



National Electrical Manufacturers Association

Representing Electrical and Medical
Imaging Equipment Manufacturers
www.nema.org

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Ambassador Demetrios Marantis
Acting U.S. Trade Representative
Office of the U.S. Trade Representative
600 17th Street, NW
Washington, DC 20508

Submitted via regulations.gov

Re: Transatlantic Trade and Investment Partnership
Docket USTR—2013—0019

Dear Ambassador Marantis,

Thank you for the opportunity to provide, on behalf of our more than 400 member companies, the following comments on United States-European Union trade and economic relations and U.S. negotiating objectives for the Transatlantic Trade and Investment Partnership agreement. Barriers to trans-Atlantic trade and investment are already relatively low, given low customs duties, high trade volumes and significant levels of cross-investment. At NEMA we believe there is significant potential to strengthen further U.S.-EU trade and investment relations to support mutually beneficial job creation, economic growth and international competitiveness.

NEMA is the U.S. association of electrical equipment and medical imaging manufacturers, founded in 1926 and headquartered in Arlington, Virginia, USA. Our member companies manufacture a diverse set of products including power transmission and distribution equipment, lighting systems, factory automation and control systems, and medical diagnostic imaging systems. Worldwide annual sales of NEMA-scope products exceed \$120 billion. The electrical equipment and medical imaging industries together support more than one million U.S. jobs.

General and product-specific negotiating objectives

In general, NEMA recommends that all U.S. free trade agreements, including any possible bilateral or regional agreement, adhere to the following principles.

- Immediate reciprocal tariff elimination

- No governmental mutual recognition agreements (MRAs) where product is not U.S. federally regulated
- National treatment
- Adequate legal and administrative infrastructure in place for implementation, transparency and enforcement of agreements
- Protection of intellectual property rights
- Elimination of technical barriers to trade (TBTs)
- Compliance with all World Trade Organization (WTO) TBT Agreement requirements
- Safe conduct of product and persons
- Energy and environmental services liberalization
- Inclusive definition of “International Standards”
- Market-driven development of product standards and conformity assessment
- Conformity attestation methods that include the optional use of the IEC Conformity Assessment Systems – IECEE, IECEx and IECQ, where appropriate

Treatment of specific goods, tariff and non-tariff barriers

Customs tariffs

NEMA supports complete and immediate U.S. and EU tariff elimination for products within its scope (see appendix). Most remaining U.S. and EU tariffs fall into the “nuisance” category and thus do not perform any useful function besides some small revenue to the various treasuries in the 28 countries. Saving time and money not having to pay import duties could provide for notable efficiencies and re-programming of company resources into more productive activities.

That said, the rules-of-origin will be very important for determining which products qualify for duty-free treatment under the TTIP.

The U.S. and the EU should work also together to develop and adopt harmonized customs classifications for traded products, so that not only are tariffs eliminated in an identical manner but also that each side shares a common and, when necessary, granular-level view of bilateral trade flows. This is especially important for products where trade is growing significantly, such as solid-state lighting technology. For example, the global lighting industry should not have to bear the costs of complexity and uncertainty perpetuated by customs authorities, who should be facilitating trade of efficient and durable LED lighting products that are in increasing demand by customers.

Existing technical barriers to trade

Standards

To date the EU has failed to adopt fully the principles determined by the World Trade Organization (WTO) Technical Barriers to Trade Committee for the development of international standards

- openness
- transparency
- impartiality and consensus
- relevance and effectiveness,
- coherence
- development

and that in these terms an “international standard” is neither automatically nor limited to a standard that is developed by one or more of the three Geneva-based standards development organizations (SDOs) – the International Electrotechnical Commission (IEC), the International Telecommunications Union (ITU), and the International Organization for Standardization (ISO). The EU should recognize and adopt the WTO TBT definition formally and in practice.

The EU authorities should recognize and leverage the fact that non-EU, non-Geneva SDOs are capable of developing standards that can enable companies to achieve compliance with the essential requirements of EU directives and regulations. The EU should recognize fully that a standard developed by international standards development organization (SDO) that meets the requirements of the WTO TBT Agreement should be accorded “presumption of conformance” to relevant EU legislation if the technical committee(s) developing the standard takes the essential requirements of the legislation into account fully when the SDO develops the standard. This would be a major new idea and significantly benefit the U.S. and EU manufacturing industries by potentially eliminating SDO activities that may be overlapping or redundant.

