Federal Environment Agency (UBA)
Devision IV Chemical and Biological Safety
Germany

Umwelt Bundes Amt
Für Mensch und Umwelt

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UBA discussion paper on criteria for endocrine disrupters for wildlife

Background

In 2011 UBA circulated a proposal on how to handel substances having endocrine disrupting properties from a regulatory perspective (see attachment).

In principle it advocates to devide three groups and suggests how to handle these three groups from a regulatory perspective as summarized in table 1:

Table 1: Summary of UBA proposal to devide three groups

Group 1	**Group 2**	**Group 3**
Endocrine Disruptors subject to hazard based measures Substances fulfilling the scientific IPCS definition and for which the endocrine activity is not the intended mode of action	**Substances having endocrine activity but which are not Endocrine Disruptors** Substances not fullfilling the the IPCS definition(e.g. in vitro endocrine activity but it is unclear if the activity results in adverse effects)	**Endocrine Disruptors for which the endocrine disruption is the intended mode of action** Substances fulfilling the IPCS Definition and for which the endocrine activity is the intended mode of action in case it results in a specific, beneficial overall profil with regard to the environment (Biocides / Pesticides) or its benefits for the society (pharmaceuticals)
Hazard based assessment and regulation: REACH: SVHC Identification Biocides, Pesticides: non-approval	**Risk based assessment and regulation (and / or further data requirements)**	**Case by case decision to exempt this group from hazard based regulation based on risk-benefit and/or socio-economic analysis**

This discussion paper further amends the proposal by suggesting a stepwise procedure for the assessment and by adapting a category approach recently suggested by the European Commission (DG Environment).

Stepwise procedure

In order to analyze whether or not a substance having endocrine disrupting properties should be regulated risk or hazard based, two steps are proposed

Step 1: *Identification of Endocrine Disruptors*

- Analysis whether or not a substance is an Endocrine Disruptor according to the IPCS / WHO definition (i.e. analysis if a substance falls in the first or second of the above mentioned group)[1].
- Categorization of substances according to the outcome
  Note: Further guidance is needed on how and based on which data / level of evidence the substances should be categorized.

Step 2: *In depth analysis of Endocrine Disruptors with an intended endocrine mode of action*
Analysis whether or not an Endocrine Disruptor should fall in the third group (intended mode of action) due to its selective endocrine activity and/or its overall beneficial profile.

Regulatory outcome and characterization

Outcome of step 1 (Identification of Endocrine Disruptors)

As a result of the first step, substances should be categorized according to their endocrine potential:

- Substances which fulfill the IPCS/WHO definition for Endocrine Disruptors should be considered as identified Endocrine Disruptors (Category 1 – known Endocrine Disruptors)
- Substances with an indication of endocrine activity but without conclusive information should be carefully checked.
  - If exhaustive information is available but no conclusion can be drawn (e.g. due to lack of knowledge) such substances should be labeled accordingly (Category 2a – suspected Endocrine Disruptors)
  - If further information would help to clarify whether or not the substance is an Endocrine Disruptor, such information should be requested under the respective legislation (Category 2b – indicated Endocrine Disruptors)

Substances allocated to category 1 or category 2 are handled differently:

- Substances allocated to category 2 (indicated or suspected Endocrine Disruptors) fall into group 2 of table 1. Either further data are awaited for a final decision (Category 2b substances) or the decision is that – despite an exhaustive set of information -

[1] Please note that the criteria should be applied to vertebrates and invertebrates. Substances interacting with the hormonal system of plants should not be considered Endocrine Disruptors.

current information/knowledge is not sufficient to decide whether or not they are Endocrine Disruptors (Category 2a substances). Such substances should be handled by the usual risk assessment methods according to the different regulations.

- For substances allocated to category 1 (identified Endocrine Disruptors) step 2 applies

The proposed categorization as well as the outcome is summarized in flow-chart 1.

Outcome of step 2: In depth analysis of Endocrine Disruptors with an intended endocrine mode of action

In general hazard based regulatory measures are considered adequate for Cat 1 Endocrine Disruptors (i.e. substances should fall in the first group described in table 1 "Endocrine Disruptors subject to hazard based measures").

