The Consumer Voice in Europe

Raising standards for consumers

Regulatory cooperation activities with the United states

BEUC & ANEC Response to the public consultation

Contact: **Léa Auffret – trade@beuc.eu**

Chiara Giovannini anec@anec.eu

(11/04/2019)

ANEC, THE EUROPEAN ASSOCIATION FOR THE CO-ORDINATION OF CONSUMER REPRESENTATION IN STANDARDISATION
Av. de Tervueren 32, box 27 – 1040 Brussels - +32 (0)2 743 24 70 - www.anec.eu
EC register for interest representatives: identification number 507800799-30

BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • consumers@beuc.eu • www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Funded by the European Union

Why it matters to consumers?

A more open transatlantic market could be beneficial for consumers. They could choose from more products. If both sides remove tariffs on industrial goods and reduce costs of product conformity assessment, it could encourage companies to compete on price, quality and innovation. However, consumers must be able to trust that products certified in the United States live up to their domestic safety requirements and are supervised properly. Consumers could also gain from exchanges between EU and US regulators but only if the aim of these talks is to protect consumers and if these discussions are transparent.

Summary

- ***Preserve checks and balances in conformity assessment***

Whereas there could be an economic value to reduce the costs associated with conformity assessment, it should not be at the expense of consumer safety. Conformity assessment is only one piece of a complex system to protect consumers. The EU must ensure that the necessary checks and balances will be preserved in this potential horizontal agreement on conformity assessment. For instance, the impartiality, independence and technical competence of the conformity assessment bodies must be guaranteed. There should also be a rigorous oversight to ensure that all products bought in the domestic market are safe and compliant with applicable standards and regulations, whatever their origin.

- ***Promote the consumer interest in dialogues between regulators***

Encouraging regulators on both sides to talk to each other to better protect consumers could be positive. We welcome the approach of the Commission to deal with regulatory cooperation outside of trade negotiations and on a voluntary basis. The fact that regulatory cooperation under TTIP would become an integral part of a binding trade agreement has led to widespread concerns about a regulatory chilling risk[1]. It is key to make sure that the primary objective of these dialogues will be to protect consumers while facilitating trade. It is important to regularly inform the public of the content and outcomes of these dialogues and who is involved. Indeed, the regulatory sphere in the US on consumer protection changed drastically under the new administration and is following a concerning deregulatory path.

- ***Cooperation on standards only with effective consumer participation***

Better exchange of information on standardisation is desirable between the EU and the US. However, it should not be underestimated that cooperation on standards linked to different legal frameworks can be complex. It requires in-depth analyses of technical issues as well as an assessment of economic and environmental impacts, which should all be performed on a case-by-case basis. We call on consumer organisations to be involved in dialogues on standards. Both sides should strengthen consumer representation in standardisation at national, regional and international levels with sufficient financial support. Cooperation between the EU and US on standards with a view to benefit consumers should focus on safety and emissions of motor vehicles and accessibility of products and services.

[1] See BEUC blog on regulatory cooperation published during the TTIP negotiations: https://www.beuc.eu/blog/will-regulatory-cooperation-in-ttip-become-a-straight-jacket-for-eu-law-making/

1. Preserve checks and balances in conformity assessment

The EU and the US administration as well as businesses aim to reduce the costs associated with conformity assessment when exporting and importing goods across the Atlantic. Therefore, there is a discussion on the current duplication of conformity assessment procedures: On 18 January 2019, the Commission recommended to open negotiations of a horizontal agreement with the United States on conformity assessment. The objective is to allow US conformity assessment bodies to certify that relevant US goods exported meet EU legal requirements and vice versa. BEUC and ANEC, the European Consumer voice in standardisation, will closely follow the process as it matters to consumers safety. As we explained in the Transatlantic Consumer Dialogue (TACD) resolution on technical barriers to trade during the TTIP negotiations, conformity assessment is only one piece of a complex system to protect consumers.

What are the differences between the EU and the US?

'Conformity assessment' is an activity to determine, directly or indirectly, that a process, product or service meets relevant standards and fulfils relevant requirements[2]. There are several conformity assessment models. There are voluntary, self-assessment schemes for lower-risk products, and mandatory audit and certification schemes for higher-risk scenarios. Yet, there are sometimes differences in regulators' assessment of what a high and a low risk product is, and which the adequate level of protection should be. For example, independent third-party testing is mandatory in the US for toys for children under twelve years whereas this is not the case in the EU.