Intelligent Transportation Systems (ITS) technologies are also a growing export sector largely based on voluntary consensus industry standards, including some developed with the support of the U.S. Department of Transportation. Many of these standards have been recognized, adopted and are being used in a growing number of countries, including in the European Union. The EU should recognize and adopt these standards more broadly rather than invest scarce resources in developing EU-only standards.

On a related level, the important standards-setting bodies CEN and CENELEC are lacking in transparency and openness inasmuch as they absolutely deny full participation by any U.S.-interested party despite legitimate business concerns and impacts. This is particularly significant

when there is specific knowledge that CEN/CENELEC standards resulting from mandates under EU directives will be developed into de facto market access requirements. As noted in previous NEMA comments to the U.S.-EU High Level Working Group on Jobs and Growth, the two sides should engage in a constructive dialogue on achieving greater reliance in both the U.S. and EU on international standards as defined by the WTO TBT Committee.

Conformity Assessment

The U.S. and EU have been at odds for over 10 years on the subject of conformity assessment for electrical and electronic products, with the EU pushing for U.S. regulators to accept Supplier's Declaration of Conformity (SDOC). The Department of Labor (DOL) has resisted this push, with NEMA's support. DOL's Occupational Safety and Health Administration (OSHA) certified an EU lab to do the mandatory third-party testing and certification required by OSHA. This measure provides market access for EU suppliers in compliance with U.S. laws and regulations to protect workers but more importantly U.S. workplace market demand for third-party certified electrical equipment. OSHA should seek to accredit additional EU-based labs that can perform mandatory testing for the U.S. market.

NEMA does not oppose SDOC. NEMA's view is that efforts to institutionalize SDOC as the only acceptable method of conformity assessment could have serious negative effects on established and successful practices in our sector. These established practices have a stellar record in identifying non-compliant and counterfeit products. SDOC should be an option rather than an obligation. Where suitable monitoring institutions are in place, the market should be allowed to determine the appropriate means of conformity assessment. This final point is the key one: The market should be allowed to determine the appropriate means of conformity assessment.

In the EU market, all avenues for obtaining required third-party certification exclude U.S. testing laboratories from the final stage of product certification—the judgment of test results and approval of the product. U.S. laboratories are not allowed by EU regulators to exercise "engineering judgment" and must therefore perform redundant, additional tests that European laboratories are not required to perform. This is much different than the treatment of EU certification bodies that are permitted to continue to use best engineering practice in their testing protocols to ensure product safety. This lack of national treatment of U.S. certification bodies (in sharp contrast to the fully open, transparent and uniform process employed by OSHA in administering the Nationally Recognized Testing Laboratory (NRTL) program) significantly increases the testing costs for U.S. product manufacturers, adds increased time to market, and has effectively required U.S. certification firms to establish operations in the EU to remain competitive. Accordingly, the U.S. and EU should provide full national treatment to U.S. and EU conformity assessment (testing and certification) bodies.

As noted above, NEMA opposes Mutual Recognition Agreements to cover products within its scope that are not federally regulated in the U.S.

It is important to note that the U.S. and EU, as developed countries, have highly sophisticated electrical infrastructures that differ in important ways. This brings with it that some products that meet EU or IEC standards for Europe are not designed or appropriate for the U.S. electrical infrastructure. At the same time, there are some products designed for the U.S. market that do not meet EU or IEC standards. Each product type is designed for its environment. A prime example is the case of surge protection devices (SPDs).

Many EU/IEC certified SPDs do not meet the requirements of the U.S. safety standard, UL 1449. The focus of EU/IEC in this area has been on protection against lightning strikes; thus the EU/IEC product is installed at the location where electrical service enters a structure. In the U.S., the SPD product is designed for lightning but also supply-generated and internally-generated transients as well; the SPDs are installed throughout the electrical system. As a result, accepting IEC-certified SPDs in the U.S. market would be a step backwards in terms of safety.

Although some products are designed specifically to standards for the local infrastructure and would not translate well to the other, there are other products where it appears that standards are an unjustified market access barrier. For example, in the EU nurse call systems that meet the international standard UL1069 are not accepted. Testing to an EU standard must be done in an EU laboratory.

