

How to navigate through changing legislation on endocrine disruptors



Endocrine disruptors (EDs) are substances that can interfere with the function of the endocrine system. As a complex network of glands, hormones and receptors, the endocrine system is the key communication and control link between the nervous system and critical bodily functions like reproduction, immunity, metabolism and behaviour. Disruption to endocrine function can have adverse effects on the health of both humans and wildlife.

Endocrine disruption can occur in a number of ways. Some chemicals mimic a natural hormone, tricking the body into over-responding or responding at inappropriate times. Other EDs block the hormone from certain receptors, or cause overproduction or underproduction of hormones.

Strong evidence in animals, limited evidence in humans

Laboratory studies have shown that a variety of chemicals can disrupt the endocrine systems of animals. There is also strong evidence that exposure to EDs can interfere with developmental and reproductive processes in wildlife, such as fish, birds, molluscs and reptiles. On the other hand, there is limited evidence that exposure to EDs can cause these effects in humans. Adverse effects have been reported in humans exposed to relatively high concentrations of certain EDs. However, it remains unclear whether these effects are occurring in the wider human

population at concentrations present in the ambient environment, drinking water and food.

The relationship between environmental contaminants and human endocrine disorders is still poorly understood and scientifically controversial. In response, new requirements have been developed to test chemicals for their potential to interfere with the endocrine system.

Possible impact on humans

Several studies have reported declines in the quality and quantity of human sperm over the last four decades. Increases in breast, prostate and testicular cancer have also been reported. Such effects may be endocrine-related, which has led to speculation that they may be caused by chemicals in our food or the environment, but considerable scientific uncertainty remains. Nevertheless, there is little doubt that small disturbances in endocrine



function, particularly during highly sensitive stages, like development, pregnancy and lactation, can lead to profound, long-term effects.

Growing body of knowledge

Due to these effects, there is increasing concern throughout the world about the impact of chemicals on human and animal health. However, scientific knowledge in this area is still growing and what constitutes an ED is still the subject of scientific debate. Identifying substances with endocrine-disrupting potential among all the chemicals in use remains a significant challenge.

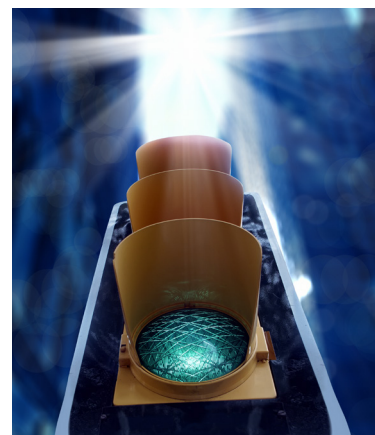
Legislative framework

In 2002, WHO defined an endocrine disruptor as a substance that shows a correlation between exposure to the substance, adverse effects, and a proven endocrine mode of action. In 2018, the EU agreed on

scientific criteria for the evaluation of EDs for the Plant Protection Products (PPP) Regulation and the Biocidal Products Regulation (BPR). Under Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), EDs can be identified as substances of very high concern along with chemicals known to cause cancer, mutations and toxicity to reproduction. The aim is to reduce their use and ultimately replace them with safer alternatives. Data requirements for identifying EDs are currently being developed for REACH and a draft proposal is expected in 2022. Within these frameworks, several testing protocols are also being developed and monitored.

Challenges and the way forward

In the meantime, data requirements along with testing and evaluation strategies for EDs represent a major challenge for manufacturers and importers in the EU. In addition, the legislation is constantly evolving. Plant protection products, biocidal products and cosmetics are currently the main focus areas, but toys, pharmaceutical products, food contact materials and other items may also come into play.



With over 50 years of experience, **TRISKELION** can help customers navigate this rapidly changing landscape. We have extensive, up-to-date knowledge of PPP, BPR and REACH along with experience in ED assessment. By thoroughly reviewing a customer's current data, our experts can:

- Identify data gaps, conduct risk assessments and recommend courses of action
- Advise on testing strategies and study plans, contract out research studies and monitoring
- Perform detailed literature searches and assess its reliability and applicability
- Draft scientifically-based expert statements and compile detailed reports for submission to the regulatory authorities

For all these services, customers have a single project manager as their point of contact to ensure streamlined communication and efficient handling of cases.