To: (TRADE)
Subject: FW: Report: Meeting with Cefic - discussion of draft Cefic/ACC proposals for TTIP

Importance: High

From: [ART. 4.1b] (TRADE)
Sent: Wednesday, December 11, 2013 2:18 PM
To: GARCIA BERCERO Ignacio (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (TRADE); **[ART. 4.1b]** (ENTR); **[ART. 4.1b]** (ENTR); **[ART. 4.1b]** (ENV); **[ART. 4.1b]** (ENV); **[ART. 4.1b]** (EEAS-WASHINGTON)
Cc: TRADE TTIP TRANSPARENCY
Subject: Report: Meeting with Cefic - discussion of draft Cefic/ACC proposals for TTIP
Importance: High

Meeting with Cefic – discussion of new draft joint ACC/Cefic proposals for TTIP – 5 December 2013, 15.00-17.30

Cefic: **[ART. 4.1b]**; **[ART. 4.1b]**; **[ART. 4.1b]**; **[ART. 4.1b]**; **[ART. 4.1b]**, BASF.

COM: **[ART. 4.1b]** DG ENTR F.1; **[ART. 4.1b]** DG ENV A.3; **[ART. 4.1b]** ENV.E.2; **[ART. 4.1b]** DG TRADE F.3; **[ART. 4.1b]** DG TRADE G.3.

Very useful meeting with Cefic which allowed for an in-depth discussion of the enclosed new draft Cefic/ACC proposals for "enhancing US-EU chemical regulatory cooperation under TTIP". Contrary to earlier joint ACC/Cefic submissions on TTIP, their new draft proposal puts a strong focus on the horizontal regulatory chapter and advocates the creation of new formal structures such as a "Joint Scientific Advisory Committee" and a specific "Chemical Sector Joint Coordinating Committee", and pleads for mutual recognition of US Pre-Manufacturing notifications and REACH registrations. Cefic and ACC also develop detailed text proposals both for the horizontal regulatory chapter and for the chemicals sectoral annex.[

] On 11 December 2013, Cefic has presented a revised joint draft paper which is supposed to reflect the discussion at the meeting we had with them on 5 December. We will now look into their revised paper with a view to the 3rd round of TTIP negotiations in Washington D.C. (the chemicals session is scheduled for Friday, 20 December, 9.00-12.30).

- **[ART. 4.1b]**summarized the state of play of the TTIP negotiations and pointed to the political stock-taking envisaged for February 2014.[
  ].

- ACC's/Cefic's draft proposals aimed at increasing transparency between EU and US regulators seem to be focused on the EU taking over the US "notice and comment" procedure. **[ART. 4.1b]** indicated that respective rules in the horizontal regulatory chapter have to be balanced, with both sides accepting similar levels of commitment. For the EU side, it will be important to ensure that also US States are taking meaningful transparency commitments.[
  ].

- The constitutional structures of both sides need to be taken into account: For instance, the EU applies specific legislative procedures on the basis of the Treaties and will thus not be in a position to simply take over the existing US "notice and comment" procedure. [

]. **[ART. 4.1b]** added that a revised Cefic/ACC paper should elaborate more on how EU and US regulators could cooperate better in the framework of existing structures (e.g. public consultations, informal bilateral contacts) instead of calling for the creation of additional bodies; it should also be mentioned that the EU already today allows the US to attend a number of important meetings, for instance the CARACAL (competent authorities for REACH and CLP), which prepares the stage for final consultation of the REACH Committee on Commission proposals.

- **[ART. 4.1b]**, **[ART. 4.1b]** and **[ART. 4.1b]** indicated that the horizontal "Joint Scientific Advisory Committee", as promoted in the draft Cefic/ACC paper, raises questions marks as to its interaction with the existing EU (and maybe also US) decision-making structures. The same goes for the integration of the proposed specific "Chemical Sector Joint Cooperation Committee" into the existing structures. **[ART. 4.1b]** explained that it may be preferable if the possible future "Regulatory Cooperation Council" as the over-arching regulatory body under TTIP would call for ad-hoc consultations on specific issues on a sectoral basis, if needed. **[ART. 4.1b]** added that the proposed Committees would be too formal – the EU and the US can cooperate, as they have done in the past, in a variety of ways, e.g. conferences, OECD-level activities etc. In any case, such new Committees should not be used as a means to push the EU to abandon its hazard-based decision making where it applies.[

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- As regards confidential business information (CBI), **[ART. 4.1b]** expressed surprise that the new draft paper advocates the exclusion of CBI from any information exchange between regulators, in contradiction to respective proposals put forward in earlier Cefic/ACC submissions. [

  ]. In the EU, the relevant REACH provisions (notably Article 118 of the REACH Regulation 1907/2006) will not be modified any time soon. Cefic defended its new proposals and stated that in its perception the actual criteria used by ECHA and EPA to recognise CBI under REACH and TSCA, respectively, are actually quite similar – EU and US regulators should thus explore possibilities for formalising a common approach.

