CZCA Minority opinion on the Union authorisation of the biocidal product family
Sodium Hypochlorite Liquid disinfectant BPF containing active chlorine released
from sodium hypochlorite discussed at BPC 42 and further proposed for
adoption via written procedure.

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The CZ CA cannot accept approval of this BPF as the active substance (hypochlorite)
undergoes decomposition to a substance of concern. 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.

CZCA is therefore of the opinion that the authorisation of this BPF is not in line with 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 as the a.s. for biocidal use 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 against authorising this BPF.