imported for research and are grown in protected environments (e.g., glasshouses, growth chambers) or in isolated fields. Those conditions prevent the introduction of quarantine pests into the PRA area. Examples of these types of movement are seeds for evaluation, germplasm development, and seeds as breeding material. Under these scenarios, NPPOs may require phytosanitary measures which should not be more stringent than needed to address the pest risk identified. Usually the seed being moved for these purposes is very expensive, unique, and in small seed lots. During the NAPPO workshop an example of tomato seed germplasm development in Chile and Argentina was shared.

Seeds for field planting: If the seed is moved for unrestricted release into the PRA area it may present higher pest risk for introduction of quarantine pests. In this scenario the NPPO of the importing country may require phytosanitary measures which should be proportionate to the assessed pest risk.

Most NPPOs of countries in the Americas do not currently consider intended use or the purpose of imported seed when determining their phytosanitary measures. There would be several advantages in considering the intended use or purpose of import as a risk factor for imported seed when establishing phytosanitary requirements. These include:

- Being able to define phytosanitary requirements by purpose of import; of specific importance to experimental seed and small seed lots;
- Simplifying seed movement;
- Promoting germplasm development programs (suitable for the region);
- Cost savings (testing + destruction of high value seed);
- Optimizing the use of public and private resources (NPPOs and industry);
- Improving import times, without endangering the sowing windows;
- Increasing the transparency and predictability of seed imports.

Pest Listing

José Ulises García Romero

Coordinator for Pest Risk Analysis
Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)

This presentation describes the criteria used by the NPPO in Mexico to decide which organisms should be included in a regulated pest list, as well as description of other lists resulting from a Pest Risk Analysis.

The IPPC indicates that contracting parties should establish and update **regulated pest lists,** to the extent possible, which include scientific names of organisms and, if requested, to make those lists available to the Secretary of the IPPC, the RPPO to which the country belongs, and to other contracting parties. ISPM 5: *The Glossary of Phytosanitary Terms* does not define "regulated pest list," therefore there are no standardized criteria for its development. However, ISPM 5 does define "quarantine pest" and "regulated non-quarantine pest." Based on these definitions, the NPPO in Mexico has developed criteria for including organisms in its regulated pest list.

- **Criterion 1:** Organisms included in the regulated pest list must be subject to regulation by the NPPO of Mexico (e.g., import requirements, Official Mexican Regulations, workplans), and there must be corresponding technical support to categorize them as quarantine pests or regulated non-quarantine pests.

- **Criterion 2:** Organisms considered for inclusion in the regulated pest list must be identified to at least the species level. Pests at the genus level are not considered for inclusion.

- **Criterion 3:** Each of the organisms must be characterized and validated in terms of presence or absence in Mexico in accordance to ISPM 8: *Determination of Pest Status in an Area*. Documented proof of economic consequences in other countries must exist.

- **Criterion 4:** Information for pests included in the Mexican Official Standard related to foreign quarantine must be validated and updated.

The technical and scientific evaluation of a pest supports the determination of its regulatory status. Therefore, this information must be sufficient to re-categorize a pest and its inclusion or exclusion from the regulated pest list.

Several other pest lists used by the NPPO of Mexico are based on PRA activities. These include development of a database for pests recorded as present in Mexico, development of a database for regulated pests for Mexico, and development of a database of regulated pests by country.

Determining Pest Risk

Nancy K. Osterbauer

Assistant Director Plant Epidemiology and Risk Analysis Laboratory (PERAL)
USDA-APHIS-PPQ-ST

Seed pests pose unique challenges for risk analysts and plant health regulators. Uncertainty is often high for these pests because of lack of information, contradictory evidence, different behavior on different hosts, and other factors. Another challenge is the global nature of seed production. Seed producers take advantage of growing seasons in different parts of the world to more quickly bring new cultivars to market. As a result, seed may be grown in multiple countries, all with different pest threats, prior to importation.

To address these challenges, the United States Department of Agriculture (USDA) conducts global seed pest risk assessments. We identify all pests that follow the seed pathway for a specific host species, determine which are quarantine pests for the United States, and then assess the unmitigated risk associated with those pests. We use these global risk assessments to inform the Regulatory Framework for Seed Health (ReFreSH), a systems-based approach to mitigating pest risk via the seed pathway.

Our seed pest risk assessments are based on four international standards: ISPM 2: *Framework for pest risk analysis* (IPPC, 2007); ISPM 11: *Pest risk analysis for quarantine pests* (IPPC, 2013); ISPM 21: *Pest risk analysis for regulated, non-quarantine pests* (IPPC, 2004); and, ISPM 38: *International movement of seed* (IPPC, 2017). ISPM 38 provides guidance for identifying seed pests that should be subjected to risk analysis. Once seed is verified as a pathway for a pest, the analyst assesses the risk that pest poses. The risk analyst considers: 1) what is the likelihood of introduction for the pest; 2) what are the consequences of its introduction; and, 3) how confident is the analyst in the available information? The final risk rating reflects all of those factors.

The analyst's first task is to determine what is at risk should the pest be introduced to a new area. Per ISPM 2, an "endangered area" is an area where ecological factors favor the establishment of a pest whose presence in the area will result in economically important loss (IPPC, 2007). Thus, for the new area to be endangered, the climate must be suitable for the pest to survive. Host plants must also be present, and

those hosts must be economically or environmentally important. The analyst also considers the damage the pest causes on the hosts and the ways the pest may spread in the area. The assessment continues only if the analyst determines that an endangered area exists.

