



National Electrical Manufacturers Association

PHILIP A. SQUAIR

Vice President, Government Relations

December 10, 2018

Edward Gresser
Chair, Trade Policy Staff Committee
Office of the United States Trade Representative
600 17th Street, NW
Washington, DC 20508

Re: Docket USTR–2018–0035, *Request for Comments on Negotiating Objectives for a U.S.-European Union Trade Agreement*

Dear Mr. Gresser,

As the leading trade association representing the manufacturers of electrical and medical imaging equipment, the National Electrical Manufacturers Association (NEMA) provides the attached comments in response to the November 15, 2018 notice inviting public input on priorities for U.S.-European Union trade agreement negotiations.

NEMA represents nearly 350 electrical equipment and medical imaging manufacturers that make safe, reliable, and efficient products and systems. Our combined industries account for 360,000 American jobs in more than 7,000 facilities covering every state. Our industry produces \$106 billion shipments of electrical equipment and medical imaging technologies per year with \$36 billion exports.

Attached please find the NEMA comments. We would welcome discussing this matter and our comments further. Our Member companies count on your careful consideration and we look forward to outcomes that meet their expectations.

If you have any questions on these comments, please contact Craig Updyke of NEMA at craig.updyke@nema.org.

Sincerely,

A handwritten signature in blue ink that reads "Philip A. Squair". The signature is written in a cursive, slightly slanted style.

Philip Squair
Vice President, Government Relations

Attachment

NEMA Comments on Negotiating Objectives for a U.S.-European Union Trade Agreement

Executive Summary

- In pursuing a new trade agreement with the European Union, the United States must achieve market access and favorable terms that are, *at a minimum*, equivalent to those afforded by the EU in trade agreements with Canada, Mexico and Japan.
- In several areas the U.S. Mexico Canada Agreement (USMCA), reached on September 30 and signed on November 30, provides even more favorable terms – in terms of openness, transparency and trade liberalization – than do previous U.S. trade agreements. Any U.S.-EU trade agreement should include commensurate commitments that provide *greater, not fewer*, opportunities for U.S.-EU trade across the North Atlantic.
- Where possible, the U.S. and EU should seek to build on and go beyond existing bilateral and multilateral trade agreements to set even higher standards for Trans-Atlantic trade.

Discussion

Put simply, the U.S. and EU take different approaches on standards, conformity assessment and regulations. While not always incompatible, these different approaches often form the basis for technical barriers to trade. Historically, more often than not, each side has proposed divergent methods to resolve these barriers without materially reducing the degree to which the goals and objectives of the standards or government policies are achieved. To defend and, in effect, promote its regulatory model (which is foremost designed to achieve a single market among its member states) the EU often proposes sector-specific Mutual Recognition Agreements (MRAs). This approach not only promotes governmental regulation but also the EU regulatory model, including the precautionary principle and self-certification of compliance. NEMA has long opposed and continues to oppose the negotiation and operationalization of MRAs for products that are not federally regulated in the U.S.

While the EU would like to take a sector-by-sector approach to resolving these trade frictions, such an approach must be supplemented by an overarching, horizontal approach by the United States to achieve reciprocity among the two parties.

In the electrical equipment sector, the primary barriers are technical, in the areas of standards, regulations and conformity assessment. As cited in our October 30, 2018, letter¹ citing foreign trade barriers, the special relationship between the EU's Standards Development Organization, CENELEC, and the International Electrotechnical Commission is a key factor. The EU's approach to conformity assessment – in which testing and certification for the EU market is to be performed by a laboratory located in the EU and accredited by EU member states – is another irritant.

In the near term, in the area of medical imaging equipment, NEMA's Medical Imaging and Technology Alliance (MITA) seeks assurances that the 2016 version of the quality management standards agreed at the international level will be accepted and implemented by EU regulators for at least five years. MITA is also closely monitoring Europe's policy position on the Medical Device Single Audit Program (MDSAP). MITA also requests that the EU database for medical devices be able to communicate with the U.S. Food and Drug Administration's database in order to ensure consistent implementation of a Unique Device

¹ Accessible at <https://www.regulations.gov/document?D=USTR-2018-0029-0072>.

Identifier (UDI) system to improve patient safety by improving tracking as well as reduce burdens on manufacturers. The U.S. and EU should also ensure any cybersecurity initiatives are harmonized, and work to mutually recognize international standards.

In general, the U.S. and EU should seek to negotiate a bilateral trade agreement of the highest standard. The EU serves as both a lucrative market for U.S.-made equipment and as a critical supply chain partner for U.S. manufacturers. Reaching consensus on trade issues between the U.S. and the EU would support manufacturing in Europe and North America, with each party maintaining separate free trade agreements with Canada and Mexico. A strong U.S.-EU trade agreement could serve to boost U.S. competitiveness and level the playing field for manufacturers in the United States who may otherwise face a disadvantage on the global stage due to trade agreements to which the U.S. is not a party.

Timely elimination of EU customs import tariffs for industrial goods, while welcome, would only open a small hole in the formidable barriers U.S. electroindustry exporters face there. A bilateral trade agreement presents a significant opportunity to level the playing field for U.S. manufacturers and service providers.

Accordingly, in addition to tariff elimination, NEMA strongly recommends U.S. negotiators seek to:

- Reach agreement on market access and best practices in the areas of transparency, fair treatment and other process-related aspects of government procurement in the European Union
- Require good regulatory, Standards, and market-driven conformity assessment practices that afford openness and transparency, enable cost-effective compliance and, whenever possible, achieve alignment that promotes and enhances market access opportunities in the European Union for U.S. electroindustry manufacturers. However, NEMA opposes Mutual Recognition Agreements (MRAs) for products that are not federally regulated in the U.S.
- Affirm the European Union's acceptance of conformity attestation methods that include the optional use of the International Electrotechnical Commission's Conformity Assessment Systems – IECCEB, IECEx and IECQ – where appropriate
- Advance U.S.-EU regulatory cooperation on medical imaging equipment to promote patient safety and minimize redundant compliance burdens on manufacturers
- Fully open the EU's market for services, including testing and technical services, distribution services, energy services, environmental services, and medical services
- Secure a mechanism and access for laboratories located in the U.S. to be accredited to test and certify equipment for EU markets, providing reciprocity for access EU labs have to become accredited for the U.S. market
- Deepen coordination on electrical safety matters, including installation and certification practices as well as anti-counterfeiting efforts and market surveillance
- Achieve the strongest possible intellectual property rights and trade secret protections as well as government cooperation in enforcement under customs service operations that facilitate efficient legitimate trade while preventing importation for sale in the U.S. of goods that are counterfeit, violate intellectual property rights, or fail to comply with U.S. requirements

- Achieve commitments related to digital trade that at least match if not exceed the disciplines agreed in the U.S. Mexico Canada Agreement
- Raise the EU's customs de minimis level from €150 to parity with the U.S. level of \$800

END COMMENTS