CEFIC-ACC RESPONSE TO EU AND U.S. CALL OF 7 SEPTEMBER 2012 FOR INPUT ON REGULATORY ISSUES FOR POSSIBLE FUTURE TRADE AGREEMENT

BACKGROUND

The June 12, 2012 report of the co-chairs of the EU-U.S. High Level Working Group on Jobs and Growth highlights the potential to create efficiencies in the transatlantic trade relationship by addressing regulatory barriers that may impede trade. Cefic[1] and ACC[2] believe that there exist important opportunities to expand and enhance chemicals trade across the Atlantic.

Two-way chemical trade between the EU and U.S (excluding pharmaceuticals), was valued at $52 billion in 2011. Given that import duties on chemicals on both sides of the Atlantic are on average about 3%, the elimination of the industrial tariffs would entail savings for consumers of chemistry in the order of $1.5 billion.

Beyond tariff liberalization, though, significant potential exists to enhance regulatory transparency and cooperation, streamline chemical regulatory reviews, and minimize the cost and burden to governments and industry alike. Indeed, enhanced regulatory cooperation can help eliminate unnecessary burdens on regional cross-border trade, reduce costs, foster investment, and promote certainty for business, the public, and economies. Perhaps most importantly, promoting regulatory cooperation should be expected to have a positive effect in job creation and maintenance on both sides of the Atlantic.

[1] Cefic, the European Chemical Industry Council, is both the forum and the voice of the European chemical industry. It aims at maintaining and developing a prosperous chemical industry in Europe by promoting the best possible economic, social and environmental conditions to bring benefits to society.

[2] 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 ten cents out of every dollar in U.S. exports.

The High Level Working Group has recognized that more effective approaches to chemical regulation can enhance the competitiveness of the EU and U.S. manufacturing industries and promote high standards for human health and environmental protection. The Working Group has committed to engage in a further discussion, including relevant sectors, to identify what policies and measures might be discussed, understand what work is already in progress, and establish a path forward that can complement a comprehensive trade agreement. The shorter-term objective is to identify the opportunities that exist for further discussion – and a full understanding of the advantages and disadvantages to further cooperation – rather than conclude agreements on specific outcomes.

INTRODUCTION

Cefic and ACC believe there are important opportunities to promote additional trans-Atlantic chemical regulatory cooperation. The principle, although a rather long-term issue, is simple: both sides agree to consult and to cooperate when adopting new chemicals regulations. If comparable regulations are adopted on both sides of the Atlantic the cost of compliance for industries could be reduced considerably through mutual recognition. Whilst not attempting the unreachable and recognizing the sovereignty of each side to legislate Cefic and ACC would suggest the following areas as a starting point in order to promote the longer term goal of regulatory cooperation:

<u>Starting Point:</u>

- Information sharing between the EU and U.S. government bodies, while ensuring appropriate protection of confidential commercial information.
- Prioritizing chemical substances for further review and assessment, including for classification.
- Alignment in chemical assessment processes, and enhanced understanding of risk management measures.
- Promoting alignment in classification and labeling and other regulatory requirements.

- A mandatory consultation process (including procedural safeguards so that each sides comments can be taken into account) when drafting new chemical regulations.

Long Term Goal:

- The adoption of chemical regulations that are comparable in effectiveness so that the concept of mutual recognition can be applied.

COOPERATION IN CHEMICALS MANAGEMENT

Europe's regulation on Registration, Evaluation and Authorization of Chemicals (REACH) and the U.S. Toxic Substances Control Act (TSCA) take very different approaches to the manner of regulating the manufacture, use and distribution of chemicals, however both systems have risk assessment as a fundamental element. REACH came into force in Europe in 2007, replacing a regulatory system first developed in the 1960's and developed over the last 40 years. TSCA was first enacted in 1976 and has similarly developed over the years. Although TSCA has not been substantially amended since, several proposals to modernize the statute have been introduced in the U.S. Congress and some level of amendment seems likely over the next few years.

Notwithstanding the differences in the chemical regulatory systems, there are fundamental elements for their efficient and effective operation. These include the data and information on which regulatory decisions are based, the processes for identifying priority substances for review and evaluation, how hazards and risks are characterized, and the need for transparency of information and rules to protect commercial and proprietary interests. Developing and agreeing on principles in these areas would help guide future cooperative work.

1. Principles for Information Sharing

In Europe, a considerable amount of information will be made publicly available, largely through the European Chemical Agency's (ECHA) web-based platform. The U.S. Environmental Protection Agency (EPA) has been taking steps to make additional information on chemicals

publicly available, including by declassifying some prior claims for confidential business information (CBI).

