POSITION PAPER

24th February 2017

Extension of the scope of the proposed endocrine disruptors criteria from 'active substances' to 'substances' in the biocidal products regulation (528/2012)

Cefic position

Cefic-EBPF does not support the extension of scope proposed by the Commission in the revised proposal for endocrine disruptors (ED) criteria in December and maintained in the latest revision of the Commission's proposal. Cefic maintains that the criteria should only apply to biocidal active substances, and not to any substance present in the final formulated product (in-line with the Commission's impact assessment).
Cefic-EBPF asks the Commission to revert to their original proposal ('active substances').
We would also like to refer to the attached position paper (17-522b-Cefic-EBPF position on the extension of scope of ED criteria-procedural considerations) addressing more technical and procedural aspects.

We cannot support the move to extend the scope of the restriction from 'active substances' to 'substances' for legal reasons.

(1) According to Article 290 of the Treaty on the Functioning of the European Union, the basic legislative act must expressly provide the objectives, content, scope and duration of the delegation of power. The BPR does not provide a mandate to the Commission to set criteria for defining ED properties across the board for all chemical substances.

(2) In the BPR, the Commission powers to define endocrine disruptors criteria were delegated to supplement the rules on the approval of active substances for use in biocides, contained in Chapter II BPR. This is the explicit objective of the delegation of powers, as provided under Art 5 BPR, and confirmed by the wording, position and context of the said provision.

(3) The legal mandate provided to the Commission for the adoption of ED criteria is clearly framed by article 5 (3). The European Parliament and the Council delegated powers to the Commission to specify the criteria under which ***active substances*** should be considered as having endocrine-disrupting properties, and therefore be excluded from approval at the outset, unless the conditions for a derogation are fulfilled.

(4) The BPR does not provide a mandate to the Commission for specifying the conditions under which a biocidal product has endocrine-disrupting properties, in the sense of Art 19(4)(d) BPR. Hence by extending the scope of the draft delegated act to all substances, the act would not only be 'ultra vires' but also create a lot of legal uncertainty for duty-holders.

By extending the scope of the criteria, the Commission may implicitly intend to supplement the BPR rules on the authorization of biocidal products contained in Chapter IV BPR. But as drafted, the criteria open the door to unpredictable public authority decisions on the ED or non-ED status of biocidal products. It remains unclear to us what the Commission means by 'substances' and to which substances the criteria would apply (non-active substances of concern, co-formulants, others?).

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As a consequence, the impact of this extension of the scope remains unclear. In the most extreme scenario, this could imply an outright ban on biocidal products for use by the general public, as the BPR does not make it possible to apply derogation for such retail products as soon as they are considered by Member State competent authorities to have endocrine-disrupting properties (socio-economic impacts and risk are not taken into account).

The Commission has not included this change in the impact assessment it conducted last year on the criteria. At the very least, such a material change to the criteria would necessitate to complement the earlier impact assessment if it were to be kept. Better regulation requires regulation to be prepared in full knowledge of its expected effects, to maximize positive impact and avoid unnecessary burdens. The Inter-Institutional Agreement on Better-Law Making agreed in April last year recognizes the need to complement the impact assessment work when substantive amendments are brought to the initial proposal.

REACH covers substances. The extension of the scope to "substances" instead of "active substances" begs the question of the coherence of this move with the ongoing REACH Refit exercise and with the Fitness check of chemicals legislation which are precisely looking into the interface of chemicals legislations with each other. This proposal seems to create new overlaps.

It is difficult to see how this could be implemented in terms of assessment of all the substances present in biocidal products. As highlighted in the biocidal competent authorities meeting, there can be up to 12-15 co-formulants in a product (such as binders, dyes, pigments, fragrances, surfactants) which are added to give products specific properties. Considering that dyes, pigments and fragrances are themselves complex formulations, we believe that the number of substances used as co-formulants may in some products be largely above this estimate. With biocidal products being largely produced by SMEs, how could companies possibly cope with the uncertainty, the additional workload and the length of the procedure to request an authorisation to place a biocidal product on the market?

Considering these arguments and the concerns outlined in the attached paper, Cefic-EBPF asks the Commission to revert to their original proposal ('active substances').

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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.