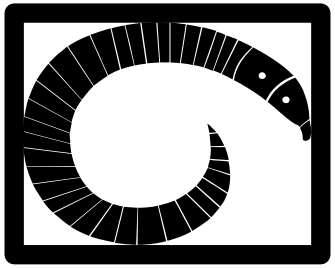
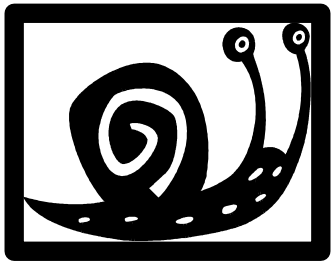
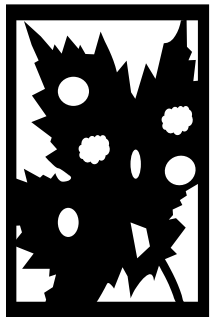
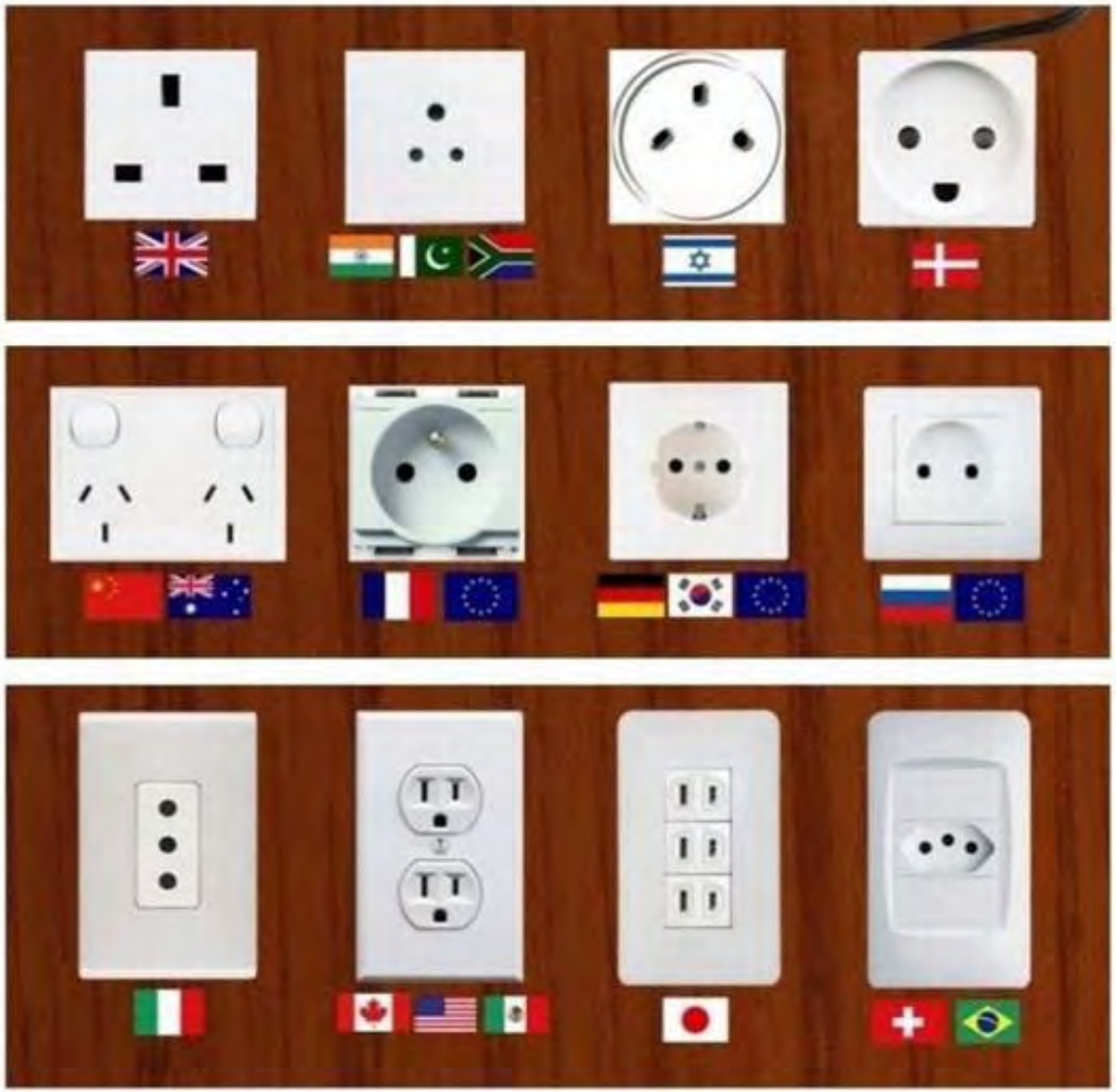
Harmonization: What is it and how do we make it work?

Christina Devorshak
USDA, APHIS, PPQ
Center for Plant Health Science and Technology

Why harmonize?



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 recognize 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)

Key SPS Provisions

- Sovereignty
- Harmonization
- Equivalence
- “Appropriate level of protection”
- Risk Assessment

- Provisional measures
- Least trade restrictive (minimal impact)
- Non-discrimination / national treatment
- Transparency / notification
- Regionalization

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**.