The EU does not require third-party certification for most products. It allows manufacturers to self-declare the conformity of their products to relevant legislation (Suppliers' Declaration of Conformity or SDoC)), if the products comply with European Harmonised Standards[3] (the "presumption of conformity"), and affix CE marking where appropriate. However, CE marking offers no assurance to consumers that a product is safe, or that it is compliant with other legal requirements. CE marking is no more than a claim from the manufacturer that the product meets European legislation and is meant for market surveillance authorities, not consumers. In other words, the manufacturer does not have to provide an independent confirmation of the claim in most cases. Consumer organisations in Europe have long expressed concerns about CE marking and still advocate strongly to not show it on the products or their product packaging.

This system of self-declaration is complemented by rules on ex-post market surveillance checks, accreditation of conformity assessment bodies (CABs)[4] and on the requirements to notify these bodies. The CABs can be private and public laboratories, inspection or certification bodies. They are tasked to check the conformity of certain products such as medical devices before they are placed on the market.

In the US, most of the products sold that are covered by a standard are manufactured in accordance with industry voluntary standards to which consumer representatives may or may not have contributed. In addition to specifying performance requirements for the product, such standards also spell out the methods to be followed to demonstrate conformity with the standard and the manner in which such conformance should be manifest on the product and its packaging. Independent third-party testing is an often-preferred method to meet these requirements.

[2] ISO/IEC Guide 2: 2004, EN ISO/IEC 17000:2004.
[3] 'Harmonised standard' means a European standard adopted on the basis of a request made by the European Commission for the application of Union harmonisation legislation (Article 2, Regulation 1025/2012 on European Standardisation).
[4] Regulation (EC) 765/2008on accreditation and the market surveillance of products.

The link with standardisation

Divergences between the means of determining conformity tend to be claimed as 'unjustified technical barriers to trade'. Mutual Recognition Agreements (MRAs)[5] may be thought by some as a suitable tool to address the problem. In this new negotiation on conformity assessment, the agreement foreseen would include some annexes of existing MRAs. However, conformity assessment is only one piece of a complex system to protect consumers. The legal framework in combination with technical standards itself are critically important.

The outcome of any certification system based upon compliance with a standard is only as good as the standard it is based on. A standard with weak or poor requirements will result in a certification process (with or without a mark) that does not provide a high level of consumer protection. In the US, competing industry standards for the same product are not unusual, where the EU features the "unique standards model" (i.e. one European Standard becomes the national standard in at least the 28 EU Member States). This permits the EU to require the effective participation of all stakeholders in the development of European Standards. This of course is further justification for consumer participation being deemed essential in ensuring that standards and conformance systems ensure a high level of consumer protection.

What could go wrong for consumers in a EU-US deal on conformity assessment?

- *Conflicts of interest and lack of independence*: for example, if a body is both setting the standards and doing the conformity assessment. This might not be in the consumer interest. Another example would be if a body would assess the conformity of a product while belonging to its manufacturer. The manufacturer interest is more likely to prevail over the consumer interest in such situation.
- *Lack of understanding of the legal requirements*: if the staff of a US conformity assessment body would not have training on EU legal requirements. In such case, the staff will not be able to properly assess if a product actually complies with EU rules.
- *Lack of oversight and control*: with such conformity assessment agreement, the US could end up enforcing EU technical rules, but the EU would not necessarily be able to oversee or control this process. If the job is not done correctly, non-compliant products could enter in the EU single market and end up in consumers' hands.

Our recommendations for a positive EU-US conformity assessment agreement for consumers

- Guarantee the impartiality, independence from vested interests, qualification and technical competence of the Conformity Assessment Bodies (CABs).
- Set up a rigorous oversight to ensure that products bought in the domestic market are safe and compliant with applicable standards and regulations.
- Evaluate whether the EU and US systems of certification, technical infrastructures and accreditation are compatible and publish the results of such an evaluation during the negotiations.

In parallel, both sides should:

- Maintain or increase the level of consumer protection offered by their systems to complement their foreseen agreement on conformity assessment. This requires a focus on all parts of the regulatory process around product safety: from setting

[5] Mutual Recognition Agreements (MRAs) are agreements on the mutual recognition of the conformity assessment of regulated products. Through an MRA, each country is given the authority to test and certify products against the regulatory requirements of the other country, in its own territory and prior to export. However, each country maintains its own technical regulations and standards. MRAs imply that each party must have comparable system of certification, accreditation and market surveillance. Impartiality, independence from vested interests and technical competence of the Conformity Assessment Bodies (CABs) must be ensured.

new legal requirements and technical standards to checking compliance through independent third parties to public law enforcement.

