Cefic – EBPF Comments on CA Document CA-Febr17-Doc.3.1.a & b: Draft criteria for the determination of endocrine-disrupting properties under the BPR

Cefic-EBPF is disappointed that Commission has retained the term “substance” instead of “active substance”, despite the legal arguments made by Industry in December 2016, when this change was first introduced. Cefic-EBPF requests Commission to revert to the original wording of ‘active substance’. We would also like to refer to the attached Cefic position paper, which provides more legal explanation supporting our position (please see 17-522a-Cefic-EBPF position on the extension of scope of ED criteria—legal considerations).

Within the existing legal text, the BPR provides clear provisions for addressing substances of concern. We, therefore, can see no added benefit in expanding the scope of the ED criteria beyond “active substance”. The implications of changing the definition to substance are indeterminable and at this current time, when no clear process exists, no mandate for the Biocide Competent Authorities (CAs) to classify non-active substances under the BPR and with no impact assessment conducted to identify the scope of the change, it is difficult to evaluate how this change will improve the functioning of the BPR or support the Commission’s Better Regulations Guidelines.

We therefore urge the Commission and Member States Competent Authorities (MS CAs) to take the following elements into account during the discussion on the current draft at the CA meeting of 28th February 2017:

1. The BPR provides clear definitions for ‘active substance’, ‘substance of concern’ and ‘substance’ in the legal text. In accordance with the BPR active substance and substance are not the same. The definition for substance is referenced back to the REACH text where the description is broader and less specific (purity, impurity content etc.) than the active substance definition under BPR.

2. There are various articles defined in the BPR, which address Substances of Concern (Article. 19(4)(d))2. For instance, MS CA may request extra data to identify the hazard characteristics. This is a practice that currently occurs under BPR product authorisation.

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1 Article 5 on exclusion criteria stipulates which active substances shall not be approved.

Article 5 (and only article 5) dictates how the Commission shall adopt delegated acts including ‘... specifying the scientific criteria for the determination of endocrine-disrupting properties’.

Article 5 is clear in referring only to active substances ‘... considered as having endocrine disrupting properties’. Article 5 .1 (d) The scientific criteria should therefore refer to ‘active substances’ as laid down in article 5.

2 Art. 19(4)(d) has no relevance whatsoever when it comes to the specification of the scientific criteria for endocrine disrupting properties. It states only that ‘A biocidal product shall not be authorised for making available on the market for use by the general public where: ... (d) it has endocrine-disrupting properties;’
3. Expanding the scope from “Active Substance” to “Substance”, will not change the current practice for identifying chemicals of concern. However, it will lead to further confusion with the BPR legal text via the introduction of new terms, which will cover more than the definition in the BPR.

Under the BPR, the eCAs have the remit to start a classification and labelling change for the **Active Substance** if the hazard characteristics indicate that this is necessary. The process is very clearly defined and it is clear who makes the final decision – ECHA RAC. It is also clear that the CLH changes have a further impact on all other legislations that have to consider CLP. The impact of some of the biocides CLP changes on other legislations has already been seen (vitamin D, ethanol etc.). Biocides CA do not have the remit to make classification decisions on biocidal products or their individual co-formulants. This would likely result in significantly diverging classifications of non-active substances within the European market and wrong conclusions drawn from inconclusive evidence.

There is no clear understanding or explanation what the impact of an ED classification made by the Biocide CA on a substance (other than active substance) means legally. It is unclear if the definition for the substance under the BPR will take precedence in all other European chemical legislation.

There are also no clear considerations how this change would be communicated to all affected users of the substance – under biocide legislation and other legislations – both within Europe and for import to Europe. This would be a similar issue to the challenge that already exists for the additional labelling of treated articles under BPR, that is above and beyond the globally harmonized and accepted CLP legislation.

Therefore, Cefic - EBPF request COM to revert to the original wording of ‘active substance’ in line with the legal arguments already made by Industry in December 2016, when this change was first introduced and re-emphasised in the attached paper in view of the 28th February 2017 CA meeting.

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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.