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 H 26
Product type(s):	14 (Rodenticide)
Active ingredient(s):	DIFENACOUM
Case No. in R4BP	BC-DT000070-52 (NA-RNL) BC-NY030680-13 (NA-MAC)
Asset No. in R4BP	ES-0000271-0000
Evaluating Competent Authority	SPAIN
Internal registration/file no	ES/APP(NA)-2018-14-00101
Date	April 2018

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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 H containing of difenacoum active substance at a level of 0.005% w/w should be taken into account. As the content of active substance has been reduced, 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 H 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 remains valid and the new information provided by the applicant to support the decrease of active substance allow granting the authorisation.

Physical, chemical and technical properties remain valid to the initial evaluation other than the stability test. No long-term stability test has been submitted; therefore a post-authorisation requirement should be included in the authorisation certificate.

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 H 26 is effective in the proposed areas of use, at the recommended dose rate.

According to Commission Regulation (EU) 2016/1179 the product RATONEX H 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 H 26 can be authorised as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors, outdoors around buildings and outdoor in open areas and waste dumps. The users can be general public, professional and trained professional. It is a ready to use block 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 H 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 H 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
Location of manufacturing sites	ESPAÑA

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

Active substance	Difenacoum
Name of manufacturer	Activa s.r.l./Dr. Tezza s.r.l.
Address of manufacturer	Via Feltre, 32
Location of manufacturing sites	20132 Milano

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 dye.
  - Information on the full composition is provided in the confidential annex (see chapter 4).

- According to the information provided the product contains no nanomaterial as defined in Article 3 paragraph 1 (z) of Regulation No. 528/2012

2.2.2 Information on the substance(s) of concern

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

2.2.3 Candidate(s) for substitution

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

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

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 2

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[1]

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 3

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 under authorisation in Spain)	**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	House mice – general public - indoor
	Rats – general public - indoor
	Rats – general public – outdoor around buildings
House mice and/or brown rats – professional– indoor and outside around buildings	House mice – professionals - indoor
	Rats – professionals - indoor
	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 rats – trained professionals - indoor
	House mice and/or rats – trained professionals – outdoor around buildings
	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:** bait station with 40g of product each 5m 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
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 from 20, 50 y 100g. Packaging material: Boxes, blister Material: Cardboard and PVC

2.4.1.1 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 2.4.1.2. Use-specific risk mitigation measures

- See section 2.5.2

2.4.1.3 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 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 4.4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

- See section 5.5

2.4.2 Use 2 - 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 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:** bait station with 100g of product each 5m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
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 from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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 5.5

2.4.3 Use 3 - Brown Rats – general public – Outdoor around building

Product Type(s)	14
Where relevant, an exact	Not relevant for rodenticides

description of the use	
Target organism(s) (including development stage)	*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:** bait station with 100g of product each 5m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
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 from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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**: bait station with 40g of product each 5m 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 24 kg Grams/kg of bait per packed bag: blocks from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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.

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

See section 2.5.4

2.4.4.5 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	**Rat:** bait station with 100g of product each 5m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professionals
Pack sizes and packaging	**Minimum pack size of 3 kg.**

material	Number of packed bags per packaging: up to 24 kg Grams/kg of bait per packed bag: blocks from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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)	*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**: bait station with 100g of product each 5m 100g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters **Mice**: bait station with 40g of product each 5m 40g of bait per bait station. If more than one bait station is needed, the minimum distance between bait stations should be of 5 meters
Category(ies) of users	Professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 24 kg Grams/kg of bait per packed bag: blocks from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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:** bait station with 100g -200g of bait per baiting point. **Mice:** bait station with 40g -50g of product each 5m
Category(ies) of users	Trained professionals
Pack sizes and packaging material[2]	**Minimum pack size of 3 kg.** Number of packed bags per packaging: Up to 24 Kg Grams/kg of bait per packed bag: blocks from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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 in 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 2.5.4.

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:** bait station with 100g -200g of bait per baiting point. **Mice:** bait station with 40g -50g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: Up to 24 Kg Grams/kg of bait per packed bag: blocks from 20, 50 y 100g. Packaging material: Boxes, blister. Material: Cardboard and PVC

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:** bait station with 100g -200g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: Up to 24 Kg Grams/kg of bait per packed bag: blocks from 20, 50 y 100g. Packaging material: Boxes, blister Material: Cardboard and PVC

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.