Next, the analyst determines the likelihood the pest could be introduced to the endangered area. The likelihood of introduction is based on both the likelihood of entry and the likelihood of establishment for the pest. To evaluate the likelihood of entry, the analyst assigns an initial risk rating that is based on the pest's seed contamination or transmission rate. This rating may then be adjusted based on post-harvest practices, such as seed treatments, and on shipping and transport conditions, such as refrigeration.

Determining the likelihood of establishment is more straightforward. For a pest that is transmitted by seed, potential establishment is always a risk because the pest is being introduced with its host into an area where the host, and presumably the pest, can grow. Once the likelihoods of entry and establishment are combined, the resulting likelihood of introduction for a seed-transmitted pest often exceeds our acceptable level of risk.

If the risk of introduction has been determined to be unacceptable, the potential consequences, should the pest be introduced, must be identified. The analyst identifies potential direct impacts, such as damage to hosts, yield losses, and increased production costs for farmers, and considers indirect impacts, such as effects on trade. If the pest can cause unacceptable direct or indirect impacts in the endangered area, then the analyst identifies it as a candidate for risk mitigation. Identifying pest risk mitigation measures is the final stage of pest risk analysis. In the United States, those mitigation measures are part of the ReFreSH systems-based approach to mitigating pest risk.

IPPC. 2004. Pest risk analysis for regulated non-quarantine pests (International Standard for Phytosanitary Measures 21). Sect. of the International Plant Protection Convention (IPPC), Rome, Italy. 22 pp.
IPPC. 2007. Framework for pest risk analysis (International Standard for Phytosanitary Measures 2). Sect. of the International Plant Protection Convention (IPPC), Rome, Italy. 20 pp.
IPPC. 2013. Pest risk analysis for quarantine pests (International Standard for Phytosanitary Measures 11). Sect. of the International Plant Protection Convention (IPPC), Rome , Italy. 40 pp.
IPPC. 2017. International movement of seeds (International Standard for Phytosanitary Measures 38). Sect. of the International Plant Protection Convention (IPPC), Rome, Italy. 22 pp.

Opportunities for PRA Harmonization

Patricia McAllister

Acting Director, Plant Production Division
Canadian Food Inspection Agency (CFIA)

Definitions of "opportunity" and "harmonization" suggest that the ISPM 38 workshop is the perfect occasion to bring together like-minded countries to work together toward a common goal of reducing the risk associated with the seed pathway. Seed trade has grown exponentially since the late 1980's and is a global industry. Seed can be produced, processed and packaged in multiple countries before reaching its final market.

Harmonization is currently limited by the diversity of import requirements in different countries, but countries are now coming together to discuss opportunities in this area. A good starting point would be

a discussion of elements such as disease, insects, soil, weed seeds, other contaminants, etc., which could lead to opportunities related to Pest Risk Analysis through the sharing of pest lists and information when new pests are associated with the seed pathway.

In working together, we can share resources and expertise and facilitate re-export of seed. Additional opportunities exist in the establishment of common phytosanitary import requirements between like-minded countries and recognition and/or sharing of testing results.

Challenges for PRA Harmonization

Maria Elena Gatti

Coordinadora
Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA)

The objective of this presentation was to highlight/explain the work of the Technical Group on Plant Quarantine within the Comité de Sanidad Vegetal del Cono Sur (COSAVE) concerning the harmonization of phytosanitary import requirements for regulated articles, specifically for seeds, for COSAVE member countries.

The Technical Group considers the guidance provided by international standards (ISPMs) as well as by COSAVE regional standards (RSPMs) when establishing a regulated plant pest list for the COSAVE region and harmonized phytosanitary requirements for regulated articles.

Procedures used by COSAVE to achieve these objectives were discussed, as were use of the COSAVE guidelines for pathway PRAs to identify quarantine pests that can move in the seed pathway, and for selection of appropriate risk management measures.

The work by COSAVE has helped countries in the region to harmonize the criteria for identifying pests associated with seed and for the strength of measures to be used. It has also strengthened the relationship that NPPOs have with industry. However, full implementation of ISPM 38 will require continued work towards validation of laboratory diagnostic techniques for pests, sampling for small seed lots, use of systems approaches as alternatives to single measure risk management, post-entry quarantine, and other phytosanitary measures.

Identifying Emerging Pest Risks and Pest Categorization

José Ulises García Romero

Coordinator for Pest Risk Analysis
Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)

This presentation proposes possible definitions for “emerging pest,” and considers the origin of the concept, criteria, and tools for identifying and categorizing emerging pests.

At present, no definition for “emerging pest” is included in ISPM 5: *The Glossary of Phytosanitary Terms*; therefore, to the extent appropriate for phytosanitary uses, concepts and terminology below are borrowed from the field of medicine. We propose the following as examples of possible definitions:

Elements to consider for the definition of an emerging pest:

1. Organisms which have been identified/described/discovered in recent years;
2. Organisms previously known, and considered to be under good control or almost absent, but which have re-emerged and are capable of causing problems locally, regionally or globally;
3. Organisms which did not previously behave as pests.

In light of these elements, it is important that organisms detected in the field, at points of entry, in imported commodities, as contaminants in containers, etc. are not defined as pests until their economic importance and damage anywhere in the world is appropriately documented. Once there is evidence that organisms have caused damage, their impacts can be further analyzed and evaluated.

For those organisms with no evidence of damage, but that are found frequently associated with any commodity, it is necessary to conduct epidemiological surveillance in order to acquire additional information on seasonality, life cycle, damage, economic impact, etc.

