



May 10, 2013

Office of the United States Trade Representative  
600 17<sup>th</sup> Street NW  
Washington, D.C. 20508

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

**Attn: Docket: USTR-2013-0019**

**Re: Trans-Atlantic Trade and Investment Partnership (TTIP)**

Dear Sir or Madam:

The American Chemistry Council (ACC)<sup>1</sup> is pleased to provide additional comments on negotiating objectives for the Trans-Atlantic Trade and Investment Partnership (TTIP), in response to the Federal Register notice published on April 1, 2013. These comments build on earlier joint comments from the United States and European chemical industries on promoting U.S.-EU Regulatory Compatibility (Docket: USTR-2012-0028) and subsequent ACC communications to USTR. They also build on the joint presentation made by ACC and Cefic (the European Chemical Industry Council) at the U.S.-EU High-Level Regulatory Cooperation Forum in April 2013. These comments do not attempt to cover every potential aspect of negotiations under the TTIP, but instead focus on the areas of highest priority for ACC and its member companies.

### **General Objectives**

ACC and its member companies are strong supporters of free and open rules-based international trade. Trans-Atlantic trade in the products of chemistry is particularly robust, and Europe remains one of the U.S. industry's largest foreign markets. The further reduction or elimination of barriers to trans-Atlantic chemical trade will promote economic growth and job creation, enhance U.S. competitiveness, and expand consumer choice. For these reasons, TTIP should be comprehensive, with no *a priori* exclusions, and negotiators should seek to achieve the highest possible levels of ambition. In all areas, including intellectual property, trade remedies, and technical barriers to trade, WTO provisions should be seen as a minimum requirement that may

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<sup>1</sup> The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$760 billion enterprise and a key element of the U.S. economy. It is one of the nation's largest exporters, accounting for twelve cents out of every dollar in U.S. exports.



be strengthened under TTIP where appropriate. ACC supports the intention of U.S. negotiators to complete negotiations on the TTIP as soon as possible, but the desire to conclude negotiations swiftly should not come at the expense of an ambitious outcome.

### **ACC's Primary Objective: Enhanced Regulatory Cooperation**

ACC strongly supports efforts to promote enhanced trans-Atlantic regulatory cooperation under the TTIP. Enhanced regulatory cooperation has the potential to significantly reduce costs for governments and industry alike, while maintaining high levels of protection for human health and the environment. The point of stronger U.S.-EU regulatory cooperation is not to impinge on regulatory mandates, but rather to ensure that those mandates do not result in unnecessary barriers to trade. A more efficient and effective trans-Atlantic regulatory environment would provide a significant boost to innovation, growth and jobs, while ensuring that regulatory objectives are achieved.

In a general sense, enhanced U.S.-EU regulatory cooperation should include the implementation of previous agreements and principles for promoting regulatory coherence. Horizontal issues that might be addressed in the context of TTIP include: assessing current areas of regulatory divergence and options for narrowing them; developing mechanisms to ensure that potential future areas of regulatory divergence are identified and addressed; determining whether differing regulatory approaches are equivalent in meeting a similar regulatory objective; and, promoting greater regulatory transparency, including in regulator-to-regulator discussions.

There may also be opportunities for specific sectors to explore options for deepening trans-Atlantic regulatory cooperation. ACC – and our European counterpart, Cefic – strongly believe that the chemical industry should be a priority sector. While approaches to regulating chemicals in the U.S. and Europe differ, there are common elements and issues in their efficient and effective operation. These issues are fundamental to a TTIP negotiation on chemical regulatory cooperation, and include:

- Data and information on which regulatory decisions are based.
- Processes for identifying priority substances.
- Approaches for characterizing risks and hazards.
- Transparency in regulatory processes
- Rules to protect commercial and proprietary interests.

In short, these are areas where the U.S. and EU can seek efficiencies within current regulatory structures, while maintaining high levels of protection for human health and the environment.

Enhanced U.S.-EU regulatory cooperation in the chemical sector should not only address actual and potential areas of regulatory divergence that impose barriers and increase costs of trans-Atlantic trade. We believe strongly that negotiators should seek efficiencies within and between regulatory systems, and where appropriate, explore opportunities for burden sharing. The scope of this enhanced cooperation should be forward looking, and focused on addressing and mitigating the potential for creating new regulatory barriers. But it should also seek to identify areas where addressing existing regulatory barriers would reduce costs for industry and governments alike.



ACC's preliminary economic analysis shows that enhancing chemical regulatory cooperation between the U.S. and the EU in areas identified below could generate an additional \$633-\$812 million in export growth for the US chemical industry. ACC estimates that the projected total effect of expanded U.S.-EU regulatory cooperation on chemicals could lead to an annual increase of \$1.9 billion to \$2.5 billion in output to the U.S. economy, and create an estimated 6,400 to 8,200 American jobs.

