EUROPEAN COMMISSION
Directorate-General for Trade

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NOTE FOR THE ATTENTION OF THE TRADE POLICY COMMITTEE

SUBJECT: **EU-US engagement on regulatory issues**

***ORIGIN*:** **Commission DG Trade Unit E.1 Canada and USA**

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OBJECTIVE: ***For information***

REMARKS:

With this note, the Commission seeks to inform the Trade Policy Committee of the prospects and parameters for EU-US engagement on regulatory issues, in light of the agreement reached by Presidents Juncker and Trump on 25 July.

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EU-US engagement on regulatory issues

Information Note

I. INTRODUCTION

With this note, the Commission seeks to inform the TPC and INTA of the prospects and parameters for EU-US engagement on regulatory issues, in light of the agreement reached by Presidents Juncker and Trump on 25 July (copy of Joint Statement attached). An Executive Working Group has been set up to implement the Joint Statement and will among other things focus on industrial tariff elimination as well as on regulatory issues and standards.

A first meeting between Commissioner Malmström and USTR Lighthizer was held in Brussels on 10 September to discuss the future implementation of the Joint Statement. They agreed to focus their immediate attention on the identification of potential areas for cooperation in the field of regulatory issues and standards. They will meet again in November to review progress made. These discussions will be prepared through a set of technical meetings involving US regulatory agencies and Commission services with competence in regulatory matters.

The Commission considers that discussions with the US on regulatory issues and standards should take place outside the context of trade negotiation. Cooperation would be voluntary, transparent and accountable, in full respect of domestic procedures and levels of protection.

The Commission will debrief Parliament, Member States and civil society at regular intervals. A meeting with Member States' experts will be organized shortly.

II. PRINCIPLES UNDERLYING FUTURE REGULATORY ENGAGEMENT WITH THE US

The EU and the US have since many years tried to improve regulatory cooperation. The process of globalisation has sharpened our mutual interest in avoiding fragmented regulatory solutions to address similar societal challenges, also in light of the development of new technologies and the emergence of alternative regulatory frameworks. In working together in selected areas, the EU and the US should be able to achieve better societal outcomes. At the same time, EU-US cooperation should be supportive of international efforts geared towards the development of regulations and standards based on high levels of protection. A number of guiding principles should be respected in this process:

- Cooperation should be limited to areas in which regulators identify a common interest. Both sides should acknowledge differences in regulatory traditions, preferences and processes when choosing areas for cooperation. Cooperation should not be envisaged where regulatory objectives and basic legislation are very different.

- Domestic law and regulatory procedures will need to be fully respected and levels of protection should at least be maintained. Cooperation should take place on a voluntary basis, respecting each side's regulatory autonomy. Discussions on regulatory issues and standards would be held outside the context of any possible trade negotiation.

- The highest levels of transparency and accountability should apply, including through civil society engagement and the pursuit of a dialogue with all interested stakeholders.

III. POSSIBLE AREAS OF FUTURE COOPERATION

The following is a preliminary list of areas where there is potential for fruitful EU and US cooperation:

A. Cooperation on conformity assessment in agreed sectors

Conformity assessment is very sector specific and both sides have developed over time different approaches. For a large number of low-risk sectors, the EU applies the supplier's declaration of conformity, which is the least burdensome form of conformity assessment. This is notably the case for all kinds of electrical low voltage equipment, most types of machinery and toys, radio and telecom equipment, some categories of medical devices, pressure equipment and personal protective equipment. For higher risk products and aspects, third party conformity assessment applies. For instance, the EU accepts neither self-declaration of conformity, nor presumption of conformity for motor vehicles, including agricultural tractors, and non-road mobile machinery with respect of emissions. In the US, compulsory third party conformity assessment is common in several areas that the EU considers low-risk.

Specific sectorial agreements could provide for mechanisms to avoid an unnecessary duplication of costs to the benefit of both regulated industries and regulators. The EU and the US have a shared interest in improving mutual recognition of conformity assessment results in areas of economic importance. A number of sectors on either side of the Atlantic are subject to comparable regulatory and procedural frameworks for inspections. Existing frameworks for mutual recognition could be extended or inspire further work in other areas.

