

Biocidal Products Committee (BPC)

Opinion on the application for renewal of the approval of the active substance:

Coumatetralyl

Product type: 14

ECHA/BPC/109/2016

Adopted

16 June 2016

Opinion of the Biocidal Products Committee

on the application for renewal of the approval of the active substance coumatetralyl for product type 14

In accordance with Article 14(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products (BPR), the Biocidal Products Committee (BPC) has adopted this opinion on the renewal in product-type 14 of the following active substance:

Common name:	coumatetralyl
Chemical name(s):	4-hydroxy-3-(1, 2, 3, 4-tetrahydro-1-naphthyl)coumarin
EC No.:	227-424-0
CAS No.:	5836-29-3

This document presents the opinion adopted by the BPC, having regard to the recommendations of the evaluating Competent Authority. The assessment report, as a supporting document to the opinion, contains the detailed grounds for the opinion.

Process for the adoption of BPC opinions

Following the submission of an application by Bayer S.A.S. on 18 December 2014 (part 1) with supporting documentation on 17 July 2015 (part II), the evaluating Competent Authority Denmark submitted its recommendations laid down in an assessment report to ECHA on 23 March 2016. In order to review the assessment report of the evaluating Competent Authority, the Agency organised consultations via the BPC and its Working Groups. Revisions agreed upon were presented and the assessment report and the conclusions were amended accordingly. The evaluating Competent Authority did not consider that a full evaluation according to the first paragraph of Article 14(2) of Regulation (EU) No 528/2012 was necessary.

Information on the fulfilment of the conditions for considering the active substance as a candidate for substitution was made publicly available on the ECHA web-site (at <http://echa.europa.eu/addressing-chemicals-of-concern/biocidal-products-regulation/public-consultation-on-potential-candidates-for-substitution>) on 17 December 2015 in accordance with the requirements of Article 10(3) of Regulation (EU) No 528/2012. Interested third parties were invited to submit relevant information by 15 February 2016.

Adoption of the BPC opinion

Rapporteur: Denmark

The BPC opinion on the renewal of the active substance coumatetralyl in product type 14 was adopted on 16 June 2016.

The BPC opinion takes into account the comments of interested third parties provided in accordance with Article 10(3) of Regulation (EU) No 528/2012.

The BPC opinion was adopted by consensus.

Detailed BPC opinion and background

1. Overall conclusion

Since coumatetralyl fulfils the criteria set in Article 5(1) of Regulation (EU) No 528/2012, the overall conclusion of the BPC is that the approval of coumatetralyl in product type 14 should normally not be renewed, unless one of the conditions for derogation in Article 5(2) is met. The process related to the demonstration of whether the conditions for derogation set in Article 5(2) are met, is not in the remit of the BPC¹. The detailed grounds for the overall conclusion are described in the assessment report.

2. BPC Opinion

2.1. BPC Conclusions of the recommendation

a) Presentation of the active substance including the classification and labelling of the active substance

This evaluation covers the use of coumatetralyl in product-type 14. Coumatetralyl has a anti-vitamin K (AVK) mode of action, disrupting the normal blood clotting mechanisms, resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. Onset of symptoms may be delayed for several days after exposure.

Specifications for the reference source are established. The minimum purity of the active substance in the Biocidal product as placed on the market is 980 g/kg. The physico-chemical properties of the active substance and biocidal product are acceptable for the appropriate use, storage and transportation of the active substance and biocidal product. Validated analytical methods are available for the active substance as manufactured and for the relevant matrices (soil, air, water, body fluids and tissues, food/feed of plant origin and food/feed of animal origin).

Coumatetralyl has an existing harmonized classification in accordance with Regulation (EC) No 1272/2008 (CLP Regulation). The amended classification and labelling for coumatetralyl which was agreed by the REACH Committee on 4 February 2016 (9th ATP which is not yet published) is:

Classification according to the CLP Regulation	
Hazard Class and Category Codes	Repr. 1B Acute toxicity-oral: Acute Tox 2 Acute toxicity-dermal: Acute Tox 3 Acute toxicity-inhalation: Acute Tox 2 STOT RE 1 Aquatic chronic 1
Labelling	
Pictograms	GHS06 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H360D May damage fertility or the unborn child H330 Fatal if inhaled H300 Fatal if swallowed H311 Toxic in contact with skin H372 Causes damage to organs (blood)

¹ See document: Further guidance on the procedures related to the examination of the exclusion criteria and the conditions for derogation under Article 5(2) (CA-Nov14-Doc.4.5-Final).

