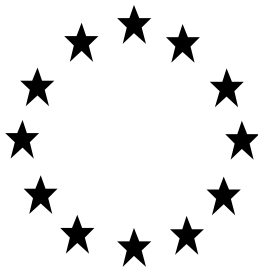
Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR NATIONAL AUTHORISATION APPLICATIONS



Product identifier in R4BP	**Ratimor Brodifacoum Fresh Bait**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-KX018723-12
Asset No. in R4BP	IE-0000011-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	**IE/BPA 70514**
Date	09.04.2018 (NA-RNL Renewal)

Version 2.0

1 Version History

Date	Version	Reason for revision
2013/07/18	Version 1.0	Initial PAR
2018/01/26	Version 1.1	MAC PAR
2018/04/09	Version 2.0	Updated at 1st Renewal of authorisation RNL

2 Overview of applications

Application type	refMS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)	Page
National Authorisation Dir.98/8/EC	IE	n/a	2013/07/18	1st Authorisation	115
NA-MAC	IE	BC-WM031623-27	2018/01/26	Major Change	513
NA-RNL	IE	BC-TE033592-41	2018/04/09	Renewal	32

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1st Renewal PAR – April 2018

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF A NATIONAL AUTHORISATION (NA-RNL)

Product identifier in R4BP	**Ratimor Brodifacoum Fresh Bait**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
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1 Conclusion

The Irish Competent Authority for the authorisation of biocidal products has processed an application for renewal for the biocidal product Ratimor Brodifacoum Fresh Bait which contains the active substance Brodifacoum (0.0029 % w/w).
The assessment presented in the Product Assessment Report for the first authorisation (2013) showed acceptable efficacy but unacceptable risks for the environment, if the product is used as a rodenticide (product-type 14) for use in and around buildings, by the general public, professionals and trained professionals, and in sewers by professionals and trained professionals.
A major change evaluation in 2017 (case number BC-WM031623-27) assessed and authorised the reduction in active substance content from 0.005% 0.0029% w/w.

The conditions for granting an authorisation according to Article 19 (1) of Regulation (EU) No 528/2012[1] (BPR) are not fulfilled.
In consequence the product can only be authorised in accordance with Article 19 (5) BPR, as this Article provides Member States with the legal basis to authorise products in cases where not authorising the product would result in disproportionate negative impacts for society when compared to the risks to human health arising from the use of the biocidal product.

Detailed information on the uses appropriate at the renewal of authorisation is presented in section 2.4. General directions for use of the product are summarised in section 2.5.

Prior to renewing the approval of anticoagulant active substances and renewing the authorisations of the respective products discussions took place at EU-level to harmonise use instructions and risk mitigation measures to the greatest possible extend. As an outcome of these discussions a set of three standard SPCs (Summary of Product Characteristics) compiling the relevant sentences for the uses that may be authorised for each of the three user categories (general public, professionals and trained professionals) has been produced (for details please refer to document CA-Nov16-Doc.4.1.b – Final).

The specific conditions from Commission Implementing Regulation (EU) 2017/1381[2] for the active substance Brodifacoum were considered for the re-assessment.

1 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, last amended by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014.

2 Commission Implementing Regulation (EU) 2017/1381 of 25 July 2017 renewing the approval of Brodifacoum as an active substance for use in biocidal products of product-type 14

The Irish CA concludes that the conditions set out in Article 5(2) b) and c) of the BPR are currently met. Anticoagulant rodenticides are considered essential to ensure appropriate rodent control in Ireland by efficient pest management and as a consequence, to prevent or control any serious danger to human and animal health in which rodents are involved.
Rodent control in Ireland currently relies largely on the use of anticoagulant rodenticides, the non-renewal of which could lead to insufficient rodent control in Ireland. This may not only cause significant negative impacts on human or animal health or the environment, but may also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences in Ireland.

The product has been classified according to the 9th ATP of Regulation (EC) No 1272/2008[3]. Detailed information on classification and labelling is provided in Section 2.3.
As a consequence of the new harmonised classification, the active substance Brodifacoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR Therefore, in line with Article 23 (1) BPR a comparative assessment for the product Ratimor Brodifacoum Fresh Bait has been conducted (for details see Section 3.10).

Comparative assessment
In line with Article 23 (1) BPR a comparative assessment for the product has been conducted (for details see Section 3.10).
In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled.
According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

Approval of the active substance
The active substance Brodifacoum is included in the Union list of approved active substances and the specific provisions laid down there are fulfilled:

The authorisations of biocidal products containing Brodifacoum are subject to the conditions listed in the Annex to Commission Implementing Regulation (EU) 2017/1381:

Composition and formulation
The ready-to-use product is a paste bait and contains the active substance Brodifacoum.
No substance of concern has been identified.
Please refer to section 5.1 for detailed information.

[3] 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

Efficacy

Effectiveness data has confirmed that Ratimor Brodifacoum Fresh Bait is effective in the proposed areas of use, at the recommended dose rate. The field trial data provided on mice (*Mus musculus)* and rats *(Rattus norvegicus* and *Rattus rattus*) endorses the lowering of active substance from 50 ppm to 29 ppm by confirming that the attractiveness and effectiveness of the bait is unaffected. Complete control of mice and rat infestations was achieved in all trials. Data previously evaluated demonstrated that Ratimor Brodifacoum Fresh Bait is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and effectiveness even under adverse environmental conditions has been established.

The conclusion of the evaluation is that the product may be authorised.

Risk assessment for human health

The human health risk assessment for this product is based on the active substance.

According to the BPC Opinion the EFSA-Guidance on dermal absorption had been taken into account when reviewing the dermal absorption of the product.

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use is unlikely.

For risk mitigation measures please refer to section 2.

Based on the risk assessment it is unlikely that the intended use(s) cause any unacceptable acute or chronic risk to professional users, bystanders and residents. Regarding the trained professional users health protection, there are no objections against the intended uses if the directions for use are followed (For details see section 2).

Risk assessment for the environment

No new data was provided. The only area where new guidance was relevant was with respect to the groundwater assessment. Following discussion at the CG-18 meeting and subsequent agreement, Tier II PEC groundwater was calculated using the FOCUS models PEARL or PELMO in the instances where Tier I indicated an exceedance of the relevant trigger value.

According to the risk assessment, the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 29 ppm in the ecotoxicology risk assessment.

In consequence the product can only be authorised in accordance with Article 19 (5) BPR.

Overall conclusion

The assessment of the biocidal product Ratimor Brodifacoum Fresh Bait remains valid. However, the authorisation has to be adapted where necessary taking into account the points mentioned above.

The biocidal product will be authorised according to Article 19 (5) BPR in conjunction with Article 23 (6) BPR.

According to Article 23 (6) BPR the authorisation of the product will be renewed for 5 years.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Ratimor Brodifacoum Fresh Bait

2.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Unichem d.o.o
	Address	Sinja Gorica 2 1360 Vrhnika Slovenia
Authorisation number	IE/BPA 70514	
Date of the authorisation	06/08/2013	
Expiry date of the authorisation	9/4/2023	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	Unichem d.o.o
Address of manufacturer	Sinja Gorica 2 1360 Vrhnika Slovenia
Location of manufacturing sites	Sinja Gorica 2 1360 Vrhnika Slovenia

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane Industrial Estate Alton Hampshire GU34 2QR UK
Location of manufacturing sites	Prazska 54 28 002 Kolin

	Czech Republic

2.2 Product composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0029

- The product contains a bittering agent and dyes.
  - Information on the full composition is provided in the confidential[4] annex (see section 5).
- According to the information provided the product contains no nanomaterial's as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on the substance(s) of concern

There are no substances of concern

2.2.3 Candidate(s) for substitution

The following substance was identified as a candidate for substitution:

- Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

- toxic for reproduction category 1A
- persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

[4] Access level: "Restricted" to applicant and authority

2.2.4 Type of formulation

Ready-to-use bait: Paste

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[5]

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
	GHS08	
Signal word		Warning
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental label elements		
Precautionary statements		
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of packaging and unused bait as hazardous waste in accordance with national regulations.
Note	-	

5 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

2.4 Use(s) appropriate after renewal of the authorisation

Table 4: Summary Table of Uses

No.	Use
1	House mice – general public – indoor
2	Rats – general public – indoor
3	Rats – general public – outdoor around buildings
4	House mice – professionals – indoor
5	Rats – professionals – indoor
6	House mice and/or rats – professionals – outdoor around buildings
7	House mice and/or rats – trained professionals – indoor
8	House mice and/or rats – trained professionals – outdoor around buildings
9	Rats – trained professionals – sewers

2.4.1 Use 1 appropriate after renewal of the authorisation – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	General public: Instruction for use indoor (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of

	the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 50g

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 50g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 50g

2.4.1.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper resistant baiting stations. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not use this product for permanent or pulse-baiting.

2.4.1.2 Use-specific risk mitigation measures

Prevent skin contact when disposing remains of baits.

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.2 Use 2 appropriate after renewal of the authorisation – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoor (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g,

	18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g,

	18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

2.4.2.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.2.2 Use-specific risk mitigation measures

Prevent skin contact when disposing remains of baits.

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.3 Use 3 appropriate after renewal of the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use outdoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with

	heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

2.4.3.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations.
- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Place the bait stations in areas not liable to flooding.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.3.2 Use-specific risk mitigation measures

Prevent skin contact when disposing remains of baits.

2.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.4 Use 4 appropriate after renewal of the authorisation – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other

	60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.4.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper resistant baiting stations. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
- [If national policy or legislation requires it] 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.
- Where control of rodents has not been achieved by a control program after 35 days, the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.4.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
-

2.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.5 Use 5 appropriate after renewal of the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10

	m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g,

	16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.5.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
- [If national policy or legislation requires it] 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.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.5.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.

2.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Keep away from food, drink and animal feeding stuffs.

2.4.6 Use 6 appropriate after renewal of the authorisation – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's

	knife/spatula up to 20 kg

2.4.6.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper resistant baiting stations. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
- [If national policy or legislation requires it] 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.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.6.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Do not apply this product directly in the burrows.

2.4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.7 Use 7 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait in covered bait points or in tamper-resistant bait stations

Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Pulsed baiting – ► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g,

	10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.7.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper-resistant bait stations or covered bait points. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- For rat infestations use bait points of up to 60 g in tamper-resistant bait stations or covered bait points. Place bait stations 10 m apart reducing to 5 m in high infestations.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and

at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not use in areas where resistance to the active substance can be suspected.
- [If national policy or legislation requires it] 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.
- Remove the remaining product at the end of treatment period.
- Do not use this product for permanent baiting.
- If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.
  [When available] Follow the specific instructions provided by the applicable code of good practice at national level.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.8 Use 8 appropriate after renewal of the authorisation – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait in covered bait points, in burrows or in tamper-resistant bait stations, or in direct application of ready-to-use bait into the burrow.
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait

	station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary - In burrows: up to 60g of bait per burrow. Pulsed baiting – ► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g,

	10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.8.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper-resistant bait stations or covered bait points. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations, or directly into the burrow. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or

contaminated by dirt.

- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary

- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not use in areas where resistance to the active substance can be suspected.
- [If national policy or legislation requires it] 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.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Remove the remaining product at the end of treatment period.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- If used for pulsed baiting: - Replace eaten bait only after 3 days and then at maximum 7 day intervals. Collect any spilled bait and dead rodents.
  [When available] Follow the specific instructions provided by the applicable code of good practice at national level.

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.8.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.8.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.9 Use 9 appropriate after renewal of the authorisation – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Bait products: - High infestation: 200g per manhole. - Low infestation: up to 200g per manhole. In case of high infestation use 200g of bait. For low infestation use 10 to 200g of bait, depending on the rate of infestation. Place and fix the bait so it cannot be moved by rodents. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.9.1 Use-specific instructions for use

- For rat infestations use bait points of 10 g to 200 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not use in areas where resistance to the active substance can be suspected.
- [If national policy or legislation requires it] 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.
- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.9.2 Use-specific risk mitigation measures

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.
- Do not use this product in permanent baiting treatments.
- Do not use this product in pulsed baiting treatments.

2.4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- Do not open the sachets containing the bait.
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed.
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Professionals & Trained Professionals: If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.2 Risk mitigation measures

- Do not use brodifacoum containing products as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- Dispose of dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- [For products to be authorised for professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall not be supplied to the general public (e.g. "for professionals only").

- [For products to be authorised for trained professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.
Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.
Contact a veterinary surgeon in case of ingestion by a pet.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call the National Poisons Information Centre (01) 809 2166".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of uneaten bait and the packaging in accordance with local requirements. *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]* Use of gloves is recommended.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.

Store in places prevented from the access of children, birds, pets and farm animals.

Keep only in original container.

2.5.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait. Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them. This product contains a bittering agent and dyes.

2.5.7 Documentation

2.5.7.1 Data submitted in relation to product application

Please see General Annexes section 4.1

2.5.7.2 Access to documentation

The applicant has a full letter of access to the data from the active substance dossier and associated [redacted]. The access includes the initial active substance and product dossiers but excludes any product studies produced after 10th November 2010.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	General public: Instruction for use indoor (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 50g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 50g

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	14

Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoor (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

3.1.3 Use 3 – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use outdoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait

	stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or

	thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

3.1.4 Use 4 – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid packed in pre-

	filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.5 Use 5 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg

	Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.6 Use 6 – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals

Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait

	station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.7 Use 7 – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Trained Professionals

Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait

	station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.8 Use 8 – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait in covered bait points, in burrows or in tamper-resistant bait stations.
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to

	remove rodent bodies. Re-fill bait when necessary
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg

	Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.9 Use 9 – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Bait products: - High infestation: 60g per manhole. - Low infestation: up to 60g per manhole. In case of high infestation use 60g of bait. For low infestation use up to 60g of bait, depending on the rate of infestation. Place and fix the bait so it cannot be moved by rodents. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.

Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in

	pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.2 Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the renewal evaluation. However, two post authorisation requirements have been identified.

Storage stability:
Based on the original storage stability data, the new formulation (with 29 ppm bromadiolone) is expected to similarly remain stable, therefore, no new data are required for authoirsation.
However, due to the decision reached during the March 2016 Working Group of the Biocidal Products Committee, a new storage stability test is needed to check that the active substance remains stable after storage for the proposed shelf life.
The applicant will have to provide the data as a post authorisation data requirement.

Analytical method for the active in the product formulation:
The analytical method has been validated for formulations containing 0.004 and 0.005 % w/w bromadiolone. However, the method has not been validated for the same formulation with a reduced content of 0.0029 % w/w (linearity, accuracy and precision should be addressed at the nominal content).
The applicant will have to provide the data as a post authorisation data requirement.

Therefore, apart from these two post-authorisation requirements outlined above, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the renewal evaluation. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid, with exception to the two post authorisation requirements identified in section 3.2 above. Refer to section 3.2.

3.5 Efficacy against target organisms

Ratimor Brodifacoum Fresh Bait is a ready-to-use, soft pasta bait formulation for the control of mice, brown rats and roof rats in a number of proposed use scenarios (section 3.1.1).

The product is intended for use by general public, professionals and trained professionals for the control of rodent infestations.

Palatability

No new palatability studies were provided as the formulation is virtually identical to the 50ppm product evaluated previously. The only difference is the lowering of the active concentration to 29ppm. Accordingly, the conclusion from the previous assessment regarding palatability remains valid.

Effectiveness

For the Major Change evaluation (2017), data was provided from three field trials carried out in Italy and conducted in-line with EPPO guideline PP 1/114(2) Field tests against synanthropic rodents (*Mus musculus, Rattus norvegicus, Rattus rattus*). In all three field trials complete control (100%) of the target populations was achieved, demonstrating the attractiveness and effectiveness of the bait product. Data from the field trials has been summarised in table 4.5 which demonstrated that the product, when used in accordance with label instructions can provide effective control of the target organisms.

The applicant should comment on the potential for the development for resistance owing to the reduction in active content in their product.

The label reference to permanent baiting must be removed from each of the general user, professional user and the trained professional user proposed labels in accordance with the BPC opinion.

Data previously evaluated demonstrated that Ratimor Brodifacoum Fresh Bait is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and effectiveness even under adverse environmental conditions has been demonstrated. Therefore, the conclusion from the previous assessment regarding effectiveness under the "sewer-use scenario" remains valid.

Resistance to the first generation anticoagulants has been widely reported in both *Rattus norvegicus* and *Mus domesticus* since the late 1950's. The incidence of resistance to first generation anticoagulants in areas in which it is established is commonly 25-85%.

The enzyme vitamin K 2, 3 epoxide reductase (VKOR) is the target for anticoagulants. Modifications in the protein structure due to polymorphisms on the gene coding the VKOR may induce anticoagulant resistance. Most resistant strains are characterised by one single nucleotide polymorphism (SNP). These SNPs cause the exchange of one amino acid in the VKOR enzyme. The biochemical mechanism of anticoagulant resistance has been studied in several geographic strains/VKORC1-variants of the Norway rat. Amino acid substitutions in the VKOR seem to alter its structure and function, resulting in decreased sensitivity to anticoagulant inhibition, depending on strain characteristics.

For house mice, a dominant autosomal warfarin-resistance gene was determined on chromosome 7 in house mice. Three VKORC1 sequence variants mediating resistance to anticoagulants seem to be widely distributed. House Mice carrying the homozygous of one of these variants (Y139C) were found highly resistant to warfarin and bromadiolone.

For roof rats, experiments on warfarin resistant rats indicated considerable instability in the resistance and suggested a multifactorial basis for resistance.

Some degree of resistance to difenacoum has been reported in the UK, Denmark, France and Germany but this is usually found in certain populations of rodents highly resistant to first generation anti-coagulants [redacted] et al., 1982[6] [redacted] 1984[7]; [redacted] et al. 1995[8]). The resistance factor tells how much the anticoagulant dose has to be multiplied to kill resistant individuals compared to sensitive ones. The resistant factors for difenacoum in the brown rats ranged from 1.1 to 8.6 ([redacted] and [redacted] 1988[9]). The study included rats resistant to warfarin and difenacoum. Resistance factors for warfarin ranged from approx. 50 to 2300. [redacted] et al. (1982) reported a fivefold difenacoum dose needed to kill difenacoum resistant rats. Considerable doubt exists as to the significance of reports in UK of resistance to second-generation anticoagulants and in the UK control failures with the second-generation products are increasingly being attributed to baiting problems rather than physiological resistance ([redacted], 1988; [redacted] et al. 1992a,b[10]).

Studies carried out in different European countries, in the UK more particularly ([redacted] et al, 2001; see annex 1) revealed the occasional occurrence of cross-resistances to second-generation anticoagulants, such as difenacoum and bromadiolone on resistant brown rats populations to coumafene. Moreover, a publication ([redacted] et al., 2012) has demonstrated that the majority (91%) of warfarin resistant rat trapped in East and West parts of Belgium were also resistant to bromadiolone. The rats trapped in the region of Flanders (Northern Belgium) carried mutation Y139F. This mutation is found extensively in France where it also confers resistance to bromadiolone [redacted] et al., 2009). The same mutation was also found in UK [redacted] et al., 2011) where applications of bromadiolone had been unsuccessful. Difenacoum is also thought to be partially resisted by rats which carry Y139F.

6 [redacted] (1982): An investigation of difenacoum resistance in Norway rat populations in Hampshire. *Annals of Applied Biology* 100, 581–587.

7 [redacted] 1984): Resistance to the second generation anticoagulant rodenticides. *In Proceedings of 11th vertebrate pest conference*, Sacramento, Ca. March 6-8, 1984: 89-94.

8 [redacted] (1995) Resistance to anticoagulant rodenticides in Germany and future strategies to control *Rattus norvegicus*. *Pestic Sci* 43, 61–67

9 [redacted] (1988): Genetics of difenacoum resistance in the rat. In: J. W. Suttie (Ed.), Current advances in vitamin K research, Elsevier, N.Y., 381–388.

10 [redacted]. (1992): Bait avoidance and effectiveness of anticoagulant rodentickitcheides against warfarin- and difenacoum-resistant populations of Norway rats (Rattus norvegicus). *Crop Protection*, Volume 11, Issue 1, February 1992, Pages 14-20

House mice carrying the homozygous Y139C sequence variant were found to be highly resistant to warfarin and bromadiolone. It is important to understand that all known resistance mutations, in both rats and mice, are capable of effective control with applications of the most potent second-generation anticoagulants (brodifacoum, difethialone and flocoumafen) and that no practical resistance to any of these active substances is presently known.
So, resistance to second generation anticoagulant rodenticides should not be underestimated.
An exhaustive study carried out at the French and European levels could enable to point-out resistant areas with first generation anticoagulants and potential cross-resistances to second-generation anticoagulants. It is one of the actions undertaken since 2010 in France by a group of scientists (Rodent program “impacts of anticoagulants rodenticides on ecosystems-adaptations of target rodents and effects on their predators”).
The document CropLife International (RRAC 2016) provides guidance to advisors, national authorities, professionals, practitioners and others on the nature of anticoagulant resistance in rodents, the identification of anticoagulant resistance, strategies for rodenticide application that will avoid the development of resistance and the management of resistance where it occurs.
The following are the essential elements of an effective program: survey, use of physical and chemical control techniques, environmental management, record keeping, monitoring and review.
The authorization holder should report any observed resistance incidents to the Competent Authorities or other appointed bodies involved in resistance management at the renewal of the product.
To ensure a satisfactory level of efficacy and avoid the development of resistance, the recommendations proposed in the SPC have to be implemented.

3.6 Risk assessment for human health

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products and applied to the dermal absorption value of 0.047% for difenacoum (obtained by read across). The original dermal absorption study for difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012) and the dermal absorption value of 0.047% was raised to 0.1% based on incorporating the standard deviation (value > 25% of mean) into the mean and rounding the figure upwards. As the concentration of a.i. in the current product has been halved compared to the original product a pro-rata correction has been applied raising the dermal absorption value to 0.2%.

3.6.1 Assessment of effects of the active substance on human health

As above.

3.6.2 Assessment of effects of the product on human health

As above.

The following new guidance had to be taken into account for the re-assessment:
A read across from difenacoum to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance (EFSA Journal 2012; 10(4):2665).

Re-assessment of the relevant data:
The product has been evaluated using the reduced active ingredient concentration and new dermal absorption.

3.6.3 Exposure assessment

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products and applied to the dermal absorption value of 0.047% for difenacoum (obtained by read across). The original dermal absorption study for difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012) and the dermal absorption value of 0.047% was raised to 0.1% based on incorporating the standard deviation (value > 25% of mean) into the mean and rounding the figure upwards. As the concentration of a.i. in the current product has been halved compared to the original product a pro-rata correction has been applied raising the dermal absorption value to 0.2%.

Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE.

The AELs considered in the risk characterization for *Brodifacoum* were:
AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
$AEL_{medium\ term}$ of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

For conducting the risk assessment on professional and amateur users the chronic AEL was selected as the endpoint, with the exception of conducting the risk assessment for loose paste. For conducting the risk assessment for professional users handling loose paste the acute AEL was used as the endpoint.

The risk assessment took into account the recommendations made in the HEEG 9, 10 and 12 opinions.

For the 'transient mouthing of poison bait' scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 10 Kg. Oral absorption was considered to be 100% for the mouthing scenarios. The acute AEL was used as the endpoint in the toddler risk assessment model.

Biocidal Exposure Risk assessment for Ratimor Brodifacoum Fresh Bait rodenticide (29 ppm).

Professional user	
	Paste
Without PPE	61.1% of AEL (0.00000202 mg/kg bw/day)
With PPE	3.1% of AEL (0.000000101 mg/kg bw/day)
Loose Paste without PPE (reverse reference)	6827 g loose paste required for the acute AEL to be exceeded
Loose Paste with PPE (reverse reference)	136 g loose paste required for the acute AEL to be exceeded
Non-trained professional user (farmer)	
	Paste
Without PPE	10.6% (0.00000035 mg/kg bw/day)
With PPE	0.5% (0.0000000175 mg/kg bw/day)
Exposure to children (Toddler)	
	Paste
Oral exposure -treated with repellent	878.78% (0.000029 mg/kg bw/day)
Oral exposure - without repellent	439393.9% (0.0145 mg/kg bw/day)

Derived values indicated safe usage scenarios for professional users handling the paste product with and without PPE. Derived values for professional users handling the paste product without PPE were 0.00000202 mg/kg bw/day (61.1% AEL). Derived values for professional users handling the paste product with PPE were 0.000000101 mg/kg bw/day (3.1% AEL).

Based on the risk assessment for professional users handling loose paste with a spatula it appears highly unlikely that the AEL will be exceeded with or without PPE. The amount of rodenticide paste required to remain in contact with skin over the application period is a considerable percentage of the amount of total paste product to be applied if PPE are not worn. A scenario where AEL is exceeded when PPE are worn is not likely given that more loose paste is required to be in contact with skin than is actually recommended to be applied when loading a bait station.

Derived values indicated safe usage for non-trained professional users (farmers) handling the paste product both with and without PPE. Derived values for non-trained professional users handling the paste product without PPE were 0.00000035 mg/kg bw/day (10.6% AEL). Derived values for professional users handling the paste product with PPE were 0.0000000175 mg/kg bw/day (0.5% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating paste without PPE indicated daily exposure scenarios of 0.00000035 mg/kg bw/day (10.6% AEL).

Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the paste product. Derived values for oral exposures in the toddler found transient mounting of a paste not containing a repellent to result in a dose of 0.0145 mg (439393.9% AEL). Derived values for oral exposures in the toddler found transient mounting of a paste containing a repellent to result in a dose of 0.000029 mg (878.78% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system toddlers are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

As shown in section 3.6.2.

3.6.4.2 Risk for the general public

As shown in section 3.6.2.

3.6.4.3 Risk for consumers via residues in food

No new data was provided nor had new guidance to be taken into account for the major change evaluation.
Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.5 Summary of risk characterisation

Derived values indicated safe usage scenarios for professional users handling the paste product with and without PPE. Derived values for professional users handling the paste product without PPE were 0.00000202 mg/kg bw/day (61.1% AEL). Derived values for professional users handling the paste product with PPE were 0.000000101 mg/kg bw/day (3.1% AEL).

Based on the risk assessment for professional users handling loose paste with a spatula it appears highly unlikely that the AEL will be exceeded with or without PPE. The amount of rodenticide paste required to remain in contact with skin over the application period is a considerable percentage of the amount of total paste product to be applied if PPE are not worn. A scenario where AEL is exceeded when PPE are worn is not likely given that more loose paste is required to be in contact with skin than is actually recommended to be applied when loading a bait station.

Derived values indicated safe usage for non-trained professional users (farmers) handling the paste product both with and without PPE. Derived values for non-trained professional users handling the paste product without PPE were 0.00000035 mg/kg bw/day (10.6% AEL). Derived values for professional users handling the paste product with PPE were 0.0000000175 mg/kg bw/day (0.5% AEL).
The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating paste without PPE indicated daily exposure scenarios of 0.00000035 mg/kg bw/day (10.6% AEL).

Derived values indicated no safe exposure scenarios for toddlers through oral exposure/transient mouthing of the paste product. Derived values for oral exposures in the toddler found transient mounting of a paste not containing a repellent to result in a dose of 0.018 mg (549242% AEL). Derived values for

oral exposures in the toddler found transient mounting of a paste containing a repellent to result in a dose of 0.000036 mg (1098% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system toddlers are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

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3.7 Risk assessment for animal health

No new data was provided, nor had new guidance to be taken into account for the renewal.
Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The previous change in active substance concentration from 0.005% to 0.0029% resulted in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

Groundwater assessment for rodenticides
As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:
- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.
- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential

groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	***In and around buildings***		***Sewer system***	
	Worst case	***Realistic***	***Worst case***	***Realistic***
PEC groundwater (mg/l)	*5.3 x 10^{-5}*	*6.62 x 10^{-6}*	*4.66 x 10^{-7}*	*3.11 x 10^{-7}*

As the previous major change led to a lower PECgw a new assessment is not necessary here.

Primary and Secondary Poisoning

The concentration in the final product is 0.0029% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

Primary Poisoning

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and $PNEC_{oral}$. The ratios PEC/PNEC are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

Acute risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: PECoral/PNECoral for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	**ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)**		**$PNEC_{oral}$ (dose, mg/kg b.w./d)**	**PEC/PNEC**	
	Step 1	**Step 2**		**Step 1**	**Step 2**
Tree sparrow	10	7.21	0.00013	76923	55461
Chaffinch	8.7	8.26	0.00013	66923	63538
Wood pigeon	3.14	2.26	0.00013	24153	17384
Pheasant	3.13	2.25	0.00013	24076	17307

Dog	1.74	1.25	0.000222	7837	5630
Pig	0.218	0.157	0.000222	981	707
Pig, young	0.696	0.501	0.000222	3135	2256

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the $EC_{oral/}PNEC_{ratio}$after 1-day and 5-day elimination of Brodifacoum. The $EC_{oral/}PNEC_{ratio}$ are above 1 after 1-day elimination of Brodifacoum indicating a potential risk (data not shown). The $EC_{oral/}PNEC_{ratio}$ for the 5-day elimination of Brodifacoum are shown below.

Tier 2 long-term risk assessment: EC_{oral}/$PNEC_{oral}$ ratio after 5-day elimination

Species	**EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = .3, AV = 1, PT = 1 (mg/kg bw)[a]**	**EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]**	**$PNEC_{oral}$ (mg/kg b.w./d)**	**Ratio EC_{oral}/$PNEC_{oral}$**
Tree sparrow	17.06	12.28	0.00013	94486
Chaffinch	15.3	11.02	0.00013	84738
Wood pigeon	5.35	3.85	0.00013	29631
Pheasant	5.33	3.84	0.00013	29520
Dog	2.96	2.13	0.000222	9600
Pig	0.371	0.267	0.000222	1203
Pig, young	1.18	0.850	0.000222	3827

[a] calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term PEC_{oral}/$PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

Secondary Poisoning

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The $PEC_{oral}/PNEC_{oral}$ values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents is calculated ($ETE_{oral\ predators}$) and compared to the $PNEC_{oral}$

Tier 2 risk assessment of secondary poisoning (non-resistant and resistant rodents)

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	0.637	0.00013	4901
	Day 5 after the last meal	0.996		7667
	Day 14 after the last meal	1.19		9155
Kestrel	Day 5 before the last meal	0.967	0.00013	7444
	Day 5 after the last meal	1.51		11644
	Day 14 after the last meal	1.80		13903
Little owl	Day 5 before the last meal	0.727	0.00013	5593
	Day 5 after the last meal	1.13		7848
	Day 14 after the last meal	1.35		10446
Tawny owl	Day 5 before the last meal	0.585	0.00013	4506
	Day 5 after the last meal	0.916		7048
	Day 14 after the last meal	1.09		8416
Fox	Day 5 before the last meal	0.234	0.000222	1056
	Day 5 after the last meal	0.366		1652
	Day 14 after the last meal	0.438		1973
Polecat	Day 5 before the last meal	0.488	0.000222	2199
	Day 5 after the last meal	0.763		3440
	Day 14 after the last meal	0.911		4107
Stoat	Day 5 before the last meal	0.698	0.000222	3145
	Day 5 after the last meal	1.09		4920
	Day 14 after the last meal	1.30		5874
Weasel	Day 5 before the last meal	1.00	0.000222	4538
	Day 5 after the last meal	1.57		7099
	Day 14 after the last meal	1.88		8477

All ratios $ETE_{oral\ predators}$ / $PNEC_{oral}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

Overall conclusion

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 29 ppm in the ecotoxicology risk assessment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

The Irish CA for biocides has processed an application for renewal for this biocidal product which contains the active substance Brodificaoum. The active substance Brodificaoum meets the criteria for exclusion according to Article 5(1) BPR as well as for substitution according to Article 10 BPR (for details see chapter 2.2.3).

Therefore, in line with Article 23 (1) BPR, a comparative assessment for this product has to be conducted.

At the 60th meeting of representatives of Members States Competent Authorities for the implementation of the BPR held on 20 and 21 May 2015, all Member States submitted to the Commission a number of questions to be addressed at Union level in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide biocidal products ('anticoagulant rodenticides'). The questions submitted were the following:

(a) Is the chemical diversity of the active substances in authorised rodenticides in the Union adequate to minimise the occurrence of resistance in the target harmful organisms?;
(b) For the different uses specified in the applications for renewal, are alternative authorised biocidal products or non-chemical means of control and prevention methods available?;
(c) Do these alternatives present a significantly lower overall risk for human health, animal health and the environment?;
(d) Are these alternatives sufficiently effective?;
(e) Do these alternatives present no other significant economic or practical disadvantages?

The information addressing these questions is provided in the Annex of the Commission Implementing Decision (EU) 2017/1532[11]. In accordance with Article 1 of Commission Implementing Decision (EU) 2017/1532, the Irish CA considered the information in the Annex during the comparative assessment of anticoagulant rodenticide biocidal products.

Conclusion

Based on the information provided in the Annex of the Commission Implementing Decision (EU) 2017/1532 the Irish CA came to the conclusion that in the absence of anticoagulant rodenticides, the use of rodenticides containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also showed some significant practical or economical disadvantages for the relevant uses.

The Irish CA also considered a number of non-chemical control or prevention methods ("non-chemical alternatives"), which in our view do not provide sufficient alternatives to anticoagulant rodenticides.

In summary it can be concluded that the criteria according Article 23(3) a), b) BPR are not fulfilled. Therefore, the authorisation of this product will be renewed for 5 years.

[11] Commission Implementing Decision (EU) 2017/532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

4 General Annexes

4.1 List of studies for the biocidal product

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
[redacted]	2017	Efficacy evaluation of Ratimor Brodifacoum Fresh Bait (brodifacoum 0.029 g/kg a.i., fresh bait) against Roof rat (*Rattus rattus* L.)	unpublished	Trial Code: 2014.BCD.SAG17	Unichem	05/02/2017	GEP	Y
[redacted]	2017	Efficacy evaluation of Ratimor Brodifacoum Fresh Bait (brodifacoum 0.029 g/kg a.i., fresh bait) against Roof rat (*Rattus norvegicus* Berk.)	unpublished	Trial code: 2013.BCD.SAG17	Unichem	05/02/2017	GEP	Y
[redacted]	2017	Efficacy evaluation of Ratimor Brodifacoum Fresh Bait (brodifacoum 0.029 g/kg a.i.,	unpublished	Trial code: 2015.BCD.SAG17	Unichem	05/02/2017	GEP	Y

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
		fresh bait) against House mouse (*Mus musculus* L.)						

4.2 Output tables from exposure assessment tools

None

4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

4.5 Summaries of the efficacy studies (B.5.10.1-xx)[12]

<table>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method, test system/concentrations applied/ exposure time</th><th>Test results; effects</th><th>Reference</th></tr>
<tr>
<td>Ratimor Brodifacoum Fresh Bait (PT14)</td>
<td>A soft Pasta Bait containing 29 ppm Brodifacoum</td>
<td>Roof rat (Rattus rattus)

Wild population located in farm buildings(cow housing, fodder, equipment and wood storage buildings) in Italy (resistance status unknown)</td>
<td>Droppings, sightings and activity established these rodents to be roof rats.
Unpoisoned bait and tracking patches were employed to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.
A 3-day lag period was used.
The trial was then undertaken using the product as per the proposed label instructions.
29ppm Ratimor Brodifacoum Fresh Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily.
Bait points which dropped below 60g or that had been spoilt were either topped up or swapped with fresh bait.
After a further 4-day lag phase a</td>
<td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>2328</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>515</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>96</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>23</td><td>0</td><td>100</td></tr>
</table>
Conservative estimate of population calculated as 30-40 rats based on pre-census baiting.
4,595g of treated bait was consumed during the 16 day baiting phase.
Tracking patch activity dropped to zero on day 14 of the baiting period as did bait consumption.
Complete (100%) effectiveness against Rattus rattus population across the trial site.
</td>
<td>[redacted]
2017</td>
</tr>
</table>

[12] If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

<table>
<tr><td></td><td></td><td></td><td>3.2
-treatment census was undertaken.</td><td>No evidence was found during the trial that the use of 29ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.</td><td></td></tr>
<tr><td>Ratimor Brodifacoum Fresh Bait (PT14)</td><td>A soft Pasta Bait containing 29 ppm Brodifacoum</td><td>Brown Rat (Rattus norvegicus)

Wild population located in farm buildings (cow housing, fodder, equipment and wood storage buildings) in Italy (resistance status unknown)</td><td>Droppings, sightings and activity established these rodents to be brown rats.
Unpoisoned bait and tracking patches were used to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.
A 3-day lag period was observed.
The trial was then undertaken using the product as per the proposed label instructions.
29ppm Ratimor Brodifacoum Fresh Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily.
Bait points which dropped below 60g or that had been spoilt were either topped up or swapped with fresh bait.
After a further 6-day lag phase a post-treatment census was undertaken.</td><td><table><tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr><tr><td>Total bait consumption (g)</td><td>3000</td><td>0</td><td>100</td></tr><tr><td>Maximum daily bait consumption (g)</td><td>600</td><td>0</td><td>100</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr><tr><td>Total activity score</td><td>110</td><td>0</td><td>100</td></tr><tr><td>Maximum daily activity score</td><td>24</td><td>0</td><td>100</td></tr></table>Conservative estimate of population calculated as a minimum of 30 rats based on pre-census baiting.
5,650g of treated bait was consumed by day 11 of the 14 day baiting phase.
Tracking patch activity dropped to zero on day 11 of the baiting period as did bait consumption.
Complete (100%) effectiveness against Rattus norvegicus population across the trial site.
No evidence was found during the trial that the use of 29ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.</td><td>[redacted] 2017</td></tr>
<tr><td>Ratimor Brodifacoum Fresh Bait (PT14)</td><td>A soft Pasta Bait containing 29 ppm Brodifacoum</td><td>House mouse (Mus musculus)

Wild population located on an</td><td>Droppings, sightings and activity established these rodents to be house mice.
Unpoisoned bait and tracking patches were used to measure</td><td><table><tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr><tr><td>Total bait consumption (g)</td><td>889</td><td>0</td><td>100</td></tr></table></td><td>[redacted] 2017</td></tr>
</table>

<table>
<tr>
<td></td>
<td></td>
<td>agricultural farm in Italy (resistance status unknown)</td>
<td>rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.
A 3-day lag period was observed.
The trial was then undertaken using the product as per the proposed label instructions.
29ppm Ratimor Brodifacoum Fresh Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily.
Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait.
After a further 3-day lag phase a post-treatment census was undertaken.</td>
<td>
<table>
<tr><td>Maximum daily bait consumption (g)</td><td>200</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td>Activity over sand patches</td><td>Pre-treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total activity score</td><td>80</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>20</td><td>0</td><td>100</td></tr>
</table>
889g of untreated bait consumed during pre-baiting census indicating 50-60 mice in the on-site population.

1,773g of treated bait was consumed by day 14 of the 17 day baiting phase.
Tracking patch activity dropped to zero by day 14 and no more bait was consumed.
Complete (100%) effectiveness against Mus musculus. population across the trial site.
No evidence was found during the trial that the use of 29ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
</td>
<td></td>
</tr>
</table>

4.6 Other

5 Confidential annex (Access level: "Restricted" to applicant and authority)

5.1 Full composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0029
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					

Annex 1 - Initial PAR – August 2013

Product Assessment Report

Ratimor Brodifacoum Fresh Bait

Active substance:	**Brodifacoun**
Product-type:	**PT 14**
Type of application:	**Authorisation**
Authorisation No:	**IE/BPA 70205 (Professional)** **IE/BPA 70206 (Non-professional)**
Date:	**06 August 2013**
Version:	**1.1**

Biocidal Product Assessment Report (PAR) related to Product Authorisation under Directive 98/8/EC.

Department of Agriculture, Food and the Marine
An Roinn Talmhaíochta, Bia agus Mara

Pesticide Registration and Control Division
Department of Agriculture, Food and the Marine
Backweston Campus
Young's Cross
Celbridge
Co. Kildare
Ireland

CONTENTS

1 General information about the product application

This application for product authorisation is for:

Trade name:	Ratimor Brodifacoum Fresh Bait
Authorisation No.:	IE/BPA 70205 (Professional and Trained Professional) IE/BPA 70206 (General public / Non-professional)

Ratimor Brodifacoum Fresh Bait trade names in other Member States (based on R4BP data):

Trade name	**Member State**
Bertram Pastenköder Brodifacoum	Germany
Ratimor Brodi Pastenköder	Austria
RATIMOR 0,005 RB	Greece
AbioFettexp. Brodi	Austria
RATIMOR BRODI PASTENSCHÄLCHEN	Germany
Glodacid Plus Rágcsálóirtó pép	Hungary
KH-Pastenköder	Germany
GLODACID PLUS mehka vaba	Slovenia
BEG Köderpaste blau	Germany
RATIMOR BRODI Pasta pose	Norway
RATIMOR BRODI PASTENSCHÄLCHEN	Germany
Pelias Effect Box	Norway

2 1.1 Applicant/ Authorization Holder

Company Name:	Unichem D.O.O.
Address:	Sinja Gorica 2, Vrhnika, SI-1360, Slovenia
Tel:	+386 117558 150
E-mail:	[redacted]
Contact:	[redacted]

3 1.2 Marketing/Distributing Company (where applicable)

Company Name:	N/A
Address:	N/A
Tel:	N/A
E-mail:	N/A
Contact:	N/A

4 1.3 General Information on the Biocidal Product

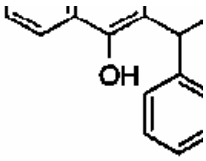
Trade name:	Ratimor Brodifacoum Fresh Bait
Manufacturer's development code number(s):	N/A
Active substance content:	0.005% w/w Brodifacoum
Main group:	MG03 Pest Control
Product type:	PT14 (Rodenticides)
Product Specification:	See Confidential Annex
Site of product formulation:	See Confidential Annex
Frame formulation (yes/no):	No
Formulation type:	Paste Bait
Ready to use product (yes/no):	Yes
Chemical/micro-organism:	Chemical Substance
Contain or consist of GMOs[13] (yes/no):	N/A
Is the product already notified/authorised (Directive 98/8/EC) (yes/no); If yes: product name:	Yes Ratimor Brodifacoum Fresh Bait PCS 96633
Is the biocidal product equivalent to the product assessed for the purpose of Annex I inclusion to 98/8/EC (yes/no):	No

Manufacturer of Formulated Product	
Company Name:	[redacted]
Address:	[redacted]
Tel:	[redacted]
E-mail:	[redacted]

[13] A copy of any written consent(s) of the competent authorities to the deliberate release into the environment of the GMOs for research and development purposes where provided for by Part B of the above-mentioned Directive was provided.

Contact:	[redacted]

5 1.4 Information on active substance(s)[14]

Active substance chemical name:	Brodifacoum
IUPAC name:	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin
CAS No:	56073-10-0
EC No:	259-980-5
Purity (minimum, g/kg or g/l):	950 g/kg
Molecular formula:	$C_{31}H_{23}BrO_3$
Structural Formula:	
Manufacturing site:	See Confidential Annex
Specification of pure active substance:	See Confidential Annex
Is a new active substance data package (source) supplied (yes/no):	No
If yes, Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	N/A
If no, does the applicant have a LoA to the active substance data packaged used to support Annex I inclusion (yes/no):	Yes (Pelgar International Ltd.)

Manufacturer of active substance(s)	
Company Name:	Pelgar International Ltd.
Address:	Unit 13 Newman Lane Industrial Estate Alton. Hants. GU34 2 QR UK
Tel:	+44 (0)1420 80744
E-mail:	[redacted]
Contact:	[redacted]

6 1.5 Information on the intended use(s) of the biocidal product

Main Group:	MG03 (Pest control)
Product-type:	PT14 (Rodenticide)
Intended use:	Brodifacoum paste bait to control rodents indoors, outdoors

14 Please insert additional columns as necessary

	around buildings and in sewers for the protection of public health, stored products and materials.
Target organisms:	(I.1) Rodents (I.1.1) Murids (I.1.1.1) Brown rats (Rattus norvegicus) (I.1.1.3) House mouse (Mus musculus and Mus domesticus)
Development stage:	(II.1) Juveniles (II.2) Adults
Function:	Rodenticide
Mode of action:	Anticoagulant III.2 long-term action III.2.1 anticoagulant III.2.1.1 ingestion toxin III.2.1.1.1 ingestion by eating
Application aim:	VII.1 Stored product protection/food protection VII.2 Health protection VII.3 Material protection (e.g. historical buildings, technical objects)
Category of users:	V.1 Non Professional/General public V.2 Professional V.3 Trained/specialised professional
Area of use (indoors/outdoors):	IV.1 Indoors IV.2 Outdoors (in and around buildings only), IV.3 Sewers (IE/BPA 70205 only)
Application method:	VI.2 Covered applications VI.2.1 In bait stations VI.2.2 Other coverings
Directions for use including minimum and maximum application rates, typical size of application area:	IE/BPA 70205, IE/BPA 70206 Indoors and outdoors (in and around buildings only) Rats (Adult and Juvenile): Secure 10-60g of bait in covered, tamper resistant baiting stations spaced 10m apart (5m apart in areas of high infestation) in areas where rats are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Mice (Adult and Juvenile): Secure 10-20g of bait, in covered, tamper resistant baiting stations spaced 5m apart (2m apart in high infestation areas) in areas where mice are active. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). In sewers (IE/BPA 70205 only) Rats (Adult and Juvenile): Secure 20-200g of bait per station to available structures to ensure the bait is not washed away. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation.
Potential for release into the environment (yes/no):	Yes
Potential for contamination of	No

food/feedingstuff (yes/no):	

7

8 1.6 Documentation

3. 1.6.1 Data submitted in relation to product application

A full new product dossier was submitted by [redacted] and a LoA was submitted giving Unichem full access to the active substance review data and the product dossier submitted by [redacted] for Ratimor Brodifacoum Fresh Bait(blue formulation only). Unichem submitted documents on packaging and product SDS in support of the product Ratimor Brodifacoum Fresh Bait containing brodifacoum. In addition, confirmatory data on the active substance was submitted and assessed by Germany. The Irish CA for Biocides agreed with the conclusion drawn on this data on Brodifacoum.

Please see the attached reference list in Annex IV.

4. 1.6.2 Access to documentation

[redacted] supported the evaluation of the active substance at EU level and has full access to the documents submitted by the [redacted] for the EU review programme. Unichem has a LoA to the full [redacted] Annex I listing and Product Dossier.

[redacted] is a member of the RDDG and has a letter of access to a study owned by the RDDG consortium, the study is 'Validation of analytical methodology to determine rodenticides in food matrices'. This study was carried out by [redacted] Study number PGD-180. Unichem as a client of [redacted] has access to this data also.

9 2. Classification, labelling and packaging

Under this heading the assessment of the classification, labelling and packaging should be summarised. Further, any result of the assessments made under the following headings that require recommendations or restrictions appearing on the label should be summarised here.

10 2.1 Harmonised classification of the active substance

Brodifacoum is not currently classified in Annex I of Council Directive 67/548/EEC or according to Annex VI of Regulation (EC) no 1907/2006 (REACH). The following classification and labelling is proposed on the basis of available data resulting from the review programme for brodifacoum and is provided in the table below according to Directive 67/548/EEC/Regulation (EC) 1272/2008. Additionally, the extrapolation of these proposals using the BG RCI converter tool (http://www.gischem.de/ghs/konverter) is also provided in the table below in accordance with Regulation (EC) 1272/2008.

Classification of the active substance, brodifacoum, according to Directive 67/548/EEC and CLP Regulation (EC) 1272/2008:

Symbol(s):	 	**Pictogram(s):**	
Indication(s) of danger:	T+ Very Toxic N Dangerous for the Environment	**Signal word(s):**	Danger
Risk phrases:	R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed. R43: May cause sensitisation by skin contact R48/23/24/25: Toxic: Danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. R61: May cause harm to the unborn child. R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.	**Hazard statements:**	H300: Fatal if swallowed. H310: Fatal in contact with skin. H317: May cause an allergic skin reaction H330: Fatal if inhaled. H360D: May damage the unborn child. H372: Causes damage to organs through prolonged or repeated exposure through inhalation. H400: Very toxic to aquatic life H410: Very toxic to aquatic life with long lasting effects.
Safety phrases:	S20/21: When eating do not eat, drink or smoke S35: The material and its container must be disposed of in a safe way S36/37: Wear suitable protective clothing and gloves S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) S60: This material and its container must be disposed of as hazardous waste. S61: Avoid release to the environment. Refer to special instructions/safety data sheet.	**Precautionary statements:**	P101: If medical advice is needed, have product container or label at hand. P103: Read label before use. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves and clothing P281: Use personal protective equipment as required. P301 + P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. P308 + P313: IF exposed or concerned: Get medical advice/attention. P314: Get medical

			advice/attention if you feel unwell. P501: Dispose of contents/container to hazardous waste facilities in accordance with national regulations.

Specific concentration limits for brodifacoum are proved below in accordance with Directive 67/548/EEC:

Specific concentration limits:	C≥2.5% 1%≤C<2.5% 0.5%≤C<1% 0.25%≤C<0.5% 0.025%≤C<0.25% 0.0025%≤C<0.025%	T+, N; R26/27/28-48/23/24/25-43-61-50/53 T+, N; R26/27/28-48/23/24/25-43-61-51/53 T+, N; R26/27/28-48/23/24/25-61-51/53 T+, N; R26/27/28-48/23/24/25-51/53 T ; R23/24/25-48/20/21/22-52/53 Xn; R20/21/22

Additionally, brodifacoum does not exhibit hazardous physical-chemical properties. Brodifacoum is thermally stable at 52°C. It is not classified as highly flammable and does not undergo self ignition below its melting point. It is not considered to be explosive or to have oxidising properties. There is no record that it has reacted with any storage container during many years of industrial production. It is concluded therefore, that there are no hazards associated with its physico-chemical properties under normal conditions of use.

11 2.2 Harmonised classification and labelling of the biocidal product

The current classification and labelling, based on the biocidal product evaluation for Ratimor Brodifacoum Fresh Bait, is provided in the tables below according to Directive 99/45/EC and Regulation (EC) 1272/2008, Annex VI, Part 3.

Classification and Labelling of the biocidal product according to Directive 99/45/EC:

Symbol(s):	N/A
Indication(s) of danger:	N/A
Risk phrases:	N/A
Safety phrases:	S1+S2: Keep locked up and out of reach of children S13: Keep away from food, drink and animal feeding stuffs. S20 + S21: When using do not eat, drink or smoke. S24: Avoid contact with skin S35: This material and its container must be disposed of in a safe way. S37: Wear suitable gloves (Professional Only) S46: If swallowed, seek medical advice immediately and show this container or label. S49: Keep only in the original container S61: Avoid release to the environment. Refer to special instructions/safety data sheet

Classification and Labelling of the biocidal product according to the CLP Regulation (EC) 1272/2008:

Pictogram(s):	N/A
Signal word(s):	N/A
Hazard statements:	N/A
Precautionary statements	P102: Keep out of reach of children. P103: Read label before use.

	P220: Keep/Store away from food, drink and animal feedingstuffs. P262: Do not get on skin P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment P280: Wear protective gloves (Professionals only) P301+310: IF SWALLOWED: Immediately call a poison centre or doctor/physician. P404+405: Store locked up in a closed container. P501: Dispose of contents/container in accordance with national regulations.

Physical-chemical properties:
Not explosive, oxidising or highly flammable and therefore does not classify from a physical-chemical point of view.

Toxicology:
There is no toxicology classification for the product under the Directive 99/45.

There is no toxicology classification for the product under the CLP Regulation 1272/2008.

Environment:
There is no environmental classification for the product under the Directive 99/45.

There is no environmental classification for the product under the CLP Regulation 1272/2008.

Other:
Further, the content of the label should be updated to comply with the labelling requirements established (for biocidal products) where the labelling requirements in Article 20(3) of Directive 98/8/EC has been implemented. The safety data sheet should comply with the requirements in Regulation (EC) 1907/2006.

Additional Labelling Requirements:

Addition safety Information:	To avoid risks to human health and the environment, comply with the instructions for use. Harmful to wildlife Use bait containers clearly marked “poison” at all surface baiting points. Remove all remains of bait, dead rodents during and after treatment and dispose of safely. Apply only in positions inaccessible to children and pets.
Special labelling provisions for Ireland:	Use Biocides Safely and Sustainably (IE/BPA 70205) Not For Amateur Sale It is illegal to use this product for uses or in a manner other than that prescribed on this label.
If a separate leaflet is attached to or supplied with the product, add the following information to the front label:	Read attached instructions before use

13 2.3 Packaging

The packaging details for the biocidal product, Ratimor Brodifacoum Fresh Bait, as presented by the applicant, are outlined below for amateur and professional users.

Nomenclature: PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride, AL = Aluminium

Amateur product packaging:
On the basis of the packaging details presented, it is considered appropriate to limit aspects of the packaging for amateur users as a risk mitigation measure. Packaging restrictions are to be limited to pre-baited bait stations and refill packs with a **maximum pack-size of 500g**. Additionally, the pasta bait should be supplied to the amateur market in sachets/wrapped in order to reduce exposure risks to amateur operators during application to bait stations.

The applicant applied for pack sizes greater that 500g for amateur products, these are detailed below with a strikethrough (i.e. ~~strikethrough~~). The Irish RMM allows a maximum pack size of 500g and therefore only pack sizes up to 500g were authorised for amateur users in Ireland. Pack sizes >500g mentioned below can be authorised in OMS.

Amateur product packaging: Cardboard or fibreboard outer

Container description:	Cardboard or fibreboard outer							
Pack size(s):	1000kg	500g	400g	225g	250g	200 g	120g	100 g
Baits per pack:	100 x 10g	50 x 10g 33 x 15g	40 x 10g	15 x 15g	25 x 10g	20 x 10g	12 x 10g 8 x 15g	10 x 10g
Pack dimensions (LxWxH):	157mm x 65mm x 280 mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	110mm x 85 mm x 70mm	110mm x 85 mm x 70mm
Outer packaging materials:	sachet of PE, PE/PP, PP, paper/PE in further cardboard or fibreboard outer (carton box)							
Inner packaging materials:	paper tea-bags							
Ready-to-use (yes/no)	Yes							
Child safety features (yes/no):	No							
If yes, please specify:	N/A							
Shelf-life:	2 years							
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.							

Continued…

Container description:	Cardboard or fibreboard outer							
Pack size(s):	150g	160g	220g	240g	260g	300 g	320g	330 g
Baits per pack:	15x10 g 10x15 g	16x10g	22x10g	24x10g 16x10g	26x10g	20x15g 30x10g	32x10 g	22x15 g 33x10 g
Pack dimensions (LxWxH):	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm
Outer packaging materials:	sachet PE, PE/PP, PP, paper/PE in further cardboard or fibreboard outer (carton box)							
Inner packaging materials:	paper tea-bags							
Ready-to-use (yes/no)	Yes							
Child safety features (yes/no):	No							
If yes, please specify:	N/A							
Shelf-life:	2 years							
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.							

Continued…

Container description:	Cardboard or fibreboard outer			
Pack size(s):	340g	350g	360g	370g
Baits per pack:	34x10g	35x10g	24x15g 36x10g	37x10g
Pack dimensions (LxWxH):	220mm x 160mm x 50mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm
Outer packaging materials:	sachet PE, PE/PP, PP, paper/PE in further cardboard or fibreboard outer (carton box)			
Inner packaging materials:	paper tea-bags			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	2 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Amateur product packaging: Pack

Container description:	Pack					
Pack size(s):	500g	400g	250g	200 g	120g	100 g
Baits per pack:	50 x 10g 33 x 15g	40 x 10g	25 x 10g	20 x 10g	12 x 10g 8 x 15g	10 x 10g
Pack dimensions (LxWxH):	220mm x 160mm x 50mm	220mm x 160mm x 50mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	110mm x 85mm x 70mm	110mm x 85 mm x 70mm
Outer packaging materials:	PE or PP packs					
Inner packaging materials:	paper tea-bag					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	2 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Continued…

Container description:	Pack						
Pack size(s):	150g	160g	220g	240g	260g	300 g	1000g
Baits per pack:	15x10g 10x15g	16x10g	22x10 g	24x10g 16x10g	26x10g	20x15g 30x10g	100 x 10g
Pack dimensions (LxWxH):	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	130mm x 110mm x 60mm	220mm x 160mm x 50mm	157mm x 65mm x 280 mm
Outer packaging materials:	PE or PP packs						
Inner packaging materials:	paper tea-bag						
Ready-to-use (yes/no)	Yes						
Child safety features (yes/no):	No						
If yes, please specify:	N/A						
Shelf-life:	2 years						
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.						

Continued…

Container description:	Pack					
Pack size(s):	320g	340g	350g	360g	370g	330g
Baits per pack:	15x10g 10x15g	34x10g	35x10g	24x15g 36x10g	37x10g	22x15g 33x10g
Pack dimensions (LxWxH):	130mm x 110mm x 60mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm	220mm x 160mm x 50mm	130mm x 110mm x 60mm
Outer packaging materials:	PE or PP packs					
Inner packaging materials:	paper tea-bag					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	2 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Amateur product packaging: Natron bag

Container description:	Natron bag
Pack size(s):	500g
Baits per pack:	15x10g 10x15g
Pack dimensions (LxWxH):	130mm x 110mm x 60mm
Outer packaging materials:	Natron bag
Inner packaging materials:	paper tea-bag
Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Amateur product packaging: Bucket

Container description:	Bucket					
Pack size(s):	500g	200g	240g	350g	400g	1000g
Baits per pack:	50 x 10g 33 x 15g	20 x 10g	24 x 10g	35 x 10g	40 x 10g	100 x 10g
Pack dimensions (LxWxH):	126mm x 126mm x 146mm	126mm x 126mm x 125mm	126mm x 126mm x 125mm	126mm x 126mm x 146mm	126mm x 126mm x 146mm	180mm x 180mm x 133mm
Outer packaging materials:	PE or PP buckets					
Inner packaging materials:	paper tea-bag					
Ready-to-use (yes/no)	Yes					
Child safety features (yes/no):	No					
If yes, please specify:	N/A					
Shelf-life:	2 years					
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.					

