Note of the Member States’ Competent Authorities for biocidal products

*This document is drafted in the interest of consistency of the implementation of Regulation (EU) No 528/2012 and with the aim of finding an agreement between Member States' Competent Authorities for biocidal products on a harmonised approach. Please note, however, it does not represent the official position of the Commission and that Member States are not legally obliged to follow the approach set out in this document, since only the Court of Justice of the European Union can give authoritative interpretations on the contents of Union law.*

**Subject: Optimisation of the second renewal process of anticoagulant rodenticides products**

# Background and purpose of the document

1. Following the discussions on the CA-Dec20-Doc.4.2 document on the second renewal of anticoagulant rodenticides products, it appears that the preferred option by the CA meeting would be to limit the postponement of the renewal of the authorisations until there are:
   1. an harmonisation of dermal absorption values to be used in the assessment of these products and,
   2. a decision of the Commisson on the questions referred to the Commission on comparative assessment in accordance with Article 23(5) of the BPR (‘an EU comparative assessment of anticoagulant rodenticides’).

This option was proposed by a Member State, and supported by many Member States and other participants during the 91st CA meeting.

1. The objective of this note is to clarify the timeline for the actions included in the first paragraph and to agree on the way forward for the second renewal of anticoagulant rodenticides products.

# Relevant provisions in the BPR

1. Article 31 of the BPR concerns the renewal of purely national authorisations (i.e. those granted in one Member State only).
2. Article 31(7) of the BPR provides that: ‘*where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the receiving competent authority shall grant a renewal for the period necessary to complete the evaluation’*.
3. Commission Delegated Regulation (EU) No 492/2014 (the Renewal Regulation) provides rules for the renewal of national authorisations granted through the mutual recognition (MR) procedure which at the time of the application for renewal, fulfil the eligibility criteria referred to in Article 1(2) and 1(3) of that Regulation.
4. The table below summarises the key provisions in Article 31 of the BPR and in Articles 2, 3, 4 and 5 of the Renewal Regulation that are relevant for this note:

|  |  |  |
| --- | --- | --- |
| **Subject** | **Article in**  **the BPR** | **Articles in**  **Reg. (EU) No 492/2014** |
| Deadline for application | 31(1) | 3(1) |
| Content of the application | 31(3) | 2 |
| Acceptance/Validation of the application | 31(4) | 3 |
| Suspension of the evaluation | 31(6) & 30(2) | 4(2) |
| Extension of the authorisation | 31(7) | 5(4) |

1. Article 23(5) of 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. Article 5(4) of Commission Delegated Regulation (EU) No 492/2014 provides that ‘*where, for reasons beyond the control of the holder of a national authorisation, no decision is taken on the renewal of that authorisation before its expiry, the respective competent authority shall grant a renewal for the period necessary to complete the evaluation’*.

# Practical implementation

## Dermal absorption values

1. The intention of the Working Group Human Health of the BPC (HH WG) was to discuss and agree a harmonised approach for the use of dermal absorption values in the evaluation of anticoagulant rodentices to avoid as much as possible potential disagreements in mutual recognition (MR) processes.
2. Recently the Commission services were informed that two documents were discussed in the HH WG:
   1. "Dermal absorption values for anticoagulant rodenticides"

This document was discussed and agreed in principle at HH WG-I-2021 on 18 March 2021. The drafting competent authority was however requested to include some additional information in an e-consultation and to seek the support of the working group on these additions to ensure the agreement by the members and associated stakeholders. On 6 April 2021 an e-consultation was launched by the secretariat of the BPC to finalise the document. During the commenting period until 29 April 2021, one authority submitted comments and these were resolved bilaterally between the drafting and commenting authority. The finalised document will be published shortly in S-CIRCABC.

* 1. "Dermal absorption values for anticoagulant rodenticides - Proposal for an alternative approach for the occupational setting"

This document was agreed at HH WG-I-2021 on 18 March 2021 and will be published shortly in S-CIRCABC.

