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

Product identifier in R4BP	MURIDOX 20 BLOQUES
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Bromadiolone
Case No. in R4BP	BC-KV013573-20
Asset No. in R4BP	ES-0003595-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00115
Date	February 2018 (renewal)

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1 Conclusion

The assessment presented in this report has shown that the ready-to-use product, MURIDOX 20 BLOQUES, with the active substance bromadiolone, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) since the conclusions of initial evaluation remain valid.

However, the biocidal product MURIDOX 20 BLOQUES contains 0.005 %w/w bromadiolone and the Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures has been applied.

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w bromadiolone only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that, this legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.

Therefore, MURIDOX 20 BLOQUES is authorised as a rodenticide product against house mice (Mus musculus) and brown rats (Rattus norvegicus). It is to be used indoors, outdoors around buildings and outdoor in open areas and waste dumps and sewers by trained professional. It is a ready to used block bait to be used in tamper-resistant bait stations or anchored in sewers.

According to the renewal of anticoagulant active substance for trained professional users the product may be authorised for use in covered and protected bait points other than tamper resistant bait stations. The applicant has not submitted any additional information to include this application method, so the ES CA does not authorise other use different to tamper resistant bait stations treatments.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

MURIDOX 20 BLOQUES

2.1.2 Manufacturer(s) of the product

Name of manufacturer	GMB INTERNACIONAL S.A.
Address of manufacturer	Calle Aurora Boreal, 6 Nave 35 (Pol. Ind. San José Valderas II - Comunidad Alameda). 28918. Leganes (Madrid). Spain
Location of manufacturing sites	Avda Mas del Oli, 144 46940. Manises (Valencia). Spain

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

Active substance	Bromadiolone
Name of manufacturer	PELGAR INTERNATIONAL LTD
Address of manufacturer	Unit 13, Newman Lane Industrial Estate GU34 2QR. Alton, Hampshire. United Kingdom.
Location of manufacturing sites	Prazska 54 280 02. Kolin. Czech Republic.

2.2 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-	Active Substance	28772-56-7	249-205-9	0,005 %

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
	benzopyran-2-one				
-	-	Non-active substance	-	-	-

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

2.2.2 Information on the substance(s) of concern

No substance of concern was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

2.2.3 Candidate(s) for substitution

No candidate for substitution was identified upon initial assessment (the application for authorisation was submitted and the assessment took place before the Biocidal Products Regulation 528/2012 entered into force).

Now that the Biocidal Products Regulation 528/2012 entered into force, the following substance(s) was/were identified as candidate(s) for substitution upon this renewal:

Bromadiolone does meet the exclusion criteria according to Article 5(1) BPR. Because the following exclusion criteria are met:

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

And therefore, Bromadiolone does meet the conditions laid down in Article 10 BPR, and is consequently a candidate for substitution.

2.2.4 Type of formulation

Ready-to-use: block

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

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Reproductive toxicity; Repr. 1B	H360D May damage the unborn child
Specific target organ toxicity — repeated exposure; STOT RE 1	H372 Causes damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
Signal word	-	Danger
Hazard statements	H360D	May damage the unborn child
	H372	Causes damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	EUH208	Contains 2-Octyl-2H-isothiazol-3-one and reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-2H -isothiazol-3-one (3:1). May produce an allergic reaction
Supplemental label elements	-	-
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P264	Wash … thoroughly after handling
	P270	Do not eat, drink or smoke when using this product.
	P280	Wear protective gloves/ protective clothing/eye protection/face protection
	P314	Get medical advice/attention if you feel unwell
	P405	Store locked up.
	P501	Dispose of contents and/ or container as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations.
Note	-	

2.4 Use(s) appropriate for <u>further</u> authorisation

In order to make proper use of the standard sentences for SPCs for rodenticides it is considered necessary to split the uses currently authorised in Spain further down:

