EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food Safety, Sustainability, and Innovation
Pesticides and Biocides

Brussels, 8 May 2024

MANDATE REQUESTING AN ECHA OPINION UNDER ARTICLE 75(1)(G) OF THE BPR 'EVALUATION OF THE ENDOCRINE DISRUPTING PROPERTIES OF MECETRONIUM ETHYL SULPHATE'

1. BACKGROUND

1. On 31 July 2007, BODE Chemie GmbH submitted an application for approval of the active substance mecetronium ethyl sulphate (MES) for product-type (PT) 1 under Regulation (EU) No 528/2012 on biocidal products (the BPR). The intended uses of MES are hygienic and surgical hand disinfection for professional use as well as non-professional use for home-dialysis and non-professional use for visitors of patients in intensive care units. The evaluating Competent Authority (eCA) is Poland.

2. During the evaluation of the application of approval of MES and following the adoption of Commission Delegated Regulation (EU) No 2017/2100 on the scientific criteria for identifying endocrine-disrupting (ED) properties of biocidal active substances, a dedicated discussion was held in 2019 between the applicant and the eCA on the ED assessment of MES.

3. On 26 March 2019, the applicant claimed that in their opinion MES has no potential for ED properties considering its molecular structure and that they would support this by submitting weight of evidence and read-across data. On 16 April 2019 the eCA agreed with this proposal.

4. An e-consultation of the Environment (ENV) Working Group (WG) on the ED assessment of MES for non-target organisms took place between 31 March and 23 April 2021 aiming to clarify whether the ED properties on non-target organisms were sufficiently investigated ("the ENV WG e-consultation") and resulting in the conclusion that there was a need to elaborate further on the assessment of ED properties for non-target organisms. The WG members responding to the e-consultation suggested either to perform studies on non-target organisms to investigate ED properties or alternatively provide more substantiated argumentation in support of the claims that the substance has no ED properties. In their comments, they also suggested to first wait for the outcome of the discussion related to ED properties for human health before conducting studies on non-target organisms.

5. Following the ENV WG e-consultation, the eCA requested the applicant to provide a more robust weight of evidence (WoE) approach for the ED assessment on non-target organisms, but did not refer to the possibility to submit studies on non-target organisms which was also pointed out during the e-consultation. As a result, the

applicant provided additional arguments (i.e., the WoE was modified with additional read-across argumentation), and no new experimental data.

6. On 7 January 2022, the eCA submitted its draft assessment report to ECHA. The draft assessment report stated that when strictly adhering to the ECHA/EFSA ED Guidance, the ED assessment for non-target organisms was not sufficiently investigated. The draft conclusion of the eCA was based on a WoE and read-across approach. Based on the comments during the peer review stage at ECHA level, a discussion in the ENV WG was required to conclude on the acceptability of the applied approach.

7. The ENV WG concluded in its meeting of 9 June 2022 ("the ENV WG meeting") that, based on the information provided, it was not possible to conclude on the ED properties of the substance for non-target organisms. The ENV WG agreed that extending the WoE would not be sufficient to conclude on the ED properties of the substance and that further testing data would be required to complete the assessment. The ENV WG discussed the recommendation for the specific studies to be performed to complete the assessment. However, the ENV WG did not ask the applicant to submit these experimental data during the WG discussion, despite the possibility provided in the BPC working procedures[1].

8. The Human Health WG concluded in its meeting of 2 June 2022 ("the Human health WG meeting") that, based on the available information, it was not possible to conclude on the ED properties of the substance with respect to human health. During the opinion forming phase, the applicant submitted a position paper on the sufficiency of the available dataset to conclude on the ED properties for human health, concluding that MES is not an ED for human health. In addition, published experimental data on another substance for read across in a WoE approach was submitted. However, the Human Health WG requested a more substantiated read-across justification and mentioned that legal aspects using published information should be considered and advised performing a legal check.

9. ECHA adopted its Opinion on MES during the 44th meeting of its Biocidal Product Committee on 27 September 2022 (the "BPC opinion"). The BPC Opinion concluded that, in the performed risk assessment which was not considering the ED criteria, no unacceptable risks were found for human health and the environment. However, no conclusion on the ED properties for humans as well as for non-target organisms could be drawn based on the available data since the information submitted (data elements 8.13.3 and 9.10 of Annex II) in the dossier was insufficient. As a result, the BPC Opinion proposed to not approve MES as active substance for use in PT 1 considering that the conditions set out under Article 4(1) of the BPR are not met.

10. On 13 October 2022, the applicant provided to ECHA a confirmation by the author of the publicly available experimental data submitted for the ED assessment on human health (read-across based on studies performed on the biocide active substances ADBAC and DDAC related to the ED discussion) consenting to the use of the published information in the BPR application process.

[1] BPC working procedures agreed at BPC-13, 'Introducing new information during the peer review process of active substance approval':

2. THE QUESTION REFERRED TO ECHA

11. Considering all the aspects of the above situation, and in particular that the eCA requested the applicant to provide a more robust weight of evidence (WoE) approach for the ED assessment on non-target organisms but did not refer to the possibility to submit further studies on non-target organisms after the ENV WG e-consultation, and that neither the eCA nor the BPC WG requested from the applicant to submit relevant studies performed on non-target organisms after the WG discussions despite the possibility to do so in the BPC working procedures, and considering that the applicant submitted a confirmation of consent of use of the data on another substance required to assess the ED properties for human health shortly after the BPC meeting, ECHA is requested, pursuant to Article 75(1)(g) of the BPR, to:

    a. liaise with the eCA of MES and exceptionally provide the opportunity to the applicant to submit the relevant data needed for the conclusion of the ED assessment on non-target organisms, in a timeframe found suitable by ECHA and the eCA;

    b. re-assess the ED properties for human health, taking into consideration the confirmation of the data owners of the published information concerning human health data on ED properties of the substances ADBAC and DDAC submitted by the applicant to ECHA on 13 October 2022;

    c. revise its opinion on the assessment of the ED properties of MES for human health and non-target organisms, and make any modification necessary to the opinion resulting from that assessment, in order to conclude whether MES meets the requirements set in Article 4(1) of the BPR to be approved.

3. ELEMENTS TO BE CONSIDERED BY ECHA WHEN ADDRESSING THIS QUESTION

    a. ECHA is invited to take into account in particular all the data submitted in the application, as well as the conclusions of the discussions in the BPC and its Working Groups.

    b. The confirmation by the authors / data owners for the possibility to use the publicly available experimental data submitted for the ED assessment on human health provided by the applicant to ECHA on 13 October 2022.

    c. The CA document "CA-Dec23-Doc.5.4 – Final' which contains agreements of Member States Competent Authorities on biocidal products on actions to progress in the review programme, in particular on elements to consider when setting deadlines to submit missing information to perform the ED assessment.

    d. The data that may eventually be submitted by the applicant in accordance with the timeframe decided by ECHA and the eCA.

4. DEADLINE FOR THE ECHA OPINION

12. ECHA shall inform DG SANTE at the latest six months after receiving this mandate on the actions taken to complete this mandate and make progress on the examination of MES in the review programme of existing active substances.