	H410 Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Repr. 1B; H360D: $C \geq 0.003 \%$ STOT RE 1; H372 (blood): $C \geq 1.0 \%$ STOT RE 2; H373 (blood) $0.1 \% \leq C < 1.0 \%$ M = 10 for Aquatic Chronic toxicity

b) Intended use, target species, effectiveness and resistance

Coumatetralyl is used to control commensal rodents. The representative product is a paste contains 0.375 g of coumatetralyl per kg of paste which is sealed in paper bags as ready to use bait. It is only examined for rat control.

Coumatetralyl is used as a rodenticide pest control substance for the control of rodents especially rats in sewage systems, in and around buildings, open areas and on waste dumps. The applicant has not supported a usage of coumatetralyl on mouse at the active substance renewal as only one safe use has to be demonstrated for re-approval of the active substance. However, this should not prevent future products authorisation on species other than rats as long as relevant robust efficacy data are submitted and a safe use can be demonstrated.

Coumatetralyl is used to control: *Rattus norvegicus* (Norway rat / brown rat), *Rattus rattus* (Roof rat / black rat) by professionals and non-professionals.

The nominal concentration of coumatetralyl in products other than contact formulations shall not exceed 375 mg/kg and only ready-for use products shall be authorised, as described in the first approval (Directive 2009/85/EC).

No new information of the evaluated product has been provided at this stage of active substance renewal.

Formulated products containing coumatetralyl are not applied directly on food or feeding stuffs. Products are not intended to be applied directly on surfaces intended for contact with food or feeding stuffs. However, coumatetralyl containing products are intended to be used in premises where food or feeding stuffs are prepared or stored.

No new information was submitted for the renewal process on the representative biocidal product. All uses relative to coumatetralyl products that are either already on the market or under development will be submitted at the stage of biocidal product renewal. New efficacy studies have been conducted with Racumin Paste (representative product) and Racumin foam since the first approval of coumatetralyl. The studies were conducted solely to support the registration of coumatetralyl based products and were submitted at product authorisation stage. Since these efficacy studies were conducted with products and the results observed in those studies do not affect any end-point or the risk assessments, the conclusions of the initial assessment are still valid for the renewal of coumatetralyl.

The distribution of resistance to anticoagulant compounds including coumatetralyl has been known for many years. The results from several studies presented in the RMM report (see section c3) also demonstrated resistance for both rat and mouse against coumatetralyl. However, the new information regarding resistance does not change the conclusions from the first approval of coumatetralyl.

According to the conditions for granting an authorisation of a biocidal products in Article 19(1)(b)(ii) of Regulation (EU) No 528/2012, products should be "sufficiently effective and have no unacceptable effect on the target organisms such as resistance, or, in the case of vertebrates, unnecessary suffering and pain". It is recognised that slow acting anticoagulant

rodenticides like coumatetralyl do cause pain for several days in rodents and are generally not considered as a humane method to control rodents. Other, more humane control methods are available: alternative active substances or biocidal products as well as non-chemical alternatives. However, as there are concerns whether these alternatives are sufficiently effective or do present other practical or economical disadvantages, anticoagulant rodenticides containing biocidal products should be accepted.

c) Overall conclusion of the evaluation including the need for risk management measures

c1) Evaluation of information submitted during the renewal

Some new studies regarding physico-chemical properties have been submitted: i) physical state: white crystalline powder. Odourless; ii) pH-value in distilled water (24°C): pH = 5.0; iii) dissociation constant (21° C): pKa = 3.9; iv) particle size distribution: The median particle size is 90.2 um. Method validation various crop groups: the limit of quantitation (LOQ), was determined to be 0.01 mg/kg. Method validation foodstuff of animal origin: the limit of quantitation (LOQ), was determined to be 0.01 mg/kg. All these new studies were conducted to fulfil data gaps that were identified within the framework of the first approval of coumatetralyl.

Some new studies regarding fate and distribution in the environment have been submitted e.g.:

Hydrolysis: coumatetralyl did not appreciatively decline under the conditions of the study and therefore can be considered stable to hydrolysis.

Phototransformation (water): the results indicate a short half-life (a few hours to one day).

