New CLP classification requirements for possible endocrine disrupting effects

With this information sheet FoBiG would like to inform you about current developments regarding the classification of substances and mixtures with regard to endocrine effects.

With the Commission Delegated Regulation (EU) 2023/707, which entered into force on 20 April 2023, Regulation (EC) No. 1272/2008 (CLP Regulation) has been extended to include new hazard classes. In addition to new hazard classes for substances that are poorly degradable in the environment (PBT/vPvB and PMT/vPvM[1]), hazard classes were defined for substances with endocrine-disrupting properties. Similar to CMR substances, a distinction is made between substances with known or presumed endocrine disrupting properties (Category 1) and substances suspected of being endocrine disruptors (Category 2). The CLP Regulation requires that the effects on human health and on the environment are assessed separately. For all substances, a possible assignment to the following new hazard classes has to be considered:

Endocrine disruption for human health			
Category 1	ED HH 1	EUH380	May cause endocrine disruption in humans
Category 2	ED HH 2	EUH381	Suspected of causing endocrine disruption in humans
Endocrine disruption for the environment			
Category 1	ED ENV 1	EUH430	May cause endocrine disruption in the environment
Category 2	ED ENV 2	EUH431	Suspected of causing endocrine disruption in the environment

The following **deadlines** apply to labelling:

Substances must be labelled accordingly no later than 1 May 2025. Substances placed on the market before 1 May 2025, do not have to be labelled accordingly until 1 November 2026.

Mixtures must be labelled accordingly no later than 1 May 2026. Mixtures placed on the market before 1 May 2026, do not have to be labelled until 1 May 2028.

At a first glance, the deadlines appear sufficiently long. But, the evaluation regarding endocrine effects involves several labour-intensive steps:

1) Identification of relevant adverse effects;
2) Checking the evidence for endocrine activity;
3) Evaluation of a plausible link between the adverse effect and the endocrine activity.

For this purpose, companies are obliged to review all available studies (*e.g.* experimental, clinical, epidemiological and population-based) and to evaluate them with regard to their relevance, to conduct comprehensive literature searches for possible further published data, to evaluate available *in silico* and *in vitro* results as well as information from structurally related substances. The final evaluation then takes place in a weight-of-evidence assessment of all available data. The situation is further complicated by the fact that under REACH there are as yet no data requirements for testing and no guidelines for evaluating possible endocrine effects.

Taking into account that company-internal preparatory work is necessary to identify substances with high priority and high evaluation effort and that the corresponding ECHA guidance is not expected to be available until mid-2024, we recommend to screen and prioritize the substance portfolio at an early stage.

FoBiG has developed an evaluation concept internally. We are happy to support you with all questions and tasks in this context.

Please do not hesitate to **contact** us: ulrike.schuhmacher@fobig.de

[1] ; see FoBiG information sheet: New classification requirements for persisting substances