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# 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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POSITION STATEMENT



- 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 disruptors, 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

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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