- **[ART. 4.1b]** offered Cefic's support to overcome remaining difficulties to achieve greater coherence on classification and labelling issues. In particular, Cefic could discuss with chemical companies with headquarters in the US and significant business activities in the EU to help – even if full implementation of the UN GHS (Globally Harmonized System) by the US may be unrealistic because of the continuing strong opposition of CropLife America to a GHS implementation in the field of pesticides (which is echoed by EPA). Even without pesticides, GHS implementation by the US in all other areas would result in 70% of all chemical substances being covered which would be a significant step forward compared to today's situation where only OSHA has implemented GHS for chemicals at the workplace. **[ART. 4.1b]** and **[ART. 4.1b]** welcomed Cefic's support [

  ]. A further goal within TTIP should be to establish a bilateral list of classified chemicals which could then become the nucleus for a global list – instead of solely promoting the UN global list of classified chemicals (see p. 14 of the draft proposal).

- **[ART. 4.1b]** and **[ART. 4.1b]** pointed out that the suggestions on "common prioritization principles" (see p. 14/15) need to be clarified. In particular, the reference to substances falling under the scope of Article 57 (f) of the REACH Regulation 1907/2006 is unclear in this context. We have to distinguish between (1) US comments on concrete EU proposals to prioritise substances for either evaluation or risk management (such as restriction or authorisation) under REACH and (2) an agreement between the EU and the US to follow common prioritization principles. [

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- **[ART. 4.1b]** and **[ART. 4.1b]** explained that Cefic's/ACC's draft new proposals concerning the "mutual acceptance of notification/registration of new substances" (see p. 15) seem particularly problematic. Mutual acceptance of notifications/registrations under REACH and TSCA would first of all require equivalence of

obligations which is doubtful in this case: REACH only requires the registration of substances produced/imported in quantities of 1 ton or more – for amounts below 1 ton, the US would have to waive pre-manufacturing notices, or a voluntary registration scheme would have to be established which might require a change of the REACH Regulation and appropriate structures to be established by ECHA. For substances above 1 ton, the situation would be inverse: the EU would have to waive registration requirements (which is not possible without an amendment of REACH), because the very limited information in pre-manufacturing notifications in the US is not comparable to REACH, which would put EU companies at a disadvantage. **[ART. 4.1b]** [

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- In the margins of the meeting, **[ART. 4.1b]** expressed interest to discuss Cefic's ideas for Rules of Origin in TTIP which are still under development. Cefic is trying to learn from experiences made with other FTAs concluded by the EU and the US and is looking into new and innovative approaches (such as e.g. relying on non-preferential RoO in TTIP). **[ART. 4.1b]** and **[ART. 4.1b]**agreed to fix a meeting between Cefic and COM (including DG TAXUD and ENTR) RoO experts to discuss this further. Such a meeting could be held in the second or third week of January 2014.

ACC-CEFIC JOINT PROPOSAL
ENHANCING U.S.-EU CHEMICAL REGULATORY COOPERATION UNDER TTIP

The business of chemistry in the European Union and the United States strongly supports a comprehensive U.S.-EU trade and investment agreement. An effective TTIP agreement will eliminate tariffs and provide a mechanism to address the potential non-tariff barriers that can arise from discordant regulatory measures. A comprehensive outcome from TTIP will spur innovation, create jobs, improve industry competitiveness, and ensure long-term growth and prosperity.

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. This document outlines the essential proposals that should guide the negotiation of TTIP horizontal and specific chemical sector provisions in order to emphasize the importance of sound regulatory policy, coordination, and cooperation.

The recommendations in this document do not contemplate changes in any underlying statutory or regulatory requirement in either jurisdiction. Rather, the document seeks to suggest areas in which coordination, cooperation, and harmonization opportunities can be created to produce a more efficient and effective trans-Atlantic regulatory environment.

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Summary of joint ACC-Cefic policy asks

- Greater transparency in Regulator to Regulator dialogue
- Establishing a Trans-Atlantic Scientific Advisory Committee (TSAC)
- Confidential Business Information (CBI)
- Data sharing
- Regulatory Impact Assessments and Enhanced Consultation when Developing Regulations

Proposed Agreement text

- Transparency in Regulator to Regulator Dialogue
  - Mechanisms for increased transparency among regulators
  - Identification of Regulatory Priorities
  - Evaluation Framework for new Regulations
- Enhanced Scientific Consultation when Developing Regulations including:
  - Trans-Atlantic Scientific Advisory Committee
  - Regulatory Impact Assessment
- Data Sharing and Protection of Confidential Business Information

SECTION 2. Draft Chemicals Annex

Summary of joint ACC-Cefic policy asks

- Scope
- Establishment of Chemical Sector Joint Coordinating Committee
- Harmonized risk and hazard assessment methodologies including data quality requirements
- Emerging Scientific Issues
- Greater coherence on Classification and Labelling issues
- Common prioritization principles
- Mutual acceptance of notification/registration of new substances

Proposed Agreement text

- Section 1. Definitions
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- Section 4. Prioritization and chemical assessment
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- Section 6. Emerging scientific issues
- Section 7. Mutual acceptation of new notifications/registrations
- Section 8. Classification and Labeling
- Section 9. Confidential Business Information

SECTION 1: HORIZONTAL ISSUES[1]

Policy Asks

GREATER TRANSPARENCY IN REGULATOR TO REGULATOR DIALOGUES

Expected result of TTIP

Development of mechanisms to increase transparency, e.g. a mechanism for early exchange of information of future regulatory activities including stakeholder consultations.; collaboration in a science-based evaluation for decision making; and collaboration in identification of future regulatory priorities.

