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	RATONEX BLOQUE 26
Product type(s):	14 (Rodenticide)
Active ingredient(s):	DIFENACOUM
Case No. in R4BP	BC-PP000075-38 (NA-RNL) BC-HE030682-55 (NA-MAC)
Asset No. in R4BP	ES-0000122-0000
Evaluating Competent Authority	SPAIN
Internal registration/file no	ES/APP(NA)-2018-14-00094
Date	February 2018 (Update February 2021)

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Application type	Ref MS	Case number/Asset number in the ref MS	Decision date	Assessment carried out (i.e. first authorisation / amendment /renewal)
NA-AAT	ES	BC-CA064703-62 / ES-0000122-0000	19/02/2021	Amendment (post-authorisation: stability long term)

1 Conclusion

The assessment presented in this report includes the major change submitted by the applicant according to Implementing Regulation 354/2013 in order to decrease the content of difenacoum active substance at a level of 0.0026% w/w due to 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. In addition, this report also includes the conditions for the renewal of the active substance, according Commission Regulation (EU) 2017/1379 of 25 July 2017.

The initial evaluation of the biocidal product RATONEX BLOQUE containing of difenacoum active substance at a level of 0.005% w/w should be taken into account. As the name of the product refers to the content in active substance of the product, the Spanish Competent Authority requested to the applicant changed the product name in order not to mislead the user and for enforcement tasks

It is concluded after evaluation of new data submitted that the ready-to-use product, RATONEX BLOQUE 26, with the active substance difenacoum, at a level of 0.0026% w/w, may be authorised for use as a rodenticide (product-type 14). Some of conclusions to the initial assessment remain valid and the new information provided by the applicant to support the decrease of active substance allows granting the authorisation.

Physical, chemical and technical properties remain valid to the initial evaluation other than the stability test. A new Long-term stability test has been submitted and the results fulfil the Guidance criteria, so a shelf-life of 2 years can be granted.

The conclusions about physical hazards and methods for detection and identification remain valid to the initial evaluation and no new information has been submitted.

New efficacy data, field trials, have confirmed that RATONEX BLOQUE 26 is effective in the proposed areas of use, at the recommended dose rate.

According to Commission Regulation (EU) 2016/1179 the product RATONEX BLOQUE 26, with the active substance difenacoum, at a level of 0.0026% w/w is classified as SPECIFIC TARGET ORGAN TOXICITY AFTER REPEATED EXPOSURE. CATEGORY 2 (STOT RE 2); H373 May cause damage to organs (blood) through prolonged or repeated exposure.

The risk assessment for the environment has been performed for the intended uses in and around buildings, open areas, and waste dumps since the concentration of the active substance has been reduced. The new evaluation shows that the conclusions for the first evaluation remain valid.

Therefore, RATONEX BLOQUE 26, can be authorised as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors, outdoor around buildings, outdoor in open areas and waste dumps. The users can be general public, professional and trained professional. It is a ready to used bait to be used in tamper-resistant bait stations.

The specific intended uses of the product are in section 2.4. of this assessment report.

Please, note that this assessment report includes all the uses requested by the applicant and assessed by ES CA, only as information for the concerned Member States.

Spanish CA only grants the use of RATONEX BLOQUE 26 according to the table 5 included in this assessment report due to our national risk mitigation measures.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

RATONEX BLOQUE 26

2.1.2 Manufacturer(s) of the product

Name of manufacturer	WILL KILL S.A
Address of manufacturer	C/ 4 DE NOVIEMBRE 6 07011 PALMA DE MALLORCA Spain
Location of manufacturing sites	C/ 4 DE NOVIEMBRE 6 07011 PALMA DE MALLORCA Spain

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

Active substance	Difenacoum
Name of manufacturer	ACTIVA S.L.R.
Address of manufacturer	VIA FELTRE 32 20132 MILANO Italy
Location of manufacturing sites	Dr. TEZZA S.R.L. VIA TRE PONTI 22 37050 SANTA MATIA DI ZEVIO (VR) Italy

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 (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4- tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active substance	56073-07-5	259-978-4	0.0026
-	-	Non-active substances	-	-	-

- The product contains a bittering agent and a dye.

Information on the full composition is provided in the confidential annex

- 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:

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

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

And therefore, difenacoum 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 bait: block

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

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Specific target organ toxicity after repeated exposure. Category 2	H373 May cause damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
Signal word		WARNING
Hazard statements	H373	May cause damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	-	
Supplemental label elements	-	
Precautionary statements	P102	Keep out of reach of children
	P103	Read label before use.
	P280	Wear protective gloves.
	P314	Get medical advice/attention if you feel unwell.
	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 evaluated in Spain further down:

Table 4

Use(s) considered appropriate for authorisation after former assessment (uses currently <u>evaluated in SPAIN</u>		**Use(s) appropriate for further authorisation**	
1	House mice and/or brown rats – general public–indoor and outside around buildings	1	House mice – general public - indoor
		2	Brown Rats – general public - indoor
		3	Brown Rats – general public – outdoor around buildings
2	House mice and/or brown rats – professionals –indoor and outside around buildings	4	House mice – professionals - indoor
		5	Brown Rats – professionals - indoor
		6	House mice and/or Brown rats – Professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – indoor and outside around buildings, outdoor open areas & waste dumps	7	House mice and/or Brown rats – trained professionals - indoor
		8	House mice and/or Brown rats – trained professionals – outdoor around buildings
		9	Brown Rats – trained professionals – outdoor open areas & waste dumps

Uses authorised in Spain according national Risk Mitigation Measures:

Table 5

Use(s) considered appropriate for authorisation after former assessment (uses currently <u>under authorisation in Spain</u>)	**Use(s) appropriate for authorisation in Spain according national Risk Mitigation Measures.**
House mice and/or brown rats – general public–indoor and outside around buildings	<u>House mice – general public - indoor</u>
	Brown rats – general public - indoor
	Brown rats – general public – outdoor around buildings
House mice and/or brown rats – professional–indoor and outside around buildings	<u>House mice – professionals - indoor</u>
	Brown rats – professionals - indoor
	Brown rats – Professionals – outdoor around buildings
House mice and/or brown rats – trained professionals – indoor and outside around buildings, outdoor open areas & waste dumps	House mice and/or Brown rats – trained professionals - indoor
	House mice and/or Brown rats – trained professionals – outdoor around buildings
	Brown rats – trained professionals – outdoor open areas & waste dumps

2.4.1 Use 1– House mice– general public – 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)

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	**Mice:** 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4m
Category(ies) of users	General public
Pack sizes and packaging material	**Maximum pack size of 100g.** Number of packed bags per packaging: up to 100g Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: plastics bags of polyethylene and cardboard boxes

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 –Brown Rats– general public – indoor

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	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats:** 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5m
Category(ies) of users	General public
Pack sizes and packaging material	**Maximum pack size of 300g.** Number of packed bags per packaging: up to 300g Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: plastics bags of polyethylene and cardboard boxes.

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– Brown Rats – general public – 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)	*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:** 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5m
Category(ies) of users	General public
Pack sizes and packaging material	**Maximum pack size of 300g.** Number of packed bags per packaging: up to 300g Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: plastics bags of polyethylene and cardboard boxes

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

2.4.4 Use 4- House mice – 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)
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	**Mice:** 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4m
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cardboard boxes and polypropylene buckets.

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

2.4.4.2 Use-specific risk mitigation measures

-See section 2.5.2

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

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

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

-See section 2.5.4

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 2.5.5

2.4.5 Use 5 – Brown Rats – professionals – indoor

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 rats)
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:** 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5m
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cardboard boxes and polypropylene buckets.

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

2.4.5.2 Use-specific risk mitigation measures

-See section 2.5.2

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

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

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

-See section 2.5.4

2.4.5.5 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

2.4.6 Use 6 – House mice and/or brown rats – 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)	*Rattus norvegicus* (brown rats) *Mus musculus* (house mice)

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:** 100 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5m. **Mice:** 50 g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 4m
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cardboard boxes and polypropylene buckets.

2.4.6.1 Use-specific instructions for use

- Protect bait from the atmospheric conditions (e.g. rain, snow, etc.). Place the bait stations in areas not liable to flooding.

- The bait stations should be visited *[for mice* - at least every 2 to 3 days at*] [for rats* - 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.

- Replace any bait in a bait station in which bait has been damaged by water or contaminated by dirt.

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

2.4.6.2 Use-specific risk mitigation measures

- Do not apply this product directly in the burrows.

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

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

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

-See section 2.5.4

2.4.6.5 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

2.4.7 Use 7 - House mice and/or brown 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 rats)
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:** 100- 200 g of bait per baiting point **Mice:** 50 g 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 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cardboard boxes and polypropylene buckets.

2.4.7.1 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.

2.4.7.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign - 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 places that are not accessible to children or non-target animals.

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

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

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

-See section 2.5.4

2.4.7.5 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

2.4.8 Use 8 – House mice and/or brown 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 rats)
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:** 100-200 g of bait per baiting point **Mice:** 50 g 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 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cardboard boxes and polypropylene buckets.

2.4.8.1 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.

2.4.8.2 Use-specific risk mitigation measures

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

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

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

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

-See section 2.5.4

2.4.8.5 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

2.4.9 Use 9 – Brown 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 rats)
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:** 100-200 g 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 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cardboard boxes and polypropylene buckets.

2.4.9.1 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

2.4.9.2 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.

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

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

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

-See section 2.5.4

2.4.9.5 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

General Public:

- 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.

- 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.

Professionals:

- 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.

- 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.

