ISPM 38 on the International Movement of Seed

21 MAY 2017

A TRAINING MANUAL PREPARED BY THE International Seed Federation
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Introduction

For many years, multiple individuals from across the seed industry have partnered with ISF to contribute to the IPPC’s development of a seed specific International Standard for Phytosanitary Measures. The culmination of these efforts was the final adoption of the standard last month. Although important to take a moment to celebrate this achievement, we also recognize the need to focus on the implementation which will be key to experiencing the practical benefits and improved international movement of seed. As we prioritize this activity at ISF, we ask all national and regional seed associations as well as seed companies to join us in our outreach efforts. Collaboration will be key to a successful, global outreach effort. The following Training Manual provides the understanding of the IPPC, the ISPMs, and the content of the newly adopted standard that will be the cornerstone of this outreach effort.

Seeds is Life!

Michael Keller
ISF Secretary General
IPPC

The legislative framework for global phytosanitary management

The International Plant Protection Convention (IPPC) was created to secure coordinated, effective action to prevent and control the introduction and spread of pests of plants and plant products. The intentions of the IPPC are summarized in the preamble of the Convention which states that contracting parties:

- recognize the necessity for international cooperation in controlling pests of plants and plant products and in preventing their international spread, and especially their introduction into endangered areas
- recognize that phytosanitary measures should be technically justified, transparent and should not be applied in such a way as to constitute either a means of arbitrary or unjustified discrimination or a disguised restriction, particularly on international trade
- desire to ensure close coordination of measures directed to these ends
- desire to provide a framework for the development and application of harmonized phytosanitary measures and the elaboration of international standards to that effect
- take into account internationally approved principles governing the protection of plant, human and animal health, and the environment

The Organization of the IPPC

The implementation of the Convention is managed by the Commission on Phytosanitary Measures (CPM), which consists of representatives of the governments of all countries that have ratified the IPPC. The CPM functions in the framework of the Food and Agriculture Organization (FAO) of the United Nations. ISF is an Observer to the IPPC and, in this capacity, allowed to attend the annual CPM meeting.

It is each country’s responsibility to set up its own organizational structure and to define its legal phytosanitary requirements to protect its area from pests not yet present, or present in a limited amount, and capable of establishing and causing severe economic and/or ecological damage. Each country has a National Plant Protection Organization (NPPO) to implement its phytosanitary policies and laws and to supervise that plants and plant products that are imported into the country meet its national requirements. Furthermore, the IPPC provides for the establishment of Regional PPOs as coordinating bodies and platforms of expertise to disseminate knowledge and to support National PPOs. RPPOs may also develop and implement regional phytosanitary standards in order to harmonize phytosanitary measures at a regional level.

The Establishment of ISPMs

The IPPC provides a number of International Standards for Phytosanitary Measures (ISPMs) that serve as guidelines and principles for countries to implement phytosanitary measures and procedures. ISPMs are developed by ad hoc Expert Working Groups with representatives of various NPPOs. This work is supervised by the IPPC Standards Committee with representatives from all 7 FAO global regions. For the past several years, IPPC has been allowing representatives of Observer organizations to participate in the ad hoc Expert Working Groups, especially when it concerns the development of standards for specific commodities, such as the ISPM on the international movement of seeds. For that reason, ISF was able to nominate an expert to participate in the development of this ISPM.
New draft standards, or drafts of existing standards that are up for review, are sent to all countries that belong to the IPPC for comments. Organizations which have an official observer status, such as ISF, are also invited to comment on draft ISPMs. At least two rounds of country consultation are conducted and there may be a third in case the draft has been changed substantially. If approved by the Standards Committee, the draft standard is forwarded to the Commission on Phytosanitary Measures (CPM) for adoption during its annual meeting.

Despite the availability of the ISPMs, different approaches to implementation by countries are observed. This lack of harmonization is a significant impediment to the international movement of plants and plant products, including seeds. ISPM 38 on the international movement of seeds is intended to provide further detailed guidance to overcome this issue for the commodity class, “Seeds for Planting”.

A Practical Way to Resolve Trade Disagreements

IPPC has a dispute settlement structure to be utilized when there are disagreements regarding the interpretation or application of the IPPC or ISPMs, but this is hardly used in practice. For that purpose, the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), provides a more practical (but still complex) way to solve disagreements.

The WTO SPS Agreement is mainly focused on fair application of effective measures to support international trade. This is explicitly demonstrated in the following paragraphs of Article 2 of the Agreement:

*Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5. [Refers to provisional emergency measures]*

*Members shall ensure that their sanitary and phytosanitary measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. Sanitary and phytosanitary measures shall not be applied in a manner which would constitute a disguised restriction on international trade.*

One of the obligations under the SPS Agreement is that countries publish intended new or adapted sanitary or phytosanitary requirements and inform the WTO Secretariat. The SPS Secretariat then notifies all SPS member countries, which are then allowed time to comment. These comments need to be taken into account when defining the final measure (except in case of emergency measures for urgent, new problems).

In case the seed industry considers a new measure technically flawed or unduly cumbersome (with easier alternative effective measure available) for trade, it is then possible to provide technical information and arguments to the NPPO of the country/countries where the seed industry is located, which are forwarded to the importing country concerned if the NPPO is in agreement. This is not an easy process, but the seed industry has been most successful by coordinating and aligning the messages prior to being delivered through the different NPPOs of exporting countries.
When the above mentioned period of comments is complete and an exporting country does not agree with the requirements set by an importing country due to the belief that the requirement is not technically justified or is unnecessary cumbersome, it may initiate a dispute settlement process under the WTO SPS Agreement. Below is an excerpt from Article 11.

In a dispute under this Agreement involving scientific or technical issues, a panel should seek advice from experts chosen by the panel in consultation with the parties to the dispute. To this end, the panel may, when it deems it appropriate, establish an advisory technical experts group, or consult the relevant international organizations, at the request of either party to the dispute or on its own initiative.

For further reading:

IPPC: https://www.ippc.int/en/publications/128/

IPPC – Frequently asked questions: https://www.ippc.int/en/faq/

WTO SPS Agreement: https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm
Pest Risk Analysis

Countries want to prevent international trade from leading to the introduction and spread of new pests that may cause unacceptable economic or environmental damage in their country. To achieve this, phytosanitary measures may be taken.

Pests can be either regulated or not, and the IPPC recognizes and defines two categories of regulated pests of plants: quarantine pests and regulated, non-quarantine pests.

1. Quarantine pests (Q) – pests that are not present in a country or ‘present but not widely distributed’, with potential economic importance and that are officially controlled.
2. Regulated Non-Quarantine Pests (RNQP) – pests that are already present and can be widespread but their presence in plants for planting (incl. seeds) combined with the intended use leads to unacceptable economic impact.