Benefits

A transparent regulator to regulator dialogue allows for Trans-Atlantic consultation at the earliest possible stage in developing regulations. Shared identification of regulatory priorities would help to provide for optimal allocation of scarce resources. Greater transparency in trans-Atlantic cooperative activity between regulators could help enhance stakeholder confidence and support regulatory cooperation.

Activities to get expected results

Development of modalities to increase transparency in regulator to regulator dialogues, including opportunities for stakeholder participation, where appropriate.

ESTABLISHING A TRANS-ATLANTIC SCIENTIFIC ADVISORY COMMITTEE (TSAC)

Expected result of TTIP

Establish a Trans-Atlantic Joint Scientific Advisory Committee (TSAC) to promote common Trans-Atlantic understanding of scientific evidence. It is recommended that the TSAC should be a cross-sectoral (i.e. horizontal) committee, including senior scientists covering all major sectors of TTIP. The Committee will have an agreed terms of reference utilizing the experience of established scientific committees on both sides of the Atlantic. The members of the committee would function under an agreed code of conduct.

Benefits

A common understanding of the scientific evidence would increase prospects for agreement on common regulatory definitions and standards. The TSAC would allow for close cooperation of

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[1] These are issues identified in earlier chemical industry submissions that may be of relevance to other industry sectors. It is not an exhaustive list of issues that the chemical industry would support in a broader regulatory cooperation chapter.

regulators and scientists and thus forms the basis for Trans-Atlantic regulatory cooperation grounded in common scientific evidence and assessment.

Activities to get expected results

- Members for the TSAC should be senior scientists, nominated and approved by the Trans-Atlantic Regulatory Cooperation Council (TRCC). Requirements for TSAC membership would need to be defined, formalized in a terms of reference and code of conduct for members and will operate according to the highest standards of science.
- In addition to its regular membership, the TSAC should have the ability to recruit senior scientific specialists as deemed necessary to address specific issues. This process should include EU and U.S. government experts as well as encouraging broad stakeholder participation (similar to U.S. EPA Scientific Advisory Committees).
- The advice of the TSAC would be requested by either the TRCC or sector specific committees such as the Chemical Sector Joint Coordinating Committee (CSJCC). Any scientific opinions and conclusions of TSAC would be shared with regulators on both sides of the Atlantic. Any scientific opinion released by the TSAC should be publicly accessible via the internet. The advice of the TSAC should be in the form of recommendations and would not be legally binding.

CONFIDENTIAL BUSINESS INFORMATION (CBI)

Expected result of TTIP

- Well defined and mutually agreed upon criteria for defining CBI and timing for claims
- Protection of intellectual property

Benefits

Enhanced transparency in chemical management would have important benefits for both industry and government. In this context, more detailed principles for the protection of trade secrets/CBI would foster the useful exchange of information between regulatory authorities while ensuring consistent protection for critical information and enforcement of rights to it. Trade secrets and CBI are critical assets and key indicators of competitiveness and innovation.

Activities to get expected result

- Develop a clear and consistent mutually accepted definition of CBI and substantiation criteria for claiming CBI
- Strive to achieve balance between transparency and protection of information
- Ensure obligations on the part of government to protect CBI submitted for the fulfillment of regulatory requirements
- Ensure respect of ownership rights, exclusive use and compensation
- Ensure the protection of CBI in the process of clearing customs

DATA SHARING

Expected results of TTIP
Development of a mechanism for data/information sharing between governments including adequate safeguards to ensure the protection of commercial and proprietary interests

Benefits
Enhanced data and information sharing would create significant efficiencies for governments and industry, including elimination of duplication in the generation, testing and submission of data and enhanced transparency.

Activities to get expected results include

- In case of data exchange between EU and U.S. authorities and vice-versa under TTIP, a company relying on data or information owned or controlled by a third party under a relevant regulatory process would be required to have the rightful and legitimate access to the data via permission of the data owner. The fact that the data may be subsequently published by the authority does not alter the status of ownership.
- Data that have been assessed and acknowledged as CBI by an authority should not be shared between authorities pursuant to TTIP: regulatory agencies should share all relevant and non-confidential data. Respective web-based mechanisms should be established.

REGULATORY IMPACT ASSESSMENTS AND ENHANCED CONSULTATION WHEN DEVELOPING REGULATIONS

Expected result of TTIP

- Mandatory impact assessments (IA) with specific focus on the Trans-Atlantic effects
- Promotion of Trans-Atlantic regulatory dialogue to share information on emerging regulations and to improve understanding of expected effects on Trans-Atlantic trade.

Benefits

Completion of impact assessments, that consider potential Trans-Atlantic effects at an early stage in the legislative process, would allow for improved cooperation and a more comprehensive understanding of the impacts on a joint Trans-Atlantic market.

