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 and RENEWAL OF A NATIONAL AUTHORISATION

Product identifier in R4BP	Ratimor Broma PE
Product type:	PT14 (Rodenticide)
Active ingredient(s):	Bromadiolone
Case No. in R4BP	BC-GJ038582-40
Asset No. in R4BP	CZ-0018693-0000 (Original 50 ppm)
Evaluating Competent Authority	Czech Republic
Internal registration/file no	MZDR 14601/2018/SOZ
Date	19. 6. 2019 (NA-RNL Renewal of first authorisation)

Content

Application type	ref MS	Case number in the refMS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-APP	UK	Not available in R4BP3. R4BP2 no. 2011/2249/12026/UK/AA/19027	3.12.2012	National authorisation
NA-MAC	CZ	BC-YU038646-94	23.10. 2018	Major change (change of active substance content from 50 mg/kg to 29 mg/kg).
NA-RNL	CZ	BC-GJ038582-40	19.6.2019	Renewal of a national authorisation

1 Conclusion

MAJOR CHANGE

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 the active substance content in the product from 50 ppm to 29 ppm and change in user groups –the product is to be used by general public only.
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. In addition to the major change, the amended assessment report ground water risk assessments.

Efficacy data has confirmed that Ratimor Broma PE 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) confirmed that the lowering of the active substance content from 50 ppm to 29 ppm did not affect the product effectiveness. Complete control of mice and rat infestations was achieved in all the field trials provided in support of the proposed major change.

The proposed major change is acceptable.

RENEWAL

The renewal of a product authorisation necessitates re-evaluation of the proposed product uses based on the new information and newly applicable guidance documents. For Ratimor Broma PE this primarily consists of re-evaluating dermal absorption in line with the applicable version of EFSA guidance on dermal absorption while factoring in the decrease in a.s. concentration in the product as accepted during the major change evaluation.
As part of the risk assessment of endocrine disruption (ED) properties of the co-formulants were examined in accordance with the UK document Assessment of Endocrine Disruption (ED) properties of co-formulants in biocidal products – draft instructions for applicants.
Furthermore, shelf life is re-evaluated based on the rules set in the section 5.6.2.2.5 of the Guidance on the BPR: Volume II Parts B+C Version 3.0 April 2018.
Apart from this new harmonized sentences for rodenticides have been used in the relevant parts of the PAR and SPC.
In addition to the renewal, the amended assessment report ground water risk assessments.

It is noted that the product is authorised only for use by general public against rats and mice.

1.1. The UKCA PAR December 2012

The UK Initial PAR is enclosed as ANNEX.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

Ratimor Plus Pellets Ratimor Plus granule Ratimor Broma PE

2.1.2 Authorisation holder

Name and address of the authorisation holder	Name	Unichem d.o.o
	Address	Sinja Gorica 2 SI-1360 Vrhnika Slovenia
Authorisation number Date of the authorisation	CZ-0018693-0000 19. 6. 2019	
Expiry date of the authorisation	19. 6. 2024	

2.1.3 Manufacturer(s) of the product

Name of manufacturer	Unichem d.o.o
Address of manufacturer	Sinja Gorica 2 SI-1360 Vrhnika Slovenia
Locat ion of manufacturing sites	Sinja Gorica 2 SI-1360 Vrhnika Slovenia

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

Active substance	Bromadiolone
Name of manufacturer	PelGar International Limited

Address of manufacturer	Unit 13 Newman Lane Industrial Estate Alton, Hampshire GU34 2QR UK
Location of manufacturing sites	Pražská 54 28002 Kolín 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 (%)
Bromadiolone	3-[3-(4'-Bromo[1,1'-biphenyl]-4-yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2H-1-benzopyran-2-one	Active substance	28772-56-7	249-205-9	0.0029

- The product contains a bittering agent and a dye.
  - Information on the full composition is provided in the confidential[1] annex (see section 6).
- 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:

- Bromadiolone

[1] Access level: “Restricted” to applicant and authority

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

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

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

Evaluation of humaneness

Chapter 6 of the TNsG on product evaluation states:

"There must be a reasoned justification for the need for a product if that product is considered, from an evaluation of the submitted data, to cause suffering or pain. In particular, Annex VI of the Directive states that an authorisation for a biocidal product intended to control vertebrates will not be given unless:

- death is synchronous with the extinction of consciousness (although it is more important that exposure leads immediately to unconsciousness, and that consciousness is not regained), or
- death occurs immediately, or
- vital functions are reduced gradually without signs of obvious suffering."

As described in section 3.1 of the Annex I CAR for bromadiolone, prepared by Sweden as Competent Authority, it is recognised that the use of bromadiolone as a rodenticide could cause suffering of vertebrate target organisms. The use of anticoagulant rodenticides is necessary as there are at present no other equally effective 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.

2.2.4 Type of formulation

Ready-to-use bait: Pellets

2.3 Classification and Labelling according to the Regulation (EC) No 1272/2008[2]

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	P260	Do not breathe dust.
	P314	Get medical advice/attention if you feel unwell.
	P501	Dispose of contents and container to hazardous waste disposal collection site
Note		

The applicant had supplied acute toxicity, irritancy and sensitisation studies on the product with the content of 0.005% Bromadiolone. 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] 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.

2.4 Use(s) appropriate after major change to 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

2.4.1 Use 1 appropriate after major change to the authorisation – House mice – general public – indoor

Product Type(s)	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the use	Not relevant for rodenticides
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	For mouse infestations use up to 40 g per bait point. Place bait stations 5 m apart reducing to 2 m in case of high infestations.
Category(ies) of users	General Public
Pack sizes and packaging material	1. Edible paper tea-bag sachets (10 g - 20 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g - polyethylene (PE) or polypropylene (PP) packs up to 50 g - natron bag up to 50 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 50 g - PE or PP buckets with lid up to 50 g - cardboard or fibre-board boxes with PE or PP bag or liner up to 50 g - cardboard or fibre-board boxes up to 50 g - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 50 g 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 40 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g - PE or PP packs up to 50 g

	- HDPE container up to 50 g - Natron bag up to 50 g - Packs up to 50 g - PP woven sack or multi-ply paper sack up to 50 g - Pail (PP) or bucket (PP or PE) with lid up to 50 g - PP or PE tub up to 50 g - 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 thermally sealing foil up to 50 g - PET/PE, PP/PE or paper/PE pouch up to 50 g - Cardboard or fibre-board pack with PE or PP bag or liner up to 50 g - Cardboard or fibre-board box up to 50 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 50 g 3. Other packaging: - loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 50g - loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 50 g

2.4.1.1 Use-specific instructions for use

- 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.

