Attention:

DG SANTE
Unit E.4 – Pesticides and Biocides
European Commission

July 4th 2018,

Dear M. Nagtzaam,

The criteria for identifying endocrine disrupting substances (EDs) in biocidal products came into effect on 7th June 2018 (Commission Delegated Regulation (EU) 2017/2100). These criteria have been long awaited, and must contribute to the general goal of the BPR to ensure a high level of protection of human health, animal health and the environment. In this respect, we would like to raise several concerns on the proposed approach by the Commission, especially on how to handle already approved substances (AS).

Approved active substances:

Currently, 141 AS are approved and thousands of biocidal products have been authorized and are available on the market and innumerable articles treated with them which may contain suspected ED AS and/or co-formulants[1]. As a consequence, **every day people and wildlife come into contact with suspected ED biocidal products.** This situation is unacceptable in terms of human health and environment protection from exposure to adverse ED substances.

In document CA-May18.Doc.7.3.b to be discussed at CA meeting in July 2018, the Commission proposes a way forward to handle already approved AS. Early review of AS is a solution to avoid more delay on withdrawal from ED biocidal products and AS from the market. According to its analysis, only 3 of the 141 AS currently approved would trigger an early review. We would like to question this approach:

One condition for early review is the existence of "significant indications" that approval conditions are no longer met (Art. 15(1) of BPR). However, as underlined in several documents at CA meetings, data gaps and absence of data on ED properties of current biocidal AS may consequently lead to a situation where known, presumed or suspected ED biocides are still allowed on the market, even after June 7th 2018. Therefore, **the Commission should ensure that all existing dossiers are updated with data on ED properties as soon as possible, and not systematically postpone the application of ED criteria.**

In point 2.8 of document CA-May18Doc.7.3.b, the Commission excludes from the scope of an early review AS under renewal, where applications were submitted before June 6th 2018, and states that even for renewal applications submitted after June 6th 2018, data required on ED criteria could possibly not be submitted in due time before the expiry date of the approval. **This approach would lead to further postponement of application of ED criteria and is not in line with the BPR: ED criteria should apply to all applications of renewal, including those submitted before June 6th 2018.** The Commission refers to difficulties that may arise for applicants to provide required data on ED properties. However, applicants have been long aware that ED criteria were being elaborated – especially given the

[1] In Germany for instance, about 180 authorized rodenticides contain the suspected ED substance difenacoum, and several hundred of authorized wood preservatives contain single substances or mixtures of other suspected ED such as propiconazole, tebuconazole, thiacloprid, cypermethrin, or dazomet.

long delay in the adoption of said criteria – and they should now be ready to apply the criteria, and have anticipated their implementation[2].

In point 3.18.c of document CA-May18.Doc7.3.b, the Commission states that if during an early review, ECHA opinion cannot conclude on ED properties of an active substance, but that indications exist that the substance *may* have ED properties, the Commission will propose to shorten the expiry date of said active substance and ensure a dossier for renewal is submitted within 24 months. This approach is not in line with the proper consideration of suspected ED biocides substances stated in article 5.2.d of the BPR, and the application of the precautionary principle, which underpins the BPR. **Therefore, approval of said AS should be cancelled.**

The Commission explains in point 4.23 and 4.24 of same document that only 3 AS would trigger an early review, based on data from the screening study performed during the impact assessment accompanying the draft regulations for setting new ED scientific criteria according to the BPR. **We question this conclusion and this figure, and would like to know more about the approach used by the Commission,** and the options of the impact assessment considered. ED criteria should cover known and suspected ED AS. According to the Impact Assessment (page 116), only 98 biocidal AS have been screened, and only those where data were available were taken into account. This does not provide a comprehensive picture of AS currently approved. According to the impact assessment, "*In total 16 biocidal substances were identified as potential ED under Option 1, five substances under Option 2 and 3 Category I, and three substances under Option 4*" Additionally, 26 active substances were identified as potential EDs under Option 3, Category 2 (page 120). **We insist that the Commission considers all the substances identified in all 4 options, and does not restrict the outcome to 3 substances only.** This would undermine the need to regulate a maximum of known, presumed or suspected ED AS. It is also necessary to extend the evaluation to the other AS not yet considered under the impact assessment.

Active Substances under assessment:

New provisions apply to on-going applications but not to AS for which the rapporteur Member State submitted an assessment report before 1st September 2013, and no opinion of the Standing Committee was delivered, because according to the interpretation of the Commission, those substances fall under the scope of former Biocidal Products Directive (BPD). This is stated in document CA.7.3.b agreed during March 2018 CA meeting. However, from our point of view, a comprehensive re-evaluation must also include such AS where the RAR was submitted before 1st September 2013. BPD provisions guarantee an early review of approved substances in the light of current scientific and technical knowledge if the approval conditions are no longer satisfied.

We urge the European Commission and the Member States to ensure that applicants and companies are updating the information needed to assess EDC properties, and to start immediately the examination and re-evaluation of all already approved AS and all biocidal products available on the market. We also urge the Commission to evaluate data gaps and to establish a clear procedure on how to deal with data gaps in regulative decision making.
We thank the Commission and Member States delegates for the attention they will pay to our contribution.

Yours sincerely,

Elisabeth Ruffinengo
Women Engage for a Common Future France

Susanne Smolka
Pesticide Action Network-Germany

[2] Judgment in Case T-521/14 Sweden v Commission , https://curia.europa.eu/jcms/upload/docs/application/pdf/2015-12/cp150145en.pdf. ED scientific criteria release was initially scheduled for December 2013.