

## Case study on „Endocrine disruptors“

### Case study introduction

Endocrine disruptors, also called endocrine disrupting chemicals (EDCs), are at the centre stage of a scientific and regulatory controversy. Chemicals shown to have endocrine disrupting effects have mostly been man-made. They were originally engineered to produce benefits most importantly – but not exclusively – for industry and agriculture, households and consumers, as well as for medical and personal health care. Yet there is a link between such widely used chemicals and disorders within the endocrine (hormonal) system. For example, EDCs are seen to be a cause for chronic diseases, including infertility, obesity, diabetes, hormone related cancers, and cardiovascular disease. And because EDCs can be found in many products that people use or consume on a daily basis – including paint, food packaging, toys, clothing, cosmetics, and medicines – they can be the cause of serious harm to human health.

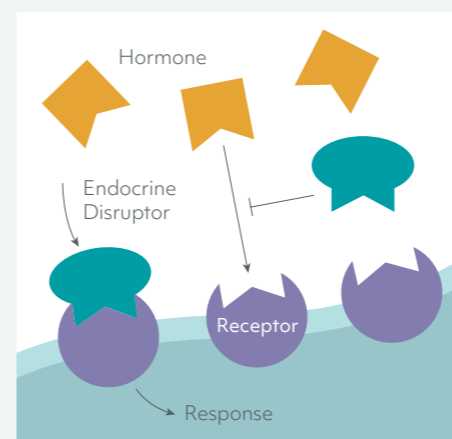
### Relevance to the precautionary principle

The precautionary principle is of utmost relevance for the governance of EDCs. Although EDCs can be seen as “a risk that concerns us all”, they pose risks especially to unborn

and young children. Moreover, the threats that EDCs pose are not limited to human health. Existing evidence indicates that exposure to EDCs also has a negative impact on wildlife health trends. The health risks for both humans and wildlife associated with EDCs became increasingly clear over the course of the 1990s. Various authorities, including the World Health Organisation (WHO) and the European Commission, subsequently issued studies investigating the potential harm caused by EDCs. But, problematically, even the very definition of EDCs remains highly contested, as do the scientific processes through which to identify them. To define which chemicals or substances are in fact to be considered EDCs is key, however, because this has important implications for how they are regulated.

The growing scientific evidence on the negative effects of EDCs for health and for the environment caused debate about the identification and regulation of EDCs within the European Union (EU). From 2014 to 2017, in particular, there has been controversy surrounding the Commission’s delay to set out scientific criteria for the determination of endocrine disrupting properties. Despite the subsequent establishment of criteria for the identification of EDCs in several – but not all – EU legislative areas, there are on-

going concerns about the suitability of the EU’s regulatory framework on EDCs. Such concerns include the absence of a horizontal definition of EDCs, which is a definition that cuts across various matters and subject areas, and more recent evidence that the health risks associated with EDC mixtures are underestimated.



EDCs general mechanism of action

### Potential impact

The fact that this issue of regulating EDCs was on the EU’s radar rather early, could lead one to expect a high level of regulation and a coherent approach. The opposite is the case, however. EDCs have sparked institutional controversy. This, however, did not change the regulatory approach of the EU regulatory authorities towards EDCs substantially, nor did this impact the use and application of the precautionary principle.

The Commission does not yet act systematically on the basis of the precautionary principle in the context of EDCs. Most notably, a ‘horizontal definition’ of EDCs is still missing and the Commission’s formulation of standards of proof are seen to be unattainable in practice. Moreover, for substances identified as endocrine disruptors, different regulatory approaches exist in dif-

ferent pieces of legislation. There is thus no harmonised EU legal framework yet on EDCs.

### Key uncertainties

Most importantly, the uncertainty about endocrine disruptors is the result of a large lack of data about the identification, the degree and the extent of risks arising from EDCs. This lack of data arises from practical scientific limitations in combination with the difficulty to disentangle the causal relationship between exposure to EDCs and biological changes or diseases.

Moreover, tests for the endocrine-disrupting properties of chemicals are highly time-consuming, and, as such, there is still a great lack of testing methods. For example, testing schemes are still in the process of being developed and revised; the hazard complexities of EDCs can only really be understood through multi-generational studies, and scientists question if current test methods are sufficiently sensitive to screen for EDCs. Thus, given large practical limitations and hazard complexity, uncertainty about EDCs in the form of a lack of data is likely to persist into the future.

And finally, there is scientific uncertainty about the effects of EDCs. It is incredibly difficult to determine the precise causal chains through which EDCs act on the hormonal

system of both humans and wildlife, including questions about whether there are thresholds for effects of EDCs, what the delayed effects of exposure are, and through which mechanisms natural hormones and EDCs may work together.



### Further information

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For the **references** used for the case study, please look into the full report available at:

[www.recipes-project.eu/results/case-study-3-endocrine-disruptors](http://www.recipes-project.eu/results/case-study-3-endocrine-disruptors)

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