Amateur product packaging: Carton

Container description:	Carton
Pack size(s):	500g
Baits per pack:	50 x 10g 33 x 15g
Pack dimensions (LxWxH):	220mm x 160mm x 50mm
Outer packaging materials:	cardboard or fibreboard
Inner packaging materials:	paper tea-bag
Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 years

Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Amateur product packaging: Carton with bag or liner

Container description:	Carton with bag or liner
Pack size(s):	500g
Baits per pack:	50 x 10g 33 x 15g
Pack dimensions (LxWxH):	220mm x 160mm x 50mm
Outer packaging materials:	cardboard or fibreboard box (carton) with PE or PP bag or liner
Inner packaging materials:	paper tea-bags
Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Amateur product packaging: Bait station

Container description:	Mouse Bait station				
Pack size(s):	10g	15g	20g	30g	40g
Baits per pack:	1 x 10g	1 x 15g	2 x 10g	3 x 10g 2 x 15g	4 x 10g
Pack dimensions (LxWxH):	115mm x 100mm x 35mm	115mm x 100mm x 35mm	115mm x 100mm x 35mm	115mm x 100mm x 35mm	115mm x 100mm x 35mm
Outer packaging materials:	cardboard or fibreboard outer				
Inner packaging materials:	paper tea-bag sachets packed in a pre-filled tamper proof PE or PP mouse bait station				
Ready-to-use (yes/no)	Yes				
Child safety features (yes/no):	No				
If yes, please specify:	N/A				

Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Amateur product packaging: Bait station

Container description:	Rat Bait station	
Pack size(s):	195g	200g
Baits per pack:	13 x 15g	20 x 10g
Pack dimensions (LxWxH):	240mm x 165mm x 90mm	240mm x 165mm x 90mm
Outer packaging materials:	cardboard or fibreboard outer	
Inner packaging materials:	paper tea-bag sachets packed in a pre-filled tamper proof PE or PP rat bait station	
Ready-to-use (yes/no)	Yes	
Child safety features (yes/no):	No	
If yes, please specify:	N/A	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Amateur product packaging: Bait station

Container description:	Mouse bait station		
Pack size(s):	20g	30 g	40g
Baits per pack:	2 x 10g	3 x 10g 2 x 15g	4 x 10g
Pack dimensions (LxWxH):	135mm x 50mm x 65mm 115mm x 100mm x 35mm	135mm x 50mm x 65mm 115mm x 100mm x 35mm	135mm x50mm x 65mm 115mm x 100mm x 35mm
Outer packaging materials:	cardboard or fibreboard outer.		
Inner packaging materials:	paper tea-bag sachets		
Ready-to-use (yes/no)	Yes		

Child safety features (yes/no): If yes, please specify:	No
	N/A
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Amateur product packaging: Blister packs

Container description:	Blister packs with tea-bag sachets		
Pack size(s):	40g	80g	200g
Baits per pack:	4 x 10g	8 x 10g	20 x 10g
Pack dimensions (LxWxH):	113mm x 59mm x 30mm	113mm x 59mm x 30mm	113mm x 59mm x 38mm
Outer packaging materials:	cardboard or fibreboard outer pack		
Inner packaging materials:	paper tea-bag sachets in further PP or PE packs (blisters)		
Ready-to-use (yes/no)	Yes		
Child safety features (yes/no): If yes, please specify:	No		
	N/A		
Shelf-life:	2 years		
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.		

Professional product packaging

Professional product packaging: Cardboard or fibreboard outer

Container description:	Cardboard or fibreboard outer		
Pack size(s):	5kg	10kg	2.5kg
Baits per pack:	500 x 10g	1000 x 10g	250 x 10g
Pack dimensions (LxWxH):	295mm x 198mm x 277mm	322x233x276 mm	225mm x 190mm x 137 mm
Outer packaging materials:	sachet of PE, PE/PP, PP, paper/PE in further cardboard or fibreboard outer (carton box)		
Inner packaging materials:	paper tea-bags		
Ready-to-use (yes/no)	Yes		
Child safety features (yes/no):	No		
If yes, please specify:	N/A		
Shelf-life:	2 years		
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.		

Professional product packaging: Pack

Container description:	Pack			
Pack size(s):	5kg	10kg	20kg	25 kg
Baits per pack:	500 x 10g	1000 x 10g	2000 x 10g	2500 x 10g 1666 x 15g
Pack dimensions (LxWxH):	240mm x 600mm x 120mm	240mm x 600mm x 120mm	550mm x 1100mm x 0.15mm	550mm x 1100mm x 0.15mm
Outer packaging materials:	PE or PP packs			
Inner packaging materials:	paper tea-bag			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	2 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Professional product packaging: Natron bag

Container description:	Natron bag			
Pack size(s):	5kg	10kg	20kg	25kg
Baits per pack:	500x10g	1000x10g	2000x10g	2500x10g
Pack dimensions (LxWxH):	240mm x 600mm x 120mm	240mm x 600mm x 120mm	550mm x 1100mm x 0.15mm	550mm x 1100mm x 0.15mm
Outer packaging materials:	Natron bag			
Inner packaging materials:	paper tea-bag			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	2 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Professional product packaging: Bucket

Container description:	Bucket						
Pack size(s):	5kg	10kg	8kg	4kg	2.5kg	2.4kg	1kg
Baits per pack:	5000 x 10g	1000 x 10g	800 x 10g	400 x 10g	250 x 10g	240 x 10g 160 x 15g	100 x 10g
Pack dimensions (LxWxH):	295mm x 198mm x 277mm	368mm x 238mm x 266mm	368mm x 238mm x 266mm	295mm x 198mm x 277mm	286mm x 198mm x 151mm	286mm x 198mm x 151mm	180mm x 180mm x 133mm
Outer packaging materials:	PE or PP buckets						
Inner packaging materials:	paper tea-bag						
Ready-to-use (yes/no)	Yes						
Child safety features (yes/no):	No						
If yes, please specify:	N/A						
Shelf-life:	2 years						
Conditions of	Store in dry, cool area. Store in tightly closed packaging. Keep in original						

storage:	containers. Store away from damp or wet conditions. Keep away from children.

Professional product packaging: Carton

Container description:	Carton			
Pack size(s):	5kg	10kg	2.5kg	
Baits per pack:	500 x 10g	1000 x 10g	250 x 10g	
Pack dimensions (LxWxH):	295mm x 198mm x 277mm	322mm x 233mm x 276mm	225mm x 190mm x 137mm	
Outer packaging materials:	cardboard or fibreboard			
Inner packaging materials:	paper tea-bag			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	2 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Professional product packaging: Carton with bag or liner

Container description:	Carton with bag or liner			
Pack size(s):	5kg	10kg	2.5kg	
Baits per pack:	500 x 10g	1000 x 10g	250 x 10g	
Pack dimensions (LxWxH):	295mm x 198mm x 277mm	322mm x 233mm x 276mm	225mm x 190mm x 137mm	
Outer packaging materials:	cardboard or fibreboard box (carton) with PE or PP bag or liner			
Inner packaging materials:	paper tea-bag			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	2 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Professional product packaging: Bait station

Container	Mouse Bait station

description:					
Pack size(s):	10g	15g	20g	30g	40g
Baits per pack:	1 x 10g	1 x 15g	2 x 10g	3 x 10g 2 x 15g	4 x 10g
Pack dimensions (LxWxH):	115mm x 100mm x 35mm	115mm x 100mm x 35mm	115mm x 100mm x 35mm	115mm x 100mm x 35mm	115mm x 100mm x 35mm
Outer packaging materials:	cardboard or fibreboard outer				
Inner packaging materials:	paper tea-bag sachets packed in a pre-filled tamper proof PE or PP mouse bait station				
Ready-to-use (yes/no)	Yes				
Child safety features (yes/no):	No				
If yes, please specify:	N/A				
Shelf-life:	2 years				
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.				

Professional product packaging: Bait station

Container description:	Rat Bait station	
Pack size(s):	195g	200g
Baits per pack:	13 x 15g	20 x 10g
Pack dimensions (LxWxH):	240mm x 165mm x 90mm	240mm x 165mm x 90mm
Outer packaging materials:	Cardboard or fibreboard outer	
Inner packaging materials:	paper tea-bag sachets packed in a pre-filled tamper proof PE or PP rat bait station	
Ready-to-use (yes/no)	Yes	
Child safety features (yes/no):	No	
If yes, please specify:	N/A	
Shelf-life:	2 years	
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.	

Professional product packaging: Bait station

Container description:	Mouse Bait station		
Pack size(s):	20g	30 g	40g
Baits per pack:	2 x 10g	2 x 15g 3 x 10g	4 x 10g
Pack dimensions (LxWxH):	135mm x50mm x 65mm	135mm x50mm x 65mm	115mm x 100mm x 35mm
Outer packaging materials:	cardboard or fibreboard outer		
Inner packaging materials:	paper tea-bag sachets		
Ready-to-use (yes/no)	Yes		
Child safety features (yes/no):	No		
If yes, please specify:	N/A		
Shelf-life:	2 years		
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.		

Professional product packaging: Blister packs

Container description:	One blister pack in carton			
Pack size(s):	40g	80g	200g	100g
Baits per pack:	40g (loose bait)	80g (loose bait)	200g (loose bait)	100g (loose bait)
Pack dimensions (LxWxH):	113mm x 59mm x 30mm	113mm x 59mm x 30mm	113mm x 59mm x 38mm	113mm x 59mm x 30mm
Outer packaging materials:	cardboard or fibreboard outer box (carton)			
Inner packaging materials:	PP or PE packs (blisters) containing loose bait			
Ready-to-use (yes/no)	Yes			
Child safety features (yes/no):	No			
If yes, please specify:	N/A			
Shelf-life:	2 years			
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.			

Professional product packaging: Blister packs

Container description:	50 blister packs in carton
Pack size(s):	4 kg
Baits per pack:	50 x 80g (loose bait)
Pack dimensions (LxWxH):	353x257x152 mm
Outer packaging materials:	cardboard or fibreboard outer pack
Inner packaging materials:	PP or PE packs (blisters) containing 80g of loose bait
Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

Professional product packaging: Mastic tube for caulking gun

Container description:	Mastic tube for caulking gun
Pack size(s):	300g
Baits per pack:	1 x 300g
Pack dimensions (LxWxH):	45mm x 45mm x 230mm
Outer packaging materials:	N/A
Inner packaging materials:	mastic tube
Ready-to-use (yes/no)	Yes
Child safety features (yes/no):	No
If yes, please specify:	N/A
Shelf-life:	2 years
Conditions of storage:	Store in dry, cool area. Store in tightly closed packaging. Keep in original containers. Store away from damp or wet conditions. Keep away from children.

15

Safety features: Covered bait stations (tamper resistant)
Wrapped bait for amateur users

14

15 PP = polypropylene, PS = polystyrene, PE = polyethylene, HDPE = high-density polyethylene, PVC = polyvinylchloride

15 Summary of the product assessment

16 3.1 Physico/chemical properties and analytical methods

Active substance (taken from the [redacted] Brodifacoum and Difenacoum Task Force CAR):
Brodifacoum is an off-white powder at 20°C and atmospheric pressure, with a relative density of 1.53. It was observed to darken and decompose at 235.8°C, whereas no decomposition or transformation occurred below 150°C. Brodifacoum is non-volatile, with a Henry's Law Constant value of 2.35E-18 $Pa.m^3.mol^{-1}$. It is essentially insoluble in water at pH 5, but its solubility proved to increase with pH, due to the variation of the ionisation degree of the 4-hydroxycoumarin group in pH range under investigation (5-9). Brodifacoum also turned out to be soluble in organic solvents; results showed that solubility did not vary with temperature, except for dichloromethane.

Brodifacoum dissociation constant was estimated to be 4.50. Log P_{ow} was found to be 4.92 at pH 7 and 20°C. As expected, Log P_{ow} decreased with higher temperature and pH. Brodifacoum is not highly flammable. Besides, it does not show explosive or oxidising properties. Reaction with container materials (mild steel) has not been observed, either. All results considered, it can be concluded that Brodifacoum does not exhibit hazardous physical-chemical properties.

Biocidal product:
Ratimor Brodifacoum Fresh Bait is not explosive, oxidising or highly flammable and does not classify from a physical-chemical point of view. The test item is stable after storage for two weeks at 54°C, for 2 years at 25°C (ambient temperature) and for 2 years at 32°C. The packaging material is stable after storage at ambient temperatures (25°C) for 2 years and at 32°C for 2 years. There were no significant changes of characteristics of the test item observed after 2 years storage at ambient temperatures (25°C) and at 32°C. The test item is a ready-to-use pasta bait and is not intended to be added or mixed with any other product.

6. 3.1.1. Identity related issues

An equivalence check was carried out by Italy that showed that the [redacted] source of Brodifacoum active substance was equivalent to the source of Brodifacoum active substance listed in Annex I of 98/8/EC (see Annex I: Confidential Information and Data).

Composition of the biocidal product Ratimor Brodifacoum Fresh Bait

Component	% w/w	g/kg	Chemical name	CAS no	Function
Brodifacoum	0.005	0.05	3-[3-(4'-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxycoumarin	56073-10-0	Active substance
Co-formulants	See Confidential Data and Information (Annex I)				

Note: The biocidal product Ratimor Brodifacoum Fresh Bait is not the same as the representative biocidal product accompanying the Annex I inclusion. See confidential information and data for details of the composition of Ratimor Brodifacoum Fresh Bait.

7. 3.1.2. Physico-chemical properties

Unichem d.o.o has obtained from [redacted] UK, a Letter of Access to the complete Annex I listing documentation as well as a LoA to the product dossier for [redacted] The RefMS accepts that the data package for [redacted] can be used in support of the authorisation of Ratimor Brodifacoum Fresh Bait (see Confidential Annex for full evaluation).

8. 3.1.3. Physical, Chemical and Technical Properties of the Biocidal Product

Summary of the Physical and Chemical Properties of the Biocidal Product Ratimor Brodifacoum Fresh Bait

Section	Study	Method	Results	Comment	Reference
1.1a	Appearance	Observation.	Physical state: soft pliable dough Colour: Blue Odour: Slight smell of peanuts	Carried out to GLP. Carried out at 22°C. The results are acceptable.	"Ratimor Brodifacoum Fresh Bait: determination of the colour, odour and physical state". Chem Service Study no.: CH-345/2006. Garofani, S., 15th May 2007.
1.1b	Appearance	Observation (appearance) Inhalation (odour)	Physical state: opaque soft solid dough Colour: Red with small pieces of a blue solid throughout Odour: A mild odour of wood	Carried out to GLP. Carried out at 20 ± 0.5°C. The results are acceptable.	"Determination of physico-chemical properties". SPL Project number: 2254/0040. Atwal, S.S. and Woolley, S.M. 15th January 2008.
1.2.1	Explosive properties	Justification	"Product is a solid paste bait. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for explosive potential and none of the components are classified as explosive. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or explosive activity. On the basis of the above, a derogation to perform this study is requested."	The justification is acceptable. The bait is not explosive.	
1.2.2	Oxidising properties	Justification	"Product is a large solid paste bait. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for oxidising potential and none of the components are classified as oxidisers. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or oxidising activity. On the basis of the above, a derogation to perform this study is requested."	The justification is acceptable. The bait is not oxidising.	
1.3.1	Flash point			No flash point data is	

Section	Study	Method	Results	Comment	Reference
				required for solids.	
1.3.2	Flammability	EEC method A 10	The 'rope' ignited with an orange flame which extinguished after 24 seconds without propagating combustion. The test material has been determined to be not highly flammable as it did not propagate combustion over the 200 mm of the preliminary screening test within 4 minutes. Not highly flammable.	Carried out to GLP. The flammability (solids) was determined by measuring the burning rate of test material prepared as a 'rope' of set dimensions. The result of the preliminary screening test obviated the need to perform the main test. The results are acceptable.	"Determination of physico-chemical properties". SPL Project number: 2254/0040. Atwal, S.S. and Woolley, S.M. 15th January 2008.
1.3.3	Auto-flammability	Justification	"Product is a solid paste bait. No evidence of flammability in use. None of the components of the product are classified as flammable under the directive 67/548/EC. Also the flammability test on a similar difenacoum formulation which applied an air-rich bunsen burner flame to the product did not show any signs of instability. On the above grounds it is not believed that the paste bait represents a flammability or spontaneous ignition hazard and a derogation for the study is requested."	The justification is acceptable.	
1.4.1	Free acidity/ Alkalinity	Justification	"Product is a paste bait composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances. On the basis of the above, a derogation to perform this study is requested."	The justification is acceptable.	
1.4.2	pH (1 %)	Justification	"Product is a paste bait composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances. On the basis of the above, a derogation to perform this study is requested."	The justification is acceptable.	
1.5.1	Viscosity	Justification	"The product is a solid paste at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is	The justification is acceptable. Not applicable as the	

Section	Study	Method	Results	Comment	Reference
			requested."	product is a solid (paste).	
1.5.2	Surface tension	Justification	"The product is a solid paste at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested."	The justification is acceptable. Not applicable as the product is a solid (paste).	
1.6a	Relative density	EEC method A 3.	1.26 at 19.6 ± 0.5^{o}C.	Carried out to GLP. Carried out on the red bait. A gas comparison pycnometer was used. The results are acceptable.	"Ratimor Brodifacoum Fresh Bait(Brodifacoum 0.005%): Determination of relative density". SPL Project number: 2254/0053. Atwal, S.S. and Woolley, S.M. 21st April 2008.
1.6b	Relative density	EEC method A 3.	1.28 at 21.4 ± 0.5^{o}C.	Carried out to GLP. Carried out on the red bait. A gas comparison pycnometer was used. The results are acceptable.	"Determination of physico-chemical properties". SPL Project number: 2254/0040. Atwal, S.S. and Woolley, S.M. 15th January 2008.
1.7.1	Storage stability (2 weeks at 54^{o}C)	CIPAC MT 46	**Appearance:** T_0 = Sachet material was oily to the touch and the red paste was soft and malleable and of smooth consistency and even colour. $T_{2\ weeks}$ = immediately on removal from the oven the bait sachet material appeared more oily and the paste bait was quite firm to the touch and paler in colour. On cooling to ambient temperature the paste hardened further and could be broken into pieces to revel a hardened exterior 'skin' and an internal softer, crumbly matrix. There was no evidence of product pack incompatibility.	Carried out to GLP. The formulation was stored in 15g doses in tissue paper sachets and the sachets bulk packed (2.5 kg) in a HDPE bucket. The test item is stable for 2 weeks at 54^{o}C which indicates that it will be stable for 2 years at ambient	"Storage stability and physical-chemical characteristics of a 0.005% w/w Paste Bait formulation of Brodifacoum". Study reference code: 96031329. Thomas, K.T. 26th May 1998.

<table>
<tr><th>Section</th><th>Study</th><th>Method</th><th>Results</th><th>Comment</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>Odour:
T_0 = Smelt of peanuts
T_{2weeks} = Smelt of peanuts

Brodifacoum content (% w/w):
<table>
<tr><th>Before storage</th><th>After storage for 2 weeks at 54^oC</th></tr>
<tr><td>0.0050</td><td>0.0050</td></tr>
<tr><td colspan="2">The values given are the mean of 3 weighings.</td></tr>
</table></td><td>temperatures.

The results are acceptable.</td><td></td></tr>
<tr><td>1.7.2a</td><td>Shelf life (storage at ambient temperatures (25^oC))</td><td>Observation (appearance) Inhalation (odour) Justification</td><td>Appearance:
T_0 = Sachet material was oily to the touch and the red paste was soft and malleable and of smooth consistency and even colour.
$T_{3months, 6months, 1 yr, 18 months, 2 yrs}$ = The paste remained soft and malleable to the touch with a smooth consistency
At each time interval the appearance of the samples was satisfactory and there was no indication of loss of product integrity. There was no evidence of product pack incompatibility.

Odour:
T_0 = Smelt of peanuts
$T_{3months, 6months, 1 yr, 18 months, 2 yrs}$ = Smelt of peanuts

Brodifacoum content (% w/w):
<table>
<tr><th rowspan="2">Before storage</th><th colspan="5">After storage for</th></tr>
<tr><th>3 months</th><th>6 months</th><th>1 yr</th><th>18 months</th><th>2 yrs</th></tr>
<tr><td>0.0050</td><td>0.0049</td><td>0.0050</td><td>0.0050</td><td>0.0050</td><td>0.0049</td></tr>
<tr><td>Change in conc.</td><td>-2%</td><td>-</td><td>-</td><td>-</td><td>-2%</td></tr>
<tr><td colspan="6">The values given are the mean of 3 weighings.</td></tr>
</table>
“Ratimor Brodifacoum Fresh Bait: Here the story is very similar to that for the [redacted] Instead of cereal</td><td>Carried out to GLP. The formulation was stored in 15g doses in tissue paper sachets and the sachets bulk packed (2.5 kg) in a HDPE bucket.

The test item is stable for 2 years at ambient temperatures (25^oC).

The results are acceptable.</td><td>“Storage stability and physical-chemical characteristics of a 0.005% w/w Paste Bait formulation of Brodifacoum”. Study reference code: 96031329. Thomas, K.T. 26th May 1998.</td></tr>
</table>

<table>
<tr><th>Section</th><th>Study</th><th>Method</th><th>Results</th><th>Comment</th><th>Reference</th></tr>
<tr><td></td><td></td><td></td><td>grains and flour, mainly flour is used, which has an even larger surface area which significantly increases the adsorption of the brodifacoum solution. Even though animal lard contains some polar substituents in its molecules, long paraffinic chains mean that there is no noticeable difference between the lard and paraffin. Moreover, the lard, mixed with flour is not a freely flowing liquid. Excess lard may be sucked into tissue paper sachets but contains no detectable amount of brodifacoum.”</td><td></td><td></td></tr>
<tr><td>1.7.2b</td><td>Shelf life (storage at 32^{o}C)</td><td>Observation (appearance)
Inhalation (odour)
Justification</td><td>Appearance:
T_0 = Sachet material was oily to the touch and the red paste was soft and malleable and of smooth consistency and even colour.
$T_{3months, 6months, 1 yr, 18 months, 2 yrs}$ = The paste remained soft and malleable to the touch with a smooth consistency
At each time interval the appearance of the samples was satisfactory and there was no indication of loss of product integrity. There was no evidence of product pack incompatibility.

Odour:
T_0 = Smelt of peanuts
$T_{3months, 6months, 1 yr, 18 months, 2 yrs}$ = Smelt of peanuts

Brodifacoum content (% w/w):
<table>
<tr><th rowspan="2">Before storage</th><th colspan="5">After storage for</th></tr>
<tr><th>3 months</th><th>6 months</th><th>1 yr</th><th>18 months</th><th>2 yrs</th></tr>
<tr><td>0.0050</td><td>0.0049</td><td>0.0050</td><td>0.0049</td><td>0.0049</td><td>0.0048</td></tr>
<tr><td>Change in conc.</td><td>-2%</td><td>-</td><td>-2%</td><td>-2%</td><td>-4%</td></tr>
<tr><td colspan="6">The values given are the mean of 3 weighings.</td></tr>
</table></td><td>Carried out to GLP. The formulation was stored in 15g doses in tissue paper sachets and the sachets bulk packed (2.5 kg) in a HDPE bucket.

The test item is stable for 2 years at 32^{o}C.

The results are acceptable.</td><td>“Storage stability and physical-chemical characteristics of a 0.005% w/w Paste Bait formulation of Brodifacoum”. Study reference code: 96031329. Thomas, K.T. 26th May 1998.</td></tr>
<tr><td>1.7.3</td><td>Packaging</td><td>Justification</td><td>Packing material: From the packing materials used by [redacted] the following materials may come into contact with the baits/AS: paper (cellulose), Polyethylene (PE) and Polypropylene (PP).</td><td>The RefMS accepts the Applicant’s justification.</td><td></td></tr>
</table>

Section	Study	Method	Results	Comment	Reference
			Paper (cellulose)/'tea-bags': cellulose is a polysaccharide and chemically the same as starch or cellulose in grain, flour, i.e. has the same degree of chemical inertness. Cellulose could potentially adsorb some AS, but in case of sachets of pasta this is not possible because brodifacoum cannot migrate through the lard due to its physico-chemical properties as explained above. Additionally, once the cellulose is impregnated with lard it will lose its ability to adsorb brodifacoum. **PE and PP**: both materials are hydrocarbons similar to paraffins with long hydrocarbon chains, which are inert and will not react with the AS under normal conditions. PE and PP do not contain any reactive substituents and because they are non polar substances, will not adsorb any AS. All the baits are solid, non-free flowing materials. Point contact with the packing material will therefore be further reduced limiting interaction. As a further observation both PE and PP are used for the packing of strong acids, strong bases, strong oxidizing chemical and strongly reducing agents (hydrides), hydrofluoric acid etc and are stable. Given the stability of these far more reactive chemicals in these packaging materials, it is clear that the inert rodenticide baits will be stable when stored in these materials. In conclusion, the rodenticide baits are all extremely stable, solid materials and will not react with the inert packaging used for [redacted] products. Given the nature of the products, it should be possible to support all the proposed packs using the storage data package available across the full range of [redacted] products.		
1.7.4	Storage stability in sunlight	Justification	"The product is supplied and stored in its original packaging. Correct seting of baits also limits the length of time the product is exposed to sunlight to the length of time it takes to place the bait, and cover it or close the bait box. Due to the very short length of time of exposure, and the known stability at a temperature of 32°C for 2 years, it is considered that further	The RefMS accepts the Applicant's justification.	

Section	Study	Method	Results	Comment	Reference
			information is unnecessary."		
1.8.1	Wettability	Justification	"The paste bait is a solid bait product, which is not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. The paste bait is not friable and is not dusty. On the basis of the above, a derogation to perform this study is requested"	The justification is acceptable. Not required. The product is a ready to use paste bait.	
1.8.2	Persistent foaming	Justification	"The paste bait is a solid bait product, which is not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. The paste bait is not friable and is not dusty. On the basis of the above, a derogation to perform this study is requested"	The justification is acceptable. Not required. The product is a ready to use paste bait.	
1.8.3.1	Suspensibility			Not required. The product is a ready to use paste bait.	
1.8.3.2	Dispersibility			Not required. The product is a ready to use paste bait.	
1.8.4	Wet/dry sieving test			Not required. The product is a ready to use paste bait.	
1.8.5	Particle size distribution in suspension	Justification	"The product is a solid paste bait. It is not composed of a large number of discrete small particles which vary in size. On the above basis a derogation to perform this study is requested."	The justification is acceptable. Not required. The product is a ready to use paste bait.	
1.8.6	Water content			Not required. The product is a ready to use paste bait.	
1.8.7	Emulsion stability			Not required. The product is a ready to use paste bait.	
1.8.8	Flowability, pourability	Justification	"The paste bait is a solid bait product, which is not added to water. Therefore characteristics applicable to products diluted	The justification is acceptable.	

Section	Study	Method	Results	Comment	Reference
	and dustability		in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. The paste bait is not friable and is not dusty. On the basis of the above, a derogation to perform this study is requested"	Not required. The product is a ready to use paste bait.	
1.9	Physical compatibility	Justification	"The product is not applied in mixture with other products. On the basis of the above, a derogation to perform this study is requested."	The justification is acceptable. Not applicable. The product is a ready to use paste bait and is not intended to be mixed with any other product.	

Conclusions:
Ratimor Brodifacoum Fresh Bait is not explosive, oxidising or highly flammable and does not classify from a physical and chemical point of view. The test item is stable after storage for two weeks at 54°C. The test item is stable for 2 years at 25°C (ambient temperature) and for 2 years at 32°C. The packaging material is stable after storage at ambient temperatures for 2 years and at 32°C for 2 years. There were no significant changes of characteristics of the test item observed after 2 years storage at ambient temperatures or at 32°C. The test item is a ready-to-use pasta bait and is not intended to be added or mixed with any other product.

Data requirements:
None.

The paste bait is considered compatible with the following packaging:

1. 'Tea-bags' in:
    a. polyethylene/polypropylene container (tubs or pails)
    b. polythene lined cardboard outers
    c. paper/polyethylene/aluminium, polypropylene, PET/polyethylene or laminated polypropylene pouches
    d. Polythene lined carton of 10kg, 15kg or 20kg
    e. HDPE or PP bait stations
    f. Secured on a fixed metal bar in an HDPE or PP bait station

2. Loose bait in
    a. bait trays with a heat-sealed lid.
    b. HDPE or PP bait station
    c. Polypropylene/polyethylene tubs/pails
    d. polyethylene/polypropylene cartridge (for use in caulking gun)

Proposed shelf life for the paste bait:
2 years (based on ambient storage stability data).

General note:
Relative density information was provided in two separate GLP studies and the information from the two studies is presented above. The results are in line with each other and the average, 1.27, is the value to be used for the endpoint.

9. 3.1.4 Analytical methods

Ratimor Brodifacoum Fresh Bait was not assessed as part of the Annex I inclusion process therefore the Notifier has submitted the following method of analysis to cover the outstanding data gap.

<table>
<tr><td>Report:</td><td>CH-346/2006</td></tr>
<tr><td>Title:</td><td>“Ratimor Brodifacoum Fresh Bait: Validation of the analytical method for the determination of the active ingredient content”</td></tr>
<tr><td>Author(s):</td><td>Garofani, S.</td></tr>
<tr><td>Date:</td><td>15th May 2007</td></tr>
<tr><td>GLP: Yes/No</td><td>Yes.</td></tr>
<tr><td>Principle of the Method:</td><td>The determination of the active ingredient was performed by HPLC using an external standard and UV detector (270 nm). The quantification of Brodifacoum was achieved by comparing the analytical standard peak area versus Brodifacoum peak area in Ratimor Brodifacoum Fresh Bait samples.</td></tr>
<tr><td>Linearity:</td><td>The linearity was performed with solutions containing 6.02, 9.03, 12.04, 15.05 and 18.06 µg/ml (ppm) of the Brodifacoum analytical standard. Four injections were carried out at each concentration.
The analytical method is linear over the range tested with a correlation coefficient r^2 of 0.99951. A calibration curve was provided and was acceptable.</td></tr>
<tr><td>Precision/repeatability:</td><td>The repeatability test was performed by six determinations of the test article. The active substance content was found to be 0.0047, 0.0047, 0.0047, 0.0051, 0.0048 and 0.0046% w/w. The mean value was 0.0048 % w/w, the Horwitz RSDr was 5.99% and standard deviation was 0.0002. The coefficient of variation was 3.38% for brodifacoum. Since the coefficient of variation was less than the Horwitz RSDr, the repeatability test for brodifacoum was acceptable.</td></tr>
<tr><td>Accuracy:</td><td>The test was performed by spiking the placebo with analytical standard at three levels corresponding to 75, 100 and 125% of the nominal concentration of the active ingredient.
<table>
<tr><th>Spike</th><th>Placebo (g)</th><th>Technical a.s (mg)</th><th>a.s. added (% w/w)</th><th>a.s. found (% w/w)</th><th>Recovery (%)</th></tr>
<tr><td>75% A</td><td>10.05</td><td>0.380</td><td>0.0037</td><td>0.0038</td><td>102.35</td></tr>
<tr><td>75% B</td><td>10.11</td><td>0.380</td><td>0.0037</td><td>0.0038</td><td>101.99</td></tr>
<tr><td colspan="5">Mean recovery (%)</td><td>102.2</td></tr>
<tr><td>100% A</td><td>10.08</td><td>0.506</td><td>0.0050</td><td>0.0051</td><td>102.36</td></tr>
<tr><td>100% B</td><td>10.00</td><td>0.506</td><td>0.0050</td><td>0.0051</td><td>101.62</td></tr>
<tr><td colspan="5">Mean recovery (%)</td><td>102.0</td></tr>
<tr><td>125% A</td><td>10.02</td><td>0.633</td><td>0.0063</td><td>0.0063</td><td>100.96</td></tr>
<tr><td>125% B</td><td>10.13</td><td>0.633</td><td>0.0062</td><td>0.0063</td><td>101.77</td></tr>
<tr><td colspan="5">Mean recovery (%)</td><td>101.4</td></tr>
<tr><td colspan="5">Overall mean recovery (%)</td><td>101.8</td></tr>
</table>
The purity of the Brodifacoum analytical standard was 99.1% w/w.</td></tr>
<tr><td>Interferences</td><td>A comparison of the chromatograms of the Brodifacoum analytical standard, solvent wash, formulation sample and placebo sample solutions showed that following the operating conditions recommended in the analytical method, the Brodifacoum peak is well separated and there are no interferences with the placebo.
No analyte interferences were detected using the analytical method</td></tr>
</table>

Conclusion:
The method was found to be linear over the range of 6 – 18 µg/ml for Brodifacoum. The method was successfully validated in terms of its recovery (mean = 101.8%), precision and specificity (no analyte interferences were detected using the analytical method). Since the coefficient of variation (3.38% for

Brodifacoum) was less than the Horwitz RSDr (5.99%), the repeatability test for brodifacoum was acceptable.

Data requirements:
None.

10. 3.1.5 Analytical method for the relevant impurities, isomers and co-formulants in the biocidal product

Not applicable.

17 3.2 Efficacy of the Biocidal Product

11. 3.2.1 Function/Field of use

PT14: Rodenticide

12. 3.2.2 Organisms to be controlled

Ratimor Brodifacoum Fresh Bait (containing 50 mg/kg brodifacoum) is a ready-to-use pasta bait intended to control the brown rat (Rattus norvegicus), roof rat (Rattus rattus) and the house mouse mice (Mus musculus). [redacted] has proposed the use area indoors, outdoors around buildings and in sewers for the protection of public health, stored products and materials. [redacted] has claimed amateur and professional use of Ratimor Brodifacoum Fresh Bait in and around buildings. For rats, each bait point will contain a maximum of 60g bait; a mouse bait point will contain a maximum of 20g bait.

Advice concerning application frequency should be included on the draft label.
There are no indications as to application rate or recommendations relating to the use of bait in sewers on the draft professional product label. This must be addressed.
There is no indication on the draft label on how long the bait can be stored while still remaining effective.

13. 3.2.3 Dose/Mode of action

Anticoagulant rodenticides are vitamin K antagonists. The main site of their action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K_1 epoxide reductase. The anticoagulants accumulate and are stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidoting therapy (vitamin K_1).

14. 3.2.4 Effects on the target organisms (efficacy)

Comprehensive data on the palatability and effectiveness of brodifacoum was assessed as part of the annex I inclusion process and the CAR confirmed that the baits are both palatible and effective in controlling the target pests. Additional data from trials using the paste formulation were provided in the form of laboratory (including studies on bait subjected to sewer like conditions) and field studies to verify the proposed label claims.

Laboratory palatability and efficacy studies:
One laboratory palatability and efficacy (choice) test conducted on mice with aged bait.
One laboratory palatability and efficacy (choice) test conducted on mice with fresh bait.
One laboratory palatability and efficacy (choice) test conducted on rats with fresh bait.
One laboratory palatability and efficacy (choice) test conducted on rats with bait with aged bait.

Field efficacy studies:
Two field studies conducted on rats (Rattus norvegicus).
Two field studies conducted on mice (Mus domesticus/mus musculus).

Simulated use and palatability study:
One simulated use (choice) study on rats using anticoagulant-free bait stored in simulated sewer conditions.

[redacted] provided the study reports from four laboratory studies conducted on RATIMOR BRODIFACOUM FRESH BAIT. The experiments were all choice studies conducted according to OEPP/EPPO (1982) and US EPA (1982) guidance. Two studies were conducted on the house mouse, one with fresh bait and one with aged bait. Two additional studies were done on the brown rat, one of which used aged bait. The results from the studies are summarised in **Table 3.1**. The results achieved demonstrated that RATIMOR BRODIFACOUM FRESH BAIT is palatable to the house mouse and the brown rat according to the criteria given in TNsG on Product Evaluation as the bait intake was much greater than 20% of the total food consumption in all the studies. The storage treatment was found not to adversely affect the palatability or effectiveness of the product. As all test animals (mice & brown rats) died within 6-9 days after the start of the baiting period the results from

the laboratory testing scheme confirm that product is both palatable to and effective against the target organisms.
Results from four field studies using RATIMOR BRODIFACOUM FRESH BAIT were also provided. The field trial programme showed an efficacy of 99.8 to 100% (total census bait take) and 98.9% to 100% (total track score) for the rat (Rattus norvegicus) and 89.8 to 96.5% (total census bait take) and 87.9 to 92.0% (total track score) for the mouse (Mus musculus). The field trial programme demonstrated high effectiveness against wild populations of the brown rat (Rattus norvegicus) and for the mouse (Mus musculus/domesticus) under normal use situations.
In addition, the performance of a so-called "blank" pasta bait which was stored under simulated sewage conditions (active substance removed and replaced with propylene glycol) was assessed. There was no detrimental effect on palatability of bait left in 'sewer' like conditions for periods up to and including 5 days. The report's conclusions indicated that the 'sewer' bait was more palatable than the normal bait.
No efficacy data using the pasta bait formulation was provided for the black rat (Rattus rattus).

Table 3.1: Experimental data on the effectiveness of Ratimor Brodifacoum Fresh Bait **containing 50 mg/kg brodifacoum.**

Test organism	Test system/Test conditions	Results	Reference
House mouse (Mus musculus)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring max/ 5 males + 5 females	The mean bait intake 49.2% of the total food consumption. The mean consumption of the test product and the reference meal were 4.1 g and 4.2 g, respectively. 100% mortality 7-9 d after the start of exposure.	B5.10.2(1)
House mouse (Mus musculus)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 46.9% of the total food consumption. The mean consumption of the test product and the reference meal were 3.6 g and 4.1 g, respectively. 100% mortality 6-8 d after the start of exposure.	B5.10.2(2)
Brown rat (Rattus norvegicus)	Choice test with fresh bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 39.5% of the total food consumption. The mean consumption of the test product and the reference meal were 29.7 g and 45.4 g, respectively. 100% mortality 6-8 d after the start of exposure.	B5.10.2(3)
Brown rat (Rattus norvegicus)	Choice test with aged bait/ 4 d exposure + 20 d post monitoring/ 5 males + 5 females	Mean bait intake 41.1% of the total food consumption. The mean consumption of the test product and the reference meal were 33.0 g and 47.2 g, respectively. 100% mortality 7-9 d after the start of exposure.	B5.10.2(4)
House mouse (Mus musculus)	Field trial	Efficacy based on total census bait take = 96.5% Efficacy based on total track score = 92.0%	B5.10.2(5)
House mouse (Mus domesticus)	Field trial	Efficacy based on total census bait take = 89.8% Efficacy based on total track score = 87.9%	B5.10.2(6)
Brown rat (Rattus norvegicus)	Field trial	Efficacy based on total census bait take = 99.8% Efficacy based on total track score = 98.9%	B5.10.2(7)
Brown rat (Rattus norvegicus)	Field trial	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%	B5.10.2(8)
Brown rat (Rattus norvegicus)	Palatability – blank paste bait (minus AS	No detrimental effect on palatability following storage of paste bait in sewer conditions for 5 days. The sewer-treated bait comprised	B5.10.2 (9)

Test organism	Test system/Test conditions	Results	Reference
	concentrate)	71.93% of the total bait consumed.	

15. 3.2.5 Known limitations (e.g. resistance)

The following resistance management strategy was proposed by the applicant:
Management of resistance
The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance. The use of a suitable arsenal of alternative rodenticides is necessary for the management of resistance. Even out-moded compounds such as zinc phosphide were beneficial when anticoagulant resistance first appeared in the UK. The newer rodenticides to which resistance has not yet developed including the anticoagulants Brodifacoum, Flocoumafen and Difethialone and the non-anticoagulants Calciferol and Bromethalin, all appear to have a role in resistance management. A consistent selection differential that places resistant individuals at a disadvantage, large or small, is needed to eliminate resistance. The most practical way to achieve this is first to stop using rodenticides to which the rodenticides are resistant and then to eliminate the resistant population by the exclusive use of non-selective or counter selective control techniques, both chemical and non-chemical. A contrary strategy is that of withholding or saving effective rodenticides while continuing to use a given anticoagulant until resistance exhausts its usefulness is sometimes put forward as a means of limiting the development of resistance. However it is generally accepted that this strategy is likely to accelerate the development and spread of resistance.

Prevention of Resistance
The following are considered the most feasible to limit the development of resistance to anticoagulants:
Maximise the use of non-chemical control techniques.
Preferential use of rodenticides and formulations to which resistance rarely develops.
Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.

Further information on resistance is also provided in the Annex Document IIIB, Section 5.11. An extensive literature review was conducted by [redacted] which concluded that commercial rodenticide baits containing 50 ppm brodifacoum and meeting current European Commission requirements for the assessment of bait palatability, measured in guideline-compliant laboratory bait choice feeding trials are likely to be fully effective for the control of resistant rodents in the EU.

In addition, the IE CA recommends the following in relation to resistance management:
The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance.

CropLife International has published a strategy for resistant management of rodenticides (RRAC 2003). The habitat management is addressed in the strategy in addition to chemical control. The access of rodents should be restricted by physical barriers and no food should be available for rodents. Rotation between different anticoagulants is not a reliable means of managing the anticoagulant resistance, as all anticoagulants have the same mode of action and the nature of resistance is also similar. The resistant individuals can be identified by conducting a blood clotting response (BCR) test (Gill et al. 1993, RRAC 2003).

Resistance management strategies
The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use.

To this extent the applicant suggests the following measures to aid in the prevention of resistance:

- Maximum use of non-chemical control techniques.
- Preferential use of rodenticides and formulations to which resistance rarely develops.
- Ensure the complete eradication of the target population whenever a rodenticide is used.
- Avoid the use of first generation anticoagulants, to which resistance develops relatively easily.
- Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.

It is recommended that the label states that any instances of resistance are referred to the manufacturer of the a.s.

In order to prevent the development and spreading of resistance, some resistance management strategies measures such as those from the Codes of Good Practices in rodent control are recommended:

- The population size of the target rodent should be evaluated before a control campaign. The number of baits and the timing of the control campaign should be in proportion to the infestation level.
- A complete elimination of rodents in the infested area should be achieved.
- The use instruction of products should contain guidance on resistance management for rodenticides.
- The authorisation holder shall report any observed resistance incident to the Competent Authorities or other appointed bodies involved in resistance management.

The proposed labels contain detailed instructions for use.

- The population size of the target rodent should be evaluated before a control campaign.
- The number of baits and the timing of the control campaign must be in proportion to the infestation level.
- Baits must be placed in a safe manner inaccessible to children and non-target species and not be applied to areas where food/feed, food utensils or food processing surfaces may come into contact with, or be contaminated by the product.
- Bait consumption should be regularly checked and consumed or spoilt bait replaced until consumption has stopped. The remaining baits and material must be removed and disposed of safely at the end of the treatment according to local/national wastes disposal regulation.
- Water must not be contaminated with the product or its container.
- The rodents' bodies all along the treatment must be disposed of according to local/national regulation.

In addition to the above applicant and label recommendations the RMS advocates the adoption of the following advice to avoid the development of resistance in susceptible rodent populations.

Details of treatment should be recorded.

- Apply effective Integrated Pest Management measures (remove alternative food sources, remove water sources, remove harbourage and proof susceptible areas against rodent access).
- Inspected baiting points weekly and replace old bait where necessary.
- Do not routinely use anticoagulant rodenticides as permanent baits. Use permanent baits only where there is a clear and identified risk of immigration or introduction or where protection is afforded to high-risk areas. (The RMS view is that routine use of anticoagulant baits should not be recommended in above described situations.) .
- Where rodent activity persists due to problems other than resistance, use alternative baits or baiting strategies, extend the baiting programme or apply alternative control techniques to eliminate the residual infestation (acute or sub-acute rodenticides, gassing or trapping).

Treatment of rodent infestations containing resistant individuals

- Where rodent infestations containing resistant individuals are identified, immediately use an alternative anticoagulant of higher potency. If in doubt, seek expert advice on the local circumstances.
- Alternatively use an acute or sub-acute but non-anticoagulant rodenticide.

- In both cases it is essential that complete elimination of the rodent population is achieved. Where residual activity is identified apply intensive trapping to eliminate remaining rodents. Gassing or fumigation may be useful in specific situations.
- Apply thorough Integrated Pest Management procedures (environmental hygiene, proofing and exclusion).

Application of area or block rodent control to eliminate resistance

- Where individual infestations are found to be resistant or contain resistant individuals it is possible that the resistance extends further to neighbouring properties.
- Where there are indications that resistance may be more extensive than a single infestation, apply area or block control rodent programmes.
- The area under such management should extend at least to the boundaries of the area known resistance and ideally beyond.

These programmes must be effectively coordinated and should encompass the procedures identified above.

16. 3.2.6 Humaneness

The use of Brodifacoum as a rodenticide could cause suffering of vertebrate target organisms. The use of anti-coagulant rodenticides is necessary as there are at present no other valuable measures available to control the rodent population in the European Union. Rodent control is needed to prevent disease transmission, contamination of food and feeding stuffs and structural damage. It is recognised that such substances do cause pain in rodents but it is considered that this is not in conflict with the requirements of Article 5.1 of Directive 98/8/EC 'to avoid unnecessary pain and suffering of vertebrates', as long as effective, but comparable less painful alternative biocidal substances or biocidal products or even non-biocidal alternatives are not available.

Conclusion:

Although the studies provided on simulated sewer conditions are non-standard they are considered adequate to support the proposed label claim on the basis of the fact that no negative effects on the palatability of the product were observed it may be concluded that the product is suitable for use in sewers.

The IE CA considers that the palatability and efficacy data provided is adequate to support the recommendation for the use of the product against rats and mice, even when stored for up to two years.

Issues identified:

The treatment frequency is 2-4 applications per year, 3-6 months apart, when re-infestation occurs. This treatment frequency recommendation should be included on the draft label.

There are no indications as to application rate or recommendations relating to the use of bait in sewers on the draft professional product label. This must be addressed.

There is no indication on the draft label on how long the bait can be stored while still remaining effective.

No efficacy data using the pasta bait formulation was provided for the black rat (Rattus rattus) therefore only claims relating to control of the brown rat may be used on the label.

18 3.3 Biocidal Product Risk Assessment (Human Health and the Environment)

17. 3.3.1 Description of the intended use(s)

The product is a paste rodenticide. It is a ready-to-use paste or pasta which contains 50 ppm (0.005% w/w) brodifacoum (56073-10-0) used by professional and amateur users. The bait is used in and around buildings and in sewer systems. The target organisms to be controlled are Brown rat, Roof rat or House rat, House mouse and Field mouse.

18. 3.3.2 Hazard Assessment for Human Health

No new exposure studies have been submitted for evaluation. Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed, leading ultimately to profuse haemorrhage. Non-target organisms are most at risk from secondary poisoning, i.e. consumption of rodent carcasses by predators such as raptors.

3.3.2.1. Toxicology of the active substance

Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It disrupts the normal blood clotting mechanisms resulting in increased bleeding tendency and, eventually, profuse haemorrhage and death. Like all anticoagulant rodenticides, brodifacoum is structurally similar to vitamin K. Blood forms a clot at the site of injury by virtue of a complicated 'clotting cascade', involving numerous clotting factors. The clotting factors are made in the liver as inactive precursors, converted to active form and allowed to circulate in the bloodstream. Vitamin K is employed in the liver in the activation process, and is used in a continuous cyclic process involving several enzymes. The anticoagulant rodenticides block these enzymes, preventing regeneration of the vitamin K and preventing activation of the clotting factors.
Brodifacoum requires labelling with the symbol T+ and the risk phrases R 28 'Very toxic if swallowed'; R27 'Very toxic in contact with the skin' and R26 'Very toxic by inhalation'. Brodifacoum is not classified as a skin irritant or eye irritant.
Repeated dosing studies show effects on blood coagulation and death at low doses (µg/kg bw/day), and therefore labelling with R48/23/24/25 is warranted.
Under the GHS scheme Acute tox. 1, H310, Acute tox. 2 H300 and STOT RE 1 H372.
The Commission Working Group of Specialised Experts on Reproductive Toxicity has unanimously recommended that all AVK rodenticides should collectively be regarded as human teratogens due to the structural similarity to and the same mode of action as the known developmental toxicant warfarin (meeting in Ispra, 19-20 September 2006). Therefore based on read across data from warfarin, brodifacoum is considered to be a possible developmental toxicant and requires the classification as Reprotoxic with the labelling R61, may cause harm to the unborn child.
An almost complete oral absorption can be considered, on the basis of amount of radioactivity recovered in the excreta and retained in the tissues. Brodifacoum is widely distributed and bioaccumulates mainly in the liver with lower concentrations in the kidney. Hepatic bioaccumulation of Brodifacoum is a non-linear vs dose and time. The elimination kinetic from the liver was biphasic, with an half-life in the range of 282-350 days. The excretion after oral administration is very slow (11 – 14% in 10 days), occurring via the urine and the bile, both as polar metabolites (glucuronide) and parent compound. The metabolism of Brodifacoum is limited and the toxicologically relevant chemical species is the parent compound.

As long as dermal absorption is concerned, on the basis of the available study and reading acroos from data on other 2nd generation anticoagulant rodenticides, two different values could be used for risk characterisation depending on the type of formulation, that is 3% (pellets and grains) or 0.047% (wax block bait).

Brodifacoum is very toxic after oral administration and also via the dermal and inhalation routes. Death was the result of internal haemorrhage. Classification with T+; R26/27/28; 'Very toxic by inhalation, in contact with skin and if swallowed' is warranted.
Brodifacoum does not fulfil the EU criteria for classification as a skin or eye irritant. Although showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer.

Summary of brodifacoum subchronic, chronic, mutagenic and reproductive toxicity.

Repeated oral exposure to Brodifacoum resulted in clinical signs and toxicity consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent (lethal haemorrhages). The NOEL for subchronic oral toxicity is in the range 0.04 -0.001 mg/kg/day (the lowest values identified with sensitive end-points, such as increases in both the kaolin-cephalin time and the prothrombin time). Based on results from the acute dermal and inhalation toxicity studies, route-to-route extrapolation, consistently with the decision adopted for Difenacoum, it is justified to assume serious damages associated to prolonged exposure through dermal and inhalation routes also. Therefore, classification with T; R48/23/24/25 “Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed” is warranted.

Genotoxicity and Carcinogenicity

Brodifacoum displayed no mutagenic activity in a standard range of genotoxicity tests. No long-term carcinogenicity study was submitted. In fact, chronic toxicity studies were not considered to be technically feasible due to the specific action of the active substance on the test/target species. However, the anticoagulant action is apparently the only pharmacological action of Brodifacoum. The active substance has no structural alerts for carcinogenicity and no concern about possible non-genotoxic carcinogenic potential can be derived from the toxicological studies. Therefore the justifications for non-submission of carcinogenicity data was considered acceptable.

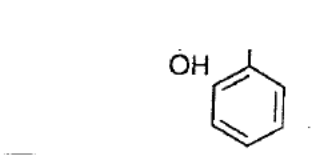
Conclusion on Reproductive toxicity

Reproductive and developmental toxicity studies on Brodifacoum did not reveal any specific effects. General toxicity effects were consistent with the mode of action of the rodenticide and its properties of anti-coagulant agent. The lowest NOAELs for rabbits and rats were 0.002 and 0.001 mg/kg bw.
In spite of these findings, a provisional decision has been made at the Technical Meeting of Classification and Labelling that [R61] should be applied to all anticoagulant active substances on the basis of analogy to Warfarin. None of the acute or subchronic performed tests gave any indication for a potential neurotoxic effect of Brodifacoum.

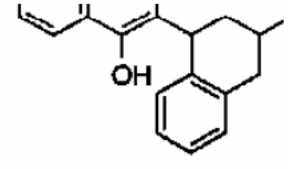
Medical data

Routine monitoring of workers (industrial users) producing Brodifacoum and formulating products has been carried out for the last forty years. Between June 1981 and September 1982, three poisoning incidents occurred with successful recovery. With the exception of these incidents, routine monitoring has shown no clinical effects in any workers. During this time there has been no evidence of allergenicity, sensitisation or any other abnormal effects induced by repeated and continual exposure to these anticoagulant rodenticides.

The molecules both have significant structural similarity to vitamin K. This structural similarity is responsible for the ability to interfere with i.e. block the enzymes used to regenerate vitamin K. The major differences in the active substances lie in their ‘tails’, which have varying degree of lipophilicity. There is long term experience with warfarin, widely used in anti-clotting therapy in humans for over forty years, with no association with increased incidence of cancer. The absence of adverse effects in millions of humans following four decades of long term warfarin therapy is considered sufficient evidence that warfarin is not carcinogenic. The structural similarity of brodifacoum to warfarin (see below), together with the negative results in the guideline mutagenicity tests, indicates that brodifacoum is not carcinogenic.



Warfarin



Brodifacoum

TMIII09 agreed to derive $AEL_{medium\ term}$ consistently with what decided for the other AVK rodenticides. Therefore, $AEL_{medium\ term}$ was calculated from the NOAEL of 0.002 mg/kg bw/day (developmental oral toxicity study in rabbit) divided by an Assessment Factor of 300 (10 for interspecies x 10 for intraspecies x 3 additional factor for severity of effects). The $AEL_{medium\ term}$ results to be of 6.7×10^{-6} mg/kg bw/day.

Conclusions:
The following AELs should be considered in the risk characterization for Brodifacoum:

- AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- $AEL_{medium\ term}$ of 6.7×10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
- AEL_{chr} of 3.3×10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

Data requirements: (List if applicable)
None.

3.3.2.2. Toxicology of the biocidal product

The toxicology of the biocidal product was examined appropriately according to standard requirements. The product was not a dummy product in the EU- review program for inclusion of the active substance in Annex I of Directive 98/8/EC.

Summary of acute toxicity data for the biocidal product Ruby Block

Parameter	Test material	Species	Result	Classification	Ref.
Acute Oral Toxicity	Brodifacoum Pasta Bait. Batch: 61509601	Rat, female, Sprague-Dawley,	LD_{50} > 2000 mg/kg bw	none.	[redacted] (2007a). study number: 2254/0025
	Acceptable (Y/N): Yes		**Method:** OECD 420 (2001)		**GLP (Y/N): Yes**
	Comments: No mortality occurred during the study at 2000mg/kg. There were no clinical signs observed. The product was mixed with arachis oil BP this is only appropriate for an oil based product.				
Acute Dermal Toxicity	Brodifacoum Pasta Bait. Batch: 61509601	Rat, male & female, Sprague-Dawley,	LD_{50} > 2000 mg/kg bw	none.	[redacted] (2007b). study number: 2254/0026
	Acceptable (Y/N): Yes		**Method:** OECD 402 (1987)		**GLP (Y/N): Yes**
	Comments: No mortality occurred during the study at 2000mg/kg. No cutaneous reactions or systemic clinical signs related to the administration of the test item were observed.				
Acute	none	none	none	none	none

<table>
<tr><th>Parameter</th><th>Test material</th><th>Species</th><th>Result</th><th>Classification</th><th>Ref.</th></tr>
<tr><td rowspan="2">Inhalation Toxicity</td><td colspan="3">Acceptable (Y/N):</td><td colspan="2">Method:</td><td>GLP (Y/N):</td></tr>
<tr><td colspan="6">Comments: Inhalation exposure is not appropriate for Pasta Bait formulation. Active substance has very low volatility and is only present at 0.005% (w/w) in the semi solid, wax product. Company justification accepted.</td></tr>
<tr><td rowspan="3">Information on mixture of biocidal products</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td></tr>
<tr><td colspan="3">Acceptable (Y/N): Yes</td><td colspan="2">Method:</td><td>GLP (Y/N):</td></tr>
<tr><td colspan="6">Not applicable since following the proposed uses of Pasta Bait and the label claims, the rodenticide Pasta Bait is not intended to be used in a mix with other biocidal products. Company justification accepted.</td></tr>
<tr><td rowspan="3">Acute Skin Irritation</td><td>Brodifacoum Pasta Bait. Batch: 61509601</td><td>Rabbit, male, NZW, 3 in total</td><td>No irritation</td><td>none</td><td>[redacted] (2007c). study number: 2254/0027</td></tr>
<tr><td colspan="3">Acceptable (Y/N): Yes</td><td colspan="2">Method: OECD 404 (2002)</td><td>GLP (Y/N): Yes</td></tr>
<tr><td colspan="6">Comments: The test item was applied at a dose of 0.5 g, on an undamaged skin area of one flank of each animal for 4 hours. Scores of 2 in two animals and 1 in the other for erythema at 24 hours had reversed 72 hours. Scores of 1 in two animals for oedema at 24 hours has reversed by 48 hours. Mean scores of 1 in two animals (24,48 &72 hours) for erythema and 0.33 for oedema were not sufficient to warrant classification. No classification required.</td></tr>
<tr><td rowspan="3">Acute Eye Irritation</td><td>Brodifacoum wax block bait. Batch: 61509601</td><td>Rabbit, male, NZW, 3 in total</td><td>Slight irritation</td><td>none</td><td>[redacted] (2007d). study number: 2254/0028</td></tr>
<tr><td colspan="3">Acceptable (Y/N): Yes</td><td colspan="2">Method: OECD 405 (2002)</td><td>GLP (Y/N): Yes</td></tr>
<tr><td colspan="6">Comments: The test item was applied at a dose of 0.1 g instilled into the conjunctival sac of one eye in each animal.
<table>
<tr><th></th><th colspan="3">Cornea</th><th colspan="3">Iris</th><th colspan="6">Conjunctivae</th></tr>
<tr><th></th><th></th><th></th><th></th><th></th><th></th><th></th><th colspan="3">Redness</th><th colspan="3">Chemosis</th></tr>
<tr><th>Time/Animal</th><th>1</th><th>2</th><th>3</th><th>1</th><th>2</th><th>3</th><th>1</th><th>2</th><th>3</th><th>1</th><th>2</th><th>3</th></tr>
<tr><td>24 hours</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>2</td><td>1</td><td>0</td><td>1</td><td>0</td><td>0</td></tr>
<tr><td>48 hours</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>1</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>72 hours</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Mean individual scores 24, 48 and 72 h</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>0.0</td><td>1.0</td><td>0.3</td><td>0.0</td><td>0.3</td><td>0.0</td><td>0.0</td></tr>
</table>
Maximum mean scores of 1 for redness and 0.3 for chemosis no classification required.</td></tr>
<tr><td rowspan="3">Skin Sensitisation</td><td>none</td><td>none</td><td>none</td><td>none</td><td>none</td></tr>
<tr><td colspan="3">Acceptable (Y/N):</td><td colspan="2">Method:</td><td>GLP (Y/N): Yes</td></tr>
<tr><td colspan="6">Comments: A skin sensitisation study is not available for the product so active substance data has been used to derive a classification. Brodifacoum showed no sensitizing potential in a LLNA study in mice, it was able to cause skin sensitization in guinea pig and fulfils the EU criteria for classification as a skin sensitizer (CAR IT). However, based on the generic concentration limits for mixtures at a Brodifacoum concentration of 0.005% w/w classification is not required by Directive 1999/45/EC or Regulation (EC) No 1272/2008.</td></tr>
</table>

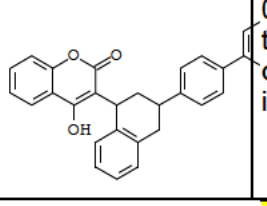
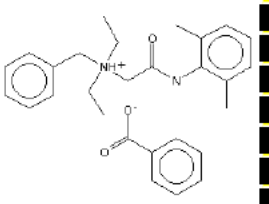
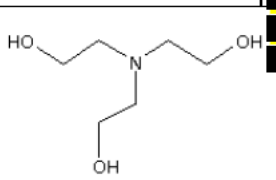
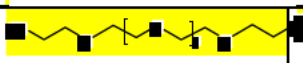
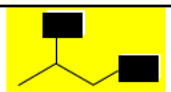
Conclusion:
According to the results of the toxicological studies, Brodifacoum paste does not classify with respect to Directive 1999/45/EC or Regulation (EC) No 1272/2008. However, safety phrases and precautionary statements are proposed by the Rapporteur.

Data requirements: (List if applicable)
None.

3.3.2.3. Toxicology of the co-formulants (substances of concern)

The biocidal product contains no other substances in quantities that would be of toxicological concern. The majority of these components are food grade materials and are not classified.

Pasta Bait

Trade name	IUPAC Name	CAS-No.	EC-No.	Molecular formula	Structural formula	Classification according to Directive 67/548/EEC
Brodifacoum (in technical concentrate)	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	56073-10-0	259-980-5	$C_{31}H_{23}BrO_3$		0.25% technical concentrate is classified
						
						
						
						

19.

