



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL  
ENVIRONMENT  
Directorate A – Green economy  
ENV.A.3 - Chemicals

## NOTE FOR GUIDANCE

*This document is an attempt to provide guidance in the interest of consistency, and has been drafted by the Commission services responsible for biocidal products with the aim of finding an agreement with all or a majority of the Member States' Competent Authorities for biocidal products. Please note, however, 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 renewal process of anticoagulant rodenticides**

### 1.- Background and purpose of the document

- (1) The renewal of the approvals of anticoagulant active substances and of the authorisations of the biocidal products containing these substances will be handled in parallel in accordance with documents CA-Feb13-Doc.5.2.b – Final<sup>1</sup> and CA-Sept14-Doc.5.2-final.Rev1<sup>2</sup> (see Annex 1).
- (2) On the occasion of these renewals the conclusions of the report on *Risk mitigation measures for anticoagulant rodenticides* (the RMMs report) will have to be taken into consideration, which is expected to result in amendments to the product authorisations according to the recommendations in that report.
- (3) Document CA-Nov14-Doc.5.2 proposes that anticoagulant rodenticides placed on the market after the date when the ATP to the CLP Regulation comes into force, shall be labelled in accordance with the new classification, as the new hazard is more severe. Should the new classification impact on

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<sup>1</sup> Note for guidance on “Substance approval and product authorisation renewals of the anticoagulant rodenticides”, available at <https://circabc.europa.eu/w/browse/386abfea-55ce-4764-8a31-f9d4f6ceaf0a>

<sup>2</sup> Note for guidance on “Complementary guidance regarding the renewal of anticoagulant rodenticide active substances and biocidal products”, available at <https://circabc.europa.eu/w/browse/9c57a733-6bb5-4dad-b3f4-23a5c25a8ad8>

the validity for non-professional users, CAs will have to take formal actions in accordance with Article 48(1)(a) and (3) of the BPR in order to restrict the products to professional use only, or where relevant, cancel the product authorisation.

- (4) As a result of the potential consequences of the new C&L and the renewal process, CAs could have to review and amend a significant number of product authorisations twice, if no action is taken to streamline the process.
- (5) Taking into account that Article 48 provides no timeline for MSs to take appropriate actions, a margin of discretion is left to them, which in the current case, could be used to ensure that the outcome of the C&L process is handled in conjunction with the renewal process.
- (6) This document provides a way forward to address the above situation and conclude the renewal process within the shortest timelines.

## **2.- Agreed way forward**

- (7) With a view to optimise the whole renewal process of anticoagulant rodenticides and address the C&L issue, it will be necessary to speed up the renewal process of both the active substance approvals and product authorisations, including the comparative assessment to be carried out at EU level.
- (8) The dates established by document CA-Sept14-Doc.5.2-final for the extension of the validity of the active substances approvals (i.e. 30 June 2018) and product authorisations (i.e. 31 August 2020) are the result of worst case estimations. Therefore, these dates should be considered as a "safety net" to cover possible exceptional cases and with a view to avoid new additional extensions, but not as the target timelines for the whole renewal process.
- (9) In addition, considering that:
  - (a) Anticoagulant substances meet the exclusion criteria, but according to the conclusions from the RMMs report, they are still necessary to maintain a satisfactory control of rodent populations within an integrated pest management approach,
  - (b) There is probably little additional knowledge which could be acquired by requesting additional or new data on the occasions of the substances approvals and product authorisations renewals,
  - (c) The RMMs report is based on a comprehensive review of the current methods available to control rodents, it discusses the pros and cons of these methods and proposes detailed RMMs to be implemented both at the active substance approval and product authorisation levels,
  - (d) The main issues to be discussed within the renewal process are these RMMs.

- (10) The following course of action was agreed to review these substances and products without delay (see annex 2):
- (a) As in particular<sup>3</sup> required in document CA-Sept14-Doc.5.2– Final.Rev1, applicants will have to provide by 31 July 2015 a critical review of those conclusions of the RMMs report of relevance to their substances and justifications that at least one of the conditions set out in Article 5(2) of the BPR is met, to justify that the approval of the active substance may be renewed. The renewal process of active substances should be completed by 31 December 2016<sup>4</sup> and should concentrate on the discussions of the proposed RMMs based on the content of the RMMs report and on the input of the applicants.
  - (b) The comparative assessment of all anticoagulant rodenticides should be done at the EU level, after the BPC opinions on the renewal of the active substances are made available (see document CA-Nov14-Doc.5.3 for further details).
  - (c) With a view to complement the RMMs to be applied within the active substances approvals, the Coordination Group should also discuss in parallel to the active substances renewal process the recommended RMMs to be implemented at the product authorisation stage and further elaborate the proposals for harmonised SPCs of the RMMs report. This set of harmonised SPCs should be agreed at the CA meeting of September 2016.
  - (d) By 28 February 2017, the applications for renewal of the product authorisations shall be completed<sup>5</sup>.
  - (e) The evaluating CAs will have to produce an assessment report and a draft harmonised SPC taking into consideration the elements of the substance renewals, of the comparative assessment and the ATP of the CLP Regulation relating to anticoagulant rodenticides by 31 August 2017<sup>6</sup>.
  - (f) For those applications falling under the scope of Regulation 492/2014, the refMS and all the CMSs should have renewed the product authorisations by 31 December 2017.

