EUROPEAN ENVIRONMENTAL CITIZENS ORGANISATION FOR STANDARDISATION

ECOS

ORGANISATION EUROPÉENNE ENVIRONNEMENTALE CITOYENNE POUR LA NORMALISATION

MUTUAL RECOGNITION OF STANDARDS IN TTIP:

ANOTHER THREAT TO CITIZENS' WELFARE AND THE ENVIRONMENT?

ECOS POSITION PAPER

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EXECUTIVE SUMMARY

The European Union's current proposal for legal provisions on regulatory cooperation under the Transatlantic Trade and Investment Partnership (TTIP) [1] implies extending regulatory and technical cooperation between the EU and US authorities by cutting red tape, developing new structures and processes to increase information exchanges, and by identifying common 'areas of interest' for further cooperation. Under a specific section on legal provisions on Technical Barriers to Trade (TBT)[2], TTIP also proposes to facilitate the harmonisation of standards based on mutual interest and reciprocity, for instance through a process of mutual recognition[3] where EU and US standards could equally provide presumption of conformity with relevant European legislation.

ECOS considers that closer regulatory convergence and technical cooperation on standards in the context of TTIP threaten citizens' welfare and the environment. In particular, we believe that:

1) The objective of cutting red tape and increasing information exchanges under amplified regulatory cooperation risks exacerbating the tendency of using standards as a *replacement* for binding regulation. Regulation is often more appropriate and effective to address societal concerns, in particular in the health and environmental areas. Resorting to standard development could emerge as an easier, more manageable option as it involves delegating work such as definitions, test methods (or any other typical area for which standards are used) to US or European Standardisation Bodies. ECOS has long warned against the growing use of standards as policy tools, arguing that maintaining the supremacy of legislation over voluntary standards in areas of public interest is crucial[4].

We therefore urge decision-makers to protect the pre-eminence of legislation over standards under TTIP's regulatory cooperation and not to jeopardise core principles of the European Standardisation System (ESS). We also believe that the proposed technical cooperation would threaten some of the hard-gained core principles which are meant to be at the backbone of the ESS, namely transparency and inclusiveness.

2) Structural divergences in the EU-US's respective standard-setting processes and philosophies are of such magnitude that this should preclude the intended establishment of mutual recognition of EU-US standards. ECOS is opposed to the mutual recognition of standards because EU and US standards in themselves are not comparable, nor is their philosophy or standard-setting processes.

3) International cooperation on standardisation should be preferred over strict bilateral EU-US collaboration when proven brings an added value to the European economy, citizens and the environment,. ECOS argues that EU-US cooperation in the existing framework for international standard definition could be improved and possibly enhanced, instead of EU-US regulatory authorities jeopardising societal and environmental interests when defining areas of common interest for closer regulatory cooperation and when limiting TBTs.

[1] http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf. This textual proposal was submitted by the EU to the US during the round of April 2015 and made public on May, 4th 2015.
[2] http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf. This textual proposal was submitted by the EU to the US during the round of March 2014 and made public on January, 7th 2015.
[3] To get an overview of the difference between harmonisation, equivalence and mutual recognition of standards, see: http://www.ceps.eu/system/files/SP%20No_99%20TTIP%20and%20Agriculture%20%281%29.pdf
[4] See ECOS' Position Paper 'The future of European standardisation: ECOS' recommendations for a transparent and inclusive standardisation system that can effectively support EU legislation and policies', July 2015.

4) Cooperation between EU and US regulators could be enhanced within the realms of existing international *fora* for standardisation, whilst avoiding the drafting of standards reflecting the lowest common denominator among national standardisation bodies.