- *[*Do not open the sachets containing the bait - *where relevant for the bait formulation in the product].*

- 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 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 rodents so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

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

- Do not open the sachets containing the bait.

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 5.3 for the information to be shown on the label)*.

-When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.

- Bait should be secured so that it cannot be dragged away from the bait station.

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

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

-Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

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

- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.

- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.

- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.

- Do not open the sachets containing the bait

2.5.2 Risk mitigation measures:

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]*.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, 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.

2.5.4 Instructions for safe disposal of the product and its packaging

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

Post-authorisation requirements:

- Long-term stability test within 2 years.

3 Assessment of the product

3.1 Use(s) considered appropriate for authorisation after former assessment (uses evaluated by 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 and outside around buildings
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	**Rats:** 3-5 baits stations with 200 g of product each 100m2 **Mice:** 2 baits stations with 50 g of product each 10m2
Category(ies) of users	General public
Pack sizes and packaging material	Blocks of 20, 50 y 100 g. in boxes of 240 and 600g

3.1.2 Use 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 and outside around buildings
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	**Rats:** 3-5 baits stations with 200 g of product each 100m2 **Mice:** 2 baits stations with 50 g of product each 10m2
Category(ies) of users	Professional
Pack sizes and packaging material	Blocks of 20, 50 y 100 g. in boxes of 240 and 600g

3.1.3 Use 3 – House mice and/or brown rats – trained professional–– indoor and outside around buildings, outdoor open areas and 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 and waste dumps
Application method(s)	The biocidal product is ready to use block bait in bait stations.
Application rate(s) and frequency	**Rats:** 3-5 baits stations with 200 g of product each 100m2 **Mice:** 2 baits stations with 50 g of product each 10m2
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Blocks of 20, 50 y 100 g. in boxes of 240 and 600g. And 7.2 and 24 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: 0.0027% w/w Difenacoum active ingredient final content: 0.0026% w/w ∆[C] = -3.70%. 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	Study ongoing Final results: April 2019 Results obtained after 4 months storage at ambient temperature: Difenacoum active ingredient initial content: 0.0027% w/w Difenacoum active ingredient final content: 0.0027% w/w ∆[C] = 0%. Up to now the result complies with the tolerance value (-10%).	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.

The renewal is conditioned to the presentation of the long term stability test; therefore a post-authorisation condition should be showed in the authorisation certificate.

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 H 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 H) 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 field 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 ship animal feed storage The test included the phases: pre-treatment census, pre-treatment lag, treatment census, post-treatment lag, post treatment census. 40g 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
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 ship animal feed factory 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

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

The most relevant routes of exposure are the following: for the evaluation of primary exposure only the dermal route is considered. The inhalation exposure is negligible, because difenacoum is a non-volatile substance and the product is a block, and the oral path is considered only for the evaluation of secondary exposure.

Summary table: relevant paths of human exposure						
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**		
	Trained professional use	**Professional use**	**General public (Non-professional)**	**Trained Professional use**	**Professional use**	**General public**

Inhalation	No	No	No	No	No	No
Dermal	Yes	Yes	Yes	Yes	Yes	Yes
Oral	n.a.	n.a.	n.a.	No	Yes	Yes

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario**	**Primary or secondary exposure Description of scenario**	**Exposed group**
1.	Application (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.	Post application (Cleaning up and disposal)	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 or ingestion of unprotected bait	Secondary exposure: incidental touched or ingestion 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 (TNsG) or 10mg (TNsG) of the product is assumed to be swallowed by an infant per poisoning event.	Bystanders (children, infants and adults)

Note: The product is ready to use, then there is no decanting or mixing and loading task.