20. 3.3.3 Exposure Assessment for Human Health

The contact gel is used as a gel in plastic bait boxes or covered/protected gel points or contact gel can be placed on strips of insulation tape or paper tape fixed to, for example, overhead pipe-ways and ductwork. The product is applied by professional pest controllers, only.

Single-use pre-treated 'gel tubes' (plastic tube containing gel - analogous to single-use pre-treated bait boxes) are also sold. As the amount of gel in a single gel point is enclosed in a sealed tube and there is no exposure to the user, the standard risk assessment for professionals applying bait from other packs is protective of this use.

The application of Block bait is regarded as a suitable worst case scenario for Paste bait. In the [redacted] study operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box this value was then doubled for 200g boxes) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks.

The most relevant route of exposure to the active substance is the dermal route. For exposure assessment only active substance from wax blocks has been modelled. The block product typically takes the form of a solid waxy block with a strong sweet smell containing 0.005% w/w Brodifacoum.

In the final CAR for brodifacoum dermal absorption values were derived from read across from data on Difenacoum. The values chosen were 0.047% for wax formulations and 3% for grain/pellet formulations. These values were deemed appropriate in the absence of product specific data.
The active substance has a low vapour pressure, therefore the potential for evaporation is low, and hence the potential for inhalation exposure is low. Inhalation exposure is only of concern during the formulation process where the active substance has a potential for becoming airborne when mixed with dry bait ingredients. In the case of wax blocks, inhalation exposure is irrelevant. Inhalation exposure from handling grain bait during loading/application and cleaning is also proposed as negligible. The only relevant inhalation exposure is assumed to be that from the decanting of loose grain, pellets and granules due to the potential release of airborne dusts.

Any potential oral exposure will be indirect exposure via possible release to the environment. Other possible exposure scenarios include dermal contact with dead animals and accidental ingestion of poison baits by children.

Key Endpoints for Exposure Assessment

The following AELs should be considered in the risk characterization for Brodifacoum:

- AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)
- $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
- AEL_{chr} of 3.3 x 10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

Data requirements: (List if applicable)
None.

3.3.3.1. Exposure to professional users

MG/PT	Field of uses envisaged	Likely concentrations at which a.s. will be used
Main group 03; PT 14	**Professional uses**	
	Rodenticide used in and around buildings Use in sewerage (only against rats)	0.005% w/w

	Non-professional uses	
	Rodenticide used in and around buildings	0.005% w/w

There are two groups of humans which may be potentially exposed to the rodenticide baits : those who handle, apply and dispose of the product or other residues such as carcasses or faeces (direct exposure) and those who may be incidentally exposed while the product is in use (incidental exposure).

3.3.3.2 Method of application

Block bait is made of paraffinic blocks to which the active substance has been added. These Brodifacoum baits are used indoors and outdoors to kill mice and rats: they are placed at the appropriate places in bait stations or covered under a curved tile, a wooden board or in a piece of tube; the animals eat some of the product and die.
Baits must be deposited in a way to minimize the risk for non-target animals and for children. Where possible, baits are secured so that they cannot be dragged away by the rodents. Preferably bait stations will be used where the bait can't be hidden, fixed or locked up.
The common strategy is to explore the site, locate runs, burrows, droppings or signs of damage and place the bait boxes at entry points into buildings and around areas where rats are known to feed. For the mice control, as mice are sporadic feeders, many bait points are placed throughout the areas where mice are known to feed.
In sewers, the bait is eaten in situ by target rodents. The brown rat is the only mammal able to live in sewers.
For house and field mice control, the recommended dose is 20 to 30 g of bait every 2 to 5 meters.
For rat control, the recommended dose is 60 to 100 g of bait every 5 to 10 meters.
In sewers, place 200 to 300 g every 30-50m (never more than 300 g at each manhole).

There are three phases for the human exposure:

- Application phase: application of rodenticides by professionals and non-professionals.
In and around domestic, industrial and commercial buildings, the product is applied manually, at measured amounts in bait boxes or covered. Professional users are assumed to wear protective gloves when handling the product unlike amateur users.
In sewerage, the bait is applied only by professionals, typically hanged to a wire tied up to the wall a few centimetres above the bottom of manholes.
Bait points are controlled regularly. Any bait eaten or damaged has to be replaced. Depending on infestation rate, an advised frequency of inspection is 3 to 5 days. During the bait inspections, also a search in the zone will be done for dead rodents.

- Use phase: Post-application, i.e. from the use of rodenticide products and from contact with the product (e.g. residential exposure including indoor air contamination, contact with the product during use). The use phase is the period when the biocidal product is waiting to be consumed by the target organism. This means that no primary exposure of humans is intended and should not take place (please refer to point 3.2.4 Secondary exposure).

- Disposal phase: Disposal (including handling of surplus formulated product, burning/incineration, dumping, empty containers, dead rodents (carcasses) disposal).
When no further bait take is observed, bait stations must not be left in place. All bait stations must be removed from the site, cleaned up and the bait and bait remainders must be disposed of in accordance with local requirements.
For sewer systems no specific removal disposal is instructed.

21. Human exposure assessment

Identification of main paths of human exposure towards active substance from its use in biocidal product

Exposure path	Industrial use[1)]	Professional use[2)]	General public[3)]	via the environment[4)]
Inhalation[5)]	Not appropriate	Yes	Yes	No
Dermal[6)]	Not appropriate	Yes	Yes	No
Oral	Not appropriate	No	Yes	No

[1)] Industrial use (manufacture of active substance and formulation of products) is not covered by BPD. Workers in formulation manufacture are not exposed to levels of a.s. that would affect blood clotting.
[2)] Includes non-trained professionals.
[3)] Indirect exposure due to transient mouthing by infants is included in the scenarios for the general public.
[4)] According to the TNsG, indirect exposure via the environment is considered to be of minor importance as the release of rodenticides to the environment is limited.
[5)] The skin is the main exposure route with a small proportion of inhalation exposure to dust when grain-based baits are mechanically handled by professionals. The active substance is of low volatility and it is incorporated at very low concentrations into a solid, non-volatile matrix. Therefore inhalation exposure is considered as negligible.
[6)] Except for the grain block bait which is always packed in individual sachets for both professionals and general public and for grain bait only for the amateurs, dermal contact with the product is a realistic scenario.

The magnitude of human exposure to block bait can be assessed by applying standard exposure models of TNsG[16] for human exposure (2007) or the Harmonised approach for the assessment of rodenticides (anticoagulants) endorsed at TM II 2011 for professionals and amateurs users. Moreover, CONSEXPO 4.1 model can be used to assess the exposure to the biocidal product used by non-professionals.

The following basic primary exposure pathways have to be considered for a risk assessment in order to sum up the exposure of humans to Brodifacoum. The main exposure path is direct skin contact during the use of the biocidal product.
Ingestion is a secondary pathway or an accidental primary exposure during the use of the biocidal product.
Inhalation is considered as negligible.
According to the various pathways, the following absorptions will be applied in the assessment:
- Inhalatory uptake fraction: 1 (default value of 100%);
  Inhalation rate: 1.25 m^3/h (default value)
- Dermal uptake: 0.047% for wax formulations and 3 % for and grain/pellet.
- Oral uptake fraction 100%

3.3.3.2.2 Professional exposure

For professional use, the operator is trained in the correct use of the bait, i.e. placement, number of bait points/boxes required based on the infestation rate area, the amount of bait or number of bait place packs per bait point/box and safe handling procedures.
The use of PPE - disposable gloves and a dust mask may be employed when decanting bait and disposable gloves may be employed when loading bait boxes and disposing of remaining bait and carcasses. However, when the bait is contained within a bait box there will be no exposure of the operator to the product.
PPE (coverall, boots and gloves) is required as standard when the bait is used in sewage systems.
Exposure calculations – professionals
The CEFIC/EBPF Rodenticides Data Development Group conducted an operator exposure study using flocoumafen (which may be considered a suitable surrogate for all other second generation anti-coagulants) to determine exposure during simulated use of rodenticide baits [redacted] 2004,

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unpublished, confidential). This study examined exposure to wax blocks (20g wax block baits, 5 blocks/bait box) and grain bait. Guidance is also taken from a confidential paper entitled "Harmonised Approach for Rodenticides" by the German Competent Authority, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA).
The daily exposure frequency and its division between different tasks are based on a survey organised by CEFIC (and based on a questionnaire answered by selected pest control companies in several EU countries), and on an agreement between Member States on the common approach for exposure assessment and ECB guidelines.

The application of Block bait is regarded as a suitable worst case scenario for Paste and Cluster Baits. In the [redacted] study operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks.

The [redacted] study determined exposure from the application phase from the following scenario: 5 operators secured 5 compressed wax blocks (each of 20g, in total 100g bait per box) into a bait station by pushing bait mounting pegs in the stations through holes in wax blocks. Three trials were conducted with 1, 5 and 10 times securing of these wax blocks. Since the results of 1, 5 and 10 securing are similar all trials were included in the calculation of the 75th percentile by the RMS. The proposed value of **28mg (of wax bait) per manipulation** is valid for loading of one bait box with 100g of wax blocks (a single manipulation constitutes the placement of a single bait station). Since the recommended amount for rat control is up to 200g bait per bait point, this exposure value is multiplied by a factor of 2 because only 100g was used in the [redacted] Study. The proposed value of **56mg (of wax bait) per manipulation** is valid for loading of one bait box with 200g of wax blocks.

For professional operators the potential total daily dermal exposure (assuming the previously agreed number of 60 manipulations from TM III/10 is applied) from the application-phase is **3360mg** wax block product (i.e. 56mg × 60 bait sites).

The [redacted] study determined exposure from the disposal or post-application phase from the following scenario: 5 operators emptied a loaded bait station by sliding the wax block off the mounting pegs into a 10 L plastic bucket. This is done 1, 5 and 10 times. The proposed value of **5.75 mg per manipulation (determined by the RMS, Difenacoum CAR 2009)** is valid for cleaning of one bait box. For the resulting potential dermal exposure of post-application-phase the agreed number of 15 manipulations (TM III/10) should be taken into account. For the post-application phase the potential total daily dermal exposure is **86 mg** wax block product (i.e. 5.75mg x 15 disposal manipulations). The size of one bait block is ignored and the figure is valid for different sized blocks (e.g. 10g, 100 g).

The calculation of PCO (pest control operator) and amateur dermal exposure in placing and clean-up of rodenticidal wax blocks, taking into account measured values (75th percentiles), defaults according to ECB guidelines and the common agreement on daily exposure frequencies (TM III/10) is presented in the following table.

Pest Control Operator, No PPE:	
Amount of exposure to product (75th percentile) during securing of 10 wax blocks (200g). Value is for placement of 1 bait station.	56.0 mg
Amount of Brodifacoum on fingers/hands (0.005% in wax block)	56 mg × (0.005 / 100) = 2.8×10^{-3} mg
Systemic dose per application at 1 bait station: (dermal absorption 0.047%, bw 60kg)	(2.8×10^{-3} mg × (0.047 / 100)) / 60kg = 2.19×10^{-8} mg/kg
Amount of exposure to product (75th percentile) during clean-up and disposal per bait station	5.75 mg
Systemic dose (Brodifacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg) per clean-up of one bait station.	2.25×10^{-9} mg/kg

Assuming 'reasonable worst case' scenario of 60 bait sites and 15 clean-ups, systemic dose per day	$((2.19\times10^{-8}$ mg/kg × 60) + $(2.25\times10^{-9}$ mg/kg × 15)) = **1.35×10^{-6} mg/kg/day** **0.00135 µg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**20% of the AEL**

Pest Control Operator, With PPE (gloves)

Default 10-fold reduction of exposure.	**1.35×10^{-7} mg/kg/day** **0.000135 µg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**2% of the AEL**

Non-Trained Professional (e.g. farmer), No PPE:

Systemic dose resulting from application of product to five bait sites plus five bait sites cleaned per day, no PPE (difenacoum concentration 0.005%, dermal absorption 0.047%, bw 60 kg).	$((2.19\times10^{-8}$ mg/kg × 5) + $(2.25\times10^{-9}$ mg/kg × 5)) = **1.2×10^{-7} mg/kg/day**
Expressed as a % of the AEL:	**0.0001 µg/kg/day**
$AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**1.5%**

Non-Trained Professional (e.g. farmer), With PPE (gloves):

Default 10-fold reduction of exposure.	**1.2×10^{-8} mg/kg/day** **0.00001 µg/kg/day**
Expressed as a % of the AEL: $AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day **(0.0067 µg/kg/d)**	**0.15%**

Application by spatula and caulking gun

This calculation covers the exposure of a professional user when applying rodenticide bait via a caulking gun or spatula. The calculation is based on the information from the worked examples database, based on bridging to the paste application of wood preservative using a trowel (reverse-reference approach). The worked examples data are ADE values inside gloves so the calculation assumes that gloves are worn.

From the wood preservative example, which addresses application of pastes by brush, trowel, caulking gun and gloved hand, a good case for bridging can be made for the contact gel application by spatula (vs trowel) and by caulking gun.

The wood preservative example assumes that the application process leads to a maximum of 30 minutes' exposure per day and we must assess whether this is a reasonable exposure time for a professional pest controller using contact gel.

Time Required to Apply and Clean up Contact Gel Points

In the case of contact gel applied by caulking gun, a case could be made that this is covered by the 14 manipulations listed for paste bait. The text in the HEEG document states:

For the handling of paste bait the following was agreed: The paste bait described in the report by [redacted] and [redacted] was paste bait deployed using prefilled cartridges. Dermal exposure was considered possible only at removal and re-attachment of the nozzle's protection cap and was assumed to occur only before the first and after the last bait placing on a given site. Hence, the number of sites visited per day (multiplied with 2) was considered to be the relevant exposure determinant.

If a user were filling a number of gel points in a small area, the same would be true for use of our contact gel caulking gun product - the user may not find it necessary to put the cap on between filling each bait station on that site.

For spatula application, an alternative way of thinking of this is again to assume that, given the contact gel is applied by spatula in the same way as wax blocks are placed in bait points, the number of manipulations would be at a maximum the same as the number for a wax block. ie. 60+15.
The applicants experts think that to apply bait, either by spatula or by caulking gun, a maximum time of 15 seconds per bait point would be plenty of time. Clean up probably takes about half a minute per bait point at most. (this time estimate agrees with UK Toban pasta bait which is applied in the same manner)
For application by caulking gun using the figure of 11 loadings and 3 clean ups, exposure is far lower than the 30 minutes used in the model.
Loading: 11 bait stations x 15 seconds = 2.75 minutes
Clean up: 3 bait stations x 30 seconds = 1.5 minutes
This gives a total handling time of 4.25 minutes.
For application by spatula and assuming the number of bait stations is the same as for wax blocks, this would give a total handling time of :
Loading: 60 bait stations x 15 seconds = 15 minutes
Clean up: 15 bait stations x 30 seconds = 7.5 minutes
Total time = 22.5 minutes
Therefore in both cases, the figure used in the modelling of 30 minutes is sufficient to cover a professional user.

Acceptable Exposure Level

The maximum level of exposure to the active substance has already been calculated in the AS review and is listed in the Assessment Report List of End Points as follows:

	VALUE	STUDY	SAFETY FACTOR
AEL_{acute}	0.0000033mg/kg/day	Rat developmental tox	300

Therefore maximum amount of AS = 0.0000033 mg/kg/day

Reverse-reference Calculation

For a non-volatile paste (such as this brodifacoum product), inhalation exposure is assumed to be negligible and so, using the dermal absorption data for this formulation (0.047%), to exceed the acceptable exposure level, active substance contamination to the skin would need to exceed:

0.0000033 x 2128
= 7.00×10^{-3} mg/kg/day
If the operator weights 60 kg then the AS contamination would have to exceed:
$7.00 \times 10^{-3} \times 60$ kg
= 0.42 mg/day
As the maximum concentration of AS in the ready-for-use paste formulation is 0.005%, then the weight of paste product containing 0.42 mg AS will be:
0.25/0.005 x 100
= 8400 mg
Assuming that dermal exposure will be predominantly to the hands and in this case, based on the worked examples database, gloves are assumed to be worn since professionals are expected to wear gloves, then the rate of actual hand exposure to the hands is required to exceed:
8400 mg / 30 min
= 280 mg/min
If it is considered that the penetration of brodifacoum through protective gloves is 10%, the operator would need to get about 84 g of product on the outside of the gloves and this would have to remain on the surface until the active had migrated through the paste and penetrated the glove.
Part 2 of the TNsG (2002) states that “in an HSE survey of pest controllers (1994) it was estimated that the median duration "using pesticides" was 120 minutes.” It expands to say that treatment time is up to 100 minutes for pastes. If the 100 minutes is applied rather than 30 as suggested by the company

84g / 100 min
= 0.84 g/min
To put this exposure in context. To recieve an exposure of paste product in excess of the AEL the operator would be required to have almost the same quanity of gel on his protective glove as would load a 100g bait station. This level of exposure is considered very unlikely.

3.3.3.3 Exposure to non-professional users

Contact gels applied by gun or syringe are professional use only and are not modelled for armature use. Block baits are considered a suitable worst case for paste bait delivered in a closed sachet.

Bait boxes for use by the general public may be supplied as sealed units or as lockable, tamper-proof units that may be refilled by the user. Bait may be used in covered/protected bait points, rather than bait boxes, where appropriate.
Calculations for non-professional exposure are presented below; the first scenario assumes no exposure during application phase while the second scenario assumes that the bait boxes would have to be loaded by the user. As for the non-trained professionals, it is assumed that a non-professional user places ten bait blocks per site (200g) on five bait sites and cleans five bait sites per day.

Product type	Exposure scenario	PPE	Inhalation uptake	Dermal uptake
14	Non-professional (amateur)	None	Not relevant	1.12×10^{-8} mg/kg/day[1)]
14	Non- professional (amateur)	None	Not relevant	1.2×10^{-7} mg/kg/day[2)]

1) scenario 1, 2) scenario 2.
Scenario 1: No dermal contact during placing of baits due to sealed bait boxes. Potential exposure is only during clean-up. Default exposure value for cleanup is 5.75mg product per bait site, bromadialone present at a concentration of 0.005% (w/w), 60kg body mass, 0.047% dermal absorption value. The value is calculated from the cleanup exposure per bait station of ((2.25×10^{-8} mg/kg) × 5).
Scenario 2: Assuming that conventional bait boxes are loaded then the exposure is equal to that of the non-trained professional (e.g. farmer) with no PPE. As a worst case scenario, scenario 2 can be taken forward to risk assessment.

3.3.3.4 Exposure to children/workers/general public

Bait points should be covered or protected in such a way to prevent access to the bait. However, the ingestion of wax block bait by infants has been assessed as a potential secondary exposure route associated with the use of Brodifacoum in rodenticide products. Secondary exposure is anticipated to be acute in nature. Two different scenarios of secondary exposure are available, the 'handling of dead rodents' scenario and the 'transient mouthing of poison bait' scenario. The former is excluded from the risk assessment due to unrealistic assumptions. The estimated exposure for the 'transient mouthing of poison bait' scenario is either $2.5\times10^{-}2$ mg/kg or 5.0×10^{-5} mg/kg, depending on the default assumptions. This results in Margin of Exposure (MOE) values of 0.01 or 6.6, respectively. It shows that infants are at significant risk for secondary exposure, i.e. there is no safe use for children.
For the 'transient mouthing of poison bait' scenario, either 5g (User Guidance) or 10 mg (TNsG, with bittering agent) of the product is assumed to be swallowed by an infant per poisoning event.
Oral exposure infant. TNsG Assumptions: Transient mouthing of poison bait (10mg) treated with repellent: (10mg × 0.00005) / 10kg bw

Transient mouthing infant. User Guidance Assumptions: Transient mouthing of poison bait (5000mg) without repellent; (5000mg × 0.00005) / 10kg bw

	Total dose (mg/kg b.w./day)	% AELacute (0.0033 µg/kg b.w.)
Oral exposure infant	0.00005	1515%
Transient mouthing infant	0.025	757575%

The RMS considered that in connection with transient mouthing of poison baits, infants are also exposed via the dermal route while handling the bait. This however is assumed to play a minor role relative to the amount that could be ingested. It is therefore not included in the overall exposure scenario.

3.3.3.5 Exposure to consumers from residues in food

Not applicable.

3.3.3.6 Overall Summary

The exposure data based on measurements in simulated use conditions are acceptable and should be used in risk assessment. The models assume that inhalation exposure is of minor importance compared with dermal exposure. The calculations have been made with the assumptions of rat control, and there are no separate calculations to assess exposure in mice control in which smaller bait sizes are used.

22. 3.3.4 Risk Characterisation for Human Health

3.3.4.1. Professional users

Caulking gun or spatula

Calculation of the exposure of a professional user when applying rodenticide bait via a caulking gun or spatula was assessed via reverse reference scenario. Assuming that dermal exposure will be predominantly to the hands and in this case, based on the worked examples database, gloves are assumed to be worn since professionals are expected to wear gloves, then the rate of actual hand exposure to the hands is required to exceed:

8400 mg / 30 min
= 280 mg/min

If it is considered that the penetration of brodifacoum through protective gloves is 10%, the operator would need to get about 84 g of product on the outside of the gloves and this would have to remain on the surface until the active had migrated through the paste and penetrated the glove.

84g / 100 min
= 0.84 g/min

Using a reverse reference scenarios for caulking and or spatula application it was calculated that a professional operator would require exposure to 84g per day on his gloves. To recieve an exposure of paste product in excess of the AEL the operator would be required to have almost the same quanity of gel on his protective glove as would load a 100g bait station. This level of exposure is considered very unlikely.

Wrapped sachet or blocks

The exposure assessment for professional pest control operators (PCOs) under reasonable worst case assumptions (60 loadings and 15 clean-ups/day), as presented above, yielded a potential dermal exposure leading to a systemic dose 0.0026µg/kg/day day for an unprotected operator during bait handling operations. Comparison to calculated NOAEL for MOE shows that the use of rodenticide baits containing 0.005% brodifacoum results in a margin of exposure of 257.

Since pest control operators wear protective gloves by default during pest control operations, a refined assessment is conducted. The resulting margin of exposure (MOE = 2570) indicates that the use of rodenticide baits containing 0.005% brodifacoum does not cause a risk for PCOs if gloves are worn.

Likewise, the exposure assessment for non-trained professionals (e. g., farmers) under reasonable worst case assumptions (five loadings and five clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 1.2×10^{-7} mg/kg/day for an unprotected person. Even without PPE, the resulting margin of exposure (MOE = 6700) indicates that use of rodenticide baits containing 0.005 % brodifacoum is not a risk at the stated exposure frequency. A refined assessment was, nevertheless, conducted since wearing of protective gloves is recommended in the instructions for use. The resulting margin of exposure (MOE = 67000) indicates a high level of protection for non-trained professional users when gloves are worn.

The result of the risk assessment concerning use of brodifacoum in bait blocks/sachets indicates that the acceptable exposure level is not exceeded for trained professionals (PCOs) without PPE (gloves). In addition, the risk is at an acceptable level without gloves for non-trained professionals. However, use of protective gloves is recommended in all cases for hygiene reasons. In the case of application for caulking gun or spatula it was concluded that exposure to 84g of bait by a PCO on a glove was exceeding unlikely and this application method was expected to yield safe exposure levels for trained operators.

3.3.4.2. Non-professional users

Blocks/sachets are supplied either in pre-sealed units or as loose blocks for use in covered/protected bait points or refillable bait boxes. An exposure assessment has been performed taking into account potential exposure both from application and post-application tasks as a worst-case scenario. In the calculations, amateurs were assumed to load five bait points and clean five bait points per day without PPE. The estimated daily systemic dose, 1.2×10^{-7} mg/kg/day, results in an MOE value of 6700 showing that there is also little risk to amateurs.

3.3.4.3. Children/Workers/general public

As a potential secondary exposure route, associated with the use of difenacoum in rodenticide products, ingestion of wax block bait by infants has been assessed. Secondary exposure is anticipated to be acute in nature. The estimated exposure for the scenario, 2.5×10^{-2} mg/kg/day or 5.0×10^{-5} mg/kg/day, depending on the default assumptions, results in MOE values of 0.01 or 6.6, respectively indicating that infants are at risk of poisoning. This should be addressed by ensuring all bromodialone products targeted for amateur use are provided in sealed packs and tamper resistant bait boxes with a bittering agent. The potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic.

3.3.4.4. Consumers from residues in food

Not applicable, product is not used to treat food stuffs.

3.3.4.5. Overall Summary

The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) as well as exposures below the threshold value for the AEL for all intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value (0.0023µg/kg/day), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

Workplace operation	PPE	Exposure path	Dose (µg/kg/day)	MOE	%AEL
Trained Professional: Placing of wax block baits and clean-up	None	Dermal, hands	0.0026	257	39
Trained Professional: Placing of wax block baits and clean-up	Protective gloves	Dermal, hands	0.00026	2570	3.9
Trained Professional: Application via caulking gun/spatula and clean-up	None	Excess of 8.4g on hands to exceed AEL			
Trained Professional: Placing of wax block baits and clean-up	Protective Glove	Excess of 84g on hands to exceed AEL			
Non-Trained Professional: Placing of wax block baits and clean-up	None	Dermal, hands	0.0001	6700	15
Non-Trained Professional: Placing of wax block baits and clean-up	Protective gloves	Dermal, hands	0.00001	6700	1.5
Amateur: Placing of wax block baits and clean-up	None	Dermal, hands	0.0001	6700	15
Secondary Exposure Transient Mouthing of bait by infants	--	Oral	5.0×10^{-5} (TNsG)	6.6	--
			2.5×10^{-2} (User Guidance)	0.35	--

23. 3.3.5 Effect and Exposure Assessment for the Environment

An overview of the EU review of environmental fate and behaviour and ecotoxicology for the active substance is presented below in conjunction with the exposure assessment and environmental effects for the biocidal product.

Environmental fate and behaviour of the active substance

24. Degradation

Biodegradation

Brodifacoum is not readily or inherently biodegradable.

The overall conclusion on biodegradation is that Brodifacoum is not readily or inherently biodegradable.

Abiotic Degradation

Brodifacoum is stable to hydrolysis (t½ > 1 year). It is however predicted to undergo rapid indirect photolysis with OH radicals and ozone (t½ = approximately 2 hours) and undergoes rapid direct photodegradation (t½ = 0.217 days). There are no predicted effects on the atmosphere.

The overall conclusion on abiotic degradation is that Brodifacoum is hydrolytically stable to hydrolysis (t½ > 1 year).

Distribution

Brodifacoum is a large aromatic organic compound of low volatility with two polar groups, which can potentially ionise at environmental pH. The active substance has a Log Pow (4.92), and is of low solubility in water (5.8 x 10-5 g/l at pH 7 and 20°C).

The DT50 value of 157 days (The Pesticide Manual 13th ed) and the Koc of 50000 (The Pesticide Manual 13th ed) indicate that Brodifacoum would be persistent and immobile in soil. The exposure to the groundwater is unlikely.

On the basis of its low volatility (vapour pressure of 2.6 10^{-22} Pa at 20°C) the exposure to the atmosphere is highly unlikely.

The overall conclusion on distribution is as follows: Brodifacoum is persistent (DT50 157 days) and immobile in soil (Koc > 9155 l/kg). Under basic conditions (high pH), Brodifacoum is not likely to be adsorbed onto soils or sewage sludge due to the ionisation of the molecule; whereas under acidic conditions (low pH), Brodifacoum is likely to be adsorbed onto soils or sewage sludge as the molecule is in its neutral or non-ionised form.

Mobility in soil

The Koc value (50000 The Pesticide Manual 13th Edition) indicates that the active substance would not be mobile in soil and is not expected to contaminate groundwater (PEC < 0.1 μg/l).

The overall conclusion on mobility in soil is as follows Brodifacoum is immobile in soil (Koc > 9155 l/kg). Brodifacoum is not expected to contaminate groundwater.

25. Accumulation

Based on a measured Log Kow = 4.92 it is considered that Brodifacoum has a potential for bioaccumulation. The BCFfish (3034) was calculated using the equation 74 of TGD (part II); the BCFearthworm (999) was calculated according to the equation 82d of TGD

The overall conclusion on bioaccumulation potential is as follows: No reliable bioaccumulation study is available. The measured log Kow = 4.92 (retrieved from CAR B) indicates that Brodifacoum can be potentially bioaccumulative and provides a calculated BCFfish = 3034. The experimental Kow confirms the adequacy of using, in CAR A, the calculated log Kow of 6.12 (rather than 8.5) and indicates that this value still overestimated the actual lipophilicity and, consequently, the BCF values estimated herein. The measured log Kow = 4.92 and a BCFfish = 3034 and BCFearthworm = 999, are considered therefore more reliable endpoints to be used in risk assessment.

3.3.5.1. Environmental effects (hazard) of the active substance (ecotoxicology)

Table 3.3.5.2-1 Summary of the eco-toxicological data for the active substance Brodifacoum

Parameter	Test material	Species	Result	Classification	Ref.
Short term toxicity testing on fish	ECO120140	Oncorhynchus mykiss	96-hour LC50 = 0.042 mg/L	Yes - R50/R53	[redacted] ENV5803/120140 (2003)
	Acceptability (Y/N): Yes		**Method:** OECD 203		**GLP (Y/N):** Yes
	Comments: None				
	Acceptability (Y/N): Yes		**Method:** OECD 202		**GLP (Y/N):** Yes
	Comments: Recorded under semi-static conditions.				
Toxicity to aquatic invertebrates	ECO120140	Daphnia magna	48 hour - EC50 = 0.25mg/l	Yes - R51 /R53	[redacted] report - ENV5802/120140
	Acceptability (Y/N): Yes		**Method:** OECD 202		**GLP (Y/N):** Yes
	Comments: Recorded under semi-static conditions.				
Growth inhibition study on algae	ECO120140	Selenastrum capricornutum (Pseudokirkneriella subcapitata)	72h ErC50 = 0.04 mg/l	Yes - R50 /R53	[redacted] Report - ENV5801/120140
	Acceptability (Y/N): Yes		**Method:** OECD 201		**GLP (Y/N):** Yes
	Comments: None				
Inhibition of microbial activity	7909101	3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage	EC10 was set > water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C	No acute toxicity	[redacted] Ref: ENV7009/120140
	Acceptability (Y/N): Yes		**Method:** OECD 209		**GLP (Y/N):** Yes
	Comments: Although the results of the study (EC50 >1003mg/l) are not reliable, the study can be used to derive the NOECmicroorganisms on the basis of the brodifacoum water solubility (EC50 > 0.058 mg/l).				
Studies on sediment dwelling organisms	-	No experimental data available for sediment dwelling organisms.	-	-	-
	Acceptability (Y/N): -		**Method: -**		**GLP (Y/N): -**
	Comments: The risk for the sediment compartment will be covered by the risk for the aquatic compartment.				
Growth inhibition of aquatic plants	-	No study submitted	-	-	-
	Acceptability (Y/N): -		**Method: -**		**GLP (Y/N): -**
	Comments: The evaluation concluded that there is no need for a study as there is no evidence that brodifacoum would be toxic to aquatic plants to a greater extent than to other aquatic organisms.				
Toxicity to earthworms	Chemex reference: ECO120140	14-day LC50	> 994 mg/kg dw	No acute or chronic toxicity	[redacted]

					Ref:ENV7010/120140
	Acceptability (Y/N): Yes		**Method:** Static test conditions according to SOP E260 based on OECD 207.		**GLP (Y/N):** Yes
	Comments: 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt.				
Toxicity to birds	Difenacoum	LD50 (Japanese quail)	19 mg/kg bw	Acute toxicity	[redacted] Study code: 04/903-115FU
	Acceptability (Y/N): Yes		**Method:** OPPTS 850.2100		**GLP (Y/N):** Yes
	Comments: An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d.				
Toxicity to mammals	04359	Two-generation fertility study (rat, parent females)	NOAEL (0.001mg/kg bw/day)	Yes	[redacted] report 03/737-202P.
	Acceptability (Y/N): Yes		**Method:** OECD 416		**GLP (Y/N):** Yes
	Comments: Although a two-generation study is not normally required for anticoagulant rodenticides, the study is relevant for the establishment of an overall NOAEL for anticoagulant effects in rodents.				

26. Effects on Aquatic Organisms including the determination of PNECs:

Toxicity data are available for aquatic organisms exposed in an acute test. In a test performed under semi-static conditions, the 96-hour LC50 was 0.042mg/L for Oncorhynchus mykiss, based on measured concentrations. Daphnia magna was less sensitive than fish, with a 48-hour EC50 of 250 µg/L recorded under semi-static conditions. The endpoint was based on immobilisation and on measured concentrations of Brodifacoum in the test media. In a 72-hour algal growth inhibition test with Selenastrum capricornutum (Pseudokirkneriella subcapitata) the ErC50was 40 µg/l. The NOEC was 10µg/l with respect to specific growth rate. Results are based on measured concentrations. The outcome is that Brodifacoum is considered very toxic to aquatic organisms. The PNEC is derived from the algae 72h ErC50 = 0.04 mg/l (or fish 72h LC50 = 0.042 mg/l), and the application of an assessment factor of 1000. Therefore the **PNEC = 0.00004 mg/l**.

No experimental data are available for sediment dwelling organisms. A PNECsediment (0.043 mg/kg wwt) was derived through the Equilibrium Partitioning Method described in the TGD. However, due to the absence of measured data for the determination of a PECsed, according to TGD a quantitative risk characterization cannot be carried out. Therefore the risk for the sediment compartment will be covered by the risk for the aquatic compartment.

Based on the result of a 3h respiration inhibition test with activated sludge from a sewage treatment plant treating predominantly domestic sewage, no effects of Brodifacoum on aerobic biological sewage treatment processes are expected. As the test was carried out at nominal concentration much higher than the water solubility of Brodifacoum, the EC10 was set as greater than the water solubility limit of 0.058 mg/l measured at pH=7 and T=20°C. According to TGD, PNEC is derived applying an AF=10 to the NOEC from the respiration inhibition test. Therefore, the **PNECmicro-organisms > 0.0058 mg/l.**

No degradation or transformation products of Brodifacoum in water were detected. Toxicity of metabolites is not of concern.

PNECaquatic organisms = 0.00004 mg/l
PNECsediment organisms = 0.00004 mg/l
PNECmicro-organisms = > 0.0058 mg/l

Conclusion on hazard to the aquatic organisms:

PNEC	Task Force
PNECaquatic organisms	0.00004 mg/l

PNECsediment organisms	0.00004 mg/l
PNECmicro-organisms	> 0.0058 mg/l

The Brodifacoum a.s. results in the classification of toxic to aquatic organisms.

27. Effects on the Atmosphere including the determination of PNECs

Brodifacoum has a low vapour pressure (1 x 10^{-6} Pa) and a Henry's Law constant of 2.18 x 10^{-3} Pa.m3mol^{-1} (pH 7). Release to air via water is expected to be negligible. This is also supported by calculations using the TGD on risk assessment for percent release to air from a sewage treatment plant where a default of 0 is given (i.e., no release to air). The manufacture of the active substance is in a closed system. There are no releases to air of Brodifacoum from manufacturing, formulating, use or disposal phases.

28. Effects on Terrestrial Organisms including the determination of PNECs:

The effect of Brodifacoum on earthworms was assessed in an acute toxicity test in which E. fetida in artificial soil was exposed to concentrations of Brodifacoum up to 994 mg/kg dw. The 14-day LC50 was greater than 994 mg/kg dry soil (the highest concentration applied) corresponding to a 14-d LC50 > 879.6 mg/kg wwt. The PNEC for terrestrial organisms is derived from the LC50 with an AF of 1000 used. Therefore, **the PNECsoil ≥ 0.88 mg/kg wwt soil**.

Conclusion on hazard to terrestrial organisms:

PNEC	Task Force
PNECsoil	> 0.88 mg/kg wwt

Earthworms were not affected after acute exposure to Brodifacoum at concentration closed to 1 g/kg dw. It is concluded that Brodifacoum is of low toxicity to earthworms. **The PNECsoil ≥ 0.88 mg/kg wwt soil.**

Effects on Birds including the determination of PNECs:

Brodifacoum is moderately toxic to birds upon acute oral exposure with a LD50 value of 19 mg/kg bw in the Japanese quail.

No studies are available on the avian short term dietary toxicity.

A 6 weeks reproduction test on the Japanese quail exposure to Brodifacoum in drinking water was submitted but it was judged not adequate for risk assessment purposes. Therefore, acknowledging the decision taken at the Biocides TMIII09, the NOEC for Brodifacoum is based on the results of the chronic toxicity study with Difenacoum (with Japanese Quail), chosen as reference chemical for second generation anticoagulants. An extrapolation factor of 8.05 was applied to correct for differences in toxicity based on the acute test results for Difenacoum (LD50 = 66 mg/kg, male and females) and Brodifacoum (LD50 = 19 mg/kg bw), both related to Japanese quail. The Brodifacoum results indicate it is very toxic to birds, with an NOEC = 0.012 mg Brodifacoum/kg diet and an NOEL = 0.0012 mg Brodifacoum/kg bw/d. According to the TGD, an assessment factor of 30 is applied to derive the PNEC. Therefore the **PNECoral-birds = 0.012 mg Brodifacoum/kg diet/30 = 0.0004 mg Brodifacoum/kg diet.** In relation to dose the **PNECoral-birds = 0.0012 mg Brodifacoum/kg bw/d/30 = 0.00004 mg Brodifacoum /kg bw/d**.

Conclusion on hazard to birds:

PNEC	PNECoral bird diet	PNECoral bird
Task Force	0.0004 mg/kg	0.00004 mg/kg bw/d

Effects on Mammals including the determination of PNECs:

The lowest mammalian NOAEL (0.001mg/kg bw/day) comes from a two-generation fertility study with rats and refers to parent females. This endpoint was converted, according to TGD, to NOEC mammal, food = 0.02 mg/kg food. As the exposure lasted 90 days as a minimum, for PNEC derivation an AF oral of 90 is applied (table 23 of TGD). Therefore, the **PNECoral-mammals = 0.02/90 = 2.22E-04**

mg/kg food, corresponding to **PNECoral-mammals = 0.001 mg/kg bw day/90 = 1.1 E-05 mg/kg bw**.

Conclusion on hazard to mammals:

PNEC	Task Force
PNECoral mammals food	2.22E-04 mg/kg
PNECoral mammals	1.1 E-05 mg/kg bw

Brodifacoum is very toxic to mammals.

Metabolites

No significant amounts of metabolites are expected to be formed in soil. In rats, no toxicologically relevant metabolites have been identified which could be introduced in soil via urine or faeces.

3.3.5.2. Environmental effects (hazard) of the biocidal product

The example products in the EU-review program for approval of the active substance for inclusion in Annex I of Directive 98/8/EC were pellet bait and wax block mixtures (formulations) containing Brodifacoum.

The aquatic, terrestrial, avian and mammalian toxicity data used for the assessment of the Annex I representative biocidal product was based on data determined in the Brodifacoum active substance studies. This included the following studies.

7.8.7.1 (1)	[redacted]	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10th Vertebrate Pest Conference (1982). Published	N	Public Domain
7.8.7.1 (2)	[redacted]	-	Effects of New Rodenticides on Owls, Institute of Terrestrial Ecology, Monks Wood Experimental Station, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published	N	Public Domain
7.8.7.1 (3)	[redacted]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain
7.8.7.1 (4)	[redacted]	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Institute of Terrestrial Ecology, Monks Wood, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published	N	Public Domain

There were no additional ecotoxicology studies provided for authorisation of the biocidal product in this process.

3.3.5.3. Environmental effects (hazard) of the co-formulants (substances of concern)

Please refer to Annex I of the consolidated Annexes I-IV which contains the confidential information on the co-formulants that are used in this product along with the active substance.

None of the co-formulants that carry an environmental classification are present at a sufficient concentration to trigger the classification of the product.

Product Classification & Labelling:

There is no requirement for classification and labelling with regard to the co-formulants used in the product.
There is no environmental classification for the product under the Directive 99/45.
There is no environmental classification for the product under the CLP Regulation 1272/2008.

29. 3.3.6 Exposure Assessment for the Environment

The environmental exposure was assessed during the EU active substance review process and the current intended uses are similar.

The rodenticide product is used by professional and amateur users. The product is intended for indoors use, in and around buildings and for use in sewers for professional users only.

It is always used in the same manner for all these purposes. Bait points are placed throughout the infested areas with 20g per bait point for mice and 20 to 60 g per bait point for rats. Application sites are located 2-5 m apart for mice and 5-10 m apart for rats. A shorter distance is used in severe infestations. The number of baits and the distances should be adapted to the infestation level. Bait points are inspected frequently and replenished when bait has been eaten.

Bait points are placed securely to help prevent access to non-target animals. For amateur use, the label prescribes to use tamper resistant bait stations for rat control. Baits for amateur mouse control have to be placed into/at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the wax blocks must be fixed by strings or wire to avoid uptake by non-target animals/humans, or uncontrolled dispersal.

Based on the environmental fate and behaviour of Brodifacoum, as outlined in the detailed calculations provided in Annex VI of this Product Authorisation Report, the environmental exposure assessment was conducted.

3.3.6.1. Aquatic compartment

Exposure to the aquatic compartment can occur following use of the product in sewers which flow into a local STP. Based on worst case ESD assumptions the maximum predicted environmental concentration (PEC) of the active substance for microorganisms in the STP is 1.93×10^{-5} mg/L. The corresponding amount in surface water is 1.77×10^{-6} mg/L. The maximum permissible concentration by directive 80/778/EEC (amended by 98/83/EC) of 0.1 µg/L is not exceeded in surface waters. Full details of the calculations are contained in Annex VI.

3.3.6.2. Atmospheric compartment

Brodifacoum has a vapour pressure of less than 10^{-6} Pa at 20^{o}C and a Henry's Law constant of less than 2.18×10^{-3} $Pa.m^3.mol^{-1}$ at pH 7. In the Assessment Report for brodifacoum it has been concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

3.3.6.3. Terrestrial compartment

Exposure of soil to the active substance occurs via direct (spillages) and disperse release (deposition by urine and faeces) after the use of the product in and around buildings. Exposure of agricultural soil via spreading of sludge from an STP is also considered in the risk assessment following use of the product in sewers.

Using ESD worst-case assumptions of the typical usage patterns and release mechanisms, the maximum concentration in agricultural soil (averaged over 30 d) after 10 years of sludge application from STP is 4.86×10^{-4} mg/kg wwt. When the applicant's dosage rates are used as inputs the figure for agricultural soil is 3.24×10^{-4} mg/kg wwt. The applicant also used data on the metabolism of brodifacoum to lower the exposure levels further; however the evaluator removed this as no exposure assessment on the brodifacoum metabolites was included.

The highest concentration of Brodifacoum in soil following use in and around buildings is 0.047 mg/kg wwt under ESD realistic worst case conditions (see table below). For a normal use pattern the ESD recommends a total of 2.6 replenishments (as opposed to 5 for the worst case). This usage pattern leads to an estimated soil concentration of 0.006 mg/kg wwt.

Sewers	**In and around buildings**
Amount of product used in control operation for each bait point: 30 kg (ESD), 20 kg (applicant).	Amount of product used in control operation for each bait point: 0.25 kg (ESD), 0.06 kg (applicant).

Number of emission days: 7 (ESD) Fraction of active ingredient released: 0.9 No. of replenishments: 5	Realistic worst-case: 21 day campaign Bait stations: 10 No. of replenishments: 5 (2.6 realistic) Bait stations are 5 m apart. Fraction released due to spillage: 0.01 Fraction ingested: 0.99 Spillage area: 0.09 m^2 (0.1 m around station) Frequented area: 550 m^2 (10 m around building)

3.3.6.4. Groundwater

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	**In and around buildings**		**Sewer system**	
	Worst case	**Realistic**	**Worst case**	**Realistic**
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}	4.66×10^{-7}	3.11×10^{-7}

3.3.6.5. Primary & Secondary Poisoning Exposure Assessment

Non-target vertebrates may be exposed to rodenticides primarily through consumption of bait and secondarily from consumption of poisoned rodents. Small pellets and whole grain baits are highly attractive to birds.

In Sewers:

Primary Poisoning:

For rodenticide applications in sewer systems, there is no primary poisoning hazard to non-target mammals or birds because this is no habitat for them (cf. ESD PT 14).

Secondary Poisoning:

The secondary poisoning hazard is relevant only if poisoned rats or cockroaches move to the surface. In that case the situation is similar to the one described below for rat control in and around buildings. However, according to CEFIC (2002) cockroaches are predominantly nocturnal and the species found in sewers e.g. Blatta orientalis will remain underground and are not significant prey items for birds.

Calculation of the Concentration in Fish:

The concentration of the active substance in fish (as food) for fish-eating predators ($PEC_{oral,\ predator}$) is only relevant for the application of the product in the sewer system since only this scenario results in emissions to surface water (via STP).

The $PEC_{oral,\ predator}$ (mg/kg wet fish) is calculated from the annual average PEC for surface water, divided by a factor of 2 since it is assumed, that only 50% of the diet comes from the local area (cf. TGD, 2003). The following table summarises the $PEC_{oral,\ fish}$ for the scenario 'sewage system'.

Predicted concentration in fish

		Tier 1[a]	**Tier 2[b]**
Input			
PEC_{water}	Annual average local PEC in surface water (mg/l) divided by 2	8.85×10^{-7}	5.90×10^{-7}
BCF_{fish}	Bioconcentration factor in fish (l/kg wet fish)	36134	36134
BMF	Biomagnification factor	10	10
Output			
$PEC_{oral,\ fish}$	Predicted environmental concentration in fish (mg/kg wet	$3.19 * 10^{-1}$	$2.13 * 10^{-1}$

	fish)		

[a] Product specific application data and default value for release
[b] Product specific application data and refined metabolism

Calculation of concentration in earthworms:
Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

Brodifacoum concentrations in earthworms

		Tier 1[a]	Tier 2[b]
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
$C_{porewater}$ sewer system	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{porewater}$ building	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$CONV_{soil}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$PEC_{oral,\ earthworm}$ sewer	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.00763	0.00326

In and around buildings:
Primary Poisoning:
Regarding the possible primary hazard to non-target animals this is assessed for birds and mammals.

Acute:
In the first tier scenario, PECoral is the concentration of the rodenticide in the food of a non-target organism. The PECoral is **50 mg/kg** (Brodifacoum present at 0.005% w/w in the product) and is used in the quantitative risk assessment for the acute and long-term situation.

In the second tier (refined) risk assessment the daily uptake (ETE) for birds and mammals is considered. This risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a a default excretion factor.

Table-1 Brodifacoum concentrations in non-target birds following a single uptake of the product

Species	Body weight (g)	Daily food intake (FIR) (g/d)[a]	Conc. of a.i. after single meal (mg/kg bw/d) (ETE)	Expected conc. after elimination[b] (mg/kg bw/d) (EC)
Tree sparrow	22	7.6	17.27	12.43

Chaffinch	21.4	6.42	15.00	10.80
Wood pigeon	490	53.1	5.42	3.90
Pheasant	953	102.7	5.39	3.88
Dog	10 000	456[d]	2.28	1.64
Pig	80 000	600[e]	0.375	0.270
Pig, young	25 000	600[e]	1.20	0.864

Long-term:
In the first tier scenario, the risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor.

Expected concentration of Brodifacoum in the animal after one meal followed by a 24-hour elimination period

Species	**Estimated daily uptake of a compound (ETE) (mg/kg b.w./d)**		**Fraction of daily uptake eliminated (number between 0 and 1) (EI)**	**Expected concentration of active substance in the animal (EC) (mg/kg b.w./d)**	
	Step 1	**Step 2**		**Step 1**	**Step 2**
Tree sparrow	17.27	12.43	0.3	12.09	8.71
Chaffinch	15.00	10.80	0.3	10.50	7.56
Wood pigeon	5.42	3.90	0.3	3.79	2.73
Pheasant	5.39	3.88	0.3	3.77	2.72
Dog	2.28	1.64	0.3	1.596	1.149
Pig	0.375	0.270	0.3	0.2625	0.189
Pig, young	1.20	0.864	0.3	0.864	0.6048

In the second tier scenario for primary poisoning long-term exposure according to the guidance agreed at the 23rd Biocides CA meeting, EC5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

EC_{oral} for different relevant species

Days	EC_{oral} (mg/kg b.w./d)						
Species	**Tree sparrow**	**Chaffinch**	**Wood pigeon**	**Pheasant**	**Dog**	**Pig**	**Young pig**
Day 1 after first meal	17.27	15.00	5.42	5.39	2.28	0.375	1.20
Day 2 before new meal	12.1	10.5	3.79	3.77	1.60	0.266	0.840
Day 3 before new meal	20.6	17.9	6.45	6.41	2.72	0.449	1.43
Day 4 before new meal	26.5	23.0	8.31	8.26	3.50	0.577	1.84
Day 5 before new meal	30.7	26.6	9.61	9.56	4.05	0.666	2.13

Secondary Poisoning:
Secondary poisoning hazard can only be ruled out completely when the rodenticide is used in fully enclosed spaces so that rodents cannot move to outdoor areas or to (parts of) buildings where predators may have access. Predators among mammals and birds may occur inside buildings or they may hunt in the immediate vicinity of buildings, e.g. parks and gardens. Scavengers may also search for food close to buildings.

Tier 1 exposure assessment:
According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been set to a default value of 5-days, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation). Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted. The assessment also takes into account the concentration in resistant rodents.

	Residues of rodenticide in target animal, mg a.s./kg b.w. with bait consumption expressed as PD		
	0.2	**0.5**	**1.0**
A normal non-resistant target rodent stops eating on day 5			
Day 1 after the first meal*	1.00	2.50	5.00
Day 2 before new meal**	0.70	1.75	3.50
Day 3 before new meal	1.19	2.97	5.95
Day 4 after the last meal	1.53	3.83	7.66
Day 5**	1.77	4.43	8.86
Day 7 (mean time to death)**	1.36	3.39	6.79
A target rodent continues eating due to resistance			
Day 14 after the meal	2.31	5.79	11.58

Tier 2 Exposure Assessment:
The refined tier 2 considers exposure of relevant species of predators, based on their bodyweights and food intakes and takes into account avoidance factor (AV), the fraction of the diet obtained in the treated area (PT) and a default excretion factor. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents

				Normal susceptible rodents caught on day 5, before their last meal.		Normal susceptible rodents caught on day 5 just after their last meal		Resistant rodents caught on day 14 just after their last meal	
Species		**Body weight *)**	**Daily mean food intake*)**	**Amount a.s. consumed by the non-target animal****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animal*****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animals********	**Concentration in non-target animal**
		(g)	**(g)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**
Barn Owl	Tyto alba	294	72.9	0.32	1.10	0.51	1.72	0.61	2.06
Kestrel	Falco tinnuncul.	209	78.7	0.35	1.68	0.55	2.62	0.65	3.13
Little owl	Athene noctua	164	46.4	0.21	1.26	0.32	1.97	0.39	2.35
Tawny Owl	Strix aluco	426	97.1	0.43	1.01	0.67	1.58	0.81	1.89
Fox	Vulpes vulpes	5 700	520.2	2.31	0.41	3.62	0.63	4.32	0.76
Polecat	Mustela putorius	689	130.9	0.58	0.85	0.91	1.32	1.09	1.58
Stoat	Mustela erminea	205	55.7	0.25	1.21	0.39	1.89	0.46	2.26
Weasel	Mustela nivalis	63	24.7	0.11	1.74	0.17	2.72	0.21	3.25

Calculation of concentration in earthworms:
Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for predators eating earthworms which have ingested the active substance absorbed to soil.

Brodifacoum concentrations in earthworms

		Tier 1[a]	Tier 2[b]
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
$C_{porewater}$ sewer system	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{porewater}$ building	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$CONV_{soil}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$PEC_{oral,\ earthworm}$ building	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.495	0.441

3.3.6.6. Overall Summary of exposure assessment

The biocidal product is a ready-to-use bait containing 0.005% Brodifacoum as the active substance. Brodifacoum is a second-generation single-dose anticoagulant rodenticide. It is used against rat at the maximal rate of 60 g of product equivalent to 3 mg a.s. per baiting post and against mouse at 20 g product equivalent to 1 mg a.s. by baiting post. This formulation is intended for indoor and outdoor uses.

PECs were calculated in accordance with the ESD for PT14. These calculations are outlined in the previous sections. Based on environmental fate and behaviour of Brodifacoum the following PEC values were determined:

Scenario	In and around buildings		Sewer system	
	Worst case	Realistic	Worst case	Realistic
PEC soil (mg/kg wwt)	0.047	0.006		
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}		
PEC microorganisms (mg/l)			1.93×10^{-5}	1.27×10^{-5}
PEC surface water (mg/l)			1.77×10^{-6}	1.18×10^{-6}
PEC agricultural soil (mg/kg wwt)			4.86×10^{-4}	3.24×10^{-4}
PEC groundwater (ag) (mg/l)			4.66×10^{-7}	3.11×10^{-7}

No new data related to the environment fate and behaviour or the ecotoxicology of the active substance or the biocidal product has been submitted by the applicant. There were three studies submitted related to secondary poisoning to dogs and foxes and the hazard/risk to barn owls which are considered only supplementary data and not considered further in the risk assessment.

PNECs were calculated based on the studies submitted for the EU approval of the active substance. PECS for assessment of primary and secondary poisoning were determined based on the ESD for PT14 and the TGD (2003).

30. 3.3.7 Risk Characterisation for the Environment

Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals.

Product containing brodifacoum are placed at secured bait points. To maximise exposure of the target rodents and minimise unintended exposure of other non-target vertebrates, the products are placed where they are most likely to be encountered by the target organisms (e.g. on habitual rat-runs).

The type of secured bait point suitable for a given situation is determined on a case-by-case basis, taking into account such factors as shielding from sunlight and moisture necessary to maintain bait integrity and the level of security required to prevent access to and/or interference by non-target animals etc.

The risks posed by products containing 50 mg Brodifacoum/kg are characterised for the following scenarios:

1. **Sewers**
2. **In and around buildings (houses, animal houses, commercial and industrial sites)**

3.3.7.1. Aquatic compartment

A contamination of surface water with Brodifacoum from the placing of product in and around buildings is highly unlikely. A lack of exposure to surface water is also stated in the EUBEES 2 emission scenario document. Contamination of surface waters is however expected to arise following use of bait blocks in sewers.

The most sensitive organism in the aquatic tests was alga with a nominal 72 hr ErC50 of 0.04 mg/L. This **$PNEC_{water}$** of 0.04/1000 AF**= 0.00004 mg/L**.

The test with micro-organisms in inhibition of microbial activity showed that concentrations that it is not likely that Brodifacoum will have a negative impact on the microbial processes in a sewage treatment plant at solubility limits. This gives a **$PNEC_{STP}$** of **= 0.0058 mg/L.**

As no specific data are available, the toxicity of Brodifacoum to sediment-dwelling organisms is covered by the risk to aquatic compartment. The application of an additional factor of 10, as done in CAR A, is considered not necessary as an experimental log Kow = 4.92 (i.e. lower than 5) is available. **Therefore, the PNECsediment organisms = 0.00004 mg/l**.

The risk characterisation for the aquatic compartment is presented in the following table applying the relevant PEC values as indicated in the table in the overall summary of the exposure assessment in the previous section.

Aquatic PEC/PNEC ratios using the realistic and worst case scenario

Exposed compartment	Endpoint	PNEC mg/L	PEC Worst case	PEC Realistic	Risk quotient PEC/PNEC
Surface water	Algae	0.00004	1.77E-06	1.18E-06	0.044
Sediment	Based on aquatic data and equilibrium partitioning method	4.348E-02	1.92E-03	1.28E-03	0.044
STP	Inhibition of microbial activity	0.0058	1.93E-05	1.27E-05	0.003

The PEC/PNEC risk quotient in all compartments are below the trigger value of 1 indicating Brodifacoum following the recommended use of the product does not cause an unacceptable risk to aquatic organisms.

Brodifacoum is not readily biodegradable under environmentally relevant conditions or during sewage treatment processes. Accordingly, the degradation of Brodifacoum in sediment is also anticipated to

be low. However, it has limited exposure to the aquatic compartment and this is confirmed by the PEC calculations. The PEC/PNEC ratio is below the level that leads to an unacceptable risk, thus the risk for unacceptable accumulation in sediment can be regarded as low.

For an indication of the risk in relation to surface water and groundwater/porewater used for drinking refer to the section on the aquatic compartment and groundwater in the exposure assessment.

Since the potential for metabolites formation is negligible, risk characterisation is not required.

Summary: No risk is identified

3.3.7.2. Atmospheric compartment

There are no releases of brodifacoum to air from manufacturing, formulating, use or disposal phases. Based on this and the physical and chemical properties of brodifacoum, the compound is not expected to contribute to global warming, ozone depletions in the stratosphere, or acidification.

Summary: No risk is identified

3.3.7.3. Terrestrial compartment

Contamination of soil following the use of product in sewers is highly unlikely during application and use. However, soil may contain low concentrations of Brodifacoum from the spreading of sludge on land derived from waste water treatment works receiving water after the baiting of sewer systems.

Exposure of the terrestrial compartment (soil) will also occur when product is deployed outdoors. Exposure is assumed to arise through a combination of transfer (direct release) and deposition via urine and faeces (disperse release) onto soil.

As there is only one test result available with soil dwelling organisms the risk assessment is performed on the basis of this result using AF and on the basis of the equilibrium partition method. For the EPM the PNEC is calculated from the aquatic toxicity data **PNECaquatic**= **0.00004 mg/kg**.

Aquatic PEC/PNEC ratios using the realistic worst case scenario

Exposed compartment	Endpoint	PNEC	PEC Worst case	Risk quotient PEC/PNEC Worst case
Sewer application of sewage sludge	Based on aquatic data and equilibrium partitioning method Based on the availability of test result with soil dwelling organisms and AF	1. 4.348 x E-02 2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg	4.86E-04	1. 0.011 2. 0.00055
In and around buildings	Based on aquatic data and equilibrium partitioning method Based on the availability of test result with soil dwelling organisms and AF	1. 4.348 x E-02 2. 14-d LC50 > 879.6 mg/kg wwt/1000 = 0.8796 mg/kg	4.68E-02	1. 1.07 2. 0.053

The PEC/PNEC ratio was greater than 1 when used **in and around buildings** when applying the EPM indicating for this calculation method that Brodifacoum, following recommended use of the product, causes an unacceptable risk to organisms in this terrestrial compartment. However, this PNEC value based in and around buildings PEC **represents only a screening value** of contamination and is superseded by the PNEC value determined from the 14-day earthworm toxicity study.

Summary: No risk is identified

Non compartment specific effects relevant to the food chain

3.3.7.4. Primary poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (cf. ESD PT 14).
Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, several non-target species are assessed for primary poisoning risk assessments.

Acute exposure:

Non-target mammals and birds are unlikely to enter sewers and feed on product in sewage systems. Therefore, there will be no significant exposure following the use of product in sewers. Rats that live underground in sewers are also unlikely to take bait and deposit significant quantities in accessible places above ground, thus preventing exposure to non-target animals living above sewers. In conclusion, the risks to non-target mammals and birds following the use of bait blocks containing Brodifacoum in sewers are considered to be very low.

