

# Endocrine disrupting biocides



## Why highly hazardous biocides must be phased out

According to the European Union's (EU) new biocide regulation, the marketing and use of biocides with highly hazardous properties will be prohibited in future. This approach is a new and important step towards improving protection of human health and the environment. However, implementation of the new regulation has been delayed, because the EU has suspended the obligatory deadline for defining criteria to identify the highly hazardous property of "endocrine disruption". The new political debate initiated by the EU Commission about how to deal with endocrine disrupting chemicals is now threatening to delay implementation of — or even reduce — the protective standards set out in European biocide regulations.

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## Hazard approach – learning from experience

The hazard approach aims to ensure that highly hazardous biocides and pesticides are banned from future use. In contrast to the classic risk approach, regulatory decisions that are based on this perspective do not take the potential for exposure to a specific substance and the probability of occurrence of negative effects into account. The hazard approach was supported by all EU bodies involved as a solution to various problems associated with the classic risk approach. Numerous examples from the past demonstrate that the usual risk assessment processes for regulating the use of chemicals are often inadequate in protecting human health and the environment and fail to meet the precautionary principle set out in EU law. Risks are frequently underestimated and decisions about threshold values or rules for use are often corrected only in part or after long delays. Just two examples are the endocrine-disrupting insecticide DDT or the antifouling agent TBT, which causes imposex (male sexual organs on female snails).<sup>7</sup>

Risk mitigation measures are not always effective in reducing exposure to an acceptable level. Some measures, for example, prove to be impossible to implement, leading to inappropriate use, poisonings, or accidents. As a result, the United Nations (UN) Food and Agricultural Organisation (FAO) has recommended, since 2006, a step-wise end to the use of highly hazardous pesticides<sup>8</sup>. A further issue is in some cases the possibility that no threshold value exists for some substances, since even the smallest concentration can have negative effects. These aspects apply especially to biocides and to endocrine disruptors.

## Biocide impacts – inadequate data

A further argument that supports the phase-out of highly hazardous biocides are the considerable gaps in existing data that make it difficult to assess the actual exposure of humans and the environment to these chemicals and the resulting impacts. Overall, the data on marketing, application, and exposure of the environment and humans to biocides is inadequate.<sup>9</sup> EU legal provisions on biocides do not require that such data be collected regularly and systematically. Rather, member states are only required to report to the EU Commission on the status of implementation of the biocide regulation every five years. Numerous biocides have to date not been subjected to an assessment of the validity of their approval within the context of the review programme for biocides that have been on the market before May 2000. As a result, the state of knowledge about the potential hazards and exposure levels differs considerably for various substances. It is expected that the review programme will not be completed until 2024<sup>10</sup>.

Exposure assessment for biocidal substances is highly complex. The EU Regulation on biocides lists 22 different types of uses of biocides, and an active substance can be approved for one or more of these types of products. Consequently, people and the environment can be exposed to a specific substance from various sources. In the course of the approval procedure, only one formulated product is examined as an example, and exposure scenarios are assessed on this basis. As a rule, the product that is assessed in this way is suggested by the applicant. With respect to use of these products, it must be taken into account that many are used by laypeople; moreover, there is a lack of harmonised standards for best practices in professional areas of use.

### Box 2 Exclusion criteria for highly hazardous biocides

(according to Art. 5(1), (EC) 528/2012)

**CMR substances:** carcinogenic or mutagenic or toxic for reproduction, Cat. 1a and 1b\*

**PBT substances:** persistent and bio-accumulative and toxic\*\*

**vPvB substances:** very persistent and very bio-accumulative\*\*

**Endocrine disruptors:** According to the EU Commission's Regulation on biocidal products and pesticides, criteria pertaining to EDs were to have been defined by 14 December 2013.

Interim criteria are: a) the combination of criteria C and R (carcinogenic and toxic for reproduction, Cat. 2\*); b) the combination of toxic for reproduction (R, Cat. 2\*) and evidence of having toxic effects on endocrine organs (e.g., the thyroid)

\* Substances that have been classified according to Regulation 1272/2008/EC (CLP) or are equivalent to such a classification

\*\* According to Regulation 1907/2006/EC, annex XIII

Six out of twenty-four biocides that are potentially relevant with respect to the drinking water supply<sup>24</sup> contain active substances that are possibly endocrine disruptive: 2-Phenylphenol, Diuron, Carbendazim, Cyproconazole, Tebuconazole and Thiacloprid.