The ability to share information is expected to be even more critical in the future. In addition, the ability to share information on the interpretation of that information will shape regulatory decisions (and transatlantic chemicals trade) for decades to come. The emergence of new assessment technologies such as computational toxicology threatens to outpace the ability to interpret the data in a regulatory context or put the information into a meaningful risk-based context. The significant investment companies make in generating information on chemicals raises important questions about the protection of Confidential Business Information (CBI) and commercial interests. It is vital that the EU and the U.S. fully explore the opportunities to cooperate to promote access to this information, as well as the regulatory consequences of applying that information.

Basic principles for information sharing include:

- Promotion of appropriate government access to useful chemical data and information, with appropriate protections against and sanctions for unlawful or inadvertent disclosure.
- Recognition of legitimate commercial interests in the appropriate protection of information (including chemical hazard, financial and ownership data) should be recognized.
- Use of Robust data summaries as an important mechanism to allow increased access to and transparency in information without jeopardizing commercial interests. The approach was successfully employed in the U.S. and ICCA/OECD efforts to ensure screening information data for high production volume (HPV) chemicals.
- A discussion on the apparent barriers to information sharing across the Atlantic.

The EU and US should explore opportunities to promote appropriate government access to information whilst recognising legitimate commercial interests in appropriate protection of information.

2. Principles for Prioritizing Chemicals for Review and Evaluation

Chemical regulatory programs in the EU and the U.S. do not appear to be well coordinated in terms of priority and the opportunities for burden-sharing between government agencies. An explicit objective of transatlantic regulatory cooperation in the chemicals sector should be to minimize the potential for duplication of effort (by both governments and industry) in chemical testing, assessment and evaluation. Common principles on approaches to prioritization for chemical assessment could help encourage work and burden sharing by either governments or industry. An understanding of how substances are prioritized for review, what use and exposure patterns prompt concern, and what information is currently available to support the review and assessment could dramatically reduce the potential for duplication of effort and streamline and expedite reviews.

General principles for prioritization processes to identify chemical substances for further review and assessment should include:

- Prioritization processes should apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Information on the use and exposure patterns that prompt the need for additional review should be transparent and public, consistent with the need to protect sensitive commercial information.
- Prioritization processes should leverage existing, available data and existing hazard classification frameworks already in use across industry and agreed by regulators, such as the Globally Harmonized System for Classification and Labelling (GHS).
- Relevant science advances should be incorporated and accounted for in prioritization programs, where there is broad acceptance in the scientific community (e.g. improvements in how persistence and bioaccumulation considerations are addressed).
- Prioritization process should allow for the use of significant new information, to ensure prioritization decisions remain current.
- Substances identified as priorities should be subject to further evaluation and assessment, rather than immediate risk management measures.

- Prioritization screening and ranking processes should provide for public review and comment with an opportunity to submit additional relevant data and information.
- As resources are limited, prioritization should fully consider both the probability of the occurrence and the consequences arising from risks, so that attention is given to the most significant issues affecting human health and the environment.

Common science- and risk-based approaches to prioritisation for chemical assessment could help encourage work and burden sharing and minimise duplication of efforts for both government and industry.

3. Principles for Coherence in Chemical Assessment Processes: Common Scientific Basis for Regulatory Decisions

A basic building block for chemicals management is information about the hazards of chemicals. Developing common principles, practices and guidelines in assessment processes will help assure a common scientific basis for regulatory decisions across the regions.

The role and impact of chemical assessments cannot be overstated. Scientific determinations serve as the foundation of effective chemical management regulatory programs. High quality, reliable science is the foundation for protecting health and the environment, instilling public confidence in regulatory systems, encouraging innovation, and fostering transatlantic competitiveness. It is critical that chemical assessments meet appropriate benchmarks for objectivity, transparency, and scientific accuracy so that all stakeholders can have confidence in their use for regulatory decision making, product development decisions, and consumer choices. Fundamental principles to promote a firm scientific foundation for chemical assessments include:

- Exploration of common data formats as one means to promote cooperative approaches to assessment.