A Pest Risk Analysis (PRA) is the technical tool used to determine whether a pest warrants to be regulated, and if so, whether as a quarantine or regulated non-quarantine pest, and thereafter to identify the appropriate phytosanitary measures. A PRA provides the rationale for phytosanitary measures for a specified PRA-area (which can be defined as either a country or a climatic zone within a country) and is based on scientific evidence. A PRA may be a bilateral process, between National Plant Protection Organizations (NPPO’s) and is made by the importing country, based on scientific publications, information on pest occurrence and pest management measures from the exporting country (country of origin).

The concept of RNQPs is quite new for seeds. As RNQPs are related to ‘plants for planting’ (including seeds), it will become a very relevant category for the global seed industry. It can be assumed that many pests that we currently consider to be ‘quality pests’ for which the seed industry has developed test protocols as well as quality management programs, may become regulated as RNQP (e.g. Xanthomonas campestris pv campestris in Brassica seeds). If that would be the case, it would be logical that the requirements ‘match’ the current protocols and samples sizes as recommended by ISF (ISHI).

Put simply, a PRA asks: What could happen? What is the risk? How likely is it to happen? What would the consequences be? Do we want to do anything about it? If so, what can be done about it?
A complete PRA consists of three stages (Fig. 1)
1. Initiation – Identification of a pest and a pathway and the area to which the PRA refers
2. Pest risk assessment – Is the risk acceptable? What is the economic impact?
3. Pest risk management – How to manage the risk? What are the appropriate phytosanitary measures?

After every step, the process may stop. If, for example, it has been established that seed is not a pathway for the introduction and spread of a certain pest, the process stops after stage 1. If the risk of introduction of a pest is acceptable, the process will stop after phase 2. In both cases, no phytosanitary measures need to be defined.

**Stage 1- INITIATION**
There are several reasons to make a PRA for seeds. The more common ones are an import of seeds of a new crop into a country or an import of seeds of a crop from a new country of origin, but PRAs are also conducted when NPPOs review their phytosanitary regulations for seeds.

Two important questions need to be answered:

What are the pests potentially associated with the seed?

Can entry with seed lead to the introduction, spread, and establishment of those pests? In other words, can "seed be a pathway" for those pests?
The list of pests likely to be associated with the seed may be generated by any combination of official sources, databases, scientific and other literature or expert consultation. The second question can be answered independent of country of origin. If done so, the list of pests to be further assessed can by considerably restricted to those for which seed is a pathway, that are absent in the PRA area and that warrant to be regulated for the PRA area.

The 'Framework for Pest Risk Analysis' is described in ISPM2 and, for seeds mainly focuses on (possibly) pathogenic organisms. Seed as a possible carrier of those organisms are included but the specific subject of 'Seed as a pathway' is not discussed. This is now addressed in detail in the new ISPM on International Movement of Seeds.

**Seed as a Pathway**

The basis to determine if seed is a pathway for the introduction and spread of a specific pest should be scientific evidence. It can be challenging for NPPO’s to find the required expert pathology knowledge and time to critically review literature.

Governments may for example base their import requirements on the ISTA Annotated list of seed borne diseases. This list cites publications on seed-borne diseases. However, the presence of a pest is not necessarily linked to transmission of the pest via the seed. The literature cited has not been critically reviewed for that aspect. Furthermore, most studies are performed under experimental conditions and do not provide information about ‘seed as a pathway’ under natural conditions. The annotated list has not been updated since 1990. Another source that may be used is the CABI Crop Protection Compendium. In case such compendiums are being used, it is recommended that the references cited are reviewed to determine if seed is a pathway.

**ISF Regulated Pest List Initiative**

To facilitate a science based approach to decide about phytosanitary measures, ISF has taken the initiative to make an overview that provides – per crop – a classification of the pest. For each crop, the list consists of all pests regulated in one or more countries, anywhere in the world, along with its classification by ISF experts. The classification is based on an extensive literature review process and expert opinions, in line with ISPM requirements. There are five classes:

- **Yes** = Seed is a known pathway
- **Pathway not proven** = Seed as a pathway is not certain because:
  - the evidence has not been verified or proven, or
  - the evidence is limited or doubtful, or
  - the evidence is conflicting
- **No** = No references found indicating seed is a pathway under natural conditions, nor is it known within the industry that seed is a pathway
- **Not a host** = No references found nor information known that the crop is a host of this pest
- **Yes, but crop not a host** = The pest may be found with the seed, however, the crop is not a host of the pest

Currently ten crops are included; tomato, brassica and bean are in preparation and will be added in 2017. Further crops, including agricultural crops, will be added in the coming years.

<table>
<thead>
<tr>
<th>Crop Species (9)</th>
<th>Regulated pests (no.) TOTAL 666</th>
<th>Is seed a pathway? (in percentages)</th>
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<tr>
<td>Carrot</td>
<td>92</td>
<td>Yes 4 Pathway not proven 8 No 46 Not a host 42</td>
</tr>
<tr>
<td>Cucumber</td>
<td>90</td>
<td>Yes 4 Pathway not proven 9 No 56 Not a host 31</td>
</tr>
<tr>
<td>Lettuce</td>
<td>64</td>
<td>Yes 5 Pathway not proven 16 No 56 Not a host 23</td>
</tr>
<tr>
<td>Melon</td>
<td>69</td>
<td>Yes 12 Pathway not proven 20 No 45 Not a host 23</td>
</tr>
<tr>
<td>Onion</td>
<td>94</td>
<td>Yes 7 Pathway not proven 13 No 44 Not a host 36</td>
</tr>
<tr>
<td>Pepper</td>
<td>107</td>
<td>Yes 8 Pathway not proven 17 No 43 Not a host 32</td>
</tr>
<tr>
<td>Spinach</td>
<td>38</td>
<td>Yes 21 Pathway not proven 8 No 34 Not a host 34</td>
</tr>
<tr>
<td>Squash &amp; pumpkin</td>
<td>54</td>
<td>Yes 9 Pathway not proven 17 No 50 Not a host 24</td>
</tr>
<tr>
<td>Watermelon</td>
<td>58</td>
<td>Yes 9 Pathway not proven 10 No 55 Not a host 26</td>
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Table 1 – Overview of pest classifications for the crops currently included in the ISF Regulated Pest List

Interestingly, about 80% of the regulated pests fall in the categories of ‘seed is not a pathway’ or ‘crop is not a host’. Pests classified as such do not warrant to be regulated by any country. In case such pests are regulated, seed associations or importers have good reason to lobby for removal of the pests and the associated import requirements from the phytosanitary regulations.

The ISF Regulated Pest List is intended to facilitate a science based, globally harmonized approach in the PRA-process. In principle, a PRA is a process that needs to be ‘repeated’ for any country that wishes to import a commodity into the PRA area (country). For a commodity such as seeds with many countries of origin, this is a very complex and time consuming process, which would benefit from a harmonized more global approach.