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)		**Use(s) appropriate for further authorisation**	
1	House mice and/or brown rats – general public– in and around buildings.	1	House mice and/or brown rats – trained professionals – indoor
2	House mice and/or brown rats – professional– in and around buildings.	2	House mice and/or brown rats – trained professionals – outdoor around buildings
3	House mice and/or brown rats – trained professional– in and around buildings, open areas, waste dumps and sewers.	3	Brown rats – trained professionals – Outdoor open areas & waste dumps
		4	Brown rats – trained professionals – Sewers

2.4.1 Use 1 – House mice and/or rats – trained professionals – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Mus musculus (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: up to 200g of bait per baiting point. Mice: up to 50g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: wax block of 25, 50, 75, 100, 150 and 200g Packaging material: Containers of corrugated board Blocks could also be supplied loose or inside individual plastic sachets (polypropylene).

2.4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.

- Follow any additional instructions provided by the relevant code of best practice.

2.4.1.2 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 *[in accordance with the applicable code of good practice, if any]*. - 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. - 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. - Do not use the product in pulsed baiting treatments. - This product shall only be used indoors and in places that are not accessible to children or non-target animals.

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

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

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

See section 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 5.5

2.4.2 Use 2 – House mice and/or rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	Mus musculus (house mice) *Rattus norvegicus* (brown rat)
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	Rats: up to 200g of bait per baiting point. Mice: up to 50g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: wax block of 25, 50, 75, 100, 150 and 200g Packaging material: Containers of corrugated board Blocks could also be supplied loose or inside individual plastic sachets (polypropylene).

2.4.2.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the baiting points in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.2.2 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.
- 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.
- 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 this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- Do not use this product in pulsed baiting treatments. - Do not apply this product directly in the burrows.

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

- 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.

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

See section 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 5.5

2.4.3 Use 3 – Rats – trained professionals – Outdoor open areas & waste dumps

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Rats: up to 200g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: wax block of 25, 50, 75, 100, 150

	and 200g Packaging material: Containers of corrugated board Blocks could also be supplied loose or inside individual plastic sachets (polypropylene).

2.4.3.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions. Place the bait stations in areas not liable to flooding.
- Replace any bait in baiting points in which bait has been damaged by water or contaminated by dirt.
- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.3.2 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 this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

- 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.

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

See section 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 5.5

2.4.4 Use 4 – Rats – trained professionals – Sewers

Product Type(s)	14
Where relevant, an exact description of the use	Not relevant for rodenticides
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rat)
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	200g per manhole
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: wax block of 25, 50, 75, 100, 150 and 200g Packaging material: Containers of corrugated board Blocks could also be supplied loose or inside individual plastic sachets (polypropylene).

2.4.4.1 Use-specific instructions for use

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.

2.4.4.2 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 pulsed baiting treatments

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

- See section 5.3.

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

See section 5.4

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

See section 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. - 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. - 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. - 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 product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.). - Where possible, bait stations must be fixed to the ground or other structures. - Bait stations must be clearly labelled to show they contain rodenticides and that they must not be

moved or opened *(see section 5.3 for the information to be shown on the label)*.
- 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.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- 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 rodent 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.
- Do not open the sachets containing the bait.

2.5.2 Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- 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").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- 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 wash the bait stations or utensils used in covered and protected bait points with water between applications.
- 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]*"
- Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

- At the end of the treatment, dispose the 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]*.

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 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 a dye.

3 Assessment of the product

3.1 Use(s) considered appropriate for authorisation after former assessment (uses currently under authorisation in Spain)

3.1.1 Use 1 – House mice and/or rats – general public– in and around buildings.

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	In and around buildings
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	For the control of rats, baits of 200g should be placed each 5 to 10 m. For the control of mice, baits of 50g should be placed each 1 to 5 m
Category(ies) of users	General public
Pack sizes and packaging material	Blocks of 25, 50, 75, 100, 150 y 200 g in containers of 250, 500 and 750 g and 1kg.