- Cooperate on the enforcement aspects linked to market surveillance.
- Collaborate on a safety-dangers alert system to inform consumers about unsafe products and injury databases to collect injury reports caused by consumer products[6].

2. Promote the consumer interest in dialogues between regulators

In a globalised context, we need regulators to cooperate to keep consumers safe and bring them concrete benefits. We welcome the change of approach of the European Commission on regulatory cooperation. It is better to develop this cooperation outside of a trade agreement, on a voluntary basis and to put regulators in the driving seat.

To make the cooperation beneficial for consumers, we encourage regulators to follow this **consumer checklist**:

- Consumer protection and consumer welfare should be defined as an overarching objective of the cooperation, at least on equal footing with the objective of trade facilitation.
- Any regulatory cooperation dialogue must involve the relevant regulators and sector specialists such as DG Justice & Consumers.
- Trade partners should not be obliged to follow each other's 'good regulatory practices' such as impact assessment procedures.
- Prevent regulatory chill effects: regulatory cooperation should never impede parties' authorities from fulfilling their mandates and shall be accompanied by guarantees to prevent delays in legislating in the public interest.

To make the cooperation positive for consumers, we recommend regulators to focus on the following consumer challenges:

- **Medical devices:** We welcome that the EU will align its practices on unique device identifiers (UDI) by using global standards. UDI can significantly enhance the effectiveness of post-market safety-related actions and contribute to better traceability and monitoring of the devices by competent authorities. The EU and the US should further cooperate to ensure alignment of electronic database specifications for UDI. In addition, we support that the EU will look on how to make use of the single audit reports within the EU's legislative framework.
- **Pharmaceuticals:** The European Commission (DG SANTE) and the US Food and Drug Administration (FDA) plan to start joint inspections of manufacturing facilities for human vaccines and plasma-derived pharmaceuticals in 2019. They could also envisage to extend the existing pharmaceutical good manufacturing practices mutual recognition agreement (MRA) to these products by 2022. This would benefit consumers as it could avoid duplicating such inspections, thereby more effectively using resources while preserving consumer safety.
- **Product safety**: Regulators should find a way to overcome the technical and procedural difficulties that are preventing them to exchange data on dangerous products. Some of these harmful products could be taken off the market more rapidly. Solutions could emerge from the upcoming EU regulation on enforcement and compliance. Indeed, it will contain an article on international cooperation listing under which conditions data on harmonised products can be exchanged. We call on

[6] In the EU, the RAPEX system for non-food dangerous products facilitates the rapid exchange of information between national authorities of 31 countries and the European Commission on dangerous products found on the market. In the US the Consumer Product Safety Commission is in charge of notifying products recalls and other safety issues to the public and of the National Electronic Injury Surveillance System (NEISS). There is no equivalent system in Europe.

the EU and the US to build on this new approach and make the necessary changes to be able to alert each other and better protect consumers.

The EU and Canada recently managed to find a solution to do so and signed an administrative arrangement7. They will now exchange rapid alerts on dangerous products, even planning to focus on harmful products sold online, and to conduct joint actions. This is the type of positive cooperation we would like to see happening between the EU and the US.

- **Cybersecurity**: In a collective move, EU and US consumer organisations in 2016 took action against flawed internet-connected toys.[8] This action was based on the findings of Forbrukerrådet[9], the Norwegian member of the BEUC network, which revealed that connected toys such as 'My Friend Cayla' had multiple security risks which compromised the children's physical safety. For example, the doll could be used by a stranger to talk to children from the distance. Similar work has been done on smartwatches for kids[10] and other consumer connected products[11]. One area to explore in transatlantic regulatory cooperation could be to exchange information about the security of connected products, to ensure that faulty and risky products can be taken of the EU and US market.

- **Connected cars:** The growing connectivity of cars presents motorists with an influx of new digital services and driving features. The potential benefits for motorists are wide ranging. However, the opportunities also present significant risks with issues such as liability, safety, data protection and fair competition within the automotive sector. These developments need to be fully addressed to ensure consumers can benefit from greater connectivity whilst simultaneously being protected. In their dialogue, EU and US authorities should strive for the highest possible level of consumer protection in terms of safety and security of connected cars as well as fair access to in-vehicle data.

