ANNEX - DETAILED COMMENTS TO THE COMMISSION'S REVISED TTIP REGULATORY COOPERATION & GOOD REGULATORY PRACTICES PROPOSALS

MARCH 2016 - TRANSPORT & ENVIRONMENT (T&), EUROPEAN ENVIRONMENTAL BUREAU (EEB), EUROPEAN PUBLIC HEALTH ALLIANCE (EPHA), EUROPEAN HEART NETWORK (EHN), THE EUROPEAN CONSUMER ORGANISATION (BEUC) AND TRANSATLANTIC CONSUMER DIALOGUE (TACD)

This detailed analysis is based on the ***revised EU textual proposals on regulatory cooperation and good regulatory practices published Monday 21st March 2016.***

EU proposal on Good Regulatory Practices

Article 1 General provisions

- Art 1) Objectives and general principles of the Regulatory Cooperation chapter should be the same as the Art 1 - General Provisions of Good Regulatory Practices including the changes that we propose. We welcome the reverse of the aim: achieve public policy objectives comes before reduction of rules considered as trade barriers.
- Art 1, 2 b) We welcome the addition of the reference to the fundamental principles of the EU. Art 3) Does make an effort to take into account the limitations of the chapter, only binding the European Union and the United States - however since the 28 Member States make up the EU, this is still ambiguous. It should specifically state in the broadest terms possible that the EU and MS may deviate from any newly established harmonised or mutual recognition norms and standards in the framework of TTIP in order to achieve a higher level of protection. This approach would be in line with the general aim expressed in Art. 1.1. It is crucial as this would allow each Party to increase its own regulatory standards which should not depend on the consent of the other Party.

Article 2 Definitions

The definitions are very short, especially in comparison to typically EU regulation and directives. No change has been made yet in that regard. Therefore we reiterate our request to define:

- good regulatory practices
- regulatory acts
- reasonable opportunity
- consider contribution
- confidential information
- ineffective
- simplification
- burden reduction
- reliable and high quality
- best information available
- relevant evidence and data
- feasible regulatory and nonregulatory alternatives
- short and long term
- periodic retrospective evaluations

In the chapter on regulatory cooperation, regulatory measures were defined, in this chapter the definitions cover regulatory acts instead. It remains unclear why such a different approach is needed

Article 3 Internal coordination

- The promise to maintain the Better Regulation agenda forces the Commission to adopt this approach for the foreseeable future and would make changes in regulatory approach impossible to change.
- Here we see a risk of pressure from the US to ask for cost-benefit analysis which could be considered as an undue influence into EU decision making

Article 5 Early information

- Art 5, 1) How does this differ from the Commission work plan publication? Or is this a demand for greater transparency on the US side? What is a major act? Who decides which major act undergoes impact assessment?

Article 6 Stakeholder consultation

- This article could be considered as codifying EU Better Regulation and US style Notice and Comment.
- The outlined procedure already exists in the EU with our public consultation, what does this seek to achieve apart from give the USTR notice and comment on delegated and implementing acts - should greater transparency be required in this field it should be done so outside of a trade agreement.
- EU should never be obliged to publish acts before their adoption by the College. This is a red line and a core European standard. A safeguard should be included in the text to avoid one party of being accused of impeding the bilateral regulatory activities by the other in case of a decision not to share/publish draft proposals (please refer to our related recommendation regarding article x3 of the regulatory cooperation chapter).
- Art 6,3) A definition should be added regarding how comments should be submitted. There must be clear guidelines on what it is to be considered as confidential and they must be made public.
- Art 6,4) What are the criteria to follow for explaining the results of the consultation process. Is it about how parties took into account the input or just statistics?

Article 7 Feedback on existing regulatory framework

- Who is going to determine what is ineffective? This is an open invitation to attack laws that industry dislikes.
- This is criminalising regulation.
- What is the protection of welfare, what does that include?
- The scope of possibility for stakeholders to submit proposals for improvements is extended to cases where existing regulatory framework had become ineffective at protection other public policy objectives, in addition to health, environment and safety. When proposals are submitted, what is happening to these views? Will they be published? If yes, anonymously or not? Will the Parties act upon this?

Article 8 Regulatory impact assessment

- We welcome the fact that there is no longer an obligation to conduct impact assessment but a declaration of intention to do so. We encourage the Commission to be even clearer in order to avoid any

misunderstanding. There is a clearer link with each party's existing regulatory framework on impact assessment

- Art 8,2 c) There is a need to be granular and analyse the impacts on different segments of society and to make a distinction between short term and long term impacts.
- Art 8,4 b) Taking into account the regulatory approaches of the other party in regulatory impact assessment is unmanageable. Impact assessments already take into account the impact on trade. We should keep our overall policy freedom to set the regulatory framework that reflects our societal approaches.
- Our concerns regarding the references to decision making based on evidence partly remain. Even if old article 8 has been removed, the new art 8,6 maintains this reference. We asked for greater clarity regarding the origin of scientific data but the new NB7 is not addressing this issue, quite the contrary. We would like to have greater clarity on the confidentiality references in this NB.

