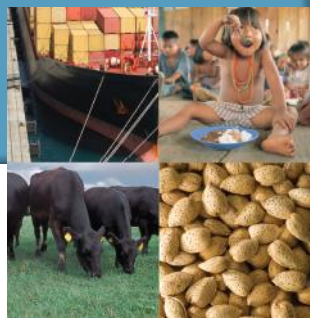
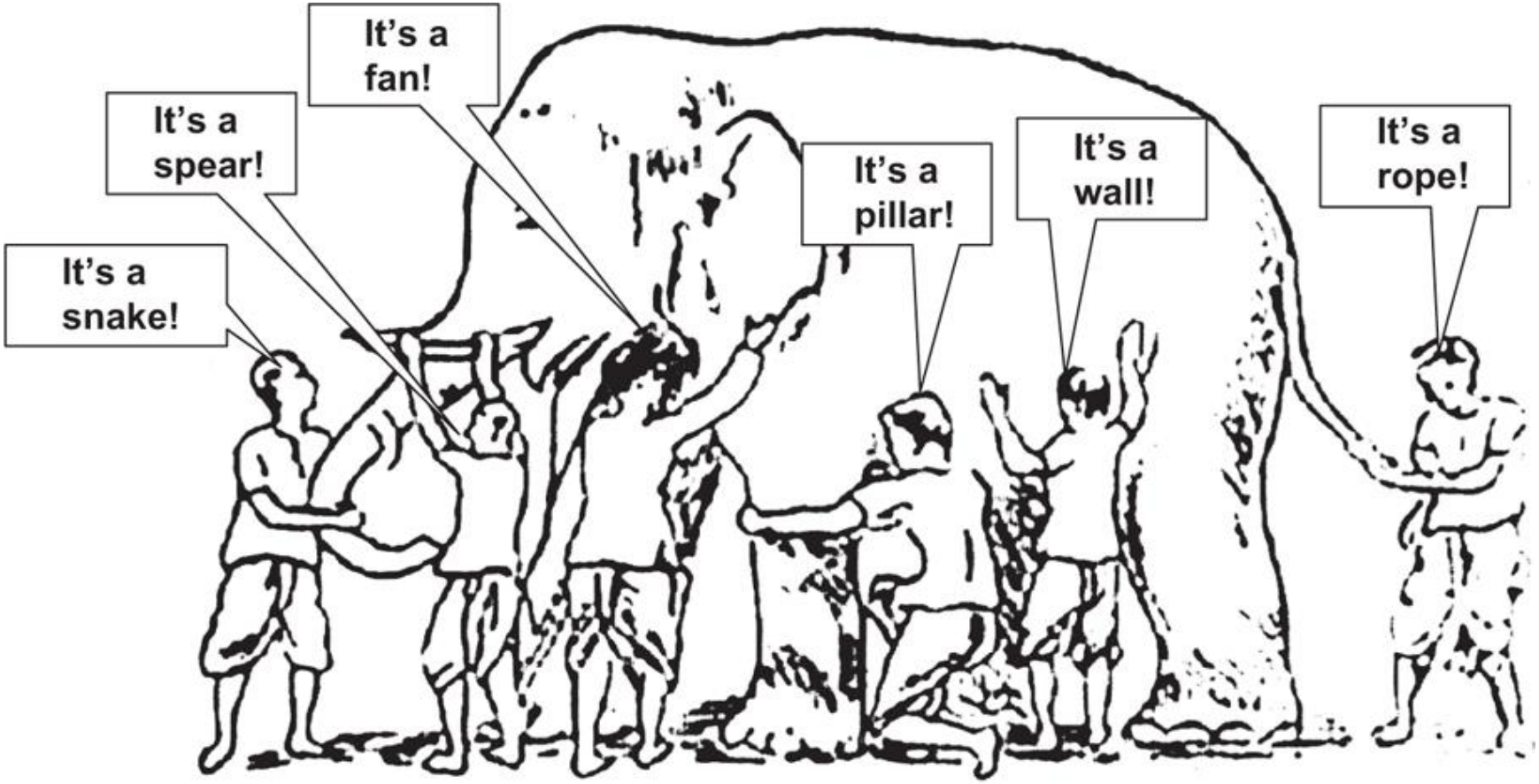
United States Department of Agriculture
Foreign Agricultural Service



Understanding the World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures

Andrew Stephens
Senior Policy Advisor
USDA/FAS/OASA
Andrew.Stephens@fas.usda.gov
+1-202-720-0663

Are Trade and Public Health like the Indian parable: The Blind Men and the Elephant?



Do we all see the same thing differently?

WTO Sanitary Phytosanitary (SPS) Agreement

- The SPS Agreement has a two-fold objective.

  It aims to both:

  - Recognize the sovereign right of Members to provide the level of health protection they deem appropriate; and

  - Ensure that SPS measures do not represent unnecessary, arbitrary, scientifically unjustifiable, or disguised restrictions on international trade.

Source: http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s1p1_e.htm

The SPS Agreement

Emphasises the following:

- Harmonisation
- Science base
- Least trade restrictiveness
- Recognition of equivalence
- Transparency

Specifically recognises:

- Codex Alimentarius - Food safety
- OIE - Animal health
- IPPC - Plant health

Stricter measures are allowed if justified by a risk assessment

What is an SPS Measure?

- According to Annex A of the SPS Agreement, an SPS measure is:
- to **protect animal or plant life or health** from risks arising from the entry, establishment or spread of **pests, diseases, disease-carrying organisms or disease-causing organisms**;
- to protect human or animal life or health from risks arising from **additives, contaminants, toxins or disease-causing organisms in foods**, beverages or feedstuffs;
- to protect human life or health from risks arising from **diseases carried by animals, plants or products thereof**, or from the entry, establishment or spread of pests; or
- to prevent or limit other damage within the territory of the Member from the entry, establishment or **spread of pests**.