2.4.1.2 Use-specific risk mitigation measures

See section 2.5.2

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

See section 2.5.3

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

See section 2.5.4

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

See section 2.5.5

2.4.2 Use 2 appropriate after major change to the authorisation – Rats – general public – indoor

Product Type(s)	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Brown rats (Rattus norvegicus) – adults and juveniles Roof rat (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	For rat infestations use up to 200 g per bait point. Place bait stations 10 m apart reducing to 5 m in case of high infestations.
Category(ies) of users	General Public
Pack sizes and packaging material	1. Edible paper tea-bag sachets (10 g - 20 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - polyethylene (PE) or polypropylene (PP) packs up to 150 g - natron bag up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g - PE or PP buckets with lid up to 150 g - cardboard or fibre-board boxes with PE or PP bag or liner up to 150 g - cardboard or fibre-board boxes up to 150 g - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150 g 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film

	sachets or PE/aluminised film sachets (10 g - 150 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - PE or PP packs up to 150 g - HDPE container up to 150 g - Natron bag up to 150 g - Packs up to 150 g - PP woven sack or multi-ply paper sack up to 150 g - Pail (PP) or bucket (PP or PE) with lid up to 150 g - PP or PE tub up to 150 g - 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 thermally sealing foil up to 150 g - PET/PE, PP/PE or paper/PE pouch up to 150 g - Cardboard or fibre-board pack with PE or PP bag or liner up to 150 g - Cardboard or fibre-board box up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g 3. Other packaging: - loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150g - loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 150 g

2.4.2.1 Use-specific instructions for use

- 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.

2.4.2.2 Use-specific risk mitigation measures

See section 2.5.2

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

See section 2.5.3

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

See section 2.5.4

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

See section 2.5.5

2.4.3 Use 3 appropriate after major change to the authorisation – Rats – general public – outdoor around buildings

Product Type(s)	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Brown rats (Rattus norvegicus) – adults and juveniles Roof rat (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	For rat infestations use up to 200 g per bait point. Place bait stations 10 m apart reducing to 5 m in case of high infestations.
Category of users	General Public
Pack sizes and packaging material	1. Edible paper tea-bag sachets (10 g - 20 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - polyethylene (PE) or polypropylene (PP) packs up to 150 g - natron bag up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to

	150 g - PE or PP buckets with lid up to 150 g - cardboard or fibre-board boxes with PE or PP bag or liner up to 150 g - cardboard or fibre-board boxes up to 150 g - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150 g 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 150 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - PE or PP packs up to 150 g - HDPE container up to 150 g - Natron bag up to 150 g - Packs up to 150 g - PP woven sack or multi-ply paper sack up to 150 g - Pail (PP) or bucket (PP or PE) with lid up to 150 g - PP or PE tub up to 150 g - 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 thermally sealing foil up to 150 g - PET/PE, PP/PE or paper/PE pouch up to 150 g - Cardboard or fibre-board pack with PE or PP bag or liner up to 150 g - Cardboard or fibre-board box up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g 3. Other packaging: - loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150 g - loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 150 g

2.4.3.1 Use-specific instructions for use

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.

2.4.3.2 Use-specific risk mitigation measures

See section 2.5.2

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

See section 2.5.3

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

See section 2.5.4

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

See section 2.5.5

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. - 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.

- Bait stations should be placed in the immediate vicinity where rodent activity has been observed (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

- Where possible, bait stations must be fixed to the ground or other structures.

- Do not open the sachets containing the bait.

- Place bait stations out of the reach of children, birds, pets, farm animals and other non-target animals.

- Place bait stations away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.

- Do not place bait stations near water drainage systems where they can come into contact with water.

- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.

- Remove the remaining bait or the bait stations at the end of the treatment period.

2.5.2 Risk mitigation measures

- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.

- Do not use anticoagulant rodenticides as permanent baits (e.g. for prevention of rodent infestation or to detect rodent activity).

- The product information (i.e. label and/or leaflet) shall clearly show that:

  - the product shall be used in adequate tamper resistant bait stations (e.g. "use in tamper resistant bait stations only").

  - users shall properly label bait stations with the information referred to in section 5.3 of the SPC (e.g. "label bait stations according to the product recommendations").

- 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.

- Search for and remove dead rodents during treatment, at least as often as bait stations are inspected.

- Dispose 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].

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 [insert country specific information. Contact a veterinary surgeon in case of ingestion by a pet [insert country specific information].
- 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 a poison centre [insert national phone number]
In the Czech republic the phone numbers for Toxicological information center are : 224 91 92 93 or 224 91 54 02]".
- Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose 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

- 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.
- Shelf life: 2 years

2.5.6 Other information

- Because of their delayed mode of action, anticoagulant rodenticides take from 4 to 10 days to be effective after consumption of the bait.
- Rodents can be carriers of disease-causing agents. 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 a dye.
- In case of common packaging for mice and rats, for non-professional users, maximum packaging size is 150 g.

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 is not granted to any [redacted] studies completed on 25 ppm baits.

For the major change the applicant submitted 3 own field efficacy studies.

3 Assessment of the product

3.1 Proposed Uses

3.1.1 Use 1 – House mice – general public – indoor

Product Type(s)	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the use	Not relevant for rodenticides
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 in sachets to be used in tamper-resistant bait station
Application rate(s) and frequency	For mouse infestations use up to 40 g per bait point. Place bait stations 5 m apart reducing to 2 m in case of 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	1. Edible paper tea-bag sachets (10 g - 20 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g - polyethylene (PE) or polypropylene (PP) packs up to 50 g - natron bag up to 50 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 50 g - PE or PP buckets with lid up to 50 g - cardboard or fibre-board boxes with PE or PP bag or liner up to 50 g - cardboard or fibre-board boxes up to 50 g - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 50 g 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 50 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 50g - PE or PP packs up to 50 g - HDPE container up to 50 g

	- Natron bag up to 50 g - Packs up to 50 g - PP woven sack or multi-ply paper sack up to 50 g - Pail (PP) or bucket (PP or PE) with lid up to 50 g - PP or PE tub up to 50 g - 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 thermally sealing foil up to 50 g - PET/PE, PP/PE or paper/PE pouch up to 50 g - Cardboard or fibre-board pack with PE or PP bag or liner up to 50 g - Cardboard or fibre-board box up to 50 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 50 g 3. Other packaging: - loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 50g - loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 50 g

3.1.2 Use 2 – Rats – general public – indoor

Product Type(s)	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the use	Not relevant for rodenticides
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 in sachets to be used in tamper-resistant bait station
Application rate(s) and frequency	For rat infestations use up to 200 g per bait point. Place bait stations 10 m apart reducing to 5 m in case of 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	1. Edible paper tea-bag sachets (10 g - 20 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - polyethylene (PE) or polypropylene (PP) packs up to 150 g - natron bag up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer

	pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g - PE or PP buckets with lid up to 150 g - cardboard or fibre-board boxes with PE or PP bag or liner up to 150 g - cardboard or fibre-board boxes up to 150 g - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150 g 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 150 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - PE or PP packs up to 150 g - HDPE container up to 150 g - Natron bag up to 150 g - Packs up to 150 g - PP woven sack or multi-ply paper sack up to 150 g - Pail (PP) or bucket (PP or PE) with lid up to 150 g - PP or PE tub up to 150 g - 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 thermally sealing foil up to 150 g - PET/PE, PP/PE or paper/PE pouch up to 150 g - Cardboard or fibre-board pack with PE or PP bag or liner up to 150 g - Cardboard or fibre-board box up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g 3. Other packaging: - loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150g - loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 150 g

