POSITION PAPER

20th June 2016

Comments on the Draft Commission Delegated Regulation setting out scientific criteria for the determination of endocrine disrupting properties pursuant to Regulation (EU) No 528/2012

The European Biocidal Products Forum (EBPF) – a Sector Group of Cefic – believes that the proposed draft does not provide scientific criteria that are fit for purpose for use under Article 5 of the BPR, and we request Member States Competent Authorities to further improve the Commission proposal.

The criteria need to go beyond the mere identification of what constitutes an endocrine disruptor for them to be appropriate for regulatory decision-making. While we support the WHO/IPCS definition of an endocrine disruptor as a starting point, on its own, it does not provide meaningful criteria needed to allow appropriate screening of the substances by distinguishing between those causing real harm and those posing no threat to human and animal safety or the environment. We consider that the current proposal falls short of including the necessary elements that allow for a full hazard characterisation. It has to be noted that an understanding of a substance's potency and consideration of the existence of a safe threshold are appropriate and necessary elements that need to be taken into account, and therefore need to be added to the current Commission proposal.

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 is not fit for purpose and needs further amendment.

Article 5(3) of the BPR (Regulation (EU) 528/2012 concerning the making available on the market and use of biocidal products) requires the Commission to "specify scientific criteria for the determination of endocrine-disrupting properties". In our view, the draft Commission delegated Regulation does not provide such criteria, but rather gives the definition of an endocrine disruptor and recommends the weight of evidence approach for assessing whether a substance falls within this definition, as follows:

(a) The draft Commission delegated Regulation brings forward (in Section A paragraph 1, and in Section B paragraph 1) the WHO/IPCS definition of an endocrine disruptor.

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Industry has consistently supported this definition. According to it, an endocrine disruptor is 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'.* Although scientifically correct, the definition does not, in itself, provide scientific criteria for the determination of endocrine disrupting properties.

(b) Further, the Commission proposal recommends that assessing whether a substance falls within this definition should be done by comparing the weight of all the available scientific evidence.
Industry fully supports the weight of evidence approach. Nevertheless, requiring a proper, objective weight of evidence assessment does not provide criteria for the determination of endocrine disrupting properties.

The shortcomings of this approach can be seen from the fact that, in the accompanying impact assessment, iodine has been identified as a potential endocrine disruptor (under Options 2 and 3 Category I) – notwithstanding the fact that this substance is a physiologically essential element. It is needed for maintaining hormone homeostasis and has a recommended daily intake. This is an alarming and certainly unintended consequence of the Commission's proposal.

We strongly believe that the purpose of regulatory measures should be to enable regulators and the industry to distinguish between substances that pose a real danger of endocrine disruption and substances that are harmless in any foreseeable conditions of use. It has to be kept in mind that an endocrine mediated effect shown in laboratory conditions or in exceptionally high doses bear no relation to real human or environmental exposures.

We recommend MS and the Commission to amend the proposal to include measurable scientific criteria for the determination of endocrine disrupting properties. Two main elements that must be taken into account for a full hazard characterisation are the understanding of a substance's potency and consideration of the existence of a safe threshold.

Industry is certainly keen to ensure that neither humans nor any non-target organisms are adversely affected by endocrine disrupting chemicals. As a basic principle, the regulatory measures (including those regarding endocrine disruption) should ensure that the society is not unnecessarily deprived of the use of 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.

It has to be kept in mind that, in the Impact Assessment, only the substances for which sufficient information was available, i.e. active substances that were approved at EU level, or where an opinion of the Biocidal Products Committee of ECHA was available, were screened. This means that the screening is not representative of all existing biocidal active substances/product types. Thus, the result of the screening should be cautiously interpreted for the potential impact on all biocidal product types/user groups on the market. It is indeed not possible to judge how representative the screening results are within and across the product groups. It is therefore difficult to foresee the real number of products that may need to be taken off the market due to arbitrarily established endocrine disrupting properties. Industry would like to remind the regulators that the already over-conservative risk assessment is leading to a significant reduction in the number and variety of substances used in biocidal products. The proposed approach may significantly contribute to this reduction. This will contribute to the increase in resistance of the harmful organisms and may endanger human and animal health and the environment.

This is why using measurable scientific criteria, considering the potency of the substance and establishing a safe threshold is crucial. The regulatory system will ensure the necessary screening, but avoid the scientifically unjustified banning of substances used in 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.