

The Role of Science and Transparency in the Regulatory Decision Making Process

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Science and the Transatlantic Trade and
Investment Partnership (TTIP)

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Key Message

The success of the TTIP will very much depend on the Transatlantic's

- 1. Cooperation on science*
- 2. Trust of one another's science*
- 3. Protection of the investments made in science*

Focus

- TTIP has three components:
 1. Market access
 2. Regulatory issues and NTBs
 3. Rules (IPRs, TSD, Competition, *etc.*)
- Regulatory issues
 - Need for mutual trust on science
 - The need for transparency and its risks

Illustrative Examples

- US ban on EU beef (BSE)
- EU bans on meat containing hormones
- US ban on French Mimolette cheese
- EU restrictions on GMOs
- Stricter US requirements on the marketing of medical devices
- Different standards for the approval of medicines
- Upcoming fears on fracking



TTIP's Regulatory Cluster

- Regulatory part of the TTIP is the hard core of the negotiations
- Objectives is to make the EU and US regulatory systems more compatible
 - This will also help to ensure a joint transatlantic leadership in the development of global norms and standards
- Horizontal: SPS Plus and TBT Plus
- And also a wide variety of sectors: motor vehicles, chemicals, pharmaceutical sector, information technology

Approaches in the Regulatory Cluster

- Find ways to cooperate on future regulators to avoid unnecessary trade barriers
 - Ensure minimum procedural standards, coordination, and consultation
- Find ways to make existing regulations more compatible
 - Mutual recognition, better coordination, (unlikely) harmonization
 - Perhaps mutual recognition of the highest standard(?)
- Create institutions that can support this effort (e.g., Regulatory Cooperation Council)



Limits (EU side)

- Art. 191(2) TFEU -- Union policy on the environment [...] shall be based on the precautionary principle
- *If strong suspicion that an activity or product may have environmentally harmful consequences measures should be taken even if scientific evidence available does not show incontrovertible causal connection*
- *Pfizer Case* -- Precautionary principle also applies in EU regulatory areas other than the environment
- *Artegodan Case* – EU Institutions “must apply” the precautionary principle



Possible Solutions

- Cooperation in the generation of science and the assessment of science
 - Regulatory Cooperation Council: include both regulators and scientists
- Transparency in the assessment of science and adoption of rules
 - Institutional transparency (EU v. US)
 - Transparency towards stakeholders

But Transparency Must Protect the Investments Made in Science

- Transparency must not result in the disclosure of CBI of operators
- Transparency has its risks
 - T-545/11, *Glyphosate* (October 2013)
Interpretation of transparency obligations (“environmental emissions) under Aarhus) required Commission to disclose information on composition of active substance



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