EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE-GENERAL

Safety of the food chain
E.4 - Pesticides and Biocides

Request for an ECHA opinion

"Questions regarding the 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).

(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 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 at the renewal stage as a mean to avoid unnecessary work duplication. This concept seems to be particularly relevant to anticoagulant rodenticides which all share the same mode of action and have broadly the same pattern of use.

(4) At the 60th meeting of representatives of Members States Competent Authorities for the implementation of Regulation (EU) No 528/2012, Member States formally agreed the submission to the Commission of a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products.

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

2.- The questions referred to the Commission to be addressed by the ECHA opinion

(5) According to Article 23(3) of the BPR, the following questions have to 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?

(b) For the different uses specified in the applications for renewal[2], are alternative authorised biocidal products or non-chemical means of control and prevention methods available?

(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?

(d) Are these alternatives sufficiently effective?

(e) Do these alternatives present no other significant economic or practical disadvantages?

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

(6) The Commission services have developed, with input from the Coordination Group, a Technical Guidance Note on Comparative assessment of biocidal products[3]. This note describes how a comparative assessment has to be carried out and how it should be investigated and concluded that the conditions in Article 23(3) of the BPR are met or not.

(7) For the particular case of anticoagulant rodenticides and with a view to avoid work duplication, the above mentioned investigations and conclusions could be based, whenever possible, on the information provided in the report on risk mitigation measures for anticoagulant rodenticides (the "RMM report"[4]). Annex I to this report already includes a comprehensive review of the current chemical and non-chemical methods available to control rodents, discussing the pros and cons of these methods.

(8) The alternatives identified in the public consultation[5] carried out by ECHA in accordance with Article 10(3) of the BPR in the context of the renewal of the active substance approvals, as well as those mentioned in the

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[2] For obvious reasons, these uses will be those that could be authorised in biocidal products according to the conditions and risk mitigation measures referred to in the opinions adopted by the Biocidal products Committee at its 16th meeting for the renewal of the active substance approvals, available at http://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval

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

[4] Available at https://circabc.europa.eu/w/browse/352bffd8-babc-4af8-9d0c-a1c87a3c3afc

[5] Available at https://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/potential-candidates-for-substitution-previous-consultations

consultation regarding whether those active substances meet at least one of the conditions for derogation to exclusion in Article 5(2) of the BPR[6] should also be considered.

(9) Taking into account that:

(a) The RMM report concluded that alternatives to anticoagulant rodenticides are limited today and rarely work as stand-alone and cost-effective control methods. Thus, they should only be considered as complementary methods to maintain a satisfactory control of rodent populations within an integrated pest management approach, together with anticoagulant rodenticides,

(b) Limited information on alternatives to anticoagulant rodenticides was obtained in the about-mentioned consultations, which also shows that those alternatives have some limitations and that some practical or economic disadvantages cannot be excluded,

(c) After the renewal of the active substances all the anticoagulant rodenticide products will be subject to a common strategy with regard to RMMs to be applied,

(d) The SPC of the renewed products will provide standardised information on RMMs, instructions for use, etc… for any authorised uses (i.e. different combinations of user category, target organisms and field of use)[7],

(e) All the anticoagulant rodenticides subject to the renewal process for the same use are likely to present a similar overall risk for human health, animal health and the environment,

(10) When preparing the opinion addressing the above-mentioned questions, ECHA should consider whether:

(a) The questions referred to in paragraph 5(a), (b), (d) and (e) may be sufficiently addressed by the RMMs report and the information collected in the two public consultations referred to in paragraph 8 above,

(b) For the purpose of the question under 5(c), the available information on questions 5(d) or (e) makes the detailed comparison referred to in Tier I-B and II of the TGN on comparative assessment unnecessary.

4.- Deadline for the ECHA opinion

(11) By May 2017[8], the Standing Committee will be consulted on a draft Commission implementing decision addressed to all MSs, which will include in an Annex the answers to the questions raised.

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6 Available at http://echa.europa.eu/view-article/-/journal_content/title/public-consultation-launched-on-eight-anticoagulant-rodenticide-active-substances

7 According to the outcome of the CG Working Party for the SPC sections of anticoagulant rodenticides

(12) These answers will be based on the ECHA opinion, and will take the form of 'points to consider at the time of the renewal of the product authorisations' rather that prescriptive instructions as to what could be authorised or not.

(13) In order to meet such deadlines, the ECHA opinion should be submitted to the Commission by the end of February 2017 at the very latest.

[8] See document CA-Nov14-Doc.5.2.a – Final, available at https://circabc.europa.eu/w/browse/7d131275-b0fc-43d5-b990-a0903f22688e