Státní zdravotní ústav

Šrobárova 49/48
Praha 10
100 00

Minority opinion on the application for approval of the active substance:

D-Allethrin Product type: 18

13 October 2021 - CZCA

The BPC 40 meeting concluded by consensus on nonapproval of D-Allethrin for PT18. The reasons given for the non-approval included no safe use for human health for some proposed uses or the environment for the other proposed uses. This is not disputed by the CZCA, though CZCA notes that these reasons may be secondary to the reference specification issue specified further in this text. This possible consequentiality should be addressed in the BPC opinion. The CZCA cannot, however, agree with the argument given in the draft BPC opinion and voiced by some of the BPC members during the discussion, considering the fact that the proposed reference specification was not covered by the compositions of batches used in (eco) toxicological studies as a sufficient reason for nonapproval. We are of the opinion that this, on its own, cannot be deemed as a reason sufficient for the a.s. non approval. This should be clearly stated in the final BPC opinion. The applicant should be free to present a ref. specification covered by the (eco) tox. studies in the future. Forbidding the applicant to do so at this stage strongly limits their rights. Such interference must be in line with the relevant legislation. In addition, even if „ justified“ based on the relevant legislation, the proportionality of the justification should be carefully considered. Thus, no formalistic reasons can be considered as sufficient in such a case. Indeed, limiting the rights of the applicant in general, and to the extent of nonapproval in particular, primarily requires reasons based on the protection of the environment and human health. It follows from the above that this cannot be the case here.
Regarding the relevant legislation, i.e. the BPR , the relevant parts are these that deal with the a.s. approval. Article 4 (1) states „ 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) and (5). Assuming, for the sake of the argument, that the only reason for nonapproval is the ref. spec. issue , a safe use is then identified for any proposed ref. specification covered by the tox. and ecotox. studies and the composition of the batches used in them. It follows that at least one biocidal product may be expected, though perhaps in the future, to fulfil the required criteria.

In conclusion: The non-approval of D-Allethrin cannot be justified based solely on the currently proposed reference specification not fitting in the specification determined by the tox. and ecotox. studies. This is not in line with the wording of the relevant parts of the BPR nor is it in line with the principles on which regulatory process should be based, which is an appropriate justification for any limitation. This should be clearly stated in the BPC opinion. It should also be clearly stated therein if the other reasons for nonapproval may be consequential to the ref. spec. issue.