Activities to get expected result

- Stakeholder consultation on regulatory proposals with significant Trans-Atlantic impact should play a central role in impact assessments. To facilitate input, a joint, web-based

consultation platform should be developed. Legislative proposals should be available online for at least 30 days to ensure sufficient time for stakeholder input. Mutual notification of regulators on both sides of the Atlantic should be mandatory.

- The TRCC should facilitate targeted dialogue on the outcome of the IAs and incorporate the stakeholder feedback so as to improve the understanding of expected effects on Trans-Atlantic trade. In the context of IAs, a dialogue at the TRCC should be mandatory, whenever a legislative proposal is of significant Trans-Atlantic impact. Based on the outcome of the IA and the stakeholder consultation, the TRCC could then provide recommendations to the respective legislators in the EU or the US.

Proposed Agreement text **Annex 1**

TRANSPARENCY IN REGULATOR TO REGULATOR DIALOGUES

Greater transparency in trans-Atlantic cooperative activity between regulators could help enhance stakeholder confidence and support regulatory cooperation. For the chemical industry, stakeholder input might include consultation with experts in particular chemistries under review on both sides of the Atlantic. This would help ensure a common understanding of the technical and scientific information that exists, and could help expedite government assessment of chemicals.

1. Each Party affirms the importance of:

    a. A transparent and open regulatory process that solicits and incorporates input from a wide range of stakeholders throughout the development and implementation of new or modified regulatory measures with potential for trans-Atlantic effects, and

    b. A meaningful consultation process on regulatory developments that includes notification of proposals for new or modified regulations and an opportunity for stakeholder input prior to a decision being made by either Party.

2. Each party should adopt a mechanism to increase transparency that includes:

    a. A modality for each Party, that allows for regular and timely information to the counterpart about upcoming legislation and regulations at an early stage a when comments and recommendations can still be taken into account.

b. A bilateral cooperation modality to publish any newly proposed or updated regulations for public review. The mechanism should provide opportunities for stakeholder comment on the proposed regulation;

3. The Parties affirm the importance of focusing scarce resources by **identifying regulatory priorities.** The Parties should establish a mechanism to document and share prioritization procedures and cooperate on identified priorities. Regulatory priorities should consider science- and risk based approaches and seek to –

    a. Maintain high levels of protection for human health and the environment;

    b. Reduce costs for governments and industry alike;

    c. Reduce unnecessary barriers to trade; and

    d. Create a more efficient and effective Trans-Atlantic regulatory environment.

4. Each Party should publish a list of regulatory priorities to be considered and shared with the other Party.

5. The Parties should agree upon an **evaluation framework** for decision making which:

    a. Uses sound and objective scientific practices in assessing risks, including internationally validated guidelines and methods;

    b. Considers the current best available science, including a description of the weight of the scientific evidence.

6. The Parties should agree upon criteria for selecting data and information sources when making regulatory decisions.

ENHANCED SCIENTIFIC CONSULTATION WHEN DEVELOPING REGULATIONS

Understanding the data used and process employed for science-based decision making is key to minimizing divergence in regulatory outcomes and reducing costs of compliance.

1. To facilitate enhanced scientific cooperation, and to provide the most up to date assessment of the state of the available science on any given issue, the Parties should establish a **Trans-Atlantic Scientific Advisory Committee,** chaired by the lead government scientists on each side and include other concerned specialists. The

Scientific Advisory Committee will have agreed terms of reference and agreed code of conduct for members and operate according to the highest standards of science. The Committee will, at the direction of the Trans-Atlantic Regulatory Cooperation Council or at the direction of sector specific committees like CSJCC, address relevant issues on which an informed assessment of the available science is required as a basis for regulatory consideration;

2. The framework should include a **Regulatory Impact assessment,** which would –

    a. Include a qualitative and quantitative assessment of the anticipated costs and benefits of the regulation;
    b. Include estimates by the regulatory agency, if and to the extent that the agency determines that accurate estimates are reasonably feasible, of –

        i. The future compliance costs of the regulation; and

        ii. Any disproportionate effects of the regulation upon any particular regions or segments of the private sector;

    c. Identify and consider the impact on Trans-Atlantic and international trade;

    d. Identify the potentially effective and reasonably feasible regulatory options likely to achieve the policy objective;

    e. Identify, where appropriate, the grounds for concluding that the selected alternatives achieves the policy objectives in a way that maximizes net benefits, including qualitative benefits, while also considering distributional impact;

    f. Provide for an early consultation period that offers stakeholders on both sides of the Atlantic an opportunity to provide input on any proposed regulation, including the cost-benefit analysis

DATA SHARING AND PROTECTION OF CONFIDENTIAL BUSINESS 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 technologies.

1. The Parties should establish a definition of CBI and substantiation criteria for claiming CBI. In this context they should establish an agreed balance between the need for transparency and the need to protect CBI

2. The Parties should develop and adopt a modality for data and information sharing considering regulatory cooperation guidelines as well as international testing guidelines.

    a. The information sharing modality should facilitate submitting appropriate claims to protect confidential information.

    b. They should recognize publically available information available to regulatory bodies and consider, as appropriate, any such information upon making any regulatory decision

3. The Parties should develop a consultation process that allows each Party and relevant stakeholders to comment on the quality, integrity and objectivity of the information provided.