- Bait stations should be placed in the immediate vicinity of places where rodent activity has been previously observed (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 2.5.3 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.

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

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait stations 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.

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

Trained professionals:

- 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 2.5.3 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.

2.5.2 Risk mitigation measures

General Public:

- 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]*.

Professionals:

- 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 at frequent intervals during treatment (e.g. at least twice a week).

- 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 use baits containing anticoagulant active substances as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

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

  - the product shall not be supplied to the general public (e.g. "for professionals only").

  - 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

- Do not wash the bait stations 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]*

Trained Professionals:

- 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]*.

2.5.2 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, always check for and remove contact lenses, 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.

2.5.3 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]*.
- 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: two 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 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.
- For general public: The package of the product should be fitted with a tactile warning

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 brown rats – general public– indoor and outside 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 rats)
Field(s) of use	Indoor Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats:** 3-5 bait stations with a maximum of 200g of product every 100m^2 **Mice:** 2 bait stations with a maximum of 50g of product every 10m^2.
Category(ies) of users	General public
Pack sizes and packaging material	Blocks of 6, 8, 10 and 15 g in 25, 50, 100, 180, 250 and 500 g, and 1kg.

3.1.2 House mice and/or brown rats – professional– indoor and outside 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 rats)
Field(s) of use	Indoor Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats:** 3-5 bait stations with a maximum of 200g of product every 100m^2

	Mice: 2 bait stations with a maximum of 50g of product every 10m^2.
Category(ies) of users	Professionals
Pack sizes and packaging material	Blocks of 6, 8, 10 and 15 g in 25, 50, 100, 180, 250 and 500 g, and 1kg.

3.1.3 Use 3 – House mice and/or brown rats – trained professional– indoor and outside around buildings, outdoor open areas & waste dumps

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 rats)
Field(s) of use	Indoor and outside around buildings, outdoor open areas & waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 2 bait stations with a maximum of 50g of product every 10m2. Rats: 3-5 bait stations with a maximum of 200g of product every 100m2
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Blocks of 6, 10 and 15 g in 1, 2.5, 3, 9, 10, 20 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 – **accelerated storage**	CIPAC MT46.3	0.0026	Difenacoum active ingredient initial content: 0.0023% w/w Difenacoum active ingredient final content: 0.0023% w/w ∆[C] = 0%. The result complies with the tolerance value (-10%).	IUCLID 3.4.1
Storage stability test – **long term storage at ambient temperature**	Guidance on Data Requirements for Active Substances and Biocidal Products	0.0026	Time: 2 years Room temperature $[C]_0$ = 0.0023% w/w $[C]_{12M}$ = 0.0022% w/w Δ[C] = -4.35% $[C]_0$ = 0.0023% w/w $[C]_{24M}$ = 0.0021% w/w Δ[C] = -8.70% Appearance: No significant differences were found before and after storage. Density: δ0= 1.3634 g/cc δ_{12M} = 1.3254 g/cc δ_{24M} = 1.3432 g/cc Based on the results obtained a shelf life of 2 years can be granted.	IUCLID 3.4.1

Apart from the properties mentioned above, 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, chemical and technical properties 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

RATONEX BLOQUE 26 is renewed with a decrease of the active substance concentration from 50 ppm to 26 ppm (major change) and a biocidal product name change (previously RATONEX BLOQUE) and is used against Brown rat (*Rattus norvegicus*) and House mouse (*Mus musculus*).

Taking into account that a complete efficacy data package with 0.005% w/w difenacoum was submitted and that the change in the formulation is basically in the content of active substance, it is assumed that the level of palatability remains the same with the new composition being at least 20% of palatability in laboratory tests.

The applicant has submitted new filed trials in order to support the efficacy of the new formulation of the product against *Rattus norvegicus* and *Mus musculus.* Please, see the summary of field trials submitted by the applicant.
In conclusion, according to the test provided, ES CA consider that the biocidal product with 0.0026 % w/w difenacoum is effective against rats and mice indoor and outdoor.

Experimental data on the efficacy of the biocidal product against target organism(s)							
Function	**Field of use envisaged**	**Test substance**	**Test organism(s)**	**Test method**	**Test system / concentrations applied / exposure time**	**Test results: effects**	**Reference**
Rodenticide	Field test (Indoor)	**Difenacoum 0.0026% w/w**	House mouse (*Mus musculus*)	Field test. According The guidance on the BPR Volume II Efficacy, assessment and evaluation, parts B + C and Transitional Guidance for PT 14	The trial was set up in a farm The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 50g were placed inside bait stations each 4 m	Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is ≤10% (according TNG for PT 14)	IUCLID 6.7
Rodenticide	Field test: (Indoor/ Outdoor)	**Difenacoum 0.0026% w/w**	Brown rat (*Rattus norvegicus*)	Field test. According The guidance on the BPR Volume II Efficacy, assessment and evaluation, parts B + C and Transitional Guidance for PT 14	The trial was set up in a farm. The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 100g were placed inside bait stations each 5 m.	Efficacy = 100 % Percentage of bait consumed after the control operation compared to the amount of bait consumed before the control operation is ≤10% (according TNG for PT 14)	IUCLID 6.7

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

Regarding human exposure no studies have been submitted; therefore, the exposure assessment has been performed using the paper "HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants)" agreed at TMII 2011. This paper was based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers et al. (2004» and the number of manipulations agreed at TMII 2010.

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

The most relevant routes of exposure are the following:

Summary table: relevant paths of human exposure			
Exposure path	**General public**	**Non trained professional**	**Trained professional**
Inhalation	Not relevant	Not relevant	Not Relevant
Dermal	Potentially significant	Potentially significant	Potentially significant
Oral	Relevant	Relevant	Negligible

Concerning dermal absorption, no study is submitted for this RATONEX BLOQUE 26. Therefore, the data on the representative products (wax block) from Annex 1 inclusion, resulting in an overall dermal absorption value of 0.047 will be used in the risk assessment for RATONEX BLOQUE 26.

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Loading and placing bait boxes	Primary exposure. During use, user will be exposed through the loading of bait. Exposure will be via the dermal route and to the hands only.	trained professionals, professionals, general public
2.	Cleaning	Primary exposure. During disposal, users will be exposed through the disposal of used bait and carcasses. Exposure will be via dermal route and to the hands only.	trained professionals, professionals, general public
3.	Touching unprotected bait	Secondary exposure: accidentally touched of unprotected bait. Indirect exposure, especially of children may happen. Two different scenarios of secondary exposure are available, the “handling of dead rodents” scenario and the “transient mouthing of poison bait” scenario. The first is excluded from the risk assessment due to unrealistic assumptions. For the latter, either 5g (User Guidance) or 10mg (TNsG) of the product is assumed to be swallowed by an infant per poisoning event.	Bystanders (children, infants and adults)

Professional exposure

Trained professionals use (pest Control Operators)

Scenario [1] – Loading and placing bait boxes

Description of Scenario [1] - *Trained professional*		
Loading 60 bait points per day (200 g of bait per bait point - 20 blocks of 10 g each-). During the process of loading, the user may be exposed by dermal contact to the bait. Trained professional users are bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Amount of exposure to product during loading: placing of 5 blocks into a bait station	27.79 mg b.p.
	Number of manipulations during loading:	60
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	1.358×10^{-6} mg/kg bw/day	-	1.358×10^{-6} mg/kg bw/day
Scenario [1]	Tier 2 / PPE(gloves)	-	6.79×10^{-8} mg/kg bw/day	-	6.79×10^{-8} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - *Trained professional*		
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Trained professional users are bounded to use PPE during the development of the different tasks of his work. The total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Amount of exposure to product during cleaning:	5.7 mg b.p
	Number of manipulations during cleaning:	15
Tier 2	PPE (gloves)	5%

Calculations for Scenario [2]

Summary table: estimated exposure from trained professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	1.74×10^{-8} mg/kg bw/day	-	1.74×10^{-8} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	8.7×10^{-10} mg/kg bw/day	-	8.7×10^{-10} mg/kg bw/day

Combined scenarios for trained professional users

Summary table: Combination scenarios from trained professional uses				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1+2] Tier 1 / No PPE	-	1.375×10^{-6} mg/kg bw/day	-	1.375×10^{-6} mg/kg bw/day
Scenario [1+2] Tier 2 / PPE (gloves)	-	6.878×10^{-8} mg/kg bw/day	-	6.878×10^{-8} mg/kg bw/day

Professionals use

Scenario [1] – Loading and placing bait boxes

Description of Scenario [1] – *professional*		
Loading 5 bait points per day (worse case: 200 g of bait per bait point - 20 blocks of 10 g each-). During the process of loading the bait, the user may be exposed by dermal contact to the bait. Professional users are not bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Amount of exposure to product during loading placing of 5 blocks into a bait station	27.79 mg b.p.
	Number of manipulations during loading:	5
Tier 2	PPE (gloves)	5%

Calculations for Scenario [1]

Summary table: estimated exposure from professional					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	1.13×10^{-7} mg/kg bw/day	-	1.13×10^{-7} mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	5.65×10^{-9} mg/kg bw/day	-	5.65×10^{-9} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] – *professional user*		
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. Professional users are not bounded to use PPE during the development of the different tasks of his work. The total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Amount of exposure to product during cleaning:	5.7 mg b.p
	Number of manipulations during cleaning:	5
Tier 2	PPE (gloves)	5%

Calculations for Scenario [2]

Summary table: estimated exposure from professional					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	5.8×10^{-9} mg/kg bw/day	-	5.8×10^{-9} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	2.9×10^{-10} mg/kg bw/day	-	2.9×10^{-10} mg/kg bw/day

