EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Safety of the food chain
Pesticides and Biocides

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 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: Implementation of the 9th ATP Regulation to anticoagulant rodenticides

1.- Background and purpose of the document

(1) Document CA-Nov14-Doc.5.2-Final[1] on "Classification and labelling of anticoagulant rodenticides" outlined an agreed way forward for Competent Authorities (CAs) of the Member States (MSs) to take into account the opinions adopted by the Committee for Risk Assessment (RAC) on the harmonised classification and labelling (CLH) of anticoagulant rodenticides until the CLH was given legal force through the Commission Regulation updating Annex VI to the CLP Regulation[2] (the "9th ATP Regulation").

(2) The REACH Committee gave a unanimous favourable opinion to the 9th ATP Regulation on 4 February 2016[3].

(3) Document CA-May13-Doc.5.4-Final.rev1[4] on "Classification and labelling of biocidal products" has been updated to clarify that new CLH has to be implemented in already authorised products in accordance with the transitional period set in the ATP Regulations.

(4) Document CA-Nov15-Doc.4.1-Final[5] on "Handling of changes to the classification and labelling of authorised biocidal products" also outlines an

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1 Available at https://circabc.europa.eu/w/browse/2535e9fe-d36a-447b-a0ca-b3f2f2c63343
2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (OJ L 353, 31.12.2008, p. 1.).
3 See the version having received the favourable opinion of the REACH Committee and its annex.
4 Available at https://circabc.europa.eu/w/browse/e4e143d0-cae8-41cb-b4b6-c762e6f44622
5 Available at https://circabc.europa.eu/w/browse/39a3eb2f-5a25-4bb4-a693-4c394f8ebad3

agreed way forward that is relevant for the practical implementation of the 9th ATP Regulation to already authorised anticoagulant rodenticides.

(5) At the 62nd CA meeting, MSs requested the Commission to provide further guidance to CAs and authorisation holders (AHs) regarding the implementation of the new CLH in the 9th ATP Regulation to already authorised anticoagulant rodenticides, including the handling of the phasing-out periods.

(6) At the 63rd CA meeting, industry representatives requested MSs and the Commission to consider whether, for the sake of reducing the administrative burden both for companies and CAs, AHs could be relieved from the obligation to notify the administrative change to remove the general public as a user category.

(7) This note aims at addressing the above-mentioned requests by taking into account the latest developments on this topic.

2.- Practical implementation of the 9th ATP Regulation *(see Annex)*

2.1.- New product authorisations:

(8) In accordance with Document CA-Nov14-Doc.5.2-Final, authorisations of all anticoagulant rodenticides are granted in accordance with the current C&L until the new ATP Regulation enters into force and in accordance with the new CLH afterwards.

(9) Document CA-Nov14-Doc.5.2-Final will become obsolete as from the date of entry into force of the 9th ATP Regulation.

2.2- Changes to already authorised products:

(10) For products already authorised by the date of coming into force of the 9th ATP Regulation, the AH shall implement the new CLH before the end of the transitional period provided for in Article 2 of the ATP Regulation[6]. However, nothing prevents the AH from implementing the new CLH already earlier[7].

(11) Should the new CLH impact on other conditions of the authorisation than C&L and trigger the submission of other consequential changes (e.g. removal of the general public or a major change to reduce the concentration of the active substance below the specific concentration limit - SCL), the agreed way forward in document CA-Nov15-Doc.4.1-Final should apply.

(12) However, considering that:

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6 I.e. 18 months after the date of entry into force of the 9th ATP Regulation.

7 Should it be the case, any period of grace regarding the making available of the products on the market cannot go beyond the date of application of the 9th ATP Regulation.

(a) The high number of product authorisations affected by the new CLH will lead to a significant workload for both AHs and CAs when dealing with the notifications of administrative changes to remove the general public as an user category from the summary of the product characteristics (SPC);

(b) The affected products will be subject to the renewal of the authorisation within the same timeframe and CAs can easily remove this user category from the SPC of the affected products when renewing the authorisations affected by the new CLH,

(13) It is agreed that, where the AH does not intend to keep the general public as a user category, by derogation of the approach agreed under document CA-Nov15-Doc.4.1-Final, the AH should be relieved from the obligation to notify the administrative change and the relevant CA would then remove any uses by the general public when concluding on the application for renewal of the product.

(14) In cases where the AH intends to apply for a major change to reduce the concentration of the active substance below the SCL in order to keep the general public as a user category, that major change needs to be agreed by the relevant CA(s) before the deadline for the implementation of the new CLH. Therefore, on account of the timelines established in Article 8 of the changes Regulation[8], it is recommended that such application is submitted as soon as possible[9].

2.3- Period of grace:

(15) Products already placed on the market with the old C&L before the date of application of the 9th ATP Regulation could in principle benefit from the period of grace set by Article 52 of the BPR, as the restrictions would only be based on a hazard classification and not to a different level of risk.

(16) However, the period of grace in Article 52 of the BPR regarding the <u>making available</u> on the market of the affected products has to be read in connection with the general provisions set in Article 2 of the 9th ATP Regulation, according to which after the entry into application of the ATP Regulation:

(a) Any biocidal product placed on the market shall comply with the new CLH; in other words, after that date there will be no placing on the market of the products with the old C&L.