SECTION 2: DRAFT CHEMICALS ANNEX[2]

Policy Asks

SCOPE

Ideally all regulatory measures that have a significant impact on transatlantic trade should be covered in a balanced manner.

A thoughtful and engaged commitment should be designed to establish a balanced sense of obligations on both sides of the Atlantic covering both the U.S. federal/EU and, mutatis mutandis the sub-federal/member states level.

ESTABLISHMENT OF CHEMICAL SECTOR JOINT COOPERATION COMMITTEE (CSJCC)

Expected result of TTIP

Joint Trans-Atlantic Chemical Sector Joint Cooperation Committee

Benefits

A joint Chemical Sector Joint Cooperation Committee would provide a mechanism for agreeing on common principles in chemical assessment which will help assure a common basis for regulatory decisions. A common understanding of the scientific evidence maximizes the possibility to agree on common regulatory definitions and standards for emerging issues

Activities to get expected result

- A Chemical Sector Joint Cooperation Committee should be established as the primary body for Trans-Atlantic cooperation for the chemical sector. The CSJCC would be a subsidiary body of the TRCC, and would be led by regulators on each side. The CSJCC would provide opportunities for stakeholder input into its work, and all relevant materials should be made publicly accessible via the internet. The Committee would have agreed terms of reference and code of conduct for members. The work products of the Committee will be in the form of recommendations and not be legally binding on either side of the Atlantic.
- Where additional expertise is required on key scientific issues, the CSJCC would have two options for gathering this expertise:

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[2] These are the issues of specific interest to the chemical industry that might be addressed in the context of an Annex to the main regulatory cooperation chapter.

    - Invite scientists and other relevant experts to give their advice directly to the CSJCC. This process should encourage broad stakeholder participation similar to the US practice at the EPA Scientific Advisory Subcommittees. Scientists and other relevant experts may be either of academic, regulatory or industry background.
    - Request a scientific opinion from the Joint Scientific Advisory Committee.
- The mandate for the CSJCC would be provided by the TRCC under criteria to be defined. The work products from the TRCC and the CSJCC will be in the form of recommendations to the Parties and will not be legally binding on either side of the Atlantic. In addition, the CSJCC would have the mandate to address additional topics of relevance to the chemical sector, e.g. topics of regulatory concern on both sides of the Atlantic, or areas where significant data gaps do not allow for a comprehensive assessment of the situation, and would benefit from scientific expert advice.
- An agreement on common scientific standards and methods should form the basis for a scientific cooperation on emerging issues. These scientific standards for hazard and risk assessment should be discussed by the CSJCC. Availability of the relevant scientific opinions shall be ensured by the process described above.
- In addition to new and emerging issues and common standards for hazard and risk assessment, other possible issues for the CSJCC could include classification and labelling and common principles for prioritization (See relevant sections).

HARMONISED RISK AND HAZARD ASSESSMENT METHODOLOGIES INCLUDING DATA QUALITY REQUIREMENTS

Expected result of TTIP

Agree on common risk assessment standards and methods including data quality and requirements based on sound and objective scientific practices and promoting the use of high quality, reliable scientific data and information.

Benefits

An agreement on common scientific standards and methods serves as the basis for closer scientific cooperation including on emerging issues.

Activities to get expected result

- An agreement on common scientific standards and methods could be handled under the CSJCC. Similar to the US OCSPP list of testing rules and the EU New Test Methods Regulation (Council Regulation (EC) No 440/2008), a joint register of mutually accepted, preferred testing methods should be established. This joint register may be based on the

OECD Testing Guidelines including all their variations which are considered as highest standard on both sides of the Atlantic.

- GLP should be the preferred standard for testing laboratories.
- Building on the practices in EU and US, common methods to assess data quality and common principles to conduct weight of evidence assessment should be established.

EMERGING SCIENTIFIC ISSUES

Expected result of TTIP

A mechanism for close cooperation on assessment and decisions related to emerging scientific issues.

Benefits

Emerging scientific issues present the EU and U.S. with opportunities to align regulations and prevent divergence prior to their enactment. Regulatory bodies should be required to consult the Joint Scientific Advisory Committee on any emerging issues in order to receive the most up-to-date information possible.

Activities to get expected result

Establish the modalities under CSJCC for early cooperation on assessment and decisions related to emerging issues including the possibility to seek scientific advice of the trans-Atlantic Scientific Committee

GREATER COHERENCE ON CLASSIFICATION AND LABELING ISSUES

Expected result of TTIP

A mechanism in place for further aligning classification and labelling based on GHS, reducing or eliminating the need for dual classifications; promoting reciprocity for labeling and promoting the UN Global List of Classified Chemicals as a common classification inventory.

Benefits

Promoting greater coherence on classification and labeling issues would help facilitate trade and provide a level playing field for companies. It would also help to promote the cost effective implementation of the Globally Harmonized System for Classification and Labeling (GHS).