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

Product Type(s)	PT14 - Rodenticides (Pest control)
Where relevant, an exact description of the use	Not relevant for rodenticides

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 in sachets to be used in tamper-resistant bait station
Application rate(s) and frequency	For rat infestations use up to 200 g per bait point. Place bait stations 10 m apart reducing to 5 m in case of 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	1. Edible paper tea-bag sachets (10 g - 20 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - polyethylene (PE) or polypropylene (PP) packs up to 150 g - natron bag up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g - PE or PP buckets with lid up to 150 g - cardboard or fibre-board boxes with PE or PP bag or liner up to 150 g - cardboard or fibre-board boxes up to 150 g - pre-filled or refillable tamper-resistant HDPE or polypropylene mouse or rat bait station. Bait stations packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150 g 2. Bait in PP/paper film sachets, PET/PE film sachets, PE/paper film sachets or PE/aluminised film sachets (10 g - 150 g) packed in: - polyethylene (PE) or polypropylene (PP) or PE/PP or paper/PE outer sachet packed in cardboard or fibreboard outer pack up to 150g - PE or PP packs up to 150 g - HDPE container up to 150 g - Natron bag up to 150 g - Packs up to 150 g - PP woven sack or multi-ply paper sack up to 150 g - Pail (PP) or bucket (PP or PE) with lid up to 150 g - PP or PE tub up to 150 g - 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 thermally sealing foil up to 150 g

	- PET/PE, PP/PE or paper/PE pouch up to 150 g - Cardboard or fibre-board pack with PE or PP bag or liner up to 150 g - Cardboard or fibre-board box up to 150 g - sachet (PE or PE/PP or PP or paper/PE) packed in cardboard outer pack/carton box or natron bag or PP/HDPE buckets with lid up to 150 g 3. Other packaging: - loose bait in prefilled or refillable tamper-resistant mice or rat bait station, packed in cardboard outer or plastic heat-sealed container or thermally sealing foil up to 150g - loose bait in tray (PVC or polystyrene or polypropylene or PET) with heat sealed lid (PET/polypropylene or PET/polyethylene or polypropylene) to be used with bait station up to 150 g

3.2 Physical, chemical and technical properties

Ratimor Broma PE has almost identical formulation as [redacted] Pellets, differing only in lower concentration of active substance (from 50 ppm to 29 ppm), consequently not influencing the physico-chemical characteristics of the product. No new data was provided nor was new guidance taken into account for the major change evaluation.

For renewal special attention was paid to shelf life for which apart from the storage stability study under ambient conditions also efficacy with the product stored under ambient for two years are required to support the claim of 24 months shelf life. Both storage 2 year stability study and data on palatability to rodents after storage of up to 2 years at ambient temperature were submitted in support of the original authorisation in the UK. The CZCA has accepted the UKCA conclusion regarding shelf life, which is 24 months.

In summary, the conclusions from the former assessment, regarding physical, chemical and technical properties remain valid.

For details see Annex - initial assessment report compiled by the UK CA 2012.

3.3 Physical hazards and respective characteristics

Ratimor Broma PE has almost identical formulation as [redacted] ellets, differing only in lower concentration of active substance (from 50ppm to 29ppm), consequently not influencing the physical hazards and respective characteristics of the product. No new data was provided, nor had new guidance to be taken into account for the major change evaluation. The same applies to renewal

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.
For details see Annex - initial assessment report compiled by the UK CA 2012.

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.
For details see Annex - initial assessment report compiled by the UK CA 2012.

3.5 Efficacy against target organisms

Ratimor Broma PE is a ready-to-use pelleted grain 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 for the control of rodent infestations.

Palatability

No new palatability studies were provided as the formulation is virtually identical to the 50 ppm product evaluated previously. The only difference is the lowering of the active concentration to 29ppm. Good palatability of pellets containing 29 ppm bromadiolone can be concluded from field trials in efficacy studies in all tested rodent species (Mus musculus, Rattus norvegicus, Rattus rattus). 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 the section 5.5. Summaries of the efficacy studies which demonstrated that the product, when used in accordance with the label instructions can provide effective control of the target organisms.
The data support the use of the product against rats and mice in and around buildings.

3.6 Risk assessment for human health

MAJOR CHANGE

Risk assessment for human health studies were performed on [redacted] pellets containing 50 ppm bromadiolone that was used for reference. As the major change rests in decrease of the active substance concentration from 50 ppm to 29 ppm it follows that the human risk assessment is covered by the evaluation in PAR (UKCA 2012) – see Annex. No new risk assessment is needed at the stage of the major change evaluation.

RENEWAL

Endocrine disruption potential:

As part of the risk assessment of endocrine disruption (ED) properties of the co-formulants were examined in accordance with the UK document Assessment of Endocrine Disruption (ED) properties of co-formulants in biocidal products – draft instructions for applicants. ED potential was identified for none of the co-formulants present in the product.

Regarding the active substance, it is not considered to have endocrine disrupting properties according to the Biocidal Products Committee opinion (ECHA/BPC/111/2016). Thus, bromadiolone does not fulfil criterion (d) of Article 5(1).

In conclusion, the product does not have ED properties.

Risk assessment for human health should be performed for the new a.s. concentration and the new dermal absorption value. The new dermal absorption value is to be based on the same study, but evaluated according to the new guidance on dermal absorption .As specified in the PAR (UKCA 2012), the study was performed with two reference products further referred to as ref. product 1 and 2. Taking into account that the application for renewal was submitted 2018 EFSA guidance on dermal abs. from 2012 should be applied. This guidance requires that SD exceeding 25% of the mean D.A. value be added to the mean value. For the reference product 1 this results in 0.36 (mean) + 0.3 (SD) = 0.66, which is rounded to 0.7%. Before applying this value, the applicability of the read across from the reference product 1 should also be re-evaluated based on the above guidance. This was done and CZCA agrees with the UKCA that the read across is possible based primarily on the fact that the reference product 1 was mixed with saline solution prior to its application on the skin, which facilitated dermal absorption via facilitating the contact between the a.s. and the skin. This approach is supported by the fact that the D.A. obtained with the reference product 2, the composition of which was closer to that of Ratimor Broma PE, was an order of magnitude lower.