However for Biocides, Pesticides and Pharmaceuticals an exemption from hazard based measures might be appropriate based on risk-benefit or socio economic considerations and thus such substances would fall in the third group:

Active biocide or plant protection substances with an intended endocrine mode of action on invertebrates:

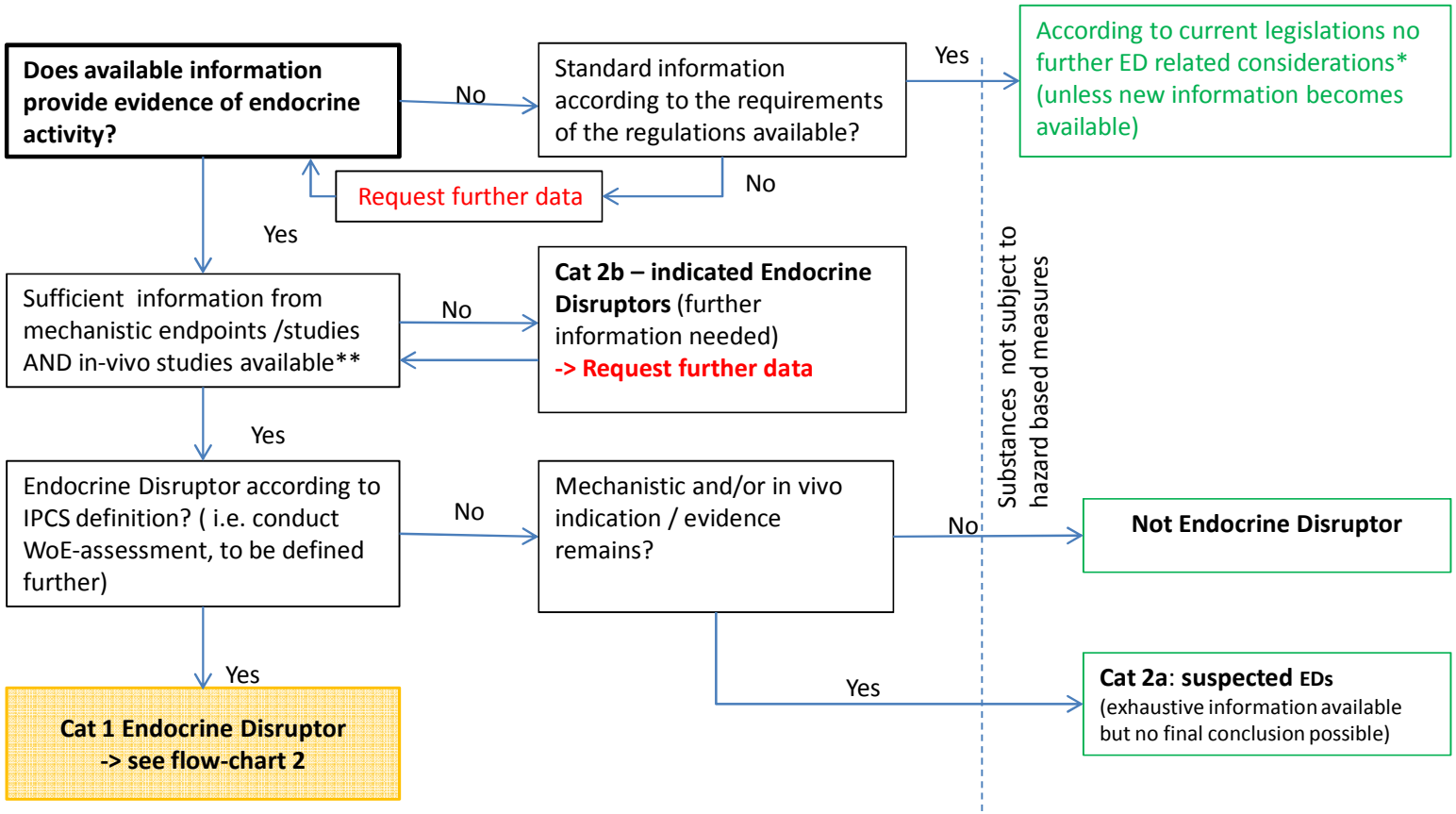
For such substances with a very specific endocrine mode of action for a group of organisms (i.e. they are not Endocrine Disruptors for vertebrates) a case by case consideration seems appropriate. If, based on a careful risk benefit analysis (including aspects such as comparative hazard profiles, specificity and persistence) or socio-economic analysis, the benefit outweighs the disprofit, it might be justified to exempt them from hazard based measures (i.e. non-approval according to the plant protection product and biocidal products legislations).

UBA suggests to analyze whether or not the Biocide and Plant protection regulations allow such an exemption.

Pharmaceuticals:
No hazard based regulation is implemented in current legislations for pharmaceuticals. Endocrine Disruptors used as human or veterinary pharmaceuticals are subject to a risk assessment procedures.

The proposed regulatory outcome for known Endocrine Disruptors (Category 1) is summarized in flow-chart 2

Flow-chart 1
Step 1 Identification of Endocrine Disruptors



*note that standard requirements in some legislations (e.g. REACH) are not sufficient to provide evidence for endocrine activity

** further criteria/ guidance needed to decide which information is considered sufficient

Flow-chart 2
Step 2 – In depth analysis of Endocrine Disruptors with intended endocrine mode of action