Activities to get expected result

- Develop procedures to identify the differences in classification and labeling for chemical substances and mixtures in the U.S. and EU;

- Seek alignment on the same UN GHS version and building block approach
- Develop mechanisms to promote mutual recognition for labels
- Promote the UN Global List of Classified Chemicals as a common classification inventory.

COMMON PRIORITIZATION PRINCIPLES

Expected result of TTIP

Common prioritization principles and burden sharing for assessments of high priority chemicals substances and, where appropriate, categories of substances (e.g. substance evaluation under REACH and high priority safety determinations under TSCA).

Benefits

Closer cooperation on prioritization of substances for further assessment would lead to cost reductions for both authorities and companies by creating opportunities for burden sharing. That would also contribute to narrowing the difference in regulatory outcomes in the long run by fostering coherence and building confidence in each other's assessments. Greater coherence in regulatory outcomes could also have a knock-on effect on down-stream legislation, further reducing regulatory divergence.

Activities to get expected result

- Adopt common risk based principles for setting priorities for assessment. This could be a task for the CSJCC, in close cooperation with subject matter experts.
- Establish a process under the CSJCC to share the results of respective prioritizations and to identify opportunities to share the burden for assessment. Identification of high priority chemicals can be seen as potential first steps to regulatory measures.
- Recognition of each other's data and studies and harmonized standards and methodologies for hazard and risk assessment are necessary for effective burden sharing (see separate proposal " Prioritization and Chemical Assessment").

MUTUAL ACCEPTANCE OF NOTIFICATION/REGISTRATION OF NEW SUBSTANCES

Expected result of TTIP

Mutual acceptance of notifications/registrations of new substances under TSCA and REACH during a limited time period.

Benefits

Mutual acceptance of notification/registration of new substances would benefit innovation as it could provide a possibility for companies to choose to register or notifying either jurisdiction and additionally test the market both in EU or the US.

Activities to get expected result

- There should be mutual acceptance of notifications/registrations under TSCA and REACH. Once a manufacturer chooses to submit a Pre-Manufacture Notification (PMN) in the US, it should be accepted as registration of a non-phase-in substance under REACH and vice versa. The required communication tools, preferentially web-based, between authorities would need to be established. It has to be ensured that CBI is effectively protected at all times.
- The mutual acceptance should be time limited. After a limited time the requirements of the jurisdiction where the chemical is marketed should be met. One could also consider a upper tonnage limit for the mutual acceptance

Proposed Agreement text **Annex 2**

Section 1. DEFINITIONS

DEFINITIONS as used in this Annex:

1. **Transatlantic Regulatory Cooperation Council** refers to a joint committee consisting of representatives of the United States and European Union responsible for central coordination and review of regulatory measures at the central level of government.

2. **Chemical Sector Joint Cooperation Committee** refers to a joint committee consisting of representatives from the United States and European Union with subject matter expertise specific to the chemical sector that reports to the TRCC. The Committee would have an agreed terms of reference and code of conduct for members

3. **Trans-Atlantic Scientific Advisory Committee** refers to the cross-sectoral, Committee composed of members of the EU Commission Scientific Committees, the scientific committees of EU agencies, members of the U.S. scientific committees and senior scientists. The Committee would have an agreed terms of reference and code of conduct for members

4. **Technical Agent** means, for the United States, membership drawn from Federal Agencies relevant to chemical risk assessment and hold regulatory, or any other agency involved in rulemaking affecting the chemical industry; and for the European Union the European Commission (including the European Chemicals Agency).

5. **Chemical** refers to a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any intentional additive, but excluding any solvent which may be separated without affecting the stability or changing its composition.

6. **Chemical Assessment** means, with respect to any chemical substance or mixture, a systematic and objective process of evaluating relevant data and information on the hazards, potential exposures to human health or the environment, or risks based on a scientific analysis of the weight of evidence that may lead to regulatory action and/or classification.

7. **Risk** is the probability that an adverse effect will result from a given exposure to a chemical. The risk posed by a chemical depends both on the intrinsic properties of the chemical (its hazard) and on the level of exposure.

8. **Screening Assessment** means, risk based tiering process for identifying existing chemical substances that may require further assessment and determination.

Section 2. SCOPE

1. This Annex covers the procedures for regulatory cooperation and oversight in the chemical sector.

2. The Chemical Sector Annex includes:
   - A Chemical Sector Joint Cooperation Committee
   - Hazard and risk assessment methodologies
   - Emerging scientific issues
   - Prioritization
   - Mutual acceptance of registrations / notifications for new chemicals
   - Classification and Labeling
   - Information sharing
   - Confidential Business Information

Section 3. JOINT COOPERATION BODY

The CSJCC is intended to be an expert body to address specific issues regarding trans-Atlantic chemical regulatory cooperation. This body would contain key chemical regulatory experts from each side of the Atlantic, and would set the agenda for chemical regulatory cooperation (factoring in input from the industry and other stakeholders). The body would have the flexibility to include relevant experts on issues placed on its agenda and the ability to bring scientists (whether government, academic or industry) together to promote collaboration on issues of

concern (this could be handled by the scientific advisory committee outlined in the horizontal issues set out above). The CSJCC would then be required to consider and take into account any recommendation from the scientific advisory committee in promoting chemical regulatory cooperation.

