LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

23th August 2019

LV CA e-consultation
CG35/CG36

Does the co-formulant should be considered as "potential" active substance due the similar chemical structure to substance included in Annex I of the Commission Regulation (EC) No 2032/2003, but in respect of which no notification has been accepted (Annex III)?

The consultation was performed in two commenting rounds. In result, 5 MSs provided responses.

First commenting round:
On a particular issue about substance used as surfactant in disinfectants, but which has a similar structure to substance included in Annex I and III of the regulation 2032/2003[1], all respondents agreed that substance in question should not be considered as a potential active substance according to criteria set up in CA-Jan18-Doc.4.2[2].

Second commenting round:
After the first commenting round two additional questions were raised by the LV CA for discussions.

1. Do MSs agree that for substances included in Annex I (existing/identified) and in parallel in Annex III (not notified) the non-biocidal effect should be supported by additional data (literature review or testing)?

In practise each MS makes a decision based on a case-by-case approach. All MSs agreed that the function of such substances in the respective product shall be clearly defined. Majority of MSs is on opinion that a testing or literature review should not be considered as default option.

However, eCA should pay particular attention to co-formulants included in Annex II (notified) of the Regulation 2032/2003 to ensure that the co-formulants are not acting as active substances in the biocidal product under the relevant condition of use. For any such co-formulant listed in Annex II, the applicant should provide a justification including scientific literature (of good quality) and/or expert judgment to reason that the co-formulant in question is not acting as an active substance. If the justification is not sufficient to alleviate the concern that the co-formulant might act as an active substance in the product, additional testing according to point 6 of the TAB on efficacy might be necessary. In case of substances listed in Annex III, the MS may require further information (expert judgement/literature data; further testing if necessary) if there is a reasonable concern that the co-formulant might act as active substance in the product.

2. Should a structural similarity to known active substance be taking into account in a context of possible biocidal effect?

[1] COMMISSION REGULATION (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, and amending Regulation (EC) No 1896/2000
[2] CA-Jan18-Doc.4.2 Addressing concerns of co-formulants that contribute significantly to a product's efficacy

Majority of MSs agreed that deep assessment of chemical structure should not be carried out. However, if MS become aware of obvious similarities to existing active substances, these should be taken into account. In this case a definition “obvious similarity” is not in place, but it can be defined as substances with same chemical profile and mode of actions, like acids.