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L. Daniel Mullaney
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Office of the United States Trade Representative
600 17th Street, NW
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Attention Mr. Mullaney:

UL appreciates the opportunity to submit comments in conjunction with the United States Government and the European Commission's request for comments on how to promote greater transatlantic regulatory compatibility. Recognizing that the US Government and the European Commission are contemplating the launch of comprehensive free trade agreement negotiations, UL supports the transatlantic initiative as a means to overcome existing barriers to trade in goods and services between our respective markets, and to mitigate risks for potential new barriers with regard to new and innovative technologies. UL believes that work in this area should complement and build upon the progress already taking place under the US – EU High Level Regulatory Cooperation Forum (HLRCF), the Transatlantic Economic Council (TEC), and the Trans-Pacific Partnership (TPP) negotiations. Given the vast structural differences in the legislative, legal, and regulatory regimes of both the United States and the European Union, it is critical that the US and the EU begin with areas where mutually beneficial change can be made expediently in order to build an appropriate amount of momentum going forward. Both parties should also ensure that the agreement is a living agreement whereby new initiatives and target sectors can be added as it makes sense to do so. In addition, it is critical that any agreement builds upon the WTO Technical Barriers to Trade principles, including preserving the decision making authority of regulators. Finally, it is essential that adequate resources be devoted to ensuring that any new tools or governing processes established under the initiative will be adequately supported, and a mechanism is established to facilitate regular engagement with the private sector.

UL is a premier global independent safety science company with more than 118 years of history. Employing more than 9,000 professionals in over 100 countries, UL has five distinct business units- Product Safety, Environment, Life and Health Sciences, Knowledge Services, and Verification Services – to meet the expanding needs of our customers and to deliver on our public safety mission. UL evaluates tens of thousands of products, components, materials, and systems for compliance to specific requirements, and enables manufacturers and the public at large to benefit from safety-standards compliant products. In 2011, an estimated 21 billion products in the global marketplace carried the UL Mark. Our role as a product certifier and service provider for manufacturers gives us vast insight regarding regulatory barriers and other restrictions that negatively impact trade.

Priority Actions

The following priority actions would support effective regulatory cooperation between the United States and the European Union.

- Build upon existing dialogues underway in the US-EU High Level Regulatory Cooperation Forum (HLRCF), the Transatlantic Economic Council (TEC), and existing commitments being undertaken by the negotiating parties of the Trans Pacific Partnership (TPP);

- Take into serious consideration the vast structural differences in the legislative, legal, and regulatory regimes of both the US and the EU and begin with areas where mutually beneficial change can be made expediently, including focusing on new and emerging technologies such as electric vehicles, Smart Grid, and cybersecurity. Sectors under consideration should be vetted by all critical stakeholders, including regulators, the private sector, and NGOs.
- Ensure that the agreement is a living agreement whereby new initiatives and targets sectors can be added as it makes sense to do so.
- Ensure that the agreement builds upon the WTO Technical Barriers to Trade principles, including preserving regulators' decision making authority.
- Ensure that adequate resources are devoted to making sure any new tools or governing processes established under the initiative will be adequately supported, and a mechanism to facilitate regular engagement with the private sector is established.

Supporting Existing Trade Dialogues: US-EU High Level Regulatory Cooperation Forum, Transatlantic Economic Council, and TPP

The US Government has astutely recognized the need to evolve current trade disciplines to cover new and emerging areas that address 21st century business patterns, opportunities, and challenges. In the US-EU High Level Regulatory Cooperation Forum (HLRCF), the Transatlantic Economic Council (TEC) and through Trans-Pacific Partnership (TPP) negotiations, there has been a strong emphasis placed on addressing critical trade priorities such as standards and regulatory harmonization, and the promotion of trade and investment in innovative products and services. The TPP chapters on TBT and Regulatory Coherence should be the starting point for any discussions with the EU on a comprehensive free trade agreement, and applied even if looking at a suite of projects versus a trade agreement.