Professional exposure

Trained professionals use (pest Control Operators)

Scenario [1] – Application (Loading and placing bait boxes)

Description of Scenario [1] - *Trained professional*		
During the process of loading the bait, the operator 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%

Description of Scenario [1] - *Trained professional*		
	Dermal absorption:	0.047%
	Operator body weight:	60 kg
	Dermal exposure data (75th percentile; for 5 contacts in one bait station):	27.79 mg BP
	Number of manipulations of bait stations per day and person:	60
	Number of contacts (200 g per bait station: loaded with 10 blocks of 20 g)	10
Tier 2	PEE (gloves, 90% of protection)	10%

Calculations for Scenario [1]

Summary table: estimated exposure from trained professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	6.79 x 10^{-7} mg/kg bw/day	-	6.79 x 10^{-7} mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	6.79 x 10^{-8} mg/kg bw/day	-	6.79 x 10^{-8} mg/kg bw/day

Scenario [2] – Post application (Cleaning up and disposal)

Description of Scenario [2] – *Trained professional user (Pest Control Operator)*		
In this scenario the operator may be in contact with the bait when the bait is cleaned and/or disposed. The size of the block does not influence this phase. Trained professional operators are bounded to use PPE during the development of the different tasks of their work. Total systemic exposure has been assessed with (Tier 2) and without PPE (Tier 1).		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	Operator body weight:	60 kg

	Dermal exposure data (75th percentile; for one bait station)	5.7 mg BP/manipulation
	Number of manipulations	15
Tier 2	PEE (gloves, 90% of protection)	10%

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)	-	1.74×10^{-9} mg/kg bw/day	-	1.74×10^{-9} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from trained professional users				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1 + 2] – Tier 1	-	6.96×10^{-7} mg/kg bw/day	-	6.96×10^{-7} mg/kg bw/day
Scenarios [1 + 2] – Tier 2	-	6.96×10^{-8} mg/kg bw/day	-	6.96×10^{-8} mg/kg bw/day

Professional user

Scenario [1] – Application (loading and placing bait boxes)

Description of Scenario [1] - *Professional*		
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. Even so, total systemic exposure has been assessed without (Tier 1) and with PPE (Tier 2).		
	Parameters	Value

Description of Scenario [1] - *Professional*		
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	User body weight:	60 kg
	Dermal exposure data (75th percentile; for 5 contacts in one bait station):	27.79 mg BP
	Number of manipulations of bait stations per day and person:	5
	Number of contacts (200 g per bait station: loaded with 10 blocks of 20 g)	10
Tier 2	PEE (gloves, 90% of protection)	10%

Calculations for Scenario [1]

Summary table: estimated exposure from professional users					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	5.65 x 10^{-8} mg/kg bw/day	-	5.65 x 10^{-8} mg/kg bw/day
Scenario [1]	Tier 2 / PPE (gloves)	-	5.65 x 10^{-9} mg/kg bw/day	-	5.65 x 10^{-9} mg/kg bw/day

Scenario [2] – Post application (Cleaning up and disposal)

Description of Scenario [2] – *Professional user*		
In this scenario the user may be in contact with the bait when the bait is cleaned and/or disposed. The size of the block does not influence this phase. Professional users are not bounded to use PPE during the development of the different tasks of their work. Even so, total systemic exposure has been assessed with (Tier 2) and without PPE (Tier 1).		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%

	User body weight:	60 kg
	Dermal exposure data (75th percentile; for one bait station)	5.7 mg BP/manipulation
	Number of manipulations of bait stations per day and person:	5
Tier 2	PEE (gloves, 90% of protection)	10%

Calculations for Scenario [2]

Summary table: estimated exposure from professional uses					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	5.804 x 10-^{9} mg/kg bw/day	-	5.804 x 10-^{9} mg/kg bw/day
Scenario [2]	Tier 2 / PPE (gloves)	-	5.804 x 10-^{10} mg/kg bw/day	-	5.804 x 10-^{10} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from professional users				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1 + 2] – Tier 1	-	6.24 x 10^{-8} mg/kg bw/day	-	6.24 x 10^{-8} mg/kg bw/day
Scenarios [1 + 2] – Tier 2	-	6.24 x 10^{-9} mg/kg bw/day	-	6.24 x 10^{-9} mg/kg bw/day

General Public (Non-professional) exposure

Although general public (non-professional users) are untrained and cannot be expected to wear protective clothing, the application pattern of *difenacoum* 0.0026% w/w block bait by the general public is similar to professional users. The use is occasional, for a short time in a single day and unlikely to be repeated more than once a week. However, in accordance with the CARs on various Rodenticides and proposed by HEEG (2010), fewer manipulations as compared to trained professionals are considered. Hence, 5 deploying and 5 cleaning manipulations are assumed for a non-professional user.

