

Biocidal Products Committee (BPC)

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

Brodifacoum

Product type: 14

ECHA/BPC/113/2016

Adopted

16 June 2016

Opinion of the Biocidal Products Committee

on the application for renewal of the approval of the active substance brodifacoum 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:	brodifacoum
Chemical name(s):	3-[(1<i>RS</i>,3<i>RS</i>;1<i>RS</i>,3<i>SR</i>)-3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin
EC No.:	259-980-5
CAS No.:	56073-10-0

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 Sygenta Crop Protection AG on 31 July 2015 to the evaluating Competent Authority the Netherlands and the submission of an application by Exponent International representing PelGar International Ltd and Activa s.r.l. on 21 July 2015 to the evaluating Competent Authority Italy, the evaluating Competent Authority the Netherlands submitted its recommendations laid down in an assessment report to ECHA on 26 March 2016. This assessment report contains the combined recommendations of both applications. 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. Both evaluating Competent Authorities 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: the Netherlands and Italy

The BPC opinion on the renewal of the active substance brodifacoum 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 brodifacoum 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 brodifacoum 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 brodifacoum in product type 14. Brodifacoum is a 4-hydroxycoumarin derivate with an anticoagulant action. Brodifacoum inhibits the vitamin K1-epoxide cycle, thereby interrupting the supply of vitamin K1 necessary for producing blood clotting factor precursors.

Specifications for the reference source are established. 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, water, body fluids and tissues, food/feed of plant (cucumber, wheat, lemon and oilseed-rape) and animal origin.

Brodifacoum has no existing harmonized classification in accordance with Regulation (EC) No 1272/2008 (CLP Regulation). The classification and labelling for brodifacoum 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. 1A; H360D Acute Tox. 1; H300 Acute Tox. 1; H310 Acute Tox. 1; H330 STOT RE1; H372 (blood) Aquatic Acute 1; H400 Aquatic Chronic1; H410
Labelling	
Pictograms	GHS06 GHS08 GHS09
Signal Word	Danger
Hazard Statement Codes	H360D: May damage the unborn child H300: Fatal if swallowed H310: Fatal in contact with skin H330: Fatal if inhaled H372: Causes damage to the blood through prolonged or

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).

	repeated exposure H410: Very toxic to aquatic life with long lasting effects
Specific Concentration limits, M-Factors	Repr. 1A; H360D: C ≥ 0.003 % STOT RE 1; H372: C ≥ 0.02 % STOT RE 2; H373: 0.002 % ≤ C < 0.02 % M =10 for Aquatic Acute toxicity M =10 for Aquatic Chronic toxicity

b) Intended use, target species, effectiveness and resistance

Brodifacoum is intended to be used for the control of commensal rodents (*Rattus norvegicus*, *Rattus rattus*, and *Mus musculus*) in and around buildings and in sewers. The intended users are professionals (trained and non-trained) and general public.

Brodifacoum is a 4-hydroxycoumarin derivate with an anticoagulant action. Brodifacoum is a high potent second generation anticoagulant. No incidences of resistance towards brodifacoum are known. However, it should be kept in mind that the use of brodifacoum has been limited in volume and time. Brodifacoum (as well as the other high potent second generation anticoagulant rodenticides) is an important substance in situations when problems with resistance occurs.

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 brodifacoum 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

An analytical method for the analysis of brodifacoum in soil was submitted. In addition, a batch analysis was provided.

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

The calculated risks of primary and secondary poisoning are high. It is recognised, however, that the risk of brodifacoum-poisoning of livestock and household animals as well as of wild seed-eating birds can be reduced to a minimum when the rodenticide is handled with diligence and care (adherence to good baiting practice). Appropriate risk mitigation measures must be taken to protect the environment.

At product authorization stage, current 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 guidance on dermal absorption.

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 difethialone 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 brodifacoum. 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	Brodifacoum fulfils criterion (c) of Article 5(1)
	Mutagenicity (M)	no classification required	
	Toxic for reproduction (R)	Cat 1A	
PBT and vPvB properties	Persistent (P) or very Persistent (vP)	P and vP	Brodifacoum fulfils criterion (e) of Article 5(1)
	Bioaccumulative (B) or very Bioaccumulative (vB)	B	
	Toxic (T)	T	
Endocrine disrupting properties	Brodifacoum is not considered to have endocrine disrupting properties. Brodifacoum does not fulfil criterion (d) of Article 5(1).		
Respiratory sensitisation properties	No classification required. Brodifacoum 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, brodifacoum fulfils criterion (e) of Article 10.		
Proportion of non-active isomers or impurities	Brodifacoum is not considered to have a significant proportion of non-active impurities. Brodifacoum does not fulfil criterion (f) of Article 10(1).		

Consequently, the following is concluded:

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

Brodifacoum does meet the conditions laid down in Article 10(1)(a) and (e) of Regulation (EU) No 528/2012, 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 BPR² 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

Brodifacoum is not considered to be a POP substance.

2.2.3. Results from public consultation

As brodifacoum 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 others 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

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))

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 brodifacoum in product type 14

As the exclusion criteria are met, brodifacoum 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 brodifacoum is renewed, the renewal shall be subject to the following conditions:

A. Generic conditions

1. Specification: minimum purity of the active substance evaluated: 950 g/kg.
2. Brodifacoum 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 brodifacoum in the products shall not exceed 50 mg/kg.
 - 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 with a maximum quantity of bait per pack of:

target species	bait type	maximum quantity of bait per pack (g)
mice only	grain, pellet or paste	50
	wax block	100
rats only or mice and rats	grain, pellet or paste	150
	wax block	300

- c. Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings.
- d. Products against *Mus musculus* shall only be authorised for use indoors.
- e. Products shall not be authorised for use in permanent or 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. Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment.

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.

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

- 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.
- 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 may be authorised for use in pulse baiting treatments.
- d. Products shall not be authorised for use as a permanent bait.
- e. 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.

Brodifacoum gives rise to concern according to Article 28(2)(a) and (b) of Regulation (EU) No 528/2012. Therefore, brodifacoum 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 brodifacoum 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 or renewing product authorisations, 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:

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.

- 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 Practices 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 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 brodifacoum. However, further information is required as detailed below.

One member of the Task Force only (i.e., PelGar International Ltd), should provide quality control data from the past five years to support their 5-batch analysis conducted in 2010 on batches manufactured in 2009. This information should be submitted to the evaluating Competent Authority (Italy) as soon as possible, but not later than October 2016.

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.

For the next renewal the following information is required:

- A method for drinking water fulfilling the relevant toxicological standard should be provided as soon as possible, but at the latest by the next renewal of the active substance.
- 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 following renewal of the active substance approval.

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