

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 debate as an opportunity to review the scientific evidence surrounding endocrine disrupting substances.

- Criteria for identifying EDs under the Biocidal Products Regulation (BPR) and Plant Protection Products Regulation (PPPR) have been published in the EU Official Journal applied to biocides and pesticides from June 2018 and November 2018 respectively.
- Technical guidance supporting the legislative criteria for identifying EDs for biocides and pesticides was also published in June 2018.
- In November 2018 the European Commission announced its intentions to evaluate EDs in other chemical legislation as part of a broad communication titled 'Towards a comprehensive European Union framework on endocrine disruptors'.

Our opinions and actions

Whilst there is a clear need to have the correct regulatory controls in place to protect our environment and human health from harm, it is CIA's position that the criteria for identifying and controlling EDs must also be fit for regulatory purpose.

CIA continues to support the European Commission's decision not to use a categories approach for biocides and pesticides; we advocate that the Commission should maintain this position in consideration of EDs associated with other chemical legislation. For the same reason and to ensure consistency across the Union, a category approach should not be implemented by individual Member States. Whilst we support the WHO-based definition as the basis for all legislative criteria taken forward, CIA would have preferred the inclusion of potency (i.e. the strength of a substance's activity) and additional criteria such as severity and reversibility of effect(s) which industry had previously advocated for. Importantly these would have ensured 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 have been 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.

With the ED scope for the BPR being widened to include all biocidal product ingredients, CIA calls for a pragmatic way forward in implementing this.

We also believe that for the PPPR, the Commission should revisit their

proposal for including a risk derogation for pesticides having a mechanism involving ED pathways, which was not included in the published criteria.

If the intention of the European Commission is to apply these criteria in the same manner to other chemical legislation then consideration must be given to both direct and indirect implications on the supply chain, particularly where risk-based considerations usually take place only after a substance is identified as a substance of very high concern (SVHC) on the basis of its intrinsic hazard properties alone (e.g. REACH).

CIA supports regulatory action to protect against exposure to proven harmful ED substances, but is equally concerned about substances of comparatively low concern being identified as possible EDs because this may result in companies immediately seeking substitutes and having to absorb the high costs associated with reformulation that might later be judged to have been unnecessary. 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 all the other costs they currently face to maintain regulatory compliant status, without adequate scientific proof that a substance causes harm to man and/or the environment. For this reason, CIA believes that the guidance for applying ED criteria must 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.

Conclusion

As this debate continues, the UK CIA asks you to lend your support to the above recommendations and encourage regulatory policy making based on sound science to enhance the protection of public health and the environment. 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. It is also critical for the regulators to demonstrate how such substances are of 'equivalent concern' compared with exposure to other SVHC's, namely carcinogens, mutagens, substances toxic to reproduction (CMR's), substances that are very persistent and very bio-accumulative (vPvB) or substances that are persistent, bio-accumulative and toxic (PBT). We ask the Commission and Member States to thereby work

with industry to ensure 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. This will inevitably result in unnecessary, 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.

Contacts:

Roger Pullin, Head of Environment & Health, Chemical Industries Association, UK

Tel. +44(0)20 7963 6738

Mob. +44(0)7951 387317

Email: pullinr@cia.org.uk

Simon Marsh, Director of Employment & Communications, Chemical Industries Association, UK

Mob: +44(0)7951 389197

Email: MarshS@cia.org.uk