PlasticsEurope
Association of Plastics Manufacturers

Endocrine Disruptors

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- **Chemical safety is paramount**
  Endocrine disruptors (EDs) are among the most discussed and investigated chemicals. The European Commission just recently set criteria to identify endocrine disrupting chemicals in the context of the Biocidal Products and Plant Protection Products Regulations. For 15 years, world-wide, science has advanced in this field, significantly improving the chemical framework in Europe. Meanwhile, more questions and concerns about the hormonal effects of substances have been raised. It is the industry's duty to take an active part in this debate and to share its views on how best to ensure safety; i.e. to identify and regulate endocrine disruptors of concern.

- **Identifying endocrine disruptors: Do not judge a book by its cover**
  PlasticsEurope supports criteria for identification of endocrine disruptors based on the WHO definition of EDs. However, for the definition to be effective in a regulatory context, more elements (such as potency) should be used to manage the potential risks of substances that can produce adverse effects directly linked to EDs mode of action. Other elements such as severity, (ir)reversibility and selectivity must also be included. The full hazard characterisation will allow differentiation between substances identified for which regulatory measures are needed and other substances of low potency that do not warrant a high concern. It is therefore crucial to adopt such an approach in order to best identify and regulate suspected endocrine disrupting substances.

- **Regulating endocrine disruptors: The dose still makes the difference**
  Certain natural substances can interact with the endocrine system, but would only cause adverse effects at doses that are never reached in real life. Below these doses, these substances can be consumed without concern. The same applies for synthetic substances that have similar effects: for these substances, safe doses are set far below the level at which any effects can be measured. Nevertheless, based on the non-monotonic dose-response hypothesis, some scientists claim that there are no thresholds below which an endocrine disrupting substance can be considered safe. According to a recent report commissioned by the European Food Safety Agency[1], this hypothesis "*as a common phenomenon is so far not supported for substances in the area of food safety*". So far, reported low dose effects could not be reproduced or confirmed by more comprehensive studies. To the contrary, most conclusive scientific results show that thresholds can in principle be set for EDs.

Key recommendations:

1. **Distinguish endocrine disruptors (EDs) from endocrine active substances**
   A substance should not be identified as an ED only because it interacts with or impacts the hormonal system. The EDs to be regulated are substances that cause *adverse* effects via that endocrine system.

2. **Make sure regulation considers the characteristics of adverse effects**
   In order to identify EDs of concern, regulation must also take into account the characteristics of the adverse effects that were observed during testing. Is the effect powerful, severe, or irreversible? Is there a link between the substance and the adverse effect? If these considerations were to be left out, it would be difficult to differentiate substances for which regulation is needed from those with the same low endocrine potency as carrots.

3. **Allow science to set thresholds for endocrine disruptors**
   Conclusive research shows that thresholds can be set for EDs. For this purpose, each substance needs to be considered on a case by case basis. In most cases a threshold can be set. Exceptionally, it may not be possible. In any case, regulation should not pre-empt the outcome of the assessment.

[1] *Review of non-monotonic dose-responses of substances for human risk assessment* EFSA, May 2016, available at http://www.efsa.europa.eu/fr/node/963923

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