Risk Analysis in the SPS Agreement and Lessons Learned from Dispute Settlement

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Risk Analysis

Risk assessment

• identification diseases / adverse effects
• evaluation of likelihood (or probability) + magnitude of consequences
• according to the SPS measure which might be applied

Risk management

• decisions on acceptability
• choice of measures
• minimizing negative effects on trade
• “consistency”

Application

• MFN
• National treatment
• Annex C – control, inspection and approval procedures
Key Provisions of the SPS Agreement

1. Non-discrimination
2. Scientific justification
   • harmonization
   • risk assessment
   • consistency
   • least trade-restrictiveness
3. Equivalence
4. Regionalization
5. Transparency
6. Technical assistance/special treatment
7. Control, inspection and approval procedures
Scientific Justification

*Articles 3 & 5*

Measures must be based on

- International standards
- Risk assessment

OR
## Normal Steps under the SPS Agreement

1. Is it an SPS measure? 
   - Article 1.1
2. Does a relevant international standard exist? 
   - Article 3
3. Is the measure based on the international standard? 
   - Article 3
4. Is this a provisional measure? 
   - Article 5.7
5. Does a risk assessment exist which complies with the SPS Agreement? 
   - Articles 5.1 – 5.3
6. Is the measure based on a risk assessment? 
   - Article 5.1
7. Is the ALOP consistent? 
   - Article 5.5
8. Is the measure the least trade-restrictive? 
   - Article 5.6
Food safety:
US/Canada vs. EC - Hormones (WT/DS26, 48)
(EC vs. US/Canada – Continued Suspension (WT/DS320, 321))
China vs. US – Poultry (WT/DS392)
[Canada vs. Korea - BSE (WT/DS391)]

Food safety + plant and animal health: (biodiversity considerations)
US/Canada/Argentina vs. EC - GMOs (WT/DS291, 292, 293)

Animal health:
Canada / US vs. Australia - Salmon (WT/DS18, 21)
[US vs. India – Avian Influenza (WT/DS430)]
[Argentina vs. US – Foot-and-Mouth Disease (FMD) (WT/DS447)]

Plant protection:
US vs. Japan - Variety Testing (WT/DS76)
US vs. Japan – Fire blight (WT/DS245)
New Zealand vs. Australia - Apples (WT/DS367)
<table>
<thead>
<tr>
<th><strong>Case/Art</strong></th>
<th><strong>Scientific justification (2.2 / 5.7)</strong></th>
<th><strong>Harmonization (3.1 – 3.3)</strong></th>
<th><strong>Equivalence (4)</strong></th>
<th><strong>Risk assess. (5.1- 5.3)</strong></th>
<th><strong>Consistency (5.5)</strong></th>
<th><strong>Least trade restr. (5.6)</strong></th>
<th><strong>Transparency (7 / Annex B)</strong></th>
<th><strong>Approval proced. (8 / Annex C)</strong></th>
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Not yet examined: Regionalization (Art. 6)
Members shall ensure that their SPS measures are based on

- an assessment, as appropriate, of the risks to human, animal or plant life or health,
- taking into account risk assessment techniques developed by the relevant international organizations.
Risk Assessment

Annex A.4 - Definitions

Food safety risks:

evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins, or disease-causing organisms in food, beverages, or feedstuffs

Pest or disease risks:

evaluation of likelihood of entry, spread, and establishment of a pest or disease according to the SPS measures which might be applied and of associated potential biological and economic consequences
Risk Assessment

In risk assessment, take into account:

- Scientific evidence
- Processes and production methods
- Inspection, sampling, and testing methods
- Pest or disease prevalence
- Ecological and environmental conditions
- Quarantine and other treatment
Risk Assessment – Lessons Learned

*Articles 5.1, 5.2 and Annex A.4*

**Question 1**
- Is there a risk assessment within the meaning of the SPS Agreement?

**Question 2**
- Is the measure based on that risk assessment?
Food safety risk assessments must:

- Identify the adverse effects arising from the additive, contaminant, toxin or disease-causing organism
- Evaluate the potential for such adverse effects to occur

