

## TRADE NEGOTIATIONS AND REGULATORY DIALOGUES WITH THE UNITED STATES

BEUC recommendations

*Including joint recommendations on conformity  
assessment with ANEC*



*Raising standards for consumers*

**Contact:** Léa Auffret – [Trade@beuc.eu](mailto:Trade@beuc.eu) – [anec@anec.eu](mailto:anec@anec.eu)

Ref: BEUC-X-2019-011 - 11/03/2019

Ref: ANEC-SC-2019-G-008

## 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.

## Context

---

In July 2018, the EU and US agreed to work on improving their trading relationship, fraught by tense debates on tariffs, as shown by this [joint statement](#). After several meetings of the EU-US executive working group, tasked to put the agreed plan in motion, the EU and the US proposed two drastically different ways forward. On the one hand the EU is envisaging a small-scale negotiation and regulatory dialogues. On the other, the United States seem to deviate from the agreed approach to pursue a much more comprehensive agreement, which would even go beyond the Transatlantic Trade and Investment Partnership (TTIP).

## Summary

---

The European Commission is proposing EU Member States to launch two trade negotiations with the United States on industrial goods tariffs and on conformity assessment. In parallel, the EU and the US intend to improve the cooperation between their regulators, among other initiatives.

- **Eliminate tariffs to the benefits of consumers**

A transatlantic trade agreement that would remove tariffs on industrial goods could be beneficial to consumers. It could contribute to bring down the price of consumer goods, to increase consumer choice and – potentially – have a positive impact on the quality of goods. However, these effects will not be automatic as consumers are not the ones directly paying tariffs in most cases, importers are. Whether or not cheaper prices due to lower tariffs will actually materialise for consumers must be carefully assessed by the Commission and Members States before overselling benefits of trade to consumers.

- **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<sup>1</sup>. 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.

- **Ensure transparency and meaningful engagement**

Since the TTIP negotiations, the European Commission, and to a lesser extent EU Member States, became more transparent and are better engaging with public interest groups. However, consumer concerns that arose during the TTIP talks are still present and even reinforced by the negative and unpredictable attitude of the current US administration. The public will need to know what is being negotiated on its behalf but also how regulatory dialogues are progressing. In addition, we call on the Commission to pursue its positive engagement with public interest groups on a regular basis and on all topics addressed by the executive working group.

## 1. Eliminate tariffs to the benefits of consumers

---

On 18 January 2019, the European Commission proposed to EU Member States to open negotiations with the United States that aim to eliminate tariffs on industrial goods. Such an agreement could be beneficial to consumers. In theory, the reduction or elimination of tariffs can contribute to reducing prices of consumer goods and increase consumer choice (this is at least the argument used by the Commission to explain why trade agreements such as the Economic Partnership Agreement with Japan will benefit consumers).

---

<sup>1</sup> 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/>

However, this is not an automatic effect. Importers will pay less, but they might not always pass on the gains of these tariff reductions to consumers. It will depend on various factors including the competitive pressure on the market. We welcome the work<sup>2</sup> of the Commission on this 'pass-through effect' and encourage its continuation. For instance, recent economic studies pointed out that tariff reductions could also have a positive impact on consumer goods quality<sup>3</sup>.

To ensure that consumers will benefit from the tariff negotiations, the EU should:

- Propose to include as a key objective of the agreement: to deliver positive effects of tariff elimination and reductions for consumers.
- Assess the direct effect of tariff reductions on consumers before communicating about such benefits. After the TTIP debacle of exaggerated consumer benefits, it is important not to mislead consumers and oversell the benefits of trade agreements. This is key to restore consumer and therefore public trust in trade policy.
- Monitor if the agreement once implemented leads to positive effects on consumers notably on prices, choice and quality.

### **Consumers should not be the collateral victims of the trade war**

In a situation where the US would impose tariffs on EU cars, the draft mandates state that the negotiating plan would be off the table. We understand that the EU would need to rebalance the impacts of such tariffs. If the Commission were to retaliate by imposing increased tariffs on US goods, guarantees must be in place for consumers. The Commission should make sure alternatives do exist for the products listed and that there will be minimal impacts on prices and choice for consumers. Indeed, consumers are the most vulnerable in this type of situation as prices tend to go up when tariffs are increased.

