

10 January 2013

AmCham EU Position on the EP's own-initiative report on the protection of public health from endocrine disruptors

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the European Parliament's own-initiative report on the protection of public health from endocrine disruptors (2012/2066(INI)). Ahead of the Environment Committee vote on the draft report, AmCham EU would like to share its views on the draft report and amendments submitted by MEPs.

Our views are summarised in the following points:

1. Use of internationally accepted definitions and approaches for the identification of 'endocrine disruptors'
2. Support for the development of science based guidance
3. Use of REACH and other existing regulations to address 'endocrine disruptors'
4. Support for a risk-based approach for the regulation of 'endocrine disruptors'

- 1. Use of internationally accepted definitions and approaches for the identification of 'endocrine disruptors'**

AmCham EU supports the use of internationally accepted definitions and approaches for the identification of 'endocrine disruptors', i.e. World Health Organisation definitions for an endocrine disrupter and adverse effects.

In addition to the WHO definition for an 'endocrine disruptor', OECD countries have also developed a conceptual framework which proposes a tiered approach for testing and assessing endocrine disrupting chemicals. This reflects current science. As a majority of EU Member States are also represented in the OECD this is a good starting point for the EU deliberations and will also facilitate coherence with developments at an international level and ensure there is no duplication of work.

Data from research are also relevant for the identification of endocrine disruptors, however, these need to be assessed as part of the robust weight

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of evidence OECD tiered approach. This will provide industry with a clear and transparent framework for the testing and assessment of chemicals for endocrine effects.

AmCham EU therefore supports the following amendments:

- **Amendment 7** by MEP Christa Klass introducing *Citation 5 a (new)*
- **Amendment 12** by MEPs Julie Girling and Miroslav Ouzký introducing *Citation 19 a (new)*
- **Amendment 60** by Julie Girling, Miroslav Ouzký amending *Paragraph 3*
- **Amendment 71** by Miroslav Ouzký amending *Paragraph 5*
- **Amendment 84** Julie Girling, Miroslav Ouzký *Paragraph 7*

2. Support for the development of science based guidance

Criteria for the identification of 'endocrine disruptors' must be based on sound scientific methods. In other words, substances should be defined as 'endocrine disruptors' for demonstrated scientific reasons. AmCham EU therefore supports the development of science based guidance for identifying endocrine disruptors, in line with WHO definitions.

A key condition deriving from the use of the WHO definition for an 'endocrine disruptor' is that a causal link needs to be established between the endocrine disrupting function and adverse effect. This is crucial to robust risk assessment and effective chemicals regulation. Moreover, it is important to distinguish between 'adverse effects' that could be the result of exposure to endocrine disrupting substances and 'effects' that may be the result of the natural response of the endocrine system.

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.

AmCham EU therefore supports the following amendments:

- **Amendment 20** Julie Girling, Miroslav Ouzký *Recital D – introductory part*
- **Amendment 29** by Oreste Rossi on *Recital D – indent 6 a (new)*
- **Amendment 51** Julie Girling, Miroslav Ouzký amending *Paragraph 2*
- **Amendment 50** by Oreste Rossi amending *Paragraph 2*
- **Amendment 64** by Oreste Rossi amending *Paragraph 3*
- **Amendment 65** Julie Girling, Miroslav Ouzký amending *Paragraph 4*
- **Amendment 66** by Vittorio Prodi amending *Paragraph 4*
- **Amendment 67** by Christa Klass amending *Paragraph 4*
- **Amendment 74** Julie Girling, Miroslav Ouzký amending *Paragraph 5*
- **Amendment 80** Julie Girling, Miroslav Ouzký amending *Paragraph 6*
- **Amendment 133** by Christa Klass amending *Paragraph 14*

- **Amendment 42** Michèle Rivasi, Carl Schlyter *Paragraph 1*
- **Amendment 52** Christa Klass amending *Paragraph 2*
- **Amendment 54** Michèle Rivasi, Carl Schlyter amending *Paragraph 2*
- **Amendment 58** Michèle Rivasi, Carl Schlyter on *Paragraph 2 a (new)*
- **Amendment 59** Michèle Rivasi, Carl Schlyter amending *Paragraph 3*
- **Amendment 75** Michèle Rivasi, Carl Schlyter amending *Paragraph 5*
- **Amendment 82** Michèle Rivasi, Carl Schlyter on *Paragraph 6 a (new)*
- **Amendment 135** Michèle Rivasi, Carl Schlyter amending *Paragraph 14*
- **Amendment 153** Michèle Rivasi, Carl Schlyter *Paragraph 17*

<p>3. Use of REACH and other existing regulations to address 'endocrine disruptors'</p>
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AmCham EU 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 disruptors will further strengthen this approach under REACH and other EU legislation.

REACH's case by case risk management approach should also be the framework to assess any possible adverse effects caused by a 'combined effect' of chemicals. It should not automatically be assumed that combined effects apply to all substances producing effects via an endocrine mode of action¹.

AmCham EU therefore supports the following amendments:

- **Amendment 96** by Oreste Rossi amending *Paragraph 9*
- **Amendment 124** by Christa Klass amending *Paragraph 13*
- **Amendment 125** by Julie Girling, Miroslav Ouzky amending *Paragraph 13*

AmCham EU does not support the following amendments:

- **Amendment 10** by Alda Sousa on Citation 8a (new)
- **Amendment 39** by Alda Sousa on Recital Ga (new)
- **Amendment 69** by Antonyia Parvanova amending *Paragraph 4*
- **Amendment 70** by Alda Sousa on *Paragraph 4a (new)*

¹ The EU Scientific Committees (SCHER, SCENIHR, SCCP) in their expert report entitled *Toxicity and Assessment of Chemical Mixtures* noted, 'Interactions (including antagonism, potentiation, and synergies) usually occur at medium or high dose levels (relative to the lowest effect levels). At low exposure levels, they are either unlikely to occur or are toxicologically insignificant'.

- **Amendment 121** by Pavel Poc on Paragraph 12a (new)

4. Supports the use of risk-based approach for the regulation of endocrine disruptors on the basis of sound science principles

AmCham EU believes that the assessment of substances for endocrine-related adverse effects should be defined on the basis of a substance-by-substance risk assessment. Each chemical substance has its own unique chemical properties and therefore chemicals should not be evaluated in families or in groups.

The EU should remain consistent with its established approach of assessing chemicals on a one on one basis of science and risk assessment. Any evaluation of a 'group of substances' would be inconsistent with the agreed principle under REACH of risk assessment of individual substances.

AmCham EU supports the use of risk-based approach towards the management of chemicals enshrined under REACH. It is important to note that a risk-based approach includes an assessment of a substance's hazard properties.

AmCham EU therefore supports the following amendments:

- **Amendment 95** by Julie Girling, Miroslav Ouzký amending *Paragraph 9*
- **Amendment 101** by Cristina Gutierrez-Cortines, Pilar Ayuso, Andres Perello Rodriguez amending *Paragraph 10*
- **Amendment 102** Julie Girling, Miroslav Ouzký amending *Paragraph 10*

AmCham EU does not support:

- **Amendment 97** by Christa Klass amending *Paragraph 9*
- **Amendment 115** Christel Schaldemose, Åsa Westlund, Pavel Poc, Judith A. Merkies *Paragraph 12*
- **Amendment 116** Sophie Auconie

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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 €1.7 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

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