Adsorption/Desorption: the Kd for coumatetralyl varies from 0.895 to 25.2 ml/g and the Koc from 61.6 to 771 ml/g). Freundlich adsorption constants (Kf) for coumatetralyl were 0.848 to 18.4 ml/g giving Kfoc values of 49.7 to 562 ml/g (1/n 0.941 to 0.980). Freundlich desorption constants were 4.01 to 22.4 ml/g (1/n 0.979 to 1.05). This new study did not change the conclusions from the first approval where a Ka range from 2.14 – 8.10 and the Kaoc range from 71- 735 cm³. However, there is a change in the endpoint Koc, primarily because the geometric mean of the data should now be used for FOCUS modelling, whereas previously it was acceptable to use the arithmetic mean. Therefore, both values will be included in the end-point list. The arithmetic mean from both studies is 258 ml/g and the geometric mean value for the data from both the original and new studies is 177 ml/g. This difference is not considered significant.

Biodegradation in soil: calculation of the rates of degradation of coumatetralyl was performed according to FOCUS (2006, 2011) guidance. The recalculated DT50 values to 12°C ranged from 13.1 to 19.4 days. At Environment Working Group there was a discussion regarding the calculation of the rates of degradation of coumatetralyl using FOCUS guidance. It was agreed that before the FOCUS calculation should be used in calculation of the rate of degradation for biocides further discussion is needed. Under the first approval, it was concluded that the half-life in soil is less than 30 days. Therefore, there is no change in the conclusion from the first approval.

The new information submitted does not change the conclusion of the evaluation carried out for the first approval.

c2) Conclusions of the initial evaluation and the need to review these

None of the new studies submitted affects the conclusion of the initial assessment of the risk assessment or PBT status and therefore support that the conclusion from the initial assessment remain valid.

The representative product contains 0.375 g of coumatetralyl per kg of paste which is sealed in paper bags as ready to use bait. It is only examined for rat control. Coumatetralyl is used for the control of rodents especially rats in sewage systems, in and around buildings and on waste dumps.

High risk to non target mammals and birds was identified following the use of coumatetralyl containing products. High PEC/PNEC ratios were estimated both for primary and for secondary poisoning.

Monitoring data from the last years demonstrate that coumatetralyl is found in non-target animals throughout Europe. Generally, the frequency of incidents is assumed to correlate with the use volumes of the anticoagulant substances.

Risk to infants accidentally ingesting bait was identified in the risk assessment. Many incidents of poisonings, both accidental and intentional, have been reported in literature for anticoagulant rodenticides.

At product authorization stage, new guidance documents should be taken into account. These includes e.g. the harmonised approach for the assessment of anticoagulant rodenticides made by HEEG (HEEG opinion 10 and 12) and new guidance on dermal absorption.

Due to the toxicity of coumatetralyl and the risk of primary and secondary poisoning of animals and humans, coumatetralyl should be used as limited as possible and all appropriate and available risk mitigation measures (RMMs) should be applied.

c3) Need for risk management measures

Anticoagulant rodenticides (AR) are divided into First Generation AR (FGAR; warfarin, chlorophacinone, coumatetralyl), requiring several days of feeding to be fully active and Second Generation ARs (SGARs; bromadiolone, difenacoum, brodifacoum, flocoumafen and difethialone), which are more potent and effective after only one day of feeding. Difethialone, brodifacoum and flocoumafen are often referred to as more potent than bromadiolone and difenacoum.

Anticoagulant rodenticides have been found in many studies in non-target animals. Some new studies were submitted for the renewal of the anticoagulant rodenticides: i) in Denmark coumatetralyl and several SGARs were found in stone martens and polecats; ii) in Scotland anticoagulant rodenticides are regularly detected in the Predatory Bird Monitoring Scheme and in incidents of suspected poisoning of animals by pesticides investigated under the Wildlife Incident Investigation Scheme; iii) in Germany several FGARs and SGARs were found in the red fox where the same was observed in Spain in several hedgehog and owl species and in Finland in several non-target animals. More studies are publicly available but these studies published between 2012 and 2016 show that there is a concern with respect to secondary poisoning of non-target organisms.

Due to the identified risk for environment and human health, anticoagulant rodenticides

have to be handled with great caution and all appropriate and available risk mitigation measures (RMMs) have to be applied. As several AR, which are quite similar regarding hazardous properties and associated risks, were assessed for possible renewal at the same time (see also the CA-document "Substance approval and product authorisation renewals of the anticoagulant rodenticides; CA-Feb13-Doc.5.2.b), the Commission initiated a project on possible risk mitigation measures which could be applied for all anticoagulant rodenticides. This resulted in the report "Risk mitigation measures for anticoagulant rodenticides as biocidal products" (Berny, P. et al., October 2014). The report distinguishes between risk mitigation measures at community level through imposing conditions in the approval for the active substance, and measures at national level when products are authorised.