(i) Pharmaceuticals

In November 2017, an agreement entered into force between the EU and US to recognise inspections of manufacturing sites for human medicines conducted in their respective territories. It updates the 1998 Mutual Recognition Agreement (MRA), by allowing for recognition of each other's inspection outcomes and hence for better use of inspection expertise and resources. Due to the reduction of the number of duplicative inspections, regulators on both sides of the Atlantic can focus inspection resources on higher risk countries, while pharmaceutical manufacturers face less costs and administrative delays associated with duplicative inspections of manufacturing sites. The update of the 1998 MRA was possible following excellent cooperation between EU and US regulators and provides a good illustration on how increased regulatory engagement can reduce costs of enforcement and benefit regulators, consumers and businesses. 15 Member States are covered by the agreement and the remaining Member States are expected to follow soon. The EU and the US could explore the extension of the 2017 agreement to veterinary medicines and vaccines. This possibility is provided for under the MRA, but we could try to translate it in a concrete commitment. Other potential areas for further cooperation between SANTE/EMA and the US Food and Drug Administration (FDA) could be explored.

(ii) Medical devices

There is scope to work on reducing duplication of regulatory costs in the area of medical devices. The EU has recently adopted new legislation in this area that will become applicable between May 2020 and May 2022, introducing a Unique Device Identification (UDI) system which is now being implemented. Compatibility between US and EU UDI's should be ensured. There is an interest in exploring how to operationalize the medical devices annex of the EU-US mutual facilitation agreement in order to reduce the cost and accelerate procedures for approval of medical devices, as well as to explore how to cooperate with the US on improving and facilitating EU participation in the international single audit system (building on principles developed through the international cooperation between regulators in the International Medical Devices Regulatory Forum). Whatever the means chosen, it should be possible to agree on a common roadmap on measures to facilitate the approval of medical devices and to avoid duplication of conformity assessment, fully in line with EU and US law. Post-market safety would be another good area to cooperate delivering benefits directly to the public in terms of increased safety (e.g. through a further developed international or bilateral exchange of information among regulators). There are also emerging areas, such as the regulation of new technologies and medical ICT where cooperation on regulatory solutions would be beneficial and ensure future close alignment.

(iii) Marine equipment

The European Marine Safety Agency (EMSA) and the US Coast Guard recently reached a technical agreement to broaden the scope of the 2004 EU-US Mutual Recognition Agreement (MRA) on the mutual recognition of certificates of conformity assessment for marine equipment. Such equipment ranges from life-saving equipment to fire protection equipment, navigational equipment and radio equipment, which all falls under several international conventions of the International Maritime Organization. This sector is of major economic

importance to the EU and US and the MRA facilitates transatlantic trade in marine equipment, by allowing EU products designated under the agreement to be accepted for sale in the US without any additional testing or certification, and vice versa. Both sides should work at soon finalising the legal and procedural steps needed to ensure the extension of the agreement can become fully effective so that it could inspire mutual recognition efforts in other areas.

B. Cooperation on more horizontal conformity assessment

The US has indicated an interest to consider a broader discussion on how to facilitate conformity assessment beyond sector-specific initiatives. The EU would expect the US to address EU concerns about the unnecessary administrative burdens, cost and difficulty of conformity assessment that the European electrical as well as machinery sector faces when certifying for export to the US. Provided these concerns can be addressed, it should be possible to explore a horizontal approach to conformity assessment, including for example the feasibility of a CETA-type solution. Such an approach can complement the sector specific approaches discussed above. There would also be an interest in exploring the feasibility of introducing less burdensome conformity assessment requirements, notably through greater use of supplier's declaration of conformity in low risk areas.

C. Cooperation on standards or technical regulations relevant for new technologies

Strong positive momentum exists with regard to cooperation between the respective standard development organisations (CEN/CENELEC/ETSI and ASTM/ANSI).[1] In order to foster that enhanced cooperation, consideration could be given to a mechanism which would allow the smooth coordination of activities on standards and which streamlines the dissemination of information. Both aspects, coordination and dissemination, are crucial to keep track of the intentions, from regulators of either side, to request the development of a standard (EU) or to reference standards in regulations (US) in commonly agreed focus-areas. As a follow up, Standard Development Organisations, from both sides of the Atlantic, could be invited to consider cooperation in the development of standards in those focus areas with a view to leverage these at the international level.

Car safety regulations are an area where cooperation on technical regulations could be particularly fruitful. The EU and US could cooperate - within the context of the UN/ECE 1998 Agreement - on the development of technical regulations for new technologies, for instance as regards to automated vehicles. Together with Japan, we could advance on the proposals to adapt UN/ECE 1998 procedures in order to facilitate US implementation of Global Technical Regulations.

