

EBPF – European Biocidal Products Forum



To:

██████████

European Commission

████████████████████

Members of the Competent Authorities for the implementation of Regulation (EU) 528/2012 on biocidal products

14th of November 2016

Re: Scientific criteria for the determination of endocrine-disrupting properties, 67th Biocides Competent Authorities meeting, 18 November 2016

Dear ██████████

Dear members of the Biocides Competent Authorities meeting,

Ahead of the 67th Biocides CA meeting on 18 November 2016 and in view of the discussion on the Commission's proposal for the criteria for endocrine disrupting properties, the European Biocidal Products Forum (EBPF) – a Sector Group of Cefic - would like to bring to your attention our position on this significant issue.

The European Chemical Industry is keen to ensure that people and the environment are not adversely affected by endocrine disruptors. However, we are, at the same time, anxious to ensure that people are not unnecessarily deprived of the use of substances that are safe.

Based on our current understanding of the revised criteria which will be discussed during the upcoming CA meeting on November 18th, we remain of the opinion that the proposed draft does not provide scientific criteria that are fit for purpose and we request Member States Competent Authorities and the Commission to further improve the proposal.

Firstly, the proposal restates the WHO/IPCS definition of an Endocrine disruptor as being a 'substance or mixture that alters function(s) of the endocrine system and consequently causes adverse effects in the intact organism, or its progeny, or (sub)-populations'. Cefic has consistently advocated the use of this definition. Whilst we welcome the efforts made by the Commission to clarify and tidy up the language of the text in order to closely follow the wording of the WHO/IPCS definition, we remain of the view that this same definition does not, in itself, provide scientific criteria for the determination of endocrine disrupting properties.

Secondly, the proposal states that assessing whether a substance falls within this definition should be done by comparing the weight of all the available scientific evidence. Cefic fully supports the weight of evidence approach, and welcomes the simplified language on this. Nevertheless, requiring a proper, objective weight of evidence assessment does not provide criteria for the determination of endocrine disrupting properties.

Chemistry making a world of difference

European Chemical Industry Council - Cefic aisbl
Avenue E. van Nieuwenhuyse 4 B-1160 Brussels Belgium
Tel. +32.2.676.72.11 mail@cefic.be www.cefic.org



Thirdly, to the best of our knowledge, the revised proposal still fails to specify measurable scientific criteria that would allow for the determination of endocrine disrupting properties. We believe that the current proposal still falls short of including the necessary elements that allow for a full hazard characterisation. Both the nature of the effect, including whether it is sufficiently severe to be considered adverse, and the characteristics of the substances, including whether it is sufficiently potent to have such an adverse effect in realistic conditions of use, need to be taken into account. The shortcomings of the current approach can be seen from the fact that, in the accompanying impact assessment, iodine has been identified as an endocrine disruptor – notwithstanding the fact that this substance is an essential element with a recommended daily intake.

The regulatory measures, including those regarding endocrine disruption, must enable regulators and the industry to distinguish between substances that pose a real danger of endocrine disruption and substances that, based on evidence and risk assessment, pose no harm to man and the environment and bring proven valuable contributions to public health and society.

We ask the Commission and the Member States to take into consideration our concerns above when reviewing the proposal.

Yours sincerely,

[Redacted signature]

EBPF manager

[Redacted name]

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.