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

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR THE RENEWAL OF A NATIONAL AUTHORISATION

Product identifier in R4BP	MURIDOX 30
Product type(s):	14 (Rodenticide)
Active ingredient(s):	Difenacoum
Case No. in R4BP	BC-RT000223-33
Asset No. in R4BP	ES-0000881-0000
Evaluating Competent Authority	SPAIN
Internal registration/file no	ES/APP(NA)-2018-14-00062
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1 Conclusion

The assessment presented in this report has shown that the ready-to-use product, MURIDOX 30, with the active substance difenacoum, at a level of 0.005% w/w, may be authorised for use as a rodenticide (product-type 14) since the conclusions of initial evaluation remain valid.

However, the biocidal product MURIDOX 30 contains 0.005 %w/w difenacoum and the Commission Regulation (EU) 2016/1179 of 19 July 2016 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures has been applied.

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

Therefore, MURIDOX 30 could be authorised as a rodenticide product against house mice (*Mus musculus*) and brown rats (*Rattus norvegicus*). It is to be used indoors and outdoors around buildings, open areas and waste dumps by trained professional. It is a ready to used grain 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.

According to the renewal of anticoagulant active substance for trained professional users the product may be authorised for use in covered and protected bait points other than tamper resistant bait stations or as a permanent treatments. The applicant has not submitted any additional information to include these application methods, so the ES CA does not authorise other use different to tamper resistant bait stations nor as a permanent treatments.

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

Spanish CA only grants the use of MURIDOX 30 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

MURIDOX 30

2.1.2 Manufacturer(s) of the product

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

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

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

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active Substance	56073-07-5	259-978-4	0,005 %

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

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

2.2.2 Information on the substance(s) of concern

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

2.2.3 Candidate(s) for substitution

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

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

- Difenacoum

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: grain

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

Table 2

Classification **Hazard classes, Hazard categories**	**Hazard statements**
Reproductive toxicity; Repr. 1B	H360D May damage the unborn child
Specific target organ toxicity — repeated exposure; STOT RE 2	H373 May cause damage to organs (blood) through prolonged or repeated exposure

Table 3

Labelling	**Code**	**Pictogram / Wording**
Pictograms	GHS08	
Signal word	-	Danger
Hazard statements	H360D	May damage the unborn child
	H373	May cause damage to organs (blood) through prolonged or repeated exposure
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	P260	Do not breathe dust/fume/ gas/mist/vapours/spray
	P264	Wash … thoroughly after handling
	P270	Do not eat, drink or smoke when using this product.
	P280	Wear protective gloves/ protective clothing/eye protection/face protection
	P314	Get medical advice/attention if you feel unwell
	P405	Store locked up.
	P501	Dispose of contents and/ or container as a hazardous waste to a registered establishment or undertaking, in accordance with current regulations.
Note	-	

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

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

Table 4

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

Uses authorised in Spain according national Risk Mitigation Measures

Table 5

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

2.4.1 Use 1 – 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 rat)
Field(s) of use	Indoor
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: up to 50g of bait per baiting point. Rats: up to 200g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg.

	Grams/kg of bait per packed bag: individual plastic (polyethylene) sachets of 15, 25, 50 and 75g. Packaging material: containers of corrugated board

2.4.1.1 Use-specific instructions for use

- Remove the remaining product at the end of treatment period.
- Follow any additional instructions provided by the relevant code of best practice.

2.4.1.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.
- Consider preventive control measures (e.g. plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use the product in pulsed baiting treatments.
- This product shall only be used indoors and in places that are not accessible to children or non-target animals.

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

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

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

See section 5.4

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

See section 5.5

2.4.2 Use 2 - Mice and/or brown rats – trained professionals – outdoor around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	Mus musculus (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor around buildings.
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Rats: up to 200g of bait per baiting point. Mice: up to 50g of bait per baiting point.
Category(ies) of users	Trained professionals
Pack sizes and packaging material[1]	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual plastic (polyethylene) sachets of 15, 25, 50 and 75g. Packaging material: containers of corrugated board

2.4.2.1 Use-specific instructions for use

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

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

2.4.2.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign *[in accordance with the applicable code of good practice, if any]*.

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

- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.

- Do not use this product in pulsed baiting treatments.

- Do not apply this product directly in the burrows.

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

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

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

See section 5.4.

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

See section 5.5.