**Stage 2 – RISK ASSESSMENT**

The process for pest risk assessment can be broadly divided into three interrelated steps:

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

The pest risk assessment should consider all aspects of each pest including information about its geographical distribution, biology and economic importance in areas where it is already present. Expert judgement is then used to assess the likelihood that it will be introduced, and its potential for establishment, spread and economic importance in the PRA area. In characterising the risk, the amount
of information available will vary with each pest and the sophistication of the assessment will vary with available tools.

It is an iterative process; it requires repeated consideration of the various elements which influence pest risk as information becomes available. It should be transparent, consistent, and based on sound science to provide the necessary technical justification to defend decisions regarding phytosanitary measures.

Uncertainty is inherent to any PRA, and is frequently the case for seeds. Estimation of the probability of introduction of a pest and of its consequences of introduction involves many uncertainties. In particular, this estimation is an extrapolation of information from where the pest actually occurs to the hypothetical occurrence of the pest in the PRA area.

Uncertainty may be attributed to things such as: lack of expertise, incomplete, inconsistent or conflicting data, imprecision in data, natural variability in data, subjective judgement, diseases of uncertain aetiology, biological unknowns of the pest or pathways, etc. ISPM 11 emphasizes the importance of documenting the areas of uncertainty and the degree of uncertainty in the pest risk assessment.

At the conclusion of this stage, information will have been gathered, evaluated and documented that identifies the pest or pathway that is being analysed, categorizes the pest(s), estimates the probability of each pest’s potential to be introduced and its potential impacts, calculates the overall potential pest risk, indicates whether the pest risk is acceptable or not, and determines if mitigation measures may be required. Any gaps in information, assumptions and uncertainty associated with the overall pest risk assessment will have been documented as well.

**Stage 3 – PEST RISK MANAGEMENT**

At the final stages of the Pest Risk Analysis, an NPPO will determine whether a pest warrants to be regulated for seeds for planting and establish the appropriate associated strength of the phytosanitary measure. The phytosanitary measure should be proportionate to the assessed pest risk for the seeds of a given species, origin, and purpose of import.

ISPM 11 clearly recognizes that zero-risk is not a reasonable option in risk management and describes pest risk management as the process of identifying ways to react to a perceived risk, evaluating the efficacy of these actions and determining the most appropriate mitigation options to achieve the desired level of protection. Countries are free to determine the required level of protection for a given pest in a specific crop and whether that level should be the same for the whole country or for certain areas (e.g. pest free areas or zones of low prevalence). It may be a challenge for industry when a country sets the required level of protection unrealistically high. In those cases a pest risk management measure may become a technical barrier to trade.

ISPM 2 provides a framework for the PRA, focuses on the initiation stage and on the characteristics for the determination of an organism as a pest. ISPM 11 describes the integrated processes to be applied both for risk assessment and for the selection of risk management options. The new ISPM 38 is more specific on risk management measures according to the purpose for which seeds are imported. It identifies various types of purposes of import with varying levels of potential pest risk; from the lowest pest risk of seeds for laboratory testing or destructive analysis, to somewhat greater pest risk of seeds for planting under restricted conditions, e.g. growth chamber or glasshouse, to the highest pest risk of seeds for field planting.
Phytosanitary measures may be defined per type of purpose depending on the identified pest risk level.

- If the seeds are not intended for planting/use in the environment – no phytosanitary measures may be needed. If imported for laboratory testing (germination but no planting) or destructive analysis – lab confinement and destruction should be sufficient as phytosanitary measure.
- Seeds for planting under restricted conditions (new breeding material, evaluation of germ plasm) – apply phytosanitary measures relevant to the assessed pest risk.
- Seeds for field planting – NPPO may require phytosanitary measures proportionate with the assessed pest risk.

These phytosanitary measures for imported seeds cannot be more stringent than the measures applied for seeds produced in the area/country. In the case of RNQPs, this means that there should be no difference between the seed tests and tolerance levels applied for locally produced seeds and those applied for imported seeds.

For further reading:

An Example of a Pest Risk Analysis – Erwinia stewartii in Maize: 

The most relevant ISPMs for a PRA:
Phytosanitary Measures

ISPM 11 describes several phytosanitary measures in general terms:

- **Applied to the consignment** - inspection, testing, treatment (most intensive is pre-entry or post-entry quarantine system)
- **Applied to prevent or reduce original infestation in the crop** – treatment of crop/field/production place, restrict composition of consignment to resistant/less susceptible species, growing under specially protected conditions, production in a certification scheme
- **To ensure the area or place of production is free from the pest** – pest-free area, pest-free place of production or pest-free production site, inspection of crop during active growth.
- In case none of above types of measures is deemed to be effective, prohibition of import of a commodity may be considered.

The new ISPM on the International Movement of Seeds describes phytosanitary measures more specific to the movement of seed. Countries have a number of options when defining phytosanitary measures for seeds. Measures can be defined and applied alone or in combination in order to manage the country’s determined level of pest risk:

- **Pest freedom**
  - Pest free areas
  - Pest free places of production
  - Pest free production sites
- **Areas of low pest prevalence**
- **Field inspection** (visual and/or backed up by laboratory testing of plant material to confirm symptoms)
- **Crop treatment**
- **Visual inspection of seeds**
- **Testing of seeds**
- **Seed treatment**
- **System approaches** - sets of integrated phytosanitary measures applied by seed producers and approved and monitored by an NPPO, resulting in assurance that the seeds produced under that regime are free of regulated pest(s).
- **Post-entry quarantine** – a defined period in which the planted seeds are grown in a confined and isolated location and inspected/tested for absence of Quarantine pests. Plants may be released by the NPPO for further distribution following inspection.
- **Prohibition** - a measure of last resort to be used only in case no other measures result in the required level of safety for the seed-transmitted pest concerned.

In practice, there are circumstances where seed exporters are unable to meet the established phytosanitary requirement(s). For example:

Field inspection: If seed is in the later stages of production or has already been harvested, a new requirement for a field inspection is not feasible. Additionally, some NPPOs refuse to perform field inspections for pests for which seed is not a pathway.

Crop/Seed treatment: When treatment with specific pesticides or specific active ingredients are required but they are not approved in either the country of production or the re-export country.
Testing of seeds: When no recognized, validated seed test exists. Even for pests for which a validated test does exist, the requirement might not be able to be met if the volume of seeds to be exported is smaller than the required sample size (ex. R&D or breeding materials). Lastly, although not restrictive, it is quite burdensome to seed exporters when exporting NPPOs do not recognize a certified test result that may have been generated on a seed lot in a previous exporting country. To meet the requirement, the seed exporter would be required to perform a duplicate test on the seed lot.

To remedy these situations and since seeds are frequently re-exported to a multitude of countries that may have defined different phytosanitary measures, the ISPM on International Movement of Seeds recommends that NPPOs define multiple equivalent phytosanitary measures to achieve the required protection. This provides operators the oftentimes required flexibility when exporting/re-exporting seeds. 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.