BACKGROUND

On 12 March 2013, the European Commission (EC) agreed on a draft negotiating mandate for a Transatlantic Trade and Investment Partnership Agreement (TTIP) with the United States which was rubber-stamped by EU Member States on 14 June 2013. Based on an EU-US High-Level Working Group on Jobs and Growth, the formal goal of this bilateral initiative is to identify policies and measures to increase EU-US trade and investment in order to *'support mutually beneficial job creation, economic growth, and international competitiveness'*[5]. Two of the world's largest economic powers are thus working to increase their cooperation and to further promote their bilateral trade. After a series of negotiation rounds, the content and form of TTIP is progressively taking shape, raising concerns – among others – for the development and use of standards relevant to public health and the environment

Generalised amalgams as to the meaning of standards on the part of EU-US negotiators and the media alike have increased confusion in the public debate on TTIP about whether higher or lower standards (in their strict sense) would be set. In this paper, we understand standards as non-binding technical specifications, adopted by a recognised standardisation body, and that provide, for common and repeated use, requirements, guidelines or characteristics for activities related to products, systems, processes or services[6].

Under TTIP, because EU and US authorities will need to communicate and cooperate to a greater degree and on more policy areas (through existing and new contact points); informing each other, justifying and ultimately agreeing on binding regulations that are relevant to the environment will become more complex and burdensome, and possibly less of a priority.

[5] http://trade.ec.europa.eu/doclib/press/index.cfm?id=917

[6] This is an adapted definition taken both from http://www.cen.eu/news/brochures/brochures/Handsonstandards.pdf and http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF (Article 2(1)).

1. EU-US regulatory cooperation: Standardisation should not replace binding regulation

With regards to regulatory cooperation, the EU put forward suggestions to the US[7] in order to increase regulatory coherence; reduce Technical Barriers to Trade (TBTs), including Sanitary and Phyto-Sanitary (SPS) measures; and align trade requirements in a series of specific industries[8]. Regulatory cooperation is presented as a good way for *'Cutting red tape and costs - without cutting corners'*. According to the EC, the general objectives of regulatory cooperation are to facilitate trade and investment by reducing *'unnecessarily burdensome, duplicative or divergent regulatory requirements'* and by promoting the *'compatibility of envisaged and existing EU and US regulatory acts'*, including the objective of determining areas of common regulatory interest.

Furthermore, TTIP's chapter on regulatory cooperation suggests that each party makes publicly available, at least once a year, a list of 'planned regulatory acts at central level' - including impact assessments and stakeholder consultations - detailing their scope and objectives. To promote regulatory compatibility at central level, bilateral cooperation mechanisms are to be established, along with a 'Regulatory Cooperation Body'[9]. All in all, EU-US regulatory cooperation implies the creation of new regulatory bodies, mandatory information exchanges on planned regulation, and both harmonisation and simplification of regulation.

For ECOS, regulatory cooperation proposed under TTIP would involve more costly and burdensome processes and structures with risks of delaying legislative deadlines and increasing public spending; along with multiplied layers of decision-making involving more decision-makers. Such cooperation would entail increasing compatibility between EU and US regulatory acts, but also subsequently between technical standards of all types.

It is worth highlighting here that widespread confusion on the definition of standards has caused misunderstandings as to the potential consequences of increased EU-US regulatory cooperation. In negotiations and public discourse from both sides of the Atlantic, the terms 'standards' and 'legislation' are being used interchangeably, which allows negotiators to claim that standards will not be lowered, when what they actually mean is that legislation shall not be weakened in the process. The TTIP regulatory

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[7] For regulatory cooperation: see the EU's textual proposal submitted by the EU to the US during the round of April 2015, made public on 4 May 2015: http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf. For Technical Barriers to Trade, see the EU's textual proposal tabled for discussion with the US in the negotiating round of 10-14 March 2014 and made public on 7 January 2015 http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153025.pdf. For Sanitary and Phytosanitary Measures (SPS), see the EU's textual proposal tabled for discussion with the US in the negotiating Round of (29 September-3 October 2014) and made public on 7 January 2015 http://trade.ec.europa.eu/doclib/docs/2015/january/tradoc_153026.pdf. See the respective EU textual proposals for specific industries (footnote 7).