Possible reasons for the rise in emerging pests:

1. Climate Change
2. Disruption of their typical surroundings through urban development
3. Development of new plant production systems
4. Development of resistance
5. Indiscriminate use of the same pest management practices
6. Inter and intraspecific species competition
7. New and more sensitive diagnostic techniques

Determination of pest status requires expert judgement concerning the information available on the actual presence of a pest in an area. Pest status is determined using information on individual pest records, survey pest records, background on pest absence, findings from general surveillance, as well as scientific publications and databases. Pest categorization requires evidence of adequate ecological/climatic conditions for establishment and spread of the pest in the PRA area.

Therefore, the NPPO must keep appropriate records to determine if the presence, appearance or detection of an organism is consistent with characteristics of an emerging pest. If this is the case, then categorization must be made following ISPM 8. Epidemiological surveillance, retention of voucher specimens, and documentation of signs or symptoms are all necessary supporting evidence to develop Pest Risk Analysis, to publish scientific articles, to establish pest free areas, and to develop pest lists, etc.

Fundamentals of Risk Management

Edward Podleckis

Senior Risk Manager
USDA-APHIS Plant Protection and Quarantine

This presentation describes some of the key principles and concepts that are the foundations of plant pest risk management as conducted within the framework of the International Plant Protection Convention

(IPPC). Individual plant pest risk management strategies are addressed in more detail in subsequent workshop presentations.

Risk management is a trio of actions. It is:

- An **analytical process** to identify, evaluate and recommend risk management options;
- A **policy decision** as to which management options are chosen and prescribed; and
- The **operational procedure** of actually implementing the risk management options.

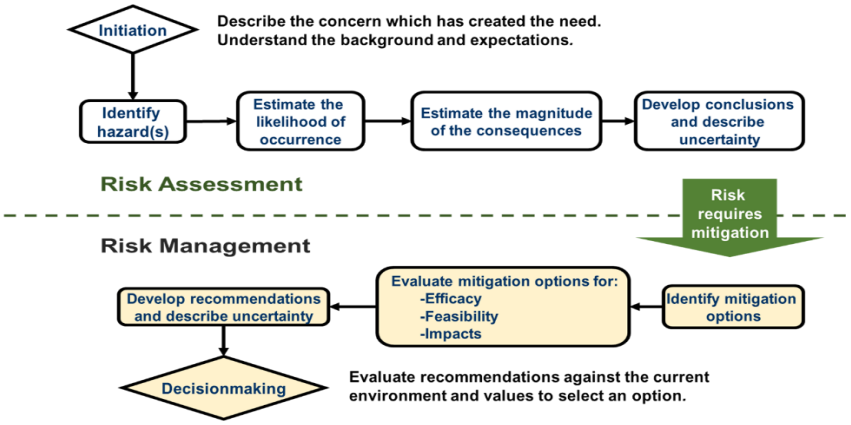
In other words, risk management asks three questions: What can be done to manage risk? How much and which management is appropriate? What options are feasible?

Key Principles of Risk Management

Several key principles guide the development of plant pest risk management within the IPPC framework. First is the principle of **Managed Risk**. There is no such thing as zero risk; even prohibition of trade carries some level of risk if, for example, it encourages smuggling. Under the IPPC, we recognize that pest risk always exists, but we manage that risk to an acceptable level. The World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) agreement instructs National Plant Protection Organizations (NPPOs) to choose the least trade restrictive measures that provide an appropriate level of protection. This the principle of **Minimal Impact.** There is an entire section of ISPM 38 devoted to guidance for NPPOs to recognize that different measures can achieve the same level of pest risk management. Accepting that different measures can produce equivalent results is the principle of **Equivalency**. The principle of **Non-discrimination** simply says that if an NPPO has differing import requirements for countries there must be phytosanitary reasons to justify those differences. Similarly, the principle of **Consistency** demands that the criteria used in selecting phytosanitary measures and their strength must be consistently applied across trading partners.

Risk assessment vs. Risk Management

This diagram shows the relationship between the plant pest risk assessment process that identifies pest risks and estimates their likelihood and consequences with the pest risk management process that identify, select and implement plant pest risk management measures.



Plant Pest Risk Management Strategies

There are a variety of strategies in the plant pest risk management toolbox.

Inspection is the most frequently used measure for phytosanitary certification. The IPPC defines inspection as a visual inspection, but special forms of examination used to inspect commodities can include laboratory testing and microscopic examination. Inspection can occur at various stages from production to the consumer, for example: before, during and after the harvest of plants and plant products; pre-shipment in the exporting country; or at the port-of-entry in the importing country.

Some of the considerations in deciding on how and when to employ inspection include the efficacy, efficiency, sensitivity of available methods; the expertise required to conduct inspections; the ease with which the pests can be detected (some commodities are easier to inspect and some types of pests lend themselves to detection by inspection better than others); and the level of detection resources required.

An important point to remember about inspection (or any other form of testing) is that no inspection protocol is 100 percent efficient and generally some sample of a consignment is inspected. The rate of sampling and the efficiency of inspectors implies that, by design, inspection protocols have some level of **tolerance** for pest presence.

