



Ministry of Environment
and Food of Denmark
Department

ED Criteria

A Policy perspective from Denmark

Endocrine disruptors in the
EU - state of play
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ED Criteria - A policy perspective from Denmark

Agenda

- **Background**
- **The criteria for endocrine disrupting properties**
- **Denmark's position on the criteria**
- **Denmark's comments on the guidance document**
- **Implementation challenges**
- **Regulatory decisions**
- **The way forward**



Background

High public and political interest in DK:

- **Health: Poor semen quality, high testicular cancer rates...**
- **Environment: inter-sex in fish in Danish streams**
- **Research – Prof. Skakkebæk one of the fathers of estrogen hypothesis and testicular dysgenesis syndrom**
- **Developing test methods since 2003 – TG 414 latest achievement**
- **Dedicated knowledge center since 2008 – in 2018-2021: 4 mio. €**

EU [Strategy on Endocrine Disruptors](#) since 1999

- Taken into account in EU legislation – *at least partly*

The 7th Environment Action Programme (EAP) provides for

- **safety concerns on ED's effectively addressed** in all EU legislation
- **harmonised hazard-based criteria** for identification of EDs
- **aims at minimisation of exposure** to EDs



Legal Framework

The **Plant Protection Products Regulation (EU) 1107/2009** and the **Biocidal Products Regulation (EU) 528/2012** provide for the establishment of scientific criteria to identify substances with endocrine disrupting properties.

Additional regulatory provisions for endocrine disruptors are covered under **REACH**, the regulations on **cosmetics** and **medical devices** (refer to REACH and BPR)



EU policy goals - Council Conclusions 2016

Council Conclusions in 2016 on the protection of human health and the environment through the sound management of chemicals

- **CALLS UPON** the Commission to **comply with the relevant 7th EAP provisions** when further developing those criteria in order to better protect humans and the environment from endocrine disruptors
- **INVITES** the Commission to subsequently **update**, as appropriate, **the 1999 EU endocrine disruptors strategy**



Legislation



Pesticide regulation (EU) 1107/2009 on ED

- An active substance shall **only be approved** ...if it is **not** considered to have **endocrine disrupting properties**.....unless the exposure.....is negligibel.

Biocide regulation (EU) 528/2012 on ED

- The following active substances shall **not be approved**....active substances which ..**on the basis of the criteria**...are considered as **having endocrine properties**...
- but 3 derogations: negligible risk, prevention of serious danger, or disproportionate negative impact on society

REACH regulation Article 57(f) – Substances of Very High Concern

- Case-by-case which give rise to an **equivalent level of concern** as CMRs PBTs and vPvBs



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The criteria for endocrine disrupting properties

BPR / PPPR:

A substance shall be considered as having endocrine disrupting properties if

- **it shows an adverse effect** in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;
- It has an **endocrine mode of action**, i.e. it alters the function(s) of the endocrine system;
- the **adverse effect is a consequence** of the endocrine mode of action.

WHO definition of ED 2002:

- 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



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Summary of ED Criteria:

- Adverse effect
- Endocrine mode of action
- Causality
- *and provisions on how to show that the substances fulfil these elements*

Denmark voted against the PPPR criteria and made a declaration on BPR criteria:

- Unprecedented high level of evidence and demand of proof of causality required
- Not in line with CMR criteria
- No categories e.g. “known”, “presumed” and “suspected”
- Do not properly reflect today’s scientific knowledge on ED’s

- Will not identify substances for which there are substantial data indicating ED – have the criteria minimised the ED challenge?



The Guidance Document for biocides and pesticides

- The GD is co-herent with the criteria
- It is highly technical/scientific
- It is intended to be used from november 2018 for both biocides and pesticides
 - It only covers: Estrogen, Androgen, Thyroid and Steroid modalities

DK welcomes:

- the GD accepts the concept of biological plausability
(i.e. does not require test of mode of action for substances where there is prior knowledge of ED properties)
- the GD paves the way for a more harmonised approach of performing peer reviews of assessment of active substances



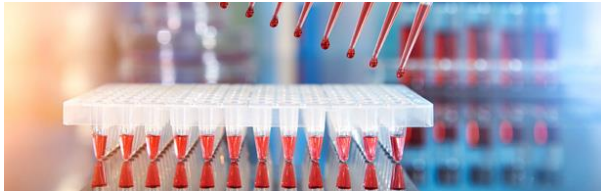
Implementation challenges for biocides and pesticides

Experience with use of criteria is necessary

- **First experience: many assessments inconclusive**

Criteria+guidelines: what do we do if results are inconclusive?

- **Request additional testing? – We already have the highest data requirements on biocides and pesticides**
- **Which additional tests/data should be required?**
- **How will additional data requirements be received by public/industry?**



Regulatory challenges for biocides and pesticides

Options: Approval or non-approval – what is the consequence of inconclusive results?

Consequences for active substances under review:

- **For pesticide and biocide active substances under the renewal process delays in decision making will occur – due to "clock stop" to obtain additional data**
- **For biocidal active substances an intermediate period between the application date of the criteria and the application date of the GD will exist. How to handle this has not been decided**
- **Regulatory decision if deadlines for additional data submissions in pesticide and biocide regulations are not met?**
- **How long a delay is acceptable?**



The way forward for biocides, pesticides and industrial chemicals

Get experience with new ED criteria for pesticides and biocides

Continue identification of ED's as Substances of Very High Concern under REACH

Compare experiences across legislation, revise criteria accordingly and amend data requirements, as appropriate

- Update ED strategy:
 - Continue to **develop/revise test methods** including *in-vitro* batteries
 - **Adjust data requirements** to new scientific achievement and include new or revised OECD TGs asap
 - **List all** identified and suspected **EDs**
 - Make **strategy for the testing and assessment** of all suspected EDs
 - **Holistic** approach to **risk management** of ED's under different legislations

Introduce "fast track" provisions for ED's in consumer products comparable to CMR substances



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Thank you for your attention!

Any Questions?

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