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<sup>3</sup> For full details of the data required for the renewal of anticoagulant rodenticides active substances see section 2.1 of document [CA-Sept14-Doc.5.2– Final.Rev1](#)

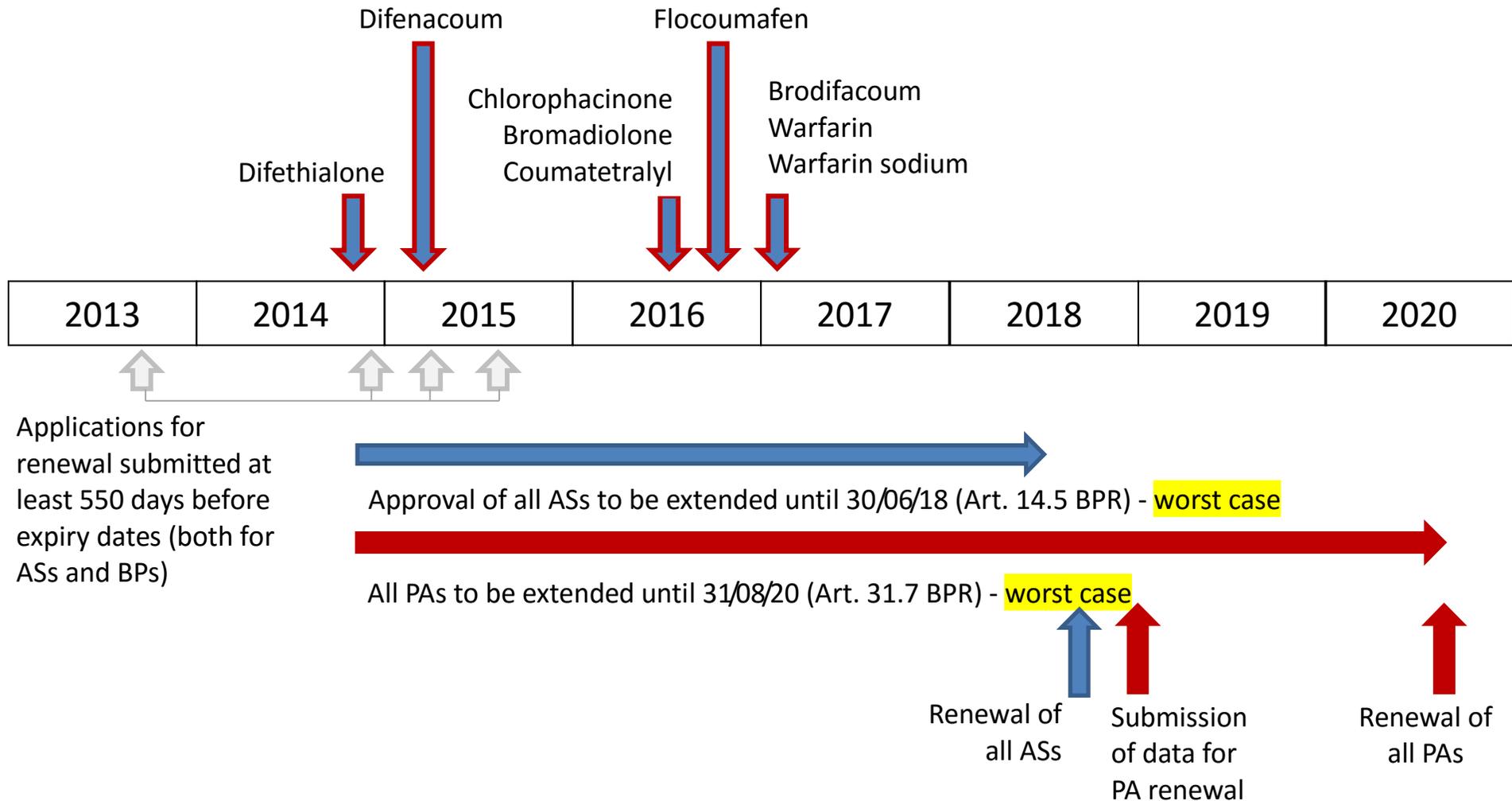
<sup>4</sup> This target would be in line with a "non-full evaluation" scenario.

<sup>5</sup> The tasks related to the critical review of the recommendations from the RMM report can be started well in advance, so this phase would be in practice limited to the submission of the administrative information linked to applications falling under the scope of Regulation 492/2014 (e.g. name of the refMS, list of agreed changes, etc.) and the harmonised draft SPCs.

<sup>6</sup> This target would be in line with a "non-full evaluation" scenario.

**Annex 1:** agreed approach for the renewal of active substances and product authorisations of anticoagulant rodenticides.

Original expiry dates of AS approvals and BP authorisations



**Annex 2:** Optimised renewal process of anticoagulant rodenticides.