3.1.2 Use 2 – House mice and/or rats – professional– in and around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	In and around buildings
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	For the control of rats, baits of 200g should be placed each 5 to 10 m. For the control of mice, baits of 50g should be placed each 1 to 5 m.
Category(ies) of users	Professional
Pack sizes and packaging material	Blocks of 25, 50, 75, 100, 150 y 200 g in containers of 250, 500 and 750 g and 1kg.

3.1.3 Use 3 – House mice and/or rats – trained professional– in and around buildings, open areas, waste dumps and sewers.

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	In and around buildings, open areas, waste dumps and sewers.
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	For the control of rats, baits of 200g should be placed each 5 to 10 m. For the control of mice, baits of 50g should be placed each 1 to 5 m In sewers (rats): 100 – 200 g per baiting point
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Blocks of 2, 50, 75, 100, 150 y 200g in containers of 1, 5, 10, 15 and 25 kg.

3.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **long term storage at ambient temperature**	Guidance on Data Requirements for Active Substances and Biocidal Products	0.005	Time: 3 years Bromadiolone active ingredient initial content: 0.0039% w/w Bromadiolone active ingredient final content: 0.0037% w/w The values do not comply with the tolerance limit at the point of manufacture (±15%). Δ[C] = -5.12% • Results after applying a correction factor (77.7) $\frac{0.0039 \cdot 100}{77.7}$ = 0.00502% initial content $\frac{0.0037 \cdot 100}{77.7}$ = 0.00476% final content Δ[C] = -5.18% the result complies with the tolerance value (-10%)	IUCLID 3.4.1

As it can be observed in the above table, the initial values do not comply with the tolerance limit at the point of manufacture stablished in the Guidance (±15%). However, the company provided us a report in which they demonstrate that this variation is due to interferences between the active substance and the paraffin. In order to sort out this problem it has been used a correction factor with which it has been obtained more acceptable data. Therefore we have decided to accept this correction and we grant a 3 years shelf-life.

Neither new data was not provided nor had new guidance to be taken into account for re-assessment other than above mentioned.

Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.3 Physical hazards and respective characteristics

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding physical hazards and respective characteristics remains valid.

3.4 Methods for detection and identification

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding methods for detection and identification remains valid.

3.5 Efficacy against target organisms

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding efficacy against target organisms remains valid.

As the efficacy with aged bait has been only proved with 2 years aged bait. The shelf life of this product will be 2 years although a long-term stability test to 3 years has been submitted.

3.6 Risk assessment for human health

3.6.1 Assessment of effects of the active substance on human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the active substance on human health remains valid.

3.6.2 Assessment of effects of the product on human health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding effects of the product on human health remains valid.

3.6.3 Exposure assessment

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding the exposure remains valid.

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for trained professional users

The conclusion from the former assessment regarding the risk characterisation for trained professional user remains valid.

3.6.4.2 Risk for professional users

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w bromadiolone only can be authorised by trained professional user because of the toxicological classification the use of PPE are mandatory. Given that, this legislation is national and in other Member States legislation could be different, each Competent Authority should consider that in order to grant the authorisation.

3.6.4.3 Risk for the general public

According to the Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, the biocidal product containing anticoagulant active substance cannot be authorised by general public if the concentration in the biocidal product is above the specific limit concentration (≥ 0.003%).

3.6.4.4 Risk for consumers via residues in food

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.5 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.

3.6.4.6 Summary of risk characterisation

The conclusion from the former assessment regarding risk characterisation remains valid, except to the authorisation for general public and professional user which have been removed to the authorisation in order to comply with the requirements laid down in Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

3.7 Risk assessment for animal health

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding animal health remains valid.

3.8 Risk assessment for the environment

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding the environment remains valid

Scenarios waste dumps and open areas not included the first assessment are included here:

EMISION ESTIMATION

Scenario [1]: waste dumps

This scenario covers control of rats and disposal of rats in waste dumps and landfills where the exposure is assumed to be higher than that described in the open area scenario. In some instances, applications of rodenticides to refuse dumps take place. Mostly the use is limited to occasions of population outbreaks of rats. Often the rodenticides are deployed around the perimeter of the dump, more than in the disposal area itself. The bait may be placed at regular places in special feeding stations in order to prevent other animals from eating the bait.

