federal public service
HEALTH, FOOD CHAIN SAFETY
AND ENVIRONMENT

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 hydrogen peroxide discussed at BPC-48 (Agenda point 08.03)

The BE CA is concerned about the overdosing resulting from the efficacy assessment. Both EN 1650 (non-healthcare) and EN 13624 (healthcare) were provided as phase 2, step 1 tests to demonstrate efficacy against fungi (surface disinfection).
EN 1650 demonstrated efficacy within 5 min, at 0.5% H_2O_2 in dirty conditions whereas
EN 13624 demonstrated efficacy within 5 min, at 5% H_2O_2 in dirty conditions.
EN 13697 was also provided as phase 2, step 2 test and demonstrated efficacy within 5 min, at 0.5% H_2O_2 in dirty conditions.
Based on a worst-case scenario taking into account both phase 2, step 1 test and phase 2, step 2 test (knowing that efficacy is also demonstrated in dirty conditions against bacteria, yeasts and tuberculosis bacilli in 5 min at 0.5% H_2O_2 and viruses in 15 min at 0.5% H_2O_2), the concentration of H_2O_2 should be as follows:

- 0.5% H_2O_2 in non-healthcare areas
- 5% H_2O_2 in healthcare areas

The products intended to be used in healthcare areas should therefore be formulated with 5% H_2O_2 and products intended to be used in non-healthcare areas should be formulated with 0.5% H_2O_2. For products intended to be used in both areas, a maximum of 5% H_2O_2 is expected.
This is not the case in meta SPC2 and meta SPC3. These products are formulated with 9.9 to 10% H_2O_2, which is a concentration up to 20 times higher what is necessary for an use in non-healthcare areas. The BE CA does not agree which such an overdosing.

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 v3.0, September 2022 p. 17 : “Overdosing is not acceptable and there are no criteria on overdosing available”