[8] Namely chemicals, cosmetics, engineering, medical devices, pesticides, ICT, pharmaceuticals, vehicles, textiles.

[9] See the EU's textual proposal submitted by the EU to the US during the round of April 2015, made public on 4 May 2015 http://trade.ec.europa.eu/doclib/docs/2015/april/tradoc_153403.pdf.

cooperation chapter would imply the removal of any form of barrier to trade, and resort to potentially weaker or even removed measures or requirements in the field of public health and the environment.

European (harmonised) standards have long been used in support of European legislation and policies, notably in order to provide guidance, technical details and best practices (e.g. terminology, common measurement methods). Standards allow for a consistent implementation of legal provisions, which in turn facilitates the free movement of goods and services in the EU. The New Legislative Framework, a package of measures aimed at improving market surveillance and boosting the quality of conformity assessments in the EU[10], has gradually led to a further increase of the use of standards. The use of standards is expected to increase further along with the EU Better Regulation Agenda, sometimes in place of binding regulatory measures.

Whilst we acknowledge that standards can bring substantial benefits, we believe that their voluntary nature and the industry domination in the standardisation process make them unsuitable to replace legally-binding measures in areas of public interest. ECOS fully supports the supremacy of legislation for achieving policy goals in those areas, so as to meet societal and environmental needs[11].

With TTIP, this tendency risks intensifying if the underlying goal of regulatory cooperation includes an increased use of standards for mutual recognition instead of legislation. This would involve relying on voluntary guidance to limit TBTs to the maximum extent. As TBTs are often directed towards safeguarding public health or the environment, we believe that their limitation or elimination would be a clear risk for the protection of core areas of public interest.

The use to standards may also increase as tighter regulatory cooperation would progressively discourage any new legislative proposal to be put forward. In such a timid legislative context, opting for looser regulatory procedures might appear quicker and more feasible than undergoing complex, lengthy and possibly contentious legal procedures. In such circumstances, resorting to standards may seem more convenient. The newly imposed duties to inform, exchange and to discuss would only obfuscate an already intricate decision-making process and apparatus and inhibit new – and yet much needed – regulatory initiatives, leading to deregulation, extensive calls for impact assessments delaying action etc. Moreover, regulatory cooperation establishes new procedures such as early warning mechanisms, consistent regulatory exchanges, joint examination; and structures such as a regulatory cooperation body and focal points which involve opaque and barely inclusive processes[12].

[10] http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

[11] http://ecostandard.org/wp-content/uploads/The-future-of-European-standardisation-ECOS-Position-July-2015.pdf

[12] These risks of decreasing transparency and potentially increased costs have been extensively described in positions of many NGOs working closely with ECOS such as EEB, FoEE, BEUC etc.

- ECOS strongly supports the pre-eminence of legislation over standards to achieve policy goals in areas of public interest. The use of standards should only aim at supporting EU legislation and policies.

- ECOS urges decision-makers to not jeopardise the essence, structure and purpose of the European Standardisation System. Instead of putting in place constraining cooperation mechanisms, EU-US regulatory cooperation could be achieved on a voluntary basis, in line with what is proposed under the EU-Canada Comprehensive Economic and Trade Agreement (CETA).

2. EU-US mutual recognition of standards: A no go

TTIP's Regulatory Cooperation chapter proposes a form of alignment of EU and US standards through their mutual recognition and to allow an equivalence of products' conformity assessments. Mutual recognition in general terms means that each partner legally accepts the products sold domestically in the other partner's market. In the TTIP context, mutual recognition applies to regulations and/or conformity tests, based on the presumption that all standards and procedures in the partner country are acceptable. Once the validity of each partner's standards and procedures is accepted, no oversight or double-checking procedure is meant to interfere in this new and unrestricted trade flow. Mutual recognition typically uses a 'negative list approach', whereby the importing country, in case it has concerns, must prove that imports of the partner country's products violates one or more of a list of agreed criteria, such as public health[13].

