



Development of Legislation and Other Instruments

BPC-43: SE Minority opinion on the BPC opinion on Formic Acid for product type 6

Sweden notes that the present opinion for formic acid in product type 6 will allow placing on the market of treated articles (i.e., liquid products preserved with formic acid) without the possibility to introduce risk mitigation measures or other conditions that may be identified as necessary at a later stage.

Since only a selection of intended uses of the treated articles has been assessed (i.e., mopping and dishwashing) at a certain concentration of formic acid in the treated article, and these uses show acceptable risk, no conditions for the placing on the market of treated articles is proposed in the opinion. Consequently, all other uses in treated articles - even those that have not been assessed - will automatically be covered by the approval. This includes uses that may have unacceptable risk, in particular articles containing formic acid at concentrations above those levels triggering classification for local effects concerning skin corrosion/irritation or eye irritation in accordance with the Regulation (EC) No 1272/2008. Also, the assessment report states that higher concentrations of the active substance might be necessary to achieve the intended effect under certain conditions of use than the concentrations used for the risk assessment that the current opinion is based on.

In case unacceptable risks may be identified at product authorisation, it will not be possible at that stage to introduce conditions regulating the placing on the market of treated articles. Furthermore, it will not be possible to restrict the placing on the market of imported articles. Adding specific requirements of appropriate risk mitigation measures in the substance approval - in line with the approval decision for a similar substance in PT6 - would ensure equal conditions for imported treated articles and articles treated within the EU.

However, the majority of the Committee agreed to propose approval of formic acid in PT6 without specific conditions for the placing on the market of treated articles, but instead referred to the product authorisation stage. For the reasons given above Sweden cannot support that position and therefore hereby submits this minority opinion.