

Orgalim call for an EU-US Mutual Recognition Agreement on Conformity Assessment for Machinery and Electrical Equipment

Introduction

At the meeting of the Trade and Technology Council (TTC) on 5 December 2022, the EU and the US agreed to “continue exploring opportunities to **improve cooperation in conformity assessment, including in machinery and other sectors**.”¹ Orgalim views EU-US cooperation on conformity assessment as a very welcome step forward in the context of the TTC and wishes to put forward recommendations as to how to achieve concrete results in this area, to the advantage of businesses on both sides of the Atlantic.

In this respect, we recommend that the EU and the US initiate talks regarding a prospective **Mutual Recognition Agreement (MRA) on Conformity Assessment for Machinery and Electrical Equipment, based on reciprocity of market access**. Such an MRA would be limited to ensuring the mutual acceptance of test results issued by accredited conformity assessment bodies (CABs) operating under the MRA and certifying conformity with the different product requirements and standards of each market.

We believe that such an agreement would deliver limited, but significant, benefits to EU and US exporters and represent a concrete positive outcome of transatlantic cooperation under the TTC.

Orgalim also wishes to stress that as part of such negotiations both parties should seek **appropriate solutions to address the issues created by the US federal structure and regulatory fragmentation**, to ensure that certificates issued by EU CABs are accepted across the entirety of the US. The objective is to guarantee reciprocity of market access for exporters on both sides of the Atlantic. In order to effectively reduce technical barriers to trade, improve market access and promote economic growth, it is essential that the EU, the US and the EFTA countries work together on MRAs.

The issue: mutual non-acceptance of conformity assessment results

Both the EU and the US currently have rules and systems in place that limit, and in some cases prohibit, the ability for CABs in one jurisdiction to certify products for the conformity assessment requirements of the other jurisdiction.

¹ EU-US Joint Statement of the Trade and Technology Council, Washington DC, 5 December 2022 ([link](#))

Taking the example of machinery products, currently only 3 out of the approximately 160 EU-domiciled notified bodies for the Machinery Directive also serve as US Nationally Recognised Testing Laboratories (NRTLs) administered by the US Occupational Safety and Health Administration (OSHA). On the other hand, no US-domiciled NRTLs are registered EU notified bodies for the Machinery Directive.

Due to the restricted number of CABs available to test products in one market for the other market's requirements, exporters on both sides have a severely limited amount of options to certify their products. This represents a considerable barrier to trade and involves unnecessary costs:

- Exporters need to **work with different CABs for similar products in their portfolio**, depending on whether such products are aimed at the domestic or the foreign export market, therefore leading to additional costs.
- Exporters often face **language barriers** due to the fact that CABs are based in the export market.
- In some cases, after preliminary inspections in the country of origin, new products have to be **shipped to the target export destination** in order to finalise the conformity assessment process, leading to considerable waiting times and additional costs.
- Even when European machinery and electrical equipment exporters utilise the limited amount of NRTLs available in Europe to certify their new product for the US market they often face **major backlogs that can last up to nine months**.

This leads to a considerable overall burden which is especially **problematic for export-oriented SMEs** that lack the material and financial resources necessary to deal with such procedures, resulting in a significant loss of market access. All of these cumulative barriers factor into why a machine produced by an EU manufacturer for the US market costs between 5-18% more than a comparable machine for the European market.

The solution: an MRA on conformity assessment for machinery and electrical equipment, based on reciprocity of market access

Orgalim recommends that the EU and the US start negotiations for an **MRA on conformity assessment for machinery and electrical equipment**, based on reciprocity of market access. Such an MRA should provide the framework for US public authorities to recognise and accept certificates that are delivered by a significantly greater number of competent CABs located in the EU, which would certify a product as meeting the technical requirements and standards of the US market, and vice versa. These certificates would be issued by CABs which have the required competences and which each party has specifically designated under the MRA for assessing the conformity of machinery and related electrical equipment products. The CABs will also be subject to monitoring by the relevant designating authority.

Under the MRA, a significant number of competent EU CABs will be eligible for recognition by OSHA as Nationally Recognised Testing Laboratories (NRTLs), while US CABs could become notified bodies under the current Machinery Directive and the future Machinery Regulation.

