AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

Science-based horizontal identification of endocrine disruptors under REACH

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 2019, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

American Chamber of Commerce to the European Union
Speaking for American business in Europe

Avenue des Arts/Kunstlaan 53, 1000 Brussels, Belgium • **T** +32 2 513 68 92
info@amchameu.eu • amchameu.eu • European Transparency Register: 5265780509-97

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) shares the EU's commitment to protect human health and the environment from endocrine disruptors (ED) whilst promoting the safe and sustainable use of chemicals, having been active stakeholders in this specific EU policy debate for over a decade. The European Commission's recent Chemicals Strategy for Sustainability (CSS) proposal is a positive move towards reaching the sustainability and competitiveness ambitions set out in the European Green Deal through ensuring the safe use of chemicals such as endocrine disruptors.

AmCham EU supports the Commission's objective to establish a horizontal, legally binding mechanism to identify endocrine disruptors based on the World Health Organisation (WHO) definition. However, moving further towards hazard-based regulatory instruments where non-approval/non-registration and risk management measures would automatically be triggered by hazard assessment and classification should be cautioned against. We therefore encourage the Commission to enhance the existing horizontal identification of EDs under the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH). Should the Commission decide to create new hazard classes under the Regulation on the classification, labelling and packaging of substances and mixtures (CLP), AmCham EU would recommend that tools are put in place, such as an ED flag, to minimise duplication, confusion and unnecessary use of resources.

Potential changes to the CLP should remain consistent with international instruments such as the UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) to ensure the level-playing field is upheld, working against deviations between EU legislation and international rules. Additional ED testing requirements under REACH should be proportionate and justifiable, taking the form of a flexible tiered approach using existing information. When considering new testing requirements, it should be considered that this would entail potentially onerous, costly requirements which would create additional hurdles for new substances. These should be avoided where possible.

Introduction

The American Chamber of Commerce to the European Union (AmCham EU) brings a unique perspective on EU chemicals legislation. Since its inception, our members have been active stakeholders in the Registration, Evaluation, Authorization and Restriction of Chemicals Regulation (REACH). We represent the entire chemicals value chain, from upstream chemicals producers to downstream users, as well as specialised consultancies and law firms. We aim to be a constructive partner and share our experience and industry insights with policy-makers at both European and national level in order to support effective and proportionate chemicals legislation that will protect human health and the environment as well as improve EU competitiveness and innovation.

AmCham EU has been actively involved in the EU policy debate on endocrine disruptors (ED) since 2011. We participated in the feedback on the European Commission's consultation conducted as part of the EU fitness check on EDs which was published together with the Commission's Communication on the Chemicals Strategy for Sustainability (CSS) on 14 October 2020.

As discussed in our response to the fitness check, we share the commitment to protect human health and the environment from endocrine disruptors as well as to promote the safe and sustainable use of chemicals. We believe this can be best achieved through robust weight-of-evidence approaches, science-based hazard strategies, mode of action and risk assessments, as well as through effective risk management.

In this context, AmCham EU supports using the World Health Organization (WHO)/International Programme on Chemical Safety (IPCS) definition as the cornerstone to establish a horizontal, legally binding mechanism to identify EDs; coherent with the criteria that have been adopted at the EU level for plant protection products and biocidal products. Horizontal criteria can support consistent identification of EDs, although it is critical that implementation of such criteria is carried out via robust expert weight of evidence assessments, followed by risk assessment and risk management at the sector level.

We note that in the action plan accompanying the CSS, the Commission suggests that horizontal ED identification could be achieved through new hazard classes under the Regulation on the classification, labelling and packaging of substances and mixtures (CLP). We urge the Commission to take into account that CLP is designed to identify, classify and communicate adverse effects, whereas endocrine disruption – as defined by the WHO – consists of an endocrine mode of action that is causally linked to an adverse effect. In this regard the CLP already identifies the adverse effects which can be caused by substances which may be acting via an endocrine mode of action.

We would like to highlight the following specific comments related to some of the key elements and actions of the CSS regarding endocrine disruptors:

1. Horizontal identification of ED would best be achieved through REACH, not CLP

Tests and data requirements in EU regulations such as REACH, Cosmetics, Biocides, and Plant Protection Products have already demonstrated that substances which cause adverse effects in animal and ecotoxicological studies and which act via an endocrine mechanism (endocrine mode of action and the biologically plausible causality link with the adverse effects) can be identified.

CLP/UN Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is designed for hazard classification based on adverse effects; therefore, many substances with adverse effects which may be caused by an endocrine mode of action are already identified under CLP/GHS. Where this is not the case, additional hazard classes should be introduced for adverse effects, not for modes of action. Endocrine activity is a mode of action potentially leading to an adverse effect and CLP/GHS is not intended to address modes of action. Including

mode of action such as endocrine activity in the CLP/GHS would create complexity, unpredictability, duplication and confusion.

Horizontal ED identification would be best achieved through Substances of Very High Concern (SVHC) listing under the REACH regulation, including by formally introducing ED criteria under REACH as is also proposed in the CSS. In this respect, we note that the Fitness Check on Endocrine Disruptors - released together with the CSS - found that while a majority of respondents from all stakeholder groups think that the absence of harmonised criteria poses a problem to a coherent approach for the identification of EDs, almost half of all stakeholders interviewed did not support introducing an ED hazard class in CLP.

Enhancing the existing ED identification under REACH with horizontal criteria and going down the CLP route would be consistent with better regulation and avoid unnecessary duplication of regulatory processes and resources.

