

## Comments on CA Document Dec16-Doc.3.1.a: Draft criteria for the determination of endocrine-disrupting properties under the BPR

In the revised draft delegated regulation setting out scientific criteria for the determination of Endocrine Disrupting (ED) properties, the following main changes have been made:

1. Replacing *active substance* with *substance* throughout the Annex.
2. Section A, Point (1): Replacing “*identified*” with “*Considered*”.
3. Section A, Point (2)(a)(i): Introducing “*in silico studies*”
4. Point 2c: deletion of “*quality reliability, reproducibility and consistency*”
5. Section B, 1a - “population relevance” has been omitted
6. Section B, point 2 (c, iii): “...and other relevant adverse effects which...” added to the original
7. Section B, 2: addition of paragraph (e) on the mode of action

We would like to comment as follows on the respective changes:

### 1. Replacing *active substance* with *substance* throughout the Annex.

We recognise that BPR includes specific requirements for non-active substances identified as substances of concern according to the definition in Article 3.1(f).

Notwithstanding the above, we believe that the legal mandate of the Commission to develop ED criteria is clearly exceeded with the broadened scope of the proposal from “active substances” to “substances”. The legal mandate provided to the Commission for the adoption of ED criteria is clearly framed by Article 5(3) BPR, which is entitled ‘exclusion criteria’ and is part of a broader Chapter on the Approval of Active Substances. Article 5.1(d) specifically refers to the ED criteria to be adopted by the Commission in connection with active substances. Article 5(3) specifies the interim criteria to be applied for active substances pending the adoption of the delegated act. Therefore, from a legal perspective, the delegated act on ED criteria should be limited to active substances.

Looking beyond the legal framework, with the current change (i.e. ‘substances’ instead of ‘active substances’) together with the use of even more subjective language into the text (i.e. “*considered*” vs “*identified*”), the introduction of “potency” and other hazard characterisation elements as well as a safety threshold into the criteria becomes paramount.

### 2. Section A, Point (1): Replacing “*identified*” with “*Considered*”.

We recommend the Commission and Member States not to use subjective language such as “considered” instead of “identified” as this is likely to lead to inconsistency at product authorisation level.

### 3. Section A, Point (2)(a)(i): Introducing “*in silico studies*”

We would like to remind that the definition refers to an adverse effect in an intact organism. Therefore, we believe that “*in silico studies*” may only be used in a weight of evidence approach to defend or weaken the link to an ED Mode of Action (MoA) but not to define a substance as having ED properties.

### 4. Point 2c: deletion of “*quality reliability, reproducibility and consistency*”

We recommend that studies used for the assessment of the criteria are accepted in line with the currently acceptable practise applied with REACH and BPR, whereby a reliability rating is continued to be used.

#### 5. Section B, 1a - "population relevance" has been omitted

The regulatory measures should enable regulators and the industry to distinguish between substances and products that pose a real danger of ED and those that are harmless in any foreseeable conditions of use.

Population relevance is an important factor when judging the effect of active substances on eco-tox systems and the removal would further lead to blurring the lines of substances that pose danger with those that don't. On the other hand no additional margin of safety for the environment will be gained through the deletion of population relevance if an effect which "by its own definition" is not relevant to the population. Moreover, the rewording requires the applicant to prove a negative, which is scientifically not possible. We thus recommend Commission and Member States to revert to the initial wording.

#### 6. Section B, point 2 (c, iii): addition of "...and other relevant adverse effects which..."

We recommend the Commission and Member States not to introduce confusing wording that may lead to different interpretation and is likely to lead to further inconsistency at product authorisation level.

#### 7. Section B, 2e: addition of: *"If the mode of action of the active substance being assessed, as defined under point 3.6 of Part A of the Annex to Commission Regulation (EU) No 283/2013, acts by regulating moulting and/or growth of harmful organisms via their endocrine system, it shall not be considered for the identification of the substance as endocrine disruptor with respect to non-target organisms"*.

We support the proposal that a substance shall not be considered as an ED for humans if the Mode of Action is not relevant for humans.

Applying the current Commission proposal as it stands would ban specific substances with proven valuable contributions to public health and society, purely on the identification of a possible effect, disregarding the fact that in their current use, there are no safety concerns to humans, animals or the environment. This, in our view, is a clear demonstration that the current proposal needs further improvement.

We remain of the opinion that measurable scientific criteria, considering the potency of the substance and establishing a safe threshold is crucial. This will ensure that the regulatory system will safeguard the necessary screening, but avoid the scientifically unjustified banning of harmless substances and products that ensure the protection of humans and animals from harmful organisms (such as disinfectants or pest control products) and contribute to a more sustainable use of a large variety of products (such as preservatives).

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#### About EBPF

The European Biocidal Products Forum (EBPF) is a sector group of Cefic, composed of more than 70 companies and trade associations representing the industry that places a wide range of biocidal products on the market for the benefit of EU citizens.