

# Regulatory dimension within TTIP- Challenges and possible outcomes

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# Outline

- Presentation
- Why regulatory convergence matters?
- Transatlantic regulatory challenges
- The study
  - The process and delimitations
  - Conclusions
- Solution?



# The National Board of Trade

- An Agency under the Ministry for Foreign Affairs
- Office in Stockholm
- Approx. 100 employees



# National Board of Trade

- Swedish governmental agency responsible for issues relating to foreign trade and trade policy
- Mission is to promote an open and free trade with transparent rules
- Provide the Government with analyses and background material, related to ongoing international trade negotiations as well as more structural or long-term analyses of trade related issues

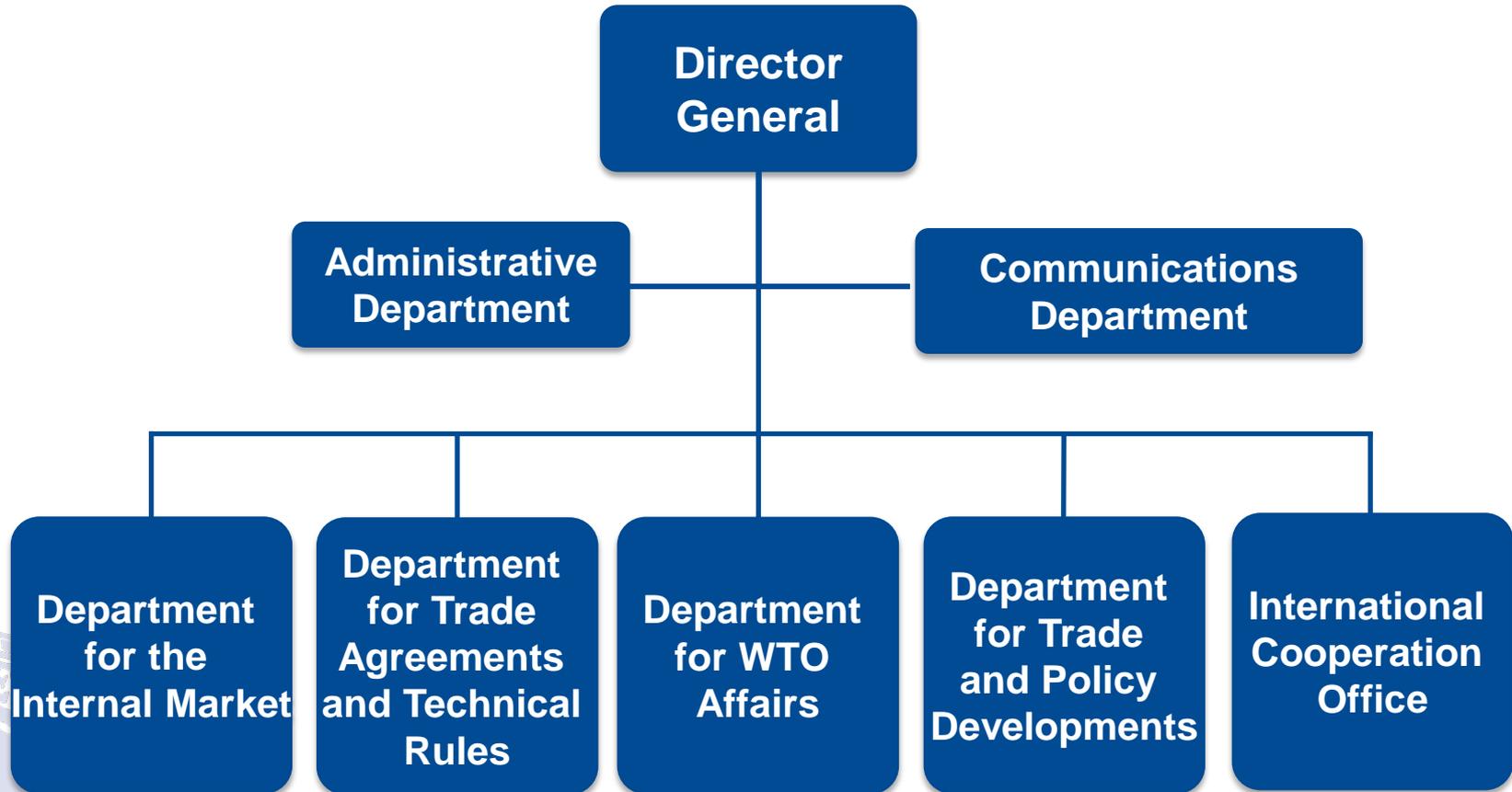


# The main working areas of the National Board of Trade

- EU Internal market
- EU trade policy and trade agreements
- The World Trade Organization (WTO)
- Trade barriers
- International trade analysis
- Trade related technical assistance
- Trade and climate, the environment



# The organization of the National Board of Trade



# Why regulatory convergence matters?

Regulatory dimension?



Transatlantic regulatory challenges?

TTIP in relation to other Free Trade Agreements?



# Regulatory dimension?

## Non-tariff barriers?

Customs procedures/ marks of origin? Import license? Rules of origin? Public procurement? Limitations on services/experts? Local marketing requirements? Transport rules or costs? Technical regulations and Standards?



# Regulatory dimension

## Regulation on industrial goods – and work aiming at preventing and removing Technical Barriers to Trade (TBT)

- Differences between various countries' *technical rules* may result in barriers to international trade
- Technical rules covers *technical regulations, standards and conformity assessment procedures*
- Technical rules are most often prepared, adopted and applied based on various legitimate safety, environmental and/or health concerns (consumer protection or environmental concern), but these may result in a barriers to trade



# Regulatory dimension and existing multilateral legal framework?

- The WTO Agreement on Technical Barriers to Trade (the TBT Agreement) aims to ensure that product requirements, and procedures that are used to assess compliance with those requirements, do not create *unnecessary* obstacles to trade.