The overriding principle behind enhanced regulatory cooperation on chemicals is that both sides should agree to consult and to cooperate when developing new chemicals regulations. Even where regulatory approaches differ, opportunities should be pursued to minimize divergence in regulatory outcomes and reduce costs of compliance. Understanding the data used and process employed for science-based decision making will be key in this regard.

In the sections below, ACC outlines our specific suggestions for enhancing chemical regulatory cooperation between the U.S. and EU. ACC recognizes that this is only a partial list of the cooperative activities that might be pursued, but these areas cover issues of particular importance to the U.S. business of chemistry.

#### A. Enhanced Scientific Cooperation

A mechanism to promote stronger trans-Atlantic scientific cooperation and enhanced coordination on scientific assessments could help minimize the potential for imposing additional regulatory barriers when revising or developing new regulations. For example, discrepancies in chemical assessments (risk assessment versus hazard assessment) could impose barriers either directly or through secondary regulations, e.g. on cosmetics, and food packaging. Enhanced scientific cooperation could include:

- Developing criteria for the reliability and quality of scientific data underpinning regulatory decisions;
- Providing opportunities for stakeholder input on emerging scientific issues; and,
- Considering the impact of new scientific developments on regulatory decisions.

An example of a current regulatory issue with potential for significant impact on trade and where enhanced scientific cooperation could help minimize the potential for regulatory divergence is the identification of endocrine disrupting chemicals of regulatory concern. At present it appears possible that approaches to identifying endocrine disrupting chemicals in the US and EU will differ significantly. It is critical that regulatory approaches in this area focus on screening and testing substances that may have endocrine disrupting properties in an effort to determine whether endocrine activity linked to these substances leads to adverse effects. We are concerned that any approach that seeks to identify potential or suspected endocrine disrupting chemicals, without hazard characterization and clear scientific evidence of adverse effects, could precipitate decisions to stop using these chemicals or products containing them, or could promote the switch to alternatives whose health effects may be less well understood.

A lack of regulatory compatibility with respect to endocrine disrupting chemicals could have a significant impact on trans-Atlantic trade, on agricultural as well as industrial goods. Regulatory compatibility is desirable not only with regard to criteria and methodology for reviewing



substances of regulatory concern, but is also desirable when it comes to questions of thresholds. Should the EU, for example, proceed to regulate endocrine disruptors in a way that does not differentiate between products that contain significant quantities of a given substance and those that contain only an incidental amount, the cascading effect on a large number of industry sectors important to both the U.S. and EU would be enormous. The EU may well decide in the coming weeks not to include such a threshold, imposing major unintended consequences on a wide range of industries, markets and consumers on both sides of the Atlantic.

The potential divergence between regulatory approaches in the U.S. and EU highlights the need to assess the impact of chemical regulatory proposals on trans-Atlantic trade as part of overall regulatory impact analysis. ACC calls for U.S. and EU regulators to explore the potential for minimizing regulatory divergence in this area, including developing a common understanding of criteria for reviewing substances of regulatory concern, testing and assessment methods, and a thorough investigation of whether adverse effects exist, and at what thresholds.

Another area where enhanced scientific cooperation could help minimize the potential for regulatory divergence is nanotechnologies. These technologies will advance innovation and competitiveness in various industries such as healthcare, electronics, and consumer products, benefiting both U.S. and European consumers while accelerating economic growth and the creation of quality jobs. Ongoing regulatory developments on both sides of the Atlantic provide an opportunity to enable the promise of nanotechnologies, consistent with sound environmental, health and safety practices.

A first crucial step towards enhanced cooperation is a common definition and understanding of nanomaterials, which will have a significant impact on the type and number of products subject to regulatory requirements. For example, relying on the count-fraction of nanoparticles as proposed by the European Commission poses challenges as a measurement technique. The International Council of Chemical Associations has instead proposed a simplified definition based on the weight-fraction of nanomaterials, which ACC supports as a solid basis for trans-Atlantic cooperation. Having such a common definition and understanding of nanomaterials would foster legal certainty and thus avoid non-tariff barriers to trade – a key objective as outlined in the final report of the High Level Working Group. It would also broaden the future scope of possible cooperation.

## B. Transparency in Cooperative Activity

Greater transparency in trans-Atlantic cooperative activity between regulators could help enhance stakeholder confidence and support for regulatory cooperation. Industry on both sides of the Atlantic is aware that regulator to regulator discussions are occurring, but information on when cooperative activity is taking place, and what issues are being addressed, is typically not made available to stakeholders in advance of the discussions. Increased transparency in cooperative activity between regulators could include:

- Opportunities for stakeholder notice and comment on the proposed agenda for cooperation.
- Opportunities to suggest that particular issues should be addressed.