Following applications in and around buildings, the empirical risk assumes direct or indirect consumption of the deployed baits. For primary poisoning the initial PEC_{oral} values assume that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and have access to the product.
The concentration in the final product is 0.005% for the active substance Brodifacoum. The PECoral is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

Tier I risk assessment: $PEC_{oral}/PNEC_{oral}$ ratio for birds and mammals exposed to Brodifacoum

	PEC_{oral} (concentration in food, mg/kg)	$PNEC_{oral}$ (concentration in food, mg/kg)	PEC / PNEC
Acute			
Bird	50	19	2.63
Mammal	50	-	-
Long-term			

Bird	50	0.0004	125000
Mammal	50	0.000011	4545454

The ratios PEC/PNEC are above 1 indicating a potential risk.

Therefore, a refined tier 2 assessment is set out below, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.09	0.0004	43175	30225
Chaffinch	15.00	10.50	0.0004	37500	26250
Wood pigeon	5.42	3.79	0.0004	13550	9475
Pheasant	5.39	3.77	0.0004	13475	9425
Dog	2.28	1.596	0.000011	207272	159600
Pig	0.375	0.2625	0.000011	34090	26250
Pig, young	1.20	0.864	0.000011	109090	78545

In Tier 2, Step 1 (worst case) AV, PT and PD are all set to 1, whilst in the realistic worst case (Step 2) these AV and PT are refined to 0.9 and 0.8, respectively.

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long -term exposure:
In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 1-day elimination of Brodifacoum

Species	EC_{oral} (mg/kg b.w./d) after 1 day		$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $PEC_{oral}/PNEC_{oral}$	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	12.09	8.71	0.0004	30225	21775
Chaffinch	10.5	7.56	0.0004	26250	18900
Wood pigeon	3.79	2.73	0.0004	9475	6825
Pheasant	3.77	2.72	0.0004	9425	6800
Dog	1.596	1.149	1.1E-05	145091	104455
Pig	0.2625	0.189	1.1E-05	23864	17182
Pig, young	0.864	0.6048	1.1E-05	78545	54982

The ratios PEC/PNEC are above 1 indicating a potential risk.

According to the guidance agreed at the 23rd Biocides CA meeting, EC_5 values are used for quantitative risk assessment of primary poisoning in the long-term situation.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 1, PT = 1 (mg/kg bw)[a]	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	30.7	22	0.0004	55260
Chaffinch	26.6	19	0.0004	47880
Wood pigeon	9.61	7	0.0004	17298
Pheasant	9.56	7	0.0004	17208
Dog	4.05	3	0.000011	265091
Pig	0.666	0.480	0.000011	43593
Pig, young	2.13	2	0.000011	139418

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Summary: Risk is identified
Overall, for primary poisoning all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

3.3.7.5. Secondary poisoning
It is unlikely that target rodents that have ingested bait blocks containing Brodifacoum will leave the sewer system and be exposed, in significant numbers, to predators or scavengers. Therefore, the secondary poisoning risks from the use of bait blocks in sewers are considered to be very low.

For the first tier assessment of secondary poisoning in and around buildings the maximum residue levels in target rodents that arise on day-5 after the last meal ($ETE_{oral\ predator}$) are compared to the PNEC values for concentration in food. The first tier assessment also assumes the following three levels of Brodifacoum bait consumption: 20%, 50% and 100% of the daily food intake of the target

rodents. For long-term exposure, it is assumed that the rodents have fed entirely on rodenticide and that the non-target animals consume 50% of their daily intake on poisoned rodents.

Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)

Organism group	$PNEC_{oral}$ (mg a.s./kg b.w.)	$ETE_{oral, predator}$ (mg a.s./kg b.w.)			$PEC_{oral}/PNEC_{oral}$ – day 5		
PD values		0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	19	2.77	6.93	13.87	3.84	9.62	19.26
Mammals	-				-	-	-
Long-term							
Birds	0.0004	1.39	3.47	6.93	10692	26692	53307
Mammals	0.000011				6261	15630	31216

Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)

Organism group	$PNEC_{oral}$ (mg a.s./kg b.w.)	$ETE_{oral, predator}$ (mg a.s./kg b.w.)			$PEC_{oral}/PNEC_{oral}$ – day 14		
PD values	-	0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	19	2.31	5.79	11.58	0.121	0.30	0.60
Mammals	-				-	-	-
Long-term							
Birds	0.0004	1.15	2.31	5.79	287	5775	14475
Mammals	0.000011				104545	231000	526363

According to the tier 1 assessment the risk for secondary poisoning of non-target predator birds and mammals during long-term exposure via rodents poisoned with Brodifacoum is very high as indicated by the trigger value of 1 being exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc.

Tier 2 risk assessment of secondary poisoning (non-resistant and resistant rodents)

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	1.10	0.0004	2750
	Day 5 after the last meal	1.72		4300
	Day 14 after the last meal	2.06		5150
Kestrel	Day 5 before the last meal	1.68	0.0004	4200
	Day 5 after the last meal	2.62		6550
	Day 14 after the last meal	3.13		7825
Little owl	Day 5 before the last meal	1.26	0.0004	3150
	Day 5 after the last meal	1.97		4925
	Day 14 after the last meal	2.35		5875
Tawny owl	Day 5 before the last meal	1.01	0.0004	2525
	Day 5 after the last meal	1.58		3950
	Day 14 after the last meal	1.89		4725
Fox	Day 5 before the last meal	0.41	0.000011	41000
	Day 5 after the last meal	0.63		63000
	Day 14 after the last meal	0.76		76000
Polecat	Day 5 before the last meal	0.85	0.000011	77272
	Day 5 after the last meal	1.32		132000
	Day 14 after the last meal	1.58		143636

Species	Exposure	ETE $_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio ETE $_{oral\ predators}$ / $PNEC_{oral}$
Stoat	Day 5 before the last meal	1.21	0.000011	121000
	Day 5 after the last meal	1.89		189000
	Day 14 after the last meal	2.26		226000
Weasel	Day 5 before the last meal	1.74	0.000011	174000
	Day 5 after the last meal	2.72		272000
	Day 14 after the last meal	3.25		325000

Summary: Risk is identified
The ratios PEC/PNEC are all above 1 indicating a potential risk even after refinement.

3.3.7.6. Secondary poisoning via the aquatic food chain

Only one of the proposed use scenarios, namely use in sewers, will lead to exposure of surface water.

Scenario	$PEC_{oral,fish}$ (mg/kg wet fish)		PNEC (mg/kg food)	PEC/PNEC	
	Tier 1[a]	Tier 2[b]		Tier 1[a]	Tier 2[b]
Application in sewer system	$3.19 * 10^{-1}$	$2.13 * 10^{-1}$	Birds: 4.0×10^{-4}	797.5	532.5
			Mammals: 2.22×10^{-4}	1396	968

From this result it is concluded that there is a risk of secondary poisoning to birds and mammals that eat fish. However, due to the low water solubility and high adsorption tendency of brodifacoum to organic matter, it is expected that the substance would preferably partition into sediments.

Summary: Risk is identified but is likely to have been overestimated
Overall, it is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded although it is likely to have been overestimated.

3.3.7.7. Secondary poisoning via the terrestrial food chain

Emissions of brodifacoum to soil take place in two scenarios. In the scenario **in and around buildings** the uptake to soil proceeds directly (when considering outdoor applications as proposed in the ESD PT 14), whereas in the scenario for the **sewer** it occurs indirectly via sewage sludge.
However, the TGD gives advice to take the 180 days averaged PEClocal for soil with respect to sewage sludge when calculating the PEC in earthworms. Hence, the mode of application given in the TGD is in fact not applicable for direct intake of substances.
In the product dossier $PEC_{oral,earthworm}$ for the direct soil intake has been calculated. The applicant advises that these figures be interpreted with care as concentrations in earthworm due to direct soil intake are not dealt with in the TGD. Soil concentrations used for the calculation represent a brodifacoum intake within a soil mixing depth of just 10 cm. Degradation has not been considered. Soil concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm to origin from the contaminated area.

Table-2: Secondary poisoning risk to earthworm-eating birds and mammals

Scenario	$PEC_{oral,earthworm}$ (mg/kg wet earthworm)		PNEC (mg/kg food)	PEC/PNEC	
	Tier 1[a]	Tier 2[b]		Tier 1[a]	Tier 2[b]
Birds					
Sewer system	0.00763	0.00326	4.0×10^{-4}	19	8.15
In and around buildings	0.495	0.441		1237	1102
Mammals					
Sewer system	0.00763	0.00326	2.22×10^{-4}	34	14.81
In and around buildings	0.495	0.441		2229	2004

[a] Product specific application data and default value for release (90% direct +indirect release)
[b] Product specific application data and refined metabolism

Summary: Risk is identified but is likely to have been overestimated
The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

3.3.7.8. Overall Summary

Based on toxicity data Brodifacoum presents a hazard to birds and non-target mammals. Non-target vertebrate animals may be exposed to the product containing Brodifacoum, either directly by ingestion of exposed product (primary poisoning) or indirectly by ingestion of the carcasses of target rodents that contain Brodifacoum residues (secondary poisoning). Brodifacoum products are non-selective and can pose a risk of primary and secondary poisoning to non-target animals. There are many uncertainties associated with quantification of the risk associated with the use of Brodifacoum products. Overall, because of the toxic nature of rodenticides and the over-riding public health requirement it is more appropriate to develop and validate risk management measures than to refine the risk assessment procedures further. It is noted that the product contains a bittering agent and this may deter some non-target animals. It is also noted that the attractiveness of the product may be impacted by the use of dye.

31. Primary poisoning:

Overall, all acute and long-term PECoral/PNECoral ratios are above the trigger value of 1 indicating acute and long-term unacceptable risks. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals.

Secondary poisoning:

Via ingestion of target rodents by non-target vertebrates

All ratios of PECoral/PNECoral are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning. Even when avoidance and elimination are taken into account the empirical exposure levels result in unacceptable risks to birds and mammals. Studies are submitted in the product dossier that indicate that the realistic risk for secondary poisoning is significantly lower than that using the PEC/PNEC approach. These studies are only considered as supplementary information.

Via the aquatic food chain

Only one of the proposed four use scenarios, namely use in sewers, will lead to exposure of surface water. It is concluded that risk to fish-eating birds and mammals in a real situation cannot be excluded it potentially is overestimated.

Via the terrestrial food chain

The results for the **in sewer** and **in and around buildings** scenario indicate a risk of secondary poisoning for birds and mammals consuming contaminated earthworms.

Conclusion for primary and secondary poisoning:

Due to the risk assessment results for primary and secondary poisoning and the uncertainty associated with quantification of this risk, risk mitigation measures must be taken into account to lead to an acceptable use of the rodenticide product.

32. The following risk mitigation measures are proposed to mitigate the primary and secondary poisoning risk to non-target mammals and lead to an acceptable use of this rodenticide:

- Use of an integrated management strategy and precautionary systems
- Unless under the supervision of a pest control operator use or other competent person do not use anticoagulants as permanent baits
- There should be proper and secure placing of baits so as to minimise the risk of consumption by other animals or children. Where possible secure baits so they cannot be dragged away.
- Users should select tamper-resistant bait boxes, secured bait boxes, covered applications or burrow baiting (placing of bait in appropriate containers or under a curved tile or in a piece of tube) to minimize exposure of non-target animals
- Monitor and replenish bait stations as appropriate
- Frequent visits to bait stations to ensure that any bait that is split or dragged out of bait stations is removed
- Unconsumed baits must be collected after termination of the control campaign and dispose of them in accordance with local requirements

- Remove dead and moribund rodents at frequent intervals, at least as often as baits are checked or replenished during a baiting campaign
- Baits should be deployed in accordance with the product labelling
- Baits should be deployed in accordance with other approved guidance on good practice.
- Restrict the use of the product to treatment campaigns of limited duration
- To minimise the likelihood of target rodents developing resistance to second-generation anticoagulant rodenticides, long-term deployment of baits as a preventative control measure is not recommended
- The resistance status of the population should be taken into account when considering the choice of rodenticide to be used.
- When the product is being used in public areas, the areas treated must be marked during the treatment period and a notice explaining the risk of primary and secondary poisoning by the anticoagulant as well as indicating the first measure to be taken in case of poisoning must be made available alongside the baits

19 3.4 Measures to protect man, animals and the environment

The information submitted covering the requirements as described in the TNsG on Data Requirements, common core data for the product, section 8, points 8.1 to 8.8 is provided below.

33. 3.4.1 Methods and precautions concerning handling, use, storage, transport or fire

Methods and precautions concerning handling and use:

- Always read the label before use and follow the instructions provided.
- Do not decant product into unlabelled containers.
- Product must be handled in a safe manner.
- Avoid all unnecessary exposure, in particular avoid ingestion.
- A thorough survey of the infested area is essential, particularly in secluded and sheltered places, to determine the extent of the infestation.
- Baits must be securely deposited in baiting stations or other coverings so as to minimise the risk of consumption by companion animals, other non-target animals and children. Where possible, secure baits so that they cannot be dragged away.
- PUBLIC AREA USE: When the product is being used in public areas and tamper-resistant bait stations are not used, the following must be implemented. When the product is being used in public areas, the areas treated must 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. When tamper-resistant bait stations are used, they should be clearly marked to show that they contain rodenticides and that they should not be disturbed.
- For use in sewers where there is no risk to children, companion animals and non-target species baits should be secured to available structures by wire to ensure the bait is not washed away.
- Dead rodent bodies, remains of unused bait or any fragments of bait found away from the bait station must be collected during all control operations to minimize the risk of consumption and poisoning to children, companion animals and other non-target animals.
- It is illegal to use this product for the intentional poisoning of non-target, beneficial and protected animals.
- Wash hands and face after application and use of the product, and before eating, drinking or smoking.
- For professional users the use of appropriate personal protective equipment (PPE) is advised.

Methods and precautions concerning storage:

- Store in a cool, dry, well-ventilated secure (lockable) place
- Store locked up in the original container
- Store original container tightly closed
- Keep/store out of reach of children and companion animals
- Keep/store away from food, drink and animal feedstuffs and products which may have an odour.

Methods and precautions concerning transport:

Hazard classification for transport: TOXIC, MARINE POLLUTANT
UN-No Coumarin derivative pesticide, solid, toxic, n.o.s (BRODIFACOUM)
Class 6.1 Hazard ID 66
Proper Shipping name Coumarin derivative pesticide, solid, toxic (contains brodifacoum)
UN-No 3027 Packing Group 1
Class 6.1

Methods and precautions concerning fire:

Suitable Extinguishing Media:

Keep fire exposed containers cool by spraying with water if exposed to fire. Fight surrounding fire with foam, water fog, or dry powder.

Extinguishing media which must not be used for safety reasons:
DO NOT USE WATER JETS
Specific hazards:
This product is not flammable but is combustible. Avoid run-off into water courses. Self-contained breathing apparatus should be won by fire-fighting personnel.

Special protective equipment for fire-fighters:
In the event of fire, wear self contained breathing apparatus, a chemical protection suit, suitable gloves and boots.

Residues:
Dispose of residues to certified waste disposal operator for incineration and licensed waste disposal site.

34. 3.4.2 Specific precautions and treatment in case of an accident

Personal precautions
Wear suitable protective clothing, gloves and eye/face protection, if applicable and where appropriate.

- Respiratory Protection: No special respiratory protection equipment is recommended under normal conditions of use with adequate ventilation.
- Hand protection: Wear gloves for professional products.
- Skin protection: No special clothing/skin protection equipment is recommended under normal conditions of use.
- Eye protection: Not required.
- Ingestion: When using this product, do not eat, drink or smoke

Personal treatment
- General advice: In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible and report the authorisation number).
- Skin contact: Obtain medical advice immediately. Remove contaminated clothing. After contact with skin, wash immediately with plenty of water, followed by soap and water in order to minimise skin contact.
- Contaminated clothing should be washed and dried before re-use.
- Eye contact: Obtain medical advice immediately. Rinse eyes immediately with copious amounts of water.
- Inhalation: Unlikely to present an inhalation hazard unless excessive dust is present. Remove person to fresh air. Obtain medical advice immediately.
- Ingestion: Do no induce vomiting. If swallowed, obtain medical advice immediately. Wash out mouth with water.

ADVICE FOR DOCTORS:
Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume treatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre; include information on the product authorisation number, product trade name and active substance. In Ireland, this is the National Poisons Information Centre, Beaumont Hospital, Dublin (01-8092166)

Environmental precautions
- Prevent accidental exposure of the product to the environment.

- Keep un-used bait locked-up and in secure storage containers
- Bait must be secured in tamper resistant bait boxes in areas away from drains, water courses and non-target organisms.

Environmental treatment

- Clean up accidental spillages promptly by sweeping or vacuum.
- If the product gets into water or soil, it should be removed mechanically. In the event of a significant accidental release, inform the appropriate authority.
- Transfer to a suitably labelled container and dispose of to a certified waste disposal operator for incineration and licensed waste disposal site.
- Subsequently, wash the contaminated area with water, taking care to prevent the washings entering sewers or drains.
- For further instructions, see section 3.4.6 below.

35. 3.4.3 Procedures for cleaning application equipment

No application equipment is required, therefore, no specific cleaning for equipment is required
If necessary, following use, bait boxes should be washed with detergent and water. The bait box should be washed out 3 times (triple rinsed).

36. 3.4.4 Identity of relevant combustion products in cases of fire

This product contains paraffin wax.

37. 3.4.5 Procedures for waste management of the biocidal product and its packaging

The best means of disposal of any product is through proper use according to the label. For the product incinerate under controlled conditions. For the pack, do not dispose of the pack in domestic refuse. Empty completely, puncture or crush and dispose of safely to Local Authority and National requirements. Dispose of packaging, remains of unused product and dead rodents to a certified waste disposal operator for incineration and licensed waste disposal site.

38. 3.4.6 Possibility of destruction or decontamination following accidental release

Air:
Brodifacoum has a low vapour pressure, therefore the potential for evaporation is low The vapour pressure is 5×10^{-5} Pa. As a rodenticide, this material is not intentionally aerosolised. Therefore, destruction in air is not a concern.

Water (including drinking water):
Prevent further leakage or spillage if safe to do so. Prevent entry into watercourses, sewers.

Soil:
Direct and/or intentional release to soil is not anticipated for the use of the product as a rodenticide. In the event of a significant accidental release, inform the appropriate authority.

39. 3.4.7 Undesirable or unintended side-effects

Toxic to mammalian and avian species, including domesticated animals, wildlife and humans. Therefore the risk to these non-target species should be considered when using bait.

40. 3.4.8 Poison control measures

The paste baits are dyed (e.g. red or blue) to make them unattractive to wildlife, and birds in particular. In addition, in case of accidental ingestion, the presence of a dye may help to confirm that there has been ingestion and thus facilitate antidote treatment.

The product contains a human taste deterrent (adversive agent – Bitrex).

To report human poisoning incidents call the relevant national poison information centre. Include information on the product authorisation number, product trade name and active substance. Where possible provide a copy of the label or safety data sheet (SDS).

In Ireland to report a poisoning incident, call: 01 (8092566 / 8379964) The Poisons Information Centre of Ireland, Beaumont Hospital, Beaumont Road, Dublin 9.

ADVICE FOR DOCTORS:
Brodifacoum is an indirect anti-coagulant. Phytomenadione, Vitamin K1, is antidotal. In the case of suspected poisoning, determine prothrombin times not less than 18 hours after consumption. If elevated, administer vitamin K1 and continue until prothrombin times normalise. Continue determination of prothrombin time for three days after withdrawal of antidote and resume treatment if elevation recurs in that time.

Report all incidents of poisonings to the relevant national poisons centre (include information on the product authorisation number, product trade name and active substance)

20 Proposal for Decision

The assessment presented in this report has shown that the ready-to-use product, Ratimor Brodifacoum Fresh Bait, formulated by [redacted] with the active substance Brodifacoum, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) for the control of rodents (rats and mice).

Physical-Chemical Properties:
Ratimor Brodifacoum Fresh Bait has been shown not to present a physical-chemical hazard to end users and does not classify as highly flammable, oxidising or explosive. The bait is stable when stored at ambient temperatures (20^{o}C) for two years, therefore a shelf life of two years is proposed. A suitable method of analysis for the determination of Brodifacoum in the bait was provided.

The source of active substance used in the biocidal product Ratimor Brodifacoum Fresh Bait is the same source of active substance that is listed in Annex I of 98/8/EC. Syngenta initially supported the source, then the task force [redacted] also supported the source, Italy carried out an equivalence check on the Task force source of Brodifacoum and found it to be equivalent to the Syngenta source. The RefMS accepted Italy's assessment.

Efficacy:
Effectiveness data has confirmed that Ratimor Brodifacoum Fresh Bait is effective in the proposed areas for use, at the recommended dose rate. *Rattus rattus*, one of the target organisms was removed from the recommended list of target organisms. There was no efficacy data provided using past bait formulation for the black rat (*Rattus rattus*). The paste bait formulation proved to be both highly palatable and effective against brown rats and mice in the trials. Ratimor Brodifacoum Fresh Bait is suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's effectiveness in adverse environmental conditions has been demonstrated.

Human Health:
The calculations presented have been made with the assumptions of rat control, and there are no separate calculations to assess exposure for mice control in which smaller bait sizes are used.

Using both the MOE and AEL approaches for risk assessment indicates that there is a satisfactory margin between the predicted exposure and the NOAEL (LOAEL) as well as exposures below the threshold value for the AEL for all intended uses by trained professionals with PPE, untrained professionals and amateurs (with and without PPE). The product is deemed suitable for authorisation and appropriate personal protective equipment is advised.

Secondary exposure from transient mouthing of the product exceeds the AEL reference value (0.0033µg/kg/day), both with the assumption of 0.01 g and 5 g of product ingested by infants. This is of concern. There is no margin of safety using the existing data and models. There is no safe scenario for indirect exposure if estimated according to TNsG and User Guidance. Mitigation and protection measures such as the inclusion of bittering agents and the enclosure of product in sealed packs and tamper resistant bait boxes are essential to reducing the risk of secondary exposure. Baits should not be placed where food, feeding stuffs or drinking water could be contaminated.

Environment:
The applicant did not submit any new environmental fate and behaviour studies with this product. Therefore the conclusions made at the Annex I inclusion stage for the active substance stand. The uses of this product were assessed here under the TGD and the PT14 ESD and all PEC/PNEC ratios were <1. However there is a risk for primary and secondary poisoning for non-target vertebrates. These identified risks are mitigated by applying all appropriate and available risk mitigation measures.

Conclusion:
During the active substance review of Brodifacoum by Italy, primary and secondary poisoning risks were identified for non-target organisms and for potential accidental poisoning incidents involving children. The assessment of those EU identified risks during the product authorisation evaluation of Brodifacoum

have also indicated a potential risk of primary and secondary poisoning to non-target animals and the potential for the accidental primary poisoning of children. Due to these findings risk mitigation measures are applied to product authorisation.

Additionally, as the target rodents are vermin and are both direct transmitters of disease (such as through biting or contamination of food/feed by urine or faeces) or indirect carriers of disease (such as disease vectors, where fleas move from rat to humans) to humans and other animals. Transmitted diseases can include leptospirosis (or Weil's disease), trichinosis and salmonella. Authorisation of this product is considered necessary on the basis of public health grounds, since rodent populations are considered to constitute a danger to public health through the transmission of disease. However, risk mitigation measures and restrictions are required to prevent the possibility of the identified risks to non-target animals, companion animals and children.

Conditions of authorisation

Two authorisations should be issued. The first authorisation covers professional and trained professional use product. The second authorisation covers amateur use product.

This authorisation of Ratimor Brodifacoum Fresh Bait is for a period of 5-years with an annual renewal.

The concentration of the active substance, Brodifacoum, in Ratimor Brodifacoum Fresh Bait shall **not** exceed 0.05 g/kg (0.005% w/w).

Only ready-to-use Ratimor Brodifacoum Fresh Bait product is authorised.

As a poison control measure, the authorisation requires that the product shall contain an aversive, bittering agent.

The authorisation requires that the product be dyed with a colour to make them unattractive to wildlife, and birds in particular.

This product shall **not** be used as a tracking poison.

The product is authorised only for use against rats and mice (for example brown rats and house mice). Authorisation of this product does **not** allow use against non-target organisms.

The authorisation of this product for professionals and trained professionals only allows for use indoors and outdoors in the following areas: Indoors, including areas such as houses, warehouses, outbuildings and commercial premises. Outdoors uses only includes in-and-around buildings. The product can also be utilised in sewers. Brodifacoum baits must not be placed where food, feeding stuffs or drinking water can become contaminated.

The authorisation of this product for amateurs allows for use of this product indoors and outdoors around buildings in the following areas: Indoors, including only privates houses and outbuildings. Outdoors uses, including only around private building premises and private gardens. Brodifacoum baits should not be placed where food, feeding stuffs or drinking water can become contaminated.

The product should be used for rodent control in tamper resistant, secured bait stations or other secure coverings. However, for use in sewers where there is no risk to children, companion animals and non-target species baits should be secured to available structures by wire to ensure the bait is not washed away.

Bait stations should be clearly marked to show that they contain rodenticides and that they should not be disturbed.

Baits shall be secured to the bait station(s) so that rodents cannot remove bait from the bait box.

For amateur use products placed on the market in Ireland packaging restrictions are to be limited to pre-baited bait stations and refill packs with a maximum pack-size of 500g. Refill packs for amateurs must contain bait that is wrapped. Loose baits or grain (without wrapping) shall not be packaged for amateurs.

All product placed on the Irish market after the date of authorisation must be in compliance with the conditions of this authorisation and shall carry the approved label with the IE/BPA authorisation number and be packaged in the approved packaging.

Prior to any amendment relating to this authorised product, such as specification, use, labelling or administrative changes, application must be made to this Authority to do so

Upon annual renewal of the biocidal product, the authorisation holder shall provide statistics to PRCD on the import and export from Ireland and also manufacture statistics where appropriate for the product for the given full annual period or part thereof.

Authorisation of the biocidal product may be subject to review, following a detailed assessment of the risks involved, in accordance with the European Communities (Authorisation, Placing on the Market, Use and Control of Biocidal Products) Regulations, 2001, as amended. This review may lead to changes in or revocation of this authorisation.

ANNEXES

Annex:

1. Confidential Information and Data
2. Summary of the Product Characteristics (SPC)
3. Study Summaries of Studies Reviewed
4. List of Studies Reviewed
5. Toxicology Calculations
6. Environmental Calculations
7. Residue Calculations

ANNEX I: Confidential Information and Data

Manufacturing site(s) of the active substance(s)[17]

Applicant:	
Company Name:	[redacted]
Address:	
Tel:	
E-mail:	[redacted]
Contact:	[redacted]

Manufacturer of the active substance(s):	
Company Name:	[redacted]
Address:	
Tel:	
E-mail:	[redacted]
Contact:	[redacted]

Manufacturing site(s) of the biocidal product[3]

Manufacturing site of the biocidal product:	
Company Name:	Unichem d.o.o.
Address:	Unichem d.o.o. Sinja Gorica 2 1360 Vrhnika Slovenia
Tel:	+386 1 755 97 02
E-mail:	[redacted]
Contact:	[redacted]

17 All sites involved in the manufacturing process of each active substance and of the product must be listed.

Assessment of the technical equivalence of Brodifacoum from two different sources [redacted]

Italy carried out an assessment on the technical equivalence of the [redacted] Brodifacoum source with the Annex I source of Brodifacoum (reference source). Brodifacoum produced by Syngenta was considered to be the reference source, since it had been evaluated first and was already included in Annex I, whereas Brodifacoum produced by [redacted] was regarded as the new source. The three reports have been sent to the Commission and are available on CIRCA in the TM section (CA-Reports\CA-Reports Review Programme\A-D\Brodifacoum\Product Type 14\Assessment Report). The [redacted] source of Brodifacoum was found to be equivalent to the Syngenta source of Brodifacoum (that is listed in Annex I of 98/8/EC). Ireland accepts the Italian evaluation.

Assessment of the technical equivalence of the [redacted] Annex I 5-batch analysis for Brodifacoum with a new 5-batch analysis from the same source with the same manufacturing process:

[redacted] produced a new 5-batch analysis to address data requirements from other countries outside the European Union. The new study covers all potential impurities of the active substance. The source and manufacturing process of Brodifacoum technical material is unchanged from that in the EU submission. As RefMS Ireland assessed the new data and found that the new 5-batch analysis data is within the specification covered by the Annex I listing. This material is therefore technically equivalent to Brodifacoum as listed in Annex I of the Biocidal Products Directive 98/8/EC.
A full technical equivalence evaluation was not carried out as the criteria for triggering a full technical equivalence evaluation were not met. The criteria are 1. Technical material from a new/different manufacturer 2. Data from industrial scale production vs pilot scale production and 3. Change in the manufacturing process, and/or manufacturing location. The full assessment can be found in the Confidential Addendum to the Product Assessment Report (Member States Only).

Assessment of equivalence of the two baits [redacted] and Ratimor Brodifacoum Fresh Bait:

Unichem d.o.o has obtained from [redacted], a Letter of Access to the complete Annex I listing documentation as well as a LoA to the product dossier for [redacted]. Ratimor Brodifacoum Fresh Bait is a Brodifacoum pasta bait formulation. It is identical to [redacted] of [redacted] apart from the dyestuff used. The dyestuff Unichem uses is covered within a proposed frame formulation of [redacted] The colour of Ratimor Brodifacoum Fresh Bait is blue, while the colour of [redacted] is blue or red. The change of colour will have no impact on the efficacy of the formulation and is proposed purely for marketing reasons. Rats and mice are nocturnal animals and therefore have relatively poor colour vision. In their normal period of activity (at night), they have monochromatic vision. A change of colour of the bait has no effect on the acceptability of that bait to rats and mice.

Given the similarity of the formulations, the RefMS accepts that the data package for [redacted] can be used in support of the authorisation of Ratimor Brodifacoum Fresh Bait

Production process for Ratimor Brodifacoum Fresh Bait:

1. The quantities of the ingredients are measured out, according to the Lot size.
2. The ingredients are added to a planetary mixer in the necessary order.
3. The mixing time and mode of the mixer is set.
4. The blended pasta is allowed to stand for 10 minutes and cool.
5. The pasta is fed from the mixer through the ‘on demand’ dosing conveyor to a volumetric dispenser head.
6. Pasta is fed into a fibre-paper ‘sandwich’ and the packaging machine set to deliver either 10g or 15g ‘T’ bags.
7. During manufacture, according to the client’s request, the ‘T-bags’ may be printed by flexographic process.
8. (Printed) Finished product is packed into polythene-lined cartons, checkweighed and sealed before labelling, palletizing and dispatch.

General note:
The composition of the [redacted] Brodifacoum Concentrate used by Unichem in their products can be found in the Confidential Addendum to the Product Assessment Report (Member States Only).

[redacted] [redacted] 18 July 2013

Product trade name: Ratimor Brodifacoum Fresh Bait

Qualitative and quantitative information on the composition/specification of the biocidal product Ratimor Brodifacoum Fresh Bait

Active substance(s)				Contents				
Common name	IUPAC name	CAS No.	EC No.	Concentration	Unit[18]	w/w (%)	Minimum purity (% w/w)	Same source as for Annex I inclusion (Y/N)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	56073-10-0	259-980-5	0.05	g/kg	0.005	95	N
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								
[redacted]								

18 g/l, g/kg, other. For biological products, the concentration should state the number of activity units/units of potency (as appropriate) per defined unit of formulation (e.g. per gram or per litre).

8.

Annex II: Summary of the Products Characteristics (SPC)

Please see separate SPC accompanying the PAR and authorisation certificate that have uploaded to the R4BP2.

Annex III: Study Summaries of Studies Reviewed

Insert study summaries with expert evaluation in data point order.

Study summaries of new data[19] submitted in support of the evaluation of the active substance (IIIA)

Physical Chemical Characteristics:
New data was submitted in support of [redacted] Brodifacoum source of active substance. This included an assessment on the reactivity of the technical concentrate towards the container material. It was argued that there will be no chemical or physical reaction between the technical concentrate and container. This information was assessed by Germany and was found to be acceptable. Ireland accepts Germany's assessment (please see Addendum to Annex I Listing Information on Data Requirements, 26.07.2011).

Methods of Analysis
New data was submitted in support of [redacted] Brodifacoum source of active substance. This included a fully validated analytical method for the determination of Brodifacoum in soil. This information was assessed by Germany and found to be acceptable. Ireland accepts Germany's assessment (please see Addendum to Annex I Listing Information on Data Requirements, 26.07.2011).

Efficacy
There were no new additional studies submitted for product authorisation.

Toxicology
There were no new additional studies submitted for product authorisation.

Environment (including Eco-Toxicology)
There were no new additional studies submitted for product authorisation.

19 Data which have not been already submitted for the purpose of the Annex I inclusion.

Study summaries of <u>new data</u> submitted in support of the evaluation of the biocidal product (IIIB)

Physical Chemical Characteristics For [redacted]

Section B3	**Physical and Chemical Properties of Biocidal Product**							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.1 Appearance (IIB III.3.1)								
3.1.1 Physical state and nature	Visual	0.005%	Paste	As specified NEW STUDIES – not reviewed by RMS	Y	1	Atwal and Woolley (2008) SafePharm Laboratories Ltd., Report No. 2254/0053 Garofani (2007) ChemService Srl., Report No. CH-345-2006	
3.1.2 Colour	Visual	0.005%	Red or blue	As specified NEW STUDIES – not reviewed by RMS	Y	1	Atwal and Woolley (2008) SafePharm Laboratories Ltd., Report No. 2254/0053 Garofani (2007) ChemService Srl., Report No. CH-345-2006	
3.1.3 Odour	Nasal inhalation	0.005%	Slight smell of peanuts	As specified NEW STUDY – not reviewed by RMS	N	N/A	Garofani (2007) ChemService Srl., Report No. CH-345-2006	
3.2 Explosive properties (IIB III3.2)	None	0.005%	Not explosive	See justification for non-submission	N	N/A		
3.3 Oxidising properties (IIB III3.3)	None	0.005%	Not oxidising	See justification for non-submission	N	N/A		

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
3.4 Flash-point and other indications of flammability or spontaneous ignition (IIB III3.4)	Based on Method A10 of Commission Directive 92/69/EEC	0.005%	Similar difenacoum formulation tested. Not highly flammable	As specified NEW STUDY – not reviewed by RMS	N	n.a.	Atwal SS and Woolley SM (2008) Report No. 2254/0040	
Flash point	None	0.005%	Not relevant to solid paste baits	Please see data waiver below	N	n.a.	See justification	
Autoflammability	None	0.005%	Not explosive	Please see data waiver below	N	n.a.	See justification	
Other indications of flammability	None							
3.5 Acidity/Alkalinity (IIB III3.5)	None	0.005%	Not relevant to paste baits which are not mixed with water	See justification for non-submission	N	n.a.		
3.6 Relative density/bulk density (IIB III3.6)	Method A3 of annex V of Directive 67/548/EEC	0.005%	1.26 (temperature: 19.6 ± 0.5°C)	As specified NEW STUDY – not reviewed by RMS	Y	1	Atwal SS and Woolley SM (2008) Report No. 2254/0053	
3.7 Storage stability - stability and shelf life (IIB III3.7)								
Effects of temperature	Observations at 3 months, 6 mnths, 1 yr, 18 months and 2 yrs (for 25°C and 32ºC). 14 days (54°C)	0.005%	Considered to be chemically stable for at least 2 years at 32°C. No significant difference observed after 3, 6, 12, 18 and 24 months at 25°C and 32ºC and 14 days at 54°C. Soft, pliable paste, pink in colour. The appearance of the samples was	As specified NEW STUDY – not reviewed by RMS	N	1	Thomas (1998) University of Wales Cardiff, Report No. 96031329	

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
			satisfactory and there was no indication of loss of product integrity.					
Effects of light			Storage and correct use of the product does not lead to exposure to sunlight.	Please see data waiver below	N	n.a.	See justification	
Reactivity towards container material			No evidence of product pack incompatibility after the storage regime.					
Other				Nothing reported				
3.8 Technical characteristics (IIB III3.8)								
Wettability/ Suspensibility	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
Wet sieve analysis	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
Emulsifiability	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
Disintegration time	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
Attrition/friability of granules; integrity of tablets	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
Persistence of foaming	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
Flowability/Pourability	None	0.005%	Not relevant to a solid	See justification	N	n.a.		

Section B3	Physical and Chemical Properties of Biocidal Product							
Subsection (Annex Point/TNsG)	**Method**	**Purity/ Specification**	**Results**	**Remarks/ Justification**	**GLP (Y/N)**	**Reliability**	**Reference**	**Official use only**
			paste bait which is not mixed with water	for non-submission				
Dustability	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.9 Compatibility with other products (IIB III3.9)	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.10 i Surface tension (IIIB III0§)	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.10 ii Viscosity (IIIB III0§)	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		
3.11 Particle size distribution (IIIB III0§)	None	0.005%	Not relevant to a solid paste bait which is not mixed with water	See justification for non-submission	N	n.a.		

Conclusions:

[redacted] is not explosive, oxidising or highly flammable and does not classify from a physical-chemical point of view. The test item is stable after storage for two weeks at 54°C, for 2 years at 25°C (ambient temperature) and for 2 years at 32°C. The packaging material is stable after storage at ambient temperatures (25°C) for 2 years and at 32°C for 2 years. There were no significant changes of characteristics of the test item observed after 2 years storage at ambient temperatures (25°C) and at 32°C. The test item is a ready-to-use pasta bait and is not intended to be added or mixed with any other product.

Data requirements:

None.

Section B3.2 Annex Point IIB III.3.2	**Explosive properties**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a solid paste bait. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for explosive potential and none of the components are classified as explosive. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or explosive activity. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	Jan 2008	
Evaluation of applicant's justification	Since none of the BP components is classified as explosive and on the basis of experience in use, no test for explosive properties is deemed necessary.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.3 Annex Point IIB III.3.3	**Oxidising properties**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a large solid paste bait. Consideration of structure and physico-chemical properties of each product component does not indicate any structural alerts for oxidising potential and none of the components are classified as oxidisers. Widespread experimental and commercial use over many years has not shown any evidence of exothermic or oxidising activity. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	Jan 2008	
Evaluation of applicant's justification	Since none of the BP components is classified as oxidiser and on the basis of experience in use, no test for oxidising properties is deemed necessary.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.4 Annex Point IIB III.3.4	**Flash-point and other indications of flammability or spontaneous ignition**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a solid paste bait. No evidence of flammability in use. None of the components of the product are classified as flammable under the directive 67/548/EC. Also the flammability test on a similar difenacoum formulation which applied an air-rich bunsen burner flame to the product did not show any signs of instability. On the above grounds it is not believed that the paste bait represents a flammability or spontaneous ignition hazard and a derogation for the study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Since none of the BP components is classified as flammable, no test for flammability is deemed necessary. Accept the applicant's justification.	
Conclusion	The applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from other Member State *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section B3.5 Annex Point IIB III.3.5	**Acidity/alkalinity and if necessary pH value (1 % in water)**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	Product is a paste bait composed of solid non-polar ingredients. It is applied as supplied and is not diluted or mixed with water or other polar substances. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Jan 2008	
Evaluation of applicant's justification	Since the BP is not liquid nor intended to be diluted with water, no information on the product pH is required.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.7 Annex Point IIB III.3.7	**Storage stability: in sunlight**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [X]	**Other justification [ ]**	
Detailed justification:	The product is supplied and stored in its original packaging. Correct siting of baits also limits the length of time the product is exposed to sunlight to the length of time it takes to place the bait, and cover it or close the bait box. Due to the very short length of time of exposure, and the known stability at a temperature of 32°C for 2 years, it is considered that further information is unnecessary.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	The applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from other Member State *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section B3.8 Annex Point IIB III.3.8	**Technical characteristics of the biocidal product, e.g. wettability, persistent foaming, flowability, pourability and dustability**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The paste bait is a solid bait product, which is not added to water. Therefore characteristics applicable to products diluted in water such as wettability, persistent foaming, flowability, pourability and dustability are not relevant. The paste bait is not friable and is not dusty. On the basis of the above, a derogation to perform this study is requested	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, the above technical characteristics are not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.9 Annex Point IIB III.3.9	**Physical and chemical compatibility with other products including other biocidal products with which its use is to be authorised**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is not applied in mixture with other products. On the basis of the above, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Nov 2005	
Evaluation of applicant's justification	Since the BP is not intended to be mixed with other products, no information regarding the physical and chemical compatibility with other products is required.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.10 i Annex Point *IIIB III0§*	**Surface tension**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is a solid paste at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, surface tension is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.10 II Annex Point *IIIB III0§*	**Viscosity**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is a solid paste at NTP. It is not a liquid, nor is it intended for liquefaction. On the above basis, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, viscosity is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State(Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B3.11 Annex Point *IIIB III0§*	**Particle size distribution**	
	Justification for non-submission of data	Official use only
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	The product is a solid paste bait. It is not composed of a large number of discrete small particles which vary in size. On the above basis a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Nov 2005	
Evaluation of applicant's justification	Due to the nature of the BP, particle size distribution is not to be investigated.	
Conclusion	The Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Methods of Analysis

Section B4.1 **Annex Point IIA4.3**	**Analytical Methods for Detection and Identification**	
	1 Reference	**Official use only**
1.1 Reference	Garofani S (2007) [redacted] Validation of the Analytical Method for the Determination of the Active Ingredient Content. ChemService Srl., Report No. CH-346/2006	
1.2 Data protection	Yes	
1.2.1 Data owner	[redacted]	
1.2.2 Companies with letter of access	None	
1.2.3 Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
	2 GUIDELINES AND QUALITY ASSURANCE	
2.1 Guideline study	EEC guideline SANCO/3030/99 rev. 4, dated 11/07/00: Working document 'Technical Material and Preparations: Guidance for generating and reporting methods of analysis in support of pre and post-registration data requirements for Annex II (part A, Section 4) and Annex III (part A, Section 5) of Directive 91/414'. AOAC Official Method 983 11 Brodifacoum and Pesticide Formulations	
2.2 GLP	Yes	
2.3 Deviations	No	
	3 MATERIALS AND MethodS	
3.1 Preliminary treatment		
3.1.1 Enrichment	A diluting mixture was produced by mixing thoroughly 400 ml dichloromethane and 600 ml methanol. 10 g of test article were placed in a 250 ml flask. To this was added 50 ml diluting mixture and 1 ml formic acid. This solution was placed in a sonication bath for 30 minutes then placed onto a magnetic stirrer overnight. An aliquot was transferred into an eppendorf and centrifuged at 8000 rpm for 10 minutes, then the supernatant was transferred to a vial for analysis.	
3.1.2 Cleanup	As described above.	
3.2 Detection		
3.2.1 Separation method	High performance liquid chromatography: HPLC column: ChemService code No. 158 Phenomenex or equivalent: Gemini 5u C6 - Phenyl 110A HPLC pre-column: C18 (ODS) 4.0 X 3.0 mm Detector: UV/Vis operating at 270 nm Eluent: Acetonitrile/Water/Acetic acid = 75/24/1 v/v/v Eluent flow: 1.0 ml/min Injection volume: 10 µL Brodifacoum ret. Time: about 16.3 minutes Total analysis time: 25 minutes	
3.2.2 Detector	This method of analysis for brodifacoum uses a uv/vis detector acting at 270 nm.	
3.2.3 Standard(s)	Brodifacoum; batch number 03L950722; 99.1% purity. Nb. Taking into account the very low AS concentration in the test article, a 100% purity value was considered in the AS content calculation.	
3.2.4 Interfering substance(s)	Placebo product spiked with analytical standard was extracted and analysed by HPLC to demonstrate lack of interference or to	

Section B4.1 Annex Point IIA4.3	Analytical Methods for Detection and Identification	
	quantify any that was occurring. There was no interference found.	
3.3 Linearity		
3.3.1 Calibration range	6 – 18 µg/ml for brodifacoum	X
3.3.2 Number of measurements	Four injections for each calibration solution for brodifacoum technical	
3.3.3 Linearity	The method was found to be linear over the range of 6 to 18 µg/ml for brodifacoum (correlation coefficient 0.99).	X
3.4 Specifity: interfering substances	No analyte interferences were detected using the analytical method	
3.5 Recovery rates at different levels	Recovery ranged between 101.4 to 102.2% with a mean value of 101.8%	
3.5.1 Relative standard deviation	The coefficient of variation was 3.38% for brodifacoum and the Horwitz RSDr was 5.99% at brodifacoum concentration of 0.0048% w/w.	
3.6 Limit of determination	Not assessed	
3.7 Precision	A precision value of 0.0005% w/w is considered to be acceptable for this test article with a declared brodifacoum nominal concentration of 0.005% w/w.	
3.7.1 Repeatability	The coefficient of variation was 3.38% for brodifacoum and the Horwitz RSDr was 5.99% at brodifacoum concentration of 0.0048% w/w. Since the coefficient of variation was less than the Horwitz RSDr, the repeatability test for brodifacoum was acceptable.	
3.7.2 Independent laboratory validation	None	
	4 Applicant's Summary and conclusion	
4.1 Materials and methods	A diluting mixture was produced by mixing thoroughly 400 ml dichloromethane and 600 ml methanol. 10 g of test article were placed in a 250 ml flask. To this was added 50 ml diluting mixture and 1 ml formic acid. This solution was placed in a sonication bath for 30 minutes then placed onto a magnetic stirrer overnight. An aliquot was transferred into an eppendorf and centrifuged at 8000 rpm for 10 minutes, then the supernatant was transferred to a vial for analysis. Analysis was completed using HPLC column ChemService code No. 158 and detection by a UV/Vis detector operating at 270 nm.	
4.2 Conclusion	The method was found to be linear over the range of 6 – 18 µg/ml for brodifacoum. No analyte interferences were detected using the analytical method. Recovery ranged between 101.4 to 102.2% with a mean value of 101.8%. A precision value of 0.0005% w/w is considered to be acceptable for this test article with a declared brodifacoum nominal concentration of 0.005% w/w. The coefficient of variation was 3.38% for brodifacoum and the Horwitz RSDr was 5.99% at brodifacoum concentration of 0.0048% w/w. Since the coefficient of variation was less than the Horwitz RSDr, the repeatability test for brodifacoum was acceptable.	
4.2.1 Reliability	1	
4.2.2 Deficiencies		

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY REFERENCE MEMBER STATE (IRELAND)
Date	24.5.2012
Materials and methods	The above method was validated in terms of linearity, precision (repeatability) and accuracy.
Conclusion	Accept the results or the Notifier.
Reliability	Accept the conclusion of the Notifier. The method of analysis is acceptable for the determination of Brodifacoum in [redacted]
Acceptability	1
Remarks	X: The calibration range in g/kg was: 0.006 – 0.018 g/kg for brodifacoum. X: The analytical method is linear over the range tested with a correlation coefficient r^2 of 0.99951. A calibration curve was provided and was acceptable.
	Comments from other Member State *(specify)*
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B4.2 (a) Annex Point *IIB IV4.2*	**Methods of Identification and Analysis in Soil**	
	Justification for non-submission of data	**Official use only**
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	A new method of determination of the active ingredient has been provided Section IIIA2.4 (a). Of the other ingredients, only the human taste deterrent is labelled as hazardous for the environment. However, this ingredient is labelled R52/53 and is present at a concentration of just 0.001% w/w, and hence is not of concern as no labelling results under the Dangerous Preparations Directive. As the active ingredient is labelled R50/53, it is reasonable to expect that any environmental hazard presented by the product can be calculated on the basis of the active ingredient content and hazard.	
Undertaking of intended data submission [X]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification.	
Conclusion	The applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA was not provided in the CAR for the determination of Brodifacoum in soil. However, a new MOA for the determination of Brodifacoum in soil was provided by [redacted] post Annex I inclusion. This was assessed by Germany and found to be acceptable. Please see Annex III: Study Summaries of Studies Reviewed.	
	Comments from other Member State *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section B4.2 (b) Annex Point *IIB IV4.2*	**Methods of Identification and Analysis in Air**	
	Justification for non-submission of data	**Official use only**
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [X]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	As the active substance has a vapour pressure of <0.01 Pa (1.9 x 10^{-21} Pa at 25°C, Section A3.2, Annex Point IIA, III.3.2.) it is considered to be of low volatility. It is also not used in spray applications. Therefore, in accordance with the TNsG on Data Requirements for the Biocidal Products Directive, analytical methods for the biocidal product in air are not required. On this basis a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicants' justification for non-submission of data is acceptable.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the Applicant's justification	
Conclusion	Agree with the RMS, the Applicants' justification for the non-submission of data is acceptable.	
Remarks	None.	

Section B4.2 (c) Annex Point *IIB IV4.2*	**Methods of Identification and Analysis in Water**	
	Justification for non-submission of data	**Official use only**
Other existing data [ ]	**Technically not feasible [X] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	The a.i. has very low solubility in water (5.80E-05 mg/L at pH7, 20°C). For determination of the concentration of the a.i. in water see new summary in section IIIA4.2 (c). Denatonium Benzoate has been classified as R52/53 in the MSDS (see Document I). This is for the 100% pure material. It states in the dangerous preparations directive (1999/45/EC), Part B (concentration limits to be used for the evaluation of environmental hazards), table 1, that if the compound with classification R52/53 is present at less than 25% in the preparation (in this case the paste bait), the preparation will not be classified as R52/53. Denatonium benzoate is less than 25% in the paste bait, therefore it is believed that an analytical method for denatonium benzoate in water is not required. On the above basis a derogation to perform this study is requested.	
Undertaking of intended data submission [X]		
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicant's justification is acceptable. As for the determination of *Brodifacoum* residues in water, please see RMS remarks in doc. IIIA, A4.2(c).	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA for the determination of Brodifacoum in water was provided in the CAR.	

Section B4.2 (d) Annex Point *IIB IV4.2*	**Methods of Identification and Analysis in Animal and human body fluids and tissues**	
	Justification for non-submission of data	**Official use only**
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [ ]**	
Detailed justification:	See the robust summary and data waiver in Section IIIA4.2 (d). There are no toxicologically relevant components in the product other than the active ingredient, excepting denatonium benzoate, a human taste deterrent, which is harmful if ingested in large amounts, with a concentration in the product lower that the a.i. concentration, and triethanolamine, which is irritating to eyes and skin, yet only present at a concentration of 0.06% w/w. The analysis in tissue and fluids, of the active component Brodifacoum, will be covered by studies on the active itself. On the above basis a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicant's justification is acceptable. Please, see RMS remarks in document IIIA, A4.2(d).	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA for provided in the CAR for the determination of Brodifacoum in human and animal body tissues.	

Section B4.2 (e) Annex Point IIB IV.4.2	**Methods of Identification and Analysis in Treated Food or Feedingstuffs**	
	Justification for non-submission of data	**Official use only**
Other existing data [ ]	**Technically not feasible [ ] Scientifically unjustified [ ]**	
Limited exposure [ ]	**Other justification [X]**	
Detailed justification:	Awaiting decision by the EU commission on which foodstuffs, residue determinations are required for. Additionally, see the robust summary in Section IIIA4.3, for the determination of the Brodifacoum content of food and feedstuff. On the above basis, a derogation to perform this study is requested.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State (Italy)	
Date	Jan 2008	
Evaluation of applicant's justification		
Conclusion	The Applicants' justification is acceptable. Please, see RMS remarks in doc. IIIA, A4.3. Note that the study presented in Section IIIA4.3 is not related to *Brodifacoum* determination in wax wheat blocks and pellets, but to *Brodifacou*m determination in food and feedstuff.	
Remarks	None.	
	Comments from Reference Member State (Ireland)	
Date	31.5.2012	
Evaluation of applicant's justification	Accept the applicant's justification	
Conclusion	Agree with the RMS, the applicants' justification for the non-submission of data is acceptable.	
Remarks	A suitable MOA for the determination of Brodifacoum in treated food and feeding stuffs was given in the CAR.	

Subsection (Annex Point)		Official use only
5.1 Product type(s) and field(s) of use envisaged (IIB5.1)		
5.1.1 Product type(s)	Product type 14 – Rodenticides Field of use indoor and outdoor use. Field of use: Rodenticide Amateur and professional use.	
5.1.2 Overall use pattern	The active substance will be used as a rodenticide for the control, primarily, of commensal rodent species. The active substance will be used in rodenticide products (baited traps and protected bait points) for use by professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm buildings. Professional users can use the product in sewers.	
5.2 Method of application including description of system used (IIB5.2)	Product type 14 – Rodenticides Field of use indoor and outdoor use. The active substance in [redacted] is the anticoagulant rodenticide Brodifacoum. The product is formulated containing 0.005% a.i. (50 ppm, 50 mg/kg). The bait formulation is supplied ready-to-use. The product is not diluted in any medium, mixed with other products, or sprayed, misted, dusted or applied to extensive areas as small particles. The product is not applied to plants. The bait is supplied as either loose bait for application with a suitable knife or spatula, as mastic tubes for application by caulking gun or as sachets or 'sausages' which are secured in protected bait points or bait boxes. The bait is placed directly near areas where rodents frequent, and is eaten directly by the target animals. The treatment frequency is 2-4 applications per year, 3-6 month apart. The amount of used product per application is often 15-50 g per baiting point. Bait points are placed typically every 5-10m for rats and 2-5m for mice. Closer placement is required for heavier infestations. The product is placed in a bait station or protected bait point or fixed to a structure such that rats and mice can eat it. In situations where bait boxes cannot be used, such as sewers, the bait is covered such that non-target organisms cannot reach them. In some other areas, bait boxes may not be required, for example areas where non-target species and bystanders do not have access. Rodents eat the bait once and die typically within the first 7 days of the campaign. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds. When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal. Baiting programmes are repeated as necessary, due to re-infestation, typically every 3-6 months.	
5.3 Application rate	The concentration of the active substance in the product is	X

and if appropriate, the final concentration of the biocidal product and active substance in the system in which the preparation is to be used, e.g. cooling water, surface water, water used for heating purposes (IIB5.3)	0.005% (50mg/kg). Pasta bait is not diluted or sprayed. Pasta bait is used as supplied without further treatment. The amount of product used per application is often up to 20-100 g per manhole. Paste bait is applied in sewerage systems typically hanging in a wire fixed to the wall a few cm above the bottom of inspection covers.
5.4 Number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals (IIB5.4)	The product is a ready to use ready formulated bait which is used as sold. It is a bait which is eaten directly by target organisms. It is not diluted in water or any other substance and applied by spraying. It is not used to treat extensive areas such as fields. The bait contains 0.005% a.i., and is in form of loose paste applied with a spatula or a caulking gun, sachets or 'sausages'. Up to 50 g bait is placed in a bait station or protected bait point or fixed to a structure such that rats and mice can eat it. In situations where bait boxes cannot be used or are not necessary, the bait is covered such that non-target organisms cannot reach it. Bait points are placed typically every 2 to 5 m for mouse infestation and 5 to 10 m for rat infestation. Closer placement is required for heavier infestations. Baiting programmes are repeated as necessary, due to re-infestation, typically every 3-6 months. The duration of the program is usually up to 6 weeks. Rodents eat the bait once and die typically within the first 7 days of the campaign. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds. When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.
5.5 Function (IIB5.5)	Rodenticide
5.6 Pest organism(s) to be controlled and products, organisms or objects to be protected (IIB5.6)	
5.6.1 Pest organism(s) to be controlled	Rats and mice: no code available All ages; all sexes; all strains, all locations; all territories; at any time of year.
5.6.2 Products, organisms or objects to be protected	Humans, animals, food, commodities and buildings/structures and components thereof. Objective: death of rats and mice and the protection of humans and animals from pathogen transmission and direct property damage.
5.7 Effects on target organisms (IIB5.7)	Signs of poisoning in rodents and other mammals are those associated with an increased tendency to bleed leading ultimately to profuse haemorrhage. After feeding on bait containing the active ingredient for 2 – 3 days the animal becomes lethargic and slow moving. Signs of bleeding are often noticeable and blood may be seen around the nose and anus. As symptoms develop the animal will lose its appetite and will remain in its burrow or nest for increasingly long

	periods of time. Death will usually occur within the first 7 days of the campaign and animals often die out of sight in their nest or burrow.
5.8 Mode of action (including time delay) in so far as not covered by section A5.4 (IIB5.8)	Brodifacoum is a vitamin K antagonist. The main site of its action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K1 epoxide reductase. Brodifacoum accumulates and is stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidotal therapy (vitamin K1).
5.9 User: industrial, professional, general public (non-professional) (IIB5.9)	
1. Industrial	
i) Open system	Industrial use. Manufacturing concentrate (0.25% technical concentrate) is used to prepare ready-to-use formulated baits containing 0.005% a.i. in covered systems.
ii) Closed system	The (0.25% technical concentrate is produced by dilution with glycols from the 5% master concentrate in fully enclosed systems.
2. Professional	
i) Open system	Professional use in and around buildings. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals In sewers, 't-bags' or 'sausages' may be applied by hanging them on a wire tied to the wall a few cm above the bottom of inspection covers. The product is not to be used in fields and has not been reviewed under the Plant Protection Products Directive.
ii) Closed system	
3. General public	Amateur use in and around buildings. Lockable, tamper-proof bait boxes are available for use by the general public. Bait boxes can be refilled. Bait may be applied in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals.
5.10 Efficacy data: The proposed label claims for the product and efficacy data to support these claims, including any available standard protocols used, laboratory tests, or field trials, where appropriate (IIB5.10)	Information on Label Claims, efficacy and resistance is presented below, in 5.10.1, 5.10.2 and 5.11 respectively.
5.10.1 Proposed label claims for the product	Control of rats and mice in and around domestic, industrial, commercial, institutional and agricultural buildings and structures including sewers.

[redacted] [redacted] is effective against strains of rodent resistant to earlier anticoagulants such as warfarin etc.
The resistance status of the rat population should be taken into account when considering the choice of rodenticide to be used.
Please see the label for further information.

5.10.2 Efficacy data

See separate Doc III-B5.10.2.

5.11 Any other known limitations on efficacy including resistance (IIB5.10)

Resistance to anticoagulant rodenticides was first discovered in Norway rats (*Rattus norvegicus*) in the UK in 1958 and is currently found in many countries of the European Union, both in Norway rats and House mice (*Mus musculus* ssp.). The practical advantages of anticoagulants for rodent control, particularly their efficacy and safety, were such that more effective anticoagulants were sought to overcome resistance rather than the more conventional approach of searching for rodenticides with an alternative mode of action. Brodifacoum was the most potent of a series of novel, so called second-generation anticoagulant rodenticides, brought to the market with the express purpose of combating resistance to the earlier anticoagulants. A summary report is available, the objective of which is to review and summarise some of the published literature on the efficacy of brodifacoum against anticoagulant resistant Norway rats and House mice (see Ref B.5.11).

Uncertainty in the use of terms has sometimes confused the issue of anticoagulant resistance. Two definitions are now widely adopted. These are: 1) 'practical resistance' occurs when a strain of rodent is present which carries an inherited ability to resist an anticoagulant to the extent that a well-conducted control programme using it will not be fully effective and 2) 'technical resistance' is said to occur when an inherited resistance can be technically demonstrated but the degree of resistance has little or no measurable practical impact.