Combined scenarios for professional users

Summary table: Combined scenarios from trained professional				
Exposure scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1+2] Tier 1 / No PPE	-	1.19×10^{-7} mg/kg bw/day	-	1.19×10^{-7} mg/kg bw/day
Scenario [1+2] - Tier2	-	5.95×10^{-9} mg/kg bw/day	-	5.95×10^{-9} mg/kg bw/day

General public (non-professional users)

Scenario [1] – Loading and placing bait boxes

Description of Scenario [1] – *General public (non-professional users)*		
During the process of loading the bait, the user may be exposed by dermal contact to the bait. General public are not bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed without (Tier 1).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Amount of exposure to product during loading placing of 5 blocks into a bait station	27.79 mg b.p.
	Number of manipulations during loading:	5

Calculations for Scenario [1]

Summary table: estimated exposure from general public (non-professional)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	1.13×10^{-7} mg/kg bw/day	-	1.13×10^{-7} mg/kg bw/day

Scenario [2] – Cleaning

Description of Scenario [2] - general public (non-professional)		
During the process of cleaning the bait, the user may be exposed by dermal contact to the bait. General public (non-professional) users are not bounded to use PPE during the development of the different tasks of his work. The total systemic exposure has been assessed without (Tier 1).		
	Parameters	Value
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Amount of exposure to product during claning:	5.7 mg b.p
	Number of manipulations during cleaning:	5

Calculations for Scenario [2]

Summary table: estimated exposure from general public (non-professional)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	5.8×10^{-9} mg/kg bw/day	-	5.8×10^{-9} mg/kg bw/day

Combined scenarios for general public (non-professional)

Summary table: Combined scenarios from general public (non-professional)				
Exposure scenario	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1+2] Tier 1 / No PPE	-	1.19×10^{-7} mg/kg bw/day	-	1.19×10^{-7} mg/kg bw/day

Exposure of the general public (Secondary exposure)

Scenario [3]

Description of Scenario [3]		
Where appropriate, exposure assessments are based on default values in EU Guidance documents. However, the default value when handling dead rodents is considered unrealistic and therefore the potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment because the available scenarios are unrealistic. For oral exposure of infants/children two sub-scenarios are made: (3.a) one for infant with 10 mg bait (default value for bait treated with repellent) and (3.b) one for children with 5 grams (TNsG on Human Exposure to Biocidal Products, User Guidance). Trained professional users should dispose unused or part-consumed products. Bait stations protect the product and should prevent access by infants (worse-case).		
	Parameters	Value
Tier 1	Infants Body weight	10 kg
	A.S. content of BP	0.0026%
	3.a. Quantity ingested (g) – with bitter agent	0.01
	3.b. Quantity ingested (g) – without bitter agent	5

Calculations for Scenario [3]

Summary table: systemic exposure from general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3.b]	Tier 1 / No PPE	-	-	0.013 mg/kg bw/d	0.013 mg/kg bw/d
Scenario [3.a]		-	-	2.6×10^{-5} mg/kg bw/d	2.6×10^{-5} mg/kg bw/d

Further information and considerations on scenario [3]

These values assume ingestion of bait, however, the presence of denatonium benzoate as an aversive agent and the location of the bait in a sealed bait station and in an inaccessible area have always been considered enough to mitigate the risk. Since the bittering agent is not 100% efficient in protecting against ingestion in all children, it is therefore important that the bait stations are kept out of reach of children (and other non-target species, including pets and livestock) during storage and use.

Monitoring data

The exposure assessment has been performed using the paper "HEEG opinion on a harmonised approach for the assessment of rodenticides (anticoagulants)" agreed at TMII 2011. This paper was based on an operator exposure study conducted by CEFIC/EBPF Rodenticides Data Development Group (Chambers *et al.* (2004)) and the number of manipulations has been proposed by the applicant

Dietary exposure

Exposure to residues in food is not assessed because no contamination of food or feedingstuff is foreseen.

Exposure associated with production, formulation and disposal of the biocidal product

Please see scenario [2] for professional exposure which is related with disposal of the biocidal product.

Aggregated exposure

No aggregated exposure is foreseeable since the product is not intended to be used under another biocidal product type.

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1.	Trained professional	Tier 2 / PPE	6.79×10^{-8} mg/kg bw/day

Scenarios and values to be used in risk assessment			
1.	Trained professional	Tier 1/ no PPE (unrealistic)	1.358 x 10^{-6} mg/kg bw/day
2.	Trained professional	Tier 2/ PPE	8.7 x 10^{-10} mg/kg bw/day
2.	Trained professional	Tier 1/ no PPE (unrealistic)	1.74 x 10^{-8} mg/kg bw/day
Combined 1 + 2	Trained professional	Tier 2/ PPE	6.87 x 10^{-8} mg/kg bw/day
Combined 1 + 2	Trained professional	Tier 1/ no PPE (unrealistic)	1.37 x 10^{-6} mg/kg bw/day
1	Professional	Tier 1 / No PPE	1.13 x 10^{-7} mg/kg bw/day
1	Professional	Tier 2 / PPE (gloves)	5.65 x 10^{-9} mg/kg bw/day
2	Professional	Tier 1 / No PPE	5.8 x 10^{-9} mg/kg bw/day
2	Professional	Tier 2 / PPE (gloves)	2.9 x 10^{-10} mg/kg bw/day
Combined 1 + 2	Professional	Tier 1 / No PPE	1.19 x 10^{-7} mg/kg bw/day
Combined 1 + 2	Professional	Tier 2 / PPE (gloves)	5.95 x 10^{-9} mg/kg bw/day
1	General public (non-professional)	Tier 1	1.13 x 10^{-7} mg/kg bw/day
2	General public (non-professional)	Tier 1	5.8 x 10^{-9} mg/kg bw/day
Combined 1 + 2	General public (non-professional)	Tier 1	1.19 x 10^{-7} mg/kg bw/day
3.b	Bystander (infants)	No PPE / Without bitter agent	0.013 mg/kg bw/d
3.a	Bystander (children)	No PPE / With bitter agent	2.6 x 10^{-5} mg/kg bw/d

3.6.4 Risk characterisation for human health

Reference values to be used in Risk Characterisation

Reference	Study	NOAEL (LOAEL) (mg/kg bw/day)	AF	Correction for oral absorption	Value (mg/kg bw/day)
AEL_{acute}	-	0.00034	300 (+ factor 2 to extrapolation from LOAEL)	-	1.1 x 10^{-6}
$AEL_{medium\text{-}term}$	-	0.00034		-	1.1 x 10^{-6}
$AEL_{long\text{-}term}$	-	0.00034		-	1.1 x 10^{-6}

ARfD	Not applicable	-	Not applicable	-	Not applicable
ADI	Not applicable	-	Not applicable	-	Not applicable

The acceptable level of exposure for short, medium and long-term exposure (AEL) is established in the EU Endpoint List as 1.1 x 10^{-6} mg/kg bw/day, based on the endpoint from the teratogenicity test in rabbits (NOAEL: 0.00034 mg/kg bw/day) and a safety factor of 3. This is considered to be a suitable endpoint for all users applying rodenticide baits, and for indirect exposure.

3.6.4.1 Risk for trained-professional users

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1 x 10^{-6}	1.35 x 10^{-6}	123	No
	Tier 2			6.79 x 10^{-8}	6.1	Yes
Cleaning / Scenario [2]	Tier 1			1.74 x 10^{-8}	1.58	Yes
	Tier 2			8.7 x 10^{-10}	0.07	Yes
Combined 1+2	Tier 1			1.37 x 10^{-6}	125	No
	Tier 2			6.87 x 10^{-8}	6.2	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

The exposure assessment for trained professional pest control operators under reasonable worst case assumptions (60 loadings and 15 clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 1.37 x 10^{-6} mg/kg/day for an unprotected operator during bait handling operations. Comparison to the LOAEL of 0.001 mg/kg/day (based on a teratogenicity test in rabbits) shows that the use of rodenticide baits containing 0.0026% difenacoum cause a potential health risk for pest control operators not wearing appropriate PPE (gloves), as indicated by the resulting margin of exposure.

Nevertheless, since pest control operators are supposed to wear protective gloves during pest control operations, a refined assessment is conducted. The resulting margin of exposure indicates that the use of this product does not cause a risk for pest control operators if gloves are worn.

The result of the risk assessment concerning use of difenacoum in RATONEX BLOQUE 26, indicates that the acceptable exposure level is not exceeded for trained professionals (pest control operators) with gloves. Even then, use of protective gloves is recommended in all cases for hygiene reasons and always expected for professional users.

Exposure during manufacture of the active substance[1] and formulation of products is beyond the scope of BPD and therefore has not been addressed.

3.6.4.2 Risk for professional

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	1.13×10^{-7}	10.3	Yes
	Tier 2			5.65×10^{-9}	0.5	Yes
Cleaning / Scenario [2]	Tier 1			5.8×10^{-9}	0.52	Yes
	Tier 2			2.9×10^{-10}	0.02	Yes
Combined 1+2	Tier 1			1.19×10^{-7}	10.8	Yes
	Tier 2			5.95×10^{-9}	0.54	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

The exposure assessment for professional user under reasonable worst case assumptions (5 loadings and 5 clean-up/day) indicates that the risk is acceptable even without the use gloves.

3.6.4.3 Risk for general public (non-professional users)

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Loading / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	1.13×10^{-7}	10.3	Yes
Cleaning / Scenario [2]	Tier 1			5.8×10^{-9}	0.52	Yes
Combined 1+2	Tier 1			1.19×10^{-7}	10.8	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

The exposure assessment for General Public user under reasonable worst case assumptions (5 loadings

and 5 clean-ups/day), indicates that the risk is acceptable without the use gloves.