Communication of new or updated phytosanitary measures

Since phytosanitary measures may impact trade, it is important that NPPOs clearly communicate new or changed measures, well in advance of implementation. This is important for NPPOs of exporting countries, to verify scientific need, feasibility and trade impact and to prepare for implementation. But it is also important for producers, to anticipate and prepare for quality management adaptations such as: new field inspections to be organized, new tests to be implemented, new seed treatments to be applied, etc.

When a new phytosanitary measure is put in place, seed exporters typically have product in varying stages of development including planned seed production, in-process seed production, recently harvested seed, as well as seed in inventory. Without sufficient equivalent phytosanitary measures available, seed exporters are sometimes left without a means to meet the newly established phytosanitary requirements. For example, if the importing NPPO requires a field inspection and provides no equivalent measure as an option, then only future seed productions have the possibility to meet this requirement. For this reason, NPPOs should also consider that some phytosanitary measures can only be applied for seeds to be harvested in the coming seasons and not for seeds already in advanced stages of growing, recently harvested, or in stock from previous harvesting years. Transitional measures are to be considered by the NPPO of the importing country to assure continuation of supplies and imports.

Article 7 of the WTO-SPS agreement identifies a number of internationally accepted ‘rules’ to streamline the international communication of new or updated phytosanitary measures between member countries. Below is an excerpt from Annex B of the agreement:

*Whenever an international standard, guideline or recommendation does not exist or the content of a proposed phytosanitary regulation is not substantially the same as the content of an international standard, guideline or recommendation, and if the regulation may have a significant effect on trade of other Members, Members shall:*

(a) publish a notice at an early stage in such a manner as to enable interested Members to become acquainted with the proposal to introduce a particular regulation;
(b) notify other Members, through the Secretariat, of the products to be covered by the regulation together with a brief indication of the objective and rationale of the proposed regulation. Such notifications shall take place at an early stage, when amendments can still be introduced and comments taken into account;
(c) provide upon request to other Members copies of the proposed regulation and, whenever possible, identify the parts which in substance deviate from international standards, guidelines or recommendations;
(d) without discrimination, allow reasonable time for other Members to make comments in writing, discuss these comments upon request, and take the comments and the results of the discussions into account.

These requirements are designed to create transparency to and predictability of the trade between member countries. Countries satisfy these requirements by posting notifications to the WTO’s SPS Notification System. These notifications include information such as the crop(s) covered, the regions/countries likely to be impacted, a summary of the proposed changes along with the rationale, as well as whether the proposed regulation is in line with the relevant international standard. If the proposed measures are not in line with the international standards, a justification is provided. Additionally, the proposed date of adoption, date of entry into force, as well as a final date for comments from member countries are provided.

The period of comment is typically 60 days, and members are encouraged to grant extensions of 30 days whenever practical due to delays in receiving, translating, or when further clarification of the notification has been requested. Unfortunately, collecting and evaluating feedback from impacted exporters by the exporting countries along with the preparation of comments and/or change proposals often takes more time than the usual 60 day period.

The WTO-SPS Agreement provides for the following exceptions in emergency situations (excerpt from Annex B):

However, where urgent problems of plant health protection arise or threaten to arise for a Member, that Member may omit some of the steps as it finds necessary, provided that the Member:
(a) immediately notifies other Members, through the Secretariat, of the particular regulation and the products covered, with a brief indication of the objective and the rationale of the regulation, including the nature of the urgent problem(s);
(b) provides, upon request, copies of the regulation to other Members;
(c) allows other Members to make comments in writing, discusses these comments upon request, and takes the comments and the results of the discussions into account.

In practice we see a number of issues when countries define and implement new or updated phytosanitary measures:
- Notification is not always done in line with WTO-SPS procedures and a new measure may ‘suddenly appear’ when applying for an import permit.
- Notifications often do not contain the exact details of requirements defined in new or updated phytosanitary measures and such information is not always easily accessible (e.g. not available online).
- Time lines for comments may be very short or absent from notifications, even when a new/updated measure is not classified as an emergency situation.
Notifications are frequently published in the native language of the country issuing the notices, which can take time for commenters to obtain the necessary translations in time to evaluate the notices and submit comments prior to the close of the period for comments.
Phytosanitary Certification

Phytosanitary certification is a process undertaken by an NPPO (National Plant Protection Organization) to attest that the seed consignments meet phytosanitary import requirements. A phytosanitary certificate is an official document issued by the plant protection organization of the exporting country to the plant protection organization of the importing country. It can be issued only by a public officer who is technically qualified and duly authorized by an NPPO. To issue the phytosanitary certificate, Additional Declarations or (ADs) may be required for pathogens, insects, weeds, or other contaminants such as soil; all of which are collectively known as Pests. An example of a phytosanitary certificate and associated additional declarations is provided in Appendix 1.

The global and timely nature of the seed trade involves long-term storage of seed as well as repeated re-export from the same seed lot to multiple destination countries. This presents challenges to the process of phytosanitary certification distinct from those of the international movement of other commodities.

A Complicated Trade Model

As can be seen from the trade model above, the movement of seed around the globe presents many challenges. If trade is limited to a transfer of seeds between two countries, phytosanitary certification is “easier” as the exporter only needs to consider the requirements of one importing country. However, in the case of re-export to more than one country the process can become very complex. Each time the seed moves from one country to another, the number of ADs or Pest inspections needed for re-export changes. This is due to the various import requirements that are added for each new country of destination.

One of the biggest challenges to industry is to develop the list of additional declarations needed to ship a crop globally. Advanced preparation is the key to success. The first step is to determine which countries the seed of a specific variety of a species/crop will ultimately end up. Second would be to identify the route of re-export. In other words, determine if and where the seed will be shipped after
arriving in the first country of export. Next, the AD information for each destination country must be identified using the country website, import permits, prior experience, and/or local NPPO databases if they exist. When this information has been collected, you can define the sum of ADs that need to be secured with the NPPO in the country of seed production or that may be secured by a seed test in the country of processing (re-export).

This process to identify and obtain the required ADs has many stakeholders within a seed company, for example:

Production – This department is constantly exploring other and better production areas for year-round production capabilities. This will constantly add to the country of origin list which can change the AD list, or create a need for a Pest Risk Assessment in the final country of destination.

Customer Service – This department has the direct contact with the customer and sales staff. Consequently, they usually have the most up to date information on countries of destination and their requirements for ADs via import permits or other official documents. This flow of information must be coordinated as a routine process to facilitate immediate action within a seed company.

Quality Control – This department provides support for testing. New pests of concern can result from updated country requirements, so if this concerns a pest for which seed has been identified as a pathway, a (new) laboratory test may be needed. New test methods that may be faster and/or more sensitive may also be developed for a known pathogen.

Quality Assurance - This department captures the actual process flow, places the necessary Quality Management procedures at the critical control points, and provides a corrective action process for noncompliance.

Complications with field inspections can occur, especially when the listed pest is classified as “seed is not a pathway” or “not a host”. This pest may not be on the producing country or state inspection list and the NPPO of the country of seed production may refuse to inspect for the organism. The NPPO of the country of production will often ask for a description of the symptoms of this pest on the species in question, and often will have extra charges for the inspection needed to issue the AD.