Several different methods are used to determine the resistance status of individual rodents. The 'lethal feeding period' method was widely used in early studies and allowed inferences on the practical significance of resistance. The 'blood clotting response test' does not permit such practical assessments but provides for the rapid and effective laboratory screening of rodents for anticoagulant resistance. A method is also available which allows resistant rodent infestations to be identified in the field. These techniques are used to establish resistance baselines and to permit identification of resistance to anticoagulants in Norway rats and House mice.

New DNA sequencing technology is now widely used to identify rodents carrying mutations of the VKORC1 gene which may confer resistance to anticoagulants. This novel method is very useful as it allows fast, cheap and certain diagnosis of the presence of resistance mutations. However, conventional laboratory and field evaluations are still required to identify the phenotypic effects of the mutated genes on the practical outcome of anticoagulant treatments. Studies of VKORC1 mutations have identified several different mutations in Norway rats and House mice found across the EU.

Blood clotting response tests of the intrinsic potency of brodifacoum against susceptible rodents have shown that it is the most potent of all anticoagulants. It is therefore reasonable to assume that brodifacoum will also be the most effective in controlling rodents that are resistant to other anticoagulants.

	Brodifacoum was developed in the UK after extensive laboratory testing and successful field trials against Norway rats and House mice. Tests of the efficacy of brodifacoum against resistant rodents were also carried out elsewhere in Europe. All tests conducted were found to confirm the efficacy of rodenticide baits containing 50 ppm brodifacoum for the control of both resistant Norway rats and House mice. Commercial rodenticide baits containing 50 ppm brodifacoum and meeting current European Commission requirements for the assessment of bait palatability, measured in guideline-compliant laboratory bait choice feeding trials (Anon., 2008), are likely to be fully effective for the control of resistant rodents in the EU.
5.11.1 Use-related restrictions	Use only in bait boxes or in such enclosures as can prevent access by non-target organisms such as domestic animals.
5.11.2 Prevention of the development of resistance	The immediate aim of resistance management is to prevent or retard the development of resistance to a given anticoagulant while, as far as is not counterproductive, permitting its continued use. The ultimate aim is to reduce or eliminate the adverse consequences of resistance. The use of a suitable arsenal of alternative rodenticides is necessary for the management of resistance. Even out-moded compounds such as zinc phosphide were beneficial when anticoagulant resistance first appeared in the UK. The newer rodenticides to which resistance has not yet developed including the anticoagulants brodifacoum, flocoumafen and difethialone and the non-anticoagulants calciferol and bromethalin (not supported in the EU), all appear to have a role in resistance management. A consistent selection differential that places resistant individuals at a disadvantage, large or small, is needed to eliminate resistance. The most practical way to achieve this is first to stop using rodenticides to which the rodenticides are resistant and then to eliminate the resistant population by the exclusive use of non-selective or counter selective control techniques, both chemical and non-chemical. A contrary strategy is that of withholding or saving effective rodenticides while continuing to use a given anticoagulant until resistance exhausts its usefulness is sometimes put forward as a means of limiting the development of resistance. However it is generally accepted that this strategy is likely to accelerate the development and spread of resistance. **Prevention of Resistance.** The following are considered the most feasible to limit the development of resistance to anticoagulants: Maximum use of non-chemical control techniques. Preferential use of rodenticides and formulations to which resistance rarely develops. Ensure the complete eradication of the target population whenever a rodenticide is used. Avoid the use of first generation anticoagulants, to which resistance develops relatively easily. 5. Maintain uncontrolled, susceptible populations in refugia from which emigration can occur.
5.11.3 Concomitant	The product is not suitable for mixing with other biocidal

use with other (biocidal) products	products being a solid bait material. There are no products with which it is likely to be used.

Evaluation by Competent Authorities	
Date	March 2013
Materials and methods	Laboratory and field studies against synanthropic rodents (*Mus musculus, Rattus norvegicus*) were conducted under differing scenarios with varying levels of rodent infestation using methods compliant with current guidelines. The studies were conducted according to agreed guidelines in accordance with the TNsG on Product Evaluation Chapter 7 and its appendices – Product Type 14 – Rodenticides. No studies provided on black rat (*rattus rattus*). **5.3** A maximum of 200g of pasta bait is to be used per manhole. The wording under table A5-1 should read “up to 60g”.
Conclusion	The studies provided are considered acceptable in support of the product authorisation of [redacted]
Reliability	1
Acceptability	Information is considered acceptable.
Remarks	None.
	Comments from …
Date	Give date of comments submitted
Results and discussion	Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion. Discuss if deviating from view of rapporteur member state
Conclusion	Discuss if deviating from view of rapporteur member state
Reliability	Discuss if deviating from view of rapporteur member state
Acceptability	Discuss if deviating from view of rapporteur member state
Remarks	

Table A5-1: Summary table of data on the method of application including description of system used

Serial number	Product type	Substance(s) used for dilution	Concentration of dilutant(s)	Other substance(s) added	Application technique	Remarks
(1)	*Include respective code(s) for product type(s) given in section 5.1*	*Give name of substance including CAS No.*	*State the concentration in percentage of the biocidal product*	*Give name and CAS No. of any other substance(s) to the biocidal product and indicate purpose*	*Include the corresponding code as given in Appendix xyz, File 4, and the corresponding term*	
(2)	*PT14*	No substance is used for dilution – the product is supplied ready to use.	0.005%	No other substance is used for dilution – the product is supplied ready to use	*By placing of ready formulated, ready to use baits as supplied in vicinity of areas where target rodents are seen. Rodents then eat baits directly*	The product is not applied by spraying, dusting, or misting. It is not applied to plants
					There are no other methods of application	

The product is a ready to use ready formulated bait, which is used as sold. It is a bait which is eaten directly by target organisms. It is not diluted in water or any other substance and applied by spraying. It is not used to treat extensive areas such as fields.
The bait contains 0.005% a.i. , and is in form of paste. Up to 50 g bait is placed in a bait station or fixed to a structure such that rats and mice can eat it. In situations where bait boxes cannot be used, the bait is covered such that non-target organisms cannot reach them. Bait points are placed typically every 5-10m for rats and every 2-5 m for mice.
Rodents eat the bait over one or more days and die typically 1-5 days later. Baiting points are inspected frequently and replenished when bait has been eaten. Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds.
When no more bait is eaten and rodent activity stops, the remains of all bait are removed for disposal.
Baiting programmes are repeated as necessary, typically every 3-6 months.

Table A5-2: Summary table of data on the number and timing of applications, and where relevant, any particular information relating to geographical variations, climatic variations, or necessary waiting periods to protect man and animals

Serial number	Product type	Application type	Number and timing of application	Waiting periods	Information on recommended variations of the application rate in different locations	Remarks
(1)	*Include respective*	*Include respective code(s) for application*	*Indicate the recommended number and timing, i.e.*	*Indicate recommended*	*Where relevant, describe how the application should be varied in*	

	code(s) for product type(s) given in section 5.1	*type(s) given in section 5.2*	*duration of application and possible reapplications*	*waiting periods and their purpose*	*different parts of the Community depending on the geographical or climatic conditions*	
(2)	PT14	BAXXX	The treatment frequency is typically 2-4 applications per year, 3-6 months apart.	No waiting times are recommended. They are without purpose in this use	There are no recommended variations in the application in different locations. For heavier infestations, baits are more closely spaced, hence there will be more bait in the area.	Product is not applied to plants by spraying
(3)	PT14	BIXXX	The treatment frequency is typically 2-4 applications per year, 3-6 months apart.	No waiting times are recommended. They are without purpose in this use	There are no recommended variations in the application in different locations. For heavier infestations, baits are more closely spaced, hence there will be more bait in the area.	Product is not applied to plants by spraying

Section B5.10.2 (1) Annex Point IIB V.5.11	Efficacy Data Laboratory Study of Pasta Bait (Mice)	
	REFERENCE	**Official use only**
Reference	Report: Palatability and Efficacy of Aged [redacted] Formulation in Laboratory Mice. [redacted] – March 2005. [redacted] Report number 06/2005.	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter of access	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
Deviations	No	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.005% w/w	
Physical state and nature	Red soft paste	
Monitoring of active substance concentration	No	
Method of analysis		
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See Table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Mice	
Controls	No separate control	

Examination		
Effect investigated	Mortality	X
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality	
Intervals of examination	Daily	
Statistics	None applied	
Post monitoring of the test organism	Yes for a maximum of 20 days	
	Results	
Efficacy		
Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.	
Begin and duration of effects	Mortality started 7 days after commencement of feeding on the test item and final death occurred 9 days after commencement of feeding on the test item.	
Observed effects in the post monitoring phase	No other effects observed.	
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings	
Other effects	No other effects noted	
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.	
Tabular and/or graphical presentation of the summarised results		
Efficacy limiting factors		
Occurrences of resistances	No resistance noted	
Other limiting factors	No other limiting factors noted	
	Relevance of the results compared to field conditions	
Reasons for laboratory testing	Intake of test substance can be monitored more accurately.	
Intended actual scale of biocide application	Not relevant to palatability study	
Relevance compared to field conditions		
Application method	Yes	
Test organism	Yes –Mice (*Mus musculus*)	
Observed effect	Yes – Test Substance found to be 100% effective against mice, as expected in field studies	
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.	
	Applicant's Summary and conclusion	
Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
Reliability	1	
Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to mice. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by mice even when normal non-toxic food	

	sources are available.
Conclusion	Product is palatable to mice and effective in killing them.
Proposed efficacy specification	100% effective against mice

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female). **2.4.1** Effect observed included palatability and mortality.
Results and discussion	The mean bait intake 49.2% of the total food consumption. The mean consumption of the test product and the reference meal were 4.1 g and 4.2 g, respectively. 100% mortality 7-9 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single test organism

Test organism (*if applicable*)

Criteria	**Details**
Species	Albino laboratory mouse (*Mus musculus*)
Strain	ICR outbred, SPF quality
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No: all adults
Other specification	Male and female 21.1 – 23.1 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant. Mice are not cultivated
Pretreatment of test organisms before exposure	6 days acclimatisation
Initial density/number of test organisms in the test system	1 per cage

Test system

Criteria	**Details**
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None

Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided *ad lib*
Aeration	Air provided *ad lib*
Method of exposure	Feed
Aging of samples	2 years old
Other conditions	None

Summary of results

Animal#	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatability ratio
		Initial	Final	[redacted]	EPA Meal				
62/R	F	21.1	21.3	3.9	4.4	8	8.59	47.0	0.9
63/R	F	21.4	21.5	4.1	4.0	7	8.87	50.6	1.0
64/R	F	21.8	22.3	4.0	4.1	8	8.51	49.4	1.0
65/R	F	21.3	21.2	3.3	4.6	8	7.17	41.8	0.7
66/R	F	21.7	22.2	3.7	4.4	7	7.91	45.7	0.8
68/R	M	22.9	23.4	4.7	3.6	9	9.55	56.6	1.3
69/R	M	23.1	23.6	4.7	3.8	8	9.44	55.3	1.2
70/R	M	22.8	23.2	3.8	4.5	8	7.72	45.8	0.8
71/R	M	22.6	22.8	3.9	4.5	7	7.99	46.4	0.9
72/R	M	22.9	23.2	4.4	3.8	7	8.91	53.7	1.2
Mean		22.2	22.5	4.1	4.2	8.0	8.47	49.2	1.0
SD				0.4	0.4	1.00	0.77	4.8	0.2
Confidence 0.1		-	-	-	-	-	-	2.5	-
Confidence 0.05		-	-	-	-	-	-	1.3	-

Section B5.10.2 (2) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Pasta Bait (Mice)

	Reference	Official use only
Reference	Report: Palatability and Efficacy of Fresh [redacted] Formulation in Laboratory Mice. [redacted] – February 2005 [redacted] - Report number 04/2005.	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter of access	None	

Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
Deviations	No	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.0051% w/w	
Physical state and nature	Red soft paste	
Monitoring of active substance concentration	No	
Method of analysis		
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female ICR outbred, SPF quality albino mice	
Controls	No separate controls	
Examination		
Effect investigated	Mortality and palatability	
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
Intervals of examination	Daily	
Statistics	None applied	
Post monitoring of the test organism	Yes for a maximum of 20 days	
	Results	
Efficacy		
Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.	
Begin and duration of effects	Mortality started 6 days after commencement of feeding on the test item and final death occurred 8 days after commencement of	

	feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed. All animals died
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
Tabular and/or graphical presentation of the summarised results	
Efficacy limiting factors	
Occurrences of resistances	No resistance noted
Other limiting factors	No other limiting factors noted
	Relevance of the results compared to field conditions
Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Mice (*Mus musculus*)
Observed effect	Yes – Test Substance found to be 100% effective against mice, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to rats when mixed with other bait bases if consumption is similar.
	Applicant's Summary and conclusion
Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1
Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to mice. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by mice, even when normal, non-toxic food sources are available.
Conclusion	Product is palatable to mice and effective in killing them.
Proposed efficacy specification	100% effective against mice

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female).

Results and discussion	Mean bait intake 46.9% of the total food consumption. The mean consumption of the test product and the reference meal were 3.6 g and 4.1 g, respectively. 100% mortality 6-8 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)
Not relevant. Single organism population used.

Test organism (*if applicable*)

Criteria	Details
Species	Mice
Strain	ICR outbred, SPF quality
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No. Adults only
Other specification	Male and female 20.7 – 23.2 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant
Pretreatment of test organisms before exposure	Acclimatisation 6 days.
Initial density/number of test organisms in the test system	10 (5 male, 5 female), 1 per cage

Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided *ad lib*
Aeration	Air provided *ad lib*
Method of exposure	Feed
Aging of samples	No
Other conditions	*None*

Summary of results

Animal#	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatability ratio
		Initial	Final	[redacted]	EPA Meal				
37/R	**F**	20.7	20.9	3.8	3.5	7	8.52	52.1	1.1
38/R	**F**	21.1	21.4	3.5	3.6	8	7.64	49.3	1.0
39/R	**F**	20.9	21.1	3.3	4.0	7	7.33	45.2	0.8
40/R	**F**	21.4	21.2	3.8	3.5	7	8.23	52.1	1.1
41/R	**F**	21.7	21.9	3.3	4.0	7	7.05	45.2	0.8
44/R	**M**	22.3	22.6	3.8	4.9	7	7.88	43.7	0.8
45/R	**M**	22.9	23.2	3.2	4.7	8	6.50	40.5	0.7
46/R	**M**	23.2	23.3	3.7	4.4	7	7.40	45.7	0.8
47/R	**M**	21.9	22.2	3.6	4.7	8	7.63	43.4	0.8
48/R	**M**	22.8	23.4	4.0	3.7	6	8.20	51.9	1.1
Mean		21.9	22.1	3.6	4.1	7.0	7.64	46.9	0.9
SD				0.3	0.5	1.00	0.61	4.2	0.2
Confidence 0.1								2.2	
Confidence 0.05								1.1	

Section B5.10.2 (3) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Pasta Bait (Rats)

	Reference	**Official use only**
Reference	Palatability and Efficacy of Fresh [redacted] Formulation in Laboratory Rats. [redacted] – February 2005 [redacted] Report number 03/2005.	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter	None	

of access		
Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
Deviations	No	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.0051% w/w	
Physical state and nature	Red soft paste	
Monitoring of active substance concentration	No	
Method of analysis		
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Wistar Rats	
Controls	No separate controls	
Examination		
Effect investigated	Mortality and palatability	
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Food consumption; mortality	
Intervals of examination	Daily	
Statistics	None applied	
Post monitoring of the test organism	Yes for a maximum of 20 days	
	Results	
Efficacy		
Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.	
Begin and duration of	Mortality started 6 days after commencement of feeding on the test	

effects	item and final death occurred 8 days after commencement of feeding on the test item.
Observed effects in the post monitoring phase	No other effects observed. All animals died
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
Tabular and/or graphical presentation of the summarised results	See Table 1.6
Efficacy limiting factors	
Occurrences of resistances	No resistance noted
Other limiting factors	No other limiting factors noted
	Relevance of the results compared to field conditions
Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Rats (*Rattus norvegicus*)
Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to rats when mixed with other bait bases if consumption is similar.
	Applicant's Summary and conclusion
Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1
Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to rats. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by rats, even when normal, non-toxic food sources are available.
Conclusion	Product is palatable to rats and effective in killing them.
Proposed efficacy specification	100% effective against rats
	Evaluation by Competent Authorities

	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty rats should be used (10 male and 10 female).

Results and discussion	Mean bait intake 39.5% of the total food consumption. The mean consumption of the test product and the reference meal were 29.7 g and 45.4 g, respectively. 100% mortality 6-8 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)
Not relevant. Single organism population used.

Test organism (*if applicable*)

Criteria	**Details**
Species	Rats
Strain	Wistar outbred, SPF quality
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No. Adults only
Other specification	Male and female 205 – 233 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant
Pretreatment of test organisms before exposure	Acclimatisation 6 days.
Initial density/number of test organisms in the test system	10 (5 male, 5 female), 1 per cage

Test system

Criteria	**Details**
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided *ad lib*
Aeration	Air provided *ad lib*
Method of exposure	Feed
Aging of samples	No
Other conditions	None

Summary of Results

Animal	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatability ratio
		Initial	Final	[redacted]	EPA Meal				
25/R	F	205	211	27.0	45.7	8	6.11	37.1	0.6
26/R	F	209	216	28.3	44.2	8	6.24	39.0	0.6
27/R	F	207	215	28.2	42.2	7	6.30	40.1	0.7
28/R	F	213	219	24.4	41.7	6	5.33	36.9	0.6
29/R	F	212	218	31.8	41.6	7	7.04	43.3	0.8
31/R	M	229	233	33.2	53.9	7	6.75	38.1	0.6
32/R	M	231	229	34.0	47.3	7	6.86	41.8	0.7
33/R	M	233	236	34.5	43.6	6	6.98	44.2	0.8
34/R	M	229	227	29.1	47.5	8	5.99	38.0	0.6
35/R	M	233	234	26.2	46.5	7	5.33	36.0	0.6
Mean		220.1	223.8	29.7	45.4	7.1	6.29	39.5	0.7
SD				3.3	3.5	0.7	0.6	2.7	0.1
Confidence 0.1		-	-	-	-	-	-	1.4	-
Confidence 0.05		-	-	-	-	-	-	1.6	-

Section B5.10.2 (4) Efficacy Data
Annex Point IIB V.5.11

Laboratory Study of Pasta Bait (Rats)

	Reference	**Official use only**
Reference	Report: Palatability and Efficacy of Aged [redacted] Bait Formulation in Laboratory Rats. [redacted] – March 2005. [redacted] - Report number 05/2005.	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter of access	None	

Criteria for data protection	Data submitted to the MS after 13 May 2000 on Biocidal Product for the purpose of its national approval.	
Guideline study	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)	
Deviations	No	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.0049% w/w	
Physical state and nature	Red soft paste	
Monitoring of active substance concentration	No	
Method of analysis		
Reference substance	Yes EPA Meal consisting of: Cornmeal (whole yellow ground corn) 65% w./w Rolled Oats Groats (ground) 25% w/w Sugar (confectioners) 5% w/w Corn oil 5% w/w	
Method of analysis for reference substance		
Testing procedure		
Test population / inoculum / test organism	See Table 1.2	X
Test system	See Table 1.3	
Application of TS	See Table 1.4	
Test conditions	See Table 1.5	
Duration of the test / Exposure time	Acclimatisation period – 6 days Administration period – 4 days Observation period – 20 days maximum	
Number of replicates performed	5 male and 5 female Rats	
Controls	No separate control	
Examination		
Effect investigated	Mortality	X
Method for recording / scoring of the effect	Monitored daily for acute or sub-acute toxicity with clinical signs. Feed consumption. Mortality	
Intervals of examination	Daily	
Statistics	None applied	
Post monitoring of the test organism	Yes for a maximum of 20 days	
	Results	
Efficacy		
Dose/Efficacy curve	Not possible Summary of results are presented in Table 1.6.	
Begin and duration of effects	Mortality started 7 days after commencement of feeding on the test item and final death occurred 9 days after commencement of feeding on the test item.	

Observed effects in the post monitoring phase	No other effects observed.
Effects against organisms or objects to be protected	No adverse effects noted on cages, feed or surroundings
Other effects	No other effects noted
Efficacy of the reference substance	No effects noted which can be attributed to the reference substance.
Tabular and/or graphical presentation of the summarised results	
Efficacy limiting factors	
Occurrences of resistances	No resistance noted
Other limiting factors	No other limiting factors noted
	Relevance of the results compared to field conditions
Reasons for laboratory testing	Intake of test substance can be monitored more accurately.
Intended actual scale of biocide application	Not relevant to palatability study
Relevance compared to field conditions	
Application method	Yes
Test organism	Yes –Rats (*Rattus norvegicus*)
Observed effect	Yes – Test Substance found to be 100% effective against rats, as expected in field studies
Relevance for read-across	Yes. Relevant for read- across on palatability and efficacy. The same bait base is equally palatable with other active substances such as difenacoum. The same active ingredient will also prove equally toxic to mice when mixed with other bait bases if consumption is similar.
	Applicant's Summary and conclusion
Materials and methods	Standard Operating Procedures and Standard Product Bait Quality Assurance Laboratory Test Method from guidelines issued by the European and Mediterranean Plant Protection Organisation (OEPP/EPPO, 1982) and the United States Environmental Protection Agency (EPA, 1982)
Reliability	1
Assessment of efficacy, data analysis and interpretation	Bait has been shown to be palatable to rats. Active ingredient has been shown to be effective in killing them. Study shows that the bait is eaten by rats even when normal non-toxic food sources are available.
Conclusion	Product is palatable to rats and effective in killing them.
Proposed efficacy specification	100% effective against rats

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	**2.3.1** TNsG on product evaluation recommends that twenty mice should be used (10 male and 10 female). **2.4.1** Effect observed included palatability and mortality.

Results and discussion	Mean bait intake 41.1% of the total food consumption. The mean consumption of the test product and the reference meal were 33.0 g and 47.2 g, respectively. 100% mortality 7-9 d after the start of exposure.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Tables for Method

(mixed) Population / Inoculum (*if necessary; include separate table for different samples*)

Not relevant. Single test organism

Test organism (*if applicable*)

Criteria	Details
Species	Albino laboratory rats (*Rattus norvegicus*)
Strain	Wistar outbred, SPF quality
Source	[redacted]
Laboratory culture	Yes
Stage of life cycle and stage of stadia	Adults
Mixed age population	No: all adults
Other specification	Male and female 208 – 226 g
Number of organisms tested	10 (5 male, 5 female)
Method of cultivation	Not relevant. Rats are not cultivated
Pretreatment of test organisms before exposure	6 days acclimatisation
Initial density/number of test organisms in the test system	1 per cage

Test system

Criteria	Details
Culturing apparatus / test chamber	Polyvinyl cages with steel mesh lids
Number of vessels / concentration	1
Test culture media and/or carrier material	None
Nutrient supply	EPA meal
Measuring equipment	Laboratory balance

Application of test substance

Criteria	Details
Application procedure	In daily feed
Delivery method	Oral via daily feed bowls
Dosage rate	Variable as test animals had treated and control feed bowls.
Carrier	None
Concentration of liquid carrier	Not relevant
Liquid carrier control	Not used
Other procedures	None

1.5 Test conditions

Criteria	Details
Substrate	None relevant
Incubation temperature	Not relevant
Moisture	Water provided ad lib
Aeration	Air provided ad lib
Method of exposure	Feed
Aging of samples	2 years old
Other conditions	None

1.6 Summary of results

Animal#	Sex	Body weight (g)		Consumption (g)		Day of death	Dose (mg/kg)	Acceptance of test item (%)	Palatability ratio
		Initial	Final	[redacted]	EPA Meal				
50/R	F	209	215	32.7	47.5	8	7.33	40.8	0.7
51/R	F	211	214	34.0	44.5	7	7.56	43.3	0.8
52/R	F	208	211	29.1	51.5	9	6.58	36.1	0.6
53/R	F	211	217	31.4	44.3	7	6.95	41.5	0.7
54/R	F	209	212	27.7	52.3	8	6.16	34.6	0.5
56/R	M	221	227	34.9	48.4	8	7.30	41.9	0.7
57/R	M	224	228	37.9	48.1	7	8.23	44.1	0.8
58/R	M	222	230	33.6	44.0	7	7.03	43.3	0.8
59/R	M	219	226	33.5	46.6	8	7.10	41.8	0.7
60/R	M	226	232	35.2	44.8	8	7.24	44.0	0.8
Mean		216	221.2	33.0	47.2	7.7	7.15	41.1	0.7
SD				2.8	2.8	0.7	0.5	3.1	0.1
Confidence 0.1		-	-	-	-	-	-	1.6	-
Confidence 0.05		-	-	-	-	-	-	1.9	-

Section B5.10.2 (5) Efficacy Data
Annex Point IIB5.10 Field trial on the efficacy of Vertox Pasta Bait on House mouse
TNsG: Pt. I-B5.10, Pt. III-Ch. 6

	Reference	Official use only
Reference	[redacted] (2006) Field trial report to determine the efficacy of [redacted] containing 0.005% w/w brodifacoum for the	

	control of an infestation of house mice (*Mus domesticus*) resident within the machinery room of a grain store on an agricultural holding [redacted] Report Number: PEL/011/05
Data protection	Yes
Data owner	[redacted]
Companies with letter of access	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval
Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).
Deviations	No strict guidelines were followed.
	Method
Test Substance (Biocidal Product)	As given in section 2
Trade name/ proposed trade name	[redacted]
Composition of Product tested	Brodifacoum 0.005% w/w
Physical state and nature	Blue paste
Monitoring of active substance concentration	No
Method of analysis	N/A
Reference substance	
Method of analysis for reference substance	N/A
Testing procedure	
Test population / inoculum / test organism	The field study was designed to investigate the efficacy of [redacted], containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the machinery room of a grain store on an agricultural holding in Hampshire.
Test system	Bait boxes were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site. Builder's sharp sand was used as the material for tracking patches. These patches measured approximately 31 x 30 cm. A balance was used that was capable of weighing up to 2 kg in graduations of 1g. <u>Pre-treatment census</u> On the first day of the trial the census bait boxes were filled with dry whole wheat to give a total box and bait weight of 90 g and the tracking patches set out with fresh sharp sand. During the next five days, bait consumption at each bait point was determined and a tracking score established. <u>Pre-treatment lag period</u> At the end of the pre-treatment census, all bait boxes (but not tracking patches) were removed and the site was left undisturbed for six days. Empty bait boxes were reintroduced to the site on the following day and the treatment phase commenced the day after. <u>Poison bait treatment</u> Poison bait boxes were placed in different positions near to those used for the census bait. A corner of the 't-bag' sachet holding

	the bait was secured by the closure of the bait box to prevent its removal by mice. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been significant bait take, another sachet was added. No bait loss was recorded on the 18th day of treatment – this followed several days when bait take had been less than 10% of the maximum consumption. As no tracks were observed on the sand trays either, the treatment was concluded and all toxic baits were removed from the site. <u>Post-treatment lag period</u> The lag period was 3 days. On day 4, the placement of the empty census bait boxes took place to allow their familiarisation by any mice present. <u>Post treatment census</u> A 5-day post treatment census was carried out with rodent tracking patches and census bait, as in the pre-treatment census.
Application of TS	In bait boxes in the field.
Test conditions	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait boxes were not placed in the same position as the census bait, but in the close proximity.
Duration of the test / Exposure time	The total test period was 41 days Poison baiting period was 18 days
Number of replicates performed	The test was only performed once but there were 51 bait points involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if the poisoned [redacted] [redacted] was just as palatable as the untreated wheat bait and to estimate the mouse population.
Examination	
Effect investigated	Mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait box was measured and the number of sites visited too, which gives an indication of the number of mice. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
Post monitoring of the test organism	Yes. A 5-day post-treatment census was carried out.
	Results
Efficacy	Efficacy of the poison bait based on the total census bait take was 99.0% Efficacy of the poison bait based on the total track score was 92.0%
Dose/Efficacy curve	N/A
Begin and duration of effects	No recordable bait take occurred during the initial 24-hour period but disturbance of the pasta sachets (gnawed paper and incisor marks in the paste) was noted in 11 of the floor placements and at 9 points on the various platforms. Substantial amounts of bait were consumed over the following 3 days (average 36 g) before reductions in total bait were recorded. Total bait consumption had fallen significantly by the 7th day of rodenticide presentation and small amounts were recorded over the following 10-day period. No disturbance of bait occurred on treatment Day 18 and the trial was terminated

The reduction in bait consumption was mirrored by activity scored from mouse tracks on the sand patches. Towards the end of the treatment phase, single tracks of padmarks appeared to move in the same direction across several adjacent sand trays and it was considered that these had been made by an individual transient animal. No tracks were observed on Day 18.

Observed effects in the post monitoring phase N/A

Effects against organisms or objects to be protected There was no evidence from this trial that the application of [redacted] is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.

Other effects None

Efficacy of the reference substance N/A

Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	57	2	99.0
Total census bait take (g)	201	2	96.5
Mean census bait take (g)	40.2	0.4	99.0
Maximum track score	28	4	85.7
Total track score	112	9	92.0
Mean track score	22.4	1.8	92.0

Efficacy limiting factors

Occurrences of resistances N

Other limiting factors N

Reasons for laboratory testing N

Intended actual scale of biocide application N

Relevance compared to field conditions N/A

Application method N/A

Test organism N/A

Observed effect N/A

Relevance for read-across N/A

Applicant's Summary and conclusion

Materials and methods The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the mice, for example, areas of alternative source of food. The survey confirmed the presence of a low to moderate mouse infestation in the study area. The positions of bait placements and rodent tracking patches were determined and marked on copies of the site map.

Pre-treatment census

The census bait boxes were charged with dry, whole wheat and

	the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next five days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established. Pre-treatment lag phase On completion of the pre-treatment census, all bait boxes (but no tracking patches) were removed from the trial site. The site was left undisturbed for a period of 6 days. Empty bait boxes were reintroduced to the site on the day following and the treatment phase commenced the day after. Poison bait treatment Poison bait boxes were laid out in different positions near to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Baits that had been eaten were replaced or topped up. Throughout the poison baiting period, daily searches for dead animals, whether rodents or non-target wildlife or domestic animals, were made by conducting a careful inspection of the site and adjacent land. All poisoned bait was removed at the conclusion of treatment when there was no bait loss after several days when bait take had been less than 10% of the maximum consumption and no tracks were observed on the sand trays. Post-treatment lag period A lag period of three days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. Empty bait boxes were placed on Day 4 to allow their familiarisation by any mice present. Where possible, the boxes were located at the original positions of the pre-treatment census baits. Post-treatment census After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of five days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
Reliability	1
Assessment of efficacy, data analysis and interpretation	Initial Infestation It was estimated from the pre-treatment census bait take of 201g and the highest daily take of 57 g that there was a low to moderate mouse infestation active in the study area. Poison baiting No recordable bait take occurred in the initial 24-hour baiting period but disturbance of the sachets (gnawed paper and incisor marks in the paste) was noted in 20 bait placements. Substantial amounts of bait (average 36 g) were consumed over the following 3 days before reductions of total take were recorded. Total bait consumption had fallen significantly by the seventh day of rodenticide presentation and small amounts were recorded over the following 10-day period. No disturbance of bait occurred on treatment Day 18 and the trial was terminated. The reduction in bait consumption was mirrored by activity scored from mouse tracks on the sand patches. Towards the end of the treatment phase, single tracks of padmarks appeared to move in the same direction across several adjacent sand trays and it was

	considered that these had been made by an individual transient animal. No tracks were observed on Day 18. There were no actual sightings of mice from Day 6 onwards and farm personnel commented that mouse 'odour' was negligible by Day 10. Dead mice were first observed in the central floor area on Day 5 of the treatment period, although few cadavers were found during the daily search. It would be expected that most mice would have died in their harbourages. <u>Post treatment</u> During the 5-day 'lag' period following the treatment phase, the adjacent flat store had been totally cleared of grain. Light disturbance of census bait occurred at a single point on the ledge of the wall around the main floor area and from another placement on the top platform. Tracks across sand patches indicated very light activity (mainly a single line of padmarks) both on the main floor and at higher levels indicating the possible presence of 1 or 2 transient animals recruited from the adjacent store.
Conclusion	The mouse infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was low to moderate and the mice were provided with ample alternative food. In spite of this, the mice took the poisoned bait. There was a reduction in bait consumption after 6 days (decreasing to about 14% of the peak consumption) suggesting that a significant level of control was already being achieved. The trial bait continued to be presented for a further 12 days. Although it was apparent that a few mice were still present following the lag period, it was considered that recruitment of animals may have occurred during the removal of cereal from the adjacent storage area.
Proposed efficacy specification	The product showed good control of an infestation of House mice.

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 96.5% Efficacy based on total track score = 92.0%
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (6) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy** Field trial on the efficacy of [redacted] on House mouse	**Data**

		Official use only
	Reference	
Reference	[redacted] 2009) Field trial report to determine the efficacy of [redacted] containing 0.005% w/w Brodifacoum, for the control of an infestation of house mice (*Mus domesticus*) resident within the machinery room of a grain store on an agricultural holding [redacted] Report Number: PEL/002/09	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter of access	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) and EPPO (1982).	
Deviations	No strict guidelines were followed.	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.005% w/w	
Physical state and nature	Red paste bait	
Monitoring of active substance concentration	No	
Method of analysis	N/A	
Reference substance		
Method of analysis for reference substance	N/A	
Testing procedure		
Test population / inoculum / test organism	The field study was designed to investigate the efficacy of [redacted] containing 0.005 % brodifacoum, for the control of House mice. The infestation used in the trial inhabited the machinery room of a grain store on an agricultural holding in Hampshire.	
Test system	Bait was placed in open plastic trays as non-target animals did not have access to the treated area. Access to the machinery room was only possible when the door was open and there were no sightings of any non-target species within the building throughout the entire study. The bait trays were used to facilitate the placement of census and poisoned baits and the weighing and removal of the baits from the site. Builder's sharp sand was used as the material for tracking patches. These patches measured 31 x 30 cm. A balance was used that was capable of weighing up to 2 kg in	

	graduations of 1g. Pre-treatment census On the first day of the trial the census bait trays were filled with dry whole wheat to give a combined tray and bait weight of 30 g and the tracking patches were set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established. Pre-treatment lag period At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed and the site left undisturbed for 6 days when bait trays for the poison bait were laid (Day 10). Poison bait treatment Poison bait boxes were placed in different positions near to those used for the census bait. Poison bait was laid the day after this short 1 day reacclimatisation period. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been significant take of bait, fresh bait was added. Throughout the main portion of the trial active searches for dead animals, whether rodent or non-target species, were undertaken. The poison treatment was concluded and all toxic baits removed from the site when there was little or no track score and bait take was greatly reduced. Post-treatment lag period The lag period was 3 days. Post-treatment census A 4 day post-treatment census was carried out with census bait points and rodent tracking patches.
Application of TS	In bait trays in the field.
Test conditions	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait, but in close proximity. Baits were applied within the machinery room of the grain store, so were protected from the weather and from non-target animals.
Duration of the test / Exposure time	The total test period was 51 days Poison baiting period was 30 days
Number of replicates performed	The test was only performed once but there were 35 bait points involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if the poisoned [redacted] was as palatable as the untreated wheat bait and to estimate the mouse population.
Examination	
Effect investigated	Mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait tray was measured and the number of sites visited too, which gives an indication of the number of mice. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-

Section B5.10.2 (6) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy Data** Field trial on the efficacy of [redacted] on House mouse

	treatment census data)]
Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.
	Results
Efficacy	Mice present on the study site did not constitute a discrete population and the two extreme levels - the sub-floor conveyor trench and the top conveyor platform - were subject to continual recruitment but efficacy assessments on the three central levels showed that a high level of control of the infestation had been achieved (95.4% when estimated by total census bait take and 93.1% by total track score).
Dose/Efficacy curve	N/A
Begin and duration of effects	The mouse population, whose sole natural diet had been cereal grain, not unexpectedly took a lot more census bait (202 g from 31 bait points) during the first 24-hour period than they did of the novel pasta bait (18 g from 12 bait points – although another 18 bait points showed signs of disturbance). The quantity of pasta consumed doubled on the following day before decreasing over the next week as mice succumbed to the poison. By Day 8 of treatment, recordable bait-take was mainly confined to the main floor area and any bait consumption on the three upper platforms had become immeasurable. The track scores, however, indicated that mice were continuing to arrive from the pit area and move between levels. From Day 21, mouse activity across sand patches generally comprised a single track or pad mark which, appearing to move in the same direction across several sand patches, suggested that they may have been made by individual transient animals. Dead mice were first observed in the central floor area on Day 4 of the treatment period, although few cadavers were found during the daily search. It would be expected that most mice would have died in their harbourage.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of [redacted] is likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A

Section B5.10.2 (6) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy Data** Field trial on the efficacy of [redacted] on House mouse

Tabular and/or graphical presentation of the summarised results	
	%
Efficacy limiting factors	
Occurrences of resistances	N/A
Other limiting factors	N/A
	Relevance of the results compared to field conditions
Reasons for laboratory testing	N/A
Intended actual scale of biocide application	N/A
Relevance compared to field conditions	N/A
Application method	N/A
Test organism	N/A
Observed effect	N/A
Relevance for read-across	N/A
	Applicant's Summary and conclusion
Materials and methods	The procedure followed six main stages as follows: <u>Site survey, census baits and rodent tracking patches</u> The survey looked for particular areas of importance to the mice, for example, areas of alternative source of food. The survey confirmed the presence of a moderate to high mouse infestation was present throughout the various levels of the study area. The position of bait placements and rodent tracking patches were determined and marked on copies of the site map. <u>Pre-treatment census</u>

Section B5.10.2 (6) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy Data** Field trial on the efficacy of [redacted] on House mouse

The census bait trays were charged with 30g (combined tray and bait weight) of whole, dry wheat and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but no tracking patches) were removed from the trial site. The site was left undisturbed for 6 days, when empty bait boxes were re-introduced to the site and the treatment phase commenced another day after that.

Poison bait treatment

Poison bait trays were laid out in different positions near to those used for the census bait. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been significant take of bait, fresh bait was added. Daily searches were made for dead mice and non-target animals, although no non-target animals had access to the building. The poison treatment was terminated when there was little or no track score and poisoned bait take was greatly reduced.

Post-treatment lag period

A lag period of three days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census baiting. Empty bait trays were laid throughout the site on Day 4, where possible in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post treatment census

After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Reliability 1

Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the total consumption of pre-treatment census bait (1330 g) and the highest daily take of 441 g that there was a moderate to high infestation of more than 100 mice in the study area.

Poison baiting

The quantity of poisoned bait consumed on the first day of baiting was 18g (from 12 bait points – another 12 showed signs of disturbance). The mouse population, whose sole natural diet had been cereal grain, not unexpectedly took a lot more census bait (202 g from 31 bait points) during the same period in the census baiting. The quantity of pasta bait consumed doubled on the following day before decreasing over the next week as mice succumbed to the poison.

By Day 8 of treatment, recordable bait-take was mainly confined

Section B5.10.2 (6) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	Efficacy Data Field trial on the efficacy of [redacted] on House mouse

	to the main floor area and any bait consumption on the three upper platforms had become immeasurable. The track scores, however, indicated that mice were continuing to arrive from the pit area and move between levels. From Day 21, mouse activity across sand patches generally comprised a single track or pad mark which, appearing to move in the same direction across several sand patches, suggested that they may have been made by individual transient animals. A total of 249 g of poisoned bait was consumed by mice from 27 of the 35 bait points set out on 5 levels. The removal of grain from an adjoining store during the study may have led to some movement of mice into the study area and some animals were also moving from one level of the treatment area to another. Dead mice were first observed in the central floor area on Day 4 of the treatment period, although few cadavers were found during the daily search. It would be expected that most mice would have died in their harbourage. <u>Post treatment</u> Light take of census bait was recorded around the ground floor, grain cleaner platform and the bin tops platform but increasing bait consumption over the census period in the conveyor trench and top platform suggested that recruitment of mice was continuing. Activity across sand patches consisted mainly of a single line of tracks which again suggested the widespread movement of one or two transient animals.
Conclusion	The mouse infestation encountered at this trial site was typical of those found on commercial and agricultural premises throughout Europe. The infestation was moderate to high and the mice were provided with plentiful alternative food. Cereal grain, their natural diet, was available in abundance and although usage of the novel pasta bait was significantly less than the whole wheat census bait, a high level of control was achieved in the main areas in less than 3 weeks treatment. Generally, most rodent infestations occurring in or around commercial and agricultural premises do not constitute discrete populations and recruitment is common. This was true for this particular infestation. The mice present at the two extreme levels – the sub-floor conveyor trench and the top conveyor platform - were subject to continual recruitment and this influenced the overall success rate. However, the independent consideration of each level showed high levels of control had been achieved in the main floor areas.
Proposed efficacy specification	The product showed a high level of control of an infestation of House mice.

Evaluation by Competent Authorities

	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 89.8% Efficacy based on total track score = 87.9%
Conclusion	Agree with applicant's version.

Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (7) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy** Field trial on the efficacy of [redacted] on Rats	**Data**

	Reference	**Official use only**
Reference	[redacted] (1995) Field trial report to determine the efficacy of [redacted] containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding [redacted] Report Number: RFT/95/1906	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter of access	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).	
Deviations	No strict guidelines were followed.	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.005% w/w	
Physical state and nature	Red paste bait	
Monitoring of active substance concentration	No	
Method of analysis	N/A	
Reference substance		
Method of analysis for reference substance	N/A	
Testing procedure		
Test population / inoculum / test organism	The field study was designed to investigate the efficacy of [redacted] containing 0.005 % brodifacoum, for the control of an infestation of warfarin-resistant Norway rats infesting the buildings of a mixed beef/dairy farm on the [redacted] the UK. The area is known as the Welsh resistance area and rat populations include a proportion of animals, often up to 90%, that are resistant to the first generation anticoagulants, such as warfarin and chlorophacinone.	
Test system	Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site. Builder's sharp sand was used as the material for tracking patches. These patches measured 15.0 x 10.5 cm. A balance was used that was capable of weighing up to2 kg in graduations of 2 or 5 g. Pre-treatment census A thorough survey of the site was made to provide data for the	

	site plans and to record areas of particular importance, such as alternative food sources for the infestation. The distribution and degree of rodent infestation was assessed. Empty census bait trays and tracking patches were laid 3 days before the placement of census baits. On the first day of the trial the census bait trays were filled with 200g of plain wheat and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established. <u>Pre-treatment lag period</u> At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed from the trial site. With the exception of the placement of empty bait trays on Day 10, the site was left undisturbed for a period of 10 days (Day 4 to Day 14). <u>Poison bait treatment</u> Poison bait trays were placed in different positions near to those used for the census bait and protected from the weather and non-target animals in the same way as were the census bait points. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had been a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point. Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife were made by conducting an inspection of the site and of the areas of land adjacent to it. The poison treatment was concluded and all toxic baits removed from the site when the track score and bait consumption reached zero. <u>Post treatment lag period</u> A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census bait. Empty bait trays were laid throughout the site 3 days before placement of the census baits, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them. <u>Post treatment census</u> After the lag period finished, 200 g fresh whole wheat was added to each bait point. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
Application of TS	In bait trays in the field.
Test conditions	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait but in close proximity and were protected from the weather and from non-target animals.
Duration of the test / Exposure time	The total test period was 36 days Poison baiting period was 15 days

Section B5.10.2 (7) **Annex Point IIB5.10** **TNsG: Pt. I-B5.10, Pt. III-Ch. 6**	**Efficacy** Field trial on the efficacy of [redacted] on Rats	**Data**

Number of replicates performed	The test was only performed once but there were 30 bait trays involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if [redacted] was as palatable as the untreated wheat bait and to estimate the rat population.
Examination	
Effect investigated	mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait tray was measured and the number of sites visited too, which gives an indication of the number of rats. A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
Post monitoring of the test organism	Yes. A 4 day post-treatment census was carried out.
	Results
Efficacy	Efficacy of the poison bait on the total census bait take was 99.8% Efficacy of the poison bait on the total track score was 98.9%
Dose/Efficacy curve	N/A
Begin and duration of effects	A total of 1634 g of rodenticide bait was taken from 23 of the 30 bait points on the first day of baiting. This was more than the amount of census bait eaten in an equivalent stage of the pre-baiting period (493g). This indicates that the rats found the pasta bait more palatable than the plain whole wheat used as the pre-treatment census bait. The quantity of [redacted] consumed in a 24-hour period increased to a maximum on treatment day 2 when 1855 g was consumed and then declined steadily until the end of the treatment period. The quantity of bait eaten on Day2 was not dissimilar to that eaten on Day 1, which indicated that the rats found the poison bait no less attractive than their normal diet. By the fifteenth day of poisoned baiting, all bait takes ceased. Tracking activity showed a similar pattern. A total of 11 dead rats and 2 dead mice were recovered from the site.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of [redacted] likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A

Section B5.10.2 (7) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy** Field trial on the efficacy of [redacted] on Rats	**Data**

Tabular and/or graphical presentation of the summarised results

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Maximum census bait take (g)	2154	11.0	99.5
Total census bait take (g)	5112	11.0	99.8
Mean census bait take (g)	1270	2.75	99.8
Maximum track score	32	1	96.9
Total track score	93	1	98.9
Mean track score	23.25	0.25	98.9

Efficacy limiting factors

Occurrences of resistances N/A

Other limiting factors N/A

Relevance of the results compared to field conditions

Reasons for laboratory testing N/A

Intended actual scale of biocide application N/A

Relevance compared to field conditions N/A

Application method N/A

Test organism N/A

Observed effect N/A

Relevance for read-across N/A

Materials and methods

Applicant's Summary and conclusion

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the rats, for example, areas of alternative sources of food. The survey confirmed the presence of a severe rat infestation in the study area. The position of bait placements and rodent tracking patches was determined and marked on copies of the site map.

Pre-treatment census

The census bait trays were charged with 200g of dry whole wheat and the tracking trays were set with fresh sharp sand on the first

day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but no tracking patches) were removed from the trial site. The site was left undisturbed for ten days, apart from the placement of the empty bait trays which were introduced to the site on Day 10, 4 days before poison baiting commenced.

Poison bait treatment

Poison bait trays were laid out in different positions near to those used for the census bait. The poisoned bait trays were protected from the weather and from non-target animals in the same way as the census bait points. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been a partial take of bait, old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point. Daily searches were made for dead animals, whether rodents or non-target organisms.

The poison treatment was concluded and all poisoned baits were removed from the site when the track score and census bait consumption reached nil.

Post-treatment lag period

A lag period of four days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post treatment census baiting. During this period, empty bait trays were laid throughout the site in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

After the lag period finished, whole, fresh wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.

Reliability 1

Assessment of efficacy, data analysis and interpretation

Initial Infestation

It was estimated from the maximum of 2154g of wheat census bait that was consumed in a 24 hour period that there was a severe infestation present in the study area. Calculations suggest that there were about 154 rats on the site but this is a minimum estimate as it is based on the assumption that the rats feed entirely on census bait and it is likely that the census bait comprised only a proportion of the total food consumption of the rats.

Poison baiting

The total bait consumed on the first day of baiting was 1634 g. This was taken from 23 of the 30 bait stations. The amount consumed increased to a maximum on treatment day 2 and then declined steadily until the end of the treatment period.

Section B5.10.2 (7) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy** Field trial on the efficacy of [redacted] on Rats	**Data**

	This showed that the rats found the poison bait no less palatable than their normal diet. By the fifteenth day of poison baiting, all bait takes ceased. Tracking activity showed a similar pattern. A total of 11 dead rats and 2 dead mice were recovered from the site. <u>Post treatment</u> During the post-treatment census period, take was recorded from 1 of the 30 census bait points on day 3 of the lag period. Similarly, activity was recorded on 1 of the 30 tracking patches.
Conclusion	The rat infestation encountered at this trial site was typical of those found on commercial, domestic and agricultural premises throughout Europe. The infestation was heavy and the rats were abundantly supplied with alternative sources of food throughout the trial site. Despite this, they fed freely on the poisoned bait from the first day of application, indicating that the bait was highly palatable to rats. A very high level of control of this warfarin-resistant Norway rat infestation was achieved after only 15 days of baiting.
Proposed efficacy specification	The product showed a high level of control of a heavy infestation of warfarin-resistant Brown rats.

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 99.8% Efficacy based on total track score = 98.9%
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (8) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	**Efficacy** Field trial on the efficacy of [redacted] on Rats	**Data**

	Reference	**Official use only**
Reference	[redacted] (1997) Field trial report to determine the efficacy of [redacted], containing 0.005% brodifacoum, for the control of an Infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding [redacted] Report Number: RFT/97/1935	
Data protection	Yes	
Data owner	[redacted]	
Companies with letter of access	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
Guideline study	Trial procedure broadly followed the guidelines set down by MAFF (1990) AND EPPO (1982).	
Deviations	No strict guidelines were followed.	
	Method	
Test Substance (Biocidal Product)	As given in section 2	
Trade name/ proposed trade name	[redacted]	
Composition of Product tested	Brodifacoum 0.005% w/w	
Physical state and nature	Red paste bait	
Monitoring of active substance concentration	No	
Method of analysis	N/A	
Reference substance		
Method of analysis for reference substance	N/A	
Testing procedure		
Test population / inoculum / test organism	The field study was designed to investigate the efficacy of [redacted] containing 0.005 % brodifacoum, for the control of an infestation of warfarin-resistant Brown rats in farm buildings.	
Test system	Bait trays were used to facilitate the placement of both census and poisoned baits and the weighing and removal of the baits from the site. Builder's sharp sand was used as the material for tracking patches. These patches measured 15.0 x 10.5 cm. A balance was used that was capable of weighing up to 2 kg in graduations of 2 g up to 500 g and in 5 g intervals above 500 g. <u>Pre-treatment census</u> A thorough survey of the site was made before the start of the trial to identify alternative food sources and assess the distribution and degree of rodent infestation. On the first day of the trial the census bait trays were filled with	

Section B5.10.2 (8) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	Efficacy Field trial on the efficacy of [redacted] on Rats	Data

	200g of plain wheat and the tracking patches set out with fresh sharp sand. During the next four days, bait consumption at each bait point was determined and a tracking score established. Pre-treatment lag period At the end of the pre-treatment census, all bait trays (but not tracking patches) were removed and the site was left undisturbed for 6 days, when empty bait trays were reintroduced to the site and the treatment phase commenced four days later. Poison bait treatment Poison bait trays were placed in different positions to those used for the census bait. Daily site visits were made to determine bait consumption and rodent tracking scores. Where there had a partial take of bait, the old bait, after weighing, was mixed with fresh clean bait and replaced in the bait point. Throughout the main portion of the trial active searches for dead animals, whether rodents, non-target animals or wildlife were made by conducting an inspection, not only of the immediate trial area but by means of a wider site survey. The poison treatment was concluded and all toxic baits removed from the site when bait consumption and tracking scores reached nil. Post-treatment lag period A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census bait. Empty bait trays were laid throughout the site, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them. Post-treatment census After the lag period finished, plain wheat was added to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
Application of TS	In bait trays in the field.
Test conditions	Bait applications were made strictly in accordance with the proposed product label. Following the MAFF/EPPO guidelines, the bait trays were not placed in the same position as the census bait, but in close proximity and were protected from the weather and from non-target animals.
Duration of the test / Exposure time	The total test period was 33 days Poison baiting period was 12 days
Number of replicates performed	The test was only performed once but there were 19 bait trays involved in the poison baiting period.
Controls	Pre-treatment census data were collected to show if the poisoned [redacted] was just as palatable as the untreated wheat bait and to estimate the rat population.
Examination	
Effect investigated	Mortality
Method for recording / scoring of the effect	The weight of bait eaten from each bait tray was measured and the number of sites visited too, which gives an indication of the number of rats.

Section B5.10.2 (8) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	Efficacy Data Field trial on the efficacy of [redacted] on Rats

	A track score was also provided which is rated 1-4 to give a field indication.
Intervals of examination	N/A
Statistics	Estimated % efficacy = 100 x [post-treatment census data/ pre-treatment census data]
Post monitoring of the test organism	Yes. A 4-day post-treatment census was carried out.
	Results
Efficacy	Efficacy of the poison bait on the total census bait take was 100% Efficacy of the poison bait on the maximum track score was 100%
Dose/Efficacy curve	N/A
Begin and duration of effects	From the outset, rats fed on the bait and 1794 g was consumed from 15 of the 19 bait trays over the first 24-hour period increasing to a maximum of 1901g on day 2 then declined steadily until the end of the treatment period. Track scores showed a similar pattern. The remaining bait was picked up at the end of the treatment period when recording was completed.
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	There was no evidence from this trial that the application of [redacted] likely to pose any significant hazard to wildlife, domestic and companion animals when applied as directed on the label.
Other effects	None
Efficacy of the reference substance	N/A
Tabular and/or graphical presentation of the summarised results	

Parameter	Pretreatment data	Post-treatment data	Estimated % efficacy
Mean census bait take	601	0	100
Maximum census bait take (g)	945	0	100
Total census bait take (g)	2404	0	100
Mean track score	14	0	100
Maximum track score	18	0	100
Total track score	56	0	100

Efficacy limiting factors	
Occurrences of resistances	N
Other limiting factors	N
R	[illegible]
Reasons for laboratory	N/A

Section B5.10.2 (8) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	Efficacy Field trial on the efficacy of [redacted] on Rats	Data

testing	
Intended actual scale of biocide application	N/A
Relevance compared to field conditions	N/A
Application method	N/A
Test organism	N/A
Observed effect	N/A
Relevance for read-across	N/A

Applicant's Summary and conclusion

Materials and methods

The procedure followed six main stages as follows:

Site survey, census baits and rodent tracking patches

The survey looked for particular areas of importance to the rats, for example, areas of alternative source of food. The survey confirmed the presence of a moderate infestation of rats that was evenly distributed across the site. The position of bait placements and rodent tracking patches was determined and marked on copies of the site map.

Pre-treatment census

The census bait boxes were charged with 200g of plain wheat and the tracking trays were set with fresh sharp sand on the first day of the trial. Over the next four days the weight of the bait taken was calculated and recorded. Fresh clean bait replaced any bait that was taken. The track score at each tracking patch was also established.

Pre-treatment lag phase

On completion of the pre-treatment census, all bait trays (but not tracking patches) were removed from the trial site. With the exception of the placement of the empty poison bait trays after 6 days (Day 10 of the trial), the site was left undisturbed for a period of 10 days. Poison bait boxes were laid out in different positions to those used for the census bait.

Poison bait treatment

Bait was applied in bait trays, which were protected from the weather and from non-target animals in the same way as the census bait points. Daily visits to the site were made to determine poisoned bait consumption and rodent tracking scores. Where there had been significant take of bait, more bait was added. Daily searches were made for dead animals, whether rodents or non-target organisms.

Post-treatment lag period

A lag period of 4 days was implemented to allow animals that had taken a lethal dose of poison to die and those that had taken a sub-lethal dose to recover sufficiently to feed on the post-treatment census baiting. During the lag period, empty bait trays were laid throughout the site, in the same positions as in the pre-treatment census, to allow rodents some time to become accustomed to them.

Post-treatment census

After the lag period finished, 200 g fresh whole wheat was added

Section B5.10.2 (8) Annex Point IIB5.10 TNsG: Pt. I-B5.10, Pt. III-Ch. 6	Efficacy Field trial on the efficacy of [redacted] on Rats	Data

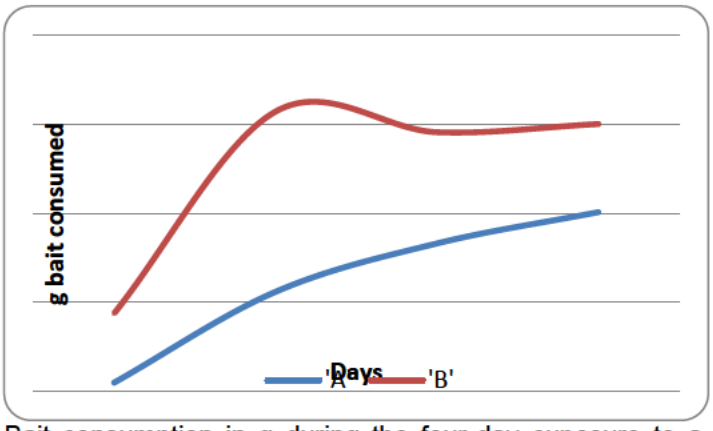
	to each bait point as in the pre-treatment census. Tracking patches were also refreshed. For a period of four days, bait was replenished where necessary and data were recorded in the same way as for the pre-treatment census data.
Reliability	1
Assessment of efficacy, data analysis and interpretation	Initial Infestation It was estimated from the maximum census bait take in 24 hours of 945g that a moderate rat infestation was present at the site (68 rats). It is considered likely that the census bait comprised only a proportion of the rats' daily food intake, as alternative foodstuffs were readily available. Therefore the number present was considerably more than the estimate. Poison baiting Rats fed on the bait from the outset and 1794g was consumed from 15 of the 19 bait trays over the 24-hour period of baiting, increasing to a maximum on Day 2 of 1901g. The trend in bait take then declined steadily until the end of the treatment period. This indicated that the rats found the novel pasta bait more palatable than the plain wheat census bait. The palatability of the bait overcame their natural caution to novel foodstuffs. By the twelfth day of baiting all bait takes ceased. Tracking activity showed a similar pattern. A total of 10 dead rats and 2 dead mice were recovered from the site. Post-treatment During the census period no take was recorded from any of the 19 census bait points. Similarly, no activity was recorded on any of the 19 tracking patches.
Conclusion	The rat infestation encountered at this trial site was typical of those found on other agricultural premises. The infestation was moderate and although alternative foodstuffs were readily available, the rats fed freely on the poisoned bait. The infestation was eliminated very quickly and poison bait consumption ceased only 12 days after the start of baiting. Total control of this warfarin-resistant Norway rat infestation was achieved.
Proposed efficacy specification	The product showed total control of an infestation of Brown rats.

