

Summary of the e-consultation “Assessment of a biocidal product containing a combination of an active substance and of an active substance “Annex I”¹”

On the 28th of April 2017, FR CA initiated an e-consultation about an application for a biocidal product TP2 that contains a combination of 2 active substances:

- One active substance for PT2 (ethanol for example)
- One active substance included in the annex I of the BPR (not in Category 6) such as sodium benzoate.

We wanted to get the other member states opinion on the following questions:

- Should sodium benzoate be considered as an active substance?
- What would be the data requirements for the risk assessment given that there is no assessment report available for sodium benzoate?

We received the comments from 2 member states (DE and DK). During the CG-24, CG members agreed on the following way forward:

- If it is demonstrated by appropriate efficacy data that the Annex I active substance (e.g. sodium benzoate) does not contribute to the efficacy of the product, the substance should be considered as a co-formulant: the assessment should be carried out considering that the biocidal product contains only one active substance (e.g. ethanol). Still, the Annex I substance might be considered as a SoC if its concentration in the biocidal product results in the classification of the product.
- In the case that the Annex I active substance (e.g. sodium benzoate) contributes to the efficacy of the product or if the applicant claims efficacy for this active substance, this substance should then be considered as an active substance for the risk assessment. Accordingly, appropriate data should be provided by the applicant in order to support the risk assessment for both actives substances (e.g. ethanol and sodium benzoate).

¹“List of active substances referred to in article 25(a)” in the Annex I of the BPR (Reg 528/2012) Category 6 excluded (eg active substances for which a dossier was submitted and assessed)