## VAICEKAUSKAITE Indre (TRADE)

**Subject:** Summary report - meeting with AmCham EU **[NOT RELEVANT]** and other TTIP-related issues

**Summary report – meeting with AmCham EU on [NOT RELEVANT] and other TTIP-related issues – 16 September 2013, 10.00-11.00**

- AmCham EU: **[ART. 4.1b]; [ART. 4.1b]** Michelin (but speaking on behalf of AmCham EU)
- DG TRADE: Henrique Carvalho (D.3), Benjamin Musall (G.3)

Key points:

- AmCham EU presented their association which has around 150 members (EU companies of US parentage). According to AmCham EU, aggregate U.S. investment in Europe amounts to € 1.7 trillion (2010) and directly supports more than 4.2 million jobs in Europe.

  **[NOT RELEVANT]**

- COM informed about the TTIP process **[NOT RELEASABLE]** . AmCham EU is highly interested in this process and also in the other "new and emerging scientific issues" relevant for the TTIP, i.e. nanotechnology and mixture toxicity. On nanotechnology, AmCham EU expressed full support for the EU's second regulatory review of 2012 and the process of reviewing certain REACH Annexes to take nanomaterials into account. AmCham EU is also interested in the review of the EU nanomaterial definition (to be adopted by the end of 2014).

25 June 2013

# AmCham EU calls for a substance by substance approach to regulate Endocrine Disruptors

The American Chamber of Commerce to the EU (AmCham EU) would like to provide input into the ongoing debate on whether thresholds could be determined for endocrine disruptors (EDs) in the context of the REACH review.

As an introductory remark, we fully support science-based approach to legislation and we were glad to read the conclusions of the 29-30 May 2013 Competitiveness Council that reinforce the need for evidence-based regulations 'by means of a robust impact assessment'. We believe that the current discussion on thresholds has many ramifications, a very broad impact on the EU industry and, as such, deserves a preliminary and thorough impact assessment.

We would like to share the following general comments for your consideration:

- A threshold as used in toxicology is the dose or exposure level at and below which no adverse effects are observed. Different substances have different thresholds and dose response curves based on differing effects depending upon their toxicological profile. Potency, threshold and dose response are key toxicological principles that are taken into consideration by agencies/regulators throughout the world to regulate chemical substances;

- Since it has been hypothesised that a few endocrine disruptors may cause adverse effects without an established exposure dose threshold, this approach needs to be replicated to demonstrate if a particular endocrine disruptor actually lacks an established threshold prior to being listed on the candidate list of substances of very high concern (SVHC) and therefore blacklisted;

- We request that as with any other substances, and with the objective of science based decision making, a risk assessment and a substance-by-substance approach is applied. Risk assessment has been successfully applied to chemicals with widely differing toxicity profiles and characteristics of human exposures used over the last 30 years;

- We believe there is no standard approach to EDs. Any *a priori* approach to EDs is therefore in our eyes, not appropriate;

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- Many ingredients/substances display low level endocrine activity, without associations on adverse impacts to human and environmental health. Threshold considerations would help delineate between ingredients of regulatory and not of regulatory concern.

- Most EDs are far less potent in producing effects than natural hormones. Again the dose effect is key in defining their impact on health and the environment;

- While we recognise that a case-by-case approach will entail a significant amount of testing and studies, we believe that it is the most appropriate route to evaluate and regulate EDs with the objectives of both protecting human health and the environment and preserve industry's competitiveness;

- The impact of adopting a non-threshold approach to endocrine disruptors and their subsequent listing on the SVHC list would be equivalent to phasing out substances *de facto*, without a proper evaluation/prioritisation. A non-threshold approach *a priori* would mean having regulatory action not targeted to a specific concern, and force production processes to be changed and the value chain to reformulate products. This would be at a significant cost to European industry for an undefined benefit. We support the goals of REACH and have invested a lot to comply with the regulation. We ask that, in absence of evidence, a particular ED should be regulated without threshold, and that risk assessment forms the basis of regulating EDs;

- A non-threshold approach on endocrine disruptors would have implications that would go far beyond the REACH authorisation process. It would have implications, not only for consumer products and the exposure of consumers, but also for any kind of manufacturing in Europe. For example, the whole body of EU worker protection legislation is based on reducing workers' exposure to hazardous chemicals to a threshold that is acceptable and does not lead to adverse effects;

- Should a non-threshold approach be adopted *a priori* for all endocrine disrupters, this would mean that for many substances unnecessarily stringent control and elimination of traces of substances would be required at all stages of the manufacturing, transportation or waste phase of a product. Such an approach would have major implications for these substances with little or no health and environmental benefit; and

- The DG Environment List of potential endocrine substances for further evaluation (developed by BKH consultants several years ago) includes many major commodity substances used in a wide variety of applications and sectors, which bring a wide range of benefits to EU society (including sustainability benefits). If non-robust criteria and a non-threshold approach are applied to identifying EDs on this list for regulatory action, many substances will be captured that can and are being used safely based on risk assessment. Use of non-robust criteria and a non-threshold approach for EDs will therefore have a major impact on these substances, the chemical sector and the downstream user sectors with no benefit for health and the

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environment. The major commodity chemicals on the list have been developed through significant investment in all aspects of research, technology, manufacturing, distribution and applications with downstream users, over a period of decades. It is estimated that this has involved hundreds of billions of euro in investment and impacts several million jobs in the EU economy. In addition to the potential impact on existing investments and employment, the uncertainty created will also impact new investment and innovation within the EU. The net impact would be to displace investment in the chemical industry, in new substances and downstream applications to countries outside the EU, with the associated impact for EU employment and the economy.

