



EPHA statement

Regulatory Cooperation in the Transatlantic Trade and Investment (TTIP) Agreement *"Regulatory cooperation in TTIP: Civil society stakeholders discussion with the EU Chief Negotiator", 2 July 2015, "European Economic and Social Committee"*

Health Policy space in the context of Regulatory Cooperation

The Regulatory Cooperation Chapter as proposed by the EU in TTIP¹ has the potential to significantly limit the health policy space both at EU and Member States level. It is essential that the Regulatory Cooperation Chapter of TTIP does not constrain the "right to regulate" of the EU and its Member States in the public interest. Appropriate policy and regulatory space are required for governments to address today's main public health challenges: chronic diseases, overweight and obesity.

Public health benefits of regulations identified as red tape in regulatory cooperation

There is a risk that regulatory cooperation (in particular a proposed horizontal chapter in TTIP) may induce **regulatory chill** in the area of health if it is largely based on the assessment that regulations are irritants to trade. While regulatory cooperation could identify existing regulations entailing costs for transatlantic trade, they should not be considered as red tape without taking into account their benefits for societal well-being. This is particularly relevant for the regulatory space to implement public health measures on alcohol, tobacco and foods high in sugar, salt or fat (HFSS)² intervening into their end price (taxation, subsidies or minimum pricing), availability (promotional measures, advertising and marketing regulations) or accessibility (school environments).

The establishment of a regulatory cooperation body to coordinate the development of policy, early consultations between the EU and the US, including potentially further impact assessment with extended stakeholder consultations earlier in the legislative process, may delay or even lead to the abandonment of regulation.³ Progressive future legislation similar to the recently adopted the Tobacco Products Directive (TPD) might be till vulnerable to delays and attempts to weaken its provision.⁴

Limited horizontal regulatory cooperation in TTIP

A clear distinction should be made between technical cooperation on the setting of standards and attempts to influence public interest policymaking. It is questionable whether a broad horizontal regulatory chapter making TTIP a 'living agreement' is needed to achieve technical cooperation as this already occurs independently in other international fora. Regulatory Cooperation in TTIP should be limited to clearly defined and studied 'sectoral' cooperation only, where potential benefits have been identified after solid and inclusive impact assessment.

Maintaining European standards in sector specific regulatory cooperation

Given the multiplicity of the mechanisms for regulatory cooperation, the effect of any agreement on regulatory cooperation will depend on what precisely is agreed and how the agreement is implemented. The potential impacts of regulatory cooperation on quality insurance in health, medical devices, pharmaceuticals, complementary and alternative medicines (CAM) and antimicrobial resistance (AMR) should be further investigated before any legally binding agreements are made.

While there might be potential beneficial aspects to regulatory cooperation in some areas, the benefits cannot be based purely on the assumption that greater regulatory liberalisation is universally beneficial. Regulatory Cooperation could have an impact on our European standards of protection of health, consumers the environment to an international or even global lowest common denominator level. Lowest common denominator standards would also be against the economic interests

¹ See EU Proposal for a Chapter on Regulatory Cooperation, originally published on February 10, 2015 available at http://trade.ec.europa.eu/doclib/docs/2015/february/tradoc_153120.pdf as amended on May 4, 2015 and available at http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf (hereinafter the EU Proposal).

² Terminology used by relevant WHO document

³ TTIP, international trade and cardiovascular health – a European Heart Network paper http://www.ehnheart.org/index.php?option=com_downloads&id=1949 http://tobaccocontrol.bmj.com/content/early/2014/08/10/tobaccocontrol-2014-051822.full?g=w_tc_open_tab

⁴ <http://www.smokefreepartnership.eu/news/sfp-welcomes-release-tobacco-products-directive-proposal>



of a knowledge-based economy like Europe. We have the innovation capacity to be at the forefront of healthy, cleaner, less polluting products and production practices, for example. **This is a competitive advantage that means our standards need to be preserved and improved for economic as well as health reasons.**

There are risks for public health in the area of mutual recognition with regard to the **fundamental differences** in the manner in which the US approaches the issue of regulation when compared to the situation in Europe. The most important single distinguisher is that while **the US adopts an evidence-based risk assessment approach, Europe adopts a precautionary approach** where the starting point is an assessment of potential risk, even where a full evidence base may not be available.⁵

Alternative avenues for the US and EU to explore for working towards greater regulatory coherence would e.g. be **acting in a more coordinated manner in multilateral standardization bodies** and using the agreed standards systematically as a basis for their own regulation. Or they could **conclude further sectoral mutual recognition agreements** relating to conformity assessment procedures and provide them with high level political support to ensure they function better than the ones from the past. In addition, **regulatory agencies involved** in regulatory cooperation could be provided with **the finances and staff to engage seriously** such efforts. As noted in a recent OECD study⁶, whether or not **a mechanism for regulatory cooperation is agreed in a legally binding way is not a crucial success factor for international regulatory cooperation**; other factors, including the domestic arrangements for international regulatory cooperation, appear to be more important.⁷ Thus, this is preferable to regulatory cooperation in TTIP.

Regulatory Cooperation and democracy

Any form of regulatory cooperation must be **transparent, democratic** and with **strong accountability**. The Regulatory cooperation chapter must contain provisions guaranteeing **parliamentary oversight** and **access for public interest stakeholders**, including **public health experts**, to the various bodies and mechanisms to provide input at all stages and levels⁸.

The planned Horizontal Chapter would provide a '**gateway**' for handling sectoral regulatory issues between the EU and the US, including by addressing both legislation and non-legislative acts. The development of such a framework for transatlantic regulatory cooperation raises **fundamental accountability problems** in relation to its interactions with the parties' respective legislatures, the EP and the US Congress. TTIP may result in **regulatory processes** that **gradually appear detached from the policy preferences of the regulated, or from the agreed policy choice, in the case of existing regulations**. The regulators' decisions, such as a **newly-agreed sectoral annexes**, should be subject to **parliamentary scrutiny**⁹. It is recommendable that the EU and US authorities foresee – in the conception and implementation of TTIP – a **parliamentary involvement** capable of guaranteeing the possibility for the legislators to provide input into the regulatory dialogue - via contributions to the yearly regulatory programme - and also offering political oversight on its output.¹⁰



EPHA is a change agent – Europe's leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe. EPHA is a member of, among others, the Social Platform, the Health and Environment Alliance (HEAL), and the EU Civil Society Contact Group. <http://www.epha.org/>

⁵ Khan, U., Pallot, R., Taylor, D. and Kanavos, P. (2015) 'The Transatlantic Trade and Investment Partnership: international trade law, health systems and public health' London School of Economics and Political Science and Modus Europe report. www.epha.org/6278

⁶ OECD, International Regulatory Co-Operation,

⁷ Regulatory cooperation under TTIP – a risk for democracy and national regulation? Christiane Gerstetter With contributions by: Lena Donat, Katharina Klaas, Katherine Weingartner September 2014

⁸ A. Alemanno, Aux Parlements de surveiller l'accord transatlantique, *Le Monde*, 24 April 2014.

⁹ A. Alemanno, The Regulatory Cooperation Chapter of the Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences, *Journal of International Economic Law*, forthcoming 2015.

¹⁰ Alberto Alemanno - The transatlantic trade and investment Partnership and the parliamentary dimension of Regulatory cooperation 2014 [http://www.europarl.europa.eu/RegData/etudes/etudes/join/2014/433847/EXPO-AFET_ET\(2014\)433847_EN.pdf](http://www.europarl.europa.eu/RegData/etudes/etudes/join/2014/433847/EXPO-AFET_ET(2014)433847_EN.pdf)