As a follow-up to the report, the Commission organised a workshop on 26 February 2015 with the aim to discuss and agree on RMMs to be recommended for anticoagulant rodenticides. The workshop was attended by representatives of several Member State Competent Authorities, the Commission, the Rodenticide Resistance Action Group (RRAG, UK), CEPA (Confederation of European Pest Management Associations), CEFIC (the European Chemical Industry Council) and members of the BPC Efficacy Working Group. A summary report presenting the results of the workshop was discussed at the CA meetings in March and November 2015 ("Revised version of the summary of the workshop on the RMM report held in Brussels on 26/02/2015"; CA-Nov15-Doc.5.4). The result of an internet survey on the relevant RMMs was included in the report.

A critical review of the RMM was submitted by the applicant of coumatetralyl when submitting the application for renewal in line with the CA document "Complementary guidance regarding the renewal of anticoagulant rodenticide active substances and biocidal products" (CA-Sept14-Doc.5.2-Final.Rev1).

Based on the report, the workshop, the applicants' critical review and other information available to the evaluating Competent Authority, recommendations on the use of anticoagulant rodenticides were prepared in order to minimise the negative impact of anticoagulant rodenticides in general and specifically for coumatetralyl. Detailed considerations for these recommendations are described in the assessment report. The proposal for renewal of the inclusion in the Union list of approved active substances in section 2.3 and the elements to be taken into account when authorising products, as described in section 2.4, are based on these considerations.

2.2. Exclusion, substitution and POP criteria

2.2.1. Exclusion and substitution criteria

The table below summarises the relevant information with respect to the assessment of exclusion and substitution criteria:

Property		Conclusions	
CMR properties	Carcinogenicity (C)	no classification required	Coumatetralyl fulfils criterion (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	Cat 1B	

PBT and vPvB properties	Persistent (P) or very Persistent (vP)	not P or vP	Coumatetralyl does not fulfil criterion (e) of Article 5(1) and does not fulfil criterion (d) of Article 10(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	not B or vB	
	Toxic (T)	T	
Endocrine disrupting properties	Coumatetralyl is not considered to have endocrine disrupting properties. Coumatetralyl does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Coumatetralyl does not fulfil criteria (b) of Article 10(1).		
Concerns linked to critical effects	As there is a concern with respect to the occurrence of primary and secondary poisoning, even when applying restrictive risk management measures, coumatetralyl fulfils criterion (e) of Article 10.		
Proportion of non-active isomers or impurities	Coumatetralyl is not considered to have a significant proportion of non-active impurities. Coumatetralyl does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

Coumatetralyl does meet the exclusion criteria laid down in Article 5(1)(c) of Regulation (EU) No 528/2012.

Coumatetralyl does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012 if approved, and is therefore considered as a candidate for substitution.

The exclusion and substitution criteria were assessed in line with the "Note on the principles for taking decisions on the approval of active substances under the BPR"² and in line with "Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR"³ agreed at the 54th and 58th meeting respectively, of the representatives of Member States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products. This implies that the assessment of the exclusion criteria is based on Article 5(1) and the assessment of substitution criteria is based on Article 10(1)(a, b, d, e and f).

2.2.2. POP criteria

Coumatetralyl exhibits certain POP characteristics. However, the substance does not fulfil the numerical screening criteria for potential for long-range environmental transport. There are no monitoring data available or other evidence indicating potential for long range environmental transport.

² See document: Note on the principles for taking decisions on the approval of active substances under the BPR (available from <https://circabc.europa.eu/d/a/workspace/SpacesStore/c41b4ad4-356c-4852-9512-62e72cc919df/CA-March14-Doc.4.1%20-%20Final%20-%20Principles%20for%20substance%20approval.doc>)

³ See document: Further guidance on the application of the substitution criteria set out under article 10(1) of the BPR (available from [https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10\(1\).doc](https://circabc.europa.eu/d/a/workspace/SpacesStore/dbac71e3-cd70-4ed7-bd40-fc1cb92cfe1c/CA-Nov14-Doc.4.4%20-%20Final%20-%20Further%20guidance%20on%20Art10(1).doc))

2.2.3. Results from public consultation

As coumatetralyl is considered as a candidate for substitution ECHA launched the public consultation in accordance with Article 10(3) of Regulation (EU) No 528/2012 together with all other anticoagulant rodenticides for which applications for renewals have been submitted. The public consultation took place from 17 December 2015 to 15 February 2016.