(b) Products already placed on the market before that date, which have not been supplied to the final user, shall also comply with the new CLH and shall therefore have been relabelled to include the new hazard and precautionary statements, pictograms, etc... resulting from the new CLH; in other words, the products with the old labels cannot stay in the supply chain.

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[8] Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

[9] See also paragraph 20.

(17) This means in practice that there will be no period of grace granted in accordance with Article 52 of the BPR for the making available on the market of the products with the old C&L (and still including the general public as an user category), as in fact the 18-month transitional period set by the 9th ATP Regulation already provides the AH and the persons making the products available on the market sufficient time to handle the stocks of the affected products.

(18) Therefore, the period of grace regarding the use of the products already supplied to final users referred to in Article 52 of the BPR (i.e. up to 6 months) would start counting after the end of the 18-month transitional period referred to in the 9th ATP Regulation (*see Annex*).

2.4.- Interaction with the renewal process

(19) The annex to this document also shows the interaction between the implementation of the new CLH in already authorised anticoagulant rodenticides and the renewal process to be finished by December 2017[10].

(20) In accordance with paragraphs 13 and 14 above, CAs shall ensure that where an application for a major change to reduce the concentration of the active substance below the SCL has not been submitted or agreed by the date of entry into application of the 9th ATP, any uses previously authorised for the general public are removed from the SPC resulting from the renewal procedure[11].

(21) During the renewal process the currently authorised products may be subject to new terms and conditions as a result of new risk mitigation measures that might be imposed by the AS renewal (e.g. maximum/minimum pack sizes, supply in ready-to-use, non-refillable temper resistant bait stations for the general public, etc.).

(22) Therefore, when renewing those products the relevant CAs shall also grant a period of grace in accordance with Article 52 of the BPR, both for the making available on the market and use provided that the new CLH has been implemented (and where relevant, the user category "general public" removed from the authorisation).

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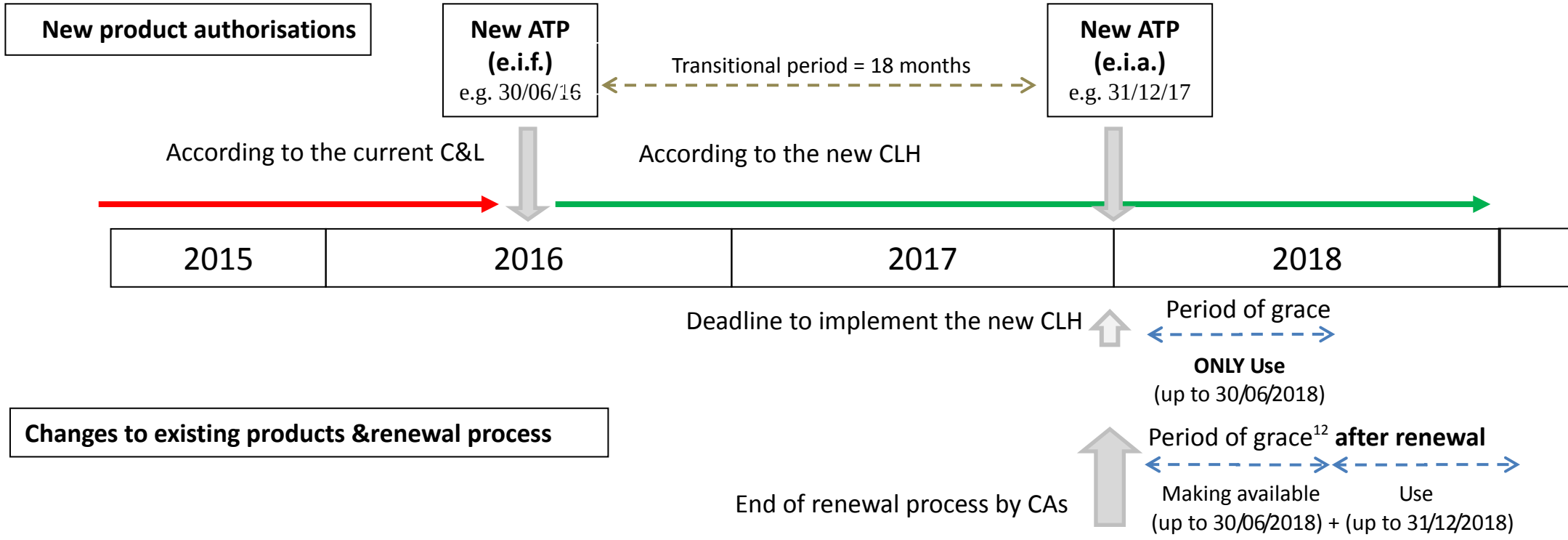
[10] See document CA-Nov14-Doc.5.2.a - Final " Optimisation of the renewal process of anticoagulant rodenticides", available at https://circabc.europa.eu/w/browse/7d131275-b0fc-43d5-b990-a0903f22688e

[11] Should it be the case, the procedure for the major change will continue being processed after the renewal of the authorisation and when agreed, implemented in the already renewed authorisation (i.e. reintroduction of any uses previously authorised for the general public for which the efficacy has been demonstrated in the application for the major change).

Annex: Overview of the relevant timelines[11] and interaction with the renewal process of anticoagulant rodenticides.



[11] Estimates based on a publication date of the 9th ATP Regulation by 10/06/2016.

[12] Provided that the new CLH has been implemented (and where relevant, the user category "general public" removed from the authorisation).