- Chemical assessments should rely on the best available scientific data and methods, and employ consistent, objective methods and models to derive realistic determinations at environmentally relevant levels of exposure.
- Development and application of consistent, transparent criteria for evaluating data and selecting studies used in assessments, to ensure that their quality, relevance and reliability can be evaluated.
- Assessments should be tailored to chemical-specific datasets, knowledge of mode of action and biological effects, and should assess the overall weight of the evidence, giving the greatest weight to information from the most relevant and highest quality studies.
- Review of the assumptions and default approaches that underlie assessment programs. Reliance on outdated default values should be minimized. Today scientists and health professionals have an advanced understanding of how the human body works, and the way chemicals interact with the body and the environment at different levels of exposure.
- Hazards and risks must be objectively characterized and presented in in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges and not simply rely on theoretical maximum exposure estimates to characterize potential risk.
- Assessments must provide full disclosure of key information. When assumptions are used in lieu of data, the assumptions must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.

A common basis for and understanding of how chemical hazards and risks are assessed will help enhance regulatory cooperation, while leaving to relevant governments the decision of how and when to apply the assessments in regulatory decisions.

Enhanced cooperation in hazard and risk assessment can also help ensure a common understanding in several critical science policy areas:

- Design and Data Acquisition. Transparency in the design of chemical assessments will help promote broad understanding of the key issues that are to be assessed and the specific methods, assumptions, and evaluation procedures that will be utilized. Input from the research community and stakeholders should be part of this activity, so that the most up-to-date data can be obtained and the most relevant methods can be considered and used.
- Data Evaluation. Transparent, consistent and scientifically objective data evaluation protocols should be used to evaluate studies.
- Data Integration and Weight of Evidence. All assessments must be based on a clear and consistent framework that takes into account and integrates all relevant data and information and gives the greatest weight to information from the most relevant and highest quality studies.
- Ensuring discussion of and reliance on accepted international standards and definitions developed by recognized organizations. At minimum common-accepted definitions will help reduce trade barriers, increase regulatory certainty and ensure objectivity and transparency. For instance: the WHO definition on endocrine disruptors should be used by both partners as a starting point for future regulatory activities.
- Regulatory requirements in Europe impose constraints on animal testing to meet data generation requirements. Where such test data are generated in order to fulfill legal requirements in the U.S., these data should be accepted by EU public authorities, and vice-versa. Recognition of specific data also with respect to marketing authorisations would reduce the potential for duplication in effort, streamline and expedite chemical assessments.
- Upcoming regulatory activities: First step: agree on definitions and assessment criteria. Long term goal: adopt regulations that are comparable in effectiveness and apply mutual recognition. Example: Can both sides agree on a transatlantic definition for nano-materials?

Common principles, practices and guidelines in chemical assessment procedures will help assure a common basis for regulatory decisions across the regions.

4. Trade Secrets/Confidential Business Information (CBI)

Trade secrets and CBI are critical assets and key indicators of competitiveness. The chemical management systems in both the EU and the U.S. are intended to make information on chemicals more transparent, particularly to the public. Wording on this is included in legislation like REACH. A key set of common principles for enhanced transparency in chemical management could have important benefits for both business and governments. More detailed principles for the protection of trade secrets / CBI could help ensure consistent protection for critical information, consistent enforcement of rights to protected information, and would foster the useful exchange of information between regulatory authorities.

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5. Classification and Labelling/Implementation of International Convention

Approaches to harmonised classifications must be based on common principles as stipulated in the Globally Harmonized System (GHS) in conjunction with considerations of other factors such as the following: weight of evidence; substance identity (e.g., impurities, composition, form and physical state) and an assessment of data accuracy and quality. Companies should have the opportunity to question a specific classification and its relevance.

The chemical industry supports a review of the potential for harmonised classifications. The benefits of harmonised classifications could include (1) supporting/promoting cost-effective GHS implementation; (2) avoiding duplication of effort; (3) applying expert systems to maximize resources and minimize costs; (4) promoting harmonization/consistency in classification; (5) providing a reference for self-classification by manufacturers; (6) facilitating international trade;

and (7) improving safety for workers and others through consistent and harmonized communications on chemical hazards and practices to follow for safe handling and use.

The well-developed chemical regulatory systems in the EU and the United States were the model for the Rotterdam Convention on Prior Informed Consent, an international agreement aimed at ensuring importing governments had appropriate information on the regulatory status of the shipments in the country of origin. The EU and the US should explore the extent to which it can harmonize the list of chemicals for which they provide export notifications, and whether there is any need for of value from such notifications for chemical transatlantic shipments.

The chemical industry supports a review of the potential for harmonised classifications based on common principles as stipulated in GHS in conjunction with considerations of other appropriate factors.

Harmonisation of the implementation of the PIC Convention could be explored and in particular the value of notifications for chemical transatlantic shipments.