The worst-case application is for the rat. The scenario is for eradication on an open dump. The scenario indicates 7 applications per year, with 40 kg product per application. There is 90% release of the bait to soil and 365 emission days.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in landfills and dumps			
Amount of product used at each refill/application	40	Kg	
Fraction of active substance in product	5E-03	%	
Number of emission days for control at waste dumps	365	days	
Number of application	7	-	
Fraction of active substance released to soil	0.9	-	
Area exposed to rodenticide	10000	m^2	
Depth of exposed soil	10	cm	
Bulk density of soil	1.7E03	Kg_{wwt}/m^3	

Calculations for Scenario [*1*]

Calculation of $E_{local\ soil}$ (equation 17, ESD PT14)

Parameter	**Definition**	**Units**	**Value**
Amount of product used per application	Qprod	g	40
Fraction of active substance in product	Fc_{prod}	-	0.00005
Number of application sites	N_{sites}	-	7
Fraction of active substance released directly to soil	$F_{release,\ soil}$	-	0.9
Local direct emission of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing} = Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release,\ soil}$ (17)**	**kg**	**1.26E-02**

Calculation of C local soil (equation 18, ESD PT14)

Parameter	Definition	Units	Value
Local direct emission of active substance to soil from a campaign	$Elocal_{soil, campaing}$ (2)	kg/m^3	1.26E-02
Area directly exposed to active substance	$AREA_{exposed-D}$	m^2	10000
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil-D}$ = (Elocal $_{soil-D-campaign}$ x10E03)/ (AREA $_{exposed-D}$ X $DEPTH_{soil}$ X RHO_{soil} x N_{sites}) (18)**	**mg/kg**	**7.41E-04**

Scenario 2: open areas

This scenario covers control of rats and water voles in open areas such as around farmland, parks and golf courses where the aim is to prevent “nuisance” from burrows or “soil heaps” or due to public hygiene reasons. Rodenticides are also used to reduce impacts on game rearing or outside food stores (potato/sugar beet clams).

The main release to the environment is expected when impregnated grain is applied into rat holes. By a spoon or a small shovel, the product is normally poured approximately 30 cm into the rat holes, depending on the slope and general accessibility of the hole. The treated holes are closed by a stone, a piece of board or similar immediately after the application to prevent unintended exposure of children or non-target organisms (e.g. birds, cats and dogs).

A typical initial dose for a rat hole is 100-200 g grain.hole-1; and normally application is repeated twice with an interval of 5-6 days. Inspection of the holes to assess the effect of the control action is usually carried out some 5-6 days after application of the poison and again with similar intervals if repeated applications are necessary.

The ES CA agrees with the selection of the PT 14 ESD, impregnated grains applied into the rat holes, to evaluate the risk of use of wax block in open areas.

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in landfills and dumps			
Amount of product used at each refilling in the control operation	200	Kg	
Fraction of active substance in product	5E-03	%	
Number of emission days for control at open areas	6	days	
Number of application	2	-	
Fraction of product released to soil during application	0.05	-	
Fraction of product released to soil during use	0.20	-	
Soil volume exposed soil around the hole	0.0085	m^3	
Bulk density of soil	1.7E03	Kg_{wwt}/m^3	

Calculations for Scenario [*2*]

Calculation of $Elocal_{soil\text{-}campaign}$ (equation 9, ESD PT14)