Bait stations for use by the general public must be supplied as lockable, tamper-proof units that may be refilled by the user.
After use the product is likely to be collected and disposed of in a controlled way (as directed by product labels).

Scenario [1] – Application (loading and placing bait boxes)

Description of Scenario [1] – *General public*		
During the process of loading 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 their work.		
	Parameters	Value
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	User body weight:	60 kg
	Dermal exposure data (75th percentile; for 5 contacts in one bait station):	27.79 mg BP
	Number of manipulations of bait stations per day and person:	5
	Number of contacts (200 g per bait station: loaded with 10 blocks of 20 g)	10

Calculations for Scenario [1]

Summary table: estimated exposure from non-professional users (General public)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [1]	Tier 1 / No PPE	-	5.65×10^{-8} mg/kg bw/day	-	5.65×10^{-8} mg/kg bw/day

Scenario [2] – Post application (Cleaning up and disposal)

Description of Scenario [2] – *General public*

In this scenario the user may be in contact with the bait when the bait is cleaned and/or disposed. The size of the block does not influence this phase. General public (non-professional users) are not bounded to use PPE during the development of the different tasks of their work.		
	Parameters	**Value**
Tier 1	A.S. content of BP	0.0026%
	Dermal absorption:	0.047%
	User body weight:	60 kg
	Dermal exposure data (75^{th} percentile; for one bait station)	5.7 mg BP/manipulation
	Number of manipulations of bait stations per day and person:	5

Calculations for Scenario [2]

Summary table: estimated exposure from non-professional uses (General public)					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [2]	Tier 1 / No PPE	-	5.804×10^{-9} mg/kg bw/day	-	5.804×10^{-9} mg/kg bw/day

Combined scenarios

Summary table: combined systemic exposure from non-professional users (General public)				
Scenarios combined	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenarios [1 + 2] – Tier 1	-	6.24×10^{-8} mg/kg bw/day	-	6.24×10^{-8} mg/kg bw/day

Exposure of the general public

Two different scenarios of secondary exposure are considered a priori: on one hand the potential exposure due to dermal contact with poisoned or dead rodents and on the other hand the oral exposure by inccidental ingestion of the bait.

Scenario [3] - Touching or ingestion of unprotected bait

Description of Scenario [3]
It is assumed that dead or poisoned rodents should not be touched and therefore this scenario is unrealistic and it is not included in the risk assessment. For oral exposure, the potential ingestion of bait by children is the worse case. As a general assumption of poison center specialists, it is assumed that children ingest 5 g of the bait. However, ingestion of 5 g represents a high overestimate of exposure, since baits contain a repellent (bitter agent), which will most likely urge the children to spit the bait. Hence, applying the general assumption of ingestion of 10 mg of bait (TNsG default for a bait with repellent), a second assessment as Tier 2 was performed.

	Parameters	**Value**
Tier 1	Amount of BP ingested	5 g
	Oral absorption	100%
	A.S. content of BP	0.0026%
	Children body weight:	10 kg
Tier 2	Amount of BP ingested, considering the presence of a bittering agent	10 mg

Calculations for Scenario [3]

Summary table: systemic exposure from secondary exposure of general public					
Exposure scenario	**Tier/PPE**	**Estimated inhalation uptake**	**Estimated dermal uptake**	**Estimated oral uptake**	**Estimated total uptake**
Scenario [3]	Tier 1 / no bittering agent	-	-	0.013 mg/kg bw/d	0.013 mg/kg bw/day
Scenario [3]	Tier 2 / with bittering agent	-	-	2.6×10^{-5} mg/kg bw/d.	2.6×10^{-5} mg/kg bw/day

Further information and considerations on scenario [4]

The presence of an aversive (bittering) 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.

Monitoring data

No monitoring 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.

Dietary exposure

Not applicable: non exposure is foreseen because the bait boxes with the product must not be placed where food, feeding stuffs, drinking water and surfaces where food is prepared an become contaminated.