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

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Rattus norvegicus* (brown rat)
Field(s) of use	Outdoor open areas Outdoor waste dumps
Application method(s)	- Ready-to-use bait to be used in tamper-resistant bait stations.
Application rate(s) and frequency	Rats: up to 200g of bait per baiting point.
Category(ies) of users	Trained professionals only
Pack sizes and packaging material	Minimum pack size of 3 kg. Number of packed bags per packaging: up to 25 kg. Grams/kg of bait per packed bag: individual plastic (polyethylene) sachets of 15, 25, 50 and 75g. Packaging material: containers of corrugated board

2.4.3.1 Use-specific instructions for use

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

2.4.3.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign [in accordance with the applicable code of good practice, if any].
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at

frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

See section 5.4.

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

See section 5.5.

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.
- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.
- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.
- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).
- Where possible, bait stations must be fixed to the ground or other structures.
- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 5.3 for the information to be shown on the label)*.
- When the product is being used in public areas, the areas treated should be marked during the treatment period and a notice explaining the risk of primary or secondary poisoning by the anticoagulant as well as indicating the first measures to be taken in case of poisoning must be made available alongside the baits.
- Bait should be secured so that it cannot be dragged away from the bait station.
- Place the product out of the reach of children, birds, pets and farm animals and other non-target animals.
- Place the product away from food, drink and animal feeding stuffs, as well as from utensils or surfaces that have contact with these.
- Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).
- When using the product do not eat, drink or smoke. Wash hands and directly exposed skin after using the product.
- The frequency of visits to the treated area should be at the discretion of the operator, in the light of the survey conducted at the outset of the treatment. That frequency should be consistent with the recommendations provided by the relevant code of best practice.
- If bait uptake is low relative to the apparent size of the infestation, consider the replacement of bait points to further places and the possibility to change to another bait formulation.
- If after a treatment period of 35 days baits are continued to be consumed and no decline in rodent activity can be observed, the likely cause has to be determined. Where other elements have been excluded, it is likely that there are resistant rodent so consider the use of a non-anticoagulant rodenticide, where available, or a more potent anticoagulant rodenticide. Also consider the use of traps as an alternative control measure.
- Do not open the sachets containing the bait.

2.5.2 Risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders about the rodent control campaign.
- The product information (i.e. label and/or leaflet) shall clearly show that the product shall only be supplied to trained professional users holding certification demonstrating compliance with the

applicable training requirements (e.g. "for trained professionals only").
- Do not use in areas where resistance to the active substance can be suspected.
- Products shall not be used beyond 35 days without an evaluation of the state of the infestation and of the efficacy of the treatment.
- Do not rotate the use of different anticoagulants with comparable or weaker potency for resistance management purposes. For rotational use, consider using a non-anticoagulant rodenticide, if available, or a more potent anticoagulant.
- Do not wash the bait stations or utensils used in covered and protected bait points with water between applications.
- Dispose dead rodents in accordance with local requirements *[The method of disposal shall be described specifically in the national SPC and be reflected on the product label]*.

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

- This product contains an anticoagulant substance. If ingested, symptoms, which may be delayed, may include nosebleed and bleeding gums. In severe cases, there may be bruising and blood present in the faeces or urine.
- Antidote: Vitamin K1 administered by medical/veterinary personnel only.
- In case of:
- Dermal exposure, wash skin with water and then with water and soap.
- Eye exposure, rinse eyes with eyes-rinse liquid or water, keep eyes lids open at least 10 minutes.
- Oral exposure, rinse mouth carefully with water. Never give anything by mouth to unconscious person. Do not provoke vomiting. If swallowed, seek medical advice immediately and show the product's container or label *[insert* country specific information*]*. Contact a veterinary surgeon in case of ingestion by a pet *[insert* country specific information*]*
- Bait stations must be labelled with the following information: "do not move or open"; "contains a rodenticide"; "product name or authorisation number"; "active substance(s)" and "in case of incident, call a poison centre *[insert national phone number]*"
- Hazardous to wildlife.

2.5.4 Instructions for safe disposal of the product and its packaging

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

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

- Store in a dry, cool and well ventilated place. Keep the container closed and away from direct sunlight.
- Store in places prevented from the access of children, birds, pets and farm animals.
- Shelf life: 2 years

2.5.6 Other information

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

3 Assessment of the product

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

3.1.1 Use 3 – House mice and/or brown rats – general public – indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	The biocidal product is ready to use grain bait in bait stations.
Application rate(s) and frequency	For the control of rats, baits of 200g should be placed each 5 to 10 m. For the control of mice, baits of 50g should be placed each 2 to 5 m
Category(ies) of users	General public
Pack sizes and packaging material	Individual polyethylene sachets of 15, 25, 50 and 75g inside corrugated board containers of 250, 500 y 750g and 1kg.