1. The Parties hereby establish the Chemical Sector Joint Cooperation Committee (CSJCC), accountable to the Transatlantic Regulatory Cooperation Council (TRCC), under the joint leadership of the Technical Agents. It shall include representatives from each Technical Agent responsible for chemical management within its country or region. The Committee would function according to an agreed terms of reference and its members will comply with an agreed code of conduct.

2. The work areas will include hazard and risk assessment methodologies, emerging scientific issues, prioritization, mutual acceptance in the field of placing new substances on the market, classification and labelling, information sharing and CBI.

3. The work products of the CSJCC will be recommendations to the TRCC and the Technical Agents and will not be legally binding on either side of the Atlantic.

4. The CSJCC may invite additional participants to facilitate the fulfillment of the mandate of the CSJCC and/or set up such expert Scientific Working Groups on a temporary or standing basis as it finds necessary for this purpose. In constituting such Scientific Working Groups, the CSJCC shall seek to ensure effective representation of the range of acknowledged scientific expertise available from both of the Parties for the subject under consideration. Alternatively, the CSJCC may request a scientific opinion from the Joint Scientific Advisory Committee (JSAC).

Section 4. PRIORITIZATION AND CHEMICAL ASSESSMENT

More specifically the CSJCC shall develop criteria for the reliability and quality of scientific data underpinning regulatory decisions to help reduce discrepancies in chemical assessments and reduce regulatory barriers either directly or through secondary regulations. 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 chemical thresholds. The EU and U.S. should develop through the CSJCC 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.

Prioritization

1. The Parties affirm the importance of focusing scarce resources by identifying regulatory priorities based upon available data and risk to health and the environment. The

Technical Agents will document and share prioritization procedures through the CSJCC. Using appropriate approaches that take into consideration hazards, use and exposure, the Technical Agents shall consider and identify existing chemical substances and where appropriate, categories of substances, that are:

a. High priority for a further assessment;

b. Low priority substances not requiring further assessment in the absence of significant new information.

2. The Technical Agents shall cooperate in identifying categories or classes of chemical substances that could assure an efficient prioritization and assessment.

a. Each Technical Agent shall share its list of chemical substances identified as high priorities for assessment with the CSJCC. The CSJCC shall compile a list of chemical substance based on the prioritization criteria that includes, at a minimum, those substances prioritized by the Technical Agents prior to the date of enactment of this Agreement and for which assessments or safety determinations have not been completed.

b. The Technical Agents shall endeavor to coordinate work on overlapping priorities to the extent possible, taking into consideration any assessments already underway. A Technical Agent may defer a safety assessment for a chemical substance for a reasonable period to allow for the other Technical Agent to complete the assessment.

Hazard and Risk Assessment Methodologies Including Data Quality Requirements

1. The Technical Agents shall develop harmonized hazard and risk assessment methodologies including data quality requirements. OECD Testing Guidelines including all their variations should be mutually accepted scientific standards and the use of high quality, reliable scientific data and information and informed public input should be promoted.

2. In conducting assessments under this Annex and for determining the relevance, quality, and reliability of data and information, the Technical Agents shall consider and recommend guidelines –

a. To develop and implement a structured framework for chemical evaluation using science-based criteria;

b. For assessing risks based on sound and objective scientific practices;

c. That promote the use of the most current and best publically available science (including peer-reviewed studies);

d. That consider the potential for threshold doses below which no adverse effects occur; and

e. That considers the weight of the scientific evidence concerning such hazards, exposures or risks, including evidence of modes of action and adverse outcome pathways.

3. The Technical Agent shall inform the public when it is conducting a chemical assessment subject to this agreement and, to the extent practicable, shall solicit relevant and reliable information from the public. The Technical Agent shall consider such information in conducting the assessment.

4. Prior to finalization, the Parties shall provide for an independent peer review of a chemical substance.

5. Consistent with relevant laws governing the protection of confidential business information, the data and information considered by a Technical Agent in taking action under this chapter shall be available to the public. Each Technical Agent shall make available to the public the guidance, procedures, and tools used in evaluating data and information under this chapter, pursuant to guidelines to be developed by the CSJCC.

Section 5. INFORMATION QUALITY

More specifically the CSJCC shall minimize demand for new information by better sharing of data and information. A common, scientific basis for regulatory decisions will help regulators on both sides of the Atlantic to understand how common issues (such as weight-of-evidence approaches) are used and could significantly reduce the burden on both governments and industry. On both sides of the Atlantic, the generation of information – including new testing data—is generally conducted by the industry at the mandate or request of government. To the extent such mandates or requests have a regulatory purpose, new information generation can be made more efficient and coordinated. The recommendation uses the term information resources as a generic reference to industry-generated information and data. Agreeing on criteria for the quality of information used by the regulatory bodies will promote the use of shared resources and minimize any duplicative procedures.

1. The CSJCC shall consider cooperative measures to promote the use of information resources to improve the efficiency and effectiveness of operations and to serve the Technical Agent mission, including burden reduction and service delivery.