Challenges occur for re-export when all of the export countries are not known at the time of production. Seed companies may not have anticipated an additional export country as the seed variety may have never been trialled or sold in that country. This may lead to unanticipated need for ADs and possible Field Inspection requirements after the seed has already been harvested. This also occurs when seed produced many years earlier does not meet the necessary requirements of today due to changing requirements. In those situations, equivalent phytosanitary measures may provide NPPOs of exporting/re-exporting countries with options to achieve the required protection. Appendix 2 of ISPM 12 provides several standardized AD texts, from which importing countries may select equivalent options. Additionally, the new ISPM gives NPPOs guidance on the importance of establishing equivalent phytosanitary measures.

A further challenge for re-exports is when the NPPO in the country of origin will only include additional declarations for the first country of export and not for further re-export. ISPM 12 clearly describes that additional official phytosanitary information which is not required for the first country
of import may be included on the phytosanitary certificate to enable certification for the re-export of seeds.

The new ISPM on the International Movement of Seed further clarifies that such a request for Additional Official Phytosanitary Information (AOPI) may be made directly by the importer/exporter to the NPPO of the certifying country. Today some countries argue that such a request may only come from the NPPO of the importing country.

To illustrate the process of phytosanitary certification, ISF has developed the flow chart on the following page. In addition, a table is provided as Appendix 4 to highlight some of the phytosanitary considerations, documentation, and best practices that are applicable during the various stages of seed production.
ISPM 38 on the International Movement of Seed – A Training Manual
For further reading:


A Systems Approach Toward Phytosanitary Management

ISPM 14 defines a Systems Approach as multiple 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 Quality Management systems as pest risk management measures. The advantage of a systems approach is that preventative controls are put in place during the entire seed supply chain process.

In general, seed companies view all pests, including those of phytosanitary concern, as a seed quality issue and take extra measures not to introduce or spread pests. If their seed contains unwanted pests including weeds or other foreign germplasm, seed quality is compromised. If that seed then enters the market, customers will complain, may need to be financially compensated and may ultimately be lost. Therefore, seed companies have developed sophisticated quality management programs (best practices) designed to protect their seed streams from exposure to pests and diseases at all stages of seed development and production up through commercialization. These practices also have the potential to manage and significantly reduce overall pest risk, and could be integrated in a systems approach.

There are various steps in seed development. The initial breeding cycle or “breeder seed” is usually small quantities of seed. This seed is used to produce the basic seed that is then multiplied to “Stock Seed”, which is then used to produce commercial quantities of seed. The seed produced and exported during the different steps of commercial seed development have varying levels of potential pest risk.

Lower Risk – Seed for Laboratory testing or destructive analysis.

Potential Medium Risk – Commercial Seed quantities that are planted under restricted conditions such as Good Seed and Plant Practices (GSPP), Greenhouse, Net house etc.
Potentially Higher Risk – Seed for open field planting.

Cultural practices, field treatments, post-harvest disinfection, inspection and other procedures may be integrated in a systems approach. ISPM 38 identifies the following seed production management practices that could contribute to reducing or properly managing pest risk:

**Pre-planting:**
- Use of healthy seed (free of regulated quarantine pests or meeting the tolerance level set for regulated non-quarantine pests)
- seed treatment (Pesticide, Fungicide, Nematicides, Bactericides)
- sanitation of seed for planting by hot water treatment, steam, deep freeze, disinfectants...etc.
- crop management (e.g. rotation or mixed planting) Very important to not follow the same species for a minimum of 3 years or more depending on the specie.
- use of sanitation crop/green manure (e.g. yellow mustard)
- field selection for specific - weeds, insects, other crop residue which may jeopardize the phytosanitary integrity.
- use of resistant varieties (section 1.5.2)
- soil treatment – fumigation, herbicides, etc.
- geographical or timed isolations
- sanitation or disinfection of irrigation water

**Pre-harvesting:**
- hygiene measures (e.g. disinfection of workers' hands and shoes, farm equipment, tools and machinery), this would include all individuals who enter or exit the field, greenhouse, net house etc.
- field inspection and, where appropriate, testing plants if symptoms are observed
- field sanitation (e.g. removal of symptomatic plants, removal of weeds)
- parent plant testing
- crop treatment for Pests- fungicides, insecticides, nematicides, and bactericides.
- protected cultivation (e.g. glasshouses, growth chambers)
- sanitation or disinfection of water

**Harvesting and post-harvest handling:**
- hygiene measures (e.g. disinfection of workers' hands and shoes, farm equipment, machinery and tools)
timely harvest (e.g. just as seed matures, in mast years for forest seed, from fruit at the pre-ripened stage) use of disinfectants during seed extraction

- seed cleaning, drying, conditioning and sorting (including color sorting)
- seed for testing to detect pests in seed storage
- seed treatment (section 1.5.3)
- sanitation (e.g. removing plant debris, soil or visibly infested plants and seeds)
- seed packaging and sealing
- mechanical treatments (e.g. separation of healthy seed).

Seed producers will need to first be aware of which pests are of phytosanitary concern to trading partners. As described in the previous chapter, this information can be difficult to find. Once identified, seed producers must define which of the above practices and in what combination will be needed for each seed species and for each stage of seed production to reduce the pest risk.

One example of a systems approach in seed production is the Good Seed and Plant Practices program used with Tomato to prevent Clavibacter michiganensis subsp. michiganensis (Cmm) infection. Another example of a system based approach that is being developed in the USA is the ReFreSH program. This program will be based on the accreditation of seed company QM systems based on the strength of their system in reducing and managing the pest risk to acceptable levels.

For further reading:

ISPM 14: Systems Approach for Pest Risk Management:

Good Seed and Plant Practices: http://gspp.eu/
Seed Testing

ISPM 38 on seeds provides guidance that there should be equivalent options to meet the desired risk level of imported seeds. The options may include measures applied and verified during seed production, in operations or as a part of seed quality testing. Within ISF there is a group who is solely focused on seed health assay development and validation. It is the International Seed Health Initiative-Vegetables group (ISHI-Veg) which now consists of more than 50 scientists from 11 different countries. They work collaboratively across seed companies, independent testing labs and lab accreditation entities to share data, pathogen isolates or strains, seeds, molecular information, etc. with the aligned goal of developing and validating seed health assays which may be used to enable the delivery of sufficiently healthy seed.

Routine Seed Health Testing

Routine seed health assays may use several different types of technology (Table 1). There are basic methods such as a grow out or seed plating, in which seeds are germinated under favourable environmental conditions to encourage disease development should the seed be contaminated with a pathogen. These assays usually require a greenhouse or growth chamber and a high level of technical expertise to inspect the seeds or seedlings to make a final assay determination. These assays require incubation times of days to weeks as this permits the pathogen to grow and infect the plant parts resulting in visible signs or symptoms. This type of assay is considered a direct method, that is, it permits the pathogen to be observed, recovered and confirmed as such via Koch’s postulates. Given the amount of time and resources associated with direct assays, many researchers are pursuing the development and implementation of indirect assays such as ELISA and PCR.