Dermal absorption according to the EFSA guidance on dermal abs. 2017: Though the read across from the reference product 1 is excluded if strictly based on the rules set out in this latest version of the guidance, considering the low D.A. value obtained with the reference product 2 , where such read across is justifiable , the CZCA concluded that the read across form ref. product 1 is acceptable. The D.A. value is then calculated as 0.36 (mean) + 0,72 (k) .0.3 (SD) = 0.6% (k is multiplication factor for 10 replicates as specified in the above guidance).
The most conservative value of 0.7% is used in risk assessment.

Risk characterization *: The risk characterization for the product renewal based on the same models and indicative exposure values as the one calculated in the original PAR (UKCA 2012). The difference from the original calculations comes from the lower a.s. concentration which was changed from 0.005 % to 0.0029% and dermal the newly derived D.A. value which was changed from 0.36 to 0.7. This leads to increase of calculated systemic exposure via dermal route 13%. The exposure via inhalation and oral route is decreased by 42%. Taking into account that the original RCRs were 31% of AEL and 4% of AEL for professional wearing appropriate PPE and no- professionals, respectively their corresponding change does not result in changing the conclusions
Regarding secondary exposure for infants after ingesting bait the RCR shall be decreased due to the decrease in the a.s. concentration. It will thus drop form 1086957% of AEL to 631951% of AEL which still presents a concern.

The risk characterization ratios based on the parameters relevant for the product characterization at the renewal are given in the following table. For comparison the last column contains these ratios for the original assessment.

User	PPE	Route	Exposure	%AEL renewal	%AEL original
professional	None	inhalation	$1.45 * 10^{-6}$		
professional	None	dermal	$1.39 * 10^{-6}$		
professional	None	Dermal+inhalation	$2.84 * 10^{-6}$	236	311
professional	RPE (FFP2-PF10)	inhalation	$1.45 * 10^{-7}$		
professional	Gloves (PF 10)	dermal	$1.39 * 10^{-7}$		
professional	None	Dermal+inhalation	$2.84 * 10^{-6}$	23.6	31
Non - professional	None	dermal	$1.1 * 10^{-7}$	4.8	4

- CZCA notes that the applicant did not apply for professional use and risk assessment for this user type is provided for information only.

Conclusions of risk characterization:
The conclusions from the original PAR (UKCA) are adopted and briefly summarized here:
Professional users (not applied for renewal in the Czech republic): The risk is acceptable provided appropriate PPE is used (i.e gloves for all tasks and RPE (FFP2 –PF10) for decanting.
Non-professional users: The risk from the proposed uses is acceptable

Secondary exposure: Unacceptable risk has been identified. The risk is mitigated by following the instructions provided in section 2.5 – general direction for use.

3.7 Risk assessment for the environment

MAJOR CHANGE
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 2012 is still valid.
For details see Annex - initial assessment report compiled by the UK CA 2012. Regarding groundwater, the recent CG decision requires this now be assessed:

Regarding groundwater, the recent CG decision requires this now be assessed:

RENEWAL:
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, 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.

Exposure of groundwater may occur as a result of soil exposure which occurs via direct (spillages) and disperse release (urine and faeces) after the use of the product in and around buildings. The calculated values should not exceed the EU trigger value of 0.1 µg/L.

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 bromadiolone, active substance of the product, is performed in a two steps approach:

Step 1:
Step 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 55 m long and 10 m wide (550 m^2). The distance between the bait stations is 5 m. 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).
Step 2:
Step 2 comprises the product specific application mode and the ESD PT14 default values regarding emissions to the environment. In this case 200 g bait is placed at each bait point. The placement of the bait is as described under Step 1. The ESD recommends a total of 2.6 replenishments (as opposed to 5 for Step 1). This is to reflect the fact that as the campaign proceeds less and less bait is eaten.

Table: Calculation of concentration in groundwater for the scenario In and around buildings (according to section 2.4.3.2 of ESD PT14, 2003):

Input		STEP 1 (default data)	STEP 2 (specific data)
Q_{prod}	Amount of product used in control operation (g) per site	250	200
$Fc_{product}$	Fraction of active substance in product	0.000029	0.000029
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)	0.0036	0.0015
$Clocal_{soil\text{-}D}$[3]	Local concentration in soil due to direct release after a campaign (mg/kg)	0.0235	0.0098
$Clocal_{soil\text{-}ID}$[4]	Concentration in soil due to indirect release after a campaign (mg/kg)	0.0035	0.0014
$Clocal_{soil}$ = $Clocal_{soil\text{-}D}$ + $Clocal_{soil\text{-}ID}$	Total concentration in soil (mg/kg)	0.0270	0.0112
$PEClocal_{soil,\ porew}$[5]	Concentration in porewater resulting from total concentration in soil (mg/L)	1.035×10^{-4}	4.295×10^{-5}

An average Koc value of 14770 ml/g was used in the calculations for derivation of Ksoil-water.

The calculated value of $PEClocal_{soil,\ porew}$ regarding to product specific application data does not exceed the EU trigger value of 0.1 µg/L therefore refinement is not necessary.

[3] $Clocal_{soil\text{-}D} = (Elocal_{soil\text{-}D\text{-}campaign} \times 1000) / (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ according to ESD: $AREA_{exposed\text{-}D}$ = 0.09 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil

$Elocal_{soil\text{-}D\text{-}campaign} = Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times F_{release\text{-}D,soil}$

[4] $Clocal_{soil\text{-}ID} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times 1000 \times F_{releaseID,soil} \times (1\text{-}F_{releaseD,soil})) / (AREA_{exposed\text{-}ID} \times DEPTH_{soil} \times RHO_{soil})$, according to the ESD $AREA_{exposed\text{-}ID}$ = 550 m², $DEPTH_{soil}$ = 0.1 m, RHO_{soil} = 1700 kg/m³ soil

[5] Eq. 67 of Guidance on the Biocidal Products Regulation, Volume IV, Part B, April 2015

Primary and Secondary Poisoning

The concentration in the final product is 0.0029% for the active substance Bromadiolone. 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. This indicates a potential risk, which must be refined.

	PEC (conc. in food, mg/kg)	PNEC (conc. in food)	PEC/PNEC
Long-term			
Birds	29	0.0087 mg/L	3340
Mammals	29	0.00019 mg/kg	153000

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.