Based on the above AmCham EU urges the European Commission to ensure:

- That the criteria for identifying EDs are based on a robust scientific approach,
- That the evaluation of chemicals for ED properties is performed on a substance-by-substance basis
- That the categorisation as having a threshold or non-threshold mechanism of action be unique to each ED substance.

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*AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €1.9 trillion in 2012 and directly supports more than 4.2 million jobs in Europe.*

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3 September

# AmCham EU Position on endocrine disruption

## AmCham EU –P osition on Endocrine Disruption

**The American Chamber of Commerce to the European Union (AmCham EU) recognises the concerns** of the public, NGOs, regulators and other stakeholders with regard to the potential for chemicals to cause adverse effects by causing an alteration in the function of the endocrine system, and is committed to working with stakeholders to address this issue. It is essential, however, that a sound scientific and rational approach is taken to this topic, and that policies and plans are based on robust science and facts rather than on unjustified fears. Because a small number of natural and synthetic hormones are highly potent and can lead to serious adverse health and environmental effects where there is exposure, does not mean that all natural and synthetic chemicals identified with some hormonal effect are all highly potent endocrine disrupters. Such an ideological approach is non-scientific and would lead to the substances of real potential concern being missed.

**AmCham EU supports the development of science based guidance,** with a tiered approach for identifying substances determined to have potential for adverse effects mediated via the endocrine system ('endocrine disruptors'). Key elements of such an approach are:

- Use of internationally accepted definitions and approaches, i.e. World Health Organization (WHO) definitions for an endocrine disrupter and adverse effects. The relevant WHO definitions are:
    - Endocrine disruptor – 'Exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)-populations'.
    - Adverse effect – 'A change in morphology, physiology, growth, reproduction, development or lifespan of an organism which results in impairment of functional capacity or impairment of capacity to compensate for additional stress or increased susceptibility to the harmful effects of other environmental influences (WHO/IPCS 2004)'.

These definitions clearly establish the causal link between the endocrine disrupting function and the adverse effect. It is key to ensure that substances are defined as endocrine disruptors for demonstrated scientific reasons.

- The use of clearly defined and internationally accepted testing methods, including guidelines and good laboratory practice such as the OECD

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POSITION STATEMENT

Conceptual Framework for the Testing and Assessment of Endocrine Disrupting Chemicals. The framework is included as Attachment I to this position paper[1] Independent of the debate about whether there is a need to further refine the OECD testing methods, there is a need to provide the industry with a clear and transparent framework for the testing and assessment of chemicals for endocrine effects. While research studies are also relevant these need to be assessed as part of the robust weight of evidence OECD tiered approach. This is a key issue to provide industry with the stability and legal certainty needed for long term investment and research programs.

- Reversibility versus irreversibility: chemicals having reversible endocrine effects and chemicals having irreversible endocrine effects should be differentiated in their identification and their management of risk.

- Use of the term 'serious adverse effects' – as outlined in the UK HSE and German BfR position paper.

- Potency, threshold and dose response, among other key toxicological principles, are key elements together with risk assessment based on sound science. These are basic principles of toxicology which are consistent with a sound science based approach and rational outcomes.

- Fair and transparent application of the EU guidance to both existing and new substances.

**AmCham believes that REACH and other existing regulations should be used to address endocrine disrupters based on substance-specific risk assessments.**

AmCham considers that REACH and other existing regulations should be used to regulate substances for adverse effects mediated via the endocrine system. Registrants under the REACH Regulation have to identify adverse effects, whether or not these are mediated via alterations in the function of the endocrine system. Development of the EU Guidance on the identification of endocrine disrupters will further strengthen this approach under REACH and other EU legislation.

**AmCham believes that the assessment of substances for endocrine-related adverse effects should be defined on the basis of a substance-by-substance risk assessment. The 'low dose theory', suggesting that there is no safe level of exposure to a substance that has the potential to interact with the endocrine system, is not substantiated by sound scientific data and should not be used as a basis for regulation in the EU.** Substances should be evaluated based on the data available on the specific substance.

[1] http://www.oecd.org/env/chemicalsafetyandbiosafety/testingofchemicals/oecdconceptualframeworkforthetestingandassessmentofendocrinedisruptingchemicals.htm

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