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	Efficacy based on total census bait take = 100% Efficacy based on maximum track score = 100%
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*

Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B5.10.2 (9) Annex Point IIB V.5.11	Efficacy Data
	Laboratory Study of Pasta Bait (Rats)

	Reference	Official use only
Reference	[redacted] 2010, The Effects of Exposure to Extreme Environmental Conditions on the Palatability of Pasta Bait. – January 2010, Pelgar International - Report number TKI/PI/100126/SimSew/PB.	
Data protection	Yes	
Data owner	[redacted]	
Companies with access to data	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
Guideline study	Study was not carried out to GLP standards but was performed to normal QA standards.	
Deviations	N/A	
	Method	
Test Substance (Biocidal Product)		
Trade name/ proposed trade name	Pasta blank bait	
Composition of Product tested	Blank pasta formulation with no AS concentrate added	
Physical state and nature	Solid paste	
Monitoring of active substance concentration	No	
Method of analysis	N/A	
Reference substance	No	
Method of analysis for reference substance	N/A	
Testing procedure		
Test population / inoculum / test organism	Captive semi-wild brown rats (*Rattus norvegicus*)	
Test system	The samples were kept in the dark in an environmentally controlled room at 30±3ºC and greater than 90% RH for 5 days. Comparative palatability was assessed using a mixed population of rats held in an open pen of approximately 120 square metres.	
Application of TS	N/A	
Test conditions	30±3ºC and greater than 90% RH.	
Duration of the test / Exposure time	5 days treatment of pasta. Palatability tested over 4 days.	
Number of replicates performed	N/A	
Controls	No separate controls	
Examination		
Effect investigated	Palatability	
Method for recording / scoring of the effect	During storage in sewer conditions, samples were examined every 24 hours to ensure equipment was functioning correctly and to record any change in the integrity of the product. Information regarding storage conditions were monitored automatically and	

Section B5.10.2 (9) Annex Point IIB V.5.11	Efficacy Data
	Laboratory Study of Pasta Bait (Rats)
	stored electronically. In the palatability part of the study, baits were weighed twice daily and replenished where necessary.
Intervals of examination	Storage – every 24 hours Palatability – baits weighed twice daily, at 09.00 and 21.00h.
Statistics	None applied
Post monitoring of the test organism	N/A
	Results
Efficacy	
Dose/Efficacy curve	N/A
Begin and duration of effects	N/A
Observed effects in the post monitoring phase	N/A
Effects against organisms or objects to be protected	The sewer-treated bait comprised 71.93% of the total bait consumed over the entire 4-day period of the trial. This bait was clearly preferred by the Brown rats.
Other effects	No other effects noted
Efficacy of the reference substance	N/A.
Tabular and/or graphical presentation of the summarised results	 Bait consumption in g during the four-day exposure to a captive population of Brown rats.
Efficacy limiting factors	N/A
Occurrences of resistances	N/A
Other limiting factors	N/A
	Relevance of the results compared to field conditions
Reasons for laboratory testing	To evaluate the effects on bait palatability of exposure to high humidity and temperature conditions similar to those likely to be found in sewers in order to confirm that the bait is suitable for use in sewers.
Intended actual scale of biocide application	Rat control in sewers.

Section B5.10.2 (9) Annex Point IIB V.5.11	Efficacy Data Laboratory Study of Pasta Bait (Rats)	
Relevance compared to field conditions	The conditions used are designed to simulate the conditions found in a sewage inspection chamber.	
Application method	Yes	
Test organism	N/A	
Observed effect	The sewer-treated bait was more palatable than the bait stored in dry conditions.	
Relevance for read-across	Yes. The data could be used to support similar paste bait formulations containing any AS.	
	Applicant's Summary and conclusion	
Materials and methods	The materials used appear valid, as does the method used. In this case the lack of GLP does not appear to be a problem as it was performed to normal QA standards and the report is signed for authenticity.	
Reliability	2	
Assessment of efficacy, data analysis and interpretation	The increased palatability, when compared with fresh blank bait, indicates that the paste bait would be effective within the criteria required i.e. when used in sewers.	
Conclusion	The lab test is valid for the kind of environment likely to be encountered in sewage treatment plants. The formulation used in the paste maintains palatability under the conditions required.	
Proposed efficacy specification	N/A	

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	March 2013.
Materials and Methods	Agree with applicant's version.
Results and discussion	No detrimental effect on palatability following storage of whole wheat bait in sewer conditions for 5 days (90% R.H. minimum temp. 28^{o}C). The sewer-treated bait comprised 71.93% of the total bait consumed.
Conclusion	Agree with applicant's version.
Reliability	1
Acceptability	Acceptable.
Remarks	None.
	Comments from ... (specify)
Date	*Give date of comments submitted*
Materials and Methods	*Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Summary and conclusion	*Discuss if deviating from view of rapporteur member state*

Section B6.1.1	Acute Toxicity	
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})	
	Reference	**Official use**

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})
Reference	[redacted] 2007) Brodifacoum paste: Acute Oral Toxicity in the Rat – Fixed Dose Method. [redacted] Report No. 2254/0025
Data protection	Yes
Data owner	[redacted]
Companies with Access to data	None
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval
	Guidelines and Quality Assurance
Guideline study	OECD 420 Method B1 *bis* Acute Toxicity (Oral) of Commission Directive 2004/73/EC
GLP	Yes
Deviations	No
	MATERIALS AND MethodS
Test material	Brodifacoum 0.005% w/w paste bait ([redacted]
Lot / Batch number	61509601
Specification	The product used in the study is a paste bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report
Description	Blue soft paste
Purity	0.005% brodifacoum
Stability	Stable under test conditions
Test Animals	
Species	Rats
Strain	Sprague-Dawley CD (Crl:CD® (SD) IGS BR)
Source	[redacted]
Sex	Female
Age/weight at study initiation	Age: Young adults, 8 – 12 weeks Weight: Female 187 - 217g
Number of animals per group	1 animal treated, then a further 4 animals treated
Control animals	No
Administration/ Exposure	Oral
Postexposure period	14 days
	Oral
Type	Gavage
Concentration	0.005% w/w
Vehicle	Arachis oil BP
Concentration in vehicle	200 mg/ml
Total volume applied	Single dose of 2000 mg/kg in 10 ml/kg of arachis oil BP
Controls	None
Examinations	Clinical observations, mortality, body weight, necropsy
Method of determination of LD_{50}	Estimated. Classified using the Globally Harmonised Classification System
Further remarks	None
	Results and Discussion
Clinical signs	There were no deaths. There were no signs of systemic toxicity.

only

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})
	All animals showed expected gains in bodyweight over the study period. No abnormalities were noted at necropsy.
Pathology	There were no treatment related findings in animals.
Other	No other significant effects noted.
LD_{50}	Females: estimated to be > 2000 mg/kg bodyweight (Globally Harmonised Classification System – Unclassified)
	Applicant's Summary and conclusion
Materials and methods	Determination of oral LD_{50} in the rat according to OECD Guideline No. 420 and Method B1 bis Acute Toxicity (Oral) of Commission Directive 2004/73/EC A single fasted nulliparous, non-pregnant female rat was treated with the test material at a dose level of 2000 mg/kg bodyweight. This was followed by a further group of four fasted females at the same dose level. The test material was administered orally as a suspension in arachis oil BP. The concentration of the test suspension was 200 mg/ml and each rat was dosed with a volume of 10 ml/kg bodyweight. All animals were dosed once only by gavage using a metal cannula attached to a graduated syringe. Clinical observations were made 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for fourteen days. Morbidity and mortality checks were made twice daily. Individual bodyweights were recorded prior to dosing and seven and fourteen days after treatment. At the end of the observation period, the animals were killed by cervical dislocation. All animals were subjected to gross pathological examination. This consisted of an external examination and opening of the abdominal and thoracic cavities. The appearance of any macroscopic abnormalities was recorded. No tissues were retained.
Results and discussion	Following a dose of 2000 mg/kg to all animals, none of the animals died. There were no signs of systemic toxicity. All animals showed expected gains in bodyweight over the study period. There were no abnormalities noted at necropsy.
Conclusion	Acute oral LD_{50} for the female rat is estimated to be > 2000 mg/kg
Reliability	1
Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*22 March 2013*
Materials and Methods	Adopt applicants version
Results and discussion	Adopt applicants version
Conclusion	Adopt applicants version
Reliability	1
Acceptability	Acceptable
Remarks	*Is the product water or oil based .Dissolution in arachis oil is only appropriate for oil based preparations?*
	Comments from ...
Date	*Give date of comments submitted*

Section B6.1.1	**Acute Toxicity**
Annex Point IIA VI.6.1.1	Acute oral toxicity test in the rat (LD_{50})
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B6_1-1. Table for Acute Toxicity

Dose [unit]	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*
2000 mg/kg	0/5	-	No abnormalities detected
LD_{50} value	Females: > 2000 mg/kg		

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat

	Reference	**Official use only**
Reference	[redacted] 2007) Brodifacoum Pastes: Acute Dermal Toxicity (Limit Test) in the Rat, [redacted] Report No. 2254/0026	
Data protection	Yes	
Data owner	[redacted]	
Companies with Access to data	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
	Guidelines and Quality Assurance	
Guideline study	OECD 402 Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC	
GLP	Yes	
Deviations	No	
	MATERIALS AND MethodS	
Test material	Brodifacoum 0.005% w/w paste bait [redacted]	
Lot / Batch number	61509601	
Specification	The product used in the study is a paste bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report	
Description	Blue paste bait	
Purity	0.005% brodifacoum	
Stability	Stable under test conditions	
Test Animals		
Species	Rats	
Strain	Sprague-Dawley CD (Crl:CD® (SD) IGS BR)	

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat
Source	[redacted]
Sex	Male and Female
Age/weight at study initiation	Age: Young adults, 8 – 12 weeks Weight: Male 245g - 263g Female 212g – 228g
Number of animals per group	10 animals/group (5 male and 5 female)
Control animals	No
Administration/ Exposure	Dermal
Postexposure period	14 days
	Dermal
Area covered	Approx 10% of the total body surface area
Occlusion	Semi-occlusive
Vehicle	No vehicle used (material moistened with arachis oil BP)
Concentration in vehicle	Not applicable
Total volume applied	2000 mg/kg
Duration of exposure	24 hours
Removal of test substance	Residual formulation was cleansed with swabs of absorbent cotton wool moistened with distilled water.
Controls	None
Examinations	Clinical observations, mortality, body weight, necropsy
Method of determination of LD_{50}	Not stated
Further remarks	None
	Results and Discussion
Clinical signs	There were no deaths. There were no signs of systemic toxicity. There were no signs of dermal irritation. All animals showed expected gains in bodyweight over the study period.
Pathology	No abnormalities were noted at necropsy.
Other	No other significant effects were noted.
LD_{50}	Males and females: > 2000 mg/kg
	Applicant's Summary and conclusion
Materials and methods	The study was conducted according to OECD 402 and Method B3 Acute Toxicity (Dermal) of Commission Directive 92/69/EEC. Five male and five female rats were used in this study. On the day before treatment, the back and flanks of each animal were clipped free of hair. The dose level, 2000 mg/kg of the formulation moistened with arachis oil BP, was applied as evenly as possible to an area of shorn skin (approximately 10% of the total body surface area). A piece of surgical gauze was placed over the treatment area and semi-occluded with a piece of self-adhesive bandage. The animals were caged individually for the 24-hour exposure period. Shortly after dosing, the dressings were examined to ensure that they were securely in place. After the 24-hour contact period, the bandage was carefully removed and the treated skin and surrounding hair wiped with cotton wool moistened with distilled water to remove any residual test material.

Section B6.1.2	**Acute Toxicity**
Annex Point IIA VI.6.1.2	Acute dermal toxicity study in the rat
	The animals were observed for deaths or overt signs of toxicity 0.5, 1, 2 and 4 hours after dosing and subsequently once daily for 14 days. After removal of the dressings and subsequently once daily for fourteen days, the test sites were examined for evidence of primary irritation and scored according to the Draize scale for erythema and eschar formation and oedema formation. Any other skin reactions, if present were also recorded. Individual bodyweights were recorded prior to application of the test material on Day 0 and on Days 7 and 14. At the end of the study all animals were killed humanely and subjected to gross necropsy. This consisted of an external examination and opening of the abdominal and thoracic cavities. The appearance of any macroscopic abnormalities was recorded. No tissues were retained.
Results and discussion	There were no deaths. There were no signs of systemic toxicity. There were no signs of dermal irritation. All animals showed expected gains in bodyweight over the study period. No abnormalities were noted at necropsy. The acute dermal LD_{50} for the formulation to male and female rats was found to be greater than 2000 mg/kg bodyweight.
Conclusion	Acute dermal LD_{50} for male and female rats is > 2000 mg/kg
Reliability	1
Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*22 March 2013*
Materials and Methods	*Adopt Applicants version*
Results and discussion	Adopt Applicants version
Conclusion	Adopt Applicants version.
Reliability	1
Acceptability	
Remarks	*Is the product water or oil based .Dissolution in arachis oil is only appropriate for oil based preparations?*
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B6_1-1 Table for Acute Toxicity

Dose [unit]	*Number of dead / number of investigated*	*Time of death (range)*	*Observations*

2000 mg/kg	0/10	-	There were no signs of dermal irritation.
LD_{50} value	The acute dermal LD_{50} for formulation to male and female rats is greater than 2000 mg/kg		

Section B6.1.3 **Annex Point IIB VI.6.1.3**	**Acute toxicity - Inhalation**	
	Justification for non-submission of data	Official use only
Other existing data [X] **Limited exposure [X]**	**Technically not feasible [X] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Active substance is of low vapour pressure at NTP. The product is formulated as a paste bait using mostly food grade materials , which are solid at NTP and of low vapour pressure. The paste bait is not friable or dusty such that airborne particles can be produced. It is therefore not respirable, does not produce respirable particles and does not produce respirable vapours. An acute inhalation study on the biocidal product is not scientifically justified as the ingredients in the product do not enhance the toxicity of the active substance, and are not themselves classified, so these end points can be satisfied by the dose-response relationship established for the technical active ingredient. Due to the low vapour pressure of the a.s and the physical state of the product, the amount of potential exposure through inhalation is minimal. Acute inhalation toxicity of the product can be extrapolated from data on the technical active substance.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	22 March 2013	
Evaluation of applicant's justification	Justification is acceptable	
Conclusion	*Justification is acceptable*	
Remarks		
	Comments from ...	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks	*Discuss if deviating from view of rapporteur member state*	

Section B6.1.4 **Annex Point IIB VI.6.1.4**	**Acute toxicity - For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate**	
	Justification for non-submission of data	Official

Section B6.1.4 Annex Point IIB VI.6.1.4	**Acute toxicity - For biocidal products that are intended to be authorised for use with other biocidal products, the mixture of products, where possible, shall be tested for acute dermal toxicity and skin and eye irritation, as appropriate**	
		use only
Other existing data [ ] Limited exposure [X]	**Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]**	
Detailed justification:	Brodifacoum paste bait is not intended to be authorised for use with other biocidal products. Therefore these data are not required.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	22 March 2013	
Evaluation of applicant's justification	Justification is acceptable	
Conclusion	*Justification is acceptable*	
Remarks		
	Comments from ...	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks	*Discuss if deviating from view of rapporteur member state*	

Section B6.2 (1) **Annex Point IIB VI.6.2**	**Acute Dermal Irritation** Skin irritation to the rabbit

	Reference	**Official use only**
Reference	[redacted] (2007) Brodifacoum paste: Acute dermal irritation in the rabbit. [redacted] Report No. 2254/0027	
Data protection	Yes	
Data owner	[redacted]	
Companies with access to data	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
	Guidelines and Quality Assurance	
Guideline study	OECD 404 Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC	
GLP	Yes	
Deviations	No	
	MATERIALS AND MethodS	
Test material	Brodifacoum 0.005% w/w paste bait [redacted]	
Lot/Batch number	61509601	
Specification	The product used in the study is a paste bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report.	
Description	Blue soft paste	
Purity	0.005% brodifacoum	
Stability	Stable under test conditions	
Test Animals		
Species	Rabbit	
Strain	New Zealand White	
Source	Accredited supplier	
Sex	Male	
Age/weight at study initiation	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg	
Number of animals per group	3	
Control animals	No	
Administration/ Exposure	Dermal	
Application		
Preparation of test substance	Test substance, 0.5 ml used as supplied.	
Test site and Preparation of Test Site	Hair was removed from the dorsal/flank area of each animal	
Occlusion	Not stated	
Vehicle	None.	
Concentration in vehicle	n/a	
Total volume applied	0.5 ml test material	
Removal of test substance	The application site was cleansed free using clean swabs of cotton wool soaked in distilled water	
Duration of exposure	4 h	

Section B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit
Postexposure period	3 days
Controls	None
Examinations	
Clinical signs	Not stated
Dermal examination	Yes
Scoring system	Draize method
Examination time points	60min, 24h, 48h, 72h
Other examinations	
Further remarks	
	Results and Discussion
Average score	
Erythema	Average score for all animals at 24h = 1.7, 48h = 0.7, 72h = 0
Oedema	Average score for all animals at 24h = 0.7, 48h = 0, 72h = 0
Reversibility	N/A
Other examinations	
Overall result	Mild irritant
	Applicant's Summary and conclusion
Materials and methods	The study follows OECD guideline 404 and Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC 0.5 ml of formulation was applied to the test site of 2.5 cm x 2.5 cm. The test site was covered with a piece of cotton gauze, secured in position with surgical adhesive tape and wrapped in an elasticated corset and the dressings left in position for 4 hours. The degree of erythema and oedema was assessed after 60 mins, 1, 2 and 3 days after removal of the dressings. A mean erythema and oedema score was calculated by adding together the individual scores at the 1, 2 and 3 day readings and dividing by nine (one site on each of three rabbits scored 1, 2 and 3 days after treatment)
Results and discussion	Following a single 4 hour application of 0.005% w/w brodifacoum paste formulation, very slight to well-defined erythema was noted at all treated skin sites at the 24-hour observation with very slight erythema noted at two treated skin sites at the 48-hour observation. Very slight oedema was noted at two treated skin sites at the 24-hour observation. One treated skin site appeared normal at the 48-hour observation and the remaining two treated skin sites appeared normal at the 72-hour observation.
Conclusion	The test material produced a primary irritation index of 1.2 and was classified as a mild irritant to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.
Reliability	1
Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*22 Match 2013*
Materials and Methods	*Adopt applicants version*
Results and discussion	Adopt applicants version.

Section B6.2 (1)	**Acute Dermal Irritation**
Annex Point IIB VI.6.2	Skin irritation to the rabbit

Conclusion	Adopt applicants version.
Reliability	1
Acceptability	Acceptable
Remarks	Is the dressing occlusive or semi occlusive? No significant effect expected on the results.
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A6_1-4S-1. Table for skin irritation study

score (average animals investigated)		time	Erythema	Edema
average Draize (0 to maximum 4)	score scores	60 min	0	0
		24 h	1.7	0.7
		48 h	0.7	0
		72 h	0	0
average score		24h, 48h, 72h	0.8	0.2
reversibility: *			c	c
average time for reversibility			72 h	48 h

* c : completely reversible
n c : not completely reversible
n : not reversible

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit

	Reference	**Official use only**
Reference	[redacted] (2007) Brodifacoum paste: Acute Eye Irritation in the Rabbit [redacted] Report No. 2254/0028	
Data protection	Yes	
Data owner	[redacted]	
Companies with access to data	None	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its product national approval	
	Guidelines and Quality Assurance	
Guideline study	OECD 405 Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC	
GLP	Yes	
Deviations	No	
	MATERIALS AND MethodS	
Test material	Brodifacoum 0.005% w/w paste bai [redacted]	
Lot/Batch number	61509601	
Specification	The product used in the study is a paste bait of the a.s (0.005% w/w) in solvents. The details of the composition of the product are not provided in the report.	
Description	Blue soft paste bait	
Purity	0.005% brodifacoum	
Stability	Stable under test conditions	
Test Animals		
Species	Rabbit	
Strain	New Zealand White	
Source	Accredited supplier, unnamed	
Sex	Male	
Age/weight at study initiation	Young adult. 12 – 20 weeks Initial body weights: 2.0 to 3.5 kg	
Number of animals per group	3	
Control animals	The left eye of each rabbit was left untreated and served as a control	
Administration/ Exposure		
Preparation of test substance	Test substance was used as supplied.	
Amount of active substance instilled	0.1ml	
Exposure period	Eye was held closed for 1 second after instillation of the test substance.	
Postexposure period	3 days	
Examinations		
Ophthalmoscopic examination	yes	
Scoring system	Draize	
Examination time points	60min, 24h, 48h and 72h	

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit
Other investigations	
Further remarks	
	Results and Discussion
Clinical signs	No corneal or iridial effects were noted during the study. Minimal to moderate conjunctival irritation was noted in all treated eyes one hour after treatment and in 2 eyes at the 24-hour observation. Minimum conjunctival irritation persisted in one treated eye at the 48-hour observation. One treated eye appeared normal at the 24-hour observation, one other treated eye appeared normal at the 48-hour observation and the remaining treated eye appeared normal at the 72-hour observation.
Average score	
Cornea	Average score for all animals at 24h=0, 48h=0, 72h=0
Iris	Average score for all animals at 24h=0, 48h=0, 72h=0
Conjunctiva	
Redness	Average score for all animals at 24h=1, 48h=0.3, 72h=0
Chemosis	Average score for all animals at 24h=0.3, 48h=0, 72h=0
Reversibility	Yes
Other	
Overall result	Mild irritant
	Applicant's Summary and conclusion
Materials and methods	The study follows OECD guideline 405 and Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC 0.1ml of 0.005% w/w brodifacoum paste bait was instilled into the right eye of one rabbit. After consideration of the ocular responses produced in the first treated animal, two additional animals were treated. The examination period was extended for 3 days. Assessment of the initial pain reaction was made using a standard six-point scale.
Results and discussion	Instillation of 0.1ml 0.005% w/w brodifacoum paste bait caused slight initial pain in all three animals. The application produced minimal to moderate conjunctival irritation. One treated eyes appeared normal at the 24-hour observation, one other treated eye appeared normal at the 48-hour observation and the remaining treated eye appeared normal at the 72-hour observation.
Conclusion	Brodifacoum 0.005% w/w pasta bait produced a maximum group mean score of 6.0 and was classified as a mild irritant (Class 4 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.
Reliability	1
Deficiencies	No

Evaluation by Competent Authorities
Use separate "evaluation boxes" to provide transparency as to the comments and views submitted

Section B.6.2 (2)	**Acute Eye Irritation**
Annex Point IIB, VI. 6.2	Eye Irritation to the Rabbit

	Evaluation by Rapporteur Member State
Date	22 March 2013
Materials and Methods	Adopt applicants version
Results and discussion	Adopt applicants version
Conclusion	Adopt applicants version
Reliability	1
Acceptability	Acceptable
Remarks	

	Comments from ...
Date	
Materials and Methods	
Results and discussion	
Conclusion	
Reliability	
Acceptability	
Remarks	

Table A6_1_4E-1. Results of eye irritation study (results based on 0.1ml volume)

.

	Cornea	Iris	Conjunctiva		
			discharge	redness	chemosis
score (average of animals investigated)	0 to 4	0 to 2	0 to 3	0 to 3	0 to4
60 min	0	0	1	1.3	0.7
24 h	0	0	0.3	1	0.3
48 h	0	0	0	0.3	0
72 h	0	0	0	0	0
Average 24h, 48h, 72h	0	0	0.1	0.43	0.1
Area effected	0	-	-	-	-
Maximum average score (including area affected, max 110)	0	0	0.2	0.86	0.2
Reversibility*	n/a	n/a	c	c	c
average time for reversion (day of no reactions)	n/a	n/a	2 days	3 days	2 days
Maximum average score was derived using the Draize method : *For cornea: Score = (Opacity(A) x Area (B) x 5)* *For iris(C): Score = (Cx5)* *For Conjunctiva: Score = (Redness (D) x Chemosis (E) x Discharge (F) x2).* *Maximum average score = 1.3* *A modification of the Kay and Calendra system (1962) was used to interpret and classify the scores* * *c : completely reversible* *n c : not completely reversible* *n : not reversible*					

Section B6.3 Annex Point IIB VI.6.3	**Skin sensitisation**	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure [X]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Buehlers test in guinea pigs has been performed on the active substance and no indication of skin sensitizing properties were identified The other ingredients of the product are not expected to cause skin sensitization. Also, direct dermal exposure is not expected to occur since the use of gloves is probable when handling highly toxic products and when performing tasks in an environment where rodent borne diseases may be present.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	22 March 2013	
Evaluation of applicant's justification	Justification is acceptable	
Conclusion	*Justification is acceptable*	
Remarks	*Justification is acceptable*	
	Comments from other Member State *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

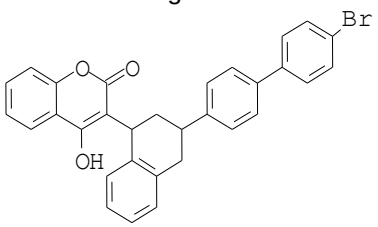
A BRIDGING CASE TO DIFENACOUM DATA IS PROPOSED

Official use only

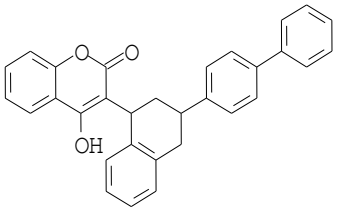
Brodifacoum and difenacoum are second generation anticoagulant rodenticides, which cause death of target organisms due to massive internal haemorrhages. All the coumarin derivatives act as vitamin K antagonists through inhibition of vitamin K reductase leading to depletion of a number of carboxylated blood coagulation factors. The effect is cumulative in nature. Haemorrhaging and subsequent death is the only effect observed in acute and repeated-dose toxicity tests. Prolongation of prothrombin time is usually observed before clinical signs of toxicity.

Both compounds are very toxic by inhalation, in contact with skin and if swallowed.

Brodifacoum and difenacoum are very similar in structure, as can be seen from the structural diagrams below.



Brodifacoum



Difenacoum

Log P*

Mol wt

Water solubility (20º)

The compounds also have very similar physico-chemical properties, the Log P, molecular weight and water solubility values being as follows:

Brodifacoum	Difenacoum
4.92	-
8.51 (calculated)	7.62 (calculated)
523.4	444.5
2.4×10^{-4} g/l (pH7.4)	4.83×10^{-4} g/l (pH6.5)

Initially, the difenacoum log P value appears significantly higher than that for brodifacoum. However, the difenacoum value is a calculated figure while an experimental value is given for brodifacoum. Using a like-for-like comparison of calculated values, the log P of both compounds is shown to be similar.

Both compounds have a high log P and molecular weight and are of low solubility in water. It is widely accepted that compounds with high Log P values and high molecular weight will show poor skin permeability. Given the similarity of structure and physico-chemical properties for both compounds, their skin penetration properties are also likely to be comparable.

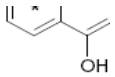
The following experimental data for dermal penetration were submitted as part of the EU review:

Difenacoum Wax blocks 0.047% Paste 0.046%

Official use only

The Italian RMS accepted a bridging approach for the representative use, the wax block formulation. The figure of

	0.047% from the difenacoum data for wax blocks was proposed by the RMS to be used as the dermal penetration figure for a wax block formulation. Based on these data, we propose that the same approach can be taken for the paste bait and a dermal penetration figure of 0.046% should be used for brodifacoum paste bait formulations. This can be supported by bridging to [redacted] data on difenacoum. The Italian RMS did not consider paste bait formulations but the same approach can apply, since data are available for the equivalent difenacoum paste bait formulation. Details of the difenacoum dermal penetration study on wax block and paste bait formulations are given below. This study was reviewed by the Finnish RMS for difenacoum as part of the AS dossier.	**Official use only**
Reference	**Reference** Davies DJ (2007) *In vitro* absorption of difenacoum from wax	

	block and pasta bait through human epidermis. [redacted] study report JV2001.	
Data protection	Yes	
Data owner	[redacted]	
Companies with access to data	[redacted]	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I authorisation.	
	Guidelines and Quality Assurance	
Guideline study	Yes OECD 428	
GLP	Yes	
Deviations	No	
	MATERIALS AND MethodS	
Test material	As given in section 2.	
Lot/Batch number	Difenacoum technical 03661 [coumarin benzene ring-U-^{14}C]-Difenacoum Code CFQ14457 Batch 1	
Specification	As given in section 2.	
Description	Difenacoum technical: off white powder	
Purity	Difenacoum technical 99.5% (w/w)	
Stability	Not specified	
Radiolabelling	[coumarin benzene ring-U-^{14}C]-Difenacoum radiochemical purity of 96.1%	
		
	* denotes the pos	
Test Animals		
Species	Human	
Strain	Not applicable	
Source	Human skin samples were obtained at surgery or post mortem	
Sex	Not specified	
Age/weight at study initiation	Not specified	**Official use only**
Number of animals per group	At least 2 different donors were used	
Control animals	Not specified	
Administration/ Exposure	Dermal	
Preparation of test site	The skin samples were immersed in water at 60ºC for 40 – 45 secs and the epidermis teased away from the dermis. Membranes were stored frozen at approximately -20ºC on aluminium foil until required for use. Discs of approximately 3.3 cm diameter of prepared skin membrane were mounted, dermal side down in diffusion cells held together with individually numbered clamps and placed in a water bath maintained at 32ºC ± 1ºC. Membrane integrity was determined by measurement of the electrical resistance across the skin membrane. Membranes with a measured resistance of <10KΩ were regarded as having a lower integrity than normal and not used for exposure to the test	

	materials. Prior to application, 25.4 µL of physiological saline was applied to the exposed surface of each membrane in order to moisten the application site and maximise the contact between the formulation and the skin surface. Cells were selected such that each application was represented by 6 intact membranes from at least 2 different donor. The receptor fluid ensured that the test substance could freely partition into the receptor fluid from the skin membrane and never reaches a concentration that would limit its diffusion.	
Concentration of test substance	Wax block (0.005% difenacoum (w/w)): 0.05 µg difenacoum/mg of dose, equivalent to 20.6 µg difenacoum/cm^2. Pasta bait (0.005% difenacoum (w/w)): 0.05 µg difenacoum/mg of dose, equivalent to 19.4 µg difenacoum/cm^2.	
Specific activity of test substance	Not specified.	
Volume applied	Not specified, total target weight of dose applied was 1000 mg for both pasta bait and wax block formulations.	
Size of test site	3.3 cm diameter	
Exposure period	8 hours, followed by a skin wash and absorption was measured for a further 16 h period (24 h total).	
Sampling time	24 h after initiation of skin contact.	
Samples	Receptor fluid samples. A pre-treatment sample was taken from each receptor chamber for analysis by LSC. The volume of fluid in the receptor chamber was maintained by the replacement of a volume of receptor fluid, equal to the sample volume immediately after each sample was taken. After the 8 h receptor fluid sample had been taken, the cells were removed from the water bath. Any residual formulation left remaining on the skin was tipped into ethanol and once dissolved a sub-sample was taken for analysis by LSC. The epidermal surface of the skin was decontaminated by gently swabbing the application site with natural sponges wetted with 3% Teepol L® and with further sponges pre-wetted with water. Decontamination was shown to be complete following assessment of residual radioactivity levels on the skin surface with a Geiger counter. The sponges were digested in Soluene 350® and made up to a recorded volume. A sample was taken for analysis. After the final receptor fluid sample had been taken, the remaining fluid in the receptor chamber was stored frozen for possible further analysis. The donor chamber was carefully removed and the underside of the donor chamber wiped with a single sponge pre-wetted with 3% Teepol L® which was added to the wash sponges. The donor chamber was washed with ethanol and the sample analysed by LSC. The surface of the skin was allowed to dry naturally. To assess penetration through the stratum corneum, successive layers of the skin surface were removed by the repeated application of adhesive tape, to a maximum of 5 strips. A strip of adhesive strips were soaked in ethanol to extract any test material. The extracts were sequentially numbered and analysed by LSC. The remaining epidermis was carefully removed from the receptor chamber, digested in Soluene 350® and the whole digest analysed.	**Official use only**
	Results and Discussion	
Toxic effects, clinical signs	None specified	
Dermal irritation	None specified	
Recovery of labelled compound	Mean recovery of radiolabelled test material was 96.7% and 104% of the applied dose for the wax block and pasta bait	

	formulations, respectively. For the wax block and pasta bait formulations, the majority of applied dose, 96.7% and 103%, respectively remained on the skin surface or was removed by gentle skin washing 8 h after application. Minimal amounts (0.043% and 0.62% for the wax block and pasta bait respectively) were removed by further washing procedures 16 h later. The mean proportion of the applied dose present in receptor fluid following the total 24 h exposure was 0.011% for wax block and 0.012 % for pasta bait. In terms of actual amounts, these percentages equate to 0.002 µg/cm^2 and 0.002 µg/cm^2, respectively. A total of 0.037% (wax block) and 0.038% (pasta bait) of the applied dose remained in the epidermal membrane following 24 h exposure. Of this total, 0.001% (wax block) and 0.004% (pasta bait) was present in the outer layers of the strata corneum.	
Percutaneous absorption	Wax block: Difenacoum absorption through the membrane between 0 – 6 h was 0.00014 µg/cm^2/h. Between 6 – 12 h, absorption increased slightly to 0.00017 µg/cm^2/h. Between 12 – 24 h, absorption slowed to 0.00004 µg/cm^2/h. Between 0 – 24 h absorption through the membrane was 0.00011 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h were 0.00079, 0.00126 and 0,00181 µg/cm^2, respectively. The representative amounts expressed as percentages of the applied dose were 0.00384, 0.00610 and 0.00878%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00235 µg/cm^2 (0.0014% of the applied dose). Pasta bait formulation: Difenacoum absorption through the membrane between 0 – 8 h was 0.00006 µg/cm^2/h. Between 8 – 24 h, absorption increased slightly to 0.00012 µg/cm^2/h. Between 0 – 24, absorption through the membrane was 0.0001 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h was 0.00037, 0.00049 and 0.00098 µg/cm^2, respectively. The respective amounts expressed as percentages of the applied dose were 0.00192, 0.00252 and 0.00504%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00236 µg/cm^2 (0.01220% of the applied dose).	**Official use only**
	Applicant's Summary and conclusion	
Materials and methods	The purpose of this study was to determine the *in vitro* percutaneous absorption of difenacoum through human skin over an 8 h exposure period to aid quantitative assessment of the hazard from human skin contact with a wax block and pasta bait formulation containing 0.005% (w/w) difenacoum,. The distribution of difenacoum within the test system following the 8 h exposure and a 16 h post exposure period (24 h total) was also determined.	
Results and discussion	The absorbed (systemically available) dose is considered to be the difenacoum detected in the receptor fluid. Material removed from the surface of the epidermis by the washing procedure and in tape strops is regarded as unabsorbed. Difenacoum recovered from the epidermis at the end of the exposure is considered to be absorbed, although hit is recognised that a proportion of this material may not be absorbed beyond the duration of the exposure investigated in this study. In vivo, the majority of the dose in the epidermis, especially that recovered from the stratum corneum would eventually be lost by desquamation. Wax block: Difenacoum absorption through the membrane between 0 – 6 h was 0.00014 µg/cm^2/h. Between 6 – 12 h, absorption increased slightly to 0.00017 µg/cm^2/h. Between 12 –	

	24 h, absorption slowed to 0.00004 µg/cm^2/h. Between 0 – 24 h absorption through the membrane was 0.00011 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h were 0.00079, 0.00126 and 0,00181 µg/cm^2, respectively. The representative amounts expressed as percentages of the applied dose were 0.00384, 0.00610 and 0.00878%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00235 µg/cm^2 (0.0014% of the applied dose). Pasta bait formulation: Difenacoum absorption through the membrane between 0 – 8 h was 0.00006 µg/cm^2/h. Between 8 – 24 h, absorption increased slightly to 0.00012 µg/cm^2/h. Between 0 – 24, absorption through the membrane was 0.0001 µg/cm^2/h. The amounts absorbed through the membrane at 6, 8 and 12 h was 0.00037, 0.00049 and 0.00098 µg/cm^2, respectively. The respective amounts expressed as percentages of the applied dose were 0.00192, 0.00252 and 0.00504%. The amount absorbed through the membrane over the entire 24 h exposure period was 0.00236 µg/cm^2 (0.01220% of the applied dose).
Conclusion	The results obtained in this study indicate that difenacoum is absorbed through human epidermis, from the wax block and pasta bait formulations at an extremely slow rate, The vast majority of the applied dose either remained on the skin surface or was removed by gently skin washing at 8 h. These data predict that difenacoum absorption through human epidermis was fastest between 6 – 12 h (0.00017 µg/cm^2/h) for the wax block formulation and 8 – 24 h (0.00012 µg/cm^2/h) for the pasta bait. As absorption continued after the formulations were removed from the skin surface it can be assumed that radioactivity remaining in the epidermis 24 h after application will be absorbed. Consequently the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046 % respectively.
Reliability	1
Deficiencies	No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State – FINLAND FOR DIFENACOUM
Date	16 January 2007
Materials and Methods	Point 3.3.5: The actual exposed membrane area is 2.54 cm^2.
Results and discussion	Agree with applicant's version. See remarks
Conclusion	Agree with applicant's version. Under the test conditions (a nominal 1000 mg sample of the formulation (0.005%, w/w) applied for 8 hours on excised human skin) the absorption of difenacoum from wax blocks and pasta bait was 0.047% and 0.046%, respectively, during 24 hours. The amount of difenacoum in *stratum corneum* is not included. Dermal absorption of 0.047% is taken forward to risk characterisation
Reliability	1
Acceptability	Acceptable
Remarks	Point 1.1: The study report number is JV2011-REG It is obvious that 'percentage of dose absorbed' is not an ideal measure of substance penetration through skin. However, that is the way it has to be expressed in order to be able to use dermal absorption study results for

	exposure assessment according to the prevailing guidance and practice. The formulation type (wax bound block) most probably retains quite effectively a fat-soluble and hydrophobic substance like difenacoum. Key study
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table 6.4- 1 Summary of difenacoum distrbution in the test system (Added by RMS)

Wax block formulation:

Test Compartment	**µg difenacoum per cm^2**		**% of applied dose**	
n = 6	**Mean**	**SEM**	**Mean**	**SEM**
Residual formulation	19.9	0.082	96.6	0.397
Decontamination (8h)	0.020	0.003	0.099	0.012
*Donor chamber	0.001	<0.001	0.003	0.001
Skin wash (24h)	0.009	0.001	0.043	0.007
**Stratum corneum*	<0.001	<0.001	0.001	0.001
Remaining epidermis	0.007	0.001	0.036	0.007
Receptor fluid	0.002	<0.001	0.011	0.002
Total recovered	**20.0**	**0.083**	**96.7**	**0.402**
Absorbed	**0.010**	**0.002**	**0.047**	**0.008**

Pasta bait formulation:

Test Compartment	**µg difenacoum per cm^2**		**% of applied dose**	
n = 5	**Mean**	**SEM**	**Mean**	**SEM**
Residual formulation	18.9	0.83	97.4	4.26
Decontamination (8h)	1.06	0.81	5.47	4.20
*Donor chamber	0.007	0.003	0.037	0.018
Skin wash (24h)	0.121	0.086	0.623	0.442
**Stratum corneum*	0.001	<0.001	0.004	0.001
Remaining epidermis	0.007	0.002	0.034	0.012
Receptor fluid	0.002	0.001	0.012	0.005
Total recovered	**20.1**	**0.325**	**104**	**1.68**
Absorbed	**0.009**	**0.003**	**0.046**	**0.017**

*Where flagged, the mass balance data were either close to or below the LOQ. To achieve reportable values, these data have not been raised to LOQ.
Stratum corneum = amount in tape strips; Remaining epidermis = epidermal tissue remaining after tape stripping; Absorbed = amount in remaining epidermis plus receptor fluid

Section B6.5 **Annex Point IIB VI.6.5**	**Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)**	
	Justification for non-submission of data	Official use only

Section B6.5 Annex Point IIB VI.6.5	**Available toxicological data relating to toxicologically relevant non-active substances (i.e. substances of concern)**
Other existing data [ ] Limited exposure [X]	**Technically not feasible [ ] Scientifically unjustified [X] Other justification [ ]**
Detailed justification:	The product is a paste bait composed of a toxic active substance, and ingredients that are not substances of concern. The ingredients are mostly food-grade substances which themselves do not contain any substances of concern. The dyestuff preparation is declared as containing no hazardous ingredients according to 91/155/EEC.
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*
	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*21.11.2006*
Evaluation of applicant's justification	Applicant's justification is applicable
Conclusion	Applicant's justification is acceptable
Remarks	
	Comments from other Member State *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B6.6(i) **Information related to the exposure of the biocidal product**

Annex Point IIB VI.6.6

		Official use only
	Reference For the agreed interpretation of data from this study, please refer to HEEG Document, 'HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants), ISPRA 10/05/2011 – agreed at TMII, 2011.	
Reference	[redacted] 2004, Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits, [redacted] Study Nº SYN/1302	
Data protection	Yes	
Data owner	CEFIC/EBPF Rodenticides data development group	
Companies with access to data	[redacted]	
Criteria for data protection	Data submitted to the MS after 13 May 2000 on existing a.s. for the purpose of its entry into Annex I	
	Guidelines and Quality Assurance	
Guideline study	No no guidelines available	
GLP	Yes	
Deviations	n/a	
	MATERIALS AND MethodS *In some fields the values indicated in the EC or OECD test guidelines are given as default values. Adopt, change or delete these default values as appropriate.*	
Test material	Nº | Task | Test item | AS 4 | Securing wax blocks in bait stations | Compressed wax blocks | Flocoumafen 5 | Clean up and disposal of wax blocks | Compressed wax blocks | Flocoumafen	
Lot/Batch number	40205	
Specification	Flocoumafen in the form of "Storm Secure 20G" wax blocks	
Description	Wax block	
Purity	0.004%	
Stability	Stable under test conditions	
Method of analysis	Residues of flocoumafen were extracted from the dosimeters by shaking with pre-dried acetone followed by concentration either under rotary evaporation or under a stream of air on a Dri-block. When required extracts were cleaned using solid phase extraction (SPE) cartridges. After addition of a known amount of an appropriate HPLC marker compound, residues were determined by reversed phase HPLC with fluorescence detection. LOQ = 0.05µg	
Exposure	Dermal exposure to the hands only	
Reasons of exposure	The purpose of the study was to simulate anticipated exposure through the use of the product.	
Frequency of exposure	Manipulations per replicate | Nº of replicates | Dosimeters sampled per trial 1 | 10 | Hand 5 | 10 | Hand 10 | 10 | Hand	
Sampling	For dermal exposure, white cotton gloves were used as dosimeters.	
Description of exposure patterns	Securing wax blocks in bait stations: A standard manipulation for this test was defined as the securing of five wax blocks into a single bait station which was then placed	

in a corner on the floor of the test site.
Clean up and disposal of wax blocks:
A standard manipulation for this test was defined as the emptying of a loaded bait station containing five wax blocks by sliding the blocks of the steel mounting rod into a bucket and cleaning out the bait station
The clean up and disposal test was run directly after the securing test.

Duration of single exposure
Not stated.
The study design assumes that the level of exposure is related to the number of bait manipulations.

Test design
The test was designed to simulate potential exposure during the use of wax bait rodenticides.
Each task was tested ten times (replicates) in trials involving 1, 5 or 10 manipulations. Where a manipulation represented a single operation, each separate task was conducted by five operators who each carried out two replicates.
New dosimeters were fitted prior to each replicate of each trial and removed for analysis afterwards.

Calculations
The amount of product was extrapolated from the quantity of active detected on the dosimeter based on 0.004% concentration of the active in the product.

Remarks
Although the study included tests on the use of grain based baits, only the sections relating to the use of wax blocks has been summarised as that is the form taken by the product and it was deemed unnecessary to include sections that bore no relevance to the dossier submitted.

Results and Discussion

Securing wax blocks in bait stations
Flocoumafen residues in gloves following a single manipulation ranged from 0.55 to 3.71 µg/sample (equivalent to 13.7 to 92.8 mg product/sample). Following 5 manipulations, levels ranged from 2.98 to 6.66 µg/sample (74.5 to 166 mg product/sample) and for 10 manipulations from 5.33 to 11.2 µg/sample (133 to 280 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)	a.s (µg/sample)	Product (mg/sample)
Mean	1.29	32.19	4.12	103.15	7.20	180.05

Clean-up and disposal
Flocoumafen residues determined during wax block clean-up were less than those measured for loading due to less direct hand contact with the product. Levels in gloves following a single manipulation ranged from 0.05 to 0.36µg/sample (equivalent to 1.27 to 9.04 mg product/sample). Following 5 manipulations, levels ranged from 0.37 to 1.75µg/sample (9.29 to 43.6 mg product/sample) and for 10 manipulations from 1.20 to 3.13 µg/sample (29.9 to 78.3 mg product/sample)

Manipulations	1		5		10	
	a.s (µg/sample)	Product (mg/sa	a.s (µg/sample)	Product (mg/sa	a.s (µg/sample)	Product (mg/sa

		mple)		mple)		mple)
Mean	0.16	4.01	1.00	24.9	2.07	51.23

Applicant's Summary and conclusion

Materials and methods

Potential exposure of professional and non-professional users during handling of anticoagulant rodenticide baits formulated as wax blocks was simulated by measurement of potential dermal residues during loading of bait stations and clean up and disposal.

Wax blocks containing 0.004% w/w Flocoumafen were used as surrogate test items. Each task was tested ten times (replicates) in trials involving either 1, 5 or 10 manipulations, where a manipulation represented a single operation (for example loading one bait station with five wax blocks). Each separate task was conducted by five operators who each carried out two replicates.

The analytical procedure was based upon extraction of the a.s. with pre-dried acetone, concentration and clean-up by solid-phase extraction (SPE) as necessary before determination by high performance liquid chromatography (HPLC) with fluorescence detection.

Exposure to product was calculated by extrapolation from the active substance content of the bait.

Results and discussion

Levels of Flocoumafen residue were dependant on the number of manipulations performed. There were considerable fluctuations between operators and replicates.

The performance of 10 bait placing manipulations, involving handling of 50 bait blocks, resulted in product residues on the hands of

185.75 mg product/person (mean) (18.58mg per bait station)

The performance of 10 clean-up manipulations resulted in product residues on the hands of

51.23 mg product/person (mean)(5.12mg per bait station)

The performance of 1 bait placing manipulation, involving handling 5 bait blocks, resulted in product residues on the hands of

36.98 mg product/person (mean)

The performance of 1 clean up manipulation resulted in product residues on the hands of 4.01mg product/person (mean)

Conclusion Non-entry field

Reliability 1

Deficiencies No

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	Evaluation by Rapporteur Member State
Date	*April 2007*
Materials and Methods	Applicants version is acceptable
Results and discussion	Adopt applicant´s version
Conclusion	Appropriate reliability indicator
Reliability	Acceptable
Acceptability	Applicants version is acceptable
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Materials and Methods	*Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion.*

Section B6.6(i) **Information related to the exposure of the biocidal product**

Annex Point IIB VI.6.6

	Discuss if deviating from view of rapporteur member state
Results and discussion	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table B6.6- 1: Residues of active substance (Flocoumafen used as a surrogate) on hand dosimeters, resulting from deploying wax block baits in bait boxes (5 blocks per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	1.65	41.2	5.16	129.06	7.08	177.01
	2	1.67	41.74	3.59	89.82	6.47	161.87
2	1	0.72	17.96	4.76	118.97	9.59	239.72
	2	1.19	29.69	4.73	118.27	6.87	171.73
3	1	1.25	31.36	2.98	74.5	7.38	184.44
	2	0.96	24.11	3.22	80.39	5.36	134.06
4	1	2.01	50.37	5.42	135.54	9.43	235.8
	2	3.71	92.75	6.66	166.42	11.21	280.2
6	1	0.55	13.7	3.15	78.78	5.58	139.53
	2	1.08	26.91	3.13	78.31	5.33	133.14
	50th percentile	1.22	30.525	4.16	104.045	6.975	174.37
	75th percentile	1.665	41.605	5.06	126.5375	8.9175	222.96
	90th percentile	2.18	54.608	5.544	138.628	9.752	243.768
	geometric mean	1.28784	32.18889	4.124405	103.1179	7.201804	180.0469
	Mean	**1.479**	**36.979**	**4.28**	**107.006**	**7.43**	**185.75**
	Standard Error	0.285359	7.137958	0.395255	9.877688	0.636235	15.90229
	Median	1.22	30.525	4.16	104.045	6.975	174.37
	Standard Deviation	0.902385	22.57221	1.249907	31.23599	2.011953	50.28744
	Sample Variance	0.814299	509.5045	1.562267	975.6871	4.047956	2528.827
	Kurtosis	4.23184	4.214188	-0.56625	-0.57575	-0.44449	-0.44609
	Skewness	1.850004	1.84583	0.65193	0.649119	0.793366	0.792521
	Range	3.16	79.05	3.68	91.92	5.88	147.06
	Minimum	0.55	13.7	2.98	74.5	5.33	133.14
	Maximum	3.71	92.75	6.66	166.42	11.21	280.2
	Sum	14.79	369.79	42.8	1070.06	74.3	1857.5
	Count	10	10	10	10	10	10
	quantity per	**1.479**	**36.979**	**0.856**	**21.4012**	**0.743**	**18.575**

bait station (mean /no of manipulations)

Table B6.6- 2: Residues of active substance (Flocoumafen used as a surrogate) on hand dosimeters, resulting from clean-up and disposal of wax block baits from bait boxes (one box per manipulation), and extrapolated product residues

Manipulations		1		5		10	
	rep no	a.s	product	a.s	product	a.s	product
Operator no		µg/sample	mg/sample	µg/sample	mg/sample	µg/sample	mg/sample
1	1	0.22	5.62	1.02	25.62	1.2	29.91
	2	0.05	1.27	0.55	13.63	1.74	43.55
2	1	0.14	3.42	1.19	29.75	2.28	57.03
	2	0.18	4.43	0.77	19.33	1.21	30.17
3	1	0.08	2.07	1.05	26.28	2.15	53.69
	2	0.18	4.59	1.07	26.75	2.72	68.05
4	1	0.36	9.04	1.16	28.9	3.13	78.32
	2	0.23	5.67	1.75	43.63	2.83	70.7
6	1	0.08	2.02	1.03	25.83	1.37	34.16
	2	0.08	2	0.37	9.29	1.87	46.75
	50th percentile	0.16	3.925	1.04	26.055	2.01	50.22
	75th percentile	0.21	5.3625	1.1375	28.3625	2.61	65.295
	90th percentile	0.243	6.007	1.246	31.138	2.86	71.462
	geometric mean	0.135686	3.410269	0.922594	23.07048	1.942384	48.52657
	Mean	**0.16**	**4.013**	**0.996**	**24.901**	**2.05**	**51.233**
	Standard Error	0.03	0.751153	0.119492	2.979104	0.218724	5.481339
	Median	0.16	3.925	1.04	26.055	2.01	50.22
	Mode	0.08	#N/A	#N/A	#N/A	#N/A	#N/A
	Standard Deviation	0.094868	2.375355	0.377865	9.420754	0.691665	17.33351
	Sample Variance	0.009	5.642312	0.142782	88.75061	0.4784	300.4507
	Kurtosis	0.798413	0.844559	1.239799	1.212496	-1.30767	-1.3038
	Skewness	0.927211	0.95074	0.245626	0.224021	0.206223	0.204209
	Range	0.31	7.77	1.38	34.34	1.93	48.41
	Minimum	0.05	1.27	0.37	9.29	1.2	29.91
	Maximum	0.36	9.04	1.75	43.63	3.13	78.32
	Sum	1.6	40.13	9.96	249.01	20.5	512.33
	Count	10	10	10	10	10	10

quantity per bait station (mean /no of manipulations)	**0.16**	**4.013**	**0.1992**	**4.9802**	**0.205**	**5.1233**

B6.6(2)
For the agreed interpretation of data from this study, please refer to HEEG Document, 'HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants), ISPRA 10/05/2011 – agreed at TMII, 2011.

- **TMIIITOX-item4- Bait Handling-REPORT.doc**
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Estimation of the Frequency of Dermal Exposure

During the Occupational Use of Rodenticides

28th July 2006

EBRC Consulting
Zeppelinstr. 8
30175 Hannover
Germany

**This report has been prepared by EBRC Consulting
under contract to the CEFIC Rodenticides Working Group.**

Introduction

In the current evaluation of rodenticides (inclusion of active substances in Annex I of the Biocides Directive 98/8/EC), the assessment of dermal exposure of professional pest control technicians (PCTs) to rodenticide baits is currently inconsistent: In particular, the assumptions regarding the frequency of bait handling are contradictory among various dossiers. The TNsG on Human Exposure (EU, 2002) and the User Guidance to the TNsG (EU, 2004) provide a variety of assumed bait handling frequencies, but no clear guidance. This has resulted in divergent exposure estimates among the CA reports for active substances published so far. Consequently, the need for agreed default exposure frequencies was identified at the Technical Meeting "Subgroup Anticoagulants" held on 18th May 2006 at the JRC, Ispra. Industry was requested to propose default values for bait handling, based on actual user data.

Some Member States also announced to provide data on bait handling frequency to the chairman of the CEFIC Rodenticide Working Group. The only contributions received in this context were general exposure scenario documents from DK and NL, as well as a written communication by DE, stating a figure of up to 300 wax blocks that may be deployed daily. However, these sources of information were not considered in the subsequent evaluation since they are not based on actual user data.

Recent surveys at three pest control companies provided extensive information on handling patterns of occupationally exposed pest control technicians (PCT) in 15 European countries (EU, N, CH). Data were requested with respect to the most relevant bait types in professional rodent control, i.e. grain bait, wax block bait, and paste bait. As a first step of analysis, this information was assessed in terms of representativeness and quality. The number of exposure events was then estimated based on the given data as presented and discussed below.

Objective of this report

This paper aims at providing useful and reliable estimates of the number of exposure events a PCT may experience during the occupational handling of different types of rodenticide baits. The objective of the current paper is therefore to propose scientifically acceptable figures for the daily bait handling frequencies. The relevant endpoints were identified as the:

typical case (median value)

and

reasonable worst case (75th percentile),

based on the presumption (see TNsG on human exposure, part 2, section 1.6) that the data base is representative and appropriate. Corresponding figures were derived for the individual bait types, respectively.

Description of data sources

The following analysis is based on data from three sources covering large parts of the EU (see below). Three pest control companies submitted data from surveys based on a common questionnaire (see "Appendix II: Used questionnaire"). Short descriptions of the respective subsets are given below and further summarised in "Appendix I: Used data":

Company 1: Multinational pest control company; the survey was conducted by sending a written questionnaire to the head office of the company involved in each European country where the company was represented. Thus, the raw data from company 1 constitute a country-by-country summary over 15 European countries.

Company 2: UK rodenticide manufacturer, providing data from customers (pest control) at company level (i.e. raw data represent averages of three specific UK companies).

Company 3: German rodenticide manufacturer and pest control company. Data were collected at the level of individual technicians. In order to avoid any bias from introducing individual data in the total data-base, the individual data were aggregated to result in average numbers across all technicians and bait types of this company, which were then integrated into the data base already comprising information from companies 1 and 2. For a detailed analysis of this data-set please review Appendix III.

Company 3 (supplementary data): An additional survey was provided by company 3, reporting numbers of deployed bait stations per day when PCTs work at the same object during their entire shift. This represents a clear worst case situation since no travelling between sites and only minimal administrative work is included, so that a maximum portion of the working time is dedicated to pest control tasks. The study only considered wax block baits. Since this survey employs a different approach these results were only used for comparison as a plausibility check but not included in the statistical analysis.

Table 1: **Characteristics of the raw data, as provided by the participating companies.**

Source	Countries involved	Number of data points	Type of data	Aggregation level

Company 1	15 European countries	15	Aggregated	Country
Company 2	UK	3	Aggregated	Company
Company 3	D	10	Individual	Technician
Company 3	D	7	Individual	Technician/Site

The data specified in Table 1 were collated into a common data base (except supplementary data from company 3). Data from company 1 and 2 were considered as equivalent, respectively, since the aggregation level of country head office (company 1) and customer (company 2) represent approximately the same level of hierarchy. The 10 individual responses from company 3 were aggregated into one data point (also see Appendix III), and are hence considered to be comparable to the former. This resulted in a data base with a sample size of $n = 19$.

Assessment of representativeness and reliability of used data

Whereas the data originate directly from the pest control business and should therefore reflect common practice, a definitive assessment of representativeness for the EU cannot be made: The sector coverage is currently unknown since figures for total volume of rodenticide consumption in the EU are not available. Furthermore, the data were not randomly collected but provided by companies which were interested to participate in this assessment.

It should be noted that data from Company 1 represent country-specific figures, while data from Company 2 represent company-specific averages for which neither the variation nor the number of used data points are reported. Furthermore, it is important to note that all submitted questionnaires represent some kind of expert judgement in the sense that apparently only supervisors completed them. Although they are considered to be very close to reality, it should be kept in mind that the data do not originate from direct observation of workers (i.e. the data do not reflect handling patterns of individual PCTs, but instead average figures on the specific aggregation level, as presented in Table 1).

Methods

Selection of relevant data

The questionnaire used for the data collection comprised 10 questions related to the handling of rodenticides ("Appendix II: Used questionnaire"). In order to estimate the number of events in which dermal exposure to rodenticides may occur, two endpoints (see "Appendix I: Used data" for raw data) were identified as relevant. Both endpoints comprise data for each bait type separately and are characterised as follows:

Question 7 (Number of handlings of rodenticides per day): This question aimed at asking for the number of sites visited per day. The data obtained by this question were used to estimate the exposure frequency regarding paste bait only, for the following reasons: According to company 1 (for whose PCTs paste bait application makes up significant parts of the business), this bait type is deployed using pre-filled cartridges. Due to the resulting spatial segregation between user and bait material, dermal exposure is only possible at removal and re-attachment of the nozzle's protection cap. This event is assumed to occur only before the first and after the last bait placing on a given site. Consequently, the number of exposure events per day to be included in the analysis was obtained by multiplying the number of sites per day by a factor of 2.

It is acknowledged that also other application types for paste bait exist on the market (e.g. pre-packed foil sachets) which may be related to different exposure patterns. These were, however, not considered in the current analysis since only data for cartridge are available.

Question 10 (Number of bait stations per day): In the case of loose grain and wax block bait, the number of bait stations handled per day is considered to be the relevant exposure determinant, i.e. each handling of a bait station is equivalent to an exposure event. Thus, the respective figures were used to directly estimate the number of exposure events (i.e. the data were used as given).

Statistical procedures

An appropriate distribution was fitted to the data (log-normal or gamma, see below). for each bait type, respectively. The program @risk 4.5.4 (Palisade Corporation) was used to fit the data to the most appropriate distribution. Tests for the goodness of fit (GoF) were carried out to validate the fitted distributions. Based on the appropriate probability distribution fitted to the data, the median and the 75^{th} percentile were calculated.

Results

The bait-type specific parameters of the fitted distributions are presented in Table 2 and Figures 1–3. According to the assumption that contact to paste bait is only possible at removal and re-attachment of the protection cap, exposure frequencies were estimated to be lowest with this bait type, wheras higher and very similar figures were obtained for loose grain bait and wax blocks.

Table 2: **Number exposure events per day and PCT.**

	Loose grain	**Wax block**	**Paste bait**	**All bait types**
Median	16.1	13.1	4.5	43.6
Mean	34.9	33.1	6.2	66.9
75th percentile	37.3	32.7	8.6	n.a.
90th percentile	79.3	74.9	14.0	n.a.
n	19	19	19	19
Fitted distribution	lognormal	lognormal	gamma	lognormal
Anderson-Darling GoF				
Critical value α=0.05	0.752	0.752	0.752	0.752
Test statistic	0.540	0.241	0.681	0.490
Accepted	Yes	Yes	Yes	Yes
Chi² GoF				
p	0.520	0.984	0.091	0.701

Evaluation of the responses to the questionnaires revealed that a PCT would normally apply more than one bait type on given working day. Conclusions as regards the actual distribution of used bait types are, however, not possible due to the degree of aggregation of the data sets. To address the case where more than one bait type is used in one day, however, it is not appropriate to add up the 75th percentiles of the various bait types, nor would a 75th percentile across all bait types be adequate, since this would correspond to an accumulation of worst cases. Such over-conservative approaches should be avoided in risk assessment.