3.6.4.4 Risk for the general public (Secondary exposure)

Adults or children may be present following application and may be incidentally exposed by touching unprotected bait under a hypothetical worse case as the product is placed inside a bait station. For products applied in bait stations or outdoors, incidental exposure will be very limited.

Infants are potentially the group most at risk as they may play inside or around buildings where baits have been placed. They could be exposed orally by chewing bait or touching their mouth with contaminated fingers.

Systemic effects

Task/ Scenario	Tier	Systemic NOAEL mg/kg bw/d	AEL_{acute} mg /kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
Infants may ingest part of the bait without bitter agent/ [3.b]	Tier 1- (no PPE)	0.00034	1.1×10^{-6}	0.013	1.18×10^{6}	No
Infants may ingest part of the bait with bitter agent/ [3.a]				2.6×10^{-5}	2364	No

Local effects

There is no need to consider local effects separately.

Conclusion

In the hypothetical case that a child may enter in contact with unprotected bait, the calculated exposure was 2364 % of AEL based on a default exposure value which assumes that infants might ingest 10 mg of poison bait and 1.18×10^{6} % of AEL when assuming that children might ingest 5 g bait. These values show that infants and children ingesting bait might be at risk. In this hypothetical worst case scenario, firstly, the bait is located inside a sealed bait station and secondly, the product contains a bittering agent which would prevent ingestion of the baits. Therefore, in practice the margins of safety are expected to be much higher than those calculated. It is also important that product labels and good practice advise users to prevent access to bait by children.

The proposed uses therefore represent an acceptable risk from indirect exposure.

3.6.4.5 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 remains valid.

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

There is no risk derived from a combined exposure because indirect exposure via the environment is considered negligible, the product is not intended to be mixed with other biocidal or non biocidal products and the product does not contain any other active substance of concern.

3.6.4.7 Summary of risk characterisation

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1.	Trained professional user	Tier 1/ no PPE (unrealistic)	1.1×10^{-6}	1.358×10^{-6}	123.4	No
1.	Trained professional user	Tier 2/ PPE	1.1×10^{-6}	6.79×10^{-8}	6.1	Yes
2.	Trained professional user	Tier 1/ No PPE	1.1×10^{-6}	1.74×10^{-8}	1.58	Yes
2.	Trained professional user	Tier 2/ PPE	1.1×10^{-6}	8.7×10^{-10}	0.07	Yes
Combined 1+2	Trained professional user	Tier 1/ No PPE	1.1×10^{-6}	1.37×10^{-6}	125	No
Combined 1+2	Trained professional user	Tier 2/ PPE	1.1×10^{-6}	6.87×10^{-8}	6.25	Yes

Scenario number	Exposed group	Tier/PPE	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
1.	professional user	Tier 1/ No PPE	1.1 x 10^{-6}	1.13 x 10^{-7}	10.3	Yes
1.	professional user	Tier 2/ PPE	1.1 x 10^{-6}	5.65 x 10^{-9}	0.5	Yes
2.	professional user	Tier 1/ No PPE	1.1 x 10^{-6}	5.80 x 10^{-9}	0.52	Yes
2.	professional user	Tier 2/PPE	1.1 x 10^{-6}	2.90 x 10^{-10}	0.02	Yes
Combined 1+2	professional user	Tier 1/ No PPE	1.1 x 10^{-6}	1.19 x 10^{-7}	10.8	Yes
Combined 1+2	professional user	Tier 2/ PPE	1.1 x 10^{-6}	5.95 x 10^{-9}	0.54	Yes
1	General public (non-professional)	No PPE	1.1 x 10^{-6}	1.13 x 10^{-7}	10.3	yes
2.	General public (non-professional)	No PPE	1.1 x 10^{-6}	5.8 x 10^{-9}	0.52	Yes
Combined 1+2	General public (non-professional)	No PPE	1.1 x 10^{-6}	1.19 x 10^{-7}	10.8	Yes
3b.	General public (Children)	Tier 1 (without bitter agent)	1.1 x 10^{-6}	0.013	1181818	No
3a.	General public (Children)	Tier 2 (with bitter agent)	1.1 x 10^{-6}	2.6 x 10^{-5}	2363	No

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.

3.8.1. Exposure assessment

General information

Assessed PT	PT 14
Assessed scenarios	Scenario [1]: in and around buildings Scenario [2]: open areas Scenario [3]: waste dumps
ESD(s) used	– EUBEES 2 Emission Scenario Document (ESD) for biocides used as rodenticides (Larsen, 2003) Calculations were performed using (ESD)
Approach	The proposed use of 'RATONEX BLOQUE 26' allows up to 200g of bait per baiting station. The bait stations are regularly inspected, refilled, and dead rodents are removed. The bait points are placed 5-10 m apart and the baiting programmes are repeated 2-3 times a year. In the ESD worst case scenario 10 tamper resistant bait stations are used each filled with 250g blocks, inspected and replenished 5 times (day 1,3,7,14,21). It is an assumption that all of the bait has been eaten. There is a large variation of the duration of a rodenticide campaign and a 21 days period represents a realistic worst case. In a typical campaign (normal use), bait.would be applied on day 1, replenished 100% on day 3, on day 7 there would be 25-50% replenishment, on day 14, 10%, on day 21 0%. Roughly the equivalent of 1.5 x 100% replenishments. (CEFIC 2002). In the so-called 'typical' scenario the replenishment is done only 1.5 times. The scenario represented by the proposed use differs from the ESD worst case scenario only regarding the amount of bait in each station, i.e. 200 g instead of 250 g; the other parameters are considered as equal to the worst case scenario.

	Exposure to surface water (and consequently to sediment) following the use of the product in and around buildings is considered to be negligible (ESD, Section 2.4.3.1 & 2.4.3.3), whereas open areas and waste dump are regarded not relevant.
Distribution in the environment	Technical Guidance Document on Risk Assessment part II (TGD II)
Groundwater simulation	BPR Guidance
Confidential Annexes	Yes, please see section 3.6
Life cycle steps assessed	Scenarios [1], [2] and [3] Production: No Formulation No Use: Yes Service life: No
Remarks	"RATONEX BLOQUE 26' is proposed for use in and around buildings, open areas or waste dumps; hence PEC calculations are required for these uses.

Emission estimation

In accordance with the approach taken in the CAR, the Predicted Environmental Concentration (PEC) in surface water, groundwater and sediment were calculated for the authorised uses (in and around buildings, open areas and waste dumps), for control of rats and mice. The PEC values were calculated with reference to the guidance documents EUBEES 2 Emission Scenario Document (ESD) for biocides used as rodenticides (Larsen, 2003), and the Technical Guidance Document on Risk Assessment part II (TGD II).

The PEC in groundwater is calculated as a direct function of the PEC in soil and therefore full calculations for both soil and groundwater are presented in the current dossier. 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 difenacoum concentration in local soil, the bulk density of the soil and the soil-water partitioning coefficient.

The main route of potential environmental exposure is from use of the product as a rodenticide. The product is placed in a bait station. Following CA-Sept16-Doc.4.1.c, bait station from category 1 is recommended to be used with RATONEX BLOQUE 26 in order to prevent any exposure to the environment or human. By doing this rats and mice can eat them and the bait is protected and avoid undesirable exposure. Baiting points are inspected frequently and replenished when bait has been consumed.

Dead rodents are removed for disposal in order to prevent them being eaten by non-target animals and birds. There is also a potential for exposure from removal of the bait from the box by the rodent and transfer to the burrow where the terrestrial compartment may be exposed. The terrestrial compartment may also be exposed via breakdown of carcasses.

As no information on toxicity of the four major metabolites is available and the 4-hydroxy coumarin moiety is still present and thus the metabolites could be potent as anticoagulants, the sum of these four metabolites

and unchanged difenacoum in faeces is taken into account in PEC calculation together with assumption that the toxicity of metabolites is comparable to parent.

The following table summarizes the input values used to calculate the fate and distribution in the environment:

Parameter	Value	Source
Molecular weight (g/mol)	444.5	EU endpoint list
Melting point	211-215 ^{o}C	EU endpoint list
Boiling point	-	EU endpoint list
Vapour pressure 20^{o}C	6.7 x 10^{-9} Pa	EU endpoint list
Vapour pressure 25^{o}C	1.9 x 10^{-11} Pa	EU endpoint list
Henry's law constant	1.75 x 10^{-6} Pa.m^{3}.mol^{-1}	EU endpoint list
Log Kow	7.6	EU endpoint list
Water solubility 20^{o}C	0.48 mg/L	EU endpoint list
Koc	1.8 x 10^{6} L/kg 426579 (acidic conditions) 17 to 165 (basic conditions)	QSAR (value used in Difenacoum's CAR)
$RHO_{product}$	1.1100 g/ml *	Physichal-chemical properties of the product.

* In view of the next to 1 g/ml and in order to simplify the calculations, 1 g/ml is considered as product density in the following assessments.

Scenario [1] - Use in and around buildings

The product is a ready-to-use bait. Under the proposed use up to 200g of bait is placed in each bait station. The bait stations are regularly inspected, refilled, and dead rodents are removed. The bait points are placed 5-10 m away from a farm building and the baiting programmes are repeated 2-3 times a year.

