# Regulatory Issues in TTIP

## Objectives and limitations

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# The mandate

25. The Agreement will aim at removing unnecessary obstacles to trade and investment, including existing NTBs, through effective and efficient mechanisms, by reaching an ambitious level of regulatory compatibility for goods and services, including through mutual recognition, harmonisation and through enhanced cooperation between regulators. Regulatory compatibility shall be without prejudice to the right to regulate in accordance with the level of health, safety, consumer, labour and environmental protection and cultural diversity that each side deems appropriate, or otherwise meeting legitimate regulatory objectives, and will be in accordance with the objectives set out in paragraph 8.
(http://data.consilium.europa.eu/doc/document/ST-11103-2013-DCL-1/en/pdf)

# The mandate – What is being discussed

Areas:

- Sanitary and Phytosanitary Measures (SPS)
- Technical Barriers to Trade (TBT)
- "Regulatory coherence"
- Sectoral provisions

Focus now on regulatory coherence and sectoral provisions.

# Some basic understandings:

## 1. What regulatory coherence is about

- Objective: reduce unnecessary regulatory incompatibilities – duplications in procedures, inconsistent product requirements, double testing…
- Instruments (toolbox): mutual recognition of equivalence, harmonisation/alignment, common rules, application of international rules/disciplines…
- Method: regulator to regulator cooperation, conclusions based on objective assessment of data/evidence

# Some basic understandings:

## 2. What regulatory coherence is NOT about

- Widespread/generalised mutual recognition or harmonisation
- Common rule-making
- Affecting regulatory sovereignty
- Negotiation on protection objectives/levels
- Changing the way each side regulates
- Slowing down rule making

# Some basic understandings:

## 2. What regulatory coherence is NOT about (contd.)

- Changing the balance of stakeholder representation
- Making trade/economic interests prevail over public policy
- Give the other side a say in domestic rulemaking
- Creating a Trans-Atlantic internal market whose rules would superimpose to those of the EU

# Some basic understandings:

## 2. What regulatory coherence is NOT about (contd.)

**Giving away or lowering in any manner the protection guaranteed by the Treaties and EU law**

This cannot and will not happen, technically (legally) and politically – in the EU or the US

# Regulatory coherence chapter

- Good regulatory practices: transparency and early warning, stakeholder consultation, impact assessment, for regulatory acts that can impact on EU-US trade and investment
- Regulatory cooperation: exchanges among regulators upon request, at early stage to be effective
- Means: recognition, approximation, joint simplification…
- Action in areas of common interest
- Promotion of international regulatory cooperation, to reduce unnecessary regulatory segmentation and improve effectiveness of regulations
- Regulatory principles of each side to be upheld (including precautionary principle!)

# The "Regulatory Cooperation Body"

The body composed of regulators in charge of monitoring the application of the regulatory provisions of TTIP, of promoting and coordinating cooperation among regulators, and of discussing matters of common interest. It will not:

- have regulatory or decision-making powers, or the power to amend or add sectoral provisions
- vet draft regulations
- offer the other party the chance to influence regulatory decisions

It should conduct its work with transparency.

# Sectoral work

9 sectors under discussion:

- motor vehicles
- pharmaceutical, medical devices, cosmetics
- chemicals, pesticides
- engineering (machinery, appliances, equipment)
- ICT
- textiles

Great commonality of objectives between EU and US

Still early to say what will be the outcome – but the EU wants something that is valuable.

# Example 1 – Motor Vehicles

Objectives:

- Mutual recognition of equivalence of as many technical regulations as possible, on the basis of sound technical evaluation
- Promotion of effective world-wide harmonisation under UNECE
- Bilateral harmonisation/convergence in certain instances
- Joint development of regulations in future areas – e.g. driving assistance or autonomous driving

# Example 2 - Chemicals

Starting point: EU and US regulations are too different → focus should be in practical cooperation steps, such as

- prioritisation of substances for assessment/review
- criteria and methodologies for evaluation
- early information on regulatory plans
- cooperation in new and emerging issues

All of this within the framework and timelines provided in each side's regulations.

# Other examples

- Recognition of each others' inspections of manufacturing facilities for pharmaceutical products and medical devices
- For medical devices, application of a unique device identification system and or a harmonised format for autorisation applications
- Fostering harmonisation of requirements (concerning e.g. testing, applications for approval, evaluation criteria, product requirements, etc.) in international fora in several sectors

# State of play, process and next steps

- Still early stages to determine likely results.
- Commission wants a transparent process: the public has the right to know what is going on.
- Will continue publishing the texts – and engaging in open discussions as discussions advance – need to ensure that there is genuine support of citizens, for whom after all TTIP should work for…
- Outcome of negotiations will in any event be scrutinised by co-legislators
- Future development of TTIP provisions ("living agreement") – To be conducted in accordance with usual EU procedures in a transparent way


# There is still some way to go...

... so we look forward to further interaction.

# Thank you.