3. Cooperation on standards only with effective consumer participation

Although the EU and US share the aim of a high level of consumer (and other public interest) protection, they have different regulatory systems intended to achieve this aim. Hence there are divergences in approach, and these have tended to lead to different standards models and conformity assessment systems. The US and EU also have very distinct processes and procedures for developing standards and use of conformity assessment modules (as explained above). From a consumer perspective, achieving a greater coherence of legislation and deeper convergence of standards is only acceptable if the requirements that provide consumers with the highest levels of protection and welfare are identified and respected.

The EU and US standardisation models, and the product safety and conformity assessment legislation, are different for historical reasons. Therefore, checks and balances are also different and special care should be taken when considering modifying single elements, such as the use of conformity assessment or standards.

---

[7] Administrative arrangement between the EU and Canada on the exchange of information on the safety of non-food consumer products https://ec.europa.eu/info/sites/info/files/aa_final_en-eu_version.pdf

[8] Consumer organisations across the EU take action against flawed internet-connected toys https://www.beuc.eu/publications/consumer-organisations-across-eu-take-action-against-flawed-internet-connected-toys/html

[9] #Toyfail, an analysis of consumer and privacy issues in three internet-connected toys, Forbrukerrådet, https://fil.forbrukerradet.no/wp-content/uploads/2016/12/toyfail-report-desember2016.pdf

[10] #WatchOut, Analysis of smartwatches for children, Forbrukerrådet, https://fil.forbrukerradet.no/wp-content/uploads/2017/10/watchout-rapport-october-2017.pdf

[11] Press release from the Belgian consumer organisation, Test-Achats, Maison connectée, maison en danger ! https://www.test-achats.be/action/espace-presse/communiques-de-presse/2018/hackable-home

Because of the substantial differences between the EU and US standardisation models, especially in terms of stakeholder involvement and inclusiveness, we do not support the proposition that standards developed in the US be accorded a presumption of conformity or equivalence with EU regulatory requirements and vice versa.

Differences in the requirements of the standards are exacerbated by differences in national and regulatory requirements around the world. For example, while EU product safety legislation is based on the precautionary principle, US legislation adopts a risk-based approach and actions are taken when there is evidence of harm. We believe that it is easier to avoid future divergence than fix divergences that have already occurred[12].

We agree that improve the exchange of information on standardisation is desirable by means of dedicated dialogues. However, it should not be underestimated that cooperation on standards linked to different legal frameworks can be complex. It requires in-depth analyses of technical issues as well as an assessment of the economic and environmental impacts, which should all be performed on a case-by-case basis.

To this end, we call on to involve consumer organisations in dialogues on standards. Both sides of the Atlantic should strengthen consumer representation in standardisation at national, regional and international levels with sufficient financial support. In our opinion, trade benefits include both the benefits of traders and the benefits of consumers.

Cooperation between the EU and US on standards with a view to benefit consumers could focus on the following areas:

- **Safety and emissions of motor vehicles:** in the framework of the UNECE *Agreement concerning the Establishing of Global Technical Regulations for Wheeled Vehicles, Equipment and Parts which can be fitted and/or be used on Wheeled Vehicles* of 1998[13], collaboration on standards (called United Nations Global Technical Regulations-UN GTRs) are useful to increase the level of vehicle safety, environmental protection, energy efficiency. Members (including EU countries and the US) of UNECE's World Forum for Harmonization of Vehicle Regulations are developing a harmonized procedure to perform real driving emission testing on open roads. In the wake of the 'diesel scandal' improved coordination for a GTR on Real-world Driving Emissions (RDE) is of great consumer relevance.
- **Accessibility of products and services**: with the adoption of the European Accessibility Act[14], several products and services, mainly in the digital areas, must be accessible. Harmonised Standards will be needed and collaboration with the US in applying accessibility legislation could be useful.

END

[12] ANEC position on alignment among the CEN, ISO and ASTM standards for toys safety, 2010, http://goo.gl/nGjKM4

[13] https://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29glob.html

[14] DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the approximation of the laws, regulations and administrative provisions of the Member States as regards the accessibility requirements for products and services.

This publication is part of an activity which has received funding under an operating grant from the European Union's Consumer Programme (2014-2020).