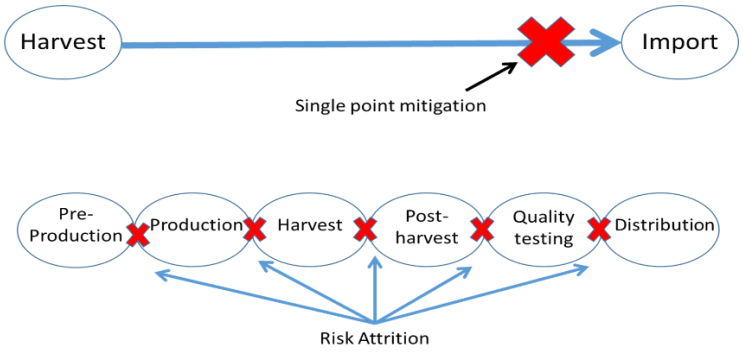
When is inspection not likely to provide an appropriate level of protection? If pests are difficult to detect or are likely to be with the commodity and easily become established via the pathway, inspection may not be sufficient and other measures such as those described below may be required.

Treatments may be used singly, in combination or as part of a systems approach, and they may include mechanical, chemical or physical treatments. The ideal treatment is highly effective on the target pest; non-toxic to plants and humans; easily and cheaply applied; not explosive or flammable; environmentally neutral; and precisely delivered. Treatments can have a variety of desired outcomes including from mortality, inactivation, devitalization, removal, sterility, non-emergence or non-sprouting to name some. Selecting the appropriate treatment requires knowledge of your desired outcome.

Pest free concepts are another risk management strategy. Probably the most familiar version of pest free concepts are the **pest free area** and **pest free place of production**. These concepts rely on biological, physical or other natural barriers to pest entry. They require effective regulation of the movement of host material into the protected area. Maintenance of pest free areas requires routine surveillance and monitoring and must include contingency plans in the event the free area is breached. Other pest-free concepts include pest-free growing season based on the life cycles of the target pest and its host, and harvest and shipping windows that rely on lack of colonization potential.

Post entry measures are mitigations applied to the commodity after entry into the importing country. They may be stand-alone measures or used as a component of a systems approach (see below). Some post entry pest risk mitigations include inspection, treatment, post entry quarantine (used for plants for planting), restrictions on intended use or limited distribution.

Systems Approach is defined in ISPM 14: *The Use of Integrated Measures in a Systems Approach for Pest Risk Management* as: "The integration of different pest risk management measures, at least two of which act independently, and which cumulatively achieve the appropriate level of phytosanitary protection." Systems approaches rely on the concept of risk attrition where a combination of mitigation measures is used in lieu of a single (presumably highly effective) measure. While singly the measures may not provide an appropriate level of protection, when taken in combination, that level can be achieved. The redundancy of the measures can compensate for uncertainty of the efficacy of measures and ensure that even if one measure fails the other measures will still reach an appropriate level of protection.



ISPM 38 (Section 2.5) supports the use of systems approaches in managing seed pest risk noting that, "Systems approaches provide the opportunity to consider both pre-harvest and post-harvest procedures in developing effective pest risk management that also includes production practices."

Finally, **Prohibition** is the most trade restrictive pest risk management strategy and is generally a measure of last resort. In fact, prohibition may have the effect of increasing risk where there is a strong motivation for trade (in other words, it may encourage riskier pathways like smuggling).

Inspection as a Phytosanitary Measure

Christina Devorshak

National Science Program Coordinator
USDA-APHIS Plant Protection and Quarantine

Inspection is historically the most widely applied phytosanitary procedure. All NPPOs apply inspection on imported products for the purpose of preventing the entry of pests into their territories; inspection is also applied to products that are exported, usually as part of phytosanitary certification. Although inspection is commonly used throughout the world, the objectives and efficacy of inspection are often not fully analyzed or understood.

The international standard ISPM 23: *Guidelines for Inspection* provides guidance on how inspection should be applied for phytosanitary purposes. It states that "inspection" is the visual examination for the detection of pests, possibly leading to phytosanitary action. Inspection is usually done to determine if pests are present, to verify effectiveness of phytosanitary measures, confirm compliance with requirements and to detect organisms for which risk has not yet been determined. It is important to note that inspection is usually not done 100%, nor is inspection considered to be 100% effective or consistent.

Inspection is a form of sampling, and as such, is based on statistical characteristics including tolerance and confidence. This also implies a threshold for acceptance of some probability that a pest may not be detected. Because inspection is used as a phytosanitary measure, it is important that NPPOs base their requirements for inspection on a technical justification. Use of inspection for seed trade presents opportunities for NPPOs and industry to follow harmonized principles laid out in relevant ISPMs, including ISPM 38 and ISPM 23.

Seed Treatments for Risk Mitigation

Diego Risso

Executive Director

and Maria Inés Ares

Seed Phytosanitary Advisor
Seed Association of the Americas

The treatment of seed either by physical treatment, coating with a chemical or biological, or a combination of both is a useful tool for disinfecting and protecting seed, seedlings, and young plants from insects, nematodes and disease during crop establishment. Treatment can also minimize the risk of pest spread, while enhancing crop production.

Seed treatments date as far back as the Egyptians, but not until late in the 20th century were more focused and broader spectrum products applied to the seed. Chemical, biological, crop enhancers and micronutrients have a far better control of pests, abiotic stress, and long-lasting foliar disease protection.

The broader spectrum products applied to seed may prevent pest spread through mixing different modes of action especially for control of fungi. These mixtures also play a role in preventing pests from becoming resistant to certain modes of action for fungicides, insecticides, nematicides, etc. They can also play a useful role in systems approaches as phytosanitary measures that NPPO´s may require to mitigate seed phytosanitary risk.