Non-target animal	Typical bodyweight (g)	Daily mean food intake (g dw/day)	Concentration of bromadiolone in bait (mg/kg)	ETE (mg/kg bw)	
				Step 1	Step 2
Dog	10 000[a]	456[b]	29	1.32	0.95
Pig	80 000[a]	600[a]	29	0.22	0.16
Pig, young	25 000[a]	600[a]	29	0.70	0.50
Tree sparrow	22[a]	7.6[a]	29	10.02	7.21
Chaffinch	21.4[a]	6.42[a]	29	8.7	6.3
Wood pigeon	490[a]	53.1[a]	29	3.14	2.26
Pheasant	953[a]	102.7[a]	29	3.12	2.25

[a] According to table 3.1 in the ESD

[b] Calculated from log FIR=0.822 log BW-0.629 according to equation on page 50 ESD

Non-target animal	PECoral = ETE, concentration of bromadiolone after one meal (mg/kg)		LD50 (mg/kg bw/d)	PECoral higher than LD50 (y/n)	
	Step 1	Step 2		Step 1	Step 2
Dog	1.32	0.95	10	n	n
Pig	0.22	0.16	3	n	n
Pig, young	0.70	0.50	3	n	n
Tree sparrow	10.02	7.21	134	n	n
Chaffinch	8.7	6.3	134	n	n
Wood pigeon	3.14	2.26	134	n	n
Pheasant	3.12	2.25	134	n	n

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
Dog	1.32	0.95	0.0000056	236000	170000
Pig	0.22	0.16	0.0000056	39000	29000
Pig, young	0.70	0.50	0.0000056	125000	89000
Tree sparrow	10.02	7.21	0.0013	7700	5600
Chaffinch	8.7	6.3	0.0013	7000	5000
Wood pigeon	3.14	2.26	0.0013	2400	1700
Pheasant	3.12	2.25	0.0013	2400	1700

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 Bromadiolone. The $EC_{oral}/PNEC_{ratio}$ are above 1 after 1-day elimination of Bromadiolone indicating a potential risk (data not shown). The $EC_{cral}/PNEC_{ratio}$ for the 5-day elimination of Bromadiolone are shown below.

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

Non-target animals	EC_{oral} AV = 1, PT = 1 (mg/kg bw)	EC_{oral} AV = 0.9, PT = 0.8 (mg/kg bw)	$PNEC_{oral}$ (mg/kg bw/day)	Ratio $EC_{oral}/PNEC_{oral}$
Dog	0.92	0.67	0.0000056	119000
Pig	0.15	0.11	0.0000056	19600
Pig, young	0.49	0.35	0.0000056	62600
Tree sparrow	7.01	5.05	0.0013	4000
Chaffinch	6.1	4.4	0.0013	3400
Wood pigeon	2.2	1.6	0.0013	1200
Pheasant	2.2	1.6	0.0013	1200

[a] calculation according to equation 21 in the ESD; 30% of a.s. is eliminated

The ratios EC/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 Bromadiolone 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 (Tyto alba)	Day 5 before the last meal	0.638	0.0013	490
	Day 5 after the last meal	1.000		770

Species	Exposure	$ETE_{oral\ predators}$ (mg a.s./kg/d)	$PNEC_{oral}$ (mg a.s./kg/d)	Ratio $ETE_{oral\ predators}$ / $PNEC_{oral}$
	Day 14 after the last meal	1.19		915
Kestrel (Falco tinnunculus)	Day 5 before the last meal	0.970	0.0013	750
	Day 5 after the last meal	1.51		1160
	Day 14 after the last meal	1.81		1400
Little owl (Athene noctua)	Day 5 before the last meal	0.729	0.0013	560
	Day 5 after the last meal	1.14		880
	Day 14 after the last meal	1.36		1050
Tawny owl (Strix aluco)	Day 5 before the last meal	0.586	0.0013	450
	Day 5 after the last meal	0.916		705
	Day 14 after the last meal	1.09		840
Fox (Vulpes vulpes)	Day 5 before the last meal	0.235	0.0000056	42000
	Day 5 after the last meal	0.366		65000
	Day 14 after the last meal	0.438		78000
Polecat (Mustela putorius)	Day 5 before the last meal	0.488	0.0000056	87000
	Day 5 after the last meal	0.763		136000
	Day 14 after the last meal	0.920		164000
Stoat (Mustela erminea)	Day 5 before the last meal	0.698	0.0000056	125000
	Day 5 after the last meal	1.09		195000
	Day 14 after the last meal	1.30		232000
Weasel (Mustela nivalis)	Day 5 before the last meal	1.00	0.0000056	179000
	Day 5 after the last meal	1.58		282000
	Day 14 after the last meal	1.88		336000

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

Calculations based on monitoring data

Monitoring data for Barn owls (Newton et al, 1997) provides a basis for calculations to determine what relevance the worst case calculations above, which indicate large implications on non-target bird and mammal populations, may have in the environment. The data based on 1100 collected birds shows that 30 % of the birds collected the recent decades have residues of second generation rodenticides. It also

shows that cca. 1 % of the collected birds had died of rodenticide poisoning (Table 5.3.10). We do not know if all birds killed by rodenticides were retrieved or how the more detailed picture for each year looks.

Table 5.3.10 Rodenticide residues in livers of Barn owls killed by rodenticides (from Newton et al, 1997)

Owl no.	Rodenticide	Rodenticide concentration (mg/kg liver)
1	Bromadiolone	0.13
2	Bromadiolone Brodifacoum Flocoumafen	0.05 0.002 0.003
3	Difenacoum	0.17
4	Bromadiolone	1.07
5	Brodifacoum	0.87
6	Bromadiolone Brodifacoum	1.72 0.07
7	Bromadiolone	0.33
8	Brodifacoum	0.42

To assess the lethal dose the report by Ramell et al, (1984) submitted by the applicant (IIIA 7.5.7.1.1) is also considered. In this study brodifacoum was used to eradicate rabbits in the field. After the treatment dead rabbits, cats and birds of different species were collected and the concentrations of rodenticides in their bodies and livers were measured. Among the collected birds were two hawks which had died by secondary poisoning and the concentration in their livers was 0.12 and 0.34 mg/kg. Another study submitted by the applicant (IIIB 7.8.7.1-02) showed that a concentration of approximately 0.6-1.25 mg/kg liver killed owls in an acute study after consumption of mice which had consumed brodifacoum. Using this data, it may be concluded that the lowest lethal dose of bromadiolone is 0.13 mg/kg liver for Barn owls, and if liver concentrations were kept below this level all of the barn owls in the study by Newton et al. (1997) would probably have been protected with the exception for owl number two, but the liver of this owl also contained two other, more potent anticoagulants.

What is then the maximum body concentration of rodenticide in a rat in order to avoid that the rodenticide concentration in the predatory bird's liver reaches 0.13 mg/kg? First of all it is assumed that the liver constitutes about 4 % of the total body weight which then for a Barn owl is 0.04*0.294 kg = 0.012 kg liver. According to the ESD, a campaign lasts for 21 days and the daily feed intake (DFI) of the owl is 0.075 kg. The lowest amount of rodenticide in the liver which will cause lethality is equal to the liver weight multiplied by the lowest lethal concentration in liver; 0.012 kg * 0.13 mg/kg = 0.00156 mg. Thus, the lowest total amount of bromadiolone that will cause lethality in a Barn owl, if reaching the liver, is 0.00156 mg or 1.56 µg.

To determine the maximum daily bromadiolone consumption during a campaign that may be lethal for a barn owl, the lowest lethal bromadiolone amount is divided by the number of days for a normal treatment

period, i.e. 0.00156 mg/21 days = 0.000074 mg/d. Thus, less than 0.074 µg bromadiolone may be consumed daily during the campaign.