The Commission should put in place a monitoring system in case of retaliation. It is crucial to observe the effects of such measures on consumer prices and choice. Information should be made available to the public, so that consumer organisations in the EU can react and find ways to mitigate potential detrimental effects on EU consumers.

---

<sup>2</sup> DG Trade chief economist note "Consumer benefits from EU trade liberalisation: How much did we save since the Uruguay Round" (2018) [http://trade.ec.europa.eu/doclib/docs/2018/february/tradoc\\_156619.pdf](http://trade.ec.europa.eu/doclib/docs/2018/february/tradoc_156619.pdf)

<sup>3</sup> Breinlich, Holger, Dhingra, Swati and Ottaviano, Gianmarco I. P. (2016) *How have EU's trade agreements impacted consumers?* CEP Discussion Paper (1417). Centre for Economic Performance, London School of Economics and Political Science, London, UK.

## 2. Preserve checks and balances in conformity assessment

---

### *Joint recommendations with ANEC, the European consumer voice in standardisation*



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<sup>4</sup>. 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<sup>5</sup> (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.

---

<sup>4</sup> ISO/IEC Guide 2: 2004, EN ISO/IEC 17000:2004.

<sup>5</sup> '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).

This system of self-declaration is complemented by rules on ex-post market surveillance checks, accreditation of conformity assessment bodies (CABs)<sup>6</sup> 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.

### **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)<sup>7</sup> 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.

---

<sup>6</sup> Regulation (EC) 765/2008 on accreditation and the market surveillance of products

<sup>7</sup> 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.

- *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 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<sup>8</sup>.

---

<sup>8</sup> 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.

### 3. 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 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 arrangement<sup>9</sup>. 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.<sup>10</sup> This action was based on the findings of Forbrukerrådet<sup>11</sup>, 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<sup>12</sup> and other consumer connected products<sup>13</sup>. 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 off 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.

#### 4. Transparency and involvement

---

Both trade negotiations and regulatory dialogues must be conducted in full transparency. Agendas and minutes of meetings and rounds must be available as well as negotiating documents. We regret the longstanding insistence on opacity of the United States in this regard. This will drastically limit our ability to know what is being negotiated on behalf of EU consumers. We call on the European Commission to continue advocating for transparency with its trade partners.

---

<sup>9</sup> 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](https://ec.europa.eu/info/sites/info/files/aa_final_en-eu_version.pdf)

<sup>10</sup> 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>

<sup>11</sup> #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>

<sup>12</sup> #WatchOut, Analysis of smartwatches for children, Forbrukerrådet, <https://fil.forbrukerradet.no/wp-content/uploads/2017/10/watchout-rapport-october-2017.pdf>

<sup>13</sup> Press release from the Belgian consumer organisation, Test-Achats, Maison connectée, maison en danger ! <https://www.test-achats.be/action/espace-presse/communiqués-de-presse/2018/hackable-home>

Engaging and involving consumer organisations will help regulators and negotiators better understand what is at stake and achieve better results for all. For instance, a discussion could be planned once a year between consumer organisations and regulators. The same should be organised between trade negotiators and consumer organisations. Furthermore, stakeholder events should be organised in the margins of trade negotiating rounds. Special effort should be made to ensure a balanced participation of both public interest groups, such as consumer organisations, and private interest groups. The task of involving consumer organisations must also rest on Member States. Indeed, there should be an effort of meaningful engagement both at EU level and at national level.

The European Commission commits in its draft mandates to involve the European Parliament at all stages of the procedure. This is very important to ensure democratic scrutiny. However, negotiations could start during the European Parliament elections. We therefore call on the Commission to adapt the negotiating calendar to the election calendar to guarantee proper parliamentary oversight.

END



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

*The content of this publication represents the views of the author only and it is his/her sole responsibility; it cannot be considered to reflect the views of the European Commission and/or the Consumers, Health, Agriculture and Food Executive Agency or any other body of the European Union. The European Commission and the Agency do not accept any responsibility for use that may be made of the information it contains.*