Seed treatment working groups in the Seed Association of the Americas (SAA) and NSAs are actively engaging with different parts of the industry, as well as with regulatory bodies in each member country, to find common ground and clearer understandings of topics such as: quarantine pests, phytosanitary requirements, and seed treatment regulations. They are also working toward common understanding of use and safe use of seed treatments and treated seed across the Americas.

Systems Approaches (or Integrated Measures for Pest Risk Management)

Christina Devorshak

National Science Program Coordinator
USDA-APHIS Plant Protection and Quarantine

A systems approach is the integration of different pest risk management measures, at least two of which act independently, and which cumulatively achieve the desired level of phytosanitary protection. Systems approaches, described in ISPM 14: *The use of integrated measures in a systems approach for pest risk management*, may be used when no single measure can achieve the appropriate level of protection, and where systems approaches are the least trade restrictive option. Systems approaches usually necessitate a good understanding of the system being managed, and the ability to manage risk at different control points in the system (e.g., throughout the pathway from point of origin to end use).

The types of measures applied in a systems approach include measures that reduce risk (for example, removing, killing, deactivating or otherwise reducing the presence of pests), measures intended to

safeguard the commodity (e.g. packaging, preventing infection) or measures intended to verify the efficacy of other measures (e.g. inspection). In designing a systems approach, it is important to consider defining endpoints of measures (e.g., mortality, pest freedom), what can be measured and achieved, feasibility, and how the systems approach can be expressed and communicated. Systems approaches often include redundant measures as a means to manage uncertainty and ensure risk is adequately managed, but redundant measures should be re-assessed as knowledge of the system improves. In all cases, systems approaches should be technically justified and based on relevant international standards.

Seed Systems Approaches: An NPPO Case Study - ReFreSH

Edward Podleckis

Senior Risk Manager
USDA-APHIS Plant Protection and Quarantine

In the United States, seed was long regarded by regulators as a relatively low risk pathway, so seed moved in U.S. 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 is completed on a consignment-by-consignment basis.

The perception of the pest risk of imported seed began to change in the United States in 2013 when Cucumber green mottle mosaic virus (CGMMV) was detected in California. The CGMMV detection prompted a USDA-APHIS-sponsored National Seed Health Summit in 2014 that gathered together regulators, academics and industry to discuss seed health issues. From this meeting arose the idea for a Regulatory Framework for Seed Health or ReFreSH. The need for ReFreSH was driven by the unique challenges of the international movement of seed in trade:

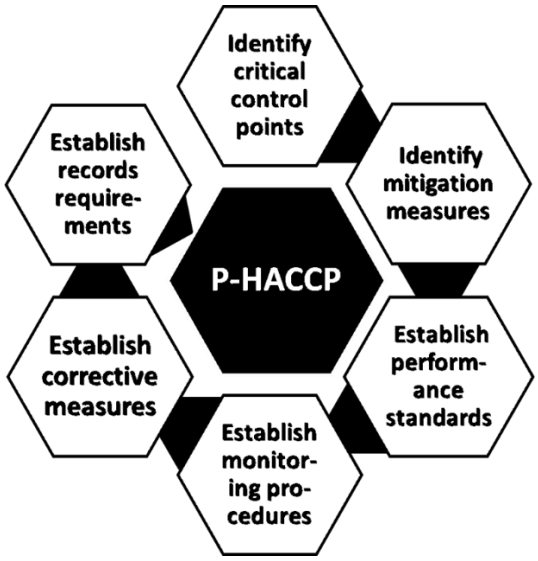
- the large number of pests potentially involved in the seed pathway;
- whether seed is a pathway for any given pest;
- appropriate phytosanitary measure(s);
- increasing demand for documents and declarations that specific pests are absent in imported seed; and
- increased strains on NPPO resources to provide certifications on a consignment basis.

ReFreSH is a voluntary, risk- and science-based systems approach that aims to provide an effective and more efficient program to manage phytosanitary risk of international seed movement by leveraging existing industry pest risk reducing practices. ISPM 38, Section 2.5 supports the idea of using systems approaches incorporating production practices. It urges NPPOs to consider how pre-harvest and post-harvest procedures and pest management practices throughout the seed production process [industry practices] may contribute to effective pest risk management and may be integrated in a systems approach.

The ReFreSH systems approach seeks to promote a harmonized global system for seed health that accommodates all seed sectors (vegetable, cereal, row crop, farm, lawn and flower) and shifts the 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. The way we envision ReFreSH working is a seed production system is approved/accredited by the NPPO of exporting country;

the NPPO of importing country accepts the accreditations as equivalent to phytosanitary certification (i.e., testing, inspection) of individual seed consignments; and accreditation is then the basis for issuing phytosanitary certificates. Of course, compliance would be assured by quality management systems and audits.

There are several ways to design a systems approach. For example, we can simply combine existing measures to achieve a qualitative "appropriate level of protection"; in other words, we throw measures together until we, as an NPPO, are comfortable that we have mitigated the pest risk. The approach we chose to use for ReFreSH is based on the Phytosanitary Hazard Analysis and Critical Control Point (P-HACCP) process. In this approach, we define critical control points in the seed production process where pest risk may be introduced, and apply measures to the identified control points to mitigate the risks. The process for designing a P-HACCP system is shown in the figure below:



For ReFreSH, eight stages of seed production were identified as critical control points at which hazards could be introduced into the seed production process and managed by the application of mitigation measures. Those eight stages are:

1. **Pre-planting: Site Selection and Preparation**

   Seed Health Risk Considerations: Introduction of pests through insufficient isolation of plants; volunteers or weeds harboring pests; errors in rotation or land management; improper equipment cleanout; improper disposition of plant material; planting in pest infected soils; introduction of pests and pathogens from media (protected environment); facility (siding, floors, drainage) containment issues; irrigation water contaminated.