Article 10 placeholder on regulatory repository
Please provide further information. Is it only related to derivative products or could it also cover other issues?

Article 11 placeholder on non-application of dispute settlement
Please provide further information.

EU proposal on Regulatory Cooperation

Preamble of the TTIP

- We welcome the addition of the intention, to not reduce, undermine or otherwise compromise the level of protection in the relevant public policy areas". It is an improvement that should be replicated outside of the preambule and mainstreamed in the core legal text of all relevant chapters of TTIP.

Article X1. Objectives and general principles

- New Art 1, 1a) - We welcome the prioritisation on addressing areas of common interest for the benefit of citizens, entities and SME as well as

public interest. However we still wonder who decides what is common interest? Moreover, regulatory cooperation should always remain an option and regulators should be free from any kind of legal or political pressure. Therefore, additional clarification is needed to make it clear that regulators are free to decide if they are willing to enter into regulatory cooperation and no justification should be required from them to ensure their autonomy.

- Art 1, b) We welcome the logic of placing the protection of public health and safety before the need to facilitate trade. To be consistent, we urge to apply it to other chapters of TTIP, including the SPS chapter (where it is still reversed). The good intentions of 1 b) are diluted by some provisions of the good regulatory practices chapter (including art 5, 7, 8 and 9).
- Artl 1, 1 c) We suggest to make clear that notion of 'predictable' regulatory environment shall not include any legitimate expectation that no change will be made and particularly it should not prevent legislators to increase the regulatory standards as the protection of citizens should always prevail to trade and commercial objectives.
- Art 1, 1 d) As mentioned in our previous comments, this codifies and internalises the Better Regulation agenda
    - Promotes the notion that regulations are burdensome and that duplication is unnecessary.
    - The "unnecessarily burdensome requirements" concept has nothing to do with regulatory cooperation. This is a mix with Better Regulation. There should only be cooperation if there is redundancy or duplication.
- Art 1, 1 e) Please clarify the aim of this provision? The Commission should not seek to bind the EU to international agreements that establish minimum standards but do not allow for partners to develop further standards (IMO / ICAO).
- Art 1,2 We welcome the addition of "not compromise" the level of protection but we would still want a clear reference to the fact that regulatory cooperation should not lead to either delays or weakening of legislation.
- Art.1,2 While the text recognises that regulatory cooperation shall not undermine the level of protection in public policy areas, in some cases entering into **regulatory cooperation, the process itself** (exchange of views, meetings, answering queries on impact assessments, additional impact assessments etc.) has the potential to compromise

(stop, delay, weaken) regulatory measures to achieve public policy objectives. Therefore, there is need to recognise the right for the parties **not to give an opportunity** for cooperation and information exchange where a party is determined to go ahead with the piece of regulation in its territory irrespective of the other party's views (e.g. *"Each party has the right to refuse regulatory cooperation if it considers that participating in the process of regulatory cooperation can compromise its regulatory measures to achieve public policy objectives"*). We welcome the clarification in footnote 8 (art X4) carving out any obligation to exchange draft legislation before their adoption by the College. We would like to see it in the text rather than in a footnote.

- Art 1, 3 c) The addition of footnote 2 is an improvement as it refers to the fundamental rights enshrined in the treaty. For clarity purpose, we recommend to clearly refer to the EU's precautionary principle and the right to follow a hazard based approach in the paragraph (not only in a footnote).

Article X2. Definitions

We regret that no meaningful changes have been made in this article and reiterate our recommendations to define:

- facilitating trade and investment
- entities subject to regulation
- SME
- unnecessarily burdensome
- divergent regulatory requirements
- recognition of equivalence
- promotion of convergence
- risk assessment
- risk management
- significant impact on trade and investment
- common interest
- stakeholders
- mutual recognition
- harmonisation
- sufficiently substantiated measures
- pre-normative research
- transparent
- internationally agreed regulatory documents

- joint initiative
- appropriate measures
- timely information

Article X3. Scope

- Art 3, 1 a) A list of the specific and sectoral provisions will be included but the criterion to qualify a significant impact on trade is not indicated.
- Art 3, 1 b) We welcome the clarification regarding the scope of the covered measures. However, the determination of common interest lacks democratic scrutiny and oversight.
- How does Art 3, 2) relate to Art 3, 1 b)?
- Please explain footnote 7

Article X4. General provisions governing regulatory cooperation

- Art 4) We reiterate our request to include reference to Art 1 to frame the objectives and principles of the general provisions 1.
- As Regulatory cooperation is considered not legally binding we propose to use less binding language, ***'may'*** or ***'should'*** instead of '*shall'* in the next version
- Art 4, 2) We suggest using '***significant*** *impact'* instead of '*impact'* to have at least a certain level of threshold – otherwise, all acts could be subject to regulatory cooperation. We stress that the definition for a significant impact is crucial for legal certainty.
- Art 4, 2 a) 'earliest possible stage' - We welcome the clarification of footnote 8. The fact that regulators shall not be obliged to exchange draft proposals (before the adoption by the Commission) should now be included in the text rather than only be in a footnote.
- Article 4, 2 b) What is the influence of "taking account" : how far does it go, is there a need to justify if you don't converge? The precautionary principle and the hazard based approach should be mentioned as example of approaches. The addition of footnote 9 is an improvement.