- Opportunity for stakeholder participation in relevant cooperative activities, where appropriate.
- For the chemical industry, stakeholder input might include consultation with experts in particular chemistries under review on both sides of the Atlantic. This approach would help ensure a common understanding of the technical and scientific information that exists, and could help expedite government assessment of chemicals.

### C. Data and Information Sharing

Minimizing demand for new information should be a key area of focus for enhanced trans-Atlantic chemical regulatory cooperation, and this can be facilitated by better sharing of data and information. Enhanced data and information sharing would result in significant efficiencies for both governments and industry, including eliminating unnecessary or duplicative generation, testing and submission of data. The ability to share relevant information – both the data itself and information on the *interpretation* of that data – is likely to become even more critical in the future given the emergence of new assessment technologies. ACC would support further efforts under the TTIP to review the potential barriers and mechanisms for facilitating trans-Atlantic data and information sharing on chemicals, including regulatory barriers. Cost considerations and the need to protect legitimate commercial information should be addressed.

### D. Prioritization of Chemicals for Review and Evaluation

Prioritization of chemicals in commerce for further assessment enables governments and industry to focus attention and limited resources on the substances of highest concern. Enhanced U.S.-EU cooperation in this area should include an agreement to establish and apply common principles for prioritization that are clear, specific, and transparent. These criteria should:

- Be science and risk-based, considering both the degree of hazard (hazard identification and characterization) and the extent of exposure potential (risk assessment).
- Be based on existing, available information.
- Have the flexibility to incorporate relevant scientific advances (e.g. understanding what emerging science and technology suggests for prioritization).
- Provide an opportunity for stakeholder review and comment at key points in the prioritization process, including the opportunity to provide additional, existing information in advance of final prioritization decisions
- Consider a chemical's uses and applications in the prioritization review process.

ACC calls for the development of an agreed process for comparing lists of chemicals prioritized for assessment in each jurisdiction. We would anticipate that the lists would contain a similar set of chemicals if the prioritization process in both jurisdictions takes account of the factors listed above, and could lead to greater efficiencies by sharing the burden of review. For example, our preliminary assessment indicates that there are at least 13 chemicals in common between USEPA's TSCA work plan<sup>2</sup> chemicals and the REACH list of Substances of Very High Concern (SVHC).

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<sup>2</sup> Information on the EPA Office of Pollution Prevention and Toxics (OPPT) work plan chemicals – the Agency's current effort to identify, prioritize, and assess existing chemical risks – is available at <http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html>.



## E. Coherence in Chemical Assessment

An important objective of regulatory cooperation should be to develop a common scientific basis for regulatory decisions. If both jurisdictions have confidence in their respective assessment procedures, there is the potential for additional efficiencies to be identified, and the burden associated with the assessment of priority chemicals to be shared between U.S. and EU regulators. A core objective should be to create certainty in the chemical assessment process on both sides of the Atlantic by understanding how common issues (such as integration of weight-of-the-evidence approaches) are addressed. While final risk management decisions should remain sovereign decisions, a common understanding on assessment could significantly reduce costs for both governments and industry by avoiding duplication and unnecessary additional testing, which would accelerate chemical reviews. ACC reaffirms the importance of the principles for coherence in chemical assessment processes identified in the joint ACC-Cefic submission on enhancing chemical regulatory cooperation from October 2012.

## F. Classification and Labeling

ACC supports the review of current differences in classifications for chemical substances between the U.S. and EU. Current differences in classifications for chemical substances create additional costs for companies and often lead to different requirements in downstream legislation. Differing regulatory approaches will require different classifications in some areas, but reducing or eliminating the need for dual classifications, where appropriate, would help facilitate trade while also supporting cost-effective implementation of the Globally Harmonized System for Classification and Labeling (GHS). It would also improve safety for workers and others by promoting consistent communication of hazard information for safe handling and use.

Specific areas where greater harmonization might be pursued include:

- Promoting the acceptable use of EU labels (in English) in the U.S. and vice versa (recognizing that labels in local languages would still be required in non-English speaking EU member states).
- Where possible, requiring that the data on which the classification was based be linked to the reported classifications for particular substances.

## Other Priority Areas

In addition to WTO-plus subjects such as investment, public procurement, and competition policy, and new disciplines such as ensuring free and fair competition with state-owned enterprises, the following areas are of priority interest to ACC and its member companies:

### A. Tariff Negotiations

Two-way trans-Atlantic trade in chemicals (excluding pharmaceuticals) was worth \$55 billion in 2012, over a third of which is intra-company trade.<sup>3</sup> While import duties on chemicals are low on both sides of the Atlantic (averaging around 3%), eliminating these remaining tariffs would

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<sup>3</sup> A summary of U.S.-EU trade in chemicals (including and excluding pharmaceuticals) for the years 2003-2012 can be found at Annex 1.



save around \$1.5 billion per year. ACC therefore urges that all remaining tariffs on trans-Atlantic trade in chemicals be eliminated immediately upon the TTIP's entry into force.

