CIA

CHEMICAL INDUSTRIES ASSOCIATION

CIA POSITION STATEMENT: NOVEMBER 2020

Endocrine Disruptors

Background

'Endocrine Disruptors' (EDs) have been subject to extensive debate for many years, capturing the attention of politicians, industry, the media, the general public and other stakeholders. The UK Chemical Industries Association (CIA) welcomes this continuously evolving debate as an opportunity to review the scientific evidence.

- Legislative criteria for identifying EDs under the Biocidal Products Regulation (BPR) and Plant Protection Products Regulation (PPPR) were adopted in 2018 with Technical guidance supporting the legislation published in 2018.
- A Fitness Check on EDs in EU legislation has been undertaken by the European Commission with the results published in a Staff Working Document[1] supporting the recently published EU Chemicals Strategy for Sustainability.[2]
- The EU currently favours unilaterally creating a new hazard class for EDs under the Classification, Labelling and Packaging Regulation as a suitable approach for managing identified ED chemicals. This is one of the many Actions proposed under the EU's Chemicals Strategy for Sustainability.

Our opinions and actions

- CIA supports regulatory action to protect against exposure to proven harmful ED substances.
- Whilst there is a clear need to have the correct regulatory controls in place to protect our environment and human health from harm, criteria for identifying and controlling EDs must also be fit for regulatory purpose.
- We are concerned about substances of comparatively low concern being prematurely identified as possible EDs because this may result in companies immediately seeking substitutes and having to absorb the high costs associated with research, development and reformulation that might later be judged to not have been required. This could have a greater negative impact on SMEs in particular, as they could be more disproportionately impacted by the need for additional unplanned investment just to stay in business, in addition to existing costs to maintain regulatory compliance, without adequate scientific evidence that a substance causes harm to man and/or the environment.
- Guidance for applying ED criteria must therefore allow regulators to identify, differentiate and focus on substances of the greatest concern from a health and environmental risk standpoint rather than follow a broad, non-specific, overly precautionary approach.
- **Managing EDs:** A recommendation in the Fitness Check is to consider a horizontal approach for the overall management of EDs. CIA supports this and promotes the use of REACH for identifying and assessing EDs, as for any other properties, but their regulation is best achieved via sector legislation to ensure specific uses and exposures are considered. REACH is the right tool to identify and assess substances – an ED assessment could be conducted similarly to a Persistent, Bio-accumulative and Toxic (PBT) assessment through a dedicated Annex leading to the identification as a Substance of Very High Concern (SVHC). This would also prevent inconsistencies arising between EU legislation such as with biocidal product co-formulants that are regulated under REACH being also assessed for ED properties under the Biocidal Products Regulation.

- **Identifying EDs:** Whilst we support the WHO-based definition of an ED as the basis for all legislative criteria taken forward, CIA remains of the view that the inclusion of potency (i.e. the strength of a substance's activity) and additional criteria such as severity and reversibility of effect(s) would enable a risk-based approach to be applied to the management of EDs. Importantly these would ensure that substances having similar ED-type properties to many naturally occurring substances found in everyday products, such as grains, beverages, vegetables and fruit, are not regulated without scientific justification. In our view, this risk-based approach would be a more practical way forward since it would allow for better differentiation between substances that cause adverse effects and those that simply show endocrine activity without causing proven harmful effects to man and/or the environment. We also stress that robust scientific criteria and methodology in the 'grouping approach' proposed in the EU's Chemicals Strategy for Sustainability shall be used to identify EDs.
- **Categories:** CIA continues to support the European Commission's decision from 2016 not to use a categories approach for biocides and pesticides and believes this should be the case across all legislation. We advocate that the Commission should maintain this position in consideration of EDs associated with other chemical legislation since this could lead to lists of substances that are seen to be EDs without validation, resulting in market deselection and stigmatisation of valuable chemicals with no benefit for human health or the environment. For the same reason and to ensure consistency across the Union, a category approach should not be implemented by individual Member States.
- **Classification:** We do not believe a new GHS/CLP hazard category is needed since any adverse effects arising from the mode of action i.e. endocrine activity are already captured by the existing hazard categories. EDs can and are already being effectively managed without this. In addition, hazard categories do not consider the exposure and risk. If a new hazard class is to be created, then CIA supports this being achieved through the UN GHS rather than the EU creating more disharmony in terms of global hazard communication.

Conclusion

As the debate on EDs continues to evolve, the UK CIA asks you to lend your support to the above and encourage regulatory policy making based on sound science to enhance the protection of public health and the environment. In our view, the most useful and meaningful regulatory definition for EDs is one that can identify those substances with ED activity that are more hazardous to the environment and/or human health than natural substances normally present in the environment that humans are exposed to daily. We ask the UK, European Commission and EU Member States to thereby work with industry to ensure both already adopted legislation and any future proposed changes, where deemed necessary, are pragmatic and workable. Furthermore, we urge that the development of the EU's framework on EDs is balanced and proportionate in its approach.

Without such an approach, many chemicals may be unjustifiably identified as EDs, leading to more stringent regulation, including bans, or will be subject to early demands from the value chain for substitution, eventually resulting in the unnecessary loss of many of the benefits they bring to society as well as any unknown potential solutions for addressing societal challenges. This will inevitably result in significant and often unaffordable reformulation costs for many companies, especially SMEs, due to upward pressure from the value chain to substitute/eliminate substances of concern before a comprehensive risk assessment or socioeconomic assessment has taken place.

References

1. https://ec.europa.eu/environment/pdf/chemicals/2020/10/Executive_summary_FC_EDC.pdf
2. https://ec.europa.eu/environment/strategy/chemicals-strategy_en

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