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

Please see scenario [2] of exposure assessment 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**	**Tier/PPE**	**Estimated total uptake**
1.	Trained Professional	Tier 1/ no PPE (unrealistic)	6.79 x 10^{-7} mg/kg bw/day
1.	Trained Professional	Tier 2/ PPE	6.79 x 10^{-8} mg/kg bw/day
1.	Professional	Tier 1/ no PPE	5.65 x 10^{-8} mg/kg bw/day
1.	Professional	Tier 2/ PPE	5.65 x 10^{-9} mg/kg bw/day
1.	General Public (Non-professional)	Tier 1/ no PPE	5.65 x 10^{-8} mg/kg bw/day
2.	Trained Professional	Tier 1/ no PPE (unrealistic)	1.74 x 10-^{8} mg/kg bw/day
2.	Trained Professional	Tier 2/ PPE	1.74 x 10-^{9} mg/kg bw/day
2.	Professional	Tier 1/ no PPE	5.804 x 10-^{9} mg/kg bw/day
2.	Professional	Tier 2/ PPE	5.804 x 10-^{10} mg/kg bw/day

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group**	**Tier/PPE**	**Estimated total uptake**
2.	General Public (Non-professional)	Tier 1/ no PPE	5.804 x 10-^{9} mg/kg bw/day
3.	General public (Children)	Tier 1 (without bitter agent)	0.013 mg/kg bw/day
3.	General public (Children)	Tier 2 (with bitter agent)	2.6 ×10^{-5} mg/kg bw/day

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[1]**	**Correction for bioavailability**	**Value (mg/kgbw/day)**
AOEL $_{acute}$ <> AOEL $_{chrónic}$	-	0.001*	10 x 10 x 3 x 2	68%	1.1 x 10^{-6}
ARfD	-	-	-	-	-
ADI	-	-	-	-	-

Assessment Factors (AF[1]) applied for difenacoum: 10 for inter-species variability and 10 for inter-individual variability and an additional safety factor of 3 for teratogenicity is used for all anticoagulant rodenticides. To extrapolate from LOAEL to NOAEL an assessment factor of 2 is considered.

Note: Another way to obtain 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.

3.6.4.1 Risk for professional users

- **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)**
Application /	**Tier 1**	**0.00034**	**1.1 x 10^{-6}**	**6.79 x 10^{-7}**	**61.74**	**Yes**

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)
Scenario [1]	Tier 2			6.79×10^{-8}	6.17	Yes
Cleaning / Scenario [2]	Tier 1			1.74×10^{-8}	1.58	Yes
	Tier 2			1.74×10^{-9}	0.15	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	Tier 1	0.00034	1.1×10^{-6}	6.96×10^{-7}	63.32	Yes
	Tier 2			6.96×10^{-8}	6.33	Yes

Local effects

There is no need to consider local effects separately.

Conclusion

Under reasonable worst case assumptions, the exposure assessment for trained professional operators shows that the use of rodenticide baits containing 0.0026% w/w difenacoum, it is considered acceptable with and without the use of PPE.

However, the use of gloves by operators is always recommended and expected for hygienic reasons.

- **Risk for 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)
Application / Scenario [1]	Tier 1	0.00034	1.1×10^{-6}	5.65×10^{-8}	5.14	Yes
	Tier 2			5.65×10^{-9}	0.51	Yes
Cleaning / Scenario [2]	Tier 1			5.804×10^{-9}	0.52	Yes
	Tier 2			5.804×10^{-10}	0.05	Yes

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)

[1] + [2]	**Tier 1**	**0.00034**	**1.1 x 10^{-6}**	**6.24 x 10^{-8}**	**5.67**	**Yes**
	Tier 2			**6.24 x 10^{-9}**	**0.56**	**Yes**

Local effects

There is no need to consider local effects separately.

Conclusion

Under reasonable worst case assumptions, the exposure assessment for professional users shows that the use of rodenticide baits containing 0.0026% w/w difenacoum, it is considered acceptable with and without the use of PPE.

