[All redactions in the document are applied in accordance with Art.4.1(b)]

Statement of the U.S. Chamber of Commerce

ON: EU-U.S. Call For Proposals on Regulatory Cooperation

TO: European Commission Directorate General for Trade

BY: U.S. Chamber of Commerce

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The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations. The Chamber is dedicated to promoting, protecting, and defending America's free enterprise system.

More than 96% of Chamber member companies have fewer than 100 employees, and many of the nation's largest companies are also active members. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large.

Besides representing a cross-section of the American business community with respect to the number of employees, major classifications of American business—e.g., manufacturing, retailing, services, construction, wholesalers, and finance—are represented. The Chamber has membership in all 50 states.

The Chamber's international reach is substantial as well. In addition to 117 American Chambers of Commerce abroad, an increasing number of our members engage in the export and import of both goods and services and have ongoing investment activities. The Chamber favors strengthened international competitiveness and opposes artificial U.S. and foreign barriers to international business.

The U.S. Chamber of Commerce appreciates the opportunity to present the following comments to the European Commission on its call for proposals for EU-U.S. regulatory cooperation activities. The Chamber is the world's largest business federation, representing the interests of more than three million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations, and it is dedicated to promoting, protecting, and defending our shared free enterprise system.

Introduction

The U.S. business community is encouraged that the United States and the European Union (EU) have returned to the negotiating table and are committed to securing tangible improvements in the transatlantic commercial relationship. We are ready to work with both sides to strengthen ties between the world's two largest economies.

In keeping with the Chamber's mission to advocate for free enterprise, competitive markets, and rules-based trade and investment, one of the Chamber's primary objectives in these negotiations will be to pursue measures that remove—and do not raise—barriers to trade. We recommend hewing closely to the negotiating objectives established in the U.S. Bipartisan Congressional Trade Priorities and Accountability Act of 2015, known as Trade Promotion Authority (TPA).

Overarching Priorities

Before addressing near term opportunities, the two sides should address a range of longstanding issues and barriers. Reducing or eliminating these barriers would significantly boost the long-term economic outlook for both the U.S. and the EU. Greater transatlantic cooperation would also provide a pathway for joint leadership in response to shared challenges in a rapidly changing global economy.

- Section 232 Tariffs: Remove expeditiously the U.S. Section 232 tariffs on imports of steel and aluminum from the European Union, and remove corresponding European retaliatory measures. Avoid imposition of U.S. Section 232 tariffs on imports of European autos or auto parts.
- Managed Trade: Oppose "grey area" measures, such as tariff-rate or snapback quotas, voluntary export restraints, and orderly marketing agreements that limit trade and violate the World Trade Organization (WTO) Agreement on Safeguards.
- Currency: Do not infringe on the Federal Reserve Bank's ability to steer the conduct of U.S. monetary policy in any efforts to address currency manipulation in this trade agreement.
- Third Countries: The U.S. and the EU should cooperate to create tangible benefits for and protect American and European companies and workers from non-market oriented policies and practices by third countries.
- Multilateral Trading System: The U.S. and EU should jointly strengthen global trade rules and institutions, including through the trilateral dialogue chaired by Ambassador Robert E. Lighthizer, United States Trade Representative, Mrs. Cecilia Malmström,

European Commissioner for Trade, and Mr. Hiroshige Seko, Minister of Economy, Trade and Industry of Japan.

- Trade in Industrial Goods: Eliminate all tariffs on non-auto industrial goods traded between the U.S. and the EU.
- Trade in Services: Promote binding commitments to services market access, including for new services.
- Trade in Agricultural Products: Address non-science-based restrictions on agricultural trade in a transparent and timely fashion.
- Intellectual Property Rights: Establish new rules to protect trade secrets, eliminate forced technology transfers, and reduce barriers to foreign direct investment.
- Promote Innovation: Ensure the highest standards of intellectual property protection across all industries to enhance U.S. and EU leadership in innovative industries.
- Regulatory Cooperation: Pursue new sectoral agreements that minimize duplicative testing and certification requirements, and create new meaningful regulatory cooperation dialogues.
- Good Regulatory Practices: Formalize a joint commitment to follow good regulatory practices, including sufficient advance notice and comment periods and in-depth stakeholder engagement.
- Emerging Technologies: Promote effective regulatory cooperation to jointly address emerging technologies and prevent unnecessary regulatory divergence.
- Data Flows: Prevent restrictions on the free flow of data.

Near Term Opportunities

There are a wide range of near term opportunities for progress both on cross-cutting horizontal issues, as well as in specific sectors. Taken collectively, these measures would provide a significant boost to the U.S. economy and strengthen the transatlantic partnership at a time when joint leadership is essential.

