EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food and feed safety, innovation
Pesticides and Biocides

Mandate requesting an ECHA opinion under Article 75(1)(g) of the BPR on questions relating to an EU comparative assessment of anticoagulant rodenticides

1. Background

(1) Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (the "BPR") establishes that, where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the receiving competent authority may refer the question to the Commission for a decision. The Commission shall adopt that decision by means of implementing acts in accordance with the examination procedure referred to in Article 82(3) of the BPR.

(2) Document CA-March14-Doc.5.4-Final[1] on "Comparative assessment of biocidal products" points out the renewal of all anticoagulant rodenticides as an example where the number of products[2] involved in the comparative assessment would justify the referral of the above-mentioned question to the Commission by reason of its scale.

(3) The above-mentioned document also introduces the concept of "product class" comparative assessment (i.e. the grouping of biocidal products containing substances considered as a candidate for substitution within a given product-type and covering the same mode of action and intended uses) at the renewal stage as a means to avoid unnecessary work duplication. This concept seems to be particularly relevant to anticoagulant rodenticides that all share the same mode of action and have broadly the same pattern of use.

(4) At the 90th and 91st meetings of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012, it was agreed to submit to ECHA a number of questions in relation to the comparative assessment of anticoagulant rodenticides to be carried out before their second renewals.

2. The questions to be addressed by the ECHA opinion

(5) Member States competent authorities agreed during the 91st CA meeting in March 2021 that the following questions should be addressed by the ECHA opinion for the purpose of the comparative assessment of anticoagulant rodenticides:

(a) Is the chemical diversity of the active substances in authorised rodenticides in the EU adequate to minimise the occurrence of resistance in the target harmful organisms?

[1] Available at https://circabc.europa.eu/w/browse/d309607f-f75b-46e7-acc4-1653cadcaf7e

[2] More than 3000 products were identified in the previous similar exercise in 2017

(b) For the different intended uses specified in the applications for renewal[3], are alternative authorised biocidal products or non-chemical means of control and prevention methods available[4]?

(c) Are these non-chemical alternatives sufficiently effective? In particular, ECHA should conclude based on the information collected via the targeted consultation mentioned in point 12 below whether there is sufficient scientific evidence from field trials to prove that rodent traps are effective to control rodent populations[5] in accordance with the criteria established in agreed Union guidance[7] and the guidance on the assessment of the efficacy and humaneness of rodent traps.

(d) Do the alternative authorised biocidal products or non-chemical alternatives present no other significant economic or practical disadvantages?

(e) Do the alternative authorised biocidal products or non-chemical alternatives present a significantly lower overall risk for human health, animal health and the environment?

(f) ECHA should also examine whether some anticoagulant active substances contained in rodenticides would have a lower overall risk for human health, animal health and the environment than others. The following information should be used to address this question:

1. Primary and secondary poisoning data and reports on accidental poisoning;
2. Data on persistence in the environment (bioaccumulation, toxicokinetics data, persistence in target organisms, degradation in the environment…);
3. Any other relevant and robust scientific information that could allow to conclude that a substance has a lower overall risk.

3. Elements to be considered by ECHA when addressing those questions

(6) The reference made in Article 23(3)(a) of the BPR to "authorised" biocidal products has to be interpreted as excluding products not yet authorised under the BPR from the comparison. Similarly, Article 23(3)(a) refers to other non-chemical alternatives that "already exist", so excluding those which are still in a development phase.

(7) The Commission services have developed, with input from the Coordination Group, a Technical Guidance Note ('the TNG') on comparative assessment of biocidal products[6]. This note describes how a comparative assessment should be carried out and how it should be investigated and concluded that the conditions in

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[3] These uses will be the ones authorised for biocidal products listed in R4BP and the ones listed in the new applications for renewal

[4] A proposal for a guidance on the assessment of the efficacy and humaneness of rodent traps has been finalised and will be the subject of a separate mandate to ECHA to check whether the principles of the efficacy guidance for chemicals is applicable also for non-chemical methods.

[5] Commission Implementing Decision (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council (Text with EEA relevance)

[6] Available at https://circabc.europa.eu/w/browse/f39ab8d9-33ff-4051-b163-c938ed9b64c3

Article 23(3) of the BPR are met or not. The assessment of the above-mentioned questions should follow the tiered approach methodology described in the TNG.

(8) For the particular case of anticoagulant rodenticides and with a view to avoid work duplication, the above-mentioned investigations could be based, among others, on the information provided in the earlier report on risk mitigation measures (RMMs) for anticoagulant rodenticides (the "RMM report"[7]). Annex I to this report includes a review of the chemical and non-chemical methods available to control rodents in 2014, discussing the pros and cons of these methods.

(9) The alternatives identified in the public consultation[8], carried out by ECHA in accordance with Article 10(3) of the BPR in the context of the first renewal of the active substance approvals, as well as those mentioned in the consultation regarding whether those active substances meet at least one of the conditions for derogation to exclusion in Article 5(2) of the BPR[9] should also be considered.

(10) Information available from R4BP on rodenticides biocidal products authorised by Member States (authorisation decisions, summary of the biocidal product characteristics (SPC), product assessment reports, comparative assessments performed at Member States' level, risk mitigation measures etc.) should also be considered.

(11) The Agency should carry out an *ad-hoc* targeted consultation to identify non-chemical alternatives available in the Member States, which meet the eligibility criteria set in paragraph 15 and section 5.2.2 of the TNG. The Agency should conclude whether the eligible non-chemical alternatives are sufficiently effective to provide similar levels of protection, control or other intended effects compared to those of the relevant biocidal product for the same use (paragraph 98 of the TNG).

(12) During this *ad-hoc* targeted consultation, users, manufacturers, NGOs and Member States authorities should be able to provide their views and relevant information on non-chemical alternatives for the use(s) included in the application for renewal of authorisations of the biocidal products subject to comparative assessment. This contribution from stakeholders will be of particular interest, as information on such alternatives is not available through R4BP.

4. Deadline for the ECHA opinion

(13) The ECHA opinion should be submitted to the Commission by the end of December 2022 at the latest except for point 6(f) of Section 2 which may require more analysis and for which an ECHA opinion should be submitted by 30 June 2023.

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7 Available at https://circabc.europa.eu/w/browse/d66ad096-37a1-4903-a3e0-24607ca3f3ea

8 Available at https://echa.europa.eu/potential-candidates-for-substitution-previous-consultations

9 Available at https://echa.europa.eu/derogation-to-the-exclusion-criteria-previous-consultations