The limit concentration in rats is then calculated as the maximum daily consumption divided by the body weight of rat consumed each day, i.e. 0.074 µg/0.075 kg = 0.99 µg kg bw. Thus, 0.99 µg/kg bw is the maximum bromadiolone concentration in rats that would not cause lethality according to monitoring data. This value must not directly be compared to a PNEC value, since it does not have any safety component (assessment factor) to account for uncertainties regarding other effects than lethality and variations in sensitivity between different individuals.

Bearing this in mind, if this effect value is compared to the PEC in rats of 13.9 mg/kg bw, which is worst case according to the ESD, a risk for secondary poisoning of barn owls is identified with a risk quotient calculated as 13.9/(0.99*10-3)= 14000.

This assessment could be refined further since the monitoring data reveals that 30 % of the population is affected by rodenticides and consequently, the PD+PF could be assumed to be 0.3. However, these figures seems to be increasing and therefore it is assumed that PD+PF = 0.5. After such refinement the risk quotient would be halved, i.e. $6.95/(0.99*10^{-3}) = 7000$. The data used for these calculations is mainly based on five individuals and therefore it might be necessary to apply assessment factors for intraspecies variations. Moreover, it could be argued that barn owl may not be the most sensitive species and that an assessment factor also for variation between species would be needed.

In conclusion, this example based on monitoring data confirms that there is a very high risk of secondary poisoning for predatory birds and mammals, and the risk quotient obtained this way even exceeds the high PEC/PNEC ratios obtained from the tier 2 calculations based on the ESD worst case. This is notable and a more thorough investigation into monitoring data and comparison with modelled data should be carried out in conjunction with the future comparative assessment of second generation rodenticides.

Discussion on risks of primary and secondary poisoning in comparison to monitoring data and proposal for risk mitigation measures

According to the calculations in accordance with the ESD and TGD II, the biocidal product with bromadiolone will cause unacceptable risks both for acute and long-term exposure and both for primary and secondary poisoning. The very high risk quotients indicate that birds and mammals that have rodents as prey or feed on carcasses of rodents are significantly threatened by the use of bromadiolone and probably also by other second generation anticoagulant rodenticides. A study that demonstrates this is that of Balcomb (1986) in which 62-92% of small birds put dead in agricultural fields had disappeared within 24 h.

It may be argued that these rodenticides have been used for a couple of decades and if the risk were as severe as indicated by the calculations performed according to the ESD, effects would have been

observed in nature on population level or at least in the amount of poisoned individuals. There have been some investigations on the concentrations of bromadiolone and other rodenticides in predators, both birds and mammals, and the figures from these investigations clearly show that predators are exposed and, as stated above, around 30 % of birds and mammals have been/are exposed to second generation anticoagulants. In an attempt to refine the risk assessment the result indicated that rodents could have rodenticide concentrations in their livers of ca 1 µg/kg before causing lethality to barn owls. When analysing the effect of rodenticides it is motivated to describe the effect from all second generation anticoagulant rodenticides together, since the effect on non-target animals will probably be additive from these substances or even higher due to compound effects. It seems from monitoring data published on barn owls that 1% of the owls had died from secondary poisoning by rodenticides (Newton et al, 1997). The question is whether this 1% lethality will have any effect on population level. It is difficult to predict the effect of rodenticides on the size of predator populations since the effect on a population depends on the size of the population, the mating behaviour, the normal average age of the population, and what animals of a population are killed by the rodenticide i.e. adult or young, females or males. Moreover, the effect may not necessarily be death but could also be decreased fertility or altered behaviour. Abnormal behaviour may e.g. lead to that more birds are killed by cars. Consequently, even a 1 % increased death rate could have an impact on the size of the population (Broman, 2003), but, looking at the barn owl population in England it seems as it has stabilised during the two last decades after a 60-70 % decline between 1930 and 1980. Figures for mammals are more uncertain, especially since many mammals may hide before they die.

The possibility of primary and secondary poisoning of non-target animals by bromadiolone campaigns on infested farms will depend on number of factors. Since risk is a combination of hazard and probability, the probability of poisoning non-target organisms has to be reduced. The probability of poisoning will depend on the duration of the treatment campaign, since the longer the campaign the higher is the probability for long-term toxic effects. Moreover, the frequency of campaigns in a specific area has to be considered, which means that campaigns have to be coordinated locally or regionally, taking into consideration the size of the hunting grounds of the species to protect. Otherwise predatory birds may catch rats with abnormal behaviour on one farm for a week and then on the next farm the next week and so forth. If the hunting grounds for a barn owl cover something like five farms the length of the exposure period to owls for poisoned rats could theoretically increase from 3 to 15 weeks. The frequency and length of the campaigns should be recorded by the professional users and could also be connected to monitoring programmes, e.g. monitoring of dead birds regarding cause of death and liver concentrations of rodenticides where the pattern of rodenticide use could be related to the variation over time of the recorded liver concentrations.

Below we have listed some suggested risk mitigation measures. See also Doc I, section 3 for the complete account for risk mitigation measures suggested for bromadiolone.

- The length of the campaign should be minimised, aiming at an optimal effect on the target rodents.

- Campaigns should be recorded and the time between campaigns should be as long as possible.
- Campaigns should be coordinated regionally to minimise the time of exposure for non-target animals that roam over large areas.
- Site inspections should be made regularly whereby bait points should be checked and dead rodents removed.
- After a campaign remaining bait should be removed.
- Monitoring programmes of dead predatory birds and mammals are recommended, where i.a. liver concentrations of bromadiolone are measured.

An important argument for the benefit of rodenticide use is that bromadiolone and/or other second generation anticoagulants are substances of great importance for the control of rodent populations that otherwise may spread diseases and cause economic loss for the society.

Overall conclusion

Although the quantity of active substance has been reduced the quantitative risk assessments pose still high unacceptable risks to non-target vertebrates via primary and secondary poisoning.

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. Product labels additionally instruct users to retrieve and securely dispose of all unconsumed baits at the end of control programmes. Both these factors limit the opportunity for exposure and reduce the primary poisoning risk to small non-target animals. Provided that baits are deployed in accordance with the product labelling and other approved guidance on good practice, the primary poisoning risk to non-target mammals may be considered to be negligible.

The risk of secondary poisoning of bromadiolone to birds and small mammals is expected to be significantly reduced by restricting its use to treatment campaigns of limited duration, limiting access of non-target animals to the blocks and removing dead and moribund rodents during a baiting campaign to minimise the opportunity secondary exposure. These mitigation measures are described in good practice guidance documents and on the labels of the products. Also, with the aim of harmonising the assessments of second generation anticoagulant rodenticides, a common approach to the use of risk mitigation measures has been agreed at the CA meeting in Nov 2016.

