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BPC-48 Minority opinion of the Austrian Competent Authority (CA) regarding the proposed setting of RMMs based on the discussion on coherent decision for the applicability of RPE (point 8.3, open issues table, discussion point 3):

The Austrian CA disagrees on the conclusion on decision taken on discussion point 3, mentioned above.

The products in this BPF were proposed to be authorized for indoor use in health care and non-healthcare area.

AT questioned the way forward which was taken especially for meta SPC 1-3 and meta-SPC 5, where a RPE (gas mask) was proposed as RMM, based on a decision on toilet disinfection product at BPC-43, where a use with the same RPE (gas mask) was not authorized for professionals.

Based on the volatility of hydrogen peroxide and its molecular size it can be expected that the molecule passes masks like FFP1 or 2 which are associated to be sufficient for low assessment factors. Thus, for vapors and small molecules the choice of mask is independent from the used assessment factor in the assessment.

The RMM was also discussed at the BPC-WG II 2023 for this product and the RMM was modified to highlight the RPE which have to be added:

*Wear a respiratory protective equipment (RPE) aerosol and gas filter with an assigned protection factor of at least 4 (filter type (code letter, color) and the standards to be specified by the authorization holder within the product information). (meta-SPC 5, Use 5.2 for trigger spray use)*

AT was searching for general advice based on this BPC 43 decision taken by the member states that indicates the position of the BPC members for upcoming products, which was also a crucial point for the actual product discussion. The Biocidal Product at BPC 43 has not been authorized based on two main argumentations:

- RPE in usage is not feasible for handling by the professional (cleaning person in hotels/hospitals) for application and re-entry
- Re-entry time of 2 hours while the general public cannot enter the room

This BPC decision was taken into account for national authorization for several products evaluated and also agreed by several member states.

As all arguments are listed in the BPC opinion at BPC43 and also described in the final Assessment report it might be discussed if both points have to apply in order to conclude likewise.

During the discussion at BPC 48 one member state pointed out that the main argumentation in BPC 43 held place on the long duration time. However the argumentation concerning the RPE cannot be ignored as the problem of re-entry time could have been mitigated by closing of cleaned rooms for a waiting period or before opening/after closing time depending on the working routine.

One member state pointed out to identify discrepancies of the possible usage of PPE at certain types of professional and search for national restrictions for certain professional user groups.

The BPC did not comment on the question of AT, if the professional user needs to be specified if wearing certain types of RPE (e.g. harmonized definition of 'trained professional for PT02').

The eCA (NL) clarified at the meeting that the product is intended to be used everywhere indoor at healthcare and non-healthcare area, whereas at commenting phase on BPC 48 the argumentation of the eCA assumed specially trained personal in hospital only, which was contradicting to the use description information given in the PAR. NL pointed out that

toilets would be excluded as the product is not intended to be used for cleaning routine and safeguard was not further assessed. To the opinion of AT this information should not be used as RMM as intended at the NL comment. The restriction does not result from an assessed risk at HH part. For this reason AT disagrees with the proposed way forward on setting an RMM for toilet restriction and safeguard assessment. The proposed information should be stated at instructions for use for every Use at meta-SPC1-3/5 as followed:

*Not for use for bathroom disinfection. Please assess the applicability of the safeguard (RPE) for the respective workplace*

To conclude AT, cannot agree to add a RMM based on a Risk not performed in the PAR and wants to add the specific information at Instructions for Use chapter in PAR and SPC for meta-SPC1-3/5.

On behalf of the Federal Minister

Mag.Dr. Paul Krajnik