Source: Annex A, and http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s3p1_e.htm

What is an SPS Measure?

- According to Annex A of the SPS Agreement:
- Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments … provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

Source: Annex A, and http://www.wto.org/english/tratop_e/sps_e/sps_agreement_cbt_e/c1s3p1_e.htm

In the WTO context - What is a Risk Assessment?

- *"Risk assessment* - 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 or phytosanitary measures which might be applied, and of associated potential biological and economic consequences;

  or the **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." SPS Annex A(4)
- Art. 5.1: Flexibility ("**appropriate to circumstances**")
- Art. 5.1: Members are to **take into account the risk assessment techniques** developed by Codex, OIE, IPPC.
- Art. 5.3 requires consideration of "the relative economic factors" including "cost-effectiveness of alternative approaches to limiting risks."

The WTO Lens on Risk Assessment

WTO cases focus on whether the Risk Assessment(RA) justifies the treatment of imports.

Is there a valid reason to:

- Restrict or ban imports?
- Were less trade restrictive options considered?
- Treat imports different than domestic products?
- Treat imports from 1 country different than others?

Some RA practitioners may see these trade elements as appropriate for “risk management” rather than “risk assessment.”

But if an SPS measure discriminates against imports and that discrimination is not supported by an RA, it could be vulnerable to challenge in the WTO.

1995-2017: 10 WTO SPS Cases all with a common failure. What was it?

EC – Hormones (1998)	**Food Safety**
Australia – Salmon (1998)	Animal Health
Japan – Agricultural Products (1999)	Plant Health
Japan – Apples (2003)	Plant Health
EC –Approval and Marketing of Biotech Products (2006)	**Food Safety** / Plant Health
Australia – Apples (2010)	Plant Health
US – Poultry (China) (2010)	**Food Safety**
India – Poultry (2014)	Animal Health
U.S. – Beef from Argentina (2015)	Animal Health
Russia – Pigs (2017)	Animal Health

Common element of the 10 cases?
Insufficient Risk Assessment

In all 10 cases WTO found insufficient risk assessments or insufficient scientific evidence to support the measure:

EC – Hormones (1998)	"[T]he scientific conclusion reflected in the EC measures . . . **does not conform to any of the scientific conclusions reached in the evidence** referred to by the European Communities."
EC – Approval and Marketing of Biotech Products (2006)	Panel found EU Member States had maintained bans (safeguards) on EC-approved biotech products **without conducting risk assessments** and thus violated SPS Article 5.1 AB noted RA vs. RM not in SPS text.

"Precautionary Principle" in WTO/SPS

- EU Commission definition: "Recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that **scientific evaluation does not allow the risk to be determined with sufficient certainty**."

- Burden of proof in EU: "in the case of an action being taken under the precautionary principle, **the producer, manufacturer or importer may be required to prove the absence of danger.**"

- But: the WTO Appellate Body in *Beef-Hormones* case said the **precautionary principle does not "override" the provisions of SPS Agreement Articles 5.1 and 5.2.**
- *See also:* Art. 5.7 allowing time-limited provisional measures when scientific evidence is insufficient

Role of Scientists in WTO Disputes

Excerpt from REPLIES BY THE SCIENTIFIC EXPERTS ADVISING THE PANEL TO QUESTIONS POSED BY THE PANEL in *EU – Biotech* dispute

Question 5: On the basis of the information before the Panel, is there any scientific evidence to support the hypothesis that Bt maize varieties are any more toxic to humans or animals than conventional maize under field conditions? If so, what risk management options exist to mitigate any resulting risks and what is their efficacy?

Dr. Nutti

107. Based on the information before the Panel, there is no evidence to support the hypothesis that Bt maize varieties are more toxic to humans or animals than conventional maize under field conditions.

Dr. Squire

108. (This response does not address the part of this question relating to humans. Toxicity was considered as part of the Response to Q.3 and some of the argument here is repeated.) Assessing a product's toxicity to ecological processes is usually more complicated than assessing the toxicity of, for example, a feedstuff for a domestic or farm animal. The domestic or farm animal may have the food under test as its sole or main diet in reality, whereas non-target organisms generally have a wider choice of food throughout the habitat. Also, the expression of a toxin in a plant and its effect on animals eating the plant are influenced by local growing conditions, the weather, the behaviour or the

What are outcomes in WTO disputes? Comply / Accept Retaliation / Pay Compensation

Dispute:	Outcome:
EU – Hormones (1998)	1999: WTO authorized U.S. to raise tariffs on $116 million of EU exports as retaliation. 2009: US-EU agreed on MOU to allow non-hormone beef to be exported in a quota in exchange for suspension of US retaliation. U.S. exporters say other countries filled TRQ. **2017** USTR hearing to consider imposing 100% tariffs on EU exports (**retaliation**)
Japan – Apples (2003)	2005: Japan and U.S. notified WTO of mutually agreed solution. Japan eliminated 6 of 9 control measures **(compliance).** Export promotion begins again in 2017.
US – Clove Cigarettes (2011) (TBT case)	2014: U.S. and Indonesia notify a mutually agreed solution. U.S. promises to consider tariff concessions on other products **(compensation)** and give fair consideration for regulation of "clove cigars."

Summary:

Assessing an SPS measure from a WTO perspective:

- Analyze **scientific / risk basis of the measure**
- How does it differ from **Codex / OIE / IPPC** standards/guidelines per SPS Art. 3?
- Will the regulation survive “peer review” by scientists?
- **Consistent** foreign and domestic treatment?
- Did regulators consider whether there are **less trade restrictive options?** (RA vs. RM)
- Procedures undertaken without **undue delay?**