SETTING THE RIGHT CRITERIA TO IDENTIFY ENDOCRINE DISRUPTORS

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There is concern about the possible negative effects of endocrine disruptors on human health and the environment. Although these substances are currently regulated by the interim criteria in place in the plant protection products and biocides products regulations, achieving regulatory clarity is in everyone's interest.

What is an Endocrine Disruptor (ED)?

In 2002 **the World Health Organisation (WHO)** published the following definition: *"An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations."*

The **endocrine system** is what is commonly known as the hormonal system. This system is naturally prepared to adapt to hormonal stimulations. The human body takes in endocrine interacting substances on a daily basis (coffee, soya, etc.) and it remains in a healthy balance on its own.

This definition requires that: The substance acts through an endocrine mode of action altering the system's function and this alteration is the cause of an adverse effect.

History and timeline

The European Commission (EC) has been working on endocrine disruptors since the 1990s. It committed to adopt final criteria in the context of the plant protection and biocides products regulations in December 2013. But unfortunately, the EC failed to meet its deadline, due to the complexity of the problem. As health and environment protection are at stake, the objective is to set the best scientific criteria.

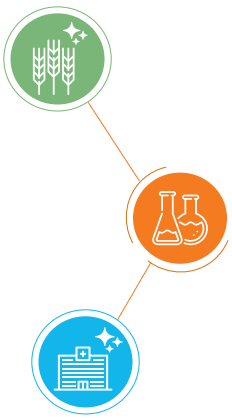
In June 2014 the EC published a roadmap with **4 policy options** to define criteria and undertook a public consultation allowing all stakeholders to inform the corresponding impact assessment. The 4 policy options are:

1. No change in the regulatory measures, interim criteria to remain
2. WHO definition to be integrated into the EU regulatory framework
3. WHO definition + categories based on the different strength of evidence of substances
4. WHO definition including potency (hazard characterisation)

The EC has completed this impact assessment. For biocides and crop protection products the impact assessment determines which substances are identified as EDs by the different policy options, and evaluates the **impact on health, economy and society.**

Why are criteria needed for Endocrine Disrupting Chemicals?

In the following, it is essential to differentiate between substances which simply interact with the endocrine system (i.e. endocrine active substances) from those which can cause an adverse effect via this interaction (i.e. endocrine disruptors).



Exposure to an endocrine active substance does not mean that it automatically causes an adverse effect on human health or the environment. For **clarity** and **legal certainty, scientific criteria** are needed to identify those chemicals of regulatory concern, and enable **harmless substances** to further bring major **value to society** and the European economy.

Chemical substances are used on a daily basis for the benefits they provide. Moreover, some directly **protect humans and the environment.** For instance, crop protection products allow farmers to grow healthy crops and biocides allow our hospitals and households to remain clean and free of germs.

Endocrine Disrupting Chemicals are currently regulated

In the absence of final criteria, **interim criteria** have been put in place for biocides and crop protection products, thereby **ensuring a secure framework** for the protection of people and the environment. Nevertheless, it is important to note that these interim criteria judge substances to be endocrine disruptors based only on their toxicological classification and not on their mode of action. For this reason, the interim criteria can lead to substances being treated as EDs when they are not. The consequence is that some useful, harmless substances will not be able to be used for the protection against specific bugs or diseases.

What should criteria look like?

We support the use of the WHO/IPCS definition. Nevertheless, for the definition to be effective in a regulatory context, **elements of hazard characterisation (such as potency) are needed**. The purpose of the definition is to enable the regulator to identify those substances that need to be regulated. If the netting is too fine to catch only the intended substances, then the regulator will fail to regulate only substances that truly pose a threat to human health or the environment.

POTENCY

is the capacity of a substance to induce adverse effects. Potency is in direct relationship with the level of concentration at which adverse effects can be observed.

Potency is not *dosage*. At similar dosage, a highly potent substance produces a greater effect whereas a substance of low potency will produce little or no effect.
Two analgesics ("painkillers") may have very different potencies. 500mg of acetylsalicylic acid will relieve a mild headache, whereas 500mg of morphine will alleviate strong pain such as that following surgery.
Unless potency is taken into account, we run the risk of considering a harmless substance as an ED. This renders the definition essentially meaningless.

SEVERITY

Severity describes the magnitude of an adverse effect and/or the nature of the adverse effect.

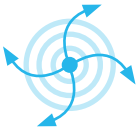
IRREVERSIBILITY

there is no recovery after exposure has stopped

Our hormone system is prepared to react to hormonal stimulations and to recover after exposure. In circumstances where the effect is permanent, we refer to it as irreversible

LEAD TOXICITY

The lead, or most sensitive, toxic effect considers the dose response of all the toxicity effects of a substance. It refers to the adverse effect that occurs at the lowest dose.



SPECIFICITY

For a substance to be considered to have endocrine disrupting properties, the adverse effect should occur as a consequence of a primary endocrine mode of action.

Are categories relevant or not?

Some stakeholders are proposing categories to distinguish types of "endocrine disruptors". Whilst having one category of confirmed endocrine disruptors would **achieve the first priority,** which is to identify the substances to which regulatory provisions apply, multiple categories would lead to regulatory uncertainty and unpredictability. At best, categories could indicate that there is a need to undertake some further testing; but that is not the purpose of these criteria. EU regulations already have adequate provisions in place to review and evaluate substances requiring additional testing.

1. **Endocrine disruptors**
2. **Suspected endocrine disruptors**
   Lack of evidence → further testing needed to identify if the substance is an ED or not
3. **Endocrine active substances**
   Substances that interact with the endocrine system but no adverse effect results

The categorisation of substances in this way is not relevant because it fails to achieve legal certainty to identify substances of regulatory concern. Cefic supports a single category which requires the following criteria to have been met after a weight of evidence approach:

Endocrine disruptors

- Adverse effect
- Endocrine mode of action
- Causality
- Relevant potency
- Severity
- Lead, or most sensitive, toxicity
- Irreversibility
- Specificity

For more information, please contact
Peter Smith
Executive Director Product Stewardship
Tel. 02 676 72 23
psm@cefic.be
www.cefic.org

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European Chemical Industry Council
Avenue E. van Nieuwenhuyse 4 B-1160 Brussels Belgium
Tel. +32.2.676.72.11
mail@cefic.be **www.cefic.org**

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