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HEALTH, FOOD CHAIN SAFETY
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Directorate-General for Environment
Division of Product Policy and Chemical Substances
Risk management - Biocides Unit

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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 and further proposed for adoption via written procedure.

This minority opinion addresses two issues :

(1) 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.

(2) The BE CA is concerned about the overdosing performed in order to reach the shelf-life claimed. The criteria to set the shelf-life is based on the efficacy results on the aged products, however the efficacy after two years is demonstrated only because at the beginning the fresh products are highly overdosed. The fresh products are to be applied as ready-to-use, therefore they should only contain the minimum concentration that is demonstrated as efficacious. If that was the case we highly doubt that the efficacy after storage would still be proven since the amount active substance, would be much lower.

The overdosing is not acceptable in accordance with :

- The Annex VI, paragraph 77 of the BPR “The evaluating body shall evaluate dose-response data generated in appropriate trials (which must include an untreated control) involving dose rates lower than the recommended rate, in order to assess if the recommended dose is the minimum necessary to achieve the desired effect.”
- The article 18(a) of the BPR : “the promotion of best practices as a means of reducing the use of biocidal products to a minimum”
- The Technical Agreement for Biocides on Analytical Methods and Physico-chemical properties v2.0, February 2020 p. 15 : “Overdosing is not acceptable and there are no criteria on overdosing available”

As a consequence the BE CA disagrees with the shelf-life set based on the results of the efficacy on aged products. The active substance contained in these products is well known to degrade rapidly, and the degradation is highly dependent on the temperature or level of (organic) impurities. The shelf-life should therefore be set in accordance with this degradation profile, not with overdosing of the fresh products.