Harmonization vs Equivalence

		Burden of proof	Applies to
Country A Country B Country… Country Z	Based on Standard I	Standard setting body (and members)	Members
Country A	Bases requirements on Standard I; Country B, C, D know requirements	Burden of proof established	Members
Country A	Accepts Country B, C, D, etc products since they conform to Standard I	Burden of proof established	Members
Country A	Recognizes Measure II from Country Z (which is different from Standard I and different from Country A's requirements)	Exporting country Z (in cooperation with importing country A)	One*

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 (Guidelines for PRA…)

What might harmonization look like for a commodity or pathway?

- Pest lists
  - Use common criteria for listing pests *associated* with commodity in a standard (one list agreed by all members)
- Diagnostic tests
  - Identify a specific test that achieves a specified result (agreed by all members)
- 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

Some notes on harmonization:

- 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*

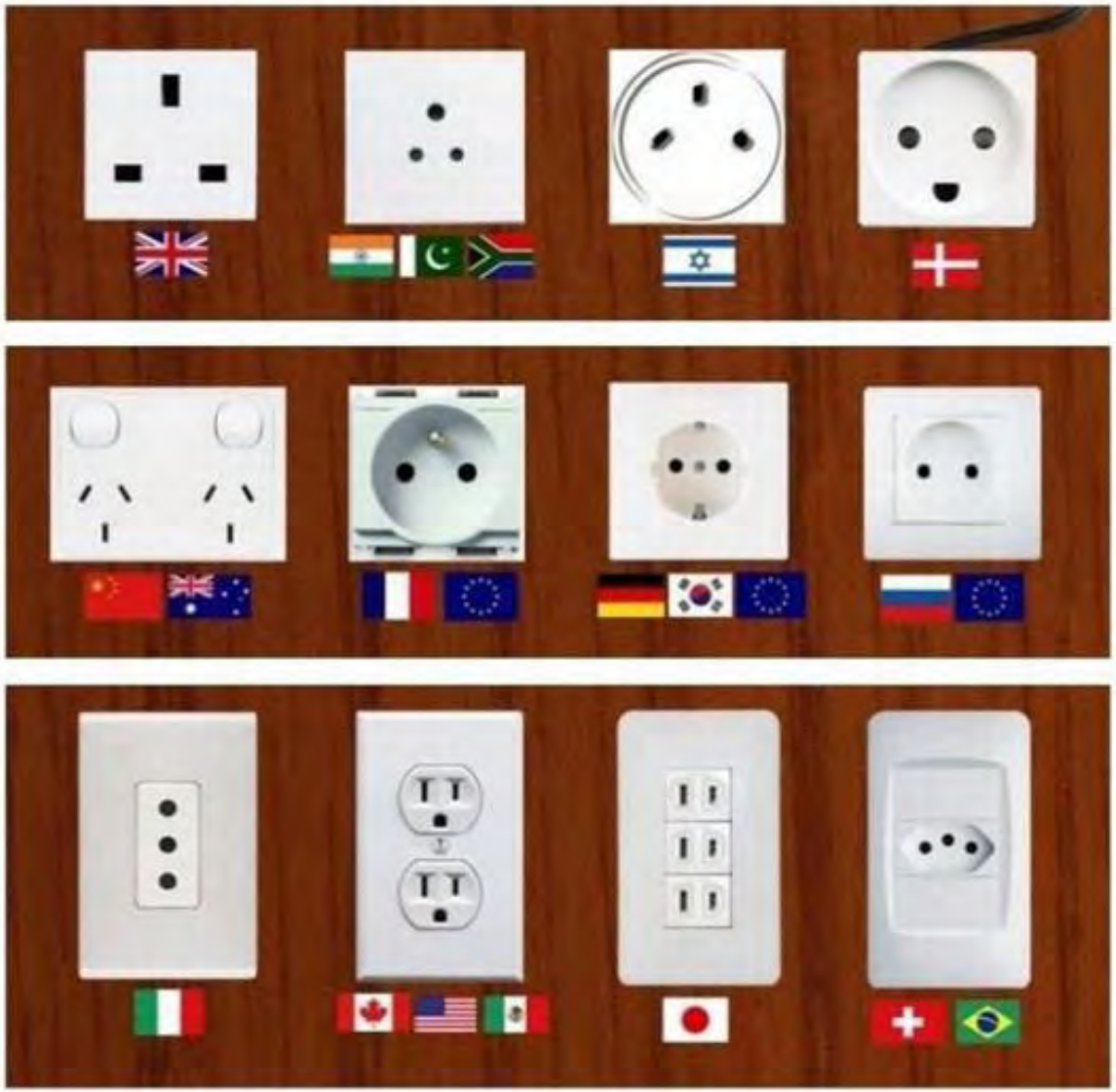
What about Pest Risk Analysis?

- 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?***

Risk assessment (Art. 5)

- "The **evaluation of the likelihood** of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary and phytosanitary measures which might be applied, and of the **associated potential biological and economic consequences**
- Burden of proof on **importing country** (mostly)
- Parts of PRA might be harmonized (like pest listing)

Why harmonize?



Harmonization Quiz!

True or False?

If I follow a diagnostic protocol for a pest that is 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?

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Tack
Asante
谢谢
Tak
mulţumesc
kiitos
Gracias
Salamat!
Terima kasih
Aliquam
Merci
Dankie
Obrigado
ありがとう
köszönöm
grazie
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Go raibh maith agat
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Thank you
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