Risk Assessment – Lessons Learned

Articles 5.1, 5.2 and Annex A.4
Risk Assessment – Lessons Learned

*Articles 5.1 – 5.2*

- non-use of international standard requires risk assessment
- no need to carry out “own” risk assessment
- risk assessment need not be quantitative
- risks must be ascertainable, not just theoretical
- can go beyond controlled lab conditions, assess risk in real world
- risk assessment can consider divergent, minority scientific views
Risk Assessment – Lessons Learned

Articles 5.1 – 5.2

Question 2

requires a rational relationship between measure and risk assessment

the risk assessment must reasonably support the measure

“based on”

‘sufficiently warranted by’, ‘reasonably supported by’ or ‘rationally related to’

NOT:

‘taken into account’ nor ‘conform to’
Risk Assessment

*Articles 5.3*

**Economic factors to consider:**

*pest or disease risk*

- Potential damage from entry, establishment or spread (loss of production or sales)
- Costs of control or eradication for importing Member
- Relative cost-effectiveness of alternative approaches to limiting risk
RISK ASSESSMENT – LESSONS LEARNED

*Articles 5.1 – 5.3*

**Plant and animal health:**

“three pronged test”

i. identify all diseases as well as consequences

ii. evaluate likelihood

iii. according to each SPS measure

Specific to actual product traded
Minimizing Negative Trade Effects

Articles 5.4

Members *should*,

when determining the appropriate level of sanitary or phytosanitary protection,
take into account the objective of *minimizing negative trade effects*. 
Members *shall* avoid *arbitrary* distinctions in appropriate level of SPS protection (ALOP) considered in different situations if distinctions result in *discrimination* or disguised restrictions on trade.
Consistency – Committee Guidelines

G/SPS/15

- Two parts:
  A. Appropriate level of sanitary or phytosanitary protection – ALOP
  B. SPS Measures
- Principal points:
  - Clear identification of the level of protection
  - Compare the level of protection / measure with
    - Previous decisions
    - International standards / other countries
  - Transparency and communication between agencies
Consistency – Lessons Learned

Article 5.5

Three cumulative elements

1) Differences in comparable situations
   Risk of the same/similar disease, or risk of the same/similar biological and economic consequences

2) Different levels are arbitrary or unjustifiable
   Also “de facto ALOP”, i.e. protection achieved by the measures applied..

3) Differences result in discrimination or disguised trade restriction
   Related “warning signals”
Least trade restrictive

Article 5.6

Once have determined the **NEED** for an SPS measure

AND

Have determined the **LEVEL** of protection needed

must select

**least-trade restrictive measure to achieve** *ALOP*

(technically and economically feasible)
Least trade restrictive – Lessons Learned

Article 5.6

Three cumulative elements

+ Complainant must establish that an alternative measure

1) Is reasonably available, taking into account technical and economic feasibility

2) Achieves the importing Member’s ALOP

3) Is significantly less restrictive to trade
Risk assessment - exception

Article 5.7 – provisional measures

Members may provisionally adopt SPS measures

✓ when relevant scientific information is insufficient
✓ on the basis of available information

In such circumstances, Members shall

✓ seeks to obtain additional information to assess risk
✓ review the measure within a reasonable period of time
Provisional measures – Lessons Learned

Article 5.7

Precaution “finds reflection in Article 5.7”, but the precautionary principle does not override obligations of Articles 5.1 and 5.2

Four elements must ALL be met:

1. Scientific information insufficient to do a risk assessment
2. Measure based on available pertinent information
3. Importing Member seeks to obtain additional information
4. Importing Member reviews measure within reasonable period
Provisional measures – Lessons Learned

Article 5.7

• Insufficient evidence ≠ scientific uncertainty

• Sufficiency of evidence may depend on ALOP

• Obligation to seek to obtain additional information “germane to” conducting risk assessment

• Reasonable time - determined on a case-by-case basis
Thank you!

Questions?