In the ESD worst case scenario (Tier 1) 10 bait stations 5 m away from a farm building are used, each filled with 250g of bait, and it is assumed that the rodenticide campaign will last for 21 days. It is also assumed that all of the bait is replenished 5 times. In the proposed real scenario (Tier 2) the replenishment is done only 1.5 times. 14% of ingested difenacoum is assumed to be excreted as a worse case.

According to the ESD the terrestrial environment is exposed via direct release at application and indirect release from the target animals' excrement. According to the ESD the fraction of release ($F_{release}$) is 0.3 + (0.6*metabolised fraction). Using the same value for the metabolised fraction as was used in the CAR (71 %), the $F_{release}$ calculated according to the ESD is therefore 0.3 + (0.6*0.71) = 0.73 . Since the toxicity of possible metabolites is unknown they will be assumed to be of similar toxicity as difenacoum.

Exposure to surface water (and consequently to sediment) following the use of the product in and around buildings is considered to be negligible (ESD, Section 2.4.3.1 & 2.4.3.3). In the same way, according to ESD § 2.4, emission to STP compartment from the scenario of in and around buildings may be considered negligible too.

A summary of in and around buildings scenario input values are provided in the following table:

Input variable/parameters for calculating the local emission				
Variable/parameter	***Symbol***	***Value***		***Unit***
Scenario: Use in and around buildings		***(Tier 1) Worse case***	***(Tier 2) Proposed use***	
Amount of product used operation for each application site	Q_{prod}	250	200	[g]
Fraction of active substance in product	$Fc_{product}$	0.0026	0.0026	[%]
Number of application sites	N_{sites}	10	10	[-]
Number of refilling times	N_{refil}	5	1.5	[-]
Number of emission days per year	$T_{emission}$	21	21	[d]
Fraction of product released to soil during use	$F_{release, soil, use}$	0.01	0.01	[-]
Area directly exposed to rodenticide	$AREA_{exposed-D}$	0.09	0.09	[m^2]
Fraction of product released indirectly to soil	$F_{released-ID,soil}$	0.9	0.9	[-]
Area indirectly exposed to rodenticide	$AREA_{exposed-ID}$	550	550	[m^2]
Depth of exposed soil	$DEPTH_{soil}$	0.1	0.1	[m]
Density of wet exposed soil	RHO_{soil}	1700	1700	[$kg.m^{-3}$]

Calculus have been performed according to EUBEES, Emission document for biocides used as rodenticides

Direct release in the realistic worst case farm scenario based on bait in bait boxes has been calculated as following (equation 2 ESD):

ESD worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	250
Fraction of active substance in product	Fc_{prod}	-	0,000026
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5

Fraction of active substance released directly to soil	$F_{release, soil}$	-	0,01
Local direct emission rate of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing}$ = (Q_{prod} x Fc_{prod} x N_{sites} x $F_{release, soil}$) (2)**	**g**	**0.00325**

Applicant's worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	200
Fraction of active substance in product	Fc_{prod}	-	0,000026
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	1.5
Fraction of active substance released directly to soil	$F_{release, soil}$	-	0,01
Local direct emission rate of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing}$ = (Q_{prod} x Fc_{prod} x N_{sites} x $F_{release, soil}$) (2)**	**g**	**0,00078**

The concentration in the soil around each bait box after direct release can be estimated by the equation (3) of the ESD for PT14:

ESD worst case

Parameter	Definition	Units	Value
Local direct emission rate of active substance to soil from a campaign	$E_{soil, D\text{-}campaing}$ (2)	g	0.00325
Area directly exposed to active substance	$AREA_{exposed\text{-}D}$	m^2	0.09
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Number of application sites	N_{sites}	-	10
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D}$ = ($Elocal_{soil\text{-}D\text{-}campaign}$ x10E3)/ ($AREA_{exposed\text{-}D}$ x $DEPTH_{soil}$ X RHO_{soil} x N_{sites}) (3)**	**mg/kg**	**0.0212**

Applicant's worst case

Parameter	Definition	Units	Value
Local direct emission rate of active substance to soil from a campaign	$E_{soil,\ D\text{-}campaing}$ (2)	g	0.000078
Area directly exposed to active substance	$AREA_{exposed\text{-}D}$	m^2	0.09
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Number of application sites	N_{sites}	-	10
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D}$ = (Elocal $_{soil\text{-}D\text{-}campaign}$ x10E3)/ (AREA $_{exposed\text{-}D}$ x $DEPTH_{soil}$ X RHO_{soil} x N_{sites}) (3)**	**mg/kg**	**0.0051**

The concentration in the soil around the bait box taking into account only disperse release can be estimated by the equation:

ESD worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	250
Fraction of active substance in fproduct	Fc_{prod}	-	0.000026
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5
Fraction released indirectly to soil	$F_{release\text{-}ID,\ soil}$		0.9
Fraction released directly to soil	$F_{release,\ soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soil	RHO_{soil}	kg/m^3	1700
Concentration in soil due to indirect (disperse) release after a campaign	**$Clocal_{soil\text{-}ID}$ = ((Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x 10^3 x $F_{release,ID\ soil}$ x (1-$F_{release,D\ soil}$)) / (AREA exposed-ID x DEPTHsoil X RHOsoil x Nsites) (4)**	**mg/kg**	**0.0031**

Applicant's worst case

Parameter	Definition	Units	Value
Amount of product used at each refill/application	Qprod	g	200
Fraction of active substance in fproduct	Fc_{prod}	-	0.000026
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	1.5
Fraction released indirectly to soil	$F_{release\text{-}ID,\ soil}$		0.9
Fraction released directly to soil	$F_{release,\ soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed\text{-}ID}$	m^2	550
Depth of exposed soil	$DEPTH_{SOIL}$	m	0.1
Density of exposed soiil	RHO_{soil}	kg/m^3	1700
Concentration in soil dur to indirect (disperse) release after a campaign	**$Clocal_{soil\text{-}ID} = ((Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times 10^3 \times F_{release,ID\ soil} \times (1-F_{release,D\ soil})) /$ (AREA exposed-ID x DEPTHsoil X RHOsoil x Nsites) (4)**	**mg/kg**	**0.000743**

Total soil concentrations around the bait boxes are the sum of the soil concentrations caused by direct and indirect pollution o the soil:

ESD worst case

Total concentration immediately direct to the bait	**$C_{local\ soil} = C_{local\ soil\text{-}D} + C_{local\ soil\text{-}ID}$**	**mg/kg**	**0.0243**

Applicant's worst case

Total concentration immediately direct to the bait	**$C_{local\ soil} = C_{local\ soil\text{-}D} + C_{local\ soil\text{-}ID}$**	**mg/kg**	**0.00584**

Calculations for Scenario [1] - Use in and around buildings

Calculation of PEC in soil

Using the scenarios outlined in the ESD for rodenticides and the TGD on risk assessment, and the calculations and assumptions presented for "in and adround buildings" scenario, the following local PEC values have been derived for the terrestrial compartment. Proposed real case values taken forward to the risk characterisation are shown in bold for the relevant scenarios assessed for 'RATONEX BLOQUE 26' are reproduced below.

SCENARIO	(Tier 1) Realistic worse case using default values	(Tier 2) Proposed realistic case*

IN/AROUND BUILDINGS		
PECsoil	0.0243 mg/kg	0.00584mg/kg

Calculation of PEC in groundwater

$PEC_{groundwater}$ 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 difenacoum concentration in local soil, the bulk density of the soil and the soil-water partitioning coefficient.

$PECsoil_{,porewater}$ = PECsoil *RHO / ($K_{soil-water}$ *1000)

Using the scenarios outlined in the ESD for rodenticides and the TGD on risk assessment, and the calculations and assumptions presented for each of the scenarios considered above, the following local PEC values have been derived for aquatic compartments. Proposed real-case values taken forward to the risk characterisation are shown in bold.

SCENARIO **Compartment**	**(Tier 1)** **Realistic worse case using default values**	**(Tier 2)** **Proposed realistic case**
IN/AROUND BUILDINGS		
Ground (pore) water		
From soil exposure	7.65×10^{-7} mg/l	**1.84×10^{-7} mg/l**

An average K_{oc} value of 1803018 ml/g (EU Endpoint List) was used in the calculations for derivation of $k_{soil-water}$ (=54090.74). However, due to the limited use of difenacoum in campaigns that last for a limited time, usually three weeks, and that good management practice prescribes that both leftover feed and dead rodents are collected and disposed of in a secure way, the exposure to groundwater is likely to be negligible.

Scenario [2] - Use in open areas

This scenario covers control of rats and watervoles in open areas such as around farmland, park and golf courses where the aim is to prevent "nuisance" from burrows or "soil heaps" or due to public hygiene reasons.

Blocks are only allowed for use in feeding stations in the Nordic countries; however, in many other countries in the EU wax blocks (100-200 g) may be placed directly inside holes. 20-30 g wax block baits are also commonly used in several countries e.g. in UK.

A typical initial dose for a rat hole in the Nordic countries is 100-200 g .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.

Input		Tier 1	
Variable/parameter	***Symbol***	***Value***	***Unit***
Amount of product used at each refilling in the control operation	Q_{prod}	200	g
Fraction of active substance in product	Fc_{prod}	0.0026	[%]
Number of application sites	N_{sites}	1	[-]
Number of refilling times	N_{refil}	2	[-]
Fraction of 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	[-]
Radius of exposed soil around the hole	R	0.14	m
Radius of hole	r	0.04	m
Length of exposed hole	l	0.3	m
Density of wet exposed soil	RHO_{soil}	1700	$kg.m^{-3}$

Calculations for Scenario [2] - Use in open areas

As in the scenario before, only local emission to soil compartment may be considered of relevance for the environment. Hence, only terrestrial compartment may be exposed for this scenario and considered of concern, so PEC for industrial soil and porewater compartments have been calculated.