ECOS strongly believes that several risks can be associated with the proposed mutual recognition of EU-US standards:

- The already fragile openness and inclusiveness of the European Standardisation System (ESS) operating under EU Regulation No 1025/2012[14] would be jeopardised, alongside the opportunity for European societal stakeholders to actively contribute throughout the standards development process;
- The EU's consolidated approach to standards, including the principle of withdrawal of conflicting standards by Member States, would be challenged. This principle, though meant at ensuring the consistence of standards, would directly conflict with the principle of mutual recognition of EU-US standards[15];
- A greater number of different types of standards could become applicable in the EU or referenced in the Official Journal of the European Union (OJEU), thereby potentially contradicting each other or decreasing their reliability in a less coherent and fragmented market;

[13] See https://www.ceps.eu/system/files/SP%20No_99%20TTIP%20and%20Agriculture%20%281%29.pdf
[14] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:316:0012:0033:EN:PDF
[15] See also the European Standardisation Organisations, CEN (the European Committee for Standardisation) and CENELEC (the European Committee for Electrotechnical Standardisation) position paper: http://www.cencenelec.eu/News/Policy_Opinions/PolicyOpinions/TTIP__std_mutual_recognition.pdf

- The different approaches and philosophies between the US and the EU risk leading to incompatible and inequivalent standard content or ambition level (see Section 3);
- Conformity assessment and market surveillance would be more complicated, in a less transparent market that would be more difficult to police, which might lead to a defective implementation of e.g. environmental and safety standards and of their overarching legislation.

Some cases of standard development offer an illustrative example of how differences between US and EU procedures might become problematic. For instance, the scope of EU-US collaboration in the field of measurement of toxicity levels for pesticides is currently being explored further, in particular with regards to methodological issues related to Maximum Residue Levels (MRLs). MRLs help ensure that residue levels do not pose unacceptable risks for consumers. This would typically require the establishment of common terminology in the sector and measurement or test methods, potentially in the form of a harmonised standard. Due to the traditionally less precautionary approach of the US, this cooperation risks leading to less strict measurement methods and terminology, thereby potentially lowering the level of public safety and environmental health in the EU.

It has often been argued that with regards to chemical regulation in general, and risk assessment in particular, the US generally adopts a rather 'risk-based' approach, whereas the EU attempts to also follow a 'hazard-based' approach embedded in the precautionary principle. This fundamental difference in approaches to risk assessment and regulatory choices is at the heart of many other topical discussions in the field of Endocrine Disrupting Chemicals (EDCs), and in the evaluation and labelling of Genetically Modified Organisms (GMOs).

Though the European Commission seems to remain relatively opposed to the mutual recognition of EU-US standards, ECOS will remain vigilant, notably considering that negotiations are still ongoing.

- ECOS is strongly opposed to the mutual recognition of standards as EU and US standards in themselves are not comparable, nor is their philosophy and processes for setting standards.
- ECOS is very concerned that TTIP will weaken the principles of inclusiveness — notably that of societal stakeholders — and transparency promoted & backed by Regulation (EU) No 1025/2012 in the development of standards at EU level.

3. Incompatibilities between EU and US's approaches to standards

As mentioned under Section 2, major differences exist between the EU and the US standardisation systems and procedures. Moreover, the EU and the US have different approaches to the use of standards in their respective markets and different procedures framing their vision of standards in general.

The EU standardisation model follows several principles which intend to safeguard its coherence and consistency. In particular, the 'national delegation principle' and consensus-based decision-making process which governs the European Standardisation System ensure that an EU standard is adopted by all national standardisation bodies and that any conflicting national standard is automatically withdrawn. Furthermore, legal obligations under Regulation (EU) No 1025/2012 require the facilitation of the effective participation of SMEs, consumers, workers, and environmental protection organisations, e.g ECOS. CEN and CENELEC standards are often aligned to ISO and IEC standards, which makes for coherence within the international market and encourages innovation and competitiveness of European companies in the global market.