Article X5. specific activates promoting regulatory compatibility

This part has the potential to compromise decision making as it seems to be unduly biased towards seeing regulation as a trade irritant. Evidence shows

that the EU is not a rule exporter**.**[1] This process **may delay or even lead to the abandonment of regulation**. To be able to engage with an additional layer of consultation and impact assessment, over and above existing EU impact assessment requirements **necessitates considerable resources**. There is a **resource asymmetry** between **business stakeholders** and **public interest stakeholders**[2]. Therefore, the cooperation mechanism could provide **a venue for industry input into regulatory decision** making that **would not be matched by public interest.** This is of concern as much regulatory intervention to help promote public collides with the interests of business stakeholders who invest vastly in avoiding or delaying it.[3] Priority for deciding on EU law has to be given to EU legislators.

- Art 5, 2) We oppose the inclusion of this article
    - NEW: what does the text imply that proposals may be submitted 'jointly'?
    - The fact that the reference to interested stakeholders has been deleted does not address our concerns. We welcome the intention of giving the same possibility to organisations having limited resources to contribute to the mechanism. It is positive to see that our request to ensure that additional efforts are needed to have public interest stakeholders' inputs has been taken into account (NB 11). However it does not solve the core issue: organisations with limited resources will not be in the same position to give input to regulators and will be outweighed by more wealthy organisations, usually representing private and commercial interests. Therefore we are still concerned by the introduction of elements of the US 'notice and comment model' into international law and binding to the EU in this article. We are particularly concerned by the addition of the obligation for the parties to give a 'timely' feedback on the submissions received. Similar to the codification of the Better Regulation agenda, this US style approach should be removed.
- Art 5, 3) As long as it does not limit the EU to international agreed decision, especially in the case of minimum standard setting.

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[1] Regulatory cooperation under TTIP – a risk for democracy and national regulation? Christiane Gerstetter With contributions by: Lena Donat, Katharina Klaas, Katherine Weingartner September 2014
https://www.boell.de/sites/default/files/ttip_study_regulatory_cooperation_under_ttip_1.pdf

[2] See further data collected by EU integrity watch.

[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?q=w_tc_open_tab

- Art 5, 4) This paragraph is more general now. However it remains necessary to include a reference to the verification of the research to be exchange, including of funding sources.

Article X6. Transparency and public participation

- Analysis of this article demonstrates a willingness to make lobbying easier and not more transparent.
- When does this take place? Where does this appear in the EU legislative proposal timeline?
- Art 6, 1) Referring to the resource asymmetry, we would like to stress that the 'open door' policy is not sufficient here as simply being open for all stakeholders do not ensure the engagement of public interest stakeholder.
- Art 6,1)b) What is the definition of 'the extent necessary to protect confidential information'? What will be the criteria put in place to avoid abusive request not to disclose contributions?
- Art 6,3) We welcome the consultation on the joint program with domestic advisory groups.

Article X8. Legislative proposal

- We find positive to see that this article no longer covers proposal under preparation. Why do we need this specific provision, what is the difference with the general provision, where you already have opportunities to comment ? Is this a duplication?

ANNEX institutional set up for implementation

- We do not see the necessity of such an institutional set-up for transatlantic cooperation. We note the reinforcement of the language in the revised version, with the replacement of 'should' by 'will' in various parts of the annex. We know that it is important for some stakeholders to secure a political commitment here but these changes are clearly in contradiction with the voluntary nature of the cooperation. 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**. 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]

- Establishing the Regulatory Cooperation Body (but with a new name).
  - Transparency - regulators should be transparent when making changes due to stakeholder comment or involvement - whether this be a government, private entity, NGO or person.
  - Include and expand terminology 'right to regulate'
- We are worried that including an Annex for the provisions on the **institutional set up** for regulatory cooperation is de facto postponing the decision on that important issue and has the potential that the details will be developed in a time when TTIP has been politically concluded. We insist on that this is an important political and not a technical issue to be discussed behind closed doors during the consolidation phase of the document.
- Members of the TTIP advisory group must have access to the development of this annex before it goes into the consolidated version of the text.
- A clear distinction should be made between technical cooperation on the setting of standards **(technical standards)** and attempts to influence public interest policymaking, including laws, regulations **(political standards).**
- 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 and participation of **public interest stakeholders** to the various bodies and mechanisms to provide input at all stages and levels[5].

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

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