## B. Trade Facilitation

Negotiations on the TTIP should focus on ensuring that both the U.S. and EU have adopted and implemented best practice procedures for facilitating trans-Atlantic trade flows. This includes harmonization of customs procedures where feasible or pursuing equivalence of process and outcomes where harmonization is not possible. Customs procedures should be transparent, efficient, and focused on eliminating unnecessary duplication. The rapid harmonization of secure trade systems, i.e., the U.S. C-TPAT and the EU AEO schemes, including movement towards implementing global WCO standards provides a good model to build on. Central customs clearance and regulatory harmonization can significantly reduce industry's compliance burden, time to market and cost. For example, in the EU, while many customs regulations are harmonized at the EU level, implementation varies by member state. Consequently, barriers arise from a lack of harmonization of IT infrastructure (e.g. separate filing requirements based on separate computer systems by country). The experience of the EU-China green lanes program, as well as U.S. discussions on Trusted Partner, can be used to develop a harmonized approach to fast-track processing for businesses that meet the appropriate criteria. The goal should be to adopt common processes for goods clearance.

Strong and effective rules of origin are also essential for the achievement of genuine market liberalization. ACC supports the rules of origin adopted in the U.S.-Korea FTA for trade in chemicals, and would like to see these extended to the TTIP.

## C. Intellectual Property

As a highly regulated industry the chemical industry often supplies confidential business information to government authorities in order to comply with regulatory requirements. It is essential that such proprietary information is adequately safeguarded from unauthorized disclosure by authorities. At the same time, where strong and effective mechanisms to protect proprietary information are in place on both sides of the Atlantic, negotiators should explore options to facilitate sharing of that information between governments when requested by the information owner(s). So long as information shared in this way is not considered public disclosure of the information, this approach has the potential to reduce costs and unnecessary duplication.

Provisions on intellectual property in the TTIP should also reflect key principles set out by the IPR working group and included in TEC commitments: preservation of the IPR norms set forth in TRIPs and WIPO-administered treaties and conventions, strengthened and better-harmonized protections for trade-secrets/confidential business information, cooperation to improve the efficiency and effectiveness of the IP system at the global level, and greater U.S.-EU alignment in the context of multilateral dialogues on IPRs and vis-à-vis third countries.

Strong IPR commitments in the TTIP are particularly important for preventing attempts by third countries to weaken IP protections in their own jurisdictions and in multilateral forums. Without



a shared strategy based on enhanced cooperation and coordination between the U.S. and EU, a number of major emerging economies will continue to erode competitiveness by failing to enforce IP rights, e.g. against counterfeiting and piracy, in their countries.

### **Conclusion**

ACC strongly supports the launch and timely completion of negotiations on a Trans-Atlantic Trade and Investment Partnership. For the chemical industry, and for the broader economy, it has the potential to provide a significant boost to growth and job creation, which in turn would promote innovation and strengthen the international competitiveness of U.S. exporters. A successful conclusion of negotiations on the TTIP would also send an important signal to the rest of the world at a time when multilateral approaches to trade liberalization have stalled. ACC looks forward to maintaining a dialogue with negotiators and regulators as the TTIP negotiations proceed.

Sincerely,



Greg Skelton  
Senior Director  
Regulatory & Technical Affairs



### Annex 1: U.S.-EU Chemicals Trade Figures, 2003-2012

The table below illustrates U.S. chemicals exports to and imports from the EU, both excluding and including pharmaceuticals. When pharmaceuticals are excluded, the trade balance between the U.S. and EU is much closer.

YEAR	U.S. EXPORTS (EXCL. PHARMA) \$M	U.S. IMPORTS (EXCL. PHARMA) \$M	TOTAL TRADE (EXCL. PHARMA) \$M	US EXPORTS (INCL. PHARMA) \$M	US IMPORTS (INCL. PHARMA) \$M	TOTAL TRADE (INCL. PHARMA) \$M
2003	14,821	17,768	32,549	27,930	56,166	84,096
2004	16,289	19,784	36,073	33,309	61,359	94,668
2005	17,790	22,624	40,413	35,542	66,227	101,769
2006	21,175	23,308	44,483	40,676	71,684	112,360
2007	23,946	25,070	49,016	47,011	77,771	124,783
2008	25,618	26,327	51,945	52,506	84,068	136,574
2009	19,425	20,430	39,855	48,775	76,693	125,468
2010	24,387	23,527	47,914	51,722	81,776	133,498
2011	25,621	26,437	52,058	50,610	88,323	138,933
2012	24,137	27,202	51,339	50,973	83,496	134,469

*Source: U.S. Department of Commerce; American Chemistry Council analysis*