On the other hand, the US standardisation system appears very fragmented, and sometimes even opaque. First, the systematic withdrawal of conflicting standards does not apply in the US, which leads to diverging specifications covering a given product or service, and subsequently to a fragmented market in the US — between state and federal level. As opposed to the EU, US Standards Developing Organisations (SDOs) do not set standards with the underlying objective of harmonising a market, whereas this forms one of the goals of the EU standardisation bodies under the 'one-product-one-standard principle' and the EU Single Market. Over 280 SDOs are accredited to develop US national standards, each with different rules and procedures, which complicates stakeholder access and participation. Finally, societal stakeholder involvement is also rendered difficult by the US's untimely procedure of 'notice and comment'[16], i.e. the *ex-post* notification of the intended use of a given standard in support of a given regulation. Another complication is that executive authorities at US federal and state levels can incorporate by reference any existing standard or technical specification.

The above mentioned incompatibilities prove all the more challenging in the process of reducing TBTs, which offers another good example of how unrealistic the mutual recognition of EU-US standards is.

The EC's proposal on TBT reduction is currently planned to be achieved by:

- Providing early warning on TBT-relevant Congress bills and TBT-relevant EU legislation;
- Providing more transparency and information exchange;
- Cooperating on standards, and referencing of standards;
- Aligning conformity assessments.

[16] This procedure is explained in the US Circular No. A-119 -- Federal Register (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities), which is currently being revised: https://www.whitehouse.gov/omb/circulars_a119_a119fr.

Transparency and inclusiveness of systems for standard development

The EC mandating process, based on draft standardisation requests sent to the European Standardisation Bodies (CEN, CENELEC and ETSI), is vastly different from the US standard drafting process and 'notice and comment' procedure. Furthermore, the principles of inclusiveness and transparency promoted in the EU are even further from being sufficiently upheld under the US standardisation procedure.

Referencing of standards

Referring to EU-harmonised standards in US legislation and vice-versa appears delicate as the parties' standard referencing system are fundamentally different and do not imply the same things. In the US, when incorporated by reference, standards usually become mandatory[17]. They remain voluntary in the EU, unless specified as allowing 'presumption of conformity' with corresponding requirements of EU legislation. In addition, the proposal of opening non-European standards for reference in the OJEU would impair the clarity and coherence of the EU market.

Conformity assessments and labelling requirements

Mutual recognition of EU-US standards would require aligning both parties' conformity assessment regimes. We believe that current conditions for conformity assessments in the US might raise concerns in that regard. Furthermore, US authorities request that US-domiciled Conformity Assessment Bodies (CABs) are granted national treatment as compared with EU-domiciled CABs. However, US CABs are not recognised as 'notified bodies' within the EU, which means that ESOs would have to endorse and take responsibility for standards developed by US — rather than EU-domiciled — CABs. The US also requests, before mutual recognition is established, that a standard developed by a US-domiciled SDO can be analysed to determine if it can provide presumption of conformity with corresponding EU legal requirements in the fields of environment, health and safety; a proposed method which again appears questionable.

Furthermore, a review of marking and labelling requirements in the EU and in the US is planned. Against this backdrop, divergent approaches to marking and labelling standards need to be reduced. This raises concerns in as much as the stated goal is to limit compulsory marking requirements as far as possible to what is 'essential' and 'least trade restrictive', thereby potentially excluding environmental safeguard measures.

Finally, the above mentioned structural differences between the EU and US standardisation systems may translate into disagreements in both parties' definition of 'areas of common interest' potentially subject to closer regulatory cooperation. The conditions to define such areas need to be clarified, especially considering the different EU-US views on what areas are priorities for legislation and/or for standard-setting. To exemplify this, the US has already clearly warned against the trade implications of the EU's

[17] On this, see the US Circular No. A-119 -- Federal Register (Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities)
https://www.whitehouse.gov/omb/circulars_a119_a119fr

revised legislation on Endocrine Disrupting Chemicals (EDCs), which is expected to raise standardisation needs[18].

