



IFRA Position on the Identification, Assessment and Management of Endocrine Disrupters

There is a growing public concern about potential human health and environmental risks posed by so-called Endocrine Disrupters (EDs), i.e. substances with hormone-like activities thereby inducing adverse effects in humans or wildlife. In response, regulatory initiatives are being proposed within the EU in order to control, restrict or ban the use of EDs. The fragrance industry represented by the International Fragrance Association (IFRA) has a long history of supporting the safety of the materials it uses through science based safety assessments and as such has the following positions on key issues surrounding the proposed regulatory initiatives on EDs:

Concerning potential human health and environmental risks posed by Endocrine Disrupters, IFRA supports the following positions:

1. **Need for a clear definition of EDs:** there is an urgent need for a common, clear and unequivocal definition of EDs. According to the current IPCS/WHO definition, EDs are *substances or mixtures that alter function(s) of the endocrine system and consequently causes adverse effects in the intact organism, or its progeny, or (sub)-populations*. Therefore, in order to qualify a substance as an ED, there must be evidence for a) an *adverse effect* (toxicity) in an intact organism, b) a confirmed endocrine mode of action and c) a *causal link* between the two.
2. **Need for science-based regulatory actions:** regulatory actions should be science-based and taken on the basis of sound scientific (robust, reproducible and consistent) data. Regulatory actions should follow an appropriate risk assessment of the substance in question taking into account its potential risk to human health and/or the environment. Regulatory actions should always include a weight of evidence approach and only be taken on the basis of potential health/environmental risks, and not on hazard alone.
3. **Regulatory actions on a case-to-case basis:** regulatory actions should be taken on a case-by-case basis; if necessary, such actions should be relevant and proportionate to potential human or environmental health risks.
4. **Need for an open and transparent regulatory process:** the development of regulations of EDs should be an open and transparent process in which all stakeholders are able to participate in a discussion where all points are properly considered and evaluated by policy makers. The 'Smart Regulation' tools that have been developed in recent years under the 'Better Regulation' policy (impact assessments, stakeholder consultations) should apply fully.

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Concerning potential human health and environmental risks posed by Endocrine Disrupters, IFRA does not support the following positions:

1. **Lists of “potential EDs”:** the mere presence of substances in such lists may be misinterpreted as a suggestion that they may pose an actual health risk without consideration of the scientific evidence or outcomes of subsequent regulatory reviews/decisions. Therefore, creation of such “black lists” does contribute neither to improve the safety of human health nor to protect the environment, but rather creates unwarranted concern about substances that actually pose no or negligible risk. In addition, past experience with similar lists of potentially dangerous substances has shown that, once a substance has been listed, it is difficult to de-list it, even in the face of new evidence that justifies the exclusion of the substance.
2. **Disregarding potency:** potency plays a key role in a scientific risk assessment of all potentially dangerous substances, including carcinogens in food. There is no scientific basis for disregarding potency in the risk assessment of EDs.
3. **No thresholds for potential adverse effects of EDs:** default assumptions have been proposed that no thresholds exist below which EDs can be safely used. However, an absence of thresholds is inconsistent with the current knowledge of toxicology and pharmacology, which suggests that thresholds exist for practically all pharmacological / toxicological effects of substances that are mediated by biochemical pathways or receptors.
4. **Regulation on the basis of hazard instead of risk:** a hazard, rather than a risk assessment based approach has been proposed for the regulation of endocrine active substances. Given that all hazardous substances are regulated in all regions of the world on the basis of their potential risk (taking into account their potency/toxicity as well as the probability and amount of human local and systemic exposure) there is no scientific basis justifying the exemption of EDs from this principle. The fact that endocrine disruption is a mode of action, and not a toxicological endpoint requires an even more stringent risk-oriented approach.

IFRA welcomes the opportunity to discuss and review the European Commission strategy on EDs, and to assist in improving the European Regulatory framework.