3.8 Assessment of a combination of biocidal products

A use with other biocidal products is not intended. For details see Annex - initial assessment report compiled by the UK CA 2012.

4 General Annexes

4.1 List of studies for the biocidal product

This annex is provided in the separate document as it contains information considered as confidential in accordance with Article 66 (2) of the BPR.

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 containing 0.003% and higher of active substance) shall not be authorised for use by the general public.

4.4 Residue behaviour

4.5 Summaries of the efficacy studies (B.5.10.1-xx)[6]

Table 5.5.1: Summary of efficacy study against black rat infestation (Rattus rattus)

Function and field of use envisaged	Ratimor Plus Pellets (PT14)
Test substance	A pelleted bait formulation containing 29 ppm Bromadiolone
Test organism(s)	Roof rat (Rattus rattus) Wild population located in agricultural habitat (breeding stables for cows, fodder and equipment warehouses) in Italy (resistance status unknown)
Test method, test	Droppings, sightings and activity established these rodents to be roof rats. Non-poisoned bait (200 g /bait station mixture of maize grain and poultry/pig

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

<table>
<tr><td>system/concentrations applied/ exposure time</td><td>feed) and tracking patches eight tracking patches (20 cm x 30 cm x 2mm of common wheat flour inside the buildings in positions different from those of the bait stations) 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 baiting phase of 14 days was then undertaken using the product as per the proposed label instructions (tamper- proof bait stations/protected bait placements containing 200g bait located 5-10 m apart).
Records of bait consumption were taken daily. Party consumed or spoilt bait were either replenished or swapped with fresh bait, when necessary.
After a further 5-day lag phase a post-treatment census lasting 6 days was undertaken using 200g of non-poisoned bait.

Regarding the tracking patches, these were used through all the three phase and smoothed over daily. The scoring used the following scale: 0= no sign of rodent tracks; 1= 1-5 individual rodent footprints; 2= >5 footprints and up to 25% of patch covered with footprints; 3= 26-95% of patch covered with footprints; 4= >95% of patch covered with footprints.

The percentage of efficacy of the test product against the rat population was calculated using the following formula:

$$\% \text{ efficacy} = 100 - \left[\frac{\text{Post-treatment rat population size index}}{\text{Pre-treatment rat population size index}} \times 100\right]$$
where:
- Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.
- Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.</td></tr>
<tr><td>Test results; effects</td><td>
<table>
<tr><td>Bait consumption</td><td>Pre-treatment census</td><td>Treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total bait consumption (g)</td><td>4129</td><td>5510</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>1003 (5th day)</td><td>847 (5rd day)</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Activity over sand patches</td><td>Pre-treatment census</td><td>Treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total activity score</td><td>103</td><td>206</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>24</td><td>24</td><td>0</td><td>100</td></tr>
</table>

Conservative estimate of population calculated as 50-60 rats based on pre-census baiting assuming that the animals ate only census bait during the census period and that rats weighed on average 150 g, and ate approximately 10% of their body weight daily in dry food then an estimate of a population size of a minimum of 50-60 rats was obtained.

Total of 5510 g of treated bait was consumed during the 14 day baiting</td></tr>
</table>

	phase. Tracking patch activity dropped to zero on day 12 of the baiting period as did bait consumption. Complete (100%) effectiveness against Rattus rattus population across the trial site. No evidence was found during the trial that the use of 29ppm Ratimor Plus Pellets bait when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
Reference	[redacted]

Table 5.5.2: Summary of efficacy study against brown rat infestation (Rattus norvegicus)

Function and field of use envisaged	Ratimor Plus Pellets (PT14)
Test substance	A pelleted bait formulation containing 29 ppm Bromadiolone
Test organism(s)	Brown Rat (Rattus norvegicus) Wild population located in farm buildings (agricultural buildings lodging cow breeding stables, fodder and equipment warehouses) in Italy (resistance status unknown)
Test method, test system/concentrations applied/ exposure time	Droppings, sightings and activity established these rodents to be brown rats. Non-poisoned bait (200g/bait station - mixture of maize grain and poultry/pig feed) and tracking patches (20 cm x 30 cm x 2mm of common wheat flour inside the buildings in positions different from those of the bait stations) were used to measure rodent populations both quantitatively and qualitatively for a period of 5 days prior to commencement of the baiting campaign. The baits were weighed and replenished at 200 grams (when necessary) with fresh census baits. A 3-day lag period was observed. The trial lasting 18 days was then undertaken using the product as per the proposed label instructions (distance of 10 m between bait stations/placement containing 200 g of the poisoned bait). 29ppm Ratimor Plus Pellets 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 were partly consumed 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 baiting was conducted using the non-poisoned baits of 200g per station/placement specified above. Regarding the tracking patches these were used throughout the test and smoothed over daily. The scoring was based on the following scale: 0= no sign of rodent tracks; 1= 1-5 individual rodent footprints; 2= >5 footprints and up to 25% of patch covered with footprints; 3= 26-95% of patch covered with footprints; 4= >95% of patch covered with footprint

<table>
<tr><td></td><td>The percentage of efficacy of the test product against the rat population was calculated using the following formula:

$$\% \text{ efficacy} = 100 - \left[\frac{\text{Post-treatment rat population size index}}{\text{Pre-treatment rat population size index}} \times 100\right]$$
where:
- Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.
- Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.</td></tr>
<tr><td>Test results; effects</td><td>
<table>
<tr><td>Bait consumption</td><td>Pre-treatment census</td><td>Treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total bait consumption (g)</td><td>4279</td><td>4029</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>958 (5th day)</td><td>699 (8th day)</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Activity over sand patches</td><td>Pre-treatment census (5 days)</td><td>Treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total activity score</td><td>100</td><td>258</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>24</td><td>24</td><td>0</td><td>100</td></tr>
</table>
The estimate of the population 40-50 rats is based on the pre-treatment census baiting assuming that the rats ate only baits and that they daily consumed about 10% of their body weight estimated to be 200g .

Tracking patch activity dropped to zero on day 16 of the baiting period as did bait consumption.

Complete (100%) effectiveness against Rattus norvegicus population was achieved

No evidence was found during the trial that the use of 29ppm bromadiolone pellets bait when used in accordance to the label guidelines posed a significant risk to non-target animals.</td></tr>
<tr><td>Reference</td><td>[redacted]</td></tr>
</table>

Table 5.5.3: Summary of efficacy study against mouse infestation (Mus musculus)

Function and field of use envisaged	Ratimor Plus Pellets (PT14)
Test substance	A pelleted bait formulation containing 29 ppm Bromadiolone
Test organism(s)	House mouse (Mus musculus)

<table>
<tr><td></td><td>Wild population located on an agricultural farm (breeding stables for hens, fodder and equipment warehouses) in Italy
(resistance status unknown)</td></tr>
<tr><td>Test method, test system/concentrations applied/ exposure time</td><td>Droppings, sightings and activity established these rodents to be mice.
Non-poisoned bait (40g/bait station - mixture of maize grain and poultry/pig feed) 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 baiting campaign was then undertaken using the product as per the proposed label instructions.(40g bait/bait station 2-5 m apart)
29ppm Ratimor Plus Pellets was placed into commercially available tamper-proof bait stations, or in protected bait placements. Records of bait consumption were taken daily.
Bait points with partly consumed or which had been spoilt were either topped up or swapped with fresh bait when necessary.
After a further 3-day lag phase a post-treatment census was undertaken using non poisoned baits as specified above.