Similarly, while many U.S. wire and cable manufacturers do have access to the EU market and can qualify for the certification marks of individual European countries, they cannot obtain the continent-wide HAR (for "Harmonized") mark that is essential for selling throughout Europe. The HAR mark arises from a cleverly-designed agreement among European testing laboratories. Not only are U.S. labs not allowed to join it because the U.S. does not officially embrace CEN/CENELEC (i.e., European) standards, U.S.-manufactured wire and cable products are not even allowed to test for the mark — even though they would almost certainly qualify. NEMA has cited this barrier many times in recent years in comments to USTR for its annual trade barriers report. We hope and expect that the TTIP provides the vehicle to eliminate this unnecessary barrier.

Opportunities for greater regulatory compatibility

As noted in previous comments to USTR, the U.S. must refrain from adopting the EU approach to regulatory development and implementation. U.S. industries and the U.S. Government have frequently complained about the EU propensity to establish regulations lacking in solid technical justification and whose burdens of implementation are not proportionate to intended consumer or

environmental benefits. Typically, these regulations are based on the “precautionary principle” approach to decision-making and are developed with non-transparent procedures.

In the electrical equipment sector, trans-Atlantic harmonization of existing regulations in and of themselves is not the goal NEMA would recommend. That said, the U.S. and EU should work together to minimize the barriers that existing regulations present to trade in safe products in the spirit that regulations should not be trade-distorting. The two partners should share data with each other that enables regulatory comparisons and enables mutual compliance.

Moreover, with renewed efforts by U.S. regulators and U.S. Customs and Border Protection, coupled with a product safety and market surveillance legislative package pending in Brussels, the time is ripe for the U.S. and EU to coordinate their initiatives to improve market surveillance and enforcement of their regulations.

In addition, the U.S. and EU should also pursue discussions on regulatory cooperation in the area of energy efficiency, with emphasis on both product-level efficiency and system-level efficiency.

In the area of medical imaging, the Medical Imaging and Technology Alliance (MITA, a division of NEMA) cites several specific, discrete regulatory areas where U.S. and EU regulators should work together. Improvements to regulatory compatibility should be achieved via mutual recognition of each other’s quality management systems and audits, of a singular standard for a medical device marketing application with electronic submission capabilities, and of a singular standard for a Global Unique Device Identification Database for medical devices.

NEMA is committed to working with the U.S and EU on questions of governance and regulatory disciplines, and to find solutions to its systemic regulatory problems, ensuring justification, transparency and openness in development of directives, as well as "national treatment" and accountability in their application.

Customs cooperation and trade facilitation

The U.S. and the EU should work together to develop and adopt harmonized customs classifications for traded products, especially for products where trade is growing significantly such as solid-state lighting technology. For example, the global lighting industry should not have to bear the costs of complexity and uncertainty maintained by customs authorities who should be facilitating trade of efficient and durable LED lighting products that are in increasing demand by customers.

As noted above, the U.S. and EU should establish greater cooperation in market surveillance as part of efforts to improve bilateral market access but also as a common approach to the shared challenge

of achieving high levels of regulatory compliance and intellectual property right protection relative to products originating in third countries.

New industries and technologies

The U.S. and EU must continue their focus and redouble their efforts to prevent barriers to trade in new and emerging industry sectors. Accordingly, both governments and industry stakeholders should work closely and collaboratively to define open and compatible standards in these areas to prevent the creation of technical barriers to trade.

- Smart Grid
- Energy storage
- Electric vehicle (“e-mobility”) supply equipment
- Advanced lighting technologies
- Intelligent Transportation Systems (ITS)
- Remanufactured equipment, especially medical imaging units

Barriers to trade in services

Expanding on the priority mentioned above of opening access for conformity assessment services providers, the U.S. and EU should also use the opportunity to open to each other their markets for energy and environmental services, technical and engineering services, and maintenance and repair services.

Thank you again for the opportunity to share our views and recommendations. We look forward to providing further advice as part of the consultation process and as negotiations proceed. If you have any questions about these comments, please contact me or Craig Updyke of my staff at 703 841 3294 or craig.updyke@nema.org.

Respectfully,



Kyle Pitsor
Vice President, Government Relations