3.6.4.2 Risk for the general public

- **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)
Application / Scenario [1]	**Tier 1**	**0.00034**	**1.1 x 10^{-6}**	**5.65 x 10^{-8}**	**5.14**	**Yes**
Cleaning / Scenario [2]	**Tier 1**			**5.804 x 10^{-9}**	**0.52**	**Yes**

Combined scenarios

Scenarios combined	Tier	Systemic NOAEL mg/kg bw/d	AEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
[1] + [2]	**Tier 1**	**0.00034**	**1.1 x 10^{-6}**	**6.24 x 10^{-8}**	**5.67**	**Yes**

Local effects

There is no need to consider local effects separately.

Conclusion

Under reasonable worst case assumptions, the exposure assessment for general public (non-professional users) shows that the use of rodenticide baits containing 0.0026% w/w difenacoum, it is considered acceptable without the use of PPE.

- **Risk for general public (secondary exposure)**

Two different scenarios of secondary exposure are considered a priori: on one hand the potential exposure due to dermal contact with poisoned or dead rodents and on the other hand the oral exposure by incidental ingestion of the bait.

It is assumed that dead or poisoned rodents should not be touched and therefore this scenario is unrealistic and it is not included in the risk assessment.

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)**
Scenario (3) Ingestion of bait by children	Tier 1	0.00034	1.1×10^{-6}	0.013	1.18×10^{6}	No
	Tier 2			2.6×10^{-5}	2364	No

Tier 1: No bittering agent

Tier 2: With bittering agent

Local effects

There is no need to consider local effects separately.

Conclusion

These values show that children ingesting bait might be at risk.

However, calculations are based on conservative assumptions which will likely overestimate actual exposure levels. Furthermore, baits are placed according to the risk mitigation measures proposed for anticoagulant rodenticides usually out of the reach of children in tamper-resistant bait stations.

Moreover, difenacoum 0.0026% w/w block baits contain a highly efficient bittering agent to prevent ingestion by children.

So the proposed uses represent an acceptable risk from indirect exposure.

3.6.4.3 Risk for consumers via residues in food

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

Accordingly, the conclusion from the former assessment regarding risks for consumers via residues in food remain valid.

3.6.4.4 Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product[3]

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.

3.6.4.5 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	1.1×10^{-6}	6.79×10^{-7}	61.74	Yes
1.	Trained professional user	Tier 2 (PPE)	1.1×10^{-6}	6.79×10^{-8}	6.17	Yes
1.	Professional user	Tier 1	1.1×10^{-6}	5.65×10^{-8}	5.14	Yes
1.	Professional user	Tier 2 (PPE)	1.1×10^{-6}	5.65×10^{-9}	0.51	Yes
1.	General public (Non-professional)	Tier 1	1.1×10^{-6}	5.65×10^{-8}	5.14	Yes
2.	Trained professional user	Tier 2 (PPE)	1.1×10^{-6}	1.74×10^{-8}	1.58	yes
2.	Trained professional user	Tier 1	1.1×10^{-6}	1.74×10^{-9}	0.15	Yes
2.	Professional user	Tier 1	1.1×10^{-6}	5.804×10^{-9}	0.52	Yes
2	Professional user	Tier 2	1.1×10^{-6}	5.804×10^{-10}	0.05	Yes
2.	General public (Non-professional)	Tier 1	1.1×10^{-6}	5.804×10^{-9}	0.52	Yes

Scenario number	Exposed group	Tier/PPE	AEL mg/kg/bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	Acceptable (yes/no)
3.	General public (Children)	Tier 1 (No bitter agent)	1.1 x 10^{-6}	0.013	1.18 x10^{6}	No
3.	General public (Children)	Tier 2 (with bitter agent)	1.1 x 10-6	2.6 x 10^{-5}	2364	No
1 + 2	Trained professional user	Tier 1	1.1 x 10^{-6}	6.96 x 10^{-7}	63.32	Yes
		Tier 2 (PPE)		6.96 x 10-8	6.33	Yes
1 + 2	Professional user	Tier 1	1.1 x 10^{-6}	6.24 x 10^{-8}	5.67	Yes
		Tier 2 (PPE)		6.24 x 10^{-9}	0.56	Yes
1 + 2	General public (Non-professional)	Tier 1	1.1 x 10^{-6}	6.24 x 10^{-8}	5.67	Yes

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.