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}	-	0.000026
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	**$Elocal_{soil\text{-}campaing}$ = (Q_{prod} x Fc_{prod} x N_{sites} x N_{refil} x($F_{release, soil, appli}$ + $F_{release, soil}$) (9)**	**g**	**$2.60x10^{-03}$**

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	$5.00x10^{-03}$
Soil volume exposed to rodenticide	$Vsoil_{exposed}$ (eq. 9a ESD)	m^3	$8.5x10^{-03}$
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**	**$1.80x10^{-01}$**

Calculation of PEC in soil

Using the scenarios outlined in the ESD for rodenticides and the TGD on risk assessment, and the calculations, the following local PEC values have been derived for the terrestrial compartment.

SCENARIO **Compartment**	**Tier 1** **(ESD worse case)**
Open areas	
Local PEC soil $mg.kg^{-1}$	**0.18**

Calculation of PEC in porewater (groundwater)

PEC 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 difenacoum concentration in local soil, the bulk density of the soil and the soil-water partitioning coefficient.

SCENARIO **Compartment**	**Tier 1** **(ESD worse case)**
Open areas	
Local PEC soil porewater $mg.L^{-1}$	5.657×10^{-6}

Scenario [3] - Use in waste dumps (trained professional)

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.

Input		**Tier 1**	
Variable/parameter	***Symbol***	***Value***	***Unit***
Amount of product used in the control operation	Q_{prod}	40	kg
Fraction of active substance in product	Fc_{prod}	0.0026	[%]
Number of applications	N_{app}	7	[-]
Fraction of product released to soil	$F_{release,soil}$	0.9	[-]
Area exposed to rodenticide	$AREA_{exposed}$	10000	m^2
Depth of exposed soil	$DEPTH_{soil}$	0.1	m
Density of wet exposed soil	RHO_{soil}	1700	$kg.m^{-3}$

<u>Calculations for Scenario [3] - Use in waste dumps</u>

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}	-	0.000029
Number of application sites	N_{sites}	-	7
Fraction of active substance released directly to soil	$F_{release,\ soil}$	-	0.73
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**	**$6.55x10^{-03}$**

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/m3	$6.55x10^{-03}$
Area directly exposed to active substance	$AREA_{exposed\text{-}D}$	m^2	10000
Depth of exposed soil	$DEPTH_{SOIL}$	M	0.1
Density of exposed soil	RHO_{soil}	kg/m^3	1700

Parameter	Definition	Units	Value
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil-D}$ = ($Elocal_{soil-D-campaign}$ x10E3)/ ($AREA_{exposed-D}$ x $DEPTH_{soil}$ x RHO_{soil} x N_{sites}) (18)**	**mg/kg**	**0.000385**

SCENARIO Compartment		**Tier 1 (ESD worse case)**
Waste dumps		
Local PEC in soil	$mg.kg^{-1}$	0.000385

Calculation of PEC in porewater (groundwater)

As in the scenario before and following the TGD on risk assessment, and the calculations and assumptions presented for each of the scenarios considered above, the following local PEC values have been derived for groundwater compartment.

SCENARIO Compartment		**Tier 1 (ESD worse case)**
Waste dumps		
Local PEC in porewater of industrial/ application soil	$mg.L^{-1}$	$1.21x10^{-8}$

Fate and distribution in exposed environmental compartments

The environmental fate and behaviour of the active substance difenacoum has been fully evaluated during the assessment for Annex I inclusion. A summary of the fate and distribution of difenacoum is presented in Section 2.2.2.1 of the final Assessment Report (17 September 2009), and the relevant endpoints appear in the EU List of Endpoints.

The formulation of difenacoum as a block bait in RATONEX BLOQUE 26 is not expected to have impact on the route or rate of degradation of the active substance difenacoum in the environment.

A summary of the fate and distribution of difenacoum in biocidal product is presented below:

Identification of relevant receiving compartments based on the exposure pathway									
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water	Other: secondary poisoning
Scenario 1	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	Yes	Yes	Yes
Scenario 2	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	Yes	Yes	Yes
Scenario 3	n.r.	n.r.	n.r.	n.r.	n.r.	n.r.	Yes	Yes	Yes

n.r.= “not relevant”

Calculated PEC values

Summary table on calculated PEC values								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[1]**	**PEC_{air}**
	[mg/m^3]	[mg/l]	[mg/kg$_{wwt}$]	[mg/l]	[mg/kg$_{wwt}$]	[mg/kg]	[mg/l]	[mg/m^3]
Scenario 1 tier 1	Neg	Neg	Neg	Neg	Neg	0.0243	7.65 x10^{-7}	
Scenario 1 tier 2	Neg	Neg	Neg	Neg	Neg	0.00584	1.84 x 10^{-7}	
Scenario 2	Neg	Neg	Neg	Neg	Neg	0.18	5.657 10^{-6}	
Scenario 3	Neg	Neg	Neg	Neg	Neg	0.000385	1.21x 10^{-8}	
[1] If the PEC_{GW} was calculated by using a simulation tool (e.g. one of the FOCUS models), please provide the results for the different simulated scenarios in a separate table.								

Primary and secondary poisoning

Difenacoum is not readily biodegradable, has a relatively high bioconcentration factor and is very toxic to both aquatic organisms and mammals, and therefore a risk assessment for secondary poisoning was performed according to TGD II. According to those calculations performed, the evaluated product with difenacoum will cause unacceptable risks both for primary and secondary poisoning. On the other hand, in order to avoid any test on mammals, a thorough bibliographic search has shown by numerous scientific reports (Newton et al., 1997; Foumier-Chambrillon, et al. 2004; Shore et al., 1999; Gillies and Pierce, 1999; Eason and Spurr, 1995) that non-target birds and mammals have been, and are continuously, exposed to second generation anticoagulant rodenticides in the environment. This exposure occurs most likely by consumption of living or dead rodents that have been poisoned by baits containing rodenticides (secondary poisoning). Moreover, year after year there are reports (Barnett et al., 2006) of accidents where non-target mammals have been poisoned by consumption of rodenticides (primary poisoning). Species included in the latter reports are e.g. dogs, badgers and squirrels. The reports include many bird species and also

honeybees but there seems to be a lack of reports, and possibly lack of research, on rodenticide effects on snakes and amphibians. The risk of difenacoum to non-target birds and mammals has been assessed according to the ESD and the TGD II. However, although difenacoum has a potential to bioaccumulate, assessment of secondary poisoning through the aquatic food chain is not performed for the following reasons: the risk assessment for the aquatic compartment indicates that there will be very low concentrations of difenacoum in the aquatic compartment, and there was no risk identified of difenacoum for surface water or sediment dwelling organisms. The justification for not performing an assessment of secondary poisoning via the terrestrial food chain is that secondary poisoning will be limited due to the small area that is potentially contaminated by difenacoum around buildings and the limited number of earthworms inhabiting this area. It seems from monitoring data published on bam 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. 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 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.

Primary poisoning

Non-target animals such as wild and domestic animals may come in contact with baits if the bait is unprotected (bad use of the product) or if bait stations have been damaged. As it was mentioned before, a tamper resistant bait station of category 1 is recommended to use for RATONEX BLOQUE 26 in order to avoid both scenarios above. Even so, well-protected bait may be encountered by animals which are small enough to be able to reach the bait, e.g. weasels, stoats and young cats (kittens), and therefore they may be subject to primary poisoning.

- ***Tier 1 assessment***

Acute exposure:

For the acute situation of primary poisoning only a qualitative risk assessment will be carried out in accordance with the decision from TM III-06. This will be done in the Tier 2 assessment below.

Long-term exposure:

In the Tier 1 assessment of primary poisoning from long-term exposure it is assumed that the whole day's food requirement is satisfied by consumption of bait, and therefore the concentration in food will be the same as the concentration of Difenacoum in the bait i.e. 26 mg/kg. This is then compared to the long-term PNEC values for birds and mammals, as calculated in the table below:

	PEC (conc. in bait)	PNEC (conc. in food)	PEC/PNEC
Birds	26mg/kg	0.0005 mg/kg	52000
Mammals	26mg/kg	7 X 10^{-3} mg/kg	3714.3

The resulting PEC/PNEC ratios reveal a high risk for both birds and mammals from long-term primary poisoning.

Tier 2 assessment

Acute exposure:

In the Tier 2 acute qualitative risk assessment the daily uptake (ETE) of difenacoum is compared with the effect data for birds and mammals: It is important to stress that this qualitative assessment is not intended to be used in the risk characterisation of primary and secondary poisoning of rodenticides and shall not be used in a comparative assessment. To refine the risk assessment the actual dose of difenacoum consumed by the bird after one day/one me al ETE is calculated using the equation below (equation 19 in the ESD). When calculating the dose both the typical body weight of the animal (BW) and daily mean food intake (Fill..) are considered. The calculations are performed in two steps where the avoidance factor (AV), the fraction of the diet obtained from the rodenticide treated are (PT) and the fraction of food type in the animals diet (PD) are all considered in accordance with the ESD. In the worst case calculations performed in the first step avoidance factors, fraction of the diet from treated areas and fraction of food type in diet are all set to the default value of 1. In the realistic worst case calculations, step 2, performed according to the ESD the AV = 0.9, PT = 0.8 and PD = 1.

