

Explanatory Note

EU Proposal for an agreement between the European Union and the United States of America on the mutual acceptance of results of conformity assessment

The Commission proposal is made in the context of the on-going work of the Executive Working Group set up under the EU-US [Joint Statement](#) of 25 July 2018 and the [Council Decision](#) of 15 April authorising the launch of negotiations for an agreement with the United States on conformity assessment.

Conformity assessment is the process of demonstrating that a product is safe and complies with all the requirements foreseen in the legislation. It reinforces consumers and other users' trust that products placed on the market meet the relevant regulations. This process can include testing, inspection and certification. In many cases, conformity assessment is performed by authorised (“accredited”) organisations, for example laboratories, inspection or certification bodies. Accreditation helps to ensure that conformity assessment bodies have the necessary technical capacity and competence to perform their duties.

EU-US trade in goods amounted to EUR 674 billion in 2018, composed mostly of industrial products (EUR 638 billion, including EUR 178 billion trade in machinery and electric and electronic equipment). Many of those products are subject to third-party conformity assessment procedures, thus making the use of conformity assessment bodies mandatory to prove the compliance of the product with the relevant rules. Both the EU and the US have their respective rules for conformity assessment and accreditation.

The EU Proposal aims at enabling exporters to seek certification of products they want to export, in the country from which they want to export them, to prove their compliance with the applicable rules in the destination country. This can facilitate trade while ensuring that a high level of protection is fully preserved. Nothing in the agreement will limit the ability of each party to regulate and set its own level of protection in technical regulations. US exports, whether certified in the US or in the EU, shall continue to be subject to the EU technical regulations.

In line with the negotiating directives, the EU Proposal is horizontal in nature and covers in principle all areas of harmonised legislation of industrial products¹, falling under the harmonised European Union framework on conformity assessment. It does not cover non-harmonised areas, as well as the specific, sensitive areas excluded in Article 3(3).

Article 4 responds to the request for a streamlined procedure in the form of a reciprocal commitment to treat operators established in the territory of the other Party no less favourable than operators established in a Party's own territory. Articles 5-9 lay down the modalities of ensuring that in the EU (where the conformity assessment system is organised on the basis of the principle of territoriality) conformity assessment bodies established in the territory of the United States can be treated in a way that is equivalent to conformity assessment bodies established in the EU. It is important to emphasise that these provisions do not contain additional commitments for the EU; their purpose is simply to lay down the relevant procedures necessary to implement the commitment contained in Article 4.

Article 13 of the EU Proposal contains the relevant provisions that aim at reducing the hurdles that the European machinery and electrical and electronics sectors are facing in connection with the conformity assessment scheme of the US Occupational Safety and Health Administration, in accordance with point 7 of the negotiating directives.

The negotiating directives made the agreement conditional upon effective public supervision by the Parties of conformity assessment bodies located in their territory. The corresponding obligation can be found in Article 7 of the EU Proposal.

The negotiating directives also provide for exploring the feasibility of introducing less burdensome conformity assessment procedures. In this context, Article 11 of the EU Proposal sets out an obligation for each Party to consider systematically in the context of reviews or drafting of new legislation the use of first-party conformity assessment (self-certification by the manufacturer) in low-risk areas where the other Party uses such lighter form of conformity assessment. It is important to emphasise however, that this obligation does not interfere with the right to regulate and each Party remains free to set the level of protection it deems appropriate.

¹ For a non-exhaustive list of EU harmonised legislation see: https://ec.europa.eu/growth/single-market/goods/new-legislative-framework_en