2. A level playing field should be maintained between CLP and GHS

According to the CSS, the Commission has plans to propose new hazard classes and criteria in the EU's CLP Regulation ahead of discussion at GHS level. Since CLP is designed to implement GHS in the EU, any policy changes should first be discussed at the international level to ensure consistency and ensure that GHS is truly harmonised across geographies. Many countries are still in the process of implementing GHS and creating new building blocks on ED and other classes will undermine GHS implementation and international harmonisation.

AmCham EU is concerned that if EU authorities plan to introduce additional hazard classes under the CLP Regulation in advance of securing GHS alignment, this would hamper clear and consistent communication on chemical hazards globally as well as potentially creating non-tariff trade barriers.

3. Horizontal ED criteria should be coherent with the WHO/IPCS definition

Horizontal criteria and/or guidance in line with the WHO/IPCS definition for identification of EDs is necessary to avoid incoherence across EU legislation; building on the criteria that have already been defined for plant protection products and biocides.

Once a substance is identified as an ED using horizontal criteria (based on the WHO definition) and a robust weight-of-evidence expert assessment then risk assessment can be conducted in line with the uses and potential exposure to promote targeted risk management at the sector level.

4. Possible options if the European Commission persists in going down the CLP route

If the Commission persists in going down the CLP route for ED, options which could minimise duplication, confusion and unnecessary use of resources could be:

- Use of an ED flag with existing categories – this approach could involve modification of existing Hazard Statements such as:
    - Cancer – Category 1A and Category 1B H350ED – May cause cancer **via an endocrine mode of action**
    - Cancer – Category 2 H350ed – Suspected of causing cancer **via an endocrine mode of action**

- Chronic toxicity (non-CMR) STOT-RE 2 – H373ED – May cause damage to organs **via an endocrine mode of action (10 – 100 mg/kg bw day).**The advantage of this approach is that there would be only small changes to the CLP with minimum duplication and no requirement for new ED 'hazard' classes. The disadvantage is that some potential EDs may be missed (those producing adverse effects between 100 and 1000 mg/kg bw/day; the latter being the limit dose in guideline studies).

- Use of an ED flag with the existing hazard categories – this could also include modification of Specific Organ Toxicity Repeat Exposure (STOT-RE) to include a third group for substances producing chronic adverse effects (non-carcinogenic, mutagenic and reprotoxic [CMR]) at doses between 100 and 1000 mg/kg bw/day. This would add to the existing two STOT-RE groups of 0 – 10 mg/kg bw/day and 10-100 mg/kg bw/day. This approach would fill a potential gap for some substances, although careful assessment would be needed to ascertain whether effects occurring at these very high doses are primary or secondary endocrine disrupting effects. For environmental effects this approach would need to adopt the existing chronic aquatic toxicity values and to appropriately use laboratory animal studies for mammals in the environment. This would require assessment of whether any effects are population-relevant to a wide range of species and whether the hazard can be presented to mammals in the environment (re: degradation, biomagnification). In this regard it should be noted that the European Court of Justice has ruled in the case of one substance (DEHP) that there was distortion of evidence in the use of laboratory animal data intended for human health assessment to determine ED for mammals in the environment. The same approach for Hazard Statements as outlined in the previous paragraph would also need to be taken. The advantage of this approach is that only small changes to the existing CLP system would be necessary; without new ED 'hazard' classes. It also fills the potential gap with the third STOR-RE category for substances producing adverse effects via an endocrine mode of action in the dose range 100 – 1000 mg/kg bw/day.

- Use of a STOR-RE approach to capture all substances which can produce adverse effects via an endocrine mode of action including both CMR substances and those producing chronic toxic effects on organs (non-CMR). The same approach as outlined in the previous paragraph would need to be taken for the environment. The advantage of this approach is that there is effectively a single dose related approach taken for all substances producing adverse effects via an endocrine mode of action. The disadvantage is that CMR substances which act via an endocrine mode of action are treated differently to those which do not act via an endocrine mode of action.

5. New ED testing requirements under REACH should be proportionate

The CSS proposes to accelerate the development and uptake of methods to generate information on endocrine disruptors through screening and testing of substances.

Specific test methods for EATS (Estrogen, Androgen, Testosterone and Steroidogenesis endpoints) regulatory tests are considered sufficient in accordance with OECD standards (see OECD Guidance Document 15[1]). For wildlife there is potential for further improvement although testing should be proportionate to tonnages, uses and potential exposure. It is not possible to test every substance for every endpoint; nor is it necessary.

[1] OECD (2018), *Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption*, OECD Series on Testing and Assessment, No. 150, OECD Publishing, Paris, https://doi.org/10.1787/9789264304741-en;

New testing under REACH would entail potentially onerous, costly requirements which would create additional hurdles for new substances. Where there is potential concern, a flexible tiered approach using existing information is more appropriate (see OECD Conceptual Framework[2]). If a concern is identified then further testing and evaluation can be conducted. If the substance is developed further then additional endocrine related tests can be considered. Mode of action assessment involves a research oriented approach and therefore a list of tests with a tick box mentality is not appropriate.

Moreover, the Commission should take animal welfare considerations into account to minimise the impact of assessing chemicals for ED properties. In order to do so, the EU should build on existing historical databases which have led to knowledge, understanding and expertise relevant to substances and their uses. In particular, balanced, proportionate testing with read-across should be used. Rejecting read-across, even where this is justified, is far from an efficient use of human and financial resources.

[2] *Ibid.*