



EUROPEAN COMMISSION

Directorate-General for Trade

Directorate F - WTO, Legal Affairs & Trade in Goods
The Acting Director

Brussels,
DG TRADE /F/FPP

11 JUN 2015

NOTE FOR THE RECORD

Subject: Highlights of the Polish position on TTIP - Report of discussion with stakeholders on regulatory cooperation in Warsaw, 10 June 2015

I made a presentation (enclosed) and had a discussion with some 60 business and other civil society stakeholders at an event organised by Poland's Ministry of Economy, chaired by TPC FM [REDACTED] and attended also by [REDACTED].

The issue most raised was the cost of **energy** and the impact of trade liberalisation on energy-intensive sectors, and there was strong interest in the energy chapter and in particular in doing away with US export restrictions. [REDACTED] indicated that this was a top priority for Poland.

There were many questions from the **cosmetics** industry, which was concerned about the lack of progress in easing access to the US market and the lack of reciprocity that would result, as the US market would still remain prohibitive due to pre-market approval authorisation costs whilst US industries would have an easier access to the EU market after the elimination of tariffs. They were interested in the launch of the pilot project for UV filters, on labelling, and on having more convergence on safety data sheets (on which in the last round OSHA proposed to launch an examination of differences).

The **pharma** industry was mostly interested in progress on GMP, and asked whether the EU would finally table a paper on generics at the July round. They asked for confirmation that IPR protection rules for pharma were not going to be reopened.

The **car** sector expressed concern mostly about tariff elimination and asked for transitional periods, but understood well that there was a link between tariffs and the regulatory area.

There was only one critical intervention on TTIP generally, from the "Institute of Global Responsibility", who asked for evidence that TTIP would not put into question EU regulations and protection and also asked for clarity about our red lines in the regulatory area. However, the representative acknowledged that it is not possible to prove that something does not exist and that instead they could tell us any concrete example of where EU regulations could be put in jeopardy among all the papers we

have published; he also seemed to accept that discussions on the issue should be based on facts, on which the Commission will always be ready to engage with all stakeholders in public.

Comment : it is worth commending Poland's Ministry of Economy for the very proactive attitude and initiatives towards TTIP they are taking, with the support of the EU Representation; this constitutes an example of cooperation between Member States and the Commission and of involvement of EU Representations in Member States.

c.c.: I Garcia Bercero, D. Redonnet, P. Sandler, [REDACTED], [REDACTED], [REDACTED],
[REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED],
[REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED], [REDACTED],
(SANTE), D. Herbert, [REDACTED], [REDACTED], [REDACTED],
[REDACTED], [REDACTED], [REDACTED] (GROW).
[REDACTED], [REDACTED]. (Representation Warsaw).

Encl.:



Regulatory Issues in TTIP

Objectives and limitations

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DG TRADE

EUROPEAN COMMISSION

**Stakeholders' seminar
Warsaw, 10 June 2015**

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, TBT 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 – regulatory procedures and deadlines to be respected*

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

See EU proposal of February 2015 at:

http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153120.pdf

- Good regulatory practices: transparency and early information on regulatory plans, stakeholder consultation, impact assessment, for regulatory acts that can impact on EU-US trade and investment. Limited to acts at EU and Federal level
- Regulatory cooperation: exchanges among regulators upon request, at early stage to be effective, to promote cooperation and compatibility of regulations
- Means: recognition, approximation, joint simplification...
- Action in areas of common interest: cooperation can be encouraged but not imposed, no obligation to achieve any determined outcome

Regulatory coherence chapter

- - *Promotion of international regulatory cooperation, to reduce unnecessary regulatory segmentation and improve effectiveness of regulations → strengthening and development of international regulatory instruments/disciplines/fora*
- - *Regulatory principles of each side to be upheld (including precautionary principle!)*
- - *Regulations covered: any regulatory acts at "central" (EU/Federal) level regardless of the type and the authority issuing them*
- - *For regulatory cooperation, regulatory exchanges can extend to sub-central (US State/EU Member State) regulations, with central authorities having a facilitating role*

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, of identifying opportunities for cooperation, 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 or scrutinise draft regulations*
 - - *offer the other party the chance to influence regulatory decisions*
- *It should conduct its work with transparency.*

Technical Barriers to Trade (TBT)

- - Objectives ("TBT+"): *a) Facilitation, and promotion of recognition, of conformity assessment procedures in order to avoid duplicative tests*
b) Developing common standards in support of regulations
c) Improving transparency/accessibility of information on technical regulations at all levels
- - Challenges due to the different regulatory approaches between the EU and the US → need for pragmatism to find win-win outcomes

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 due to joint EU-US industry proposals. Still early to say what will be the outcome, but the EU wants TTIP to deliver concrete outcomes upon entry into force, whilst having a built-in agenda for further work*

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*
- - *Aligning procedures for the approval of biosimilars and generic medicines*
- - *For medical devices, application of a unique device identification system and of a harmonised format for authorisation applications*
- - *Greater alignment of cosmetics approval procedures*
- - *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 EU 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.