In total 80 contributions were submitted by stakeholder's organisations, companies, non-governmental organisations, independent experts and national bodies. Below a summary of the information submitted is presented where it should be noted that no peer review has taken place.

Most contributions are based on position papers prepared by the European Chemical Industry Council (CEFIC) and the Confederation of European Pest Management Associations (CEPA) and stating that currently no significant and effective alternative to anti-coagulant rodenticides is readily available. In addition it is sometimes suggested that a major improvement for the environment would be to limit the use of rodenticides, based on integrated pest management and/or professional pest management companies only. In the CEPA position paper it is stated that until recently no common harmonized requirement existed across Europe for the licensing and monitoring of either the pest management companies themselves, or the technicians who undertake the application. In 2015, "EN 16636 Pest management services - Requirements and competences" was published. This standard and an accompanying certification scheme have since been launched by CEPA.

The alternatives mentioned in the contributions fall into two groups:

1. to be used to kill rodents (e.g. chemical alternatives, mechanical or electrical traps or glue-/sticky-boards), and
2. measures to be taken to restrict access of rodents to food sources.

Ad 1) As chemical alternatives alphachloralose, hydrogen cyanide, aluminium phosphide, carbon dioxide and powdered corn cob are mentioned but at the same time some limitations in terms of use (limited to use for – indoor - mouse control or fumigants which can only be used by trained professionals), efficacy and effectiveness of using these substances are listed.

Mechanical and electrical traps are proposed in some contributions as a serious alternative to anticoagulant rodenticides due to technical progress in trap development, for example multi-catch traps and equipping traps with electronic communication devices limiting the frequency of inspection to when a rodent is actually killed by the trap. Traps have been developed for mouse and rats, with dedicated traps for the control of rats in sewers. Limited testing on efficacy and effectiveness for rodent control has been carried out, for example on the control of house mice. Other contributions state that traps cannot be considered as cost-effective and efficient as the use of an efficacious rodenticide. The following disadvantages are mentioned: requirement of a high degree of skill, adverse impacts of non-target wild life and humaneness. It is stated that traps may provide effective control of small infestations, in particular for mice. Some of these disadvantages are particularly relevant for glue-/sticky boards, which are not allowed in some MS.

Ad 2) Measures to restrict access to food sources, are rather considered as complementary techniques. Examples are habitat modification, rodent proofing and the use of repellents. It is stated in a contribution that no chemical repellents for rodent control are approved under Regulation (EU) No 528/2012 and there is no convincing scientific evidence that electromagnetic devices are effective.

2.3. BPC opinion on the application for renewal of the approval of the active substance coumatetralyl in product type 14

As the exclusion criteria are met, coumatetralyl should normally not be renewed unless one of the conditions for derogation set in Article 5(2) of Regulation (EU) No 528/2012 is met.

If coumatetralyl is renewed, the renewal shall be subject to the following conditions:

A. Generic conditions

1. Specification: minimum purity of the active substance evaluated: 980 g/kg.
2. Coumatetralyl is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of Regulation (EU) No 528/2012.
3. The authorisations of biocidal products are subject to the following condition(s):
 - a. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.
 - b. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.
 - c. The nominal concentration of coumatetralyl shall not exceed 375 mg/kg in products other than contact formulations and shall not exceed 4000 mg/kg in contact formulations.
 - d. Products shall contain an aversive agent and a dye.
 - e. Products shall not be authorised in the form of tracking powder.
 - f. Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals.
 - g. Only ready-to-use products shall be authorised.
 - h. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include, for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category.
 - i. Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the national SPC and be reflected on the product label.

B. Specific conditions per user category⁴

B.1. General public

The authorisations of biocidal products are subject to the following conditions:

- a. Products shall only be authorised for use in tamper-resistant bait stations.
- b. Products shall only be supplied in a maximum quantity of bait per pack of:

⁴ See CA-March16-Doc.5.4.a, that describes each user category.

target species	bait type	maximum quantity of bait per pack (g)
mice only	grain, pellet or paste	250
	wax block	500
rats only or mice and rats	grain, pellet or paste	750
	wax block	1,500

- c. Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings.
- d. Products containing against *Mus musculus* shall only be authorised for use indoors.
- e. Products shall not be authorised for use as a permanent bait or in pulse baiting treatments.
- f. Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken*.
- g. Persons making products available on the market for the general public shall make sure that the products are supplied with information, other than the leaflet referred to in point e, on the risks associated with these products, on measures to limit their use to the minimum necessary and on appropriate precautionary steps to be taken.