Regarding the tracking patches these were used throughout the test and smoothed over daily. The scoring was based on the following scale: 0= no sign of rodent tracks; 1= 1-5 individual rodent footprints; 2= >5 footprints and up to 25% of patch covered with footprints; 3= 26-95% of patch covered with footprints; 4= >95% of patch covered with footprint

The percentage of efficacy of the test product against the rat population was calculated using the following formula:

$$\% \text{ efficacy} = 100 - \left[\frac{\text{Post-treatment rat population size index}}{\text{Pre-treatment rat population size index}} \times 100\right]$$
where:
- Pre-treatment index: average weight of the bait amounts eaten on the last 4 days of the Pre-treatment census.
- Post-treatment index: average weight of the bait amounts eaten on the last 4 days of the Post-treatment census.</td></tr>
<tr><td>Test results; effects</td><td>
<table>
<tr><td>Bait consumption</td><td>Pre-treatment census</td><td>Treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total bait consumption (g)</td><td>1376</td><td>1518</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily bait consumption (g)</td><td>326 (5th day)</td><td>258 (4th day)</td><td>0</td><td>100</td></tr>
<tr><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Activity over sand patches</td><td>Pre-treatment census</td><td>Treatment census</td><td>Post-treatment census</td><td>% control</td></tr>
<tr><td>Total activity score</td><td>91</td><td>175</td><td>0</td><td>100</td></tr>
<tr><td>Maximum daily activity score</td><td>21</td><td>22</td><td>0</td><td>100</td></tr>
</table>
</td></tr>
</table>

	1376 g of untreated bait consumed during pre-baiting census indicating 75-85 mice in the on-site population (assuming that the animals ate only census bait during the census period and that mice weighed 12-24 grams, and showed an average daily intake of 3.5-4 grams). Total of 1518 g of treated bait was consumed by day 11 of the 14 day baiting phase. Tracking patch activity dropped to zero by day 11 and no more bait was consumed after day 12. Complete (100%) effectiveness against Mus Musculus population across the trial site. No evidence was found during the trial that the use of 29ppm bromadiolone pellets when used in accordance to the label guidelines posed a significant risk to non-target or companion animals.
Reference	[redacted]

4.6 Other

None.

5 **Annexes**

Documentation on original studies of pasta formulation containing 50 mg/kg of bromadiolone. Access to Task Force studies is granted with Letter of Access from [redacted] Letter of Access grants the permission to Unichem to all studies that were made on 50ppm formulations and access is limited for authorisation purposes of rodenticide products in the EU only.

5.1. ANNEX A. LIST OF STUDIES

Table A1. Additional information supported in support of the active substance

Table A2. Studies submitted in support of the biocidal product

This annex is provided in a separate document with access level restricted to the applicant and member state authorities as it contains information considered as confidential in accordance with Article 66 (2) of the BPR.

5.2 ANNEX B. PHYSICO-CHEMICAL PROPERTIES, STORAGE STABILITY AND ANALYTICAL METHODS

Table B1. Physico-chemical properties and storage stability.

End pont/study	Method	Result	Reference
3.1 Physical state and nature, colour and odour	Visual and olfactory inspection	Light pink cylindrical pellets approximately 4 mm in diameter and 48 mm in length. Slight pleasant smell of cereal	B3.1 Garofani, 2007a
3.2 Explosive properties	Statement	Applicant: Consideration of structure and physico-chemical properties does not suggest any explosive potential and widespread experimental and commercial use over many years has not shown any exothermic or explosive activity. UK CA: the active does not contain any groups associated with being explosive and none of the co-formulants are classified as being explosive. The formulation will not be explosive.	B3.2
3.3 Oxidising properties	Statement	Applicant: Consideration of structure and physico-chemical properties does not suggest any explosive potential and widespread experimental and commercial use over many years has not shown any exothermic or explosive activity. UK CA: the active does not contain any groups associated with being oxidising (oxygen is bonded to C or H only). None of the co-formulants are classified as being oxidising. The formulation will not be oxidising.	B3.3
3.4 Flammability and other indications of flammability or spontaneous ignition	Method A10 of Commission Directive 92/69/EEC	Not highly flammable	B3.4 Atwal & Woolley, 2008a
3.5 Acidity/ alkalinity/pH	Statement	Not relevant. The biocidal product does not contain any acid or alkaline ingredients. Moreover, the product is not intended to be used in aqueous solutions.	B3.5

3.6 Relative density/bulk density	Method A3 of Commission Directive 92/69/EEC/CIPAC MT 159	1.43 at 20.4 ± 0.5ºC (relative density)	B3.6 Atwal & Woolley 2008b
3.7 Storage stability and shelf life	CIPAC MT 46.		B3.7 Thomas, 1999
	Accelerated storage stability	Analysis of the a.s. at 54ºC after 0 and 14 days = 0.0049 % and 0.0049 % respectively	
	Long term storage stability and shelf life	Analysis of the a.s. at 25ºC after 0, 12, 24 and 36 months = 0.0049%, 0.0050%, 0.0048% and 0.0049% respectively. Analysis of the a.s. at 40ºC after 0, 12, 24 and 36 months = 0.0049%, 0.0047%, 0.0048% and 0.0048% respectively.	
3.8 Technical characteristics: dust content and friability	CIPAC MT 171	Before friability treatment: Dust content after storage for 0, 1, 2 and 3 year at 25°C = 0.0007%, 0.001%, 0.0006% and 0.0003% Dust content after storage for 0, and 14 days at 54°C = 0.0007%, and 0.0003% After friability treatment: Dust content after storage for 0, 1, 2 and 3 year at 25°C = 0.017%, 0.01%, 0.015% and 0.009% Dust content after storage for 0, and 14 days at 54°C = 0.009%, and 0.007%	B3.8 Thomas 1999
3.9 Compatibility with other products	Statement	Not relevant to a ready for use solid pellet bait which is not mixed with other products	B3.9
3.10 Surface tension	Statement	Not relevant to a ready for use solid pellet	B3.10
3.10 Viscosity	Statement	Not relevant to a ready for use solid pellet	B3.10
3.11 Particle size distribution	Statement	Not relevant to a ready for use solid pellet	B3.11

6 Confidential annex (Access level: “Restricted” to applicant and authority)

6.1 Full composition of the product

This annex is provided in a separate document with access level restricted to the applicant and member state authorities.