Making Change Expediently and Creating a Living Agreement

The structural differences in the legislative, legal, and regulatory regimes of both the US and the EU and should not be the subject of efforts to promote greater transatlantic regulatory compatibility. Negotiators ought to initially focus efforts on making progress in areas where mutually beneficial change can be made expediently in order to build an appropriate amount of momentum going forward. By focusing on sectors relating to new and innovating technology, progress can be realized to ensure that regulatory barriers between the US and EU are not erected unintentionally in the first place. Excellent work is taking place related to electric vehicles, Smart Grid, and cybersecurity and we encourage this work to continue. UL's suggestions for these sectors were the subject of our 2012 0001 Federal Register response in February 2012 so we will not resubmit this information. Sectors targeted by the US and EU for regulatory harmonization should be those where tangible progress is likely. Sectors under consideration by the US and EU for regulatory compatibility should also be vetted by all stakeholders, including US and EU regulators, the private sector, and NGOs. Lastly, the agreement should be able to govern additional sectors and initiatives over time. Given the rapid pace of technological advancement, this is critical.

Health IT

One area where UL recommends additional work take place under the Transatlantic Economic Council is the health information technology industry. We welcome the opportunity for US and EU stakeholders to continue to participate in e-health discussions, including through the implementation of the e-health MOU and more broadly under this initiative. UL's Health Sciences industry team recognizes the upcoming changes and developments in healthcare associated with e-Health, when medical devices, electronic health records, mobile phones and many more applications will be linked in the short future in a

comprehensive interoperable environment. UL and stakeholders in this sector are convinced that next to the technical feasibility and development, safe interoperability must be addressed.

Initiatives such as the development of AAMI/UL 2800 standards are intended to support the composition of an interoperable medical system consisting of individual system components (such as medical devices, but potentially including other devices that are not specifically medical in nature). When effectively implemented, these standards will support “Plug and Play” interoperability, helping to demonstrate that component-level risk management addresses the possibility of new hazards being introduced when these components are incorporated into interoperable medical systems.

The AAMI/UL 2800 family of standards is not intended to replace or supplant existing implementation standards or profiles. This family of standards instead aims to map existing implementation practices into a Risk Management framework and to address further safety issues where applicable. Through the use of a clearly defined architecture and interface constraints, this family of standards will also help demonstrate through tests that such devices fulfill their declared risk control capabilities relative to their specified basic safety and essential performance requirements, both in their “stand-alone” and in their “system component” capacities. The standards can be invoked, potentially with independent conformity assessment requirements, as determined to be appropriate by system assemblers and possibly regulators, for increased assurance of safety and effectiveness.

Preserving Regulator’s Decision Making Authority

UL believes that any transatlantic agreement focused on promoting greater transatlantic regulatory compatibility ought to embrace the World Trade Organization’s (WTO) Technical Barriers to Trade (TBT) Agreement that makes clear that protection of public safety is paramount. The agreement recognizes that no country “should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal or plant life, or health of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate...” Regulators in both the US and EU should retain this authority. However, in areas where regulators from the US and EU concurrently choose to cooperate, it is imperative that the regulatory impact assessment consider the full cost to society of such an endeavor and not just focus on the immediate cost of compliance, as it belies greater liability costs to the minimum funding requirement and greater societal costs.

Devoting Adequate Resources to Manage New Tools or Governing Processes

UL welcomes the commitment of USTR and our regulators to forge a transatlantic agreement that holds such promise for enhancing trade between the US and EU and promoting both job creation and growth. As the agreement is negotiated, we encourage both sides to ensure that the commitments undertaken and any new tools or governing processes that are developed to guide, manage, and review the effects of the cooperation, are within sufficient scope and administered with adequate resources. An agreement between the US and EU has the potential to set international best practices on regulatory cooperation so we recommend that resource requirements are closely taken into consideration. In addition, UL believes the agreement should establish an institutionalized mechanism for engaging the private sector on regulatory convergence or alignment matters, given the role of the private sector or quasi-private sector in standards and conformity assessment matters in both the United States and the European Union.

UL would again like to thank the US Trade Representative for the opportunity to comment on ways to promote greater regulatory compatibility between United States and the European Union. UL strongly supports the United States and the European Union working together on emerging technologies, utilizing both public and private sector resources to facilitate the development of these sectors, addressing inherent safety issues, and identifying areas for regulatory convergence to mitigate any unnecessary barriers to global and transatlantic trade. By addressing challenges early in the development cycle, the United States

and European Union can cooperate in establishing regulatory frameworks that help promote innovation while safeguarding the public.

UL is pleased to speak with the Federal Government further about this topic. If you have questions about this document, please do not hesitate to contact Jennifer Boger, Trade Manager, Global Government Affairs, at 202-296-7841 or Jennifer.Boger@ul.com.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ann Weeks". The signature is written in dark ink on a light background.

Ann Weeks
Vice President, Global Government Affairs