- Harmonize and align customs classifications for goods based on their uses.
- Eliminate or significantly streamline licensing requirements for U.S. LNG exports to non-FTA partner countries such as the EU.
- Resolve longstanding market access issues, such as increasing EU imports of non-hormone treated beef from the U.S.
- Declare an in-principle agreement to maintain existing market access levels for services, and establish a framework for cooperation towards elimination of services trade restrictions in third countries.
- Launch a dialogue on standards and conformity assessment that includes active stakeholder engagement.

Digital Trade

- Ensure the EU-U.S. Privacy Shield remains in place.
- Prohibit data localization requirements, including in third countries.
- Work towards developing common mechanisms around data privacy and data transfers to promote further compatibility and ease of doing business, as well as to facilitate interoperability with other privacy regimes (e.g. APEC CBPR).

- Enhance coordination and cooperation on cybersecurity to prevent regulatory divergence and align national cyber regulations with industry-supported international standards and best practices.
- Jointly engage with third countries to ensure that cybersecurity regulations are not used to establish barriers to trade and investment.
- Expand cooperation to reduce the frequency and magnitude of cyberattacks by facilitating cross-border threat intelligence sharing and the implementation of international cyber norms.
- Eliminate practices that deter investment, delay innovation, and cut consumers off from the best digital products and services.
- Protect algorithms and source code by prohibiting transfer or access as a condition for market entry.
- Secure bilateral agreement under the U.S. CLOUD Act and EU e-Evidence Regulation for law enforcement access to data.
- Secure EU-wide exception to allow for text and data mining under the new EU Copyright Directive.
- Include protections for online platforms and marketplaces to host lawful speech and commerce without being treated as the originators of content.

Customs and Trade Facilitation

- Harmonize and simplify customs clearances processes to include processes for obtaining immediate release of goods upon arrival and to facilitate low value shipments.
- Improve transatlantic customs clearance efficiency for private shipments.
- Rely more on advanced data mechanisms to pre-clear goods and reduce costs.
- Facilitate submission and processing of documentation via Single Window.
- Raise European *de minimis* to commercially meaningful levels to facilitate SME trade and e-commerce.
- Work to improve, expand, and—where possible—encourage greater convergence of U.S. and EU trusted trader programs.
- Create sector-specific "fast lane" processing pilot projects.
- Improve upon common data elements for imports and exports.
- Create binding rules on express delivery shipment channels.

Small & Medium-sized Enterprises (SMEs)

- Establish a committee of SME representatives and government officials to develop policy proposals to facilitate SME trade and investment.
- Set up a dedicated website to ensure SMEs have ready access to tailored information on: protecting intellectual property; foreign investment regulations; business registration procedures; employment regulations; and taxation procedures.

Sector-specific Priorities

- **Automobiles**
  - Work to establish mutual recognition of existing standards, in close coordination with industry.
  - Develop a common framework for joint U.S.-EU development of future standards.

- **Energy**
  - Do not regulate LNG pricing or institute EU quotas for U.S. LNG imports.
  - Remove EU duties on base oils.
  - Encourage the EU to renew its Energy Star Agreement with the U.S. and recognize any subsequent revisions to the Energy Star program.

- **Medical Devices**
  - Promote greater cooperation between relevant U.S. and European. regulators to reduce unnecessary duplication of testing, spur innovation, and provide greater access to the best available medical devices.
  - Secure necessary changes to the transition period for the EU Medical Device Regulation (MDR).[1]
  - Secure assurances that CE-marked medical devices certified by UK-based Notified Bodies will remain legally valid in the EU market when the UK leaves the EU, with or without a Brexit Withdrawal Agreement.

- **Services**
  - Establish binding market access and national treatment commitments for services, including transportation, logistics, information and communication technologies, and financial services.
  - Promote greater stakeholder engagement opportunities within existing fora, e.g. the EU-U.S. Joint Financial Regulatory Forum, to identify and address specific regulatory issues and resolve longstanding concerns.
  - Ensure EU regulatory practices vis-à-vis third-country providers do not result in disadvantages or unequal treatment, and that deference and outcomes-based approaches are practiced so as to minimize extraterritorial application of EU rules.
  - Rescind EU proposals that would subject U.S. financial service providers to double supervision in the EU at both the national and ESMA level (e.g. benchmark providers).