2. **Pre-planting: Seed and Plant Inputs**

   Seed Health Risk Considerations: Seed source or transplants infected with pathogens or pests; inadequate inspection or testing for pests.

3. **Production: Pre-harvest**

Seed Health Risk Considerations: Loss of containment or insufficient isolation of plants; volunteers or weeds harboring pests and pathogens; improper equipment cleanout; improper disposition of plant material; weed control in borders and adjacent fields is not adequate; inadequate inspection or testing for pests; sanitation practices for field equipment and personnel not followed; disease or pest outbreak.

4. **Production: Seed Harvest**

Seed Health Risk Considerations: Seed lots not properly managed to prevent co-mingling of infested and clean lots; no procedures in place to prevent potential contamination during harvest; movement of contaminated field equipment between sites.

5. **Post-harvest: Conditioning and Treatment**

Seed Health Risk Considerations: Inadequate pest and pathogen control in seed cleaning, conditioning and packaging; inappropriate disposal of "discard" materials; inadequate facility and equipment cleanout and containment.

6. **Post-harvest: Handling and Storage**

Seed Health Risk Considerations: No systems in place to prevent seed exposure to pests in storage; inadequate system to maintain integrity and traceability of seed lots to meet regulatory requirements for documentation of origin, in-transit, and re-export; introduction and spread of pests and pathogens from transportation equipment and container selection.

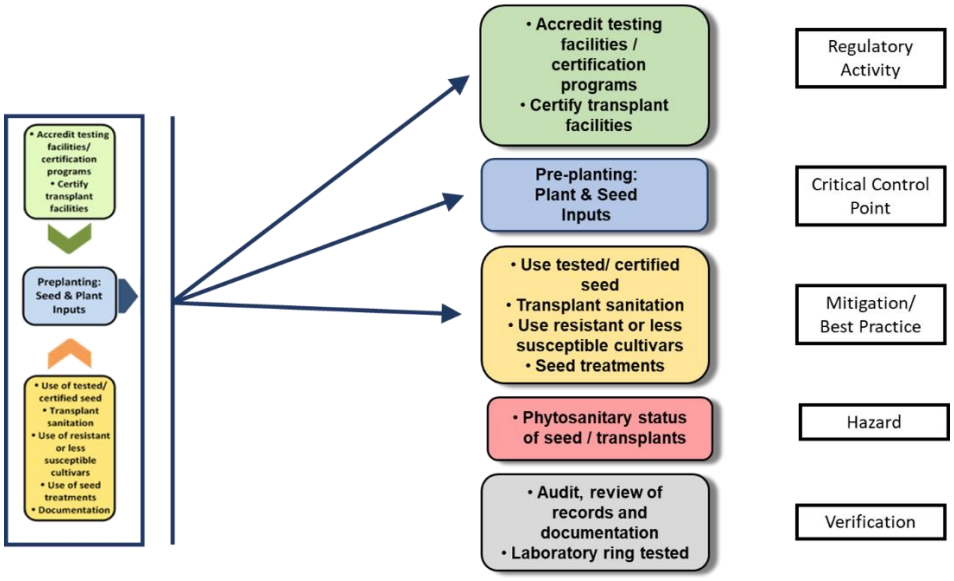
7. **Post-harvest: Seed Quality Testing**

Seed Health Risk Considerations: Improper seed health testing techniques used; inadequate audits and controls; inadequate testing facilities.

8. **Distribution and Transport**

Seed Health Risk Considerations: Inadequate system to maintain integrity and traceability of seed lots to meet regulatory requirements for documentation of origin, in-transit, and re-export; introduction and spread of pests and pathogens from transportation equipment and container selection.

For each of these critical control points, production practices and regulatory activities to mitigate pest risk are identified. An example of one such critical control point is shown below.



USDA-APHIS plant Protection and Quarantine has developed a draft ReFreSH accreditation standard document that describes the essential elements of ReFreSH and outlines the responsibilities of all participants in the ReFreSH Program. The standard covers the ReFreSH application and enrollment process; participating entity's responsibilities; the authorizing NPPO's responsibilities; and non-conformance and corrective measures. In addition to the draft accreditation standard, APHIS is developing a draft ReFreSH Manual. This manual will serve as a guide and template for the manual that participating entities in ReFreSH must provide as part of the enrollment process.

Some of the topics covered in the ReFreSH Manual are listed below.

Management and Organization

- An organizational chart; a description of positions, responsibilities assigned to manage ReFreSH Program
- A description of training for employees involved in planning and implementing the ReFreSH Program
- A description of the places of production, places of operations and places of seed health evaluation

Seed health Management Plan

- Describes the pest management practices implemented by the organization to mitigate seed pathway hazards identified for each of the critical control points of seed production
- Includes records that are used to ensure the plan has been implemented and followed
- Includes procedures for reporting regulated pest detections to the certifying authority

Audits and System Improvements (Quality Management System)

- Includes procedures for conducting regular systems improvements (e.g., audits) to ensure conformance with the ReFreSH Standards.
- Title/position of person responsible for the systems improvement
- Procedures establishing a timeline, scope and reporting of the results

- Procedures to notify the certifying authority of non-conformances and for implementing corrective actions

Records and Documents

- Defines procedures for maintaining the ReFreSH Manual
- Record Requirements for ReFreSH: Traceability records, Audit records, Seed health management plan records, Training records.