SHORT TERM IMPLEMENTATION PATH

1. Implement the 2002 Guidelines on Regulatory Cooperation

A commitment by the EU and U.S. governments to fully implement the 2002 EU-U.S. Guidelines on Regulatory Cooperation and the "Common Understanding of Regulatory Principles and Best Practices" of 2011 would be a key first step in promoting more open, efficient chemical regulatory environments. Full and detailed implementation of the guidelines – including interactive consultation with affected industry would be invaluable to removing unnecessary barriers and inefficiencies for chemical industry and our customers.

The 2002 Guidelines specifically refer to regular consultation and an exchange of data and information, including information on planned new regulations. Full implementation of the Guidelines would help promote more efficient Trans-Atlantic chemical regulation by:

- Enhancing the quality of technical regulation
- Minimizing the potential for divergence in regulation due to interpretative or technical misunderstandings
- Increasing predictability and certainty in the development and implementation of chemical regulation
- Inviting relevant stakeholders on either side of the Atlantic to participate in appropriate rulemakings
- Promoting transparency by disclosure and access to the research and analysis that support chemical regulation
- Providing a means to engage the expertise of government and industry experts in a dialogue
- Promoting increased public understanding of chemical regulation.

2. Commit to and Exchange Regulatory Impact Analysis

A significant benefit of greater regulatory cooperation is business certainty. In particular, the EU and U.S. should commit to adopting only those chemical regulations that are consistent with health and environmental policy objectives, with the least economic impact on competition and the least regulatory burden.

A commitment to assess the impact of chemical regulatory proposals would be a useful first step to enhanced regulatory cooperation. Such a commitment would not jeopardize the sovereign rights of governments on both sides of the Atlantic to identify, develop and implement regulatory priorities. Indeed, the impact assessment could help identify further opportunities to cooperate, build government and public trust in the respective systems, and perhaps identify opportunities to share appropriately the burden of government chemical assessment and oversight.

Conducting regulatory impacts assessments on chemical regulatory proposals would identify those measures that exceed a threshold of economic impact agreed by the Parties. At a minimum, the assessments should identify:

- The problem and policy objective intended to be addressed, including a description of the need for regulatory action and the magnitude of the problem.
- The regulatory alternatives considered in proposing a regulatory solution, consistent with the policy objective, whether non-regulatory and/or voluntary means have been considered or are appropriate, consistent with domestic or regional law. The costs and benefits of the alternatives should be addressed, including specifically the costs and benefits for two-way Trans-Atlantic trade.
- Where feasible and appropriate, a demonstration that the recommended regulatory alternative maximizes net benefits, including qualitative benefits, and an explanation why the recommended approach is preferred over other alternatives.
- The best available scientific, technical, economic, and other information upon which the proposal is based.

- The existence of potentially conflicting requirements arising from the chemical or other regulatory programs, or other applicable international consensus standards that might affect the need for a regulatory outcome.

Nothing in a chemical regulatory impact analysis should require the disclosure of confidential information, including information that would compromise a financial or commercial interest if disclosed, or if it is prohibited by law.

A commitment by each Party to periodically review significant chemical regulatory measures for their impact on Trans-Atlantic trade would also be an important commitment to identifying such measures and ensuring that they are as effective as possible in achieving the desired policy objectives. This would allow, for example, a periodic review of the state of transatlantic chemical trade, the impact of new and emerging technologies, and how improved regulatory cooperation could enhance the effectiveness of the regulatory programs.

Importantly, this approach would permit the EU and the U.S. to recognize the value of enhanced regulatory alignment with respect to chemicals, and could serve as a useful model for extension to other goods and service sectors.

First steps to promote more open, efficient chemical regulatory environments could include a commitment to fully implement the 2002 Guidelines for Regulatory Cooperation and a commitment to assess the impact of chemical regulatory proposals.

EXPECTED POSITIVE EFFECTS OF ENHANCED COOPERATION AND VALUE ESTIMATE

It is difficult to quantify the savings that would result from the above proposals. However, addressing the opportunities for regulatory cooperation in these areas can help minimize the potential for duplication of effort by government and industry, create efficiencies by ensuring high-quality, reliable information is the basis for decision-making, enhance the value of trans-Atlantic chemicals trade and offer guidance to the rest of the world in setting justifiable and usable regulation. Developing and agreeing on principles in these areas would help guide future cooperative work and set the stage to leverage all the efficiencies and effectiveness possible.

Improved cooperation in chemical regulation could also have the important ancillary benefit of minimizing the potential for duplication or inconsistency in the regulatory requirements applied by member government or subsidiary government bodies.

Additional trans-Atlantic chemical regulatory cooperation could minimise the cost and burden to government and industry alike by, as a first step, agreeing principles in five fundamental areas.