

Hamburg, 4<sup>th</sup> April 2017

To: Members of Biocides Competent Authorities (CA) Meeting

*Sent by email only*

**PAN Germany comments ahead of the CA meeting on 7<sup>th</sup> April 2017 on the draft delegated regulation for the determination of endocrine disrupting properties with special focus on the proposed loophole for substances that have an intended endocrine mode of action**

Dear Members of Biocides Competent Authorities (CA) Meeting,

Ahead of the discussions on the criteria for endocrine disrupting chemicals in the Competent Authority (CA) meeting on 7<sup>th</sup> April 2017 under the Biocides 528/2012 Regulation, we would like to share our comments regarding the revised draft Commission proposal.

As an environmental and consumer protection organisation, PAN Germany would like to express its major concerns with regard to the proposed exemption concerning non-target organisms for substances that have an intended mode of action to control the target organisms via their endocrine system (ANNEX, Section B, point 3) in the latest draft proposal from March 2017.

**We recommend to delete the exemption clause<sup>1</sup> from the proposal because:**

1. it excludes certain substances with known endocrine disrupting properties from the identification without any scientific justification;
2. it is a regulatory measure and mixes substance identification with risk management;
3. it would undo the ban of sale to the general public of products with endocrine disrupting properties under Art. 19(4)(d), which is clearly beyond the mandate of the Commission to come up with scientific criteria for identifying EDs;
4. it is unclear what the consequences would be for Article 19(1)(b)(iv) in particular the third indent, on the conditions for granting a product authorisation (no unacceptable effects on non-target organisms);
5. it is unclear what the consequences would be for the data requirements e.g. on "identification of endocrine activity" (Annex II, Title 1, point 9.10) and "effects on any other

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<sup>1</sup> Delete: "If the intended biocidal mode of action of the active substance being assessed, within the meaning of point 6.5 of Annex II of Regulation (EU) No 528/2012, consists of controlling target harmful organisms other than vertebrates, via their endocrine system, the effect on organisms being of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms."

specific, non-target organisms (flora and fauna) believed to be at risk” (Annex II, Title 1, point 9.1.8);

6. it is unclear what the consequences will be for the labelling requirements under Article 68(2)(n);
7. such substances may no longer qualify as candidates for substitution under Art. 10(1)(e) and thus escape the requirements of the comparative assessment procedure (Article 23).

It is clearly inappropriate for the Commission to adopt exemptions such as the exclusion of certain biocides from regulatory requirements via the backdoor of a delegated act. The proposed exclusion clause will decrease the level of protection of the environment and for human health. This is diametrically opposed to the intention and the spirit of the BPR.

**We therefore urge you to ensure that ALL substances with endocrine-disrupting properties will be identified in the context of the delegated act under discussion. Any regulatory changes of the basis act that you might like to see would require a modification via the ordinary legislative procedure and should not be dealt with by the delegated act. Your decision will be a critical contribution to the urgent efforts to prevent endocrine-related diseases for Europeans and averting damage from our ecosystems.**

Yours sincerely,



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