In order for ReFreSH or any one of the similar systems approaches being pursued by other countries to be successful and achieve global harmonization, it must be accepted by multiple trading partners. After all, re-export is a key part of the global seed trade. The most viable path to multilateral acceptance is by working through the IPPC. In 2018, the IPPC Secretariat issued a call for potential topics for new standards, revisions of existing standards and implementation materials to assist in implementation of standards.

At a meeting of the International Seed Federation (ISF) Systems Approach Working Group in Rome of that year, NSA and NPPO representatives from Australia, Chile, the Netherlands, South Africa and the United States agreed that the most viable path to multilateral acceptance of this approach was through a proposal for a systems approach annex to ISPM 38 (see article by Zlotina in these Proceedings). Further, they felt that since, at the time, ReFreSH was the most developed systems approach, it could serve as model for the annex. And since ReFreSH is being developed in a NAPPO member country, NAPPO was a logical choice to sponsor the proposal. The NAPPO Secretariat drafted the proposal, gathered support from other regional and national plant protection organizations and submitted the proposal to 2018 call for topics - standards and implementation. In the spring of 2019, the proposal was approved and given priority 1 on the IPPC Standards Committee work schedule. It is proposed that the annex provide a detailed inventory of seed-focused risk management measures and risk reducing production practices, a general framework for systems approach and guidance on accreditation and audit.

USDA-APHIS Plant Protection and Quarantine continues its work to develop ReFreSH in collaboration with the seed industry and the ISF Systems Approach Working Group.

Accreditation and Audits

Patricia McAllister

Acting Director, Plant Production Division
Canadian Food Inspection Agency (CFIA)

A systems approach is defined by in ISPM 5 as “a pest risk management option that integrates different measures, at least two of which act independently, with cumulative effect”. Such a system could provide an alternative to single measures to meet the appropriate level of phytosanitary protection of an importing country and ideally would be accepted by multiple countries providing opportunities for future cooperation.

A systems approach can also offer opportunities for innovation and flexibility in risk management. Measures can cover a wide spectrum of activities from cultural practices to surveillance and testing and the use of pest free areas and pest free places of production. Measures should be clearly defined, efficacious, mandatory and able to be monitored and controlled by the responsible NPPO. Examples of types of possible systems include critical control point systems (HACCP), seed certification/ OECD seed schemes, good seed and plant practices and quality management systems (QMS). A good system is based on an established outcome based on a flexible framework. Verification can include in country systems audits, document audits, trial periods, international accreditation processes and third-party audits. Ideally a common system will meet the needs of multiple importing countries to reduce the burden on producer, exporter, and NPPO.

Proposed Systems Approach Annex to ISPM 38

Marina Zlotina

IPPC Technical Director
USDA-APHIS Plant Protection and Quarantine, International Phytosanitary Standards

The International Plant Protection Convention (IPPC) is a multilateral treaty for international cooperation in plant protection. There are currently 183 contracting parties to the IPPC. IPPC is governed by Commission on Phytosanitary Measures (CPM). IPPC's scope includes plants, plant parts, plant products, plant pests, conveyances, and any objects and materials capable of harboring, transporting or spreading pests.

IPPC is one of the three standard-setting bodies named in the Sanitary and Phytosanitary Agreement (SPS) of the World Trade Organization (WTO) and is responsible for developing plant health standards. Forty-three International Standards for Phytosanitary Measures (ISPMs) are currently adopted, not counting individual schedules for Phytosanitary Treatments and pest Diagnostic Protocols.

Development of ISPMs follows the IPPC standards setting process. The process starts with a call for contracting parties to submit topics to be developed as new standards. After topics are approved for further development, the drafting process will start, followed by contracting parties (Consultation) reviewing the draft standards, and finally adopting new ISPMs.

In response to the last call for topics in 2018, IPPC contracting parties submitted 36 proposals for new standards or tools to improve implementation of the existing ISPMs. The North American Plant Protection Organization (NAPPO), with support from its member countries, other Regional Plant Protection Organizations (RPPOs), and NPPOs submitted a proposal to develop a new Annex for ISPM 38.

ISPM 38 provides a general framework of requirements for international movement of seeds but lacks specific guidance on implementation. Despite the efforts by NPPOs and industry to harmonize regulations in international seed trade, considerable differences still remain. The new Annex is intended to improve the implementation of ISPM 38 through incorporating the use of systems approaches to manage the phytosanitary risks in seed moved internationally.

The Annex will represent a general framework of risk management measures, including existing seed industry practices plus a quality management system (i.e., defined audit and verification standards),

providing consistent implementation. The Annex will outline a globally harmonized system to accredit compliance with the systems approach and to be recognized by NPPOs. The accreditation will serve as the basis for phytosanitary certification and will provide a voluntary alternative to the current system of consignment-by-consignment certification.

The proposal for the new Annex to ISPM 38 was approved by the IPPC contracting parties in April 2019 for further development with a high priority.