Indirect methods provide an indication of pathogen presence as these assays detect specific proteins or nucleic acids which are known to be indicative for the pathogen. Unlike direct assays, indirect assays do not result in the recovery and confirmation of a pathogen. Additionally, indirect assays will not distinguish between live and dead cells (or inactivated virions in the case of viruses); they only confirm that a protein similar enough to the desired target is present. There is a possibility of cross reactions occurring with indirect assays. Given that regulatory (e.g., seed import rejections) or quality decisions (e.g., seed lot destruction) may be taken based on the outcome of routine seed health assays, it is important to recover and confirm pathogen presence which can only be done with a direct method. For this reason, as stated in the ISF Viewpoint on Indirect Seed Health Tests position paper, “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”.

This position is also reflected in the below section of the new ISPM 38. The challenge for the seed industry is to explain and convey this message to NPPOs and to provide alternative solutions for confirmatory tests:

*Molecular and serological diagnostic methods are considered indirect protocols to detect pests in seeds.*
Indirect methods may give a positive result even when no viable pests are present. Consequently, when testing seeds with these methods, results should be interpreted carefully. Confirmatory tests or additional tests based on a different biological principle may be required to confirm the presence of a viable pest in a sample. NPPOs should ensure that internationally recognized or validated diagnostic protocols are used to avoid false positives or false negatives.

**Recommended Sample and Subsample Sizes for Seed Health Testing**

During assay development and validation, ISHI-Veg also determines the appropriate sample and subsample size for each target. Subsample size is related to the assay sensitivity, that is, the largest number of seeds in which a single infected seed can be consistently detected. Sample sizes are related to the epidemiology of the disease and the desired confidence to have detected the target pathogen during the testing process. For this reason, the sample sizes vary across the different methods that ISHI-Veg has developed. ISHI-Veg continues to monitor assay performance as it is implemented and routinely used and if there are method performance issues, the method is improved to ensure seeds are healthy if they pass an ISHI-Veg test.

The ISHI-Veg recommended sample sizes for testing should be used as reference when discussing testing protocols with NPPOs. This is relevant both for Quarantine Pests as well as for Regulated Non-Quarantine Pests.

ISHI-Veg validated testing protocols and recommended sample size can be found at: [http://www.worldseed.org/our-work/phytosanitary-matters/seed-health/ishi-veg/#protocols](http://www.worldseed.org/our-work/phytosanitary-matters/seed-health/ishi-veg/#protocols)

**Sampling of Small Seed Lots**

The guidance provided in ISPM 31 is not helpful for sampling very small seed lots such as those for trialling seed or breeding line increases, in which the seeds may come from only a few plants. In case the guidance of ISPM 31 would be followed strictly, for lots with fewer than 2000 seeds, a high percentage, if not all, of the seeds would have to be tested to ensure the lot was free of pathogen contamination. A new approach which factors in the epidemiology of diseases would be very useful to enable seed movement globally. Given the contagious nature of diseases, coupled with the spread on/in a plant and within a plant population, it is highly unlikely that only one seed is contaminated if a mother plant(s) is infected. A new sampling model that considers this dynamic of plant diseases would be very useful to enable the continued shipment of small lots.

The new ISPM 38 includes an entire section on this subject:

4.2.1 Sampling of small lots

*Testing of samples that are taken in accordance with ISPM 31 from a small lot may result in the destruction of a large proportion of the lot. In such cases, alternative sampling methodologies (e.g. clustering small samples of different lots for testing) or equivalent phytosanitary procedures 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.*
Seed Health Testing and Seed Treatments

An additional challenge is testing material: ISHI-Veg recommends that only untreated seeds or seeds with no seed treatment residue be tested. It is known that seed treatments may impact seed assay accuracy. An example is on brassica seeds where some seed sanitation efforts may leave a low pH residue which is released upon the addition of seed to the buffer in which the bacteria are extracted from the seeds. If the buffer is not sufficient to counteract the acid residue, the acid residue may inhibit *Xanthomonas spp.* recovery from contaminated seeds. For this reason, there are two methods for the detection of *Xanthomonas spp.* on brassica seeds available through ISHI-Veg: one for untreated seed and one for treated seed.

Table 1. Methods used in routine seed health testing

<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>

For further reading:

Outreach

Although countries can now begin implementing ISPM 38, it may take many years until we see practical changes in line with the new standard that will better facilitate the international movement of seeds for planting in a practical and science based manner. Even more so, it may be very unlikely that countries will make amendments to their phytosanitary framework and requirements unless challenged to do so by stakeholders.

It is therefore important for our industry that ISF and the national and regional seed associations raise awareness of the new standard as well as plan for education and outreach to try to achieve the needed changes in the national phytosanitary measures in a reasonable timeframe.

With the new ISPM, the focus must shift from ad-hoc problem solving targeting individual trade impeding new/emergency phytosanitary measures to a long term, systematic change of phytosanitary requirements and measures. This will require a working knowledge of the ISPMs, long term relations with regulators and NPPOs, and an agile approach to address the required changes unique to each country. National seed associations and seed companies from both importing and exporting countries will need specialists with the working knowledge of the ISPMs as well as the specific assignment to work on achieving these long term changes.

**Step 1 – NSAs must prepare to engage their NPPO**

Preparation of outreach is to be done country by country and needs to be based on the specific issues identified per priority country. During the preparation, experts of seed companies and national seed associations need to develop proposals to address the discrepancies between the new ISPM and the existing phytosanitary requirements. These proposals need to be science-based and need to address the reason why the country has regulated that specific pest-crop combination in an effective and feasible way. The proposals must reference the specific section/clause of the ISPM and include a technical justification for the de-regulation of pests that have little to no relevance to seeds. The references cited in the ISF Regulated Pest List are an excellent resource to support these proposals. Similarly, these proposals may also include recommendations on how to best regulate a relevant pest for seeds. Additionally, proposals may include recommendations on equivalent measures to be accepted by the NPPOs of the importing countries. Depending on the relationship between the NSA and the NPPO, it might be useful to consult the NPPO expert(s) at this stage to get advice on the best approach for proposing changes in their current phytosanitary requirements. In case support of the NPPO of the exporting country can be obtained, discussions on a change of a phytosanitary requirement with a country which imports seeds from that country is likely to be more successful.

**Step 2 – Country-specific outreach using shared, global best practices**

Outreach is coordinated and led by the national seed association in the country concerned. Outreach should be a combination of making a formal written request for changes as well as a face to face meeting with experts of the NPPO and responsible regulators to provide explanation and any background information. The NPPO/regulators may request additional data or trials to be performed, and the national associations should be prepared to support such efforts. In case a country is clearly unwilling to enter into a constructive and fact-based discussion on a needed change in phytosanitary requirements, approaching the Regional Plant Protection Organization (RPPO) may be considered.
When lobbying for updating of national phytosanitary requirements of countries, the RPPO of the region may be an important player, since we often see similar requirements of countries belonging to the same RPPO.