Parameter	**Definition**	**Units**	**Value**
Amount of product used at each refilling in the control operation	Q_{prod}	g	200
Fraction of active substance in product	Fc_{prod}	-	0.00005
Number of application sites	N_{sites}	-	1
Number of refills per site	N_{refil}	-	2
Fraction of the product released to soil during application	$F_{release,\ soil,\ appl}$	-	0.05
Fraction of product released to soil during use	$F_{release,\ soil,\ use}$		0.2
Local emission of active substance to soil during a campaign	$\mathbf{Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times (F_{release,\ soil,\ appli} + F_{release,\ soil})}$ **(9)**	**g**	**5.00E-03**

Calculation of $Clocal_{soil\text{-}campaign}$ (equation 10, ESD PT14)

Parameter	Definition	Units	Value
Local emission to soil from the episode	$Eloca_{lsoil\text{-}campaign}$	g	5.00E-03
Soil volume exposed to rodenticide	$Vsoil_{exposed}$ (eq. 9a ESD)	m^3	8.50E-03
Density of wet exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil after a campaign	**$Clocal_{soil\text{-}campaing}$ = ($E_{localsoil\text{-}campaign}$ x 10^3)/($V_{soilexposed}$ x RHO_{soil}) (10)**	**mg/kg**	**3.46E-01**

CALCULATED PEC VALUES

Summary table on calculated PEC values[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[2]**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1	-	-	-			$7.4\ 10^{-4}$	$2.84\ 10^{-3}$	
Scenario 2	-	-	-			0.346	1.33	

Use in waste dumps

This scenario covers control of rats and disposal of rats in waste dumps and landfills where the exposure is assumed to be higher than that described in the open area scenario. In some instances, applications of rodenticides to refuse dumps take place. Mostly the use is limited to occasions of population outbreaks of rats. Often the rodenticides are deployed around the perimeter of the dump, more than in the disposal area itself. The bait may be placed at regular places in special feeding stations in order to prevent other animals from eating the bait.

<u>Calculation of PEC in soil</u>

Direct release;

See in/around buildings calculus.

$Clocal_{soil\text{-}D} = Elocal_{soil\text{-}D\text{-}campaign} * 10^6 / (Area_{exposed\text{-}D} * Depth_{soil} * RHO_{soil})$

Where;

$Elocal_{soil\text{-}D\text{-}campaign} = Q_{prod} * Fc_{prod} * N_{app} * 10^3 * F_{release\text{-}ID,soil}$

$Area_{exposed\text{-}D} * Depth_{soil}$ = 1000 m^3 (10 000 m^2 x 0.01 m assumed by ESD)

RHO_{soil} = 1700 kg m^{-3} (TGD II)

$F_{release\text{-}ID,soil}$ = 0.9

Local direct emission to soil is calculated for ESD worst case and proposed use scenarios;

ESD worst and proposed case

$Clocal_{soil\text{-}D}$ = $Elocal_{soil\text{-}D\text{-}campaign}$ * 1000 / ($Area_{exposed\text{-}D}$ * $Depth_{soil}$ * RHO_{soil})

= (40 * 0.00005 * 7 * 0.9) * 10^6 / 1.7 x 10^6

= 0.000741 mg/kg soil

In this scenario according to ESD $PEClocal_{soil}$ = $Clocal_{soil\text{-}D}$ and considering the worst case,

$PEClocal_{soil}$ = 0.000741 mg/kg

Calculation of PEC in groundwater

PEC in groundwater was calculated according to equation 67 in TGD II, where it is assumed that PEC local groundwater equals to PEC local pore water in agricultural soils.

$PEClocal_{soil,\ porewater}$ = $PEClocal_{soil}$ * RHO_{soil} / ($k_{soil\text{-}water}$*1000)

$PEClocal_{soil,\ porewater}$ = 0.000741 * 1700 / (443.3*1000) = 2.84 10^{-6} mg/l

An average K_{oc} value of 14770 ml/g was used in the calculations for derivation of $k_{soil\text{-}water}$.

Use in open areas

This scenario covers control of rats and water voles in open areas such as around farmland, parks and golf courses where the aim is to prevent “nuisance” from burrows or “soil heaps” or due to public hygiene reasons. Rodenticides are also used to reduce impacts on game rearing or outside food stores (potato/sugar beet clams).