Appendix 1 – Final Agenda

"Americas focused" ISPM 38 (International Movement of Seeds) Implementation Workshop

March 5-7, 2019; IICA, San Jose, Costa Rica

March 5

Time	Topic	Speaker
Welcome/Introductions		
8:30 - 9:00	Registration	
9:00 - 9:10	Welcome from NAPPO	*José Ulises García Romero (SENASICA)*
9:10 – 9:20	Welcome from Costa Rican NPPO	*Fernando Araya Alpízar (SFE)*
9:20 – 9:30	Introduction to IICA	*Rob Ahern (IICA)*
9:30 – 10:00	Participants introduce themselves	
10:00 – 10:15	Workshop Overview, Logistics and Goals	*Stephanie Bloem (NAPPO)*
10:15 – 10:30	Overview of the Global Seed Industry	*Ric Dunkle (ASTA)*
10:30 – 10:45	Overview of the Seed Industry in the Americas	*Inés Ares (SAA)*
10:45 - 11:00	**Break**	
11:00 – 11:20	Overview of ISPM 38 – highlighting areas to focus-on for implementation	*Ed Podleckis (APHIS)*
Pest Risk Assessment – PRA		
11:20 - 11:40	Principles of PRA (Guidelines as per ISPM 2, 11)	*Stephanie Bloem (NAPPO)*
11:40 – 12:00	Seeds as Pests and as Pathways for Pests (seed borne vs. seed transmitted, examples, evaluating evidence for existence of pathway)	*Marina Gutierrez Olivares (SENASICA)*
12:00 – 12:15	ISF Regulated Pests Database	*Radha Ranganathan (ISF)*
12:15 – 12:30	Intended Use as a Risk Factor	*Natalia Fernandez Eraso (Bayer)*
12:30 - 13:00	Review/Discussion	*All*
13:00 - 14:15	**Lunch**	
14:15 - 14:30	Pest Listing	*José Ulises García Romero (SENASICA)*
14:30 - 14:45	Determining Pest Risk	*Nancy Osterbauer (APHIS)*
14:45 - 15:00	Opportunities for PRA Harmonization	*Patricia McAllister (CFIA)*
15:00 – 15:15	Challenges for PRA Harmonization	*María Elena Gatti (SENASA, Argentina)*
15:15 – 16:00	Discussion - Harmonizing Seed PRAs under ISPM 38	*All*
16:00 – 16:15	**Break**	
16:15 – 16:30	Identifying Emerging Pest Risks and Pest Categorization (NPPOs)	*José Ulises García Romero (SENASICA)*
16:30 – 16:45	Responding to Emerging Pest Risks (Industry)	*Samantha Thomas (Bayer)*
16:45 - 17:45	Review/Discussion	*All*
17:45	**Adjourn**	

March 6

9:00 - 9:15	Review of Day 1 and preview of Day 2	*Stephanie Bloem (NAPPO)*
Pest Risk Management		
9:15 - 9:45	Fundamentals of Risk Management (including equivalence, strength of measures)	*Ed Podleckis (APHIS)*
9:45 - 10:00	Inspection	*Christina Devorshak (APHIS)*
10:00 - 10:15	Sampling	*Tracy Bruns (Iowa State Univ.)*
10:15 -10:30	Sampling Small Seed Lots	*Kurt Kleinhesselink (Voloagri)*
10:30 - 10:45	**Break**	
10:45 - 11:45	Discussion - Challenges for movement of small lots, mixture, combination and group of seeds	*All*
11:45 – 12:15	Diagnostic Protocols – types (indirect vs. direct), selection, validation	*Tracy Bruns (Iowa State Univ.)*
12:15 – 12:30	Seed Treatments for Risk Mitigation	*Diego Risso (SAA)*
12:30 – 12:45	Alternative Chemical Treatments for Organic Seeds	*Dale Krowlikowski (Germains)*
12:45 - 14:00	**Lunch**	
14:00 – 14:30	Principles of Systems Approaches	*Christina Devorshak (APHIS)*
14:30 – 15:00	Best Management Practices/Quality Management Systems – Industry	*Samantha Thomas (Bayer)*
15:00 – 15:30	Systems Approach Strategies - NPPO	*Ed Podleckis (APHIS)*
15:30 - 15:45	**Break**	
15:45 - 16:00	Accreditation and Audits	*Patricia McAllister (CFIA)*
16:00 – 16:15	Proposed Systems Approach Annex to ISPM 38	*Marina Zlotina (APHIS)*
16:15 – 17:30	Group discussion - Identify the top five challenges to achieve harmonization where action is needed	*All*
17:30	**Adjourn**	

March 6 – 20:00 – 21:30 - "Brainstorming session" at the Hotel Hyatt Pinares - a session for industry colleagues and NPPO/RPPO colleagues to get together to identify the steps needed for successful implementation of ISPM 38 – Each group should answer the question - what will successful implementation look like and what can we/will we do to make it happen?

March 7

9:00 - 9:15	Review of Day 2 and preview of Day 3	*Stephanie Bloem (NAPPO)*
Implementation		
9:15 - 9:35	Industry views - what steps are needed by companies for successful implementation of ISPM 38?	*Radha Ranganathan (ISF) - results from evening brainstorming*
9:35 - 10:15	COSAVE-NAPPO: what steps are needed by RPPOs and NPPOs for successful implementation of ISPM 38?	*Christina Devorshak (APHIS) and Stephanie Bloem (NAPPO) – results from evening brainstorming*
10:15 - 10:30	**Break**	
Summary/Next Steps		
10:30 - 11:30	Discussion: what coordinated steps must NPPOs, RPPOs and industry take for successful implementation of ISPM 38?	*All*
11:30 - 12:00	Overall Workshop Summary and Next Steps/Action Items	*Stephanie Bloem (NAPPO)*
12:00 –12:30	Close of the workshop - NAPPO	*José Ulises García Romero (SENASICA)*
12:30	**Adjourn**	