

Consultation response

Comments on the Commission Communication entitled: “Towards a comprehensive European Union framework on endocrine disruptors”

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 more than €2 trillion in 2017, directly supports more than 4.7 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

Executive summary

AmCham EU supports the Commission's proposal of launching a cross-cutting Fitness Check in line with Better Regulation requirements and looks forward to participating with other stakeholder's in the public consultation.

AmCham EU is also supportive of the Commission's other proposals on further research including on robust hazard and risk assessment, international cooperation including the development of OECD test guidelines, the annual forum on ED, and the consolidated website of up-to-date information. With respect to exploring possibilities on the international classification system, AmCham EU would highlight the need for caution in order to avoid complexity, duplication and confusion.

Further details are provided below. Comments are made by the sections of the Commission's communication.

The Science of Endocrine Disruptors

AmCham EU is committed to ensuring the safe and environmentally acceptable use of chemical substances and recognizes the importance of testing/assessing chemicals for their potential adverse endocrine-related effects and to identify safe limits of exposure. This allows the right risk management measures to be put in place. Existing toxicology studies identify adverse effects regardless of the mechanism of action allowing for correct regulatory controls. Information on mechanisms or modes of action which have a demonstrated plausible biological link to the adverse effects can then provide supplementary information to understand human and environmental relevance, and to enhance potential risk management considerations.

Concerning threshold/non-threshold effects, the current scientific paradigm supported by strong evidence is that thresholds exist for endocrine effects and scientific data is lacking to support the hypothesis that EDs operate via a non-threshold mechanism. EDs should therefore be regulated as threshold substances. This consideration is not limited to EDs (viz. EFSA report 2016).

We support strong links between scientific knowledge/evidence and regulation/ regulatory decision-making. Where policy runs ahead of the scientific consensus, a clear distinction should be made between what is policy driven and what is science driven. As with other modes of action, we regard biological thresholds and homeostasis as scientifically based. Assuming EDs to be non-threshold would be a policy decision unless the body of evidence evolved to the extent that a revision of the long-standing principles of homeostasis and biological threshold is justified. This applies to natural EDs as well as to man-made ED's.

Combined effects may be relevant in some cases where there is common mode of action or an antagonistic mode of action, since combined effects may be additive, synergistic or inhibitory. Under REACH, this has been considered (LMW phthalates). These effects are not limited to EDs and should be systematically addressed within the Commission's programme(s) re: JRC review of 2016 and EFSA's recent action launching an open consultation on a draft Guidance for combined exposure to multiple chemicals.

EU policy and regulation of endocrine disruptors so far – EU research and development of test guidelines on endocrine disruptors

AmCham EU supports the research and development aims as outlined in this section including in particular the Horizon 2020 Projects on new testing methods. AmCham EU is engaging in Horizon 2020 via its Long-Range Research Initiative and is contributing to endocrine research via this program.

We support the future actions aimed at addressing knowledge gaps. European funding can facilitate this provided it is not spread thinly over too many areas. We believe there is value to be gained by considering large-scale, focused collaborative research such as that conducted in the US in the BPA-Clarity study. It is very helpful for complex problems like low dose effects and thresholds

We support the Commission's engagement with the OECD for test method development/validation. Work should focus on endpoints where potential gaps have been identified (e.g., neurotoxicity). Method development for regulatory purposes should consider immediate relevancy and utility of the test outcome to the regulatory question. Beyond the EU/OECD, the Commission should continue to follow developments elsewhere (e.g., the US EPA).

AmCham EU acknowledges the significant progress which has been made in the development of criteria for Biocides and Plant Protection Products as well as regulation of substances for endocrine disrupting properties under REACH and other regulations. With respect to potential horizontal criteria AmCham EU would agree that use of the broadly accepted definition of the World Health Organization is appropriate and would also highlight that guidance will likely be needed under the REACH regulation for ED substances of "equivalent level of concern" to CMRs, PBT, vPvBs.

Taking forward the EU's policy on endocrine disruptors

With respect to ensuring a high level of protection of EU citizens and the environment AmCham EU from EDs AmCham EU considers that it will be important to utilize risk assessment and risk management in achieving this goal, without which many beneficial substances could be lost which can in practice be used safely. Such an approach will also help to ensure consistency and coherency with other sectors such as food and drink where naturally occurring components and ingredients such as vitamins can have endocrine disrupting properties.

With respect to the main proposal of launching a cross-cutting Fitness Check in line with Better Regulation requirements, AmCham EU is very supportive and looks forward to participating together with other stakeholders.

With respect to the other proposals for taking forward the EU's policy:

- **Support for further research under Horizon 2020 and Horizon Europe** – AmCham EU, as already noted, is supportive. In particular research for the further development of robust weight of evidence hazard assessment, risk assessment and risk management of chemicals, including for combined effects is of high importance to ensure that the substances that

really matter are identified and that resources are focused on these substances. In line with the inclusive approach highlighted AmCham EU is ready to continue the engagement and cooperation with other stakeholders on this important matter, including at the international level.

- **Annual Forum on endocrine disruptors** – AmCham EU is supportive and ready to contribute and participate
- **The Commission will step up its support to the work of relevant international organizations** – AmCham EU is supportive and will continue to proactively promote work via the International Council of Chemical Associations (ICCA) on this important topic.
- **The Commission will also explore possibilities for the inclusion of endocrine disruptors in the existing international system for classification of chemicals** – AmCham EU recognizes the Commission would like to explore this further but would express caution with regard to potential complexity, duplication and confusion arising from introducing mode of action into a system which already captures adverse effects, including from substances which act via an endocrine mode of action.
- **Commission will launch a one-stop shop web portal on endocrine disruptors** – AmCham EU is supportive of ensuring robust up-to-date information on endocrine disruption is made available to the public, to support the safe use of chemicals and the myriad of essential products which rely upon such substances.