1. The documents mentioned above introduce an approach to harmonise the evaluation of dermal absorption studies in accordance with the EFSA guidance (2017) and present a refinement option for the professional user. The refinement option is based on the evaluation of existing studies and it does not require developing new data by the applicant.
2. The BPC document on the guidance on dermal absorption, which was agreed at BPC 24 on 8 March 2018[[1]](#footnote-1) states that ‘*The applicability date of the EFSA Guidance on dermal absorption[[2]](#footnote-2) (2017) should be determined according to the rules set for the applicability of guidance for biocidal products and biocidal active substances. As the basis for establishing the specific applicability timelines, the date of endorsement of this document at the BPC should be used’*.
3. Therefore, the EFSA Guidance on dermal absorption (2017) is applicable for all product renewal applications submitted as of 8 March 2020 and also both documents cited in paragraph 11 are applicable for the upcoming renewals.

## Comparative assessment at EU level

1. At the 90th and 91st CA meetings, Member States and industry representatives supported the preparation of an opinion by ECHA on a comparative assessment addressed at Union level in accordance with Article 23(5) of the BPR to facilitate the second renewal of anticoagulant rodenticides products.
2. In parallel to this mandate, the Commission has requested ECHA to formulate an opinion on whether the principles for determining the efficacy of chemical rodenticides as included in the current ECHA efficacy guidance, are also applicable to rodent traps. The opinion will be based on the guidance developed by the German Environment Agency and is aimed to facilitate the consideration of rodent traps in the forthcoming comparative assessment for the products.
3. The opinion of ECHA on the EU comparative assessment is expected for December 2022.

## Proposal for a way forward

1. Following the elements provided above, it is proposed that Member States grant a renewal[[3]](#footnote-3) for the relevant authorisations **until 1 July 2024** as indicated in the Annex I to this document. This approach would allow Member States to take into account in the evaluation of the renewal applications the conclusions of the discussion on dermal absorption, as well as the outcome of the comparative assessment at EU level.
2. The Commission reminds that the procedures of the BPR and the Renewal Regulation continue to apply. In order to allow the Member States to extend the duration of their current authorisations in accordance with the provisions of Article 31(7) of the BPR and Article 5(4) of the Renewal Regulation, applications for renewals must be submitted by companies for their products at the latest 550 days before the expiry of their authorisations.
3. It is acknowledged that this option does not exclude the possible need to amend or cancel the authorisations after the examination of the second renewal of the active substances foreseen before June 2024 if, where appropriate, the implementing act of the concerned active substance would so require in accordance with Article 14(6) of the BPR.
4. Past experience with the renewal of active substances shows that the examination is often delayed and extensions of approvals of the active substances are usually needed, and there is no indication so far that this might not be the case for anticoagulant active substances.

# Proposed actions

1. The Member States agreed on the proposed way forward at the CA meeting of June 2021.

**Annex 1 – List of anti-coagulant rodenticides and their regulatory deadlines for approval and authorisation**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Expiry date of approval of active substances | Earlier expiry date of product authorisations | Proposed date of exipiry of the product authorisation after prolongation | Deadline for submitting applications for renewal of authorisations |
| Difethialone | 30 June 2024 | April 2023 | 1st July 2024 | November 2021 |
| Difenacoum | 30 June 2024 | March 2023 | 1st July 2024 | October 2021 |
| Chlorophacinone | 30 June 2024 | February 2023 | 1st July 2024 | September 2021 |
| Bromadiolone | 30 June 2024 | April 2023 | 1st July 2024 | November 2021 |
| Coumatetralyl | 30 June 2024 | February 2023 | 1st July 2024 | September 2021 |
| Flocoumafen | 30 June 2024 | December 2023 | 1st July 2024 | June 2022 |
| Brodifacoum | 30 June 2024 | December 2022 | 1st July 2024 | June 2021 |
| Warfarin | 30 June 2024 | February 2023 | 1st July 2024 | September 2021 |

1. Available [here](https://webgate.ec.europa.eu/s-circabc/d/a/workspace/SpacesStore/4243a91f-af00-4aae-9ccd-581d318a91c8/Dermal%20absorption%20-%20applying%20EFSA%20Guidance.pdf) [↑](#footnote-ref-1)
2. [Guidance on dermal absorption | European Food Safety Authority (europa.eu)](https://www.efsa.europa.eu/en/efsajournal/pub/4873). EFSA Journal 2017;15(6):4873 [↑](#footnote-ref-2)
3. In accordance with the wording of Article 5(4) of Commission Delegated Regulation (EU) No 492/2014. This is a procedural step implying that competent authorities would need to extend the current authorisation for the period necessary to complete the evaluation i.e. in this case until 1 July 2024. [↑](#footnote-ref-3)