**The Role of ISF**

To aid in the preparation of outreach, ISF has developed this Training Manual and associated future workshops to bring awareness of the new ISPM as well as provide a broader understanding of the IPPC, ISPMs, and ISPM creation process. Furthermore, the workshops aim to illustrate the importance of the preparation of outreach to be performed in each country as well as the coordination needed to ensure a harmonized implementation.

In order for ISF to provide the coordination necessary to ensure the harmonization of outreach efforts, it will be necessary for ISF to be informed of the preparation of outreach and outreach activities taking place at a national level. Cooperation and sharing of best practices and experiences will be essential. In the preparation of outreach phase, written proposals should be made available to ISF such that these proposals can be shared amongst the seed associations. These proposals can then be harmonized prior to the final outreach to ensure that the implementation of the new ISPM by the NPPOs is also harmonized.

Further training and additional workshops will be necessary to provide continued awareness and training on the new ISPM. ISF will assist with the coordination and preparation of these workshops to provide a consistent message, foster the exchange of best practices, and drive the exchange of outreach proposals across the seed associations.

**Practical lobbying and outreach opportunities for the seed industry:**

Seed companies/seed associations may assist by:

- Participation in reviewing and preparing new ISF Regulated Pest Lists as well as updating existing ISF Regulated Pest Lists – Please contact the ISF Secretariat
- Comparing the list of regulated pests with the ISF Regulated Pest List to identify whether Seed is a Pathway for each of the pests.
- Communication of the ISF Regulated Pest Lists to your NPPO or other regulatory bodies
- Referring to the ISF Regulated Pest Lists in case of new import requirements in countries
- Providing technical evidence in case countries have defined the ‘required level of protection’ unrealistically high
- Providing technical evidence in case countries have defined impractical pest risk management measures and providing more practical, but efficient alternative measures
- Proposing practical pest risk management measures for seeds imported for intended uses other than open field planting
- Proposing practical solutions for phytosanitary imports of small seed quantities
- Promoting the use of alternative, equivalent phytosanitary measures
- Promoting the use of Seed Health testing protocols developed by ISF’s International Seed Health Initiative (ISHI)
- For re-exports, urge your NPPO to provide additional declarations for future re-export from importing country
- If re-export requirements are not science-based (ie. ISF Regulated Pest List indicates “Seed is not a Pathway” or “Not a Host”), urge your NPPO to contact the NPPO that is requiring it.
Appendix 1 - List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>AD</td>
<td>Additional Declaration</td>
</tr>
<tr>
<td>AOPI</td>
<td>Additional Official Phytosanitary Information</td>
</tr>
<tr>
<td>CPM</td>
<td>Commission on Phytosanitary Measures</td>
</tr>
<tr>
<td>IPPC</td>
<td>International Plant Protection Convention</td>
</tr>
<tr>
<td>ISHI</td>
<td>International Seed Health Initiative</td>
</tr>
<tr>
<td>ISPM</td>
<td>International Standard on Phytosanitary Measures</td>
</tr>
<tr>
<td>NPPO</td>
<td>National Plant Protection Organization</td>
</tr>
<tr>
<td>PRA</td>
<td>Pest Risk Analysis</td>
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<tr>
<td>RPPO</td>
<td>Regional Plant Protection Organization</td>
</tr>
</tbody>
</table>
Appendix 2 – Basic Phytosanitary Principles of the IPPC

ISPM No. 1: (Phytosanitary principles for the protection of plants and the application of phytosanitary measures in international trade, 2006) describes twenty eight principles, eleven of which are basic principles and seventeen operational principles. The eleven basic principles are fundamental to all aspects of IPPC-related activities undertaken by a member country. They are:

- **Sovereignty**—countries have the sovereign authority to utilise phytosanitary measures to regulate the entry of plants and plant products or other regulated articles, for the purpose of preventing the introduction and/or spread of quarantine pests into their country.

- **Necessity**—phytosanitary measures may only be applied where such measures are necessary to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.

- **Managed risk**—phytosanitary measures should be based on a policy of managed risk, recognizing that risk of the spread and introduction of pests always exists when importing plants, plant products and other regulated articles.

- **Minimal impact**—phytosanitary measures should be consistent with the pest risk involved and should represent the least restrictive measures available to address that risk. They should result in the minimum impediment to international movement of people, commodities and conveyances.

- **Transparency**—countries should publish and disseminate phytosanitary requirements, restrictions, and prohibitions promptly and the rationale for such measures should be made available upon request.

- **Harmonisation**—phytosanitary measures should be based, wherever possible, on international standards, guidelines and recommendations developed within the framework of the IPPC.

- **Non-discrimination**—phytosanitary measures should be applied without discrimination between countries of the same phytosanitary status. For a particular quarantine pest, phytosanitary measures should be no more stringent when applied to imported goods than measures applied to the same pest within the territory of the importing country.

- **Technical justification**—phytosanitary measures should be technically justified based on an appropriate pest risk analysis or, where applicable, another comparable examination and evaluation of available scientific information.

- **Cooperation**—countries should cooperate to prevent the spread and introduction of pests of plants and plant products, and to promote measures for their official control.

- **Equivalence**—importing countries should recognise alternative phytosanitary measures proposed by exporting countries as equivalent when those measures are demonstrated to achieve the appropriate level of protection determined by the importing country.
- Modification—modifications of phytosanitary measures should be determined on the basis of a new or updated pest risk analysis or relevant scientific information. Countries should not arbitrarily modify phytosanitary measures.

In addition to the eleven basic principles, ISPM No. 1 (2006) also describes the seventeen operational principles, which either relate to the establishment, implementation and monitoring of phytosanitary measures or to the administration of a phytosanitary system.
Appendix 3 – An Example of a Phytosanitary Certificate with Additional Declarations
TOMATO SEEDS (SOLANUM LYCOPERSICUM)

CONSIGNMENT COMPLIES WITH ANNEX IV-A.1, POINT 48.C OF EC PLANT HEALTH DIRECTIVE 2000/29/EC.

CONSIGNMENT COMPLIES WITH POINT 48.C (TESTED FREE FROM CLAVIBACTER MICHIGANENSIS SSPE MICHIGANENSIS, XANTHOMONAS CAMPESTRIS PV. VESICATORIA AND POTATO SPINDLE TUBER VIROID)

CONSIGNMENT COMPLIES WITH 2004/200, ANNEX I C. THE SEEDS HAVE BEEN OBTAINED BY MEANS OF AN APPROPRIATE ACID EXTRACTION METHOD AND B SEEDS HAVE UNDERGONE OFFICIAL TESTING FOR PEPINO MOSAIC VIRUS ON A REPRESENTATIVE SAMPLE AND USING APPROPRIATE METHODS, AND HAVE BEEN FOUND: IN THESE TESTS, FREE FROM PEPINO MOSAIC VIRUS.