- The Agreement contains provisions with which WTO members are to comply with when they are *preparing, adopting and applying* technical regulations, standards and conformity assessment procedures



# Free Trade Agreements and TBT

- TBT, TBT+ and
- Sectors are increasingly important (South Korea- motor vehicles, electronics, chemicals, pharmaceuticals, Canada, Japan)



Input from business essential for a good negotiation results



# The transatlantic regulatory challenge

## EU

Uniform system for technical harmonization

- Harmonization in a number of important areas for industrial goods (connection between legislation and standards)
- Uniform system for conformity assessment (requirements for conformity assessment follow systematically the risk level of a product) and is based on European and International standards
- For non-harmonized areas mutual recognition is used
- Common principles for product safety and enforcement (market surveillance)

## US

Federal rules combined by regulative autonomy on state levels

*(dormant commerce clause /supremacy clause/ pre-emption doctrine)*

- Highly independent regulatory authorities
- Market driven, decentralized national standards system that is operated by a large number of standardizers that compete with each other

# Examples of regulatory differences

## EU

### Horizontal

High degree of manufacturers declaration

*Environment*

### Sectors

**Automotives:** EU/UN(ECE) standards - approval by regulatory authorities

**Pharmaceuticals:** national pharma markets (MS responsibility), national pricing

**Chemicals:** no data – no market

## US

### Horizontal

High degree of third party certification

*Marking, fees, taxes*

### Sectors

**Automotives:** national, FMVSS, standards-self certification

**Pharmaceuticals:** no regulatory fragmentation between states and pricing

**Chemicals:** market access- surveillance



# The study

- Assignment by Ministry for Foreign Affairs
- TTIP in relation to WTO and already signed FTA:s
- Regulatory differences between EU and USA
- The possibilities for regulatory convergence in certain, in beforehand chosen sectors (automobiles, pharmaceuticals, ICT, medical devices and chemicals)
- Specific focus: Swedish priorities in relation to European priorities
- Expectations: To be able to form an opinion concerning which sectors are suitable for regulatory co-operation and which paths and regulatory tools are suitable for various product sectors



# Delimitations

- Other sectors suitable for regulatory convergence?
- Non-harmonised areas?
- Services, public procurement, horizontal environmental framework?