ETE = (FIR/BW)*C* AV*PT*PD (mg /kg bw*day) Eq 19

ETE values calculated for acute exposure (ETE)

Non-target animal	Typical bodyweight (g)	Daily rnean food intake (g dw/day)	Concentration of difenacoum in bait (mg/kg)	ETE (rng/kg bw)	
				Step 1	Step 2
Dog	10 OOOa	456[b]	26	1.1856	0.85
Pig	80000 a	600 a	26	0.195	0.14
Pig, young	25000 a	600 a	26	0.624	0.449
Tree sparrow	22 a	7.6 a	26	8.98	6.47
Chaffinch	21.4 a	6.42 a	26	7.80	5.62
Wood pigeon	490 a	53.1 a	26	2.82	2.03
Pheasant	953 a	102.7 a	26	2.80	2.02

a According to table 3.1 in the ESD

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

The ETE values calculated for acute exposure for the worst case (step 1) and the realistic worst case (step 2) are compared to the LD50 values in the table below. Risk is foreseeable if the PECoral is higher than LD50.

PEC values calculated for birds and mammals

Non-target animal	PEC_{oral} = ETE, concentration of difenacoum after one meal (mg/kg)		LDso (mg/kg bw/d)	PEC_{oral} higher than LDso (y/n)	
	Step 1	Step 2		Step 1	Step 2
Dog	1.1856	0.85	1.8	n	n
Pig	0.195	0.14	1.8	n	n
Pig, young	0.624	0.449	1.8	n	n
Tree sparrow	8.98	6.47	56	n	n
Chaffinch	7.80	5.62	56	n	n
Wood pigeon	2.82	2.03	56	n	n
Pheasant	2.80	2.02	56	n	n

The ETE values calculated for acute exposure for the worst case (step 1) and realistic worst case (step2) are compared to the LD 50 values. This comparison indicates that birds are not at risk for acute primary poisoning while the situation for mammals is more uncertain.

• Long term EXPOSURE

The long-term risks of difenacoum are determined by the expected concentrations (EC) in the animal after metabolism and elimination, which is regarded as PEC. The EC is calculated by using the actual dose of the substance consumed by a non-target animal each day (ETE) using the realistic worst case scenario (step 2), calculated in table above. When calculating the long-term risks, elimination and metabolism of the substance (El) have to be considered. According to the ESD, a default value of 0.3 for El can be used if no studies are submitted that show different.

The PNEC values used for birds (0.1 µg/kg bw/day) and mammals (0.3 µg/kg bw/day) are those calculated in the final Assessment Report for difenacoum (September 2009).

Calculations are performed according to equation 20 in the ESD;

$$EC = ETE*(1-El) \qquad \text{Eq.20}$$

The following table shows the maximum and minimum values of PEC calculated for each group of organism for a long-term exposure:

PEC/PNEC ratios for primary poisoning - Tier 2 assessment long term

Non-target animal	PEC* = EC_i Concentration of difenacoum after one day of elimination (mg/kg)	PNEC dose (mg/kg bw/day)	PEC/PNEC
Dog	0.784	0.0001	7840
Pig	0.098	0.0001	980
Pig, young	0.3143	0.0001	3143
Tree sparrow	4.529	0.0003	15097
Chaffinch	3.934	0.0003	13113
Wood pigeon	1.421	0.0003	4737
Pheasant	1.414	0.0003	4713

*considering 5.28% as the daily uptake eliminated of difenacoum

The result of the PECIPNEC calculations shows that there are very high risks for long-term primary poisoning of both mammals and birds. The calculations are based on that bait is consumed only during one day and then eliminated from the animal, but it should also be considered that an animal might consume bait again before the first dose is eliminated. On the other hand it should been taken into consideration that the actual doses are strictly worst case and that consumption of these quantities of difenacoum bait by the non-target animal exemplified above are generally not realistic. These results are discussed and compared to monitoring data after the assessment of secondary poisoning in the next section.

Secondary poisoning

- **Secondary poisoning via the terrestrial food chain**

Secondary poisoning of difenacoum occurs when poisoned rodents are caught by predators and eaten by scavengers that hunt and forage around difenacoum treated areas. It has been reported by Shore et al. (1999) that there is an increased hazard of exposure for predators during the winter months which might be caused by the fact that there are less preys available in the winter season. It should be also considered that behaviour of poisoned rodents might change as presented in two reports referred to in the ESD. According to these reports more than half of the rats that died by rodenticide poisoning died away from cover. Moreover, it seemed as the rats changed their behaviour when still alive and were more active during the days than rats normally are and also spent more time unprotected above ground. Such behaviour can make them a more easy prey to predators and they are also more easily found by scavengers. It was found, when water voles were studied during a campaign, that 38% of them died above ground (Saucy et al., 2001, in ESD).

Tier 1 assessment (Short term) and Tier 2 assessment (long term)

Calculations of the risk for secondary poisoning of scavengers and predators are done by determining the concentration of difenacoum in their food, i.e. the poisoned rodents. This PECoral is then compared to the LC50 values presented in section 2.2.8 for a qualitative risk assessment.

According to the ESD section 3.3.1 the consumption of rodenticides makes up at least 20% of total consumptions in a choice test and could in a worse case be up to 100%, whilst 50% would be considered the normal situation. Therefore, in the calculations PD values are set to 0.2, 0.5 and 1.0. The fraction of daily uptake eliminated is 0.3 (EI). The FIR/BW quotient is a default value set to 0.1, i.e. it is assumed that the rats eat 10% of their bodyweight each day. The avoidance factor (AV) is 1, which means no avoidance, since rats is their natural prey, and the fraction of diet (PD) obtained in the area is set to 1. The calculation is done according to equation 19 in the ESD (ETE = (FIR/BW)*C* AV*PT*PD (mg /kg bw*day)).

	Residues in target animal (mg/kg bw) with bait consumption in % of daily consumption (PD)		
	20%	**50%**	**100%**
Day 1 after the first meal	0.5	1.25	2.5
Day 2 after the first meal	0.35	0.875	4.25
Day 5 after the first meal	0.887	2.22	6.93
Day 7 after the first meal	1.03	2.57	7.65
Day 14 after the first meal	1.16	2.89	8.28

The difenacoum concentration in rats goes on increasing after consuming bait for 7 days. On the other hand, regarding that LD50 in rat for acute toxicity is established at 1.8 mg/kg (male rat), it seems reasonable to think that when the target animal consumes 50% of bait it will die after the 5th day because the expected concentration of active substance in the rat is above the LD50. Therefore, this concentration will be considered in the subsequent calculations for non-target organisms.

Toxicity derived by the active substance concentration in the non-target animal is calculated according ESD excel-datasheet for short-term (tier 1) and long-term (tier 2) for all expected predators (non-target animals).

The rodents are assumed to eat the bait over five or fourteen successive days, whereas the predator or the scavenger is assumed to eat the poisoned rodents during one day.

The predator is assumed to have caught the rodent after the last meal on day 5 or day 14. Only resistant rodents are assumed to eat bait over 14 days. In the following table, values used to estimate the concentration in predators are shown:

Non-target animal	**Body weight (Bw) [g]**	**Food intake rate (FIR) [g.d^{-1}]**	**Concentrations in the non-target**	**Concentrations in the non-target**

Predator			animals (short term)	animals (long term)
			$ETE_{non-target}$ ($mg.kg^{-1}bw.d^{-1}$))	$ETE_{non-target}$ ($mg.kg^{-1}bw.d^{-1}$))
Barn owl	294	72.9	0.894	0.447
Kestrel	209	78.7	1.36	0.679
Little owl	164	46.4	1.02	0.51
Tawny owl	426	97.1	0.822	0.411
Fox	5700	520.2	0.316	0.165
Polecat	689	130.9	0.685	0.342
Stoat	205	55.7	0.98	0.49
Weasel	63	24.7	1.41	0.707

As in the case of primary poisoning, risk is for secondary poisoning is calculated as the quotient of PEC/PNEC for each animal. For birds the PNEC (dose) from the reproduction test is used, whereas for mammals the PNEC (dose) calculated from the 90 day rabbit test is chosen. Risk quotients can be seen in the table below:

Non-target animal	Tier 1			Tier 2		
	PEC short term (mg/kg bw)	PNEC dose (mg/kg/day)	PEC/ PNEC	PEC long term (mg/kg bw)	PNEC dose (mg/kg/day)	PEC/ PNEC
Barn owl	0.86	0.0001	8940	0.43	0.0001	4470
Kestrel	1.31	0.0001	13600	0.653	0.0001	6790
Little owl	0.98	0.0001	10200	0.49	0.0001	5100
Tawny owl	0.79	0.0001	8220	0.395	0.0001	4110
Fox	0.316	0.007	45.1	0.158	0.007	23.6
Polecat	0.659	0.007	97.9	0.329	0.007	48.9
Stoat	0.942	0.007	140	0.471	0.007	70
Weasel	1.36	0.007	201	0.68	0.007	101

The worst case calculations according to the ESD show very high risks for secondary poisoning of difenacoum to both birds and mammals. The concentrations in the rodents in principle need to be reduced with 2-4 orders of magnitude in order to bring down the risk for non-target animals to acceptable levels. The PNECoral is based on the highest concentration causing no effects in the test with long- term exposure.

Primary and secondary poisoning is deemed similar for the three scenarios.

- **Secondary poisoning via the aquatic food chain**

The risk of secondary poisoning via the aquatic food chain is considered insignificant due to the low water solubility and high adsorption of difenacoum. It is also assumed that mechanical screening of sewage water will reduce the concentration in the recipient water, although this reduction cannot be quantified.

The proposed uses of RATONEX BLOQUE 26 were also be considered to be acceptable, with the use of appropriate risk mitigation via label warnings.