2. The CSJCC shall issue or update guidelines to provide the Technical Agents procedural guidance for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information)

3. When scientific information that permits relevant comparisons of risk is reasonably available, each Party shall use the information to place the nature and magnitude of a risk to health, safety, or the environment being analyzed in relationship to other reasonably comparable risks

Section 6. EMERGING SCIENTIFIC ISSUES

More specifically for emerging scientific issues, 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 a part of overall regulatory impact analysis. Emerging scientific issues present the EU and U.S. with opportunities to align regulations and prevent divergence prior to their enactment. Regulatory bodies should be required to consult the Joint Scientific Advisory Committee on any emerging issues in order to receive the most up-to-date information possible.

1. The Technical Agents shall establish modalities to enhance cooperation on decisions related to emerging scientific issues and shall:

    a. Ensure that decisions are based on the best reasonably obtainable scientific, technical, economic, and other information, within the boundaries of the authorities and mandates of each Technical Agent. For this purpose, the CSJCC may seek scientific expertise or request a scientific opinion from the JSAC;

    b. Promote innovation and technological progress;

2. Strive to reach an appropriate level of consistency in risk assessment and risk management procedures across the Technical Agents through the CSJCC, considering safety, health and environmental impacts, and exposure mitigation for the necessary chemicals.

Section 7. MUTUAL ACCEPTANCE OF NEW NOTIFICATIONS/REGISTRATIONS

In the U.S., registrants must submit all available data for a new chemical through a Pre-Manufacture Notification (PMN) to EPA. In the EU, all data collection and risk assessments are obligatory for the registrant under REACH of any chemical substance. The mutual acceptance of notifications/registrations of new substances under TSCA and REACH encourage regulatory

cooperation by allowing companies to register or notify in either jurisdiction and additionally test the market both in the EU or the US

1. The Technical Agents shall develop a modality that allows for the mutual acceptance of notifications and registrations of new substances under the current regulations in place in each jurisdiction (i.e., TSCA and REACH) without changing any substantive legal requirements under either regulatory system.

    a. All registrants much fulfill all jurisdictional requirements within xx years of notification or registration.

    b. The Technical Agents shall inform a registrant existing registrations (if any) and any additional data requirements necessary under current regulations.

Section 8. CLASSIFICATION & LABELING

More specifically, current differences in classifications for chemical substances create additional costs for companies and governments. 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) Agreeing upon standardized templates to be used on both sides of the Atlantic will help to leverage all work that has already been done and is not intended to change any current statutory or regulatory requirements already in place in either jurisdiction..

1. The Technical Agents shall develop procedures to identify the differences in classification and labeling of chemical substances and mixtures between EU Regulation (EC) No 1272/2008 on the classification, labeling and packaging of substances and mixtures (CLP Regulation) and U.S. OSHA Hazard Communication Standard 29 CFR Part 1910.1200 final rule (HCS 2012).

    a. Parties shall seek to ensure alignment on the same UN GHS version and building block approach (hazard classes and categories), and have procedures in place to implement newer GHS versions at the same time.

    b. Parties shall seek to ensure the same rules for mixture classification, i.e., using the same mixture thresholds or cut-off values for certain endpoints.

2. *Label Reciprocity*. Both Parties shall create a mechanism through acceptance of a standard template that will allow the Technical Agents to mutually accept each other's compliant product labels or hybrid labeling through acceptance of required label content (not format).

a. Relabeling of imported product shall be allowed post customs clearance and not mandated at point of entry.

3. *Development of Common Classification Inventory.* In accordance with the UN Subcommittee of Experts on GHS (UNSCEGHS), the parties shall defer to the UN Global List of Classified Chemicals as a common classification inventory.

4. *Trade Secrets.* Parties shall seek to assure the protection of trade secrets as it pertains to chemical identify and composition percentages of hazardous substances on the label and SDS.

Section 9. CONFIDENTIAL BUSINESS INFORMATION

The protection of confidential business information (CBI) is essential for industries to retain incentives for innovation. Health and safety effects data and information should not be considered CBI. The U.S. and EU authorities should have the authority to share CBI with one another for the purpose of assessing the safety of chemicals when the governments demonstrate that they have equivalent procedural safeguards to protect the rights of CBI claimants as well as the government possessing the CBI.

1. The Technical Agents shall develop a common definition of what constitutes CBI and the basic principles for sharing that information.

2. The Technical Agents' common definition shall recognize as CBI all trade secrets and commercial or financial information obtained from a person and privileged or confidential, i.e., *any* information that pertains to business interests that have been developed or acquired by a business where –

    a. either the legislator has presumed the disclosure of the information to undermine the protection of the commercial interests

or:

    b. The business has asserted a CBI claim that has not expired, been waived, or withdrawn;

- The business has taken reasonable measures to protect the confidentiality;

- The information is not reasonably obtainable without the business' consent by use of legitimate means;

- No statute or law specifically requires its disclosure; and either

- The business demonstrates disclosure if likely to cause substantial competitive harm, or (b) the information is voluntarily submitted to the government and its disclosure is likely to impair the government's ability to obtain the necessary information in the future. Courts usually focus on (a) when evaluating this final factor.