3.8.1.1 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 H 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 represent 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 H 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 H 26 in order to prevent any exposure to the environment or human. By doing this rats and mice can eat them and the beat is protected and avoid undersirable 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)

Parameter	Value	Source
$RHO_{product}$	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 l 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 250 ml 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]

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***	
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 rom a campaign	$\mathbf{Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release, soil})}$ **(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	**$Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release, soil})$ (2)**	**g**	**0,00078**

The concentration in the soil around each bait box after direct release can ve 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]	**$Clocal_{soil\text{-}D} = (Elocal_{soil\text{-}D\text{-}campaign} \times 10E3)/ (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (3)**	**mg/kg**	**0.0212**

Applicant's worst case

Parameter	Definition	Units	Value
Local direct emission rate of active substance to soil from a	$E_{soil, D\text{-}campaing}$ (2)	g	0.000078

campaign			
Area directly exposed to active substance	$AREA_{exposed-D}$	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]	**$Clocal_{soil-D}$ = (Elocal $_{soil-D-campaign}$ x10E3)/ (AREA $_{exposed-D}$ 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 product	Fc_{prod}	-	0.000026
Number of application sites	N_{sites}	-	10
Number of refills per site	N_{refil}	-	5
Fraction released indirectly to soil	$F_{release-ID, soil}$		0.9
Fraction released directly to soil	$F_{release, soil}$		0.01
Area indirectly exposed to rodenticide	$AREA_{exposed-ID}$	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	**$Clocal_{soil-ID}$ = ((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 product	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 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**	**0.000743**

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 H 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	$kg.m^{-3}$

<u>Calculations for Scenario [2] - Use in open areas</u>

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

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

Parameter	Definition	Units	Value
Local emission to soil from the episode	$Eloca_{lsoil\text{-}campaign}$	g	5.00E-03
Soil volume exposed to rodenticide	$Vsoil_{exposed}$ (eq. 9a ESD)	m^3	8.50E-03
Density of wet exposed soil	RHO_{soil}	kg/m^3	1700
Local concentration in soil after a campaign	**$Clocal_{soil\text{-}campaing} = (E_{localsoil\text{-}campaign} \times 10^3) / (V_{soilexposed} \times RHO_{soil})$ (10)**	**mg/kg**	**1.80E-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.

Calculations for Scenario [3] - Use in waste dumps

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**	**6.55E-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	6.55-03
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
Local concentration in soil due to direct release after a campaign [mg/kg]	**$Clocal_{soil\text{-}D} = (Elocal_{soil\text{-}D\text{-}campaign} \times 10E3) / (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (18)**	**mg/kg**	**0.000385**

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 H 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	7×10^{-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.

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

ETE values calculated for acute exposure (ETE)

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, of difenacoum after one (mg/kg)		LDso (mg/kg bw/d)	PEC_{oral} higher than LDso	
	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

- **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 Predator	Body weight (Bw) [g]	Food intake rate (FIR) [g.d^{-1}]	Concentrations in the non-target animals (short term)	Concentrations in the non-target animals (long term)
			$ETE_{non\text{-}target}$ (mg.kg^{-1}bw.d^{-1}))	$ETE_{non\text{-}target}$ (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 H 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.

3.8.1.2 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 ¡,tglkg 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 areasliable 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 H 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		0.0243	0.877	0.03	No

buildings'					
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 H 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 H 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:

Calculated PEC/PNEC values for groundwater				
Scenario /Tier	**PEC_{gw} (mg/L)**	**Thresould value (mg/L)**	**$PEC_{gw}/PNEC_{gw}$**	**Risk**
Scenario [1] - 'In and around buildings' / Tier 1	$1.439X10^{-6}$	1 E-4	<1	No
Scenario [2] - 'Open areas' / Tier 1	$1.08x\ 10^{-5}$		<1	No
Scenario [3] - 'Waste dumps' / Tier 1	$1.89X10^{-8}$		<1	No

Conclusion: As can see in the table above, all PECgw are well-below the maximum permissible concentration according to Directive 80/778/EEC (1×10^{-4} mg/L). Hence, the risk to groundwater from the proposed uses is acceptable.

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 H 26’ falls within the ‘risk envelope’ of the uses already evaluated and authorised. The proposed use of ‘RATONEX H 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 Decision 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 Decision 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.