- ECOS urges decision-makers not to compromise environmental and public health priorities in the definition of areas of common EU-US interest for closer regulatory cooperation and in the notification of TBTs.
- ECOS believes that structural differences between the EU and the US in terms of standard development systems, referencing of standards, conformity assessments and labelling requirements would impair the clarity, coherence and purpose of existing and future harmonised standards.

4. International cooperation on standardisation already in place

Decision-makers need to be reminded that close cooperation already exists between CEN and CENELEC and their international counterparts, ISO and IEC. In this context, one may question why such international *fora* for standardisation are not simply more or better utilised by the EU and the US, or why cooperation is not improved or enhanced at international level, instead of promoting bilateral cooperation.

This would ensure the development of coherent and consistent standards at international level whilst preserving each party's freedom to develop more stringent standards at regional level. For instance, more attention could be given to overcoming current and future opposing positions within these *fora*, whilst avoiding the drafting of standards reflecting the lowest common denominator among international experts. Though it is delicate to provide concrete examples, it is clear that there are standards which trigger conflicting EU-US views, for instance in the field of biofuels, refrigerants, waste and nanotechnologies. Increased bilateral cooperation between the EU and the US could also potentially be detrimental to the coherence and effectiveness of the standard adoption processes under ISO and IEC, considering the already existing shortcomings of these processes, which at times result in opting for the lowest common denominator.

Moreover, the US' resort, reference and implementation of ISO and IEC standards are insufficient and mostly not encouraged by the US government. The US relationship with international standardisation bodies deserves a little more attention. Although the US technical advisory group to ISO and IEC participates and actively contributes to the work done at ISO and IEC level, including by providing valuable expertise, there are reasons to believe that the US does not systematically adopt internationally agreed standards as US standards, as opposed to what EU national standardisation bodies commonly do. This can be explained by several factors, e.g. the US might have a limited interest in international standards as their relevant authorities can set their own, 'fit-for-purpose' standards in a timely manner, and thus may want to avoid potentially lengthy and complex ISO and IEC level procedures if the resulting standards are

[18] See among others http://www.euractiv.com/sections/science-policymaking/trade-should-trump-health-concerns-hormone-disruptor-debate-us-tells.

not considered fully suitable to their needs. However, this could be considered as such by each and every country.

Finally, at EU-US level, informal cooperation agreements between CEN-CENELEC and their US counterparts are already in place and US experts already have access, like any other experts, to standardisation procedures both at CEN-CENELEC level and within ISO-IEC. This constitutes another route for each party to be able to participate in each other's standardisation system in an effective way, without setting new obscure rules and procedures.

- ECOS urges EU and US decision-makers to direct their efforts at improving EU-US cooperation on standards in the existing framework for international standard definition instead of strengthening their cooperation solely at bilateral level.

Annex 1: List of Abbreviations

CAB	Conformity Assessment Bodies
CEN	European Committee for Standardisation
CENELEC	European Committee for Electrotechnical Standardisation
CETA	Comprehensive Economic and Trade Agreement
EC	European Commission
ECOS	European Environmental Citizens' Organisation for Standardisation
EDC	Endocrine Disrupting Chemicals
ESO	European Standardisation Organisation
ESS	European Standardisation System
GMO	Genetically Modified Organisms
IEC	International Electrotechnical Commission
MRL	Maximum Residue Levels
OJEU	Official Journal of the European Union
SDO	Standards Developing Organisations
SME	Small and medium-sized enterprise
SPS	Sanitary and Phyto-Sanitary
TBT	Technical Barriers to Trade
TTIP	Transatlantic Trade and Investment Partnership