



# Endocrine Disruptors

What can we expect



**Craig Barker**



# Endocrine Disruptors

---

## What is the endocrine system?

The endocrine system is a complex system of glands that regulates levels of hormones. These glands and hormones control or influence various bodily functions such as metabolism, blood pressure, growth and reproduction. Well-known hormones include adrenaline, insulin, estrogens and testosterone.

## What is an endocrine active chemical?

An endocrine active substance is a chemical which causes a reaction with the hormone system (endocrine effect) via a receptor (lock and key) mechanism. Such endocrine activity should not necessarily be regarded as an adverse.

# Endocrine Disruptors

---



## What is an endocrine disrupting chemical?

An endocrine disruptor is an 'exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes **adverse effects** in an intact organism, or its progeny, or (sub) populations.' (World Health Organization (WHO)/Programme for Chemical Safety (IPCS))

# Endocrine Disruptors

---



## State of Play

There are four pieces of legislation within the European Community that have requirements that deal explicitly with Endocrine Disruption, ED.

**Plant Protection Product Regulation, PPPR  
(1107/2009)**

**Chemicals Regulation REACH (1907/2006)**

**Biocidal Product Regulation BPR (528/2012)**

**Cosmetics Products Regulation (1223/2009)**

The first three pieces of legislation require action during 2013 with the fourth piece by 2015.

# Endocrine Disruptors

---



On behalf of the Commission, DG ENVI was given the task of defining the strategy and setting of criteria suitable for working across the various regulatory requirements.

Initial proposals were to adopt a system very similar that that used for carcinogens – criteria defining three categories.

This proposal has now reduced to two categories:

- 1. Endocrine disruptors**
- 2. Suspected endocrine disruptors**

# Endocrine Disruptors

---



**Industry does not agree with the use of two categories and has been advocating for only one set of criteria.**

**We believe that the second category covers only substances that exhibit limited evidence of endocrine mediated adverse effects and as such are insufficient to place them into category one.**

**These substances are therefore perfect candidates for stigmatisation!**

# Endocrine Disruptors

---



The criteria is also lacking in many aspects deemed necessary to make a suitable determination across many various types of legislation.

Firstly identification of Endocrine Disruptors must clearly show an endocrine **Mode of Action**

Criteria should also make use of comprehensive **Hazard Assessment** requirements (**Identification and Characterisation**) and thus take account of Potency Lead toxicity, Severity and Irreversibility

# Endocrine Disruptors

---



## Other Players

**Apart from DG ENVI there are other significant players within the Commission.**

**DG SANCO (Crop protection and Cosmetics)**

**DG ENTR (REACH)**

**Other interested DG's include Trade, R&I, AGRI to name but a few.**

**Together with the EU Parliament who had earlier debated the ED topic under Åse Westlund's Own Initiative and the Member State Competent Authorities.**

# Endocrine Disruptors

---



**Further issues which have only recently come in the debate!**

**At a meeting of the CARACAL in May a proposal was made to consider endocrine disruptors as non-threshold substances and as such limit the authorisation to those substances meeting the requirements defined by a socio economic assessment, SEA.**

**At the Last Ad hoc meeting on EDs many Member States agreed with industry that **experimental thresholds** for EDs can be set but that it would be extremely difficult to define a suitable **regulatory threshold**.**

# Endocrine Disruptors

---



## Next steps

DG ENVI is presently informally discussing with the other DGs their proposals.

Shortly they will enter into the formal Commission discussions – **Inter-Service Consultation**

By mid- to late July this process is expected to be complete and the criteria is expected to be released following the summer break in September

# Endocrine Disruptors

---



## What is now industry's stance:

**We still feel the criteria will cause many problems especially regarding the none use of full hazard characterisation and thus capture too many substances.**

**A second category will cause many concerns for those substances listed as this holds an unknown future.**

**An impact assessment should be commissioned regarding this issue (not technically required as the criteria is not a change to legal requirements).**

**The ability to use standard risk assessment (exposure derived) techniques must be supported in the Authorisation process.**