

Development of Legislation and Other Instruments

BPC-42: SE Minority opinion on the BPC opinion on the union authorisation of the biocidal product family Sodium hypochlorite Liquid disinfectant BPF containing active chlorine released from sodium hypochlorite

During the storage tests for the product family, the content of the relevant impurity chlorate was recognized to be outside the range of the reference specification set for sodium hypochlorite, the releaser of the active substance.

Sweden is of the opinion that for a storage stability study to accurately reflect the degradation of the active substance and formation of relevant impurities in the product over time, the composition of the active substance used for product formulation should be within the reference specification when the stability study of a product is started. That means, in this case that the chlorate content at T=0 should have been within the specification in relation to the content of the active substance. In our opinion, the shelf life of the product family could not be determined and new data demonstrating the storage stability should have been requested.

A presentation was provided by ECHA and a discussion on the reference specification was held at the Committee's meeting. However, the discussion did not bring sufficient clarity on the legal perspective, nor on the approach used by the evaluating Competent Authority. Thus, the concern remains regarding the stability and safety of the products. Therefore, Sweden cannot support the opinion and submits herewith a minority opinion.