3.1.2 Use 3 – House mice and/or brown rats – professional– indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	The biocidal product is ready to use grain bait in bait stations.
Application rate(s) and frequency	For the control of rats, baits of 200g should be placed each 5 to 10 m. For the control of mice, baits of 50g should be placed each 2 to 5 m
Category(ies) of users	Professional
Pack sizes and packaging material	Individual polyethylene sachets of 15, 25, 50 and 75g inside corrugated board containers of 250, 500 y 750g and 1kg.

3.1.3 Use 3 – House mice and/or brown rats – trained professional– indoor

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rat)
Field(s) of use	Indoor
Application method(s)	The biocidal product is ready to use grain bait in bait stations.
Application rate(s) and frequency	For the control of rats, baits of 200g should be placed each 5 to 10 m. For the control of mice, baits of 50g should be placed each 2 to 5 m
Category(ies) of users	Trained Professional
Pack sizes and packaging material	Individual polyethylene sachets of 15, 25, 50 and 75g inside corrugated board containers of 1, 5, 10, 15 and 25Kg.

3.2 Physical, chemical and technical properties

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

3.3 Physical hazards and respective characteristics

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

3.4 Methods for detection and identification

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

3.5 Efficacy against target organisms

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

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.

3.9.4.1 Information on dermal absorption

	Re-assessment of the relevant data
Justification	In the inicial evaluation for authorisation of 'Muridox 30' (conducted in 2013) concluded, in the absence of access to the study data underlying the EU Endpoint values, a default value of 10% was appropriate. After re-assessment we concluded the final **value of 3%** for dermal absorption in the case of **grain and pellet**, in formulations with **difenacoum**, data was already collected in the assessment report of the active substance for a pellet formulation. So we consider this more refined and approximate value for re-evaluation.

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.
The most relevant routes of exposure are the following:

Exposure path	Trained professionals	Professional user	General public
Inhalation	Not relevant	Not relevant	Not relevant
Dermal	Potentially signifcant	Potentially signifcant	Potentially signifcant
Oral	Negligible	Negligible	Relevant

Due to the new harmonized classification of difenacoum, published in the 9th ATP of CLP Regulation, and according to article 19 of BPR, Muridox 30 (difenacoum 0.005%) will not be authorised for use for the general public (non-professional user).

In addition, in Spain, there is a national legislation about user's categories. In this legislation, three user categories (trained professional, professional and non-professional user) are included. Regarding of this, the professional user (for example, livestock farmers) is extrapolated to non-professional user. Therefore, Muridox 30 (difenacoum 0.005%) will not be authorised for professional user either.

3.6.3.1 List of scenarios

In accordance with the CAR on Difenacoum (CA Finland, 2009) for risk assessment, a value of 3% dermal penetration is used for Difenacoum 0.005 % w/w (grain).

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	Application (deploying bait stations)	Primary exposure during the deploying the product or loading and placing the grain bait in sachets in the bait boxes. The HEEG paper does not include information for grain bait in sachets, therefore data for loose bait will be taken into account for the assessment, as a worst case, although decanting task will not be considered. The only relevant inhalation exposure is determined during decanting of loose grain On the other hand, following HEEG Opinion (2010) 63 loading manipulations are assumed for professional operator.	Trained professional (Pest Control Operators)
2.	Post-application (Cleaning). (Refillable and sealed bait stations)	Primary exposure during cleaning/disposal of bait boxes. The operator emptied a loaded bait station containing grain bait. As in the exposure scenario before, only potential dermal exposure is foreseeable, while inhalation exposure is assessed as negligible. On the other hand, following HEEG Opinion (2010) 16 cleaning manipulations are assumed for professional operator.	Trained professional (Pest Control Operators)
3	Ingestion of bait by children	Secondary exposure: It is assumed that a child might ingest 5 g of the bait or 10mg where the presence of the biter agent in the product is taken in account	Bystanders (Children)

3.6.3.2 Trained professional user (Pest Control Operator)

Pest Control Operators are trained in the correct use of the grain bait, i.e. placement, number of bait stations required based on the infestation rate area, the amount of grain bait per bait station and safe handling procedures. They will be exposed during loading of bait stations, application of the bait and clean-up. The exposure will be via the dermal route, with the theoretical inhalation exposure being negligible, due to the fact that product is applied inside sachets. Gloves are worn when loading bait stations and disposing of remaining bait and carcasses.

The HEEG paper does not include information for grain bait in sachets, therefore data for loose bait will be taken into account for the assessment, as a worst case, although decanting task will not be considered. Therefore, the total daily exposure frequency will be of 79 manipulations, for the placing of 200g bait (maximum dose for