Státní zdravotní ústav

Šrobárova 49/48
Praha 10
100 00

Minority opinion on the Union authorisation of the biocidal product family:

HYPO-CHLOR Product Family,

7 March October 2022 - CZCA

The BPC meeting no. 42 adopted by majority the BPC opinion autorising the placing on the EU market and the subsequent use of the Hypo – Chlor Product Family. This despite the fact that the active substance (hypochlorite) undergoes decomposition to such an extent that before the end of the shelf life its composition is far from the approved reference specification. During the decomposition a substance of concern is generated. This compromises the safety of the products in the family as a whole. Consequently, the risk to human health due to use of the mixtures made available to the consumer remains unknown.

One of the arguments for the majority BPC opinion was that the products are formulated using the a.s. from the reference source and, therefore, i tis unclear if any action can be taken from the legal point. CZCA does not agree with such interpretation of the BPR. The BPR covers both the placing on the market and the use of the biocidal products. Thus the conditions set in article 19, which specifies the conditions for granting an authorisation, must be fulfilled also throughout the expected product use. This is confirmed by the wording of article 19 (2, a) which states:" The evaluation of whether a biocidal product fulfils the criteria set out in point (b) of paragraph 1 shall take into account the following factors: (a) realistic worst case conditions under which the biocidal product may be used " Obviously, as the risk assessment did not take into account the real composition of the mixtures used by the consumer, this condition is not fulfilled. Any product for which this and/or other conditions are not fulfilled, should not normally be authorised.

Another argument used in support of the majority opinion was that the BPR does not cover the unstable active substances and the products based on these substances. This could lead to unpredictability and legal uncertainty damaging the interest of the applicant and/or stakeholders. However, the innate instability of this active substance is well known in general and should be known to the applicant and stakeholders in particular. Even though unstable active substances are not specifically mentioned in the BPR, it follows from the above text that the BPR, by covering also the product use, covers substances that may become toxic during the storage due to their innate instability. This is incarnated in article 4 which lays out the conditions for the active substance approval. In particular, it requests that : "An active substance shall be approved for an initial period not exceeding 10 years if at least one biocidal product containing that active substance may be expected to meet the criteria laid down in point (b) of Article 19(1) taking into account the factors set out in Article 19(2) …" Interpreting this in the light of the above arguments it follows that for unstable active substances it may difficult to fulfil this expectation. It elicits the question if the hypochlorite should have been approved at all. That is if we may expect in the future a product fulfilling the conditions specified in article 19. In this case, unlike for stable substances ,a change in the manufacturing process appears to be of little use. An amendment of the assessment of the a.s. could shed light on this issue. This, however, is impossible to perform without the further information.

In conclusion, CZCA is for non-authorising the Hypo – Chlor Product Family.