Another area for cooperation is cybersecurity, where the EU and the US could consider enhancing cooperation on the development of globally relevant standards. Other areas could include industrial collaborative and service robots as well as additive manufacturing.

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[1] CEN, the European Committee for Standardization. CENELEC is the European Committee for Electrotechnical Standardization. ETSI is the European Telecommunications Standards Institute. ANSI is the American National Standards Institute; ASTM is the largest US-based standards development organization.

D. Food safety

The EU and the US could cooperate in a number of food safety areas where levels of protection are similar, and where regulatory preferences are reconcilable. No engagement will take place in areas characterized by important systemic differences for instance as regards different attitudes on risk assessment and management. In any event, regulatory cooperation can only be undertaken in full respect of each side's legislation, including legislation related to the approval of GMO's, pesticides and the prohibition of hormones treatment for the meat sector.

Therefore, it would be important to focus cooperation efforts on less sensitive areas, where interests coincide. In the food sector, EU and US regulators have recently cooperated well on an equivalency agreement for bi-valve molluscs and the recognition of food safety systems in areas regulated by the US Food and Drug Administration. This cooperation could be extended to other areas, provided the interests of both sides can be addressed in a balanced manner. In this respect, we expect the US to move forward with the long-awaited publication of a final rule for apples and pears.

IV. CONCLUDING REMARKS

The case for EU and US engagement on regulatory issues has always been strong and there are many important lessons learnt out of more than 25 years of engagement between our regulators. Closer and more effective transatlantic cooperation between regulators in the context of the Executive Working Group set up last summer could result in concrete, tangible results that should improve transatlantic regulatory cooperation, reduce tensions and result in stronger levels of protection, lower regulatory barriers and cost savings for public authorities and companies. Benefits could be of particular significance for small and medium size enterprises. Clearly, regulatory cooperation between the EU and the US can only be successful where interests coincide and if both sides fully acknowledge and respect the differences in their regulatory traditions, preferences and processes.

The immediate objective of the Executive Working Group will be to identify a number of concrete actions where regulatory cooperation can facilitate transatlantic trade, while fully respecting existing levels of protection. Once these areas have been identified, there would be a need to set up a transparent process to monitor the follow-up as well as to consider input from all interested stakeholders.

European Commission - Statement

Joint U.S.-EU Statement following President Juncker's visit to the White House

Washington, 25 July 2018

We met today in Washington, D.C. to launch a new phase in the relationship between the United States and the European Union – a phase of close friendship, of strong trade relations in which both of us will win, of working better together for global security and prosperity, and of fighting jointly against terrorism.

The United States and the European Union together count more than 830 million citizens and more than 50 percent of global GDP. If we team up, we can make our planet a better, more secure, and more prosperous place.

Already today, the United States and the European Union have a $1 trillion bilateral trade relationship – the largest economic relationship in the world. We want to further strengthen this trade relationship to the benefit of all American and European citizens.

This is why we agreed today, first of all, to work together toward zero tariffs, zero non-tariff barriers, and zero subsidies on non-auto industrial goods. We will also work to reduce barriers and increase trade in services, chemicals, pharmaceuticals, medical products, as well as soybeans.

This will open markets for farmers and workers, increase investment, and lead to greater prosperity in both the United States and the European Union. It will also make trade fairer and more reciprocal.

Secondly, we agreed today to strengthen our strategic cooperation with respect to energy. The European Union wants to import more liquefied natural gas (LNG) from the United States to diversify its energy supply.

Thirdly, we agreed today to launch a close dialogue on standards in order to ease trade, reduce bureaucratic obstacles, and slash costs.

Fourthly, we agreed today to join forces to protect American and European companies better from unfair global trade practices. We will therefore work closely together with like-minded partners to reform the WTO and to address unfair trading practices, including intellectual property theft, forced technology transfer, industrial subsidies, distortions created by state owned enterprises, and overcapacity.

We decided to set up immediately an Executive Working Group of our closest advisors to carry this joint agenda forward. In addition, it will identify short-term measures to facilitate commercial exchanges and assess existing tariff measures. While we are working on this, we will not go against the spirit of this agreement, unless either party terminates the negotiations.

We also want to resolve the steel and aluminum tariff issues and retaliatory tariffs.

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