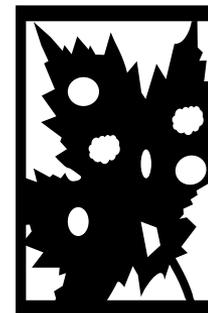
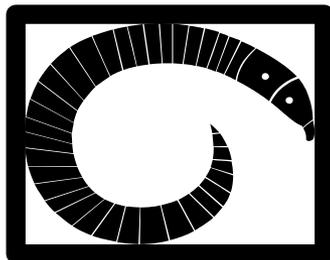


Harmonization: What is it and how do we make it work?

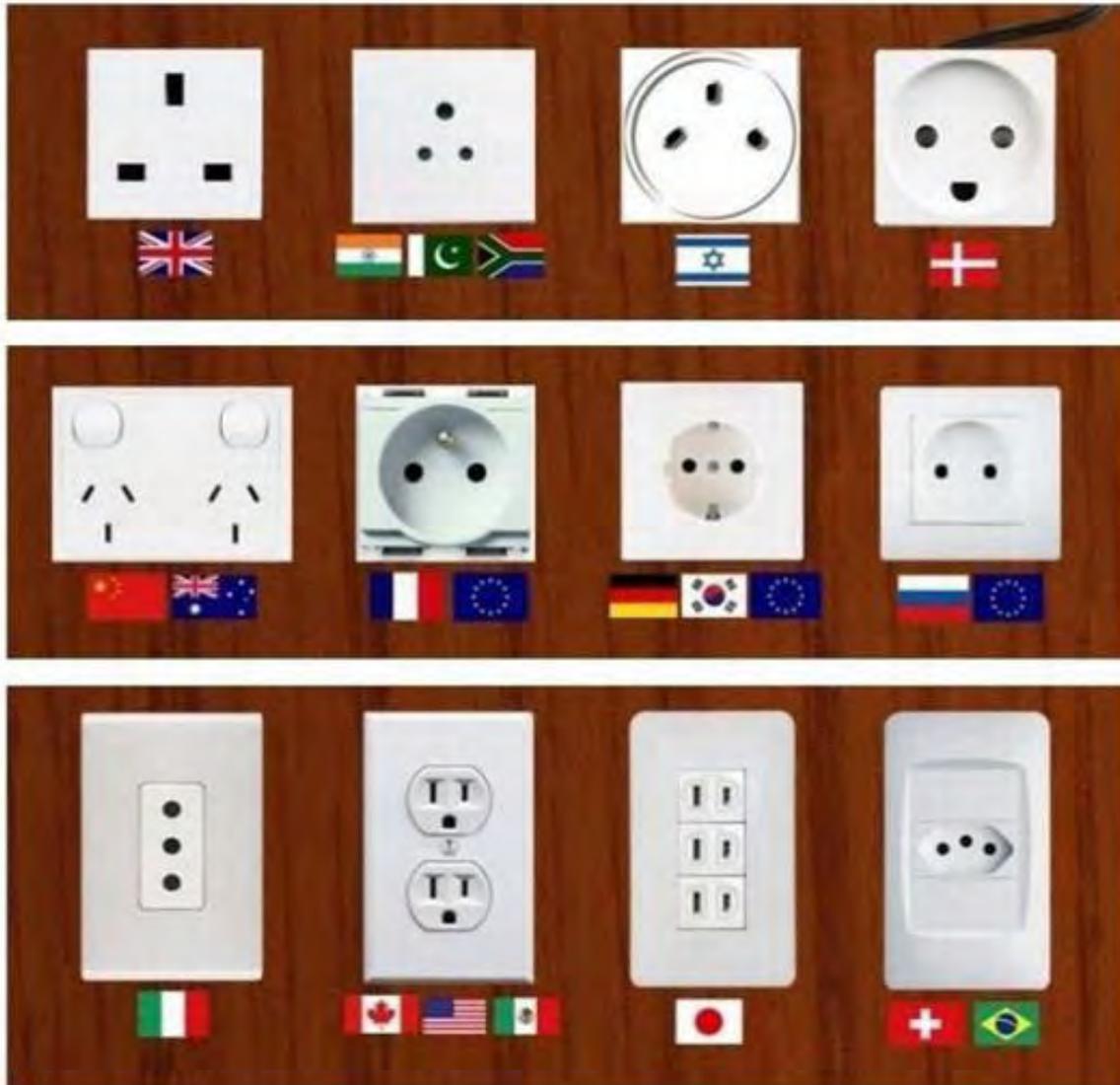


Christina Devorshak

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
- 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...”.

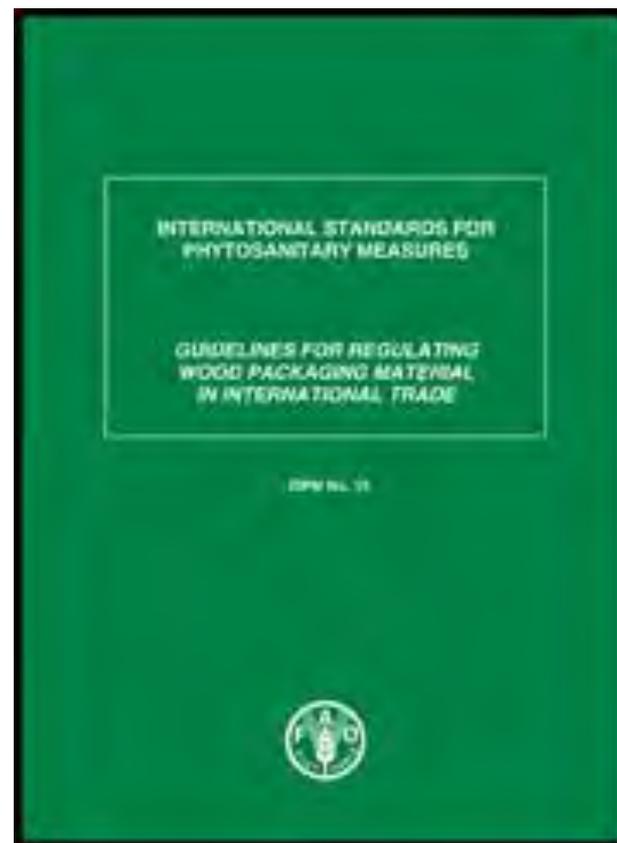
“Harmonization”

- 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

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

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 for seed work look like?