- **Financial Services**
  - Promote regulatory equivalence and ongoing regulatory cooperation to encourage continued cross border activity with appropriate levels of oversight.
  - Ensure the free flow of data and prohibit data localization requirements, including for financial services.
  - Ensure other digital trade elements of the agreement also apply to the financial sector, i.e. no carve outs for the sector in terms of coordination and collaboration on cyber,

[1] Background: More than one year after the May 2017 entry into force of the MDR, it is clear that the transition period is not sufficient and, without adjustments, will lead to significant regulatory bottlenecks, cause disruption in the supply of medical devices and, ultimately harm patient access to medical devices. The EU's regulatory system – especially the EU-designated Notified Bodies – does not have the capacity to implement the new MDR in the specified timeframe either for medical devices (2017-2020) or for in vitro diagnostic products (IVDs) (2017-2022). The MDR's transition period must be changed now to allow for more time to ensure a smooth transition to the new regulations. The EU should: (1) extend the implementation dates; (2) grandfather medical devices and IVDs already on the market; (3) postpone evaluation of products on the market; or some combination of these measures.

protection of source codes and algorithms, forced technology transfer and the purchase of use of particular technologies.
- Collaborate to create and enhance a regulatory sandbox for fintech companies, as well as traditional financial institutions, on an equal basis.
- Promote the use of cloud technologies in the financial sector.
- Engage with stakeholders to discuss broadening cross-border supply commitments for financial services.
- Include broad commitments on procurement of financial services.

- **Chemicals**
  - Eliminate U.S. and EU chemical tariffs immediately, and collaborate to make eliminating tariffs on chemicals a multilateral objective.
  - Regulatory cooperation in chemicals management:
    - Promote more efficient and effective cooperation between EU and U.S. regulatory chemicals management systems, focusing on common principles for information sharing, prioritizing chemicals for review and evaluation, and coherence in hazard and risk assessment (based on the weight of scientific evidence).
    - Institute a harmonized approach to data assessment to simplify the registration process and improve transparency and efficiency, while providing effective human health and environmental protections
  - Focus on establishing common principles for data quality, including utility, objectivity (which includes reproducibility), and integrity.
  - Re-engage on existing U.S.-EU pilot projects to identify further areas of cooperation and promote the mutual recognition of data.[2]
  - Promote greater coordination between the newly upgraded TSCA and REACH to achieve our shared goals of high standards of health and human safety: foster more efficient compliance by large and small companies; encourage innovation and access to market; create resource sharing opportunities for regulators; and support greater transparency and credibility with the public.

- **Pharmaceuticals**
  - Zero-tariff market access should apply to pharmaceuticals and to biopharmaceutical R&D and manufacturing inputs.
  - Jointly promote high-level global standards on intellectual property and innovation, particularly in multilateral organizations.
  - Encourage early resolution of patent disputes to ensure market predictability, and prevent infringing products from making it to the market.
  - Promote greater regulatory cooperation efforts between the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) to reduce

[2]For example, commitments should include the promotion of greater coherence between diverging U.S. and EU Classification and Labelling schemes and the implementation of the UN Globally Harmonized System for Classification and Labeling (GHS) as a common classification inventory (effectively leveraging existing work). Such a common approach would reduce or eliminate the need for dual classifications for chemical substances, reduce costs and inefficiencies for companies and governments, and facilitate trade.

unnecessary duplication of testing, spur pharmaceutical innovation, and provide greater access to medicines, including:
    - Better alignment of U.S.-EU pediatric scientific approaches to minimize duplication and streamline medicines development for children, thereby reducing the time necessary to get innovative products to the market and lowering costs, while avoiding redundant clinical trials on children.
    - Manufacturing changes: EMA and FDA should work together to develop a more harmonized approach to post-approval variation submissions for manufacturing changes. This should include aligning classification of changes, type of submission required, and timelines.
  - Work to ensure pricing and reimbursement systems accurately and fairly reflect the value of R&D processes.
  - Extend existing mutual recognition agreement to cover veterinary medicines and vaccines.
  - Create a U.S.-EU medicines and medical devices working group to ensure ongoing coordination and provide transparent opportunities for stakeholder engagement.

- **Agriculture and Biotechnology**
  - Encourage timely, transparent, science-based approval systems for biotechnology and chemistry products. Already established timelines must be respected.
  - Establish a working group with stakeholder involvement to identify and address specific regulatory issues, and resolve longstanding concerns.

- **Delivery Services**
  - Ensure the U.S. and EU remain world leaders in effective postal regulation.
  - Commit to fair, non-discriminatory treatment of non-postal service providers through the inclusion of a delivery services sectoral annex in the agreement to ensure that U.S. and EU consumers and businesses retain access to world-class delivery service options.

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