Instead, to account for the alternation between bait types on a given working day, the median of the bait handling frequency across all bait types was calculated in addition to the bait-type specific estimates. This was done by adding up the relevant reported exposure frequencies per data set (e.g. for C1-01: 10 + 10 + 3 = 23, etc., *cf*. Appendix I) and fitting an appropriate distribution (see Table 2). Accordingly, the typical number of exposure events of a PCT using several bait types during his entire shift is given as 44 (median). Other parameters are not provided since this would be misleading for the reasons given above.

It is further noted that according to the responses to the questionnaire it is likely that also baits based on several active substances are used alternately. Thus, the presented figures entail an additional inherent conservatism with respect to exposure to a specific active substance.

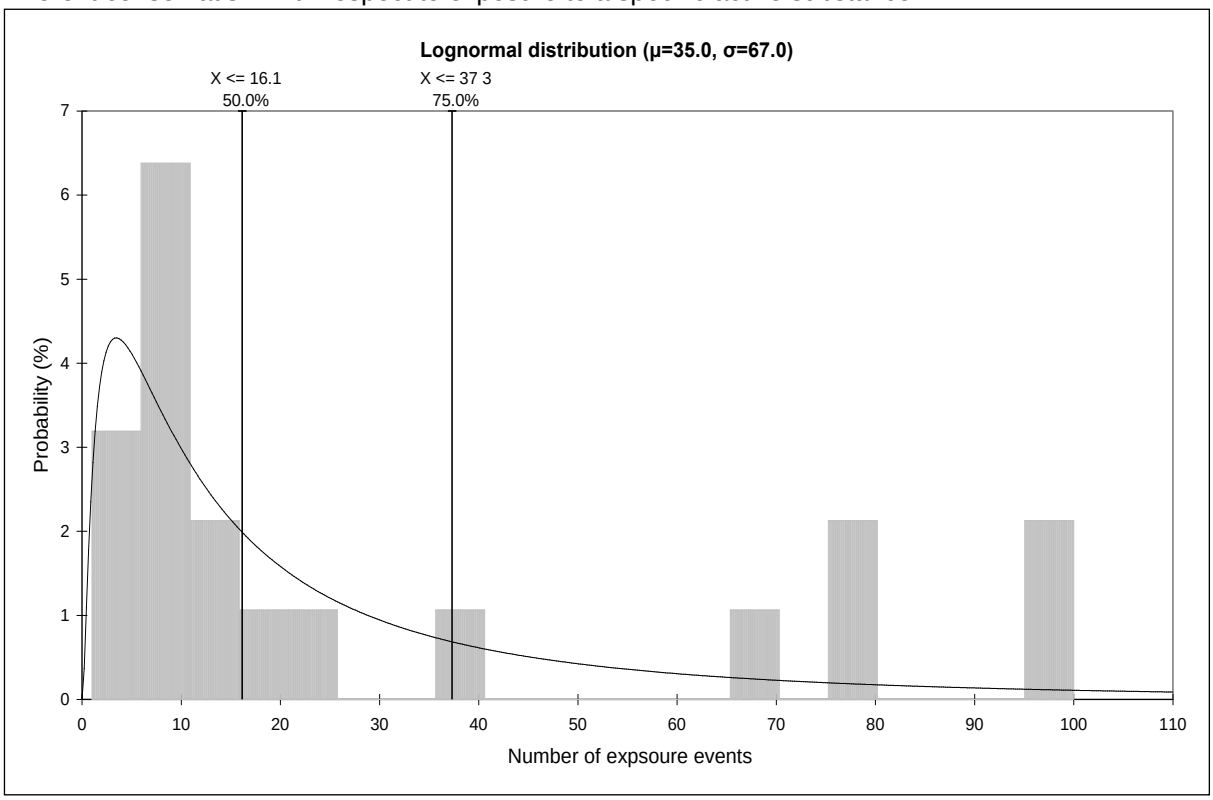

Figure 1: **Frequency vs. fitted distribution for the number of exposure events during the use of loose grain bait.**

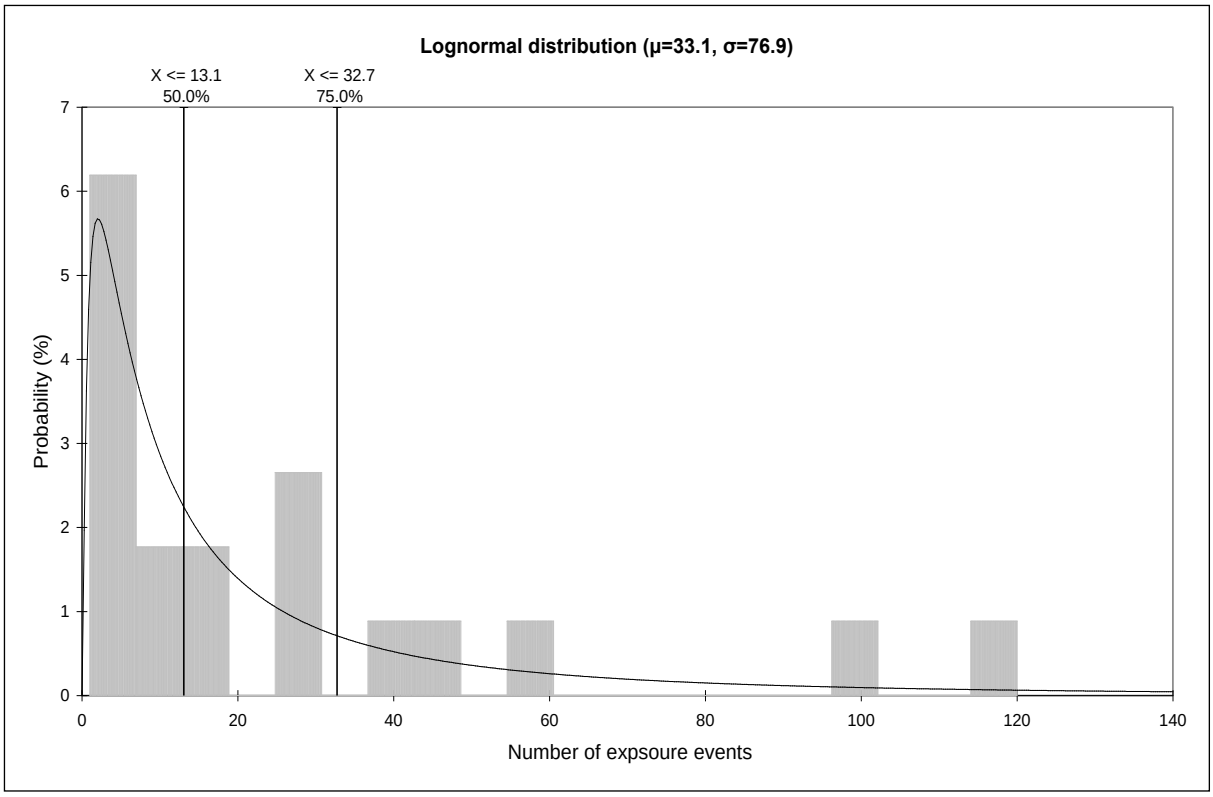

Figure 2: **Frequency vs. fitted distribution for the number of exposure events during the use of wax block bait.**

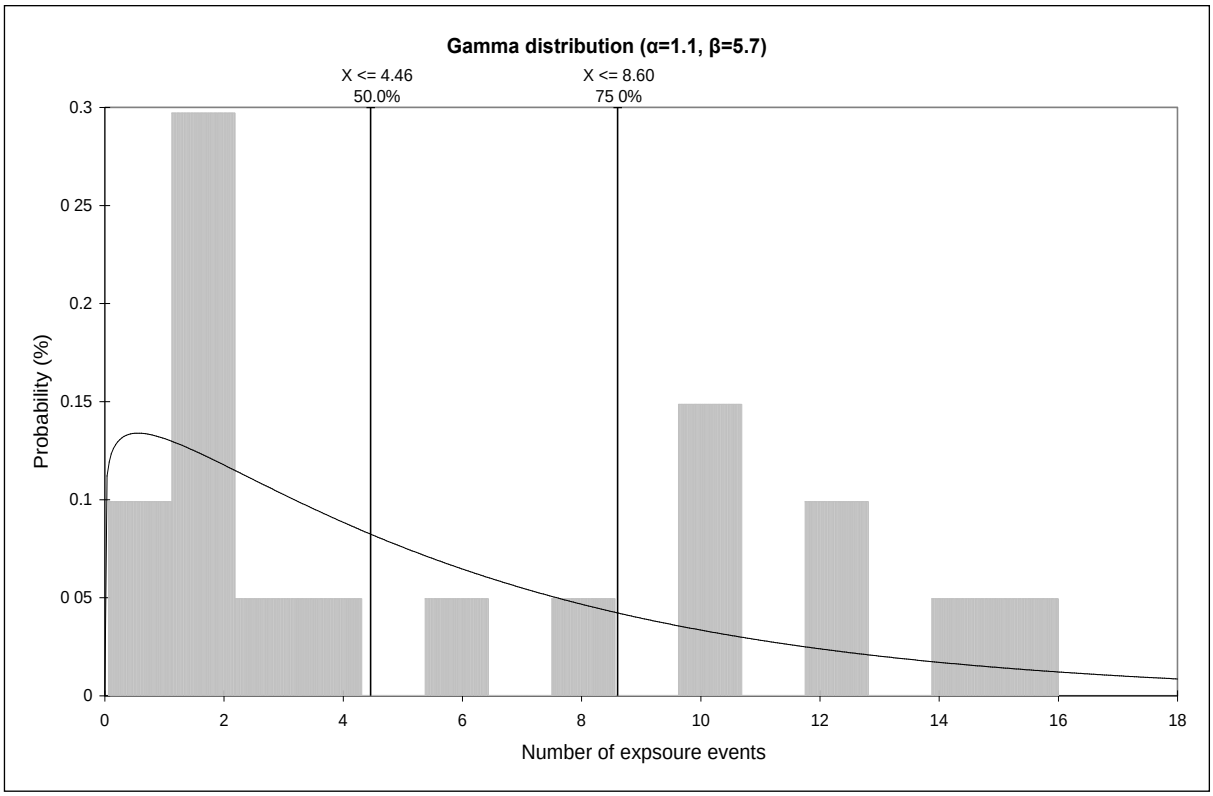

Figure 3: **Frequency vs. fitted distribution for the number of exposure events during the use of paste bait.**

Discussion and conclusions

Based on the submitted user survey data, PCTs alternating between several bait types on a normal full working day may be expected to experience 44 exposure events per day (typical case, median).

The figures for the bait-type specific reasonable worst case presented here are considered as sufficiently conservative estimates, for the following reasons: In Appendix IV, a case study under the worst case assumption of continuous rodent control work at one large site (i.e. no travelling and no other tasks not directly related to rodent control) is presented. The mean maximum number of bait stations is given as 91, and the overall maximum as 130.

Thus, the 75th percentiles of 37, 33 and 9 exposure events identified as the reasonable worst cases here are considered as highly relevant figures for risk assessment. Even if the spectrum of used baits is shifted towards wax blocks or grain bait (which reveal very similar exposure frequencies), the data in Appendix IV show that the maximum number of bait contacts is limited to a range of approx. 50 to 130. This is, however, only valid in the exceptional case of continuous rodent control work at large sites (no travelling etc.). It is further emphasised in this context that a PCT's working day is usually not exclusively made up of rodent control, but also other pest control activities like insecticide treatment etc. occur.

Since the current analysis is based on data obtained from a EU-wide survey, it may be considered as sufficiently representative.

In conclusion, the following reasonable worst case figures for the frequency of exposure of a PCT during a representative full working day to the respective bait types are proposed:

Loose grain bait: 37
Wax block bait: 33
Paste bait: 9

References

EU (2002): Technical Notes for Guidance: Human Exposure to Biocidal Products – Guidance on exposure estimation. European Chemicals Bureau, Ispra, Italy, Report No. B4-3040/2000/291079/MAR/E2, June 2002 (http://ecb.jrc.it/Documents/Biocides/HUMAN_EXPOSURE/).

EU (2004): Human exposure to biocidal products (TNsG June 2002) – user guidance version 1. European Chemicals Bureau, Ispra, Italy, October 2004 (http://ecb.jrc.it/Documents/Biocides/HUMAN_EXPOSURE/).

Appendix I: Used data

	Loose Grain		Bait Block		Paste Bait	
Submission	Application	Bait station	Application	Bait station	Application	Bait station
C1-01	1.0	10.0	1.0	10.0	3.0	30.0
C1-02	9.0	20.0	6.0	120.0	6.0	120.0
C1-03	8.0	10.0	3.0	5.0	8.0	80.0
C1-04	2.0	10.0	1.5	10.0	1.0	10.0
C1-05	1.0	40.0	1.0	30.0	2.0	80.0
C1-06	5.0	4.0	2.0	1.0	5.0	25.0
C1-07	2.0	80.0	4.0	60.0	0.4	10.0
C1-08	1.0	12.0	1.0	15.0	1.0	15.0
C1-09	1.0	25.0	1.0	26.0	1.0	100.0
C1-10	5.0	6.6	5.0	6.6	5.0	6.6
C1-11	5.0	100.0	1.0	41.0	6.0	160.0
C1-12	2.0	100.0	6.0	100.0	1.0	100.0
C1-13	0.2	1.0	0.2	1.0	4.0	20.0
C1-14	2.0	80.0	0.4	25.0	5.0	200.0
C1-15	7.0	10.0	7.0	2.0	7.0	50.0
C2-01	7.0	70.0	2.0	15.0	1.0	15.0
C2-02	4.0	4.0	6.0	6.0	1.0	1.0
C2-04	1.6	6.6	1.6	6.6	1.6	6.6
C3-01	0.12	3.7	n.d.	47	0.04	n.d.

Appendix II: Used questionnaire

QUESTIONNAIRE ABOUT RODENTICIDE USE IN EUROPE

Please answer the following 10 questions.
Questions refer to the use of ready-to-use formulations only. (Information about concentrates, gels, dusts and fumigants are not required).
Only estimates and average figures are required.

1. Which ready-to-use rodenticides are used? Also, please specify the active ingredient and %

Loose grain baits:
Bait block formulations:
Paste baits:

2. How much rodenticide is purchased by Pest Control each year? (Average figures in kilos).

Loose grain baits:
Bait block formulations:
Paste baits:

3. What is the advised dosage per bait station? (Average figures in grams)

Loose grain ready-to-use baits:
Bait block formulations:
Paste baits:

4. How many Pest Control Technicians are there in your Company?

5. Do all Pest Control Technicians handle rodenticides in their normal job? (If no, please specify how many Technicians handle rodenticides).

6. How long is the average working day? (in hours)

7. How often does a Pest Control Technician handle rodenticides? (e.g. how many times per day or per week or per month or per year).

Loose grain ready-to-use baits:
Bait block formulations
Paste baits:

8. For what part of his working time does a Pest Control Technician handle rodenticides? Give an indication: 0% to 100%.

Loose grain ready-to-use baits:
Bait block formulations
Paste baits:

9. How long does it take for a Pest Control Technician to inspect and fill rodenticide at a bait station?Give an estimate in minutes/seconds and only include from opening to closing the bait station. (DO NOT include cleaning out.)

Loose grain ready-to-use baits:
Bait block formulations
Paste baits:

10. On average, how many bait stations would a Pest Control Technician fill per day?

Loose grain ready-to-use baits:
Bait block formulations:
Paste baits:

END. Thank you.

DATE……
NAME……
POSITION…….
COMPANY……
COUNTRY……

Appendix III: Summary of data from Company 3

As described above, the data subset submitted by company 3 consists of 10 values for individual technicians. To avoid any bias by giving too much weight to these data (the data represent only one company but comprise 10 observations), the average numbers were used in the analysis. The submitted data and the used average numbers are displayed in the table below.

Table 3**: Data of Company 3 forming the basis of the aggregation procedure.**

	Loose Grain		Bait Block		Paste Bait	
Technician	Application	Bait station	Application	Bait station	Application	Bait station
01	0.02	20	n.d.	50	0.01	n.d.
02	0.01	5	n.d.	20	0.00	n.d.
03	0.20	5	n.d.	50	0.05	n.d.
04	0.20	1*	n.d.	50	0.00	n.d.
05	0.01	1*	n.d.	50	0.00	n.d.
06	0.15	1*	n.d.	40	0.10	n.d.
07	0.10	1*	n.d.	80	0.02	n.d.
08	0.05	1*	n.d.	50	0.05	n.d.
09	0.40	1*	n.d.	30	0.02	n.d.
10	0.05	1*	n.d.	50	0.10	n.d.
Company average	0.12	3.7	n.a.	47	0.04	n.a.

n.d.: no data provided;

*: values were stated to be close to zero and therefore set to 1 as a conservative approach

Appendix IV: Summary of rodent control on large sites (company 3)

Company 3 provided an additional user survey reflecting the worst case assumption that a PCT is exclusively working at only one large site during his entire working day, so that no travelling etc. takes place. The survey was conducted at a company located in Germany using predominantly block bait formulations. Figures were presented for one application in the sewerage (only maximum value given) and six other objects (average and maximum values). The provided data are presented in the table below:

Table 4: **Data of Company 3 for continuous rodent control work on a given working day.**

Application	**Arithmetic mean**	**Maximum**
Sewerage	n.d.	100
Object 1	45	75
Object 2	20	100
Object 3	30	105
Object 4	35	82
Object 5	20	50
Object 6	55	130
All (arithmetic mean)	34	91

n.d.: no data provided

The above data are not included in the statistical analysis for deriving exposure frequencies since they were obtained in a different context and are therefore incompatible with the user survey. Instead, they may serve as a plausibility check as follows: The mean maximum exposure frequency in the case of continuous pest control work at a large site is 91 (also see table above). This is slightly higher than the 75^{th} percentile estimated from the user survey data (81 bait points handled per day). Therefore, the 75^{th} percentile (which is related to the typical case of more erratic work at several smaller sites) can be considered as a sufficiently conservative estimate for the reasonable worst case.

<table>
<tr><td>Section B6.6
Annex Point IIB.VI.6.6</td><td>Exposure data relating to the biocidal product</td><td></td></tr>
<tr><td></td><td></td><td>Official use only</td></tr>
<tr><td>6.6.1 Human exposure towards biocidal product</td><td></td><td></td></tr>
<tr><td>6.6.1.1 Production</td><td>The most relevant route of exposure to the active substance is the dermal route. The active substance has a low vapour pressure, therefore the potential for evaporation is low, Hence, the potential for inhalation exposure is low. Inhalation exposure is only of concern during the formulation process where the active substance has a potential for becoming airborne when mixed with dry bait ingredients. Any potential oral exposure will be indirect exposure via possible release to the environment.
Use in Product type 14
<table>
<tr><th>Exposure path</th><th>Industrial use</th><th>Professional use</th><th>General public</th><th>Via the environment</th></tr>
<tr><td>Inhalation</td><td>No</td><td>No</td><td>No</td><td>No</td></tr>
<tr><td>Dermal</td><td>No</td><td>Yes</td><td>Yes</td><td>Yes</td></tr>
<tr><td>Oral</td><td>No</td><td>No</td><td>No</td><td>Yes</td></tr>
</table></td><td></td></tr>
<tr><td>6.6.1.2 Intended use(s)</td><td>It is proposed that the product will be used as a rodenticide for the control, primarily, of commensal rodent species (Rattus norvegicus, Rattus rattus, and Mus domesticus) by both professional and amateur users. The product is intended for use in domestic, industrial and commercial buildings including in and around farm building. Use of this product in fields is not supported.
Bait boxes for use by the general public are supplied as lockable units and can be refilled.
The paste bait can be fixed into position, either within bait stations as paste bait adhering directly to the surface or by fixing sachets within a bait box or tying sachets to a fixed object so that rodents and water flows cannot dislodge them. The bait is then eaten in situ by target rodents.</td><td></td></tr>
<tr><td>6.6.1.3 Professional exposure</td><td>Dermal exposure
Professional exposure arises from loading the bait into the bait point, applying the paste bait in sewers and disposal of empty bait points.
Exposure can be estimated using the results from the CEFIC exposure study.
The CEFIC exposure study also assumes that there will be no PPE when a more realistic scenario would assume that the majority of professional use would be covered by gloves as a minimum requirement.
Inhalation exposure
The only potential inhalation exposure to professionals will be from dusts containing the active substance, formed during the final mixing of paste in the formulation process. LEV is not available at the formulation site.
Oral exposure
Workers and pest control operatives are not expected to be exposed by the oral route to the active substance or product. Although the active substance is very toxic by acute oral exposure (LD50 rat, oral = <5 mg/kg) good industrial hygiene, such as washing before eating or smoking will reduce the risk of accidental oral exposure.</td><td></td></tr>
</table>

Section B6.6 Annex Point IIB.VI.6.6	**Exposure data relating to the biocidal product**	
6.6.1.4 Consumer and secondary exposure	Dermal exposure The dermal exposure scenario for disposal of old bait and carcasses for non-professional use is the same as that for professional users (see section 1.2.2.3) The use of the CEFIC exposure study scenario, assuming one exposure task per day, gives an estimated dermal systemic exposure for non-professional use. Inhalation exposure There will be no inhalation exposure to the biocidal product from amateur use. Oral exposure Users are instructed to wash hands after placing the bait point and after disposing of the bait point and carcasses. There will therefore be no oral exposure to the active substance or biocidal product from amateur use.	
6.6.2 Human exposure towards substances of concern within the biocidal product	There are no substances of concern within the biocidal product.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted.	
	Evaluation by Rapporteur Member State	
Date	[redacted]COMMENT: This section from the original EU submission has been amended. The original submission referred to amateur products being only supplied in pre-filled sealed bait boxes. In reality, if supplied in bait boxes, these are lockable and may be refilled. Where bait boxes are not suitable or necessary, baits may be applied in covered/protected bait points. Secondly, this section has been extensively amended to remove exposure calculations, which the RMS stated should only be included in IIB and IIC.	
Materials and methods		
Conclusion		
Reliability		
Acceptability		
Remarks		
	Comments from….	
Date	*Give date of comments submitted*	
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub) heading numbers and to applicant's summary and conclusion. Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Reliability	*Discuss if deviating from view of rapporteur member state*	
Acceptability	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section B6.7.1.1 Annex Point *IIIB XI 1.1*	**Food and feedingstuffs studies - If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin**	
	Justification for non-submission of data	Official use only

Section B6.7.1.1 **Annex Point *IIIB XI 1.1***	**Food and feedingstuffs studies - If residues of the biocidal product remain on feedingstuffs for a significant period of time, then feeding and metabolism studies in livestock shall be required to permit evaluation of residues in food of animal origin**	
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [X]** **Other justification [ ]**	
Detailed justification:	Rodenticide paste bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Paste bait is used in situations where foods or feedingstuff are not present or are unlikely to be contaminated.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	*April 2007*	
Evaluation of applicant's justification	Applicant's justification is considered acceptable	
Conclusion	Adopt applicant's version	
Remarks	None	
	Comments from other Member State *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Section B6.7.1.2 **Annex Point *IIIB XI.1.2***	**Food and feedingstuffs studies - Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product**	
	Justification for non-submission of data .	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Rodenticide paste bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Paste bait is used in situations such as sewers where foods or feedingstuff are not present or where they are unlikely to be contaminated.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	*April 2007*	
Evaluation of applicant's justification	Applicant's justification is considered acceptable	
Conclusion	Adopt applicant's version	

Section B6.7.1.2 Annex Point *IIIB XI.1.2*	**Food and feedingstuffs studies - Effects of industrial processing and/or domestic preparation on the nature and magnitude of residues of the biocidal product**
Remarks	None
	Comments from other Member State *(specify)*
Date	*Give date of comments submitted*
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Remarks	

Section B6.7.2 **Annex Point *IIIB XI 2***	**Other test(s) related to the exposure to humans** **Suitable test(s) and a reasoned case will be required for the biocidal product**	
	Justification for non-submission of data	Official use only
Other existing data [ ] **Limited exposure [ ]**	**Technically not feasible [ ] Scientifically unjustified [ ]** **Other justification [ ]**	
Detailed justification:	Rodenticide paste bait is not applied to foods or feedingstuffs. The active substance is not volatile and the product is not applied by spraying or dusting such that food or feedingstuffs could be contaminated. Paste bait is used in situations such as sewers where foods or feedingstuff are not present or where they are unlikely to be contaminated. Active substance is poorly absorbed by dermal route (as shown by acute oral toxicity compared to dermal toxicity) and does not vaporise readily at NTP. Product does not contain any other substances of concern, and most are food-grade materials. The product is used primarily in situations like sewers where good hygiene standards are necessary because of biological hazards, including wearing gloves and other protective clothing.	
Undertaking of intended data submission [ ]	*Give date on which the data will be handed in later (Only acceptable if test or study is already being conducted and the responsible CA has agreed on the delayed data submission.)*	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	Evaluation by Rapporteur Member State	
Date	*April 2007*	
Evaluation of applicant's justification	Applicant's justification is considered acceptable	
Conclusion	Adopt applicant's version	
Remarks	None	
	Comments from other Member State *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Annex IV: List of studies reviewed

List of <u>new data</u>[20] submitted in support of the evaluation of the active substance (IIIA)

Not applicable

20 Data which have not been already submitted for the purpose of the Annex I inclusion.

List of <u>new data</u> submitted in support of the evaluation of the biocidal product (IIIB)

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
3.1.1 3.1.2 3.6	Atwal SS and Woolley SM	2007	Determination of Relative Density. [redacted] Report No. 2254/0053 GLP, Unpublished	Y	[redacted]
3.1.1 3.1.2 3.1.3	Garofani S	2008	[redacted] Determination of the Colour, Odour and Physical State [redacted] Report No. CH-345/2006 GLP, Unpublished	Y	
3.4	Atwal SS and Woolley SM	2008	[redacted] (0.005% difenacoum): Determination of Physico-chemical Properties. [redacted] Ltd., Report No. 2254/0040 GLP, Unpublished	Y	
3.7	Thomas KT	1998	Storage Stability and Physical-Chemical Characteristics of a 0.005% w/w Paste Bait Formulation of Brodifacoum School of Pure and Applied Biology, University of Wales Cardiff, Report No. 96031329 GLP, Unpublished	Y	
4.1	Garofani S	2007	[redacted] Validation of the Analytical Method for the Determination of the Active Ingredient Content. [redacted] Report No. CH-346/2006 GLP, Unpublished	Y	
5.10.1	[redacted]		Product Label: [redacted] Unpublished.	N	
5.10.2(1)	[redacted]	2005a	Report: Palatability and Efficacy of Aged [redacted] Laboratory Mice. [redacted] Report No. 06/2005 GLP, Unpublished	Y	
5.10.2(2)	[redacted]	2005b	Report: Palatability and Efficacy of Fresh [redacted] Formulation in Laboratory Mice. [redacted], Report No. 04/2005 GLP, Unpublished	Y	
5.10.2 (3)	[redacted]	2005c	Palatability and Efficacy of [redacted] in Laboratory Rats [redacted] Report No. 03/2005. GLP, Unpublished	Y	
5.10.2 (4)	[redacted]	2005d	Report: Palatability and Efficacy of Aged [redacted] Formulation in Laboratory Rats. [redacted] Report No. 05/2005. GLP, Unpublished	Y	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
5.10.2 (5)	[redacted]	2006	Field trial report to determine the efficacy of [redacted] containing 0.005% w/w brodifacoum for the control of an infestation of house mice (*Mus domesticus*) resident within the machinery room of a grain store on an agricultural holding [redacted] Report Number: PEL/011/05. Unpublished	Y	[redacted]
5.10.2 (6)	[redacted]	2009	Field trial report to determine the efficacy of [redacted] containing 0.005% w/w brodifacoum for the control of an Infestation of house mice (*Mus domesticus*) resident within the machinery room of a grain store on an agricultural holding [redacted] Report No. PEL/002/09, Unpublished	Y	[redacted]
5.10.2 (7)	[redacted]	1995	Field trial report to determine the efficacy of [redacted] containing 0.005% w/w brodifacoum, for the control of an infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding [redacted] Report No. RFT/95/1906, Unpublished	Y	[redacted]
5.10.2 (8)	[redacted]	1997	Field trial report to determine the efficacy of [redacted] containing 0.005% brodifacoum, for the control of an infestation of Warfarin-resistant Norway rats (*Rattus norvegicus*) on an agricultural holding [redacted] Report No. RFT/97/1935, Unpublished	Y	[redacted]
5.10.2 (9)	[redacted]	2010	The Effects of Exposure to Extreme Environmental Conditions on the Palatability of Pasta Bait. [redacted] Report No. TKI/PI/100126/SimSew/PB, Unpublished	Y	[redacted]
5.11	[redacted]	2010	Expert Review of the Effectiveness of Brodifacoum for the Control of Rats and Mice Resistant to other Anticoagulants [redacted] Unpublished	Y	[redacted]

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
6.1.1	[redacted]	2007a	Brodifacoum Paste: Acute Oral Toxicity in the Rat – Fixed Dose Method [redacted] Report No. 2254/0025 GLP, Unpublished	Y	[redacted]
6.1.2	[redacted]	2007b	Brodifacoum paste: Acute Dermal Toxicity (Limit Test) in the Rat [redacted] Report No. 2254/0026 GLP, Unpublished	Y	[redacted]
6.2 (1)	[redacted]	2007c	Brodifacoum paste: Acute Dermal Irritation in the Rabbit [redacted] Report No. 2254/0027 GLP, Unpublished	Y	[redacted]
6.2 (2)	[redacted]	2007d	Brodifacoum paste: Acute Eye Irritation in the Rabbit [redacted] Report No. 2254/0028 GLP, Unpublished	Y	[redacted]
6.4 (1)	[redacted]	2007	*In vitro* absorption of difenacoum from wax block and pasta bait through human epidermis [redacted] Report No. JV2001 GLP, Unpublished	Y	[redacted]
6.6 (1)	[redacted]	2004	Study to Determine Potential Exposure to Operators During Simulated Use of Anticoagulant Rodenticide Baits [redacted] Report No. SYN/1302. Unpublished.	Y	[redacted]
6.6 2(2)	[redacted]	2006	Estimation of the Frequency of Dermal Exposure During the Occupational Use of Rodenticides [redacted] Consulting., Unpublished.	Y	[redacted]
7.8.7.1 (1)	[redacted]	1982	A Review of the Secondary Poisoning Hazard to Wildlife from the use of Anticoagulant Rodenticides Proceedings of the 10th Vertebrate Pest Conference (1982). Published	N	Public Domain
7.8.7.1 (2)	[redacted]	-	Effects of New Rodenticides on Owls, Institute of Terrestrial Ecology, Monks Wood Experimental Station, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published	N	Public Domain
7.8.7.1 (3)	[redacted]	1994	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Pesticide Science, 42, 179-184. Published	N	Public Domain

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP /(Un)Unpublished	Data Protection Claimed (Yes/No)	Owner
7.8.7.1 (4)	[redacted]	-	The Toxicity of Three Second-Generation Rodenticides to Barn Owls, Institute of Terrestrial Ecology, Monks Wood, Abbots Ripton, Huntingdon, Cambs PE17 2LS Published	N	Public Domain

ANNEX V: Toxicology Calculations

Insert relevant exposure/effect calculations undertaken, if applicable.

ANNEX VI: Environmental Calculations

V. ENVIRONMENTAL FATE & BEHAVIOUR CALCULATIONS

V.1 Environmental exposure assessment

The product contains the anticoagulant active substance brodifacoum (CAS No. 56073-10-0) at a concentration of 0.005% w/w (50 mg/kg). The product is designed to be used by **professionals and amateurs** in and around buildings infested by rats or mice. Furthermore, **professional use** of the product is envisaged in the area of rodent control in sewer systems.

For rat abatement (by amateurs and professionals), bait points containing 60g of bait are established, at distances of 5-10m apart. For mouse control, bait points consist of 20g of bait, placed at distances of 2-5m apart. Bait points are protected to help prevent access to non-target animals. The label gives instruction to place the baits securely, i.e., in a way minimizing the risk of consumption by other animals or children. For amateur use the label prescribes to use tamper resistant bait stations for rat control. For amateur mouse control baits have to be placed into or at a covered or protected bait station. For professional rodent control the use of tamper resistant bait stations is not compulsory however, if tamper resistant bait stations are not employed, the baits must be fixed by strings or wire to avoid uptake by non target animals/humans, or uncontrolled dispersal.

Since non-target animals and the general public have no entrance to sewer infrastructure, a risk for primary poisoning does not arise due to rodent control in this compartment. The product can be applied by the 'pulsed-baiting' technique - at heavily infested sites bait points have to be replenished after 3-4 days and after 1 week. Thereafter, bait points should be checked weekly for curative treatment and every month for preventive treatment. Clearance of the rodent infestation should be achieved in 7-35 days.

In accordance with the TGD on Risk Assessment (EC, 2003[21]) and with the aid of the Emission Scenario Document for PT 14 (J. Larsen, 2003[22], in the following referred to as ESD PT 14), a quantitative approach is performed in order to estimate potential brodifacoum residues in environmental compartments, arising from its use as rodenticide, and local Predicted Environmental Concentrations (PECs) are calculated. These PECs will be compared with the Predicted No Effect Concentrations (PNEC), i.e., the concentrations below which unacceptable effects on organisms will most likely not occur. The PNEC values are derived from the relevant ecotoxicological studies. In the following environmental exposure assessment the active substance is exclusively taken into consideration as no further environmentally relevant substance is formed in the course of brodifacoum release into environmental compartments (*cf.* CA Report for brodifacoum).

Besides denatonium benzoate (Bitrex®) none of the other ingredients in the product is classified with an environmentally relevant R-phrase (EU 99/45) or Hazard Statement (EU CLP 1272/2008). Bitrex® is classified with R52/R53 or H411. However, due to its significantly lower aquatic toxicity compared to brodifacoum (most sensitive species for Bitrex® is *Daphnia magna* with an EC_{50} of 13 mg/L, compared to brodifacoum with a lowest LC_{50}/EbC_{50} of 40 mg/L for fish and algae, respectively), and its very low content in the product (0.001% w/w), Bitrex® does not have to be contemplated in this context.

Regional and continental PECs have not been calculated as they are not considered relevant for rodenticide use because the low consumption of rodenticide products leads to a negligible regional contribution (*cf.* Section 2.2, ESD PT 14).

Emissions to the environment from the use of brodifacoum in the product

Exposure during the production and formulation of brodifacoum should be addressed under other EU legislation (e.g. REACH) and not repeated under Directive 98/8/EC. The Biocides Technical Meeting

21 Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003

22 Larsen, 2003: Emission scenario document for biocides used as rodenticides. EUBEES 2 report ENV.C3/SER/2001/0058.

(TMI06) agreed that a risk assessment for production and formulation of the active substance was not required, unless the active substance was totally new to the EU market and manufactured in the EU. This is not the case for brodifacoum which is an existing biocidal active substance within the EU.
Hence, the environmental exposure assessment focuses on the use and disposal of the rodenticide, which is in line with the scenarios proposed by the ESD.

V.1.1 Fate and distribution of brodifacoum in the environment

Details on the environmental fate and behaviour of brodifacoum are given in the CA Report for the active substance with regard to its inclusion in Annex I of Directive 98/8/EC.
The active substance is hydrolytically stable (t½ > 1 year), of low water solubility, ($5.8\ 10^{-5}$ g/l at pH 7 20°C). It has a low vapour pressure and undergoes indirect photodegradation rapidly (t½ = approx 2 hours). It is not readily and not inherently biodegradable.
In addition to this, supportive data in the literature (EHC 175 , WHO 1995) showed that a study by Hall and Priestley (1992) indicated that the half-life was 157 days with a mean total of 35.80% of applied radioactivity (as radiolabelled brodifacoum) being recovered as $^{14}CO_2$ at 52 weeks. The levels of radioactivity accounted for by volatiles other than $^{14}CO_2$ were less than 2% over the study period of 52 weeks.
The Koc of 50000 (The Pesticide Manual 13th ed) indicate that the active substance would be persistent and immobile in soil. The exposure to the groundwater is unlikely.
The potential for the substance to ionise at environmental pH indicates that *Brodifacoum* is likely to absorb strongly to soil particles or sediment if released to the environment.

V.1.1.1 PEC calculations

The ESD PT 14 categorises scenarios according to the application surrounding (area of use) of the rodenticide and the application type (formulation). The PECs for the scenarios relevant to this product are presented below. It must be noted that the ESD PT 14 does not provide a scenario for the indoor use of rodenticides even though it is possible for a product to reach the sewer system due to cleaning processes following indoor use. However, these environmental emissions are considered negligible compared to emissions from outdoor use around buildings. Therefore, environmental emissions arising from the indoor use can be regarded to be covered by allowance for outdoor applications, as a conservative assumption. Since rat abatement requires higher application amounts compared to mouse control, the exposure assessment includes application amounts and distances for placing the bait for the former target organisms (rat).
Emissions to the environment have been calculated in a two-tiered approach. In a first tier, the default values of the ESD PT 14 regarding application amounts and mode of use are used to calculate the worst-case PECs (first column in the tables). For refinement (Tier 2), product-specific application amounts and mode of use are used to derive PEC values that more closely reflect the realistic usage. The applicant also used data on the metabolism of brodifacoum to lower the exposure levels further; however the evaluator for the RMS removed this as no exposure assessment on the brodifacoum metabolites was included.

Sewer system

The product is used in sewer systems solely by professionals. Detailed usage instructions are provided on the label.
The ESD PT 14 proposes the scenario of pulsed baiting as a realistic worst case for rodenticide use in a city having a serious rat problem. A campaign of 21 days is assumed, with control operations at days 7 and 14. The revisit at day 7 requires the highest refill of baits (1/3 of the rodenticide has been consumed and must be replaced) so only the first 7 days of the campaign are observed. This scenario has been taken for the current risk assessment.

As outlined above, a two-tiered approach is conducted, comprising the following assumptions:

Tier 1:

In an area corresponding to 10,000 inhabitants, 300 portions of baits (300 g of bait per portion) are applied to 300 cesspools (in total 90 kg product in the catchment of one STP). During the first 7 days of control operation, 1/3 of the baits being placed are lost. Hence, the amount of product either being consumed by rodents or spilled (Q_{prod}) accounts for 30 kg. The fraction of the active substance released to the sewer system ($F_{released}$) is set to 0.9 by default.

Tier 2:

The applicant recommends a dosage rate of 200g to be placed at each of the 300 cesspools. This corresponds to a total mass of product of 20kg. In addition the applicant suggested refining the PEC values by including data on the metabolisation of Brodifacoum. However as explained above the

evaluator for the RMS removed this as no exposure assessment on the brodifacoum metabolites was included.
Regarding the fate and behaviour of brodifacoum in a STP, the SimpleTreat model, implemented in EUSES 2.1, was used. Accordingly, the bulk of the active substance when entering a STP is translocated into sewage sludge (80.3%) with the remainder being present in the STP effluent after wastewater treatment.
The input parameters for EUSES 2.1 are summarized in the following table. They have been adopted from the list of endpoints of the CA Report for brodifacoum.

Table 3: Input parameter for EUSES calculation

Parameter	Unit	Value	Condition
Molar mass	g/mol	523.4	
Melting point	°C	232	
Boiling point	°C	Not applicable	
Vapour pressure	Pa	10^{-6}	20°C
Henry's constant	$Pa*m^3*mol$	$2.18*10^{-3}$	pH 7
Water solubility	mg/L	0.24	pH 7, 20°C
Log P_{ow}		4.92	
DT_{50} in soil	d	157	20°C
		298	12°C
K_{oc} (soil)	L/kg	50000	Pesticide Manual 13th ed.
Distribution in STP		80.3% sludge	SimpleTreat distribution

Using these input parameters and the Tier 1 and Tier 2 approaches explained above environmental concentrations have been assessed and are presented in the following table:

Table-4: Brodifacoum concentrations in environmental compartments for the scenario 'sewer system'

		Tier 1[a]	Tier 2[b]
Input			
Q_{prod}	Amount of product used in control operation (kg)	30	20
$Fc_{product}$	Fraction of active substance in product	0.00005	0.00005
$T_{emission}$	Number of emission days	7	7
$F_{released}$	Fraction of active ingredient released	0.9	0.9
Output			
$Elocal_{water}$[c]	Mean local emission of active substance to waste water during episode (g/d)	0.193	0.129
C_{infl}[d]	Concentration in sewage water to local STP (mg/L)	9.64×10^{-5}	6.43×10^{-5}
Local concentrations in different compartments after elimination processes in STP according to TGD (2003) calculated by EUSES 2.1			
PEC_{stp}	PEC for microorganisms in the STP (mg/L)	1.93×10^{-5}	1.27×10^{-5}
$PEClocal_{water}$	Local PEC in surface water during emission episode (mg/L)	1.77×10^{-6}	1.18×10^{-6}
$PEClocal_{sediment}$	Local PEC in fresh-water sediment during emission episode (mg/kg)	1.92×10^{-3}	1.28×10^{-3}
$PEClocal_{soil}$	Through application of sewage sludge (mg/kg)	4.86×10^{-4}	3.24×10^{-4}
$PEClocal_{soil, porew}$	Concentration in porewater/groundwater of agricultural soil (mg/L)	4.66×10^{-7}	3.11×10^{-7}

[a] ESD default application data
[b] Product specific application data
[c] $Elocal_{water} = (Q_{prod} \times Fc_{product} / T_{emission}) \times F_{released}$
[d] $C_{influent}$ = $Elocal_{water}$ / total volume of sewage water per day (related to standard STP scenario in TGD with 200 L per person per day and 10000 inhabitants per STP)

In and around buildings
As mentioned above, in the ESD PT14 emissions to the environment from the indoor use of rodenticides are considered to be insignificant compared to those arising from the outdoor use. Hence, the emission pathway: indoor use → disposal or cleaning operation → STP will not be contemplated.
The current risk assessment focuses on rat control because rat abatement with the product requires higher application amounts related to an area compared to mice control. The product can be applied by amateurs and professionals with the same maximum application amounts (60g bait maximum per bait point with a minimum distance of 5m between points) however the modes of application may be slightly different for the two user groups. **Amateurs are instructed to always use tamper resistant bait stations**, reducing the risk for unintended uptake by humans and non-target vertebrates as well as leading to a decrease in exposure of soils if applied around buildings. **The use of tamper resistant bait stations is not obligatory for professionals.** However, if professionals do not employ tamper resistant bait stations they are instructed to secure baits by strings or wire in order to limit access to the baits, and dispersal.
In conjunction with rodenticide applications **in and around buildings** the main exposed environmental compartment is soil contaminated by spills during the application, refilling and disposal (1% direct release) as well as from indirect release via urine and faeces (90% per default).
The environmental risk assessment for brodifacoum, a.s. of the product, is performed in a two steps approach:
Tier 1:
Tier 1 comprises the ESD PT 14 default values regarding dosages and emissions to the environment. Ten bait stations, each containing 250 g, are assumed to be placed within an area 55m long and 10m wide ($550m^2$). The distance between the bait stations is 5m. The ESD PT 14 assumes that during a campaign (21 days) a complete refill of each bait station 5 times is necessary (day 1, 3, 7, 14 and 21).
Tier 2:
Tier 2 comprises the product specific application mode and the ESD PT14 default values regarding emissions to the environment (*cf.* Tier 1). In this case 60g bait is placed at each bait point. The placement of the bait is as described under Tier 1. The ESD recommends a total of 2.6 replenishments (as opposed to 5 for Tier 1). This is to reflect the fact that as the campaign proceeds less and less bait is eaten.

Table-5: Brodifacoum concentrations in environmental compartments for the scenario 'in and around buildings'

Input		**Tier 1[a]**	**Tier 2[b]**
Q_{prod}	Amount of product used in control operation (g) per site	250	60
$Fc_{product}$	Fraction of active substance in product	0.00005	0.00005
N_{sites}	Number of application sites	10	10
N_{refill}	Number of refilling times	5	2.6
$F_{releaseD, soil}$	Fraction of product released directly to soil	0.01	0.01
$F_{releaseID, soil}$	Fraction of unmetabolised active ingredient released indirectly to soil	0.9	0.9
Output			
$Elocal_{soil\text{-}D\text{-}campaign}$	Local direct emission of active substance to soil from a campaign (g/camp)	0.006	0.0008
$Elocal_{soil\text{-}ID\text{-}campaign}$	Local indirect emission of active substance to soil from a campaign (g/camp)	0.557	0.069
$Elocal_{soilcampaign}$	Local emission of active substance to soil from a campaign (g/camp)	0.563	0.070

$Clocal_{soil-D}$ [c]	Local concentration in soil due to direct release after a campaign (mg/kg)	0.041	0.005
$Clocal_{soil-ID}$ [d]	Concentration in soil due to indirect release after a campaign (mg/kg)	0.006	0.0007
$Clocal_{soil}$ = $Clocal_{soil-D}$ + $Clocal_{soil-ID}$	Total concentration in soil (mg/kg)	0.047	0.006
$PEClocal_{soil, porew}$ (acc. to TGD, eq.67)	Concentration in porewater resulting from total concentration in soil (mg/L)	5.3×10^{-5}	6.62×10^{-6}

[a] Default application data and values for release
[b] Product specific application data
[c] $Clocal_{soil-D}$ = ($Elocal_{soil-D-campaign}$ x 1000) /($AREA_{exposed-D}$ x $DEPTH_{soil}$ x RHO_{soil} x N_{sites}) according to ESD: $AREA_{exposed-D}$ = 0.09 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil, $Elocal_{soil-D-campaign}$ = Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x $F_{release-D,soil}$
[d] $Clocal_{soil-ID}$ = (Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x 1000 x $F_{releaseID,soil}$ x (1-$F_{releaseD,soil}$)) / ($AREA_{exposed-D}$ x $DEPTH_{soil}$ x RHO_{soil}), according to the ESD $AREA_{exposed-ID}$ = 550 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil.
$Elocal_{soil-ID-campaign}$ = Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x $F_{releaseID,soil}$ x (1- $F_{releaseD,soil}$)

V.1.2 PEC in surface water, sewage treatment plant, groundwater and sediment

Using the relevant scenarios outlined in the ESD PT14, the modes of calculation of the TGD, and the assumptions laid down above, the following PEClocal have been derived for aquatic compartments.

Table-6: Summary of brodifacoum PEC values obtained in the aquatic environment

Compartment/Scenario	Tier 1[a]	Tier 2[b]
SEWER SYSTEM		
PEC_{stp} (mg/L)	1.93×10^{-5}	1.27×10^{-5}
$PEClocal_{water}$ (mg/L)	1.77×10^{-6}	1.18×10^{-6}
$PEClocal_{sediment}$ (mg/kg)	1.92×10^{-3}	1.28×10^{-3}
$PEClocal_{soil, porewater}$ (mg/L)	4.66×10^{-7}	3.11×10^{-7}
IN AND AROUND BUILDINGS		
$PEClocal_{soil, porewater}$ (mg/L)	5.3×10^{-5}	6.62×10^{-6}

[a] ESD default application data and values for release
[b] Product specific application data

V.1.3 PEC in air

Brodifacoum has a vapour pressure of less than 10^{-6} Pa at 20°C and a Henry's Law constant of less than 2.18×10^{-3} Pa x m^3 x mol^{-1} at pH 7. In the Assessment Report for brodifacoum it has been concluded that releases to air from manufacturing, formulating, use or disposal phases are not to be expected. An exposure assessment for air is therefore not required.

V.1.4 PEC in soil

The following table contains a summary of the $PEClocal_{soil}$ derived from the different exposure scenarios.

Table-7: Summary of brodifacoum PEC values for soils

Compartment/Scenario	Tier 1[a]	Tier 2[b]
SEWER SYSTEM		
$PEClocal_{soil}$ (mg/kg) (via sewage sludge)	4.86×10^{-4}	3.24×10^{-4}
IN AND AROUND BUILDINGS		

$PEClocal_{soil}$ (mg/kg)	0.047	0.006

[a] ESD default application data and values for release
[b] Product specific application data

V.1.5 Summary of calculated PECs

See tables 2, 3, 4 & 5

V.1.6 Primary and Secondary Poisoning

Basically the same set of physiological processes is responsible for maintaining life for warmblooded animals, i.e. mammals and birds. Therefore, the use of rodenticides meant **for killing selected pest mammals** has to be considered a general hazard to non-target mammals and birds as well.

Non-target animals are potentially at risk in two ways: 1) from direct consumption of the baits (primary poisoning) and 2) through eating rodents that have taken up/accumulated the poison (secondary poisoning). Though similarities exist there are differences as to the susceptibility to or tolerance of the different rodenticides among mammals and birds. These differences may be due to differences in their normal diets, feeding habits, ecological or other factors.

The exposure scenarios and assessments give a basis for evaluating the primary and secondary poisoning risk to non-target animals according to the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning. These are not described in the TGD (2003) but are described in the ESD PT14 (**CA-Jun03-Doc.8.2-PT14)**.

V.1.6.1 Primary Poisoning

Referring to rodenticide applications **in sewer systems**, there is no primary poisoning hazard to non-target mammals or birds because this is not a habitat for them (*cf.* ESD PT 14).

Regarding the possible primary hazard to non-target animals following applications **in and around buildings**, the label claim of the product contains precautious measures to be undertaken in order to minimise the risk for bait uptake by non-target vertebrates. Amateurs are given instruction to use tamper resistant bait boxes for bait application. Professionals are directed to place the baits so that the baits are inaccessible for non-target animals and children. Accordingly, baits have to be put in tamper resistant stations, or fixed by strings or wire.

The ESD PT14 proposes several non-target species to be assessed for primary poisoning risk assessments. Several bird and mammalian species are proposed (tree sparrow, chaffinch, woodpigeon and pheasant pigs and dogs), all these species will be taken into account in the current risk assessment.

Acute and Long-Term risk assessment for primary poisoning of a non-target organism:
Tier 1:

In the first tier scenario, the risk is characterised by the ratio between PECoral and PNECoral. PECoral is the concentration of the rodenticide in the food of a non-target organism. PNECoral is the No Effect Concentration for oral intake.

This evaluation can be used for both short- and long-term exposure. According to the TGD (2003), the PNECoral is based on; $LC50_{bird}$, $NOEC_{bird}$ or $NOEC_{mammal}$, which is divided by a specific assessment factor mentioned in the TGD (2003) Table 23.

The acute and long-term PNECoral values for birds and mammals are calculated from toxicity data in the CAR and reported in following table.

Organism group	Species / test	Results[1]	Assessment factor	PNEC (concentration in food, mg/kg)[3]	PNEC (dose, mg/kg b.w./d)[3]
Acute					
Birds	Laughing Gull	-	3 000	0.72 mg/kg food	0.09
Mammals	Rat (teratogenicity)	3.33E-06 mg/kg bw	300	0.000067 mg/kg	0.00000335
Long-term					
Birds	Mallard Duck (Difenacoum read-across)	1.28E-05 mg/kg bw/d.	30	0.00013 mg/kg diet	0.00001625
Mammals	Rat (2-gen)	1.1 E-05 mg/kg bw	90	2.22E-04 mg/kg food	0.000111

[1] CAR Brodifacoum

[2] According to TGD, the $PNEC_{mammal}$ can be calculated from toxicity studies of 28 days, 90 days or chronic. Therefore, the acute $PNEC_{mammal}$ is based on NOAEL from 28-d toxicity study.

[3] Calculated using conversion factor from Table 22 in the TGD: 8 for birds, 20 for rats and 33.3 for rabbit.

The concentration in the final product is 0.005% for the active substance Brodifacoum. The Tier 1 assessment assumes that there is no bait avoidance by the non-target animals and that they obtain 100% of their diet in the treated area and has access to the product. The PECoral is 50 mg/kg (Brodifacoum present at 0.005% w/w in the product) and is used in quantitative risk assessment for the acute and long-term situation.

	PEC_{oral} (concentration in food, mg/kg)	**$PNEC_{oral}$ (concentration in food, mg/kg)**	**PEC / PNEC**
Acute			
Bird	50	0.72	69.44
Mammal	50	0.000067	746
Long-term			
Bird	50	0.00013	384
Mammal	50	0.000222	225

The ratios PEC/PNEC are above 1 indicating a potential risk, which must be refined.

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc. The body weights, daily food intakes and estimates of the product ingestion, based on sufficient bait being accessible to satisfy a day's food intake requirement, are presented below for a representative non-target mammal.

The values for the estimated daily intake (ETE) are calculated for non-target birds and mammals consuming the product. The calculation is a first step conducted according to the following equation, using the default values given in the ESD:

ETE = (FIR/BW)*C*AV*PT*PD (mg/kg bw/d) (eq 19, ESD)

Where:
ETE is the Estimated Theoretical Exposure to the active substance,
FIR is the non-target animal's daily food intake (fresh weight),
b.w. is bodyweight,
C is the concentration of active substance in the fresh diet (bait),
AV is the avoidance factor (default 1.0 = no avoidance),
PT is the fraction of diet obtained in the treated area (default 1.0)
PD is the fraction of food type in the diet (default 1.0).

In a second step, the avoidance factor (AV) is set to 0.9 and the fraction of the diet obtained in the treated area (PT) is set to 0.8. In a third step expected concentrations are calculated, assuming a default excretion factor of 0.3.

Table-8 Brodifacoum concentrations in non-target birds following a single uptake of the product

Species	**Body weight (g)**	**Daily food intake (FIR) (g/d)[a]**	**Conc. of a.i. after single meal (mg/kg bw/d) (ETE)**	**Expected conc. after elimination[b] (mg/kg bw/d) (EC)**
Tree sparrow	22	7.6	17.27	12.09
Chaffinch	21.4	6.42	15.00	10.80
Wood pigeon	490	53.1	5.42	3.90
Pheasant	953	102.7	5.39	3.88
Dog	10 000	456[d]	2.28	1.64
Pig	80 000	600[e]	0.375	0.270
Pig, young	25 000	600[e]	1.20	0.864

[a] *cf*. Table 3.1 of ESD PT 14
[b] Default excretion factor = 0.3
[c] AV = 0.9, PT = 0.8
[d] From EUBEES 2, Section 3.2.1,Table 3.1,
[e] From EUBEES 2, Section 3.2.1, page 50: for mammals: log (FIR) = 0.822*log(BW)-0.629,

[f] From EUBEES 2, it seems reasonable to consider a portion of 600 g bait as the normal upper limit for what is available to non-target animals in several EU countries. The 600 g portion is the largest one permitted for use by non-professionals in several countries.

The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: $PEC_{oral}/PNEC_{oral}$ for non-target animals accidentally exposed to bait containing Bromadiolone after one meal

Non-target animals	ETE, concentration of Bromadiolone after one meal (one day) (mg/kg b.w.)		$PNEC_{oral}$ (dose, mg/kg b.w./d)	PEC/PNEC	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.09	0.00013	132846	93000
Chaffinch	15.00	10.50	0.00013	115384	80769
Wood pigeon	5.42	3.79	0.00013	41692	29153
Pheasant	5.39	3.77	0.00013	41461	29000
Dog	2.28	1.596	0.000222	10270	7254
Pig	0.375	0.2625	0.000222	1689	1182
Pig, young	1.20	0.864	0.000222	5405	3927

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-term risk assessment for primary poisoning of a non-target organism:
Tier 1:
In this assessment, long-term exposure also has to be taken into account in the evaluation of primary poisoning of rodenticides. The EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated as follows:

$$EC = ETE \times (1 - El)$$

EC values are based on the calculations for ETE above but an elimination factor has to be taken into account. The default value for an elimination factor of (*El*) = 0.3 per day, stated in the EUBEES 2, has been used. This is a reasonable average default value for elimination, as anticoagulant rodenticides are eliminated from the body mainly through faeces.

Expected concentration of Bromadiolone in the animal after one meal followed by a 24-hour elimination period

Species	Estimated daily uptake of a compound (ETE) (mg/kg b.w./d)		Fraction of daily uptake eliminated (number between 0 and 1) (El)	Expected concentration of active substance in the animal (EC) (mg/kg b.w./d)	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	17.27	12.43	0.3	12.09	8.71
Chaffinch	15.00	10.80	0.3	10.50	7.56
Wood pigeon	5.42	3.90	0.3	3.79	2.73
Pheasant	5.39	3.88	0.3	3.77	2.72
Dog	2.28	1.64	0.3	1.596	1.149
Pig	0.375	0.270	0.3	0.2625	0.189
Pig, young	1.20	0.864	0.3	0.864	0.6048

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 1-day elimination of Bromadiolone

Species	EC_{oral} (mg/kg b.w./d) after 1 day		$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $PEC_{oral}/PNEC_{oral}$	
	Step 1	Step 2		Step 1	Step 2
Tree sparrow	12.09	8.71	0.00013	93000	67000
Chaffinch	10.5	7.56	0.00013	80769	58154
Wood pigeon	3.79	2.73	0.00013	29154	21000
Pheasant	3.77	2.72	0.00013	29000	20923
Dog	1.596	1.149	0.00022	7189	5176
Pig	0.2625	0.189	0.00022	1182	851
Pig, young	0.864	0.6048	0.00022	3892	2724

The ratios PEC/PNEC are above 1 indicating a potential risk.

According to the guidance agreed at the 23rd Biocides CA meeting, EC_5 values are used for quantitative risk assessment of primary poisoning in the long-term situation. Calculations of the expected concentrations (EC) for 5-days exposure considering elimination are calculated.

The EC_n (expected concentration of active substance in the animal after n days) can be calculated by use of **ESD equation 21**:

$$EC_n = \sum_{n=1}^{n-1} ETE * (1 - EL)^n$$

All parameters AV, PT and PD are set to 1 as a worst-case scenario.

The principle in the calculations is for the first 5 days that the animal eats the same daily amount and eliminates 30% of its content of residues. EC_3 is the concentration of residues in the animal before a new meal on Day 3 and so forth. Therefore, the concentration of residues on Day 5 is calculated stepwise this way:
$EC_3 = (EC_2 + ETE) * (1 - 0.3)$
$EC_4 = (EC_3 + ETE) * (1 - 0.3)$
$EC_5 = (EC_4 + ETE) * (1 - 0.3)$

EC_{oral} for different relevant species

Days	EC_{oral} (mg/kg b.w./d)						
Species	Tree sparrow	Chaffinch	Wood pigeon	Pheasant	Dog	Pig	Young pig
Day 1 after first meal	17.27	15.00	5.42	5.39	2.28	0.375	1.20
Day 2 before new meal	12.1	10.5	3.79	3.77	1.60	0.266	0.840
Day 3 before new meal	20.6	17.9	6.45	6.41	2.72	0.449	1.43
Day 4 before new meal	26.5	23.0	8.31	8.26	3.50	0.577	1.84
Day 5 before new meal	30.7	26.6	9.61	9.56	4.05	0.666	2.13

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 1, PT = 1 (mg/kg bw)[a]	EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]	$PNEC_{oral}$ (mg/kg b.w./d)	Ratio $EC_{oral}/PNEC_{oral}$
Tree sparrow	30.7	22	0.00013	170031
Chaffinch	26.6	19	0.00013	147323
Wood pigeon	9.61	7	0.00013	53225
Pheasant	9.56	7	0.00013	52948
Dog	4.05	3	0.000222	13135
Pig	0.666	0.480	0.000222	2160
Pig, young	2.13	2	0.000222	6908

[a] calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:
Overall, all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

V.1.7 Non compartment specific exposure relevant to the food chain (secondary poisoning)

According to the ESD PT 14, the secondary poisoning hazard following sewage system applications is relevant only if poisoned rats or cockroaches move to the surface. However, since cockroaches are predominately nocturnal and the species found in sewers will remain underground, they are not significant prey for birds.

