federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

Directorate-General for Environment
Division of Product Policy and Chemical Substances
Risk management - Biocides Unit

07 March 2022

Minority opinion of the Belgian Competent Authority (BE CA) regarding the Union authorisation application for a biocidal product family containing active chlorine released from sodium hypochlorite discussed at BPC-42

The BE CA raised a concern regarding the fact that the chlorate contents measured during storage tests are outside of the reference specifications set at the active substance approval stage.
The active substance is unstable and degrades rapidly which led to this situation. Indeed the active substance used for this BPF, which is manufactured from an approved source, degraded in the time between its manufacture, the formulation of the biocidal product and the start of the storage tests allowing the formation of impurities, including chlorates, at a level outside of the reference specifications.

The BE CA is therefore questioning the compliance of this biocidal product family with the Art 19(1)(a) and 19(1)(c) of the BPR. Moreover, the innate efficacy, human health and environmental risk evaluation rely upon the level of impurities formed since these need to be assessed.
It was stated during the BPC discussion that the assessment covers this exceedance of chlorates level however, the BE CA is still not confident about that. Indeed, the content of chlorate has been assessed for the products that have spent a precise time between the formulation of the product and the beginning of storage test and it is well known that chlorate concentration is dependent on the time. It means that this assessment is valid only for this precise timeframe and is not covering situations when the product is put on the market and left for more time unsold. Consequently, when the product is supplied to the end-user, there is no certainty about the chlorate content and the risk it may bring.

It was also stated during the meeting that for other applications the chlorate content was within the reference specifications demonstrating that it can be achieved. Although it was correctly pointed out that for one Union application the content was obtained via calculations (approach that has been accepted by the Member States), it is not true for at least one other UA case where tests were available. In a national case the storage tests resulted in a chlorate content outside of the reference specifications and the evaluating competent authority required new tests on fresh products. The BE CA considers that this approach could have been followed also in the present case.

The BPC decided to take a pragmatic approach on this issue, however the BE CA is concerned about the precedent that it could create on the acceptance of measurements outside of the reference specifications. Indeed, active chlorine substances are not the only active substances available for biocidal product formulation that could be considered as unstable. However, there is no agreement at EU-level on the definition of an unstable substance, which means that there is no framework to define what might be acceptable or not. The establishment of such a framework is necessary and should be initiated via working-group discussion.