Looking at the existing situation in the US, OSHA currently requires NRTL marking for 37 product categories² in all the US states and territories over which it has direct federal jurisdiction (27 out of 56). The remaining US states and territories (29 out of 56)³ operate under so-called "state plans", which have to ensure a level of safety at least equivalent to that of OSHA, and must be approved by OSHA. These states may implement the NRTL marking system or alternatively an equivalent one. When states operating under state plans implement their own programme for

² <https://www.osha.gov/nationally-recognized-testing-laboratory-program/products-requiring-approval>

³ <https://www.osha.gov/stateplans/>

recognising testing laboratories, OSHA requires them to accept certifications of NRTLs recognised by OSHA for testing of equipment and materials where state safety requirements are the same as the federal⁴ equivalent.

In short, while state plans may sometimes have stricter requirements than OSHA's prerequisites, NRTL marking is a "bare minimum" for product acceptance throughout the US. However, it should be noted that there is no clear guidance from OSHA directing local Authorities Having Jurisdiction (AHJs) to treat NRTLs as interchangeable. While countless AHJs do not discriminate against particular NRTL markings, there is a grey area in the US regulatory system which allows discrimination to happen⁵. Therefore, for an MRA to be effective, it is imperative that OSHA publishes guidance explicitly directing the AHJs to treat all NRTL markings as equal and interchangeable.

These specific features of the US system require the negotiation of effective solutions to guarantee that the future certificates and test results issued by CABs qualifying as NRTLs are accepted across the entirety of the US, by federal, state, and local authorities. We call on the negotiators to strive to achieve reciprocity in market access, ensuring that the level of acceptance of EU CABs certificates in the US is comparable to the EU single market for certificates issued by notified bodies under the Machinery Directive. For reciprocity to be achieved, US OSHA should consider requiring a common "NRTL mark" for machinery and electrical equipment products, which would be designed to be accepted throughout the entirety of the US, making it virtually impossible for AHJs to discriminate against the certificates of differing NRTLs. The requirement of a common NRTL mark would provide more regulatory certainty for both European exporters and American manufacturers of machinery and electrical equipment, as they would have more assurance that their products would not be rejected by an AHJ just because they used the services of one NRTL instead of another.

Therefore, if negotiated as suggested, an MRA on conformity assessment for machinery and electrical equipment would bring limited, but significant, benefits to exporters on both sides of the Atlantic:

- Exporters would benefit from **reduced waiting times due to increased choice and availability of CABs**. These reduced delays would decrease opportunity costs for machinery exporters, as these manufacturers would more quickly be able to have their new products certified for the importing market.
- Exporters would incur **reduced costs** associated with conformity assessment, resulting from:
 - Increased competition among CABs that would drive prices down in the long term.
 - The elimination of the need to ship products to the target export market to have the products certified.
 - The ability for exporters to liaise with one single CAB based in their home market rather than having similar products shipped to separate CABs in the EU and the US.
- Exporters would benefit from **reduced or no language barriers**.

It should be noted that available econometric data shows that the existence of an MRA makes a positive difference both to the **value of exports (15-40% increase)** and to the **potential for firms to export (new) products to (new) markets (up to 50% increase in the potential to export)**⁶.

Also, in the fields covered by federal agency competence in the US (FCC, FDA), the **EU and the US have had an MRA in place since 1998** covering radio equipment, electromagnetic compatibility (EMC), recreational craft, medical devices, and good manufacturing practices for pharmaceuticals. This could serve as a possible template for a future MRA covering machinery and electrical equipment, provided the acceptance of conformity assessment results issued by CABs designated under such an MRA is effectively extended to all levels of public administration. For example, as

⁴ https://www.osha.gov/sites/default/files/enforcement/directives/CPL_01-00-004.pdf

⁵ <https://www.osha.gov/nationally-recognized-testing-laboratory-program/frequently-asked-questions>

⁶ *How Important are Mutual Recognition Agreements for Trade Facilitation?*, ECIPE Policy Brief, December 2022 ([link](#))

a result of this 1998 MRA, over 60 CABs located in the EU are currently recognised by the US Federal Communications Commission (FCC) as laboratories which are competent to test European exports to meet US regulatory requirements⁷. In addition, the 1998 MRA allowed for the use of a common "FCC mark" for the US market, an attribute which could serve as a precedent for a common "NRTL mark" in an MRA for machinery and electrical equipment.

Conclusion

In conclusion, Orgalim fully supports an EU and US MRA on Conformity Assessment for Machinery and Electrical Equipment, which we believe would benefit exporters and represent a positive outcome of transatlantic cooperation under the TTC. However, we caution negotiators to keep in mind the importance of ensuring reciprocity of market access for exporters on both sides of the Atlantic.

⁷ OET Laboratory Division Equipment Authorization System (EAS), U.S. Federal Communications Commission ([link](#))

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