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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

American Chamber of Commerce to the European Union
Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium
Telephone 32-2-513 68 92 Fax 32-2-513 79 28
Email: info@amchameu.eu

Secretariat Point of Contact: Leah Charpentier ; leah.charpentier@amchameu.eu +32 2 289 1015

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AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

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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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 U.S. investment in Europe totaled $2.2 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

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American Chamber of Commerce to the European Union – Avenue des Arts/Kunstlaan 53, B-1000 Brussels, Belgium
Telephone 32-2-513 68 92 – Fax 32-2-513 79 28 – info@amchameu.eu– www.amchameu.eu

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