# Historical review and Swedish positions before the study

- Former transatlantic regulatory initiatives
- High Level Working Group for Jobs and Growth and the Final Report
- A horizontal regulative chapter
- Common transatlantic sectoral interests
- The US position before negotiation
- Former comments by Swedish National Board of Trade on transatlantic regulatory co-operation



## Procedures for increased transparency based on the TBT agreement within WTO and existing FTAs in force

- Introduction to the TBT agreement – notification procedure in the EU (94/34 procedure) and in the US respectively
- Possible solutions for transparency within the framework of TTIP – both horizontally and vertically
- Consideration to third countries with FTAs in force – transparency and changes in material requirements
- Obligation to fulfil existing commitments and consider new possibilities that also benefits third countries



## Regulatory tools

- The analysis of regulatory tools and models is not a new assignment for the National Board of Trade
- Improved mechanisms for transparency was in focus in previous analysis
- Current negotiation directives implies an ambitious approach



# TTIP Regulatory toolbox

- Horizontal mechanisms for improved transparency between EU and U.S.
- It is not realistic to have one tool or model to cover all sectors within the transatlantic dimension- solutions to be found in the sectors
- Find possibilities and common nominators in order to step by step improve transatlantic trade landscape in specific areas and where the parties have a significant trade interest



## Regulatory tools

- Difference in structure of authorities/agencies and organisations does not need to form the negotiations if certain conditions are met:
  - Clear channels for a bilateral dialogue, especially between corresponding authorities
  - A forum where specific regulatory interests may be discussed
  - A process that enables an objective assessment of existing and future regulations, with an equal representation from both parties
  - A clear mandate
  - International commitments
  - Regulatory outcomes within areas that are currently not transparent or harmonized in the member states in the EU or at state level in the US



# Swedish priorities?



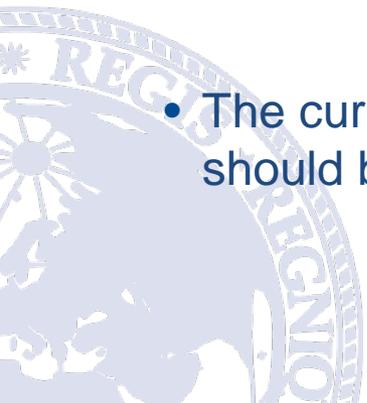
# Swedish priorities?

- Public authorities
- Economic operators



## Medical devices

- Good conditions for a regulatory cooperation
- Regulatory cooperation should be built on the global forum for cooperation IMDRF
- Regulatory cooperation should, along with the priorities of the commission, create additional value for economic operators (mutual recognition, one-stop-shop for conformity assessment and harmonized incident reporting)
- The currently ongoing and extensive revision of legislation within the EU should be considered



# ICT

- Analysis within the ICT sector was focused on industrial ICT products
- Business representatives from the ICT sector in Sweden expresses more or less the same position as the European business organisations and the European Commission
- Areas for future regulatory cooperation within TTIP should, according to the industry, be focused on areas such as environment, conflict minerals and nano material.
- The Swedish Post and Telecom Authority has expressed some concern concerning revisions of the legislative framework for ICT within the EU

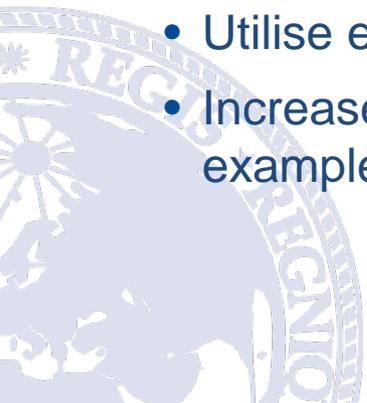


## ICT sector - continued

The main technical barriers to trade raised by the industry are measures related to conformity assessment, transparency, and standardisation issues in general. Other challenges within the sector are horizontal such as regulations in electrical safety and environment.