Conclusions based on monitoring data

Two experimental studies on the secondary poisoning in Barn Owls have been submitted. Tier 1 and Tier 2 risk characterization are recalculated for the Barn Owl on the basis of the measured concentrations in rats and mice with the experimental data provided in the Difenacoum Task Force Annex I inclusion dossier. The risks are significantly lower than with the ESD calculations however they are still considerably higher than 1 indicating an unacceptable risk for secondary poisoning of the Barn Owls.

On the other hand, Newton *et al.* (1997) after monitoring data for Barn owls, provides a basis for calculations to determine what relevance the worst case calculations 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 1% of the collected birds had died of rodenticide poisoning. Difenacoum residues in the liver were not measured in either test, and hence the comparison to the monitoring data is difficult. The residue levels measured from dead barn owls ranged from 0.05-0.2 mg/kg in liver.

3.8.2. Risk characterisation

According to the risk calculation the proposed normal use of difenacoum causes unacceptable risk for primary and secondary poisoning of non target vertebrates. However, the risk for primary poisoning is assumed to be negligible in the ESD if the rodenticidal baits are used according to the label instructions. In the aquatic food chain (fish-eating birds and mammals) risk for secondary poisoning is considered insignificant. In the terrestrial food chain secondary poisoning is possible via contaminated soil invertebrates and rodents, and the latter animals are the most likely source or difenacoum residues in raptorial birds and mammalian predators. Not only the risk characterisation shows risk for secondary poisoning, but also the published laboratory studies confirm bioaccumulation of difenacoum in the owls. Bioaccumulation of difenacoum in predators has been shown in the measurements of difenacoum residues in the animal carcasses found from the field in United Kingdom. The target organ for difenacoum is liver and difenacoum residues in the carcasses have been measured from the liver. In one laboratory study highest residues were measured in the liver, and residues in other tissues including the wax tissue were low. Owls exposed to difenacoum showed variable effects from no foreseeable effects to death.

Other observed effects were increased coagulation times and haemorrhages. The effects disappeared gradually after the end of exposure. Population level effects of difenacoum have not been studied.

In the laboratory studies, the owls fed entirely or mostly on poisoned rodents which may not be probable in the field conditions. The carcasses found from the field were diagnosed to have died to other reason than difenacoum and difenacoum residues were assumed to be sublethal. It is, however, possible that sublethal difenacoum residues have contributed to the death of predators. Reproductive effects of difenacoum in avian or mammalian predators or scavengers have not been studied in the laboratory or in

field experiments. Dose-related effects on the reproduction were observed in Japanese quail in the reproduction study. The NOEC of 0.31 mg/l drinking water and NOEL of 58 µg/kg/bw were determined in this study. The residues in the liver were not measured in the reproduction test, and hence the comparison to the monitoring data is difficult. The residue levels measured from dead bam owls ranged from 0.05-0.2 mg/kg in liver.

In conclusion difenacoum does not fulfil the environmental acceptance criteria due to bioaccumulation and unacceptable effects in the non-target vertebrates.

Atmosphere

Conclusion: Due to the physical-chemical properties of difenacoum, the release to air is considered to be negligible. Therefore no risk assessment is performed for the atmosphere.

Sewage treatment plant (STP)

Conclusion: This scenario is not considered of concern, because the product is not intended to be used in sewers or places next to water courses nor areas liable to flooding. In addition, the recommended bait station is a tamper resistant of category 1, which is resistant to tampering by children and dogs and weather-resistant. Hence the emission to the environment is really unlikely.

Aquatic compartment

Conclusion: Following ESD report for PT14 and taken in account that 'RATONEX BLOQUE 26' is proposed for use in and around buildings, open areas or waste dumps; risk assessment is not required for the aquatic compartments because no product's release is foreseeable and any unfortunately release can be deemed not relevant.

Terrestrial compartment

Realistic worse case predicted soil concentrations (PECs) for difenacoum have been calculated for the use scenarios in and around buildings, open areas and waste dumps anticipating normal use. The resulting PEC/PNEC ratios for the soil are summarised in the Table below.

The calculated PEC/PNEC values indicate that there is no concern for the terrestrial compartment for these specific emission scenarios (Tier 1).

Calculated PEC/PNEC values					
Scenario /Tier		**PEC_{soil} (mg/kg)**	**$PNEC_{soil}$ (mg/kg)**	**$PEC/PNEC_{soil}$**	**Risk**
Scenario [1] - 'In and around buildings'		0.0243	0.877	0.03	No
Scenario [2] - 'Open areas'		0.18		0.2	No

Scenario [3] - 'Waste dumps'		0.000385		$4.4x10^{-4}$	No

Conclusion: For the authorised uses the exposure to soil estimated for the ESD worst case resulted in a PEC/PNEC ratio ≤1, indicating an acceptable risk to soil organisms.

As exposures estimated for the proposed use of 'RATONEX BLOQUE 26" are below those calculated for the ESD worse case, the risk to soil organisms from the proposed use with 0.0026% formulation is acceptable.

Groundwater

Concentrations in soil pore water were calculated for the use of 'RATONEX BLOQUE 26' in all proposed scenarios: in and around buildings, open areas and waste dumps. According to ESD and TGN the potential exposure to STP and surface water (and hence sediment) from the proposed use is considered to be negligible.

Exposure to groundwater for the proposed uses (realistic worst case, normal use) were derived from PECsoils and the new threshold value in groundwater for difenacoum of 0.01 µg/L was used for the risk assessment ECHA/BPC/112/2016:

Calculated PEC/PNEC values for groundwater				
Scenario /Tier	**PEC_{gw} (mg/L)**	**Threshold value (mg/L)**	**$PEC_{gw}/PNEC_{gw}$**	**Risk**
Scenario [1] - 'In and around buildings' / Tier 1	$1.439X10^{-6}$	1 E-5	<1	No
Scenario [2] - 'Open areas' / Tier 1	$1.08x\ 10^{-5}$		>1	Yes
Scenario [3] - 'Waste dumps' / Tier 1	$1.89X10^{-8}$		<1	No

Conclusion: As can see in the table above, the risk is unacceptable for the "open are" scenario. For the rest of scenarios evaluated, PECgw are well-below the maximum permissible according to the new threshold. Hence, as a tier 2, a FOCUS modelling was realized to refine the PEC groundwater for the "open areas" scenario.

Parameters use in FOCUS:

Model used	**FOCUS PEARL**
Years of simulation	1
Application rate	0.0009 kg/ha (open areas)
Standard crop for arable land	Maize (for agricultural soil) Grass (alfalfa)
Application depth	Incorporation 0 cm

Date of application	12 application per year
Molar mass	444.5 g.mol-1
Vapour pressure	< 10^{-6} Pa at 20°C
Water solubility	1.7 mg.L-1 at 20°C
Kom	1048266.3 L.kg-1 at 20°C
Freundlich exponent	1
DT50soil	833 d at 12°C
Coefficient for uptake for plant	0

The same results were obtained for all scenarios, see the following table:

LOCATION	**MAIZE**	**ALFALFA**
CHATEAUDUN	0.00000	0.00000
HAMBURG	0.00000	0.00000
JOKIOINEN	0.00000	0.00000
KREMSMUENSTE	0.00000	0.00000
OKEHAMPTON	0.00000	0.00000
PIACENZA	0.00000	0.00000
PORTO	0.00000	0.00000
SEVILLA	0.00000	0.00000
THIVA	0.00000	0.00000

According to the FOCUS modelling, the risk is acceptable in groundwater for the use of RATONEX BLOQUE 26 in all scenarios.

Primary and secondary poisoning

According to the risk calculations the proposed normal use of difenacoum causes unacceptable risk for primary and secondary poisoning of non-target vertebrates. However, the risk for primary poisoning is assumed to be negligible in the ESD if the rodenticidal baits are used according to the label instructions and if security bait boxes are used (Category 1).

In the aquatic food chain (fish-eating birds and mammals), risk for secondary poisoning is considered insignificant.

In the terrestrial food chain, secondary poisoning is possible via contaminated soil invertebrates and rodents, and the latter animals are the most likely source for difenacoum residues in raptorial birds and mammalian predators.

Not only the risk characterisation shows risk for secondary poisoning, but also the published laboratory

studies confirm bioaccumulation of difenacoum in the owls. Bioaccumulation of difenacoum in predators has been shown in the measurements of difenacoum residues in the animal carcasses found from the field in United Kingdom. Owls exposed to difenacoum showed variable effects from no foreseeable effects to death. The effects disappeared gradually after the end of exposure. Population level effects of difenacoum have not been studied.

Theoretical calculations may overestimate the residues accumulating in predators. In the laboratory studies, the owls fed entirely or mostly on poisoned rodents which may not be probable in the field conditions. The carcasses found from the field were diagnosed to have died to other reason than difenacoum and difenacoum residues were assumed to be sublethal. It is, however, possible that sublethal difenacoum residues have contributed to the death of predators. Reproductive effects of difenacoum in avian or mammalian predators or scavengers have not been studied in the laboratory or in field experiments.

Mixture toxicity

No mixture toxicity is foreseeable, as the only substance of concern is Difenacoum.

Overall conclusion on the risk assessment for the environment of the product
Since the proposed use of ‘RATONEX BLOQUE 26’ falls within the ‘risk envelope’ of the uses already evaluated and authorised. The proposed use of ‘RATONEX BLOQUE 26’ is acceptable and may also be authorised for its use in and around buildings, in open areas and waste dumps.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As difenacoum 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 difenacoum is justified.

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

See Confidential PAR

4.1 List of studies for the biocidal product

See Confidential PAR