THE PARENT PLANTS WERE INSPECTED DURING ACTIVE GROWTH AND FOUND FREE FROM ARABIS MOSAIC NEMOVIRUS (ARMV)

ALTERNARIA BRASSICOLA (BLACK LEAF SPOT AND GREY LEAF SPOT)

BROAD BEAN WILT VIRUS

CLAVIBACTER MICHIGANENSIS SUBSP. SEPEDONICUS

CUCUMBER MOSAIC VIRUS (CMV)

DIDYMELLA (PHOMA) LYCOPERSICI DIDYMELLA STEM ROT)

ERWINIA CAROTOVORA SUBSP. CAROTOVORA (BACTERIAL SOFT ROT)

FUSARIUM OXYSPORUM FSP RADICE-LYCOHERICIS (FUSARIUM CROWN AND ROOT ROT)

FUSARIUM OXYSPORUM FSP LYCOPERSICI (FUSARIUM WILT)

MACONELLCCOCUS HIRSUTUS

PEPINO MOSAIC VIRUS (PEMV)

PSEUDOMONAS CORRUGATE (TOMATO PITH NECROSIS)

PSEUDOMONAS SYRINGAE PV SYRINGAE (BACTERIAL BROWN SPOT)

PHOMA ANDIGENA

POTATO SPINDLE TUBER VIROID (PSTV)

RALSTONIA SOLANACEARUM = PSEUDOMONAS SOLANACEARUM (BACTERIAL WILT)

TOBACCO MOSAIC VIRUS (TMV, TOBAMO VIRUS)

TOBACCO APICAL STUNT VIROID

TOBACCO ASPERMYS VIRUS

TOBACCO BLACK RING VIRUS (TBKV)

TOBACCO BUNGHY TOP VIROID (TBTV)

TOBACCO BUSHY STUNT VIRUS (TBSV)

TOBACCO CHLOROTIC DWARF VIROID

TOBACCO MOSAIC VIRUS (TOMY, TOBAMO VIRUS)

TOBACCO PLANTA MACHO VIROID

TOBACCO RING SPOT VIRUS (TORSV, NEPO VIRUS)

TOBACCO SPOTTED WILT VIRUS (TSWV)

VERTICILLIUM ALBO-ATRUM, VERTICILLIUM DAHLIAE (BACTERIAL WILT)

PEPPER CHAF FRUIT VIROID

PERONOSPORA HYOSCYAMI PV. TABACINA

PHYTOPHTHORA CAPSICI (PHYTOPHTHORA ROOT ROT)

TROGODERMA GRANARIUM

TROGODERMA SP

MACONELLCUS HIRSUTUS

THE SEEDS HAVE BEEN INSPECTED AND FOUND FREE FROM THE FOLLOWING DISEASES:

PSEUDOMONAS SYRINGABPV TOMATO = PSEUDOMONAS PUNNCTULANS (BACTERIAL SPECK)

XANTHOMONAS CAMPESTRIS PV. VESICATORIA = XANTHOMONAS VESICATORIA (BACTERIAL LEAF SPOT)
## Appendix 4 – Phytosanitary Considerations, Documentation, and Best Practices

### During Various Stages of Seed Production

<table>
<thead>
<tr>
<th>Stages</th>
<th>Further Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Breeding Material Confined to Laboratory, Growth Chamber, Greenhouse, Screenhouse Seed for Use in Open Air Breeding Programs, Variety Testing, Seed Stock Increases, Seed Production, Commercial Sales</td>
<td></td>
</tr>
<tr>
<td><strong>Identification of Phytosanitary Concern</strong></td>
<td></td>
</tr>
<tr>
<td>- Pest risk is minimal if germplasm remains confined and not exposed to environment of country of destination.</td>
<td></td>
</tr>
<tr>
<td>- Consider seed lot size based on seed testing import requirements.</td>
<td></td>
</tr>
<tr>
<td>- Importing country may require a PRA; may impose post entry quarantine (if company has capacity for ensuring confinement), mandatory seed treatments or seed testing prior to entry.</td>
<td></td>
</tr>
<tr>
<td>- Consider seed lot size based on seed testing import requirements.</td>
<td></td>
</tr>
<tr>
<td>- Importing country may require a PRA if it is a new market access: import permit may be required; phytosanitary certificate usually required. Depending on size of seed lot being exported, sample size required for a seed test may be an issue. Seed treatment may also be required. Re-export issues may be a consideration. All pests of concern to the country of final destination will have to be addressed before entry will be allowed.</td>
<td></td>
</tr>
<tr>
<td>- In addition to import permit, phytosanitary certificate is usually required; if re-export is envisioned, a re-export certificate will be required: check with NPPO of final country of import for requirements. Any pests not addressed in the first country of export will have to be mitigated in the country of re-export. The country of import will often require specific additional declarations (AD) for pests of concern based on its specific phytosanitary requirements (seed test, field inspection, seed treatment, etc.) If seed re-export is envisioned, the seed producer is encouraged to ask the NPPO of the country of origin to include information on pests of concern to the country of final destination on the phytosanitary certificate under “other official phytosanitary information.”</td>
<td></td>
</tr>
<tr>
<td>- Proper pre-plant site preparation (pre-plant weed control, maintain weed free buffers); pest management practices for key pests; frequent field inspections, rogueing, removal of field from production if necessary; post harvest seed cleaning and conditioning; seed testing</td>
<td></td>
</tr>
</tbody>
</table>

### Documentation

<table>
<thead>
<tr>
<th>Stage</th>
<th>Required Documents</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research and Breeding</strong></td>
<td>Import permit, general permit, and/or phytosanitary certificate may be required: check with NPPO of importing country.</td>
</tr>
<tr>
<td><strong>Seed Production Stage</strong></td>
<td>Import permit; post entry quarantine permit; phytosanitary certificate (check with NPPO for requirements); Phytosanitary certificate requirements (field inspections, seed testing) must be fulfilled by official NPPO inspectors and labs or third parties officially recognized by the NPPO.</td>
</tr>
<tr>
<td><strong>Commercial Sales</strong></td>
<td>Import permit may be required; phytosanitary certificate usually required (certification usually based on official field inspections, seed tests, seed treatments, production in an official pest free area, etc.: check with NPPO of importing country).</td>
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</tbody>
</table>

### Applicable Best Practices

- Documentation and use of proper biosecurity and sanitary protocols;
- Training of workers;
- Frequent monitoring of plants;
- Removal (rogueing) of infected plants;
- Testing of seeds (where applicable); Seed testing (if possible or applicable); frequent field inspections; rogueing of suspect plants; pre-planting weed control and rogueing of weed plants; use of buffer zones; seed cleaning and conditioning post harvest.