Possible solutions for technical barriers to trade:

- Mutual recognition of conformity assessments and certification or a harmonization of standards seem to be the most appropriate measures to decrease current barriers within the sectors.
- An ICT cooperation body
- Utilise experiences of existing MRA
- Increase transparency through different initiatives (international examples)



# Pharmaceuticals

- Industry specific aspects: Pharmaceutical companies that are involved in R&D, companies that are involved in trade in generics. Production is located to third countries
- Regulations: Production, application for approval, sales and market surveillance. The starting point in the EU and the US is the same, i.e. that pharmaceuticals shall be safe and efficient
- There is a relatively comprehensive international cooperation between the EU, US and Japan which have created a similar approach in several areas



## Pharmaceuticals cont.

- The European Medicines Agency (EMA) and their American counterpart (FDA) cooperate in some areas
- Divergence in interpretations of guidelines, fragmented EU market for pharmaceuticals, difference in culture of consensus in the US, differences in intellectual property - trade barriers
- The key for an immersed cooperation is increased transparency between the EMA and FDA, a more uniform application in the EU and mutual recognition in areas where the requirements are equivalent and measures of harmonisation in new areas

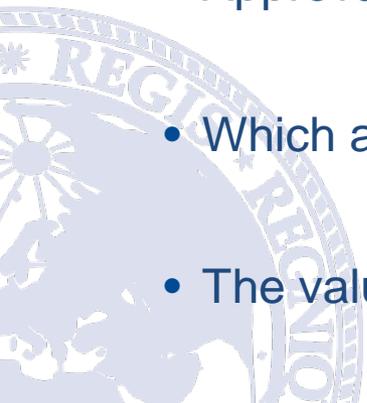


# Chemicals

- There is a fundamental difference concerning the distribution/burden of responsibility between the chemical regulations of the EU and the US. Within the EU there is "no data, no market" requirement for the producers, while the burden of proof and responsibility in the US is in principle the opposite, any chemical may be placed on the market until there is enough proof that the chemical constitutes an unreasonable risk.
- A future cooperation within the area of chemicals should stem from a best endeavour to increase exchange of information and an increase in transparency of regulations. The strive towards a harmonised chemical regulation does not seem realistic of several reasons
- Third countries have changes their legislation in order to be more compatible with Reach, for instance Korea and India
- Already established systems that could constitute a base for increased cooperation are GHS for classification and labelling of chemicals and MAD for generation of data

## Automotives

- The proposal from the industry regarding regulatory convergence by mutual recognition seems workable
- The approach should be based on an assessment of regulations in connection to an analysis of the effect of those regulations. If the regulations are considered to be equal in effect the regulations should be included in a mutual recognition by the EU and the US
- The EU and the US should jointly work towards international regulations (GTR- Global Technical Regulations and WVTA- Whole Vehicle Type Approval)
- Which approach is suitable for the negotiations? Other policy areas?
- The value of TTIP for Swedish vehicle industry





# The solution?

- Companies on both sides of Atlantic know their business model and existing barriers....

**..but the current regulatory structures also involve a large amount of money**

- Transparency is positive...

**... but transparency must be put in relation to "the right to regulate"- here EU and US have different approaches (precautionary principle- scientific data)**



***Thank you !***

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# More information?

MORE INFORMATION



# Transatlantic history

1990	1995	1998	2002	2005	2007	2011	2013
Transatlantic Declaration	New Transatlantic Agenda (NTA)	Transatlantic Economic Partnership (TEP)	Guidelines for Regulatory Cooperation and Transparency	High-Level Regulatory Cooperation Forum	Transatlantic Economic Council (TEC)	High Level Working Group for Jobs and Growth	TTIP negotiations launched in July



# High Level Working Group for Jobs and Growth

- Established in 2011
- Identify policies and measures to increase bilateral trade and investments
- Final report published in February 2013
- A comprehensive free trade agreement based on three pillars:
  - market access
  - regulatory issues and non-tariff barriers
  - rules addressing shared global trade challenges and opportunities
- Negotiations launched in July