- Pest lists
 - Use common criteria for listing pests *associated* with seed 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 seed/pest combination that achieves a specified effect (agreed by all members)

What does harmonization for seed work **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 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



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)

Pest Risk Analysis Process Overview

Stage 1: Initiation

Define scope

Stage 2: Pest Risk Assessment

Pest
categorization

Estimate
likelihood of
introduction

Estimate
consequences

Develop
conclusions
and describe
uncertainty

Re-evaluation

Develop
recommendations

Compare
assessed
risk to
proposed
mitigations

Evaluate
options for
efficacy,
feasibility,
and impact

Identify
mitigation
options

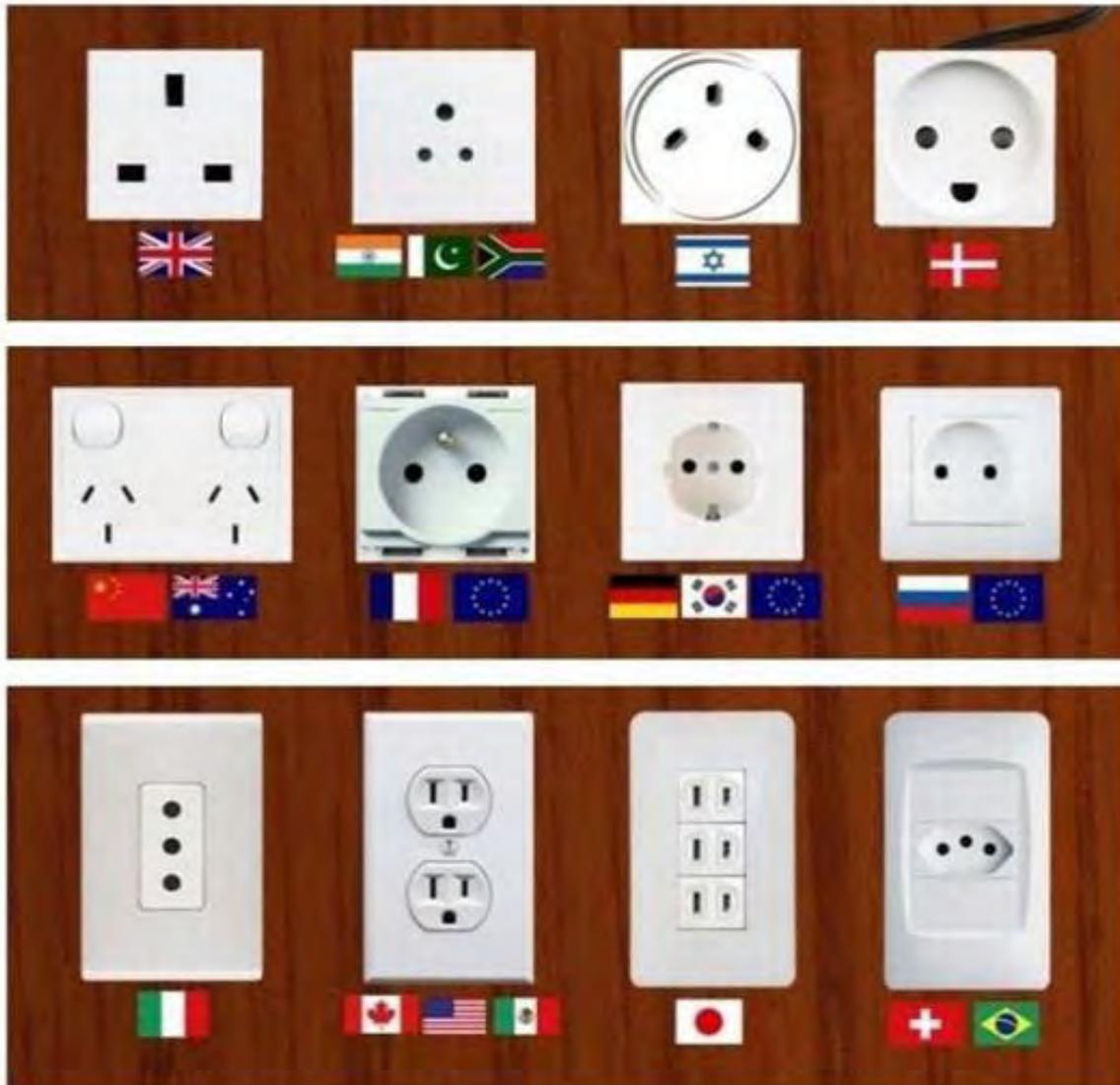
Does the risk
require
mitigation?

Stage 3: Pest Risk Management

Decision making

Regulatory
decisions

Why harmonize?



dank u
 Tack ju faleminderit
 Asante 谢谢 Tak mulțumesc
 kiitos
Salamat! Gracias
 Merci Terima kasih Aliquam
 ありがとう Dankie Obrigado
 köszönöm grazie
 Aliquam Go raibh maith agat
 děkuji Thank you