Secondary poisoning hazard can also be ruled out when the rodenticide is used in fully enclosed spaces. If buildings are not fully closed, predators may occur inside buildings or hunt in the vicinity of a building, and are potential targets for secondary poisoning.

Consideration is required for **predators eating fish** which have been exposed to the active substance.

Calculations for secondary poisoning are also undertaken according to the ESD PT 14 for **predators eating the rodent carcasses** and **earthworms** which have ingested the active substance absorbed to soil.

V.1.7.1 Calculation of concentration in rodents

The following assumption is followed: a rodent of a size occurring in EU countries consumes an average daily amount of food equivalent to about 10% of its body weight.

According to the ESD PT 14, a normal susceptible rodent may eat anticoagulant rodenticide for a number of days before it stops eating. The feeding period has been **set to a default value of 5-days**, which corresponds to the feeding pattern observed in laboratory experiments. The mean time until death has been set to a default value of 7-days. Concentrations in contaminated rodents have been calculated for the time point immediately after the last meal. The factor PD (fraction of food type in diet) is set to 0.2 (minimum factor for normal case), 0.5 (normal use situation), and 1.0 (worst case situation).

Anticoagulant rodenticides are eliminated from the body mainly through faeces. A worst-case scenario assumes that the target rodent will eat continuously during the whole period and that the elimination of active substance is 30% per day during the whole period. Regarding the elimination rate, the default of 0.3 supported by the ESD is adopted.

The concentrations in rodents have been assessed according to **equation 19 of the ESD.** This equation for ETE (see primary poisoning) is used for calculating the amount of active substance being consumed by the target rodent. A reasonable value for factor PD in the equation is necessary for the full scenario.

ETE = (FIR/BW)*C*AV*PT*PD (mg/kg bw/d) (eq. 19, ESD)

The value for FIR/BW is set to a default of 0.1, i.e., the food intake is 10% of the body weight.

The calculation of the concentration in rodents after 5 days of bait consumption, immediately after the last meal, follows the procedure:

Total daily consumption is 100% (PD =1.0, worst case situation). After the first meal on day 1 the rodenticide in the rat accounts for:

ETE = 0.1 * 50 * 1* 1* 1 = 5 mg/kg

The concentration for day 2 just before the second meal is assessed, using a value of 0.3 for elimination (El).

EC_2 = 5 * (1 - 0.3) = 3.5 mg/kg **(eq. 20, ESD)**

For the following days the concentrations are:

EC_3 = (EC2 +ETE) * (1-0.3) = (3.5 +5) * 0.7 = 5.95 mg/kg

EC_4 = (EC3 +ETE) * (1-0.3) = (5.95 +5) * 0.7 = 7.665 mg/kg

EC_5 = (EC4 +ETE) * (1-0.3) = (7.665 +5) * 0.7 = 8.866 mg/kg

EC_6 = (EC5 + ETE) * (1 - 0.3)

For considering the elements in a secondary poisoning scenario for resistant rodents, the concentration of active substance that may be present after a 14-day control operation should be included in the calculations. However, this is considered as a special type of a worst-case scenario, which should only be considered in cases of resistance problems.

For the resistant rodent the calculations have been continued until Day 14 after the meal.

So the concentration in the rat before its last meal on the 5th day is 8.866 mg/kg. Once the ETE is added this results in **13.87 mg/kg**, i.e., this is the concentration **after** the last meal on the 5th day. The following table gives a summary of the expected active substance concentrations in the rodents, using PD values of 1.0, 0.5 and 0.2.

Residues of Bromadiolone in target rodent in mg a.s./kg b.w. at different times during a control operation (concentration of active substance in rodenticide bait 0.005%)

	Residues of rodenticide in target animal, mg a.s./kg b.w. with bait consumption expressed as PD		
	0.2	**0.5**	**1.0**
A normal non-resistant target rodent stops eating on day 5			
Day 1 after the first meal*	1.00	2.50	5.00
Day 2 before new meal**	0.70	1.75	3.50
Day 3 before new meal	1.19	2.97	5.95
Day 4 after the last meal	1.53	3.83	7.66
Day 5**	1.77	4.43	8.86
Day 7 (mean time to death)**	1.36	3.39	6.79
A target rodent continues eating due to resistance			
Day 14 after the meal	2.31	5.79	11.58

Equation for ETE is used for calculation of rodenticide in target animal on Day 1 immediately after first meal.
**Equation for EC (primary poisoning) is used for calculating the value for Day 2 before new meal.

The assessment indicates an increased concentration in resistant rodents. The users should be aware of resistance problems and thereby avoid this risk by checking the resistance status of the rodent population in the area to be controlled and by considering the choice of the rodenticide to be used.

Regarding a control operation against normal susceptible rodents, it is seen that the highest concentration of active substance is found in rodents that have just taken their last meal on the fifth day before they are going to die. The realistic worst case is considered best described when the target rodent has consumed an amount of rodenticide making up 100% of its daily food intake.

Table-9: Brodifacoum concentrations in rodents after 5 days of product uptake, immediately after the last meal (PD = fraction of food type in diet)

	PD = 1.0	**PD = 0.5**	**PD = 0.2**
Expected concentration in rodents immediately after a last meal on day 5 (mg a.i./kg rat, value corresponds to PEC_{oral} mg/kg food)	13.87	6.93	2.77

Tier 1 risk assessment:
For the first tier exposure assessment of secondary poisoning, the maximum residue levels in target rodents arise on day-5 after the last meal (ETEoral predator). The Estimated Theoretical Exposure to an active substance in food of a rodent-eating predator is calculated as follows:

$$ETE_{oral,predator} = (EC_n + ETE_{rodent}) \times F_{rodent}$$

where:
$ETE_{oral, predator}$: Estimated Theoretical Exposure to an active substance in food of a predator per day
EC_n: Expected concentration of active substance in the rodent on day "n" before the last meal
ETE_{rodent}: Estimated uptake of active substance by rodent on day "n" (*i.e.* intake of rodenticide in the last meal, no elimination)
F_{rodent}: Fraction of poisoned rodents in predator's diet

The first tier assessment also assumes the three levels of bait consumption: 20%, 50% and 100% of the daily food intake of the target rodents. For long-term exposure, it is assumed that the rodents have fed entirely on rodenticide (i.e. 100%, PD = 1) and that the non-target animals consume 50% of their daily intake on poisoned rodents (Frodent = 0.5).

Tier 1 risk assessment of secondary poisoning at day 5 (non-resistant rodents)

Organism group	**$PNEC_{oral}$ (mg a.s./kg b.w.)**	**$ETE_{oral, predator}$ (mg a.s./kg b.w.)**	**$PEC_{oral}/PNEC_{oral}$ – day 5**

PD values		0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	0.72	2.77	6.93	13.87	3.84	9.62	19.26
Mammals	0.000067				41343	103432	207014
Long-term							
Birds	0.00013	1.39	3.47	6.93	10692	26692	53307
Mammals	0.000222				6261	15630	31216

Tier 1 risk assessment of secondary poisoning at day 14 (resistant rodents)

Organism group	**$PNEC_{oral}$ (mg a.s./kg b.w.)**	**$ETE_{oral, predator}$ (mg a.s./kg b.w.)**			**$PEC_{oral}/PNEC_{oral}$ – day 14**		
PD values	-	0.2	0.5	1.0	0.2	0.5	1.0
Acute							
Birds	0.72	2.31	5.79	11.58	3.20	8.04	16.08
Mammals	0.000067				34477	86417	172835
Long-term							
Birds	0.00013	1.15	2.31	5.79	8846	17769	44538
Mammals	0.000222				5227	10500	26318

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned is very high as indicated by the above the trigger value of 1 is exceeded in all cases. Therefore, a refined tier 2 assessment is set out below, based on representative species.

Tier 2 exposure and risk assessment:

The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. Food intake of non-target animals can vary significantly, depending on the metabolic rates of species, the nature of their food, weather conditions, time of year, etc. Several bird and mammal species are chosen to refine the risk assessment:

Birds: barn owl, kestrel, little owl and tawny owl.

Mammals: fox, polecat, stoat and weasel.

The bodyweights and food intake are drawn from the EUBEES 2 guidance and on documents referred to in SANCO/4145/2000[23].

In the following table, the expected values for uptake of active substance by a bird of prey or a mammal predator after a single day of exposure are presented and the expected concentration in the non-target animals as a second tier exposure estimation of secondary poisoning. In the following table, concentrations in weasel, kestrel, and some other birds and mammals have been calculated after a single day of exposure for PD = 1 (rodents diet consisted entirely of the product). The parameter F_{rodent} (fraction of poisoned rodents in predator's diet) is set to 0.5.

23 http://ec.europa.eu/food/plant/plant_protection_products/approval_active_substances/docs/wrkdoc19_en.pdf

Table-10: Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents

				Normal susceptible rodents caught on day 5, before their last meal.		Normal susceptible rodents caught on day 5 just after their last meal		Resistant rodents caught on day 14 just after their last meal	
Species		**Body weight *)**	**Daily mean food intake*)**	**Amount a.s. consumed by the non-target animal****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animal*****	**Concentration in non-target animal**	**Amount a.s. consumed by the non-target animals********	**Concentration in non-target animal**
		(g)	**(g)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**	**(mg)**	**(mg a.s./kg b.w.)**
Barn Owl	*Tyto alba*	294	72.9	0.32	1.10	0.51	1.72	0.61	2.06
Kestrel	*Falco tinnuncul.*	209	78.7	0.35	1.68	0.55	2.62	0.65	3.13
Little owl	*Athene noctua*	164	46.4	0.21	1.26	0.32	1.97	0.39	2.35
Tawny Owl	*Strix aluco*	426	97.1	0.43	1.01	0.67	1.58	0.81	1.89
Fox	*Vulpes vulpes*	5 700	520.2	2.31	0.41	3.62	0.63	4.32	0.76
Polecat	*Mustela putorius*	689	130.9	0.58	0.85	0.91	1.32	1.09	1.58
Stoat	*Mustela erminea*	205	55.7	0.25	1.21	0.39	1.89	0.46	2.26
Weasel	*Mustela nivalis*	63	24.7	0.11	1.74	0.17	2.72	0.21	3.25

Like for the first tier risk assessment, the $ETE_{oral\ predator}$ is compared to the $PNEC_{oral}$.

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	1.10	0.00013	8461
	Day 5 after the last meal	1.72		13230
	Day 14 after the last meal	2.06		15850
Kestrel	Day 5 before the last meal	1.68	0.00013	12920
	Day 5 after the last meal	2.62		20150
	Day 14 after the last meal	3.13		24080
Little owl	Day 5 before the last meal	1.26	0.00013	9690
	Day 5 after the last meal	1.97		15150
	Day 14 after the last meal	2.35		18080
Tawny owl	Day 5 before the last meal	1.01	0.00013	7770
	Day 5 after the last meal	1.58		12150
	Day 14 after the last meal	1.89		14540
Fox	Day 5 before the last meal	0.41	0.000222	1846
	Day 5 after the last meal	0.63		2837
	Day 14 after the last meal	0.76		3423
Polecat	Day 5 before the last meal	0.85	0.000222	3828
	Day 5 after the last meal	1.32		5945
	Day 14 after the last meal	1.58		7117

Species	Exposure	ETE $_{oral\ predators}$ (mg a.s./kg/d)	PNEC$_{oral}$ (mg a.s./kg/d)	Ratio ETE $_{oral\ predators}$ / PNEC$_{oral}$
Stoat	Day 5 before the last meal	1.21	0.000222	5450
	Day 5 after the last meal	1.89		8513
	Day 14 after the last meal	2.26		10180
Weasel	Day 5 before the last meal	1.74	0.000222	7837
	Day 5 after the last meal	2.72		12252
	Day 14 after the last meal	3.25		14639

All ratios $ETE_{oral\ predators}$ / $PNEC_{oral}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

V.1.7.2 Calculation of the concentration in fish

The concentration of the active substance in fish (as food) for fish-eating predators ($PEC_{oral,\ predator}$) is only relevant for the application of the product in the sewer system since only this scenario results in emissions to surface water (via STP). The $PEC_{oral,\ predator}$ (mg/kg wet fish) is calculated from the annual average PEC for surface water, divided by a factor of 2 since it is assumed, that only 50% of the diet comes from the local area (*cf.* TGD, 2003).

$PEC_{oral,\ predator} = PEC_{water} * BCF_{fish} * BMF$ (eq. 76, TGD, 2003)

The bioconcentration factor (BCF_{fish}) is calculated with the aid of **equation 75 of the TGD**, using a log P_{ow} of 6.12. The biomagnification factor is set to 10 according to the TGD.

The following table summarises the $PEC_{oral,\ fish}$ for the scenario 'sewage system'.

Predicted concentrations in fish

		Tier 1[a]	Tier 2[b]
Input			
PEC_{water}	Annual average local PEC in surface (mg/l) divided by 2	8.85×10^{-7}	5.90×10^{-7}
BCF_{fish}	Bioconcentration factor in fish (l/kg wet fish)	36134	36134
BMF	Biomagnification factor	10	10
Output			
$PEC_{oral,\ fish}$	Predicted environmental concentration in fish (mg/kg wet fish)	$3.19 * 10^{-1}$	$2.13 * 10^{-1}$

[a] Product specific application data and default value for release

[b] Product specific application data and refined for metabolism

V.1.6.3 Calculation of concentration in earthworms

The $PEC_{oral,\ predator}$ is calculated according to the TGD:

$PEC_{oral,\ predator} = C_{earthworm}$ (eq 80, TGD, 2003)

$C_{earthworm} = (BCF_{earthworm} * C_{porewater} + C_{soil} * F_{gut} * CONV_{soil}) / (1 + F_{gut} * CONV_{soil})$ (eq 82c, TGD 2003)

$BCF_{earthworm} = (0.84 + 0.012Kow)/RHO_{earthworm}$ (eq 82d, TGD, 2003)

Where $RHO_{earthworm}$ is 1 by default

So, $BCF_{earthworm}$ = (0.84 + 0.012*1318257)/1 = 15820 $l/kg_{wwtearthworm}$

For PEC_{soil} the PEC_{local} is used with respect to sludge applications. The concentration in soil is averaged over a period of 180 days. As for the aquatic food chain it is assumed, that just 50% of the diet comes from the affected region. Hence, the PEC_{soil} averaged over 180 days as well as the $PEC_{porewater}$ are divided by 2.

According to the TGD soil concentrations due to sewage sludge (indirect emissions) are the basis for calculating potential concentrations in earthworms. However, in the current risk assessment a direct intake of the active substance in soils is applicable for the scenario 'in and around buildings'. **EUSES 2.1.1** does not give a result for potential concentrations in earthworms for this scenario and it becomes acknowledged, that the required input parameter for calculating the $PEC_{oral,\ earthworm}$ according to equation 81 of the TGD cannot be assessed for the respective scenarios. An attempt, nonetheless, is made to calculate $PEC_{oral,\ earthworm}$ for the direct soil intake. Soil concentrations taken for the calculation

represents an active substance intake within a soil mixing depth of just 10 cm. Degradation has not been considered. However, concentrations are halved since the TGD assumes only 50% of the soil uptake by earthworm is to original soil from the contaminated area.
The parameter F_{gut} is set to 0.1 (kg dwt/kg wwt) and the conversion factor for soil concentration wet-dry weight ($CONV_{soil}$) is set to 1.13 kg wwt/kg dwt.
The $PEC_{oral,earthworm}$ are summarised in the following table:

Table 5.1-11: Brodifacoum concentrations in earthworms

		Tier 1[a]	**Tier 2[b]**
Input			
C_{soil} sewer system	Concentration in soil averaged over a period of 180 days and divided by 2 (mg/kg wwt)	8.70×10^{-5}	3.70×10^{-5}
C_{soil} building	Concentration in soil immediately after intake divided by 2 (mg/kg wwt)	0.0056	0.0050
$BCF_{earthworm}$	Bioconcentration factor in earthworm (L/kg wet fish)	15820	15820
$C_{porewater}$ sewer system	Concentration in porewater (mg/L) divided by 2	5.35×10^{-7}	2.29×10^{-7}
$C_{porewater}$ building	Concentration in porewater (mg/L) divided by 2	3.48×10^{-5}	3.10×10^{-5}
F_{gut}	Fraction of gut loading in worm (kg dwt/kg wwt)	0.1	0.1
$CONV_{soil}$	Conversion factor for soil concentration wet-dry weight soil (kg wwt/kg dwt)	1.13	1.13
Output			
$PEC_{oral,\ earthworm}$ sewer	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.00763	0.00326
$PEC_{oral,\ earthworm}$ building	Predicted environmental concentration in earthworm (mg/kg wet earthworm)	0.495	0.441

[a] Product specific application data and default value for release
[b] Product specific application data and refined metabolism

Environmental effects assessment

Aquatic compartment

Ecotoxicological studies with the product on aquatic organisms are not required as the toxicity of the product is expected to be entirely driven by that of the active substance.

As no substances of concern or active substances other than brodifacoum have been identified in the product, the toxicity of product can be derived from the data available from the active substance. This is in line with the conclusion drawn in Document IIB of the Assessment Report.

The PNECsediment calculation is as follows:

PNECsoil = Ksusp-water/RHOsusp x PNECwater x 1000 (TGD Eq 70)

= 1250/1150 x 0.00004 mg/l x 1000

= 4.348 x 10^{-2} mg/kg

Atmosphere

Not applicable.

Terrestrial compartment

According to the TNsG on data requirements (Ch. 2.5, Part B), additional data is required with the formulation if this is intended for outdoor use in form of baits, granulates or powder. However, as no additional substances of concern or active substances other than brodifacoum have been identified in the product, the toxicity of product can be derived from the data available from the active substance. This is in line with the conclusion drawn in Document IIB of the Assessment Report.

Non compartment specific effects relevant to the food chain (secondary poisoning)

In the frame of the Annex I inclusion of brodifacoum, the applicant had submitted several studies, dealing with secondary poisoning of non-target vertebrates. The studies have been discussed in detail in Section 4.2.4 of Doc. IIA of the CA Report. The studies indicate that secondary toxicity is dependent on a variety of factors, related to exposure (like dose and treatment levels, habitat of the non-targets) and effect (species and condition of the animal).

ANNEX VII: Residue Calculations

No residue calculations are required as Ratimor Brodifacoum Fresh Bait is a ready to use bait, which is used to kill rats and mice. Ratimor Brodifacoum Fresh Bait will not come into contact with the human food chain. The bait may be used indoors, outdoors around buildings and in sewers (professional only). The bait will be placed at protected bait points in dry locations, protected from the weather to help prevent access by non target animals.

Annex 2 - MAC PAR – January 2018

Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE MAJOR CHANGE OF A NATIONAL AUTHORISATION (NA-MAC)

Product identifier in R4BP	**Ratimor Brodifacoum Fresh Bait**
Product type:	14 (Rodenticide)
Active ingredient(s):	Brodifacoum
Case No. in R4BP	BC-WM031623-27
Asset No. in R4BP	IE-0000011-0000
Evaluating Competent Authority	Ireland – Department of Agriculture, Food & the Marine
Internal registration/file no	**IE/BPA 70514**
Date	26.01.2018 (NA-MAC Major Change)

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1 Conclusion

Implementing Regulation 354/2013 outlines the procedure for making changes/amendments under the Biocidal Products Regulation (EU) 528/2012. According to Implementing Regulation 354/2013, this application for change requires a Major Change evaluation. The change involves a reduction of active substance content in the product from 50 ppm to 29 ppm. The reduction in active substance content has been necessary due to the application of new CLP requirements for certain AVK rodenticides according to the 9th ATP (Commission Regulation (EU) 2016/1179).

The product has been evaluated using the reduced active ingredient concentration. New efficacy trials have been provided by the applicant in order to address the reduced content of active ingredient. The 29 ppm assessment report also considers new dermal absorption risk assessment and ground water risk assessments.

Effectiveness data has confirmed that Ratimor Brodifacoum Fresh Bait is effective in the proposed areas of use, at the recommended dose rate. The field trial data provided on mice (*Mus musculus)* and rats *(Rattus norvegicus* and *Rattus rattus*) endorses the lowering of active substance from 50 ppm to 29 ppm by confirming that the attractiveness and effectiveness of the bait is unaffected. Complete control of mice and rat infestations was achieved in all trials. Data previously evaluated demonstrated that Ratimor Brodifacoum Fresh Bait is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and effectiveness even under adverse environmental conditions has been established.

The conclusion of the evaluation is that the product may be authorised.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Ratimor Brodifacoum Fresh Bait

2.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Unichem d.o.o
	Address	Sinja Gorica 2 1360 Vrhnika Slovenia
Authorisation number	IE/BPA 70514	
Date of the authorisation	06/08/2013	
Expiry date of the authorisation	31/08/2020	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	Unichem d.o.o
Address of manufacturer	Sinja Gorica 2 1360 Vrhnika Slovenia
Location of manufacturing sites	Sinja Gorica 2 1360 Vrhnika Slovenia

2.1.4 Manufacturer(s) of the active substance(s)

Active substance	Brodifacoum
Name of manufacturer	PelGar International Limited
Address of manufacturer	Unit 13 Newman Lane Industrial Estate Alton Hampshire GU34 2QR UK
Location of manufacturing sites	Prazska 54 28 002 Kolin

	Czech Republic

2.2 Product composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 12

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0029

- The product contains a bittering agent and dyes.
  - Information on the full composition is provided in the confidential[24] annex (see section 5).
- According to the information provided the product contains no nanomaterials as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012:

2.2.2 Information on the substance(s) of concern

There are no substances of concern

2.2.3 Candidate(s) for substitution

The following substance was identified as a candidate for substitution:

- Brodifacoum

Brodifacoum meets the following exclusion criteria according to Article 5(1) BPR:

- toxic for reproduction category 1A
- persistent and very persistent, bioaccumulative and toxic

Therefore Brodifacoum meets the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

[24] Access level: "Restricted" to applicant and authority

2.2.4 Type of formulation

Ready-to-use bait: Paste (PA)

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[25]

Table 13

Classification **Hazard classes, Hazard categories**	**Hazard statements**
STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure

Table 14

Labelling	**Code**	**Pictogram / Wording**
	GHS08	
Signal word		Warning
Hazard statements	STOT RE 2	H373: May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental label elements		
Precautionary statements	P260	Do not breath dust.
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of packaging and unused bait as hazardous waste in accordance with national regulations.
Note	-	

25 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

The applicant has supplied acute toxicity, irritancy and sensitisation studies on the product with a content of 0.005% Brodifacoum. On the basis that no acute classification was required at this concentration no classification for acute toxicity is proposed for the product containing the active substance at the lower concentration.

2.4 Use(s) appropriate after major change to the authorisation

Table 15: Summary Table of Uses

No.	Use
1	House mice – general public – indoor
2	Rats – general public – indoor
3	Rats – general public – outdoor around buildings
4	House mice – professionals – indoor
5	Rats – professionals – indoor
6	House mice and/or rats – professionals – outdoor around buildings
7	House mice and/or rats – trained professionals – indoor
8	House mice and/or rats – trained professionals – outdoor around buildings
9	Rats – trained professionals – sewers

2.4.1 Use 1 appropriate after major change to the authorisation – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	General public: Instruction for use indoor (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of

	the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 50g

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 50g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 50g

2.4.1.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper resistant baiting stations. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service
- Do not use this product for permanent or pulse-baiting.

2.4.1.2 Use-specific risk mitigation measures

Prevent skin contact when disposing remains of baits.

2.4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.2 Use 2 appropriate after major change to the authorisation – Rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoor (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g,

	18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g,

	18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

2.4.2.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.2.2 Use-specific risk mitigation measures

Prevent skin contact when disposing remains of baits.

2.4.2.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.2.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.2.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.3 Use 3 appropriate after major change to the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use outdoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with

	heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

2.4.3.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations.
- Place the bait stations in areas not liable to flooding.
- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- Place the bait stations in areas not liable to flooding.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.3.2 Use-specific risk mitigation measures

Prevent skin contact when disposing remains of baits.

2.4.3.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

None

2.4.3.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.3.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.4 Use 4 appropriate after major change to the authorisation – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other

	60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.4.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper resistant baiting stations. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
- [If national policy or legislation requires it] 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.
- Where control of rodents has not been achieved by a control program after 35 days, the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.4.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

2.4.4.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.4.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.4.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.5 Use 5 appropriate after major change to the authorisation – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors

Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg

	Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.5.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the

extent of the infestation.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
- [If national policy or legislation requires it] 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.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.5.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

2.4.5.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.5.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.5.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Keep away from food, drink and animal feeding stuffs.

2.4.6 Use 6 appropriate after major change to the authorisation – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg

	Other 20g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.6.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper resistant baiting stations. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- For rat infestations use bait points of up to 60 g in tamper resistant baiting stations. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

- The resistance status of the target population should be taken into account when considering the choice of rodenticide to be used. In those areas where evidence of resistance to specific active ingredients is suspected, avoid their use.
- [If national policy or legislation requires it] 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.
- Using this product should eliminate rodents within 35 days. The product information (i.e. label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.
- Do not use this product for permanent or pulse-baiting.

2.4.6.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Do not apply this product directly in the burrows.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

2.4.6.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.6.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.6.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.7 Use 7 appropriate after major change to the authorisation – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE

	pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg

	Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.7.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper-resistant bait stations or covered bait points. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- For rat infestations use bait points of up to 60 g in tamper-resistant bait stations or covered bait points. Place bait stations 10 m apart reducing to 5 m in high infestations.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not use in areas where resistance to the active substance can be suspected.
- [If national policy or legislation requires it] 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.

- Remove the remaining product at the end of treatment period.
- Do not use this product for permanent baiting.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.7.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait stations close to water drainage systems, ensure that bait contact with water is avoided.

2.4.7.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.7.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.8 Use 8 appropriate after major change to the authorisation – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait in covered bait points, in burrows or in tamper-resistant bait stations.
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or

	paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.8.1 Use-specific instructions for use

- For mouse infestations use bait points of up to 20 g in tamper-resistant bait stations or covered bait points. Place bait stations 5 m apart reducing to 2 m in high infestations.
- The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.

- For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary

- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not use in areas where resistance to the active substance can be suspected.
- [If national policy or legislation requires it] 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.
- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.
- Remove the remaining product at the end of treatment period.

- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.

2.4.8.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- When used in burrows: Baits must be placed to minimise the exposure to non-target species and children. Cover or block the entrances of baited burrows to reduce the risks of bait being rejected and spilled.
- Wear protective chemical resistant gloves during product handling phase (EN374).

2.4.8.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.8.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.8.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.4.9 Use 9 appropriate after major change to the authorisation – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Bait products: - High infestation: 60g per manhole. - Low infestation: up to 60g per manhole. In case of high infestation use 60g of bait. For low infestation use up to 60g of bait, depending on the rate of infestation. Place and fix the bait so it cannot be moved by rodents. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other

	0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

2.4.9.1 Use-specific instructions for use

- For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.
- The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary
- [Where relevant] Place paste bait with a sufficiently elongated applicator (spatula) to reduce hand exposure - avoid reaching into the bucket.
- [Where relevant] Specify how the equipment (e.g. spatula) shall be cleaned and how contact with residues of the bait can be avoided.
- Follow any additional instructions provided by the relevant code of best practice.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not use in areas where resistance to the active substance can be suspected.
- [If national policy or legislation requires it] 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.
- Baits must be applied in a way so that they do not come into contact with water and are not washed away.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.9.2 Use-specific risk mitigation measures

- [If national policy or legislation requires it] Place baits only in sewer systems which are connected to the sewage treatment plant.
- Do not use this product in permanent baiting treatments.
- Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them.

2.4.9.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

When placing bait points close to surface waters (e.g. rivers, ponds, water channels, dykes, irrigation ditches) or water drainage systems, ensure that bait contact with water is avoided.

2.4.9.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

None

2.4.9.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

None

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

- Do not open the sachets containing the bait.
- Bait stations should be placed in the immediate vicinity where rodent activity has been observed.
- Where possible, bait stations must be fixed to the ground or other structures.
- Do not place bait stations near water drainage systems where they can come into contact with water.
- Prior to the use of rodenticide products, non-chemical control methods (e.g. traps) should be considered.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.
- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- Professionals & Trained Professionals: If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.2 Risk mitigation measures

- Do not use brodifacoum containing products as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- Dispose of dead rodents in accordance with local requirements [The method of disposal shall be described specifically in the national SPC and be reflected on the product label].
- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).
- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.
- Using this product should eliminate rodents within 35 days. The product information (i.e.

label and/or leaflet) shall clearly recommend that in case of suspected lack of efficacy by the end of the treatment (i.e. rodent activity is still observed), the user should seek advice from the product supplier or call a pest control service.

- [For products to be authorised for professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall not be supplied to the general public (e.g. "for professionals only").
- [For products to be authorised for trained professional users:] The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the applicable training requirements (e.g. "for trained professionals only".

2.5.3 Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
Antidote: Vitamin K1 administered by medical/veterinary personnel only.

In case of: Dermal exposure, wash skin with water and then with water and soap.
Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label.
Contact a veterinary surgeon in case of ingestion by a pet.

Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call the National Poisons Information Centre (01) 809 2166".

Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of uneaten bait and the packaging in accordance with local requirements. *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]* Use of gloves is recommended.

2.5.5 Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf-life: 24 months

Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight. Store in places prevented from the access of children, birds, pets and farm animals. Keep only in original container.

2.5.6 Other information

Because of their delayed mode of action, anticoagulant rodenticides may take from 4 to 10 days to be effective after effective consumption of the bait. Rodents can be disease carriers. Do not touch dead rodents with bare hands, use gloves or use tools such as tongs when disposing them. This product contains a bittering agent and dyes.

2.5.7 Documentation

2.5.7.1 Data submitted in relation to product application

Please see General Annexes section 4.1

2.5.7.2 Access to documentation

The applicant has a full letter of access to the data from the active substance dossier and associated [redacted] products. The access includes the initial active substance and product dossiers but excludes any product studies produced after 10th November 2010.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	General public: Instruction for use indoor (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 50g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 50g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 50g

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	14

Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoor (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

3.1.3 Use 3 – Rats – general public – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use outdoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait

	stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	General Public
Pack sizes and packaging material	Maximum quantity of bait per pack 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g).PE or PP packs up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet (PE, or PE/PP, or PP, or paper/PE) packed in natron bag up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). PP or PE buckets with lid or jerrican or pail with lid or tubes up to 150 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes with PE bag or liner up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Cardboard or fibre-board boxes up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or

	thermo seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in cardboard outer or plastic heat-sealed container or thermo-seal foil up to 150g Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). One or more sachets packed in bait tray with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in cardboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 150g Other Bait tray (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 150g

3.1.4 Use 4 – House mice – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (mice): For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg

	Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid packed in pre-

	filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 20 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.5 Use 5 – Rats – professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Instruction for use indoors (rats): For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g,

	13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg

	Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.6 Use 6 – House mice and/or rats – professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Professionals

Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait

	station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.7 Use 7 – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Indoors
Application method(s)	Ready-to-use bait in covered bait points or in tamper-resistant bait stations
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary.
Category(ies) of users	Trained Professionals

Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 60g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait

	station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.8 Use 8 – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	House mouse (*Mus musculus*) – adults and juveniles Brown rats (*Rattus norvegicus*) – adults and juveniles Roof rats (*Rattus rattus*) – adults and juveniles
Field(s) of use	Outdoors around buildings
Application method(s)	Ready-to-use bait in covered bait points, in burrows or in tamper-resistant bait stations.
Application rate(s) and frequency	► For mouse infestations use bait points of up to 20 g. Place bait stations 5 m apart reducing to 2 m in high infestations. The bait stations should be visited at least every 2 to 3 days at the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to remove rodent bodies. Re-fill bait when necessary. ► For rat infestations use bait points of up to 60 g. Place bait stations 10 m apart reducing to 5 m in high infestations. Place the bait stations in areas not liable to flooding. Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt. The bait stations should be visited only 5 to 7 days after the beginning of the treatment and at least weekly afterwards, in order to check whether the bait is accepted, the bait stations are intact and to

	remove rodent bodies. Re-fill bait when necessary
Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg

	Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid packed in pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 60 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 60 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.1.9 Use 9 – Rats – trained professionals – sewers

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Brown rats (*Rattus norvegicus*) – adults and juveniles
Field(s) of use	Sewers
Application method(s)	Ready-to-use bait to be anchored or applied in bait stations preventing the bait from getting into contact with waste water.
Application rate(s) and frequency	Bait products: - High infestation: 200g per manhole. - Low infestation: up to 200g per manhole. In case of high infestation use up to 200g of bait. For low infestation use up to 200g of bait, depending on the rate of infestation. Place and fix the bait so it cannot be moved by rodents. Regularly check bait consumption and replace consumed or spoilt bait until consumption has stopped. Repeat treatment in situations where there is evidence of new infestation (e.g. fresh tracks or droppings). Make frequent inspections of the bait points during the first 10-14 days.

Category(ies) of users	Trained Professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 20 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP packs up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in aluminium or laminated PP or PET/PE pouches with or without cardboard outer up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g). Sachet packed in PE, or PE/PP, or PP, or paper/PE) packs and in natron bag up to 25 kg Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PP or PE buckets with lid or jerrican or pail with lid or tubes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes with PE bag or liner up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in cardboard or fibre-board boxes up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in prefilled or refillable tamper-resistant HDPE or PP rat or mouse bait station. Bait stations packed in carboard outer or plastic heat-sealed container or thermo seal foil up to 20 kg Edible paper tea-bag sachets Edible paper tea-bag sachets (10g, 10.5g, 11g, 11.5g, 12g, 12.5g, 13g, 13.5g, 14g, 14.5g, 15g, 15.5g, 16g, 16.5g, 17g, 17.5g, 18g, 18.5g, 19g, 19.5g, 20g) in PE or PP blister packs. Blister packs packed in carboard outer or plastic heat-sealed container or thermo-seal foil up to 20 kg Other PP, PE or PET bait tray (up to 200 g) with heat sealed lid packed in

	pre-filled or refillable tamper-resistant HDPE or PP rat or mouse bait station, Bait stations packed in carboard outer or blister pack or cardboard sleeve or hear sealed bag or heat sealed outer with cardboard topper up to 10 kg Other PP, PE or PET bait tray (up to 200 g) with heat sealed lid or PE or PP or aluminium foil sticker and cardboard outer up to 10 kg Other 20 g polyethylene film 'sausage' in a collagen or PE outer casing for use in mouse bait boxes, packed in fibreboard outer up to 10 kg Other 200 g polyethylene film 'sausage' in a collagen or PE outer casing for use in rat bait boxes, packed in fibreboard outer up to 10 kg Other 0.1, 0.15, 0.2 or 0.3 kg mastic tubes for application by caulking gun. Mastic tubes packed in cardboard outer pack up to 20 kg Other Loose paste in PP or PE packs for application by decorator's knife/spatula up to 20 kg

3.2 Physical, chemical and technical properties

No new data was provided nor had new guidance to be taken into account for the major change evaluation.
However, two post authorisation requirements have been identified.

Storage stability:
Based on the original storage stability data, the new formulation (with 29 ppm bromadiolone) is expected to similarly remain stable, therefore, no new data are required for authoirsation.
However, due to the decision reached during the March 2016 Working Group of the Biocidal Products Committee, a new storage stability test is needed to check that the active substance remains stable after storage for the proposed shelf life.
The applicant will have to provide the data as a post authorisation data requirement.

Analytical method for the active in the product formulation:
The analytical method has been validated for formulations containing 0.004 and 0.005 % w/w bromadiolone. However, the method has not been validated for the same formulation with a reduced content of 0.0029 % w/w (linearity, accuracy and precision should be addressed at the nominal content).
The applicant will have to provide the data as a post authorisation data requirement.

Therefore, apart from these two post-authorisation requirements outlined above, the conclusion from the former assessment regarding physical, chemical and technical properties remains valid.

3.3 Physical hazards and respective characteristics

No new data was provided, nor had new guidance to be taken into account for the major change evaluation.
Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

No new data was provided, nor had new guidance to be taken into account for the major change evaluation.

Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Ratimor Brodifacoum Fresh Bait is a ready-to-use, soft pasta bait formulation for the control of mice, brown rats and roof rats in a number of proposed use scenarios (section 3.1.1).

The product is intended for use by general public, professionals and trained professionals for the control of rodent infestations.

Palatability

No new palatability studies were provided as the formulation is virtually identical to the 50ppm product evaluated previously. The only difference is the lowering of the active concentration to 29ppm. Accordingly, the conclusion from the previous assessment regarding palatability remains valid.

Effectiveness

Data was provided from three field trials carried out in Italy and conducted in-line with EPPO guideline PP 1/114(2) Field tests against synanthropic rodents (*Mus musculus, Rattus norvegicus, Rattus rattus*). In all three field trials complete control (100%) of the target populations was achieved, demonstrating the attractiveness and effectiveness of the bait product.

Data from the field trials has been summarised in table 4.5 which demonstrated that the product, when used in accordance with label instructions can provide effective control of the target organisms.

The applicant should comment on the potential for the development for resistance owing to the reduction in active content in their product.

The label reference to permanent baiting must be removed from each of the general user, professional user and the trained professional user proposed labels in accordance with the BPC opinion.

Data previously evaluated demonstrated that Ratimor Brodifacoum Fresh Bait is particularly suitable for use in damp or wet conditions such as those encountered in sewer systems and the product's palatability and effectiveness even under adverse environmental conditions has been demonstrated. Therefore, the conclusion from the previous assessment regarding effectiveness under the "sewer-use scenario" remains valid.

3.6 Risk assessment for human health

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products and applied to the dermal absorption value of 0.047% for difenacoum (obtained by read across). The original dermal absorption study for difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012) and the dermal absorption value of 0.047% was raised to

0.1% based on incorporating the standard deviation (value > 25% of mean) into the mean and rounding the figure upwards. As the concentration of a.i. in the current product has been halved compared to the original product a pro-rata correction has been applied raising the dermal absorption value to 0.2%.

3.6.1 Assessment of effects of the active substance on human health

As above.

3.6.2 Assessment of effects of the product on human health

As above.

The following new guidance had to be taken into account for the re-assessment:
A read across from difenacoum to brodifacoum was regarded as appropriate and in-line with section 6.6.2 of the guidance (EFSA Journal 2012; 10(4):2665).

Re-assessment of the relevant data:
The product has been evaluated using the reduced active ingredient concentration and new dermal absorption.

3.6.3 Exposure assessment

The new EFSA guidance on dermal absorption was taken into account for the re-assessment of the brodifacoum containing products and applied to the dermal absorption value of 0.047% for difenacoum (obtained by read across). The original dermal absorption study for difenacoum was reinterpreted using EFSA guidance on dermal absorption (2012) and the dermal absorption value of 0.047% was raised to 0.1% based on incorporating the standard deviation (value > 25% of mean) into the mean and rounding the figure upwards. As the concentration of a.i. in the current product has been halved compared to the original product a pro-rata correction has been applied raising the dermal absorption value to 0.2%.

Exposure levels for amateur users are taken to be the same as that of a non-professional user without PPE.

The AELs considered in the risk characterization for *Brodifacoum* were:
AEL_{acute} of 0.0000033 mg/kg/day based on the maternal NOEL from a teratogenicity study of 0.001 mg/kg bw/day (rat, maternal effect)

$AEL_{medium\ term}$ of 6.7 x 10^{-6} mg/kg bw/day based on the NOAEL from a developmental study (female rabbit) of 0.002 mg/kg bw/day
AEL_{chr} of 3.3 x 10^{-6} mg/kg bw/day based on the NOAEL for females from the reproductive 2-generation study in rat of 0.001 mg/kg bw/day

For conducting the risk assessment on professional and amateur users the chronic AEL was selected as the endpoint, with the exception of conducting the risk assessment for loose paste. For conducting the risk assessment for professional users handling loose paste the acute AEL was used as the endpoint.

For the 'transient mouthing of poison bait' scenario, 10 mg (TNsG, with bittering agent/repellent) of the product is assumed to be swallowed by an infant per poisoning event as stated in: The Human Exposure to Biocidal Products (Technical Notes for Guidance – June 2002). The weight of the infant is assumed to be 8 Kg based on HEEG opinion endorsed at TM II 2013.

Biocidal Exposure Risk assessment for Ratimor Brodifacoum Fresh Bait rodenticide (29 ppm).

Professional user	
	Paste
Without PPE	61.1% of AEL (0.00000202 mg/kg bw/day)
With PPE	3.1% of AEL (0.000000101 mg/kg bw/day)
Loose Paste without PPE (reverse reference)	14.4 g loose paste required for the acute AEL to be exceeded
Loose Paste with PPE (reverse reference)	289.6 g loose paste required for the acute AEL to be exceeded
Non-trained professional user (farmer)	
	Paste
Without PPE	10.6% (0.00000035 mg/kg bw/day)
With PPE	0.5% (0.0000000175 mg/kg bw/day)
Exposure to children (Infant)	
	Paste

Oral exposure -treated with repellent	1098% (0.00003525 mg/kg bw/day)
Oral exposure - without repellent	549242% (0.018125 mg/kg bw/day)

Derived values indicated safe usage scenarios for professional users handling the paste product with and without PPE. Derived values for professional users handling the paste product without PPE were 0.00000202 mg/kg bw/day (61.1% AEL). Derived values for professional users handling the paste product with PPE were 0.000000101 mg/kg bw/day (3.1% AEL).

Based on the risk assessment for professional users handling loose paste with a spatula it appears highly unlikely that the AEL will be exceeded with or without PPE. The amount of rodenticide paste required to remain in contact with skin over the application period is a considerable percentage of the amount of total paste product to be applied if PPE are not worn. A scenario where AEL is exceeded when PPE are worn is not likely given that more loose paste is required to be in contact with skin than is actually recommended to be applied when loading a bait station.

Derived values indicated safe usage for non-trained professional users (farmers) handling the paste product both with and without PPE. Derived values for non-trained professional users handling the paste product without PPE were 0.00000035 mg/kg bw/day (10.6% AEL). Derived values for professional users handling the paste product with PPE were 0.0000000175 mg/kg bw/day (0.5% AEL).

The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating paste without PPE indicated daily exposure scenarios of 0.00000035 mg/kg bw/day (10.6% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the paste product. Derived values for oral exposures in the infant found transient mounting of a paste not containing a repellent to result in a dose of 0.018 mg (549242% AEL). Derived values for oral exposures in the infant found transient mounting of a paste containing a repellent to result in a dose of 0.000036 mg (1098% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for professional users

As shown in section 3.6.2.

3.6.4.2 Risk for the general public

As shown in section 3.6.2.

3.6.4.3 Risk for consumers via residues in food

No new data was provided nor had new guidance to be taken into account for the major change evaluation.
Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.5 Summary of risk characterisation

Derived values indicated safe usage scenarios for professional users handling the paste product with and without PPE. Derived values for professional users handling the paste product without PPE were 0.00000202 mg/kg bw/day (61.1% AEL). Derived values for professional users handling the paste product with PPE were 0.000000101 mg/kg bw/day (3.1% AEL).

Based on the risk assessment for professional users handling loose paste with a spatula it appears highly unlikely that the AEL will be exceeded with or without PPE. The amount of rodenticide paste required to remain in contact with skin over the application period is a considerable percentage of the amount of total paste product to be applied if PPE are not worn. A scenario where AEL is exceeded when PPE are worn is not likely given that more loose paste is required to be in contact with skin than is actually recommended to be applied when loading a bait station.

Derived values indicated safe usage for non-trained professional users (farmers) handling the paste product both with and without PPE. Derived values for non-trained professional users handling the

paste product without PPE were 0.00000035 mg/kg bw/day (10.6% AEL). Derived values for professional users handling the paste product with PPE were 0.0000000175 mg/kg bw/day (0.5% AEL). The exposure assessment indicated a safe use for amateur users (general public) who were considered as non-professional users without PPE. Derived values for non-professional users manipulating paste without PPE indicated daily exposure scenarios of 0.00000035 mg/kg bw/day (10.6% AEL).

Derived values indicated no safe exposure scenarios for infants through oral exposure/transient mouthing of the paste product. Derived values for oral exposures in the infant found transient mounting of a paste not containing a repellent to result in a dose of 0.018 mg (549242% AEL). Derived values for oral exposures in the infant found transient mounting of a paste containing a repellent to result in a dose of 0.000036 mg (1098% AEL). However, the design of the rat bait boxes will incorporate a tamper-proof seal system to prevent easy access to internal compartments. As a result of incorporating a tamper proof seal system infants are not expected to be able to gain access to the rodenticides and subsequent mouthing scenarios are deemed unlikely.

3.7 Risk assessment for animal health

No new data was provided, nor had new guidance to be taken into account for the major change. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

The change in active substance concentration from 0.005% to 0.0029% will result in a lower environmental exposure. Therefore the exposure assessment carried out in 2013 is still valid. Regarding groundwater, the recent CG decision requires this now be assessed:

Groundwater assessment for rodenticides
As required by Article 31(3) of the BPR and Article 2(1)(f) of Regulation 492/2014, when carrying out their assessment of whether the conclusions of the first authorisation regarding Article 19(1)(iv) remain valid, applicants will have to address the groundwater assessment. Since no new guidance was agreed in the past that could become applicable at the time of the completion of the applications for renewal by 28/02/2017, the guidance of reference are the existing methods that are applied since years as standard tools for the assessment of active substances:
- Tier I according to Vol. IV Part B (the former TGD), as provided in chapter 2.3.8.6 of this guidance document.
- Tier II using the FOCUS models PEARL or PELMO for refinements in case Tier I would lead to an exceedance of the relevant trigger values.

The previous exposure assessment contained a Tier 1 assessment of groundwater PECs. The following is an extract from the report:

Exposure of groundwater may occur as a result of soil exposure which occurs via residues present in sewage sludge after using the product in sewers and via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. As an indication for potential groundwater levels, the concentration in soil porewater in the various scenarios was examined. The calculated values do not exceed the EU trigger value of 0.1 µg/L.

Scenario	***In and around buildings***		***Sewer system***	
	Worst case	***Realistic***	***Worst case***	***Realistic***
PEC groundwater (mg/l)	5.3×10^{-5}	6.62×10^{-6}	4.66×10^{-7}	3.11×10^{-7}

As the major change will lead to a lower PECgw a new assessment is not necessary here.

Primary and Secondary Poisoning

The concentration in the final product is 0.0029% for the active substance Brodifacoum. The assessments were carried out according to the ESD PT14 (CA-Jun03-Doc.8.2-PT14 and the TGD (2003). It involves tiered approaches for assessing the risks through both primary and secondary poisoning.

Primary Poisoning

In the first tier scenario, the risk is characterised by the ratio between PEC_{oral} and $PNEC_{oral}$. The ratios PEC/PNEC are above 1 for both short and long term exposure (data not shown). This indicates a potential risk, which must be refined.

Acute risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the refined risk assessment the daily uptake (ETE) is compared to the PNEC for birds and mammals. The PNEC values for each representative animal are compared with the ETE values to provide an indication of the risk to non-target animals ingesting a daily dose of the product.

Tier 2 acute risk assessment: PECoral/PNECoral for non-target animals accidentally exposed to bait containing Brodifacoum after one meal

Non-target animals	**ETE, concentration of Brodifacoum after one meal (one day) (mg/kg b.w.)**		**$PNEC_{oral}$ (dose, mg/kg b.w./d)**	**PEC/PNEC**	
	Step 1	**Step 2**		**Step 1**	**Step 2**

Tree sparrow	10	7.21	0.00013	76923	55461
Chaffinch	8.7	8.26	0.00013	66923	63538
Wood pigeon	3.14	2.26	0.00013	24153	17384
Pheasant	3.13	2.25	0.00013	24076	17307
Dog	1.74	1.25	0.000222	7837	5630
Pig	0.218	0.157	0.000222	981	707
Pig, young	0.696	0.501	0.000222	3135	2256

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Long-risk assessment for primary poisoning of a non-target organism:

Tier 2:

In the long-term risk assessment, the EC (expected concentration of active substance in the animal) after metabolism and other elimination is calculated and used to calculate the $EC_{oral/}PNEC_{ratio}$after 1-day and 5-day elimination of Brodifacoum. The $EC_{oral/}PNEC_{ratio}$ are above 1 after 1-day elimination of Brodifacoum indicating a potential risk (data not shown). The $EC_{oral/}PNEC_{ratio}$ for the 5-day elimination of Brodifacoum are shown below.

Tier 2 long-term risk assessment: $EC_{oral}/PNEC_{oral}$ ratio after 5-day elimination

Species	**EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = .3, AV = 1, PT = 1 (mg/kg bw)[a]**	**EC_{oral} after 5 days (mg/kg b.w./d) with excretion factor = 0.3, AV = 0.9, PT = 0.8 (mg/kg bw)[a]**	**$PNEC_{oral}$ (mg/kg b.w./d)**	**Ratio $EC_{oral}/PNEC_{oral}$**
Tree sparrow	17.06	12.28	0.00013	94486
Chaffinch	15.3	11.02	0.00013	84738
Wood pigeon	5.35	3.85	0.00013	29631
Pheasant	5.33	3.84	0.00013	29520
Dog	2.96	2.13	0.000222	9600
Pig	0.371	0.267	0.000222	1203
Pig, young	1.18	0.850	0.000222	3827

[a] calculation according to equation 21 in the ESD

The ratios PEC/PNEC are above 1 indicating a potential risk even after refinement.

Conclusion:

Overall, all acute and long-term $PEC_{oral}/PNEC_{oral}$ ratios are still above the trigger value of 1 indicating acute and long-term unacceptable risks

Secondary Poisoning

A Tier 1 risk assessment was carried out to assess the risk for poisoning of non-target predator birds and mammals during acute and long-term exposure via rodents poisoned. The $PEC_{oral}/PNEC_{oral}$ values exceeded the trigger value of 1 (data not shown). Therefore, a refined tier 2 assessment was carried out, based on representative species. The refined tier 2 risk assessment considers exposure of relevant species of predators, based on their bodyweights and food intakes. The Brodifacoum concentrations in non-target mammals and birds consuming contaminated rodents is calculated ($ETE_{oral\ predators}$) and compared to the $PNEC_{oral}$

Tier 2 risk assessment of secondary poisoning (non resistant and resistant rodents)

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
Barn owl	Day 5 before the last meal	0.637	0.00013	4901
	Day 5 after the last meal	0.996		7667
	Day 14 after the last meal	1.19		9155
Kestrel	Day 5 before the last meal	0.967	0.00013	7444
	Day 5 after the last meal	1.51		11644
	Day 14 after the last meal	1.80		13903
Little owl	Day 5 before the last meal	0.727	0.00013	5593
	Day 5 after the last meal	1.13		7848
	Day 14 after the last meal	1.35		10446
Tawny owl	Day 5 before the last meal	0.585	0.00013	4506
	Day 5 after the last meal	0.916		7048
	Day 14 after the last meal	1.09		8416
Fox	Day 5 before the last meal	0.234	0.000222	1056
	Day 5 after the last meal	0.366		1652
	Day 14 after the last meal	0.438		1973
Polecat	Day 5 before the last meal	0.488	0.000222	2199
	Day 5 after the last meal	0.763		3440
	Day 14 after the last meal	0.911		4107
Stoat	Day 5 before the last meal	0.698	0.000222	3145
	Day 5 after the last meal	1.09		4920
	Day 14 after the last meal	1.30		5874

Species	Exposure	ETE $_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio ETE $_{oral\ predators}$ / $PNEC_{oral}$
Weasel	Day 5 before the last meal	1.00	0.000222	4538
	Day 5 after the last meal	1.57		7099
	Day 14 after the last meal	1.88		8477

All ratios $ETE_{oral\ predators}$ / $PNEC_{oral}$ are above the trigger value of 1 indicating an unacceptable risk of secondary poisoning.

Overall conclusion

According to this risk assessment the risk for poisoning of non-target predator birds and mammals during primary (acute and long-term exposure) and secondary poisoning is high as the trigger value is exceeded in all cases.

No safe use was established for the Brodifacoum product at a concentration of 29 ppm in the ecotoxicology risk assessment.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As brodifacoum is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).

The Opinion states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Opinion forms the basis of the Commission Implementing Decision addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

On the basis of this comparative assessment, the authorisation of rodenticide products containing brodifacoum is justified.

4 General Annexes

4.1 List of studies for the biocidal product

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
[redacted]	2017	Efficacy evaluation of Ratimor Brodifacoum Fresh Bait (brodifacoum 0.029 g/kg a.i., fresh bait) against Roof rat (*Rattus rattus* L.)	unpublished	Trial Code: 2014.BCD.SAG17	Unichem	05/02/2017	GEP	Y
[redacted]	2017	Efficacy evaluation of Ratimor Brodifacoum Fresh Bait (brodifacoum 0.029 g/kg a.i., fresh bait) against Roof rat (*Rattus norvegicus* Berk.)	unpublished	Trial code: 2013.BCD.SAG17	Unichem	05/02/2017	GEP	Y
[redacted]	2017	Efficacy evaluation of Ratimor Brodifacoum Fresh Bait (brodifacoum 0.029 g/kg a.i.,	unpublished	Trial code: 2015.BCD.SAG17	Unichem	05/02/2017	GEP	Y

Author	Year	Title	Publication	Report no.	Legal entity owner	Report date	GLP/ GEP	Data Protection Claimed
		fresh bait) against House mouse (*Mus musculus* L.)						

4.2 Output tables from exposure assessment tools

None

4.3 New information on the active substance

Under the 9th Adaptation to Technical Progress of the Classification and Labelling regulation (Commission Regulation (EU) 2016/1179), anticoagulant rodenticides were classified as Toxic to Reproduction Category 1A or 1B with a specific concentration limit of 0.003%. Under Article 19 of the Biocidal Products Regulation, biocidal products with such classifications (including anticoagulant rodenticides at this and higher concentrations) shall not be authorised for use by the general public.

4.4 Residue behaviour

No assessment necessary.

4.5 Summaries of the efficacy studies (B.5.10.1-xx)[26]

<table>
<tr><th>Function and field of use envisaged</th><th>Test substance</th><th>Test organism(s)</th><th>Test method, test system/concentrations applied/ exposure time</th><th>Test results; effects</th><th>Reference</th></tr>
<tr>
<td>Ratimor Brodifacoum Fresh Bait (PT14)</td>
<td>A soft Pasta Bait containing 29 ppm Brodifacoum</td>
<td>Roof rat (Rattus rattus)
[redacted]</td>
<td>Droppings, sightings and activity established these rodents to be roof rats.
Unpoisoned bait and tracking patcheswere employed to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.
A 3-day lag period was used.
The trial was then undertaken using the product as per the proposed label instructions.
29ppm Ratimor Brodifacoum Fresh Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily.
Bait points which dropped below 60g or that had been spoilt were either topped up or swapped with fresh bait.
After a further 4-day lag phase a</td>
<td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>2328</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>515</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>96</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>23</td><td>0</td><td>100</td></tr>
</table>
Conservative estimate of population calculated as 30-40 rats based on pre-census baiting.
4,595g of treated bait was consumed during the 16 day baiting phase.
Tracking patch activity dropped to zero on day 14 of the baiting period as did bait consumption.
Complete (100%) effectiveness against Rattus rattus population across the trial site.
</td>
<td>[redacted]</td>
</tr>
</table>

26 If an IUCLID file is not available, please indicate here the summaries of the efficacy studies.

<table>
<tr>
<td></td>
<td></td>
<td></td>
<td>3.2
-treatment census was undertaken.</td>
<td>No evidence was found during the trial that the use of 29ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.</td>
<td></td>
</tr>
<tr>
<td>Ratimor Brodifacoum Fresh Bait (PT14)</td>
<td>A soft Pasta Bait containing 29 ppm Brodifacoum</td>
<td>Brown Rat (Rattus norvegicus)
[redacted]</td>
<td>Droppings, sightings and activity established these rodents to be brown rats.
Unpoisoned bait and tracking patches were used to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test.
A 3-day lag period was observed.
The trial was then undertaken using the product as per the proposed label instructions.
29ppm Ratimor Brodifacoum Fresh Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily.
Bait points which dropped below 60g or that had been spoilt were either topped up or swapped with fresh bait.
After a further 6-day lag phase a post-treatment census was undertaken.</td>
<td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>3000</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>600</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><th>Activity over sand patches</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total activity score</td><td>110</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>24</td><td>0</td><td>100</td></tr>
</table>
Conservative estimate of population calculated as a minimum of 30 rats based on pre-census baiting.
5,650g of treated bait was consumed by day 11 of the 14 day baiting phase.
Tracking patch activity dropped to zero on day 11 of the baiting period as did bait consumption.
Complete (100%) effectiveness against Rattus norvegicus population across the trial site.
No evidence was found during the trial that the use of 29ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
</td>
<td>[redacted]</td>
</tr>
<tr>
<td>Ratimor Brodifacoum Fresh Bait (PT14)</td>
<td>A soft Pasta Bait containing 29 ppm Brodifacoum</td>
<td>House mouse (Mus musculus)
[redacted]</td>
<td>Droppings, sightings and activity established these rodents to be house mice.
Unpoisoned bait and tracking patches were used to measure</td>
<td>
<table>
<tr><th>Bait consumption</th><th>Pre-treatment census</th><th>Post-treatment census</th><th>% control</th></tr>
<tr><td>Total bait consumption (g)</td><td>889</td><td>0</td><td>100</td></tr>
</table>
</td>
<td>[redacted]</td>
</tr>
</table>

		[redacted]	rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the test. A 3-day lag period was observed. The trial was then undertaken using the product as per the proposed label instructions. 29ppm Ratimor Brodifacoum Fresh Bait was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily. Bait points which dropped below 20g or that had been spoilt were either topped up or swapped with fresh bait. After a further 3-day lag phase a post-treatment census was undertaken.	<table><tr><td>Maximum daily bait consumption (g)</td><td>200</td><td>0</td><td>100</td></tr><tr><td></td><td></td><td></td><td></td></tr><tr><td>Activity over sand patches</td><td>Pre-treatment census</td><td>Post-treatment census</td><td>% control</td></tr><tr><td>Total activity score</td><td>80</td><td>0</td><td>100</td></tr><tr><td>Maximum daily activity score</td><td>20</td><td>0</td><td>100</td></tr></table> 889g of untreated bait consumed during pre-baiting census indicating 50-60 mice in the on-site population. 1,773g of treated bait was consumed by day 14 of the 17 day baiting phase. Tracking patch activity dropped to zero by day 14 and no more bait was consumed. Complete (100%) effectiveness against *Mus musculus.* population across the trial site. No evidence was found during the trial that the use of 29ppm Brodifacoum Pasta Bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.	

4.6 Other

5 Confidential annex (Access level: "Restricted" to applicant and authority)

5.1 Full composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Brodifacoum	3-[3-[4-(4-bromophenyl)phenyl] tetralin-1-yl]-2-hydroxy-chromen-4-one	Active substance	56073-10-0	259-980-5	0.0029
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					
[redacted]					