## Trade in goods

- EU and the US trade goods and services to a value of €2 billion every day.
- China and the EU are trading more than €1 billion every day.
- Swedish exports to the US (2012): 75 billion SEK
- Swedish imports from the US (2012): 36 billion SEK



# Investments

- More than €2.8 trillion on both sides of the Atlantic.
- Swedish investments in the US: €32.7 billion
- US investments in Sweden: €17.8 billion



## Negotiation areas - specified

- **Tariffs** – average between the EU and the US (3-4%)
  - T-shirt:
    - \* 16.5% tariff into the US
    - \* 12 % into the EU
  - Veal:
    - \* 36,4% tariff into to the US
    - \* 12.8 % + 1555.93 kr/100 kg into the EU
  - Motor vehicles for the transport of goods (spark-ignition internal combustion piston engine):
    - \* 25% tariff into the US
    - \* 22% into the EU
  - According to WTO rules: “...the duties and other restrictive regulations of commerce... are eliminated on substantially all the trade between the constituent territories in products originating in such territories.”



## Negotiation areas - specified

Cont.

- **Rules of origin** – needed in order to determine if the goods originate in the area and fulfil the requirements of being eligible for preferential treatment under the free trade agreement.
  - Wholly obtained products
  - Sufficiently worked or processed products
- **Trade Facilitation** - trade and customs procedures
  - Trusted trader programmes and modern customs administrations
  - Increased demand for information due to terrorism (pre arrival and pre departure declarations – 100% scanning of containers?).



## Negotiation areas - specified

Cont.

- **Sanitary and Phytosanitary measures**
  - hormone-treated beef
  - GMO
  - chlorine-washed chickens
  
- **Trade in Services** - restrictions in some service sectors such as:
  - data flow
  - maritime services
  - air transport services
  - temporary movement of workers (Mode 4)



# Negotiation areas - specified

**Cont.**

- **Investment**
  - MFN, national treatment
  - Investor-state dispute settlement
  
- **Public Procurement**
  - “Buy America (n)”
  - Government Procurement Act
  
- **Geographical Indications**
  - Protection for feta cheese and French wines etc.



## Potential gains from TTIP

- According to a report from Centre for Economic Policy Research:
  - ✓ EU:           € 119 billion a year  
                  € 545 in disposable income each year for a family of 4 in the EU
  - ✓ US:           € 95 billion a year  
                  € 655 per family in the US
- National Board of Trade published a report in 2012:  
“Potential Effects from an EU–US Free Trade Agreement – Sweden in Focus”



## Changes in aggregate trade flows

*Per cent change in trade according to country/country groups using fixed prices.*

<b>Exporter/ Importer</b>	<b>Sweden</b>	<b>EU26</b>	<b>USA</b>	<b>RoW</b>	<b>World</b>
Sweden	-	-1.1	<b>16.6</b>	-0.9	0.3
EU26	-0.8	-1.4	19.5	-0.8	0.4
USA	<b>14.6</b>	19.8	-	-2.9	2.5
RoW	0.6	0.4	-1.5	0.4	0.0
World	0.3	0.4	2.7	-0.4	0.4

*Source: GTAP version 8. Simulation results from the limited scenario.*

## Next steps

- Political stock taking 17-18 of February - **"Stepping up a gear"**
- 4<sup>th</sup> round of negotiations 10-14 March
- Another 4 rounds of negotiations during 2014
- Ambition by the European Commission and United States Trade Representative to conclude the negotiations by 2014



# Negotiation process

## Before

- Public consultation
- Impact Assessment
- European Council gives negotiating directives to the commission

## During

- Negotiation rounds
- Dialogue between the European commission and the member states of the EU

## After

- Legal scrubbing
- Initialling
- Translation
- Signing
- Approval
- Provisional application
- Ratification
- Enter into force



# Summary

- TTIP negotiations started in July
- HLWGJG recommended a comprehensive agreement that addresses a broad range of bilateral trade and investment issues
- Important (and difficult) to reduce non-tariff barriers
- Once a comprehensive agreement is concluded – a lot of potential