B.2. Professional users

The authorisations of biocidal products are subject to the following conditions:

- a. Products shall not be authorised for use in sewage, open area or waste dumps.
- b. Products shall not be authorised for use in permanent or pulse baiting treatments.
- c. Products shall only be authorised for use in tamper-resistant bait stations.
- d. Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public.

B.3. Trained professional users

The authorisations of biocidal products are subject to the following conditions:

- a. Products may be authorised for use in sewage, open area or waste dumps and in and around buildings.
- b. Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations.
- c. Products shall not be authorised for use as a permanent bait or pulse baiting treatments.

* The wording of this provision was amended on 19 July 2016 to correct an editorial mistake.

- d. Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

Coumatetralyl gives rise to concern according to Article 28(2)(a) and (b) of Regulation (EU) No 528/2012. Therefore, coumatetralyl cannot be included in Annex I of Regulation (EU) No 528/2012.

2.4. Elements to be taken into account when authorising or renewing products⁵

1. The active substance coumatetralyl is considered as a candidate for substitution, and consequently the competent authority shall perform a comparative assessment as part of the evaluation of an application for national authorisation. However, in the context of the renewal of the existing product authorisations the comparative assessment was referred to the Commission in line with Article 23(5) of Regulation (EU) No 528/2012 (CA-March14-Doc.5.4-Final).
2. As far as possible, decisions of authorisation of anticoagulant rodenticides products should be harmonised. On the other hand, on duly justified grounds, Member States can propose to derogate from mutual recognition under Article 37 of Regulation (EU) No 528/2012, and decide to refuse to authorise or adjust the use of anticoagulant rodenticides to protect vulnerable groups or the environment, for instance to reduce the risk of primary and secondary poisoning.
3. The following recommendations and risk mitigation measures have been identified for the uses assessed. Authorities should consider these risk mitigation measures when authorising products, together with possible other risk mitigation measures, and decide whether these measures are applicable for the concerned product:
 - a. Products should not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
 - b. In addition to the general requirement in Article 69 of Regulation (EU) No 528/2012, product information should include elements regarding:
 - i. Storage away from the reach of children and pets;
 - ii. Recommendation for the general public and professional users regarding the frequency of revisiting the treated area;
 - iii. Recommendation to wear protective gloves and wash hands when removing dead bodies and uneaten bait.
 - c. It should be encouraged to set up training schemes in each member state to ensure that trained professionals are properly trained to use anticoagulant rodenticides.
 - d. Member states should encourage the application of Codes of Best Practices in rodent control. These codes of best practice may include instructions for use regarding the planning, documentation, application and servicing as well as termination of a rodent control campaign.
 - e. For trained professionals the frequency of visits should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment.
 - f. Information should be available for professionals as well as non-professionals on

⁵ Some of the elements may be subject to refinement by the *Working Party on SPCs for anticoagulant rodenticides* developing a harmonised wording that will be included in the SPCs.

non-chemical measures to prevent and control rodent infestations.

- g. Product information of products authorised for the general public against rats and mice shall recommend that in case of suspected lack of efficacy by the end of the treatment, the user should contact a pest control service or the supplier of the product.
- h. A minimum quantity of 5 kilograms of bait per pack is recommended for products supplied to professional or trained professional users.
- i. Trained professional users are required to carry out a pre-baiting survey of the infested area in order to determine the extent of the infestation.
- j. Bait stations should be clearly labelled to show they contain rodenticides (including product name, active substance and a contact phone number) and that they should not be moved.
- k. When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- l. At product authorisation new human exposure calculations should be performed taking into account HEEG opinion 10 and 12⁶.

2.5. Requirement for further information

Sufficient data have been provided to verify the conclusions on the active substance, permitting the proposal for the renewal of coumatetralyl.

For the next renewal the following information is required:

- Applicants should provide within the application for the next renewal all new data available to them on resistance to the active substance on the target organisms in the EU.
- A general discussion will take place on data requirements for renewal at the BPC, ACP and Environment Working Groups. It may be possible that a Working Group requests additional data to be submitted for the next renewal of the active substance approval.

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⁶ The Human Exposure Expert Group (HEEG) prepared opinions in the context of the Biocidal Products Directive (BPD) on harmonised approaches to biocide exposure assessment. The opinions are available from the ECHA website at http://echa.europa.eu/view-article/-/journal_content/title/support-biocides-heeg-opinions.