Harmonization: What is it and how do we make it work?

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Why harmonize?*

* There will be a quiz with valuable prizes at the end of this talk!
Organizations and Agreements

• World Trade Organization (WTO)
  – Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)
  – www.wto.org

• International Plant Protection Convention (IPPC)
  – www.ippc.int

• North American Plant Protection Organization (NAPPO)
  – www.nappo.org
What are the options for deciding measures?

• Harmonize: everybody do the same thing, and accept the same thing
  – The standard setting organization does the work (mostly)

• Equivalence: one country recognizes another country’s actions as equal (case by case)
  – Exporting country does the work (mostly)

• Risk analysis: each country decide each case one at a time based on identified risk
  – Importing country does the work (mostly)
What’s it all about?

**SPS Article 2:** “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...”.
“Harmonization”

• Article 3: “To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations”

• Measures may “conform to” international standards

• BUT....
  Measures can achieve a higher level of protection if based on scientific justification (risk assessment)
Types of Phytosanitary standards

- Reference standards
  - Glossary of Phytosanitary Terms
- Pest risk analysis standards
- Concept standards
  - Guidelines for pest free areas
- Specific standards
  - Wood packaging
  - Fruit fly standards
  - Seeds (draft)
“Equivalence”

Article 4: **Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own** or from those used by other Members trading in the same product, if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection.
<table>
<thead>
<tr>
<th>Harmonization / Equivalence / Risk Assessment</th>
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<tbody>
<tr>
<td><strong>Country A</strong></td>
</tr>
<tr>
<td>Recognizes Measure II from Country Z (which is different from Standard I and different from Country A’s requirements)</td>
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<td>Based on Standard I</td>
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<td><strong>Burden of proof</strong></td>
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<td><strong>Applies to</strong></td>
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<td><strong>Members</strong></td>
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<tr>
<td><strong>Exporting country Z</strong> (in cooperation with importing country A)</td>
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<tr>
<td><strong>Burden of proof established</strong></td>
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<td><strong>Members</strong></td>
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<tr>
<td><strong>PRAs for pests, commodities, countries or policies</strong></td>
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<tr>
<td><strong>Country A</strong></td>
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<td><strong>Variable</strong></td>
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- **Country A**
- **Country Z**
- **Burden of proof**
- **Standard setting body (and members)**
- **Members**
- **One**
- **Exporting country Z**
- **Burden of proof established**
- **Members**
Options for harmonization

EXAMPLES:

• Measures
  – ISPM 15
  – Pest free areas

• Actions
  – Inspection
  – Certification

• Procedures
  – Risk analysis
  – Pest listing
  – Diagnostic test
  – Treatment
What does harmonization look like?

• Measure: Treated wood packing material
  – Use and compliance with ISPM 15 mark

• Action: Phytosanitary Certification
  – PCs conform to Model Phytosanitary Certificate

• Procedure: Pest risk analysis
  – Use ISPM 11 to develop PRAs
What does harmonization look like?

• Pest lists
  – Use common criteria for listing pests associated with commodity in a standard (one list agreed by all members)

• Requirements
  – Asian Gypsy Moth requirements for ships and containers (NAPPO)

• Treatments
  – Identify a specific treatment for a commodity/pest combination that achieves a specified effect (agreed by all members)
What does harmonization **NOT** look like?

• **Pest lists**
  – Use different criteria and develop separate lists for the same hosts or pests

• **Diagnostic tests**
  – Each country identify their own tests, but no consensus on a specific test

• **Treatments**
  – Each country identify treatments they deem acceptable but no consensus on a specific treatment
Some notes on harmonization:

• Where a country’s appropriate level of protection is different than a specified effect they may elect not to use that [test, treatment, etc] – principles of sovereignty and ALOP

• Harmonization may be “agreed measures” that reach a specified effect, *but that specified effect may or may not be based on risk or a pest risk assessment*
Let’s talk about benefits and participation...

• Who benefits?
  – Countries, States + local governments, and industries

• What are the benefits?
  – Greater predictability
  – Fair, transparent and technically justified

• Why participate?
  – Provide inputs and expertise
  – Ensure valuable perspectives are incorporated

• How to participate?
  – Serve as an expert
  – Provide comments
  – Contact PPQ – IPS team
What about Pest Risk Analysis?

• As the basis for harmonization...
• To establish equivalence...
• When a country wants to establish measures different than a standard...
• When there is no specific standard...
• *Who does the work?*
Harmonization Quiz!

True or False?

Only experts from the National Plant Protection Organization (in the case of the US, PPQ) can participate in IPPC or NAPPO standard setting work.
Harmonization Quiz!

True or False?

Regional standards developed by NAPPO play an important role in promoting safe trade and a North American approach between Canada, Mexico and the United States for the benefit of countries, states and industries in these countries.
Harmonization Quiz!

True or False?

If I follow a diagnostic protocol for a pest and that protocol has been adopted by the IPPC or NAPPO, my trading partners should accept the results of my testing.
Harmonization Quiz!

Which of the following is NOT harmonization?

A. A standard provides a list of all known hosts of a pest, based on scientific information, and agreed upon by all Members

B. A standard provides a list of all known diagnostic tests for a pathogen, based on scientific information, used by different countries

C. A standard describes a procedure for designating and recognizing a pest free area for a pest, based on scientific information, and agreed upon by all Members
Harmonization Quiz!

For each example below, does it describe harmonization, equivalence or pest risk analysis?

1. My country has determined the risk associated with importing live, rooted birch trees to be unacceptable
2. My country bases its regulations for wood packing material on ISPM 15
3. My country has asked Country Z to recognize hot water treatment of “bingo-fruit” as an acceptable mitigation for “bingo-fruit” borer
Harmonization Quiz!

True or False?

If a commodity has been treated for a quarantine pest following a phytosanitary treatment adopted by the IPPC, my country MUST accept that commodity.
Harmonization Quiz!

True or False?

By following agreed-upon international and regional standards, countries can manage risk in a least trade restrictive manner?