The main release to the environment is expected when impregnated grain is applied into rat holes. By a spoon or a small shovel, the product is normally poured approximately 30 cm into the rat holes, depending on the slope and general accessibility of the hole. The treated holes are closed by a stone, a piece of board or similar immediately after the application to prevent unintended exposure of children or non-target organisms (e.g. birds, cats and dogs).

A typical initial dose for a rat hole is 100-200 g grain.hole-1; and normally application is repeated twice with an interval of 5-6 days. Inspection of the holes to assess the effect of the control action is usually carried out some 5-6 days after application of the poison and again with similar intervals if repeated applications are necessary.

The ES CA agrees with the selection of the PT 14 ESD, impregnated grains applied into the rat holes, to evaluate the risk of use of wax block in open areas.

Calculation of PEC in soil

Direct release;

Number of emission days per campaign is estimated to be 6 days during which the treatment is repeated twice. However, as previously mentioned when applying a rodenticide into a hole it is assumed that only the lower half of the hole and its surrounding environment is exposed.

Clocalsoil-D = Elocalsoil-D-campaign * 1000 / (Areaexposed-D * Depthsoil * RHOsoil)

The exposed soil area is assumed to be the lower half of the burrow wall surrounding an 8 cm diameter tunnel, with the mixing soil depth of 10 cm and up to 30 cm from the entrance hole.
Thus the total soil volume is:

ESD worst case

$Vsoil_{exposed}$ = 0.0085 m^3 (ESD page 31)

$Clocal_{soil-D}$ = $Elocal_{soil-D-campaign}$ * 1000 / ($Vsoil_{exposed}$ * RHO_{soils})
= (200 * 0.000005 * 1 * 2 * (0.05+0.2)) * 1000 / 14.45
= 0.346 mg/kg

In this scenario according to ESD $PEClocal_{soil}$ = $Clocal_{soil-D}$ then,

$PEClocal_{soil}$ = 0.346 mg/kg

Calculation of PEC in groundwater

PEC in groundwater was calculated according to equation 67 in TGD II, where it is assumed that PEC local groundwater equals to PEC local pore water in agricultural soils. The concentration in the soil pore waters is determined by the predicted bromadiolone concentration in local soil, the bulk density of the soil and the soil-water partitioning coefficient.

$PEClocal_{soil, porewater}$ = $PEClocal_{soil}$ * RHO_{soil} / ($k_{soil-water}$*1000)

$PEClocal_{soil, porewater}$ = 0.346 * 1700 / (443.3 *1000)
= 1.33 10^{-3} mg/l

An average K_{oc} value of 14770 ml/g was used in the calculations for derivation of $k_{soil-water}$.

RISK CHARACTERISATION

From the first assessment the PNEC soil use in this risk assessment is 0.099 mg/kg.

Terrestrial compartment

Calculated PEC/PNEC values	
	$PEC/PNEC_{soil}$
Scenario 1	0.74 10-2
Scenario 2	3.49

The PEC/PNEC ratio in open areas is above 1.0 and indicates that there are unacceptable risks to the terrestrial compartment when this product is used in the tunnels of open areas. However, the PEC/PNEC ratios calculated indicate a marginal risk based on the PEC that represents a localised "hotspot" of contamination near the entrance of each baited tunnel. According to the EUBEES 2 scenario, the use near the openings of the tunnels is covered by the assessment of the scenario "in and around buildings" with bait box. So, there is no unacceptable risk for the terrestrial compartment (including groundwater) when this product is used near the openings of the tunnels of the target rodents.

Groundwater

Risk to ground water has been detected in open areas however considering the localised treated area in the tunnels, the risk for groundwater was not considered relevant.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As bromadiolone 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 (EU) 2017/1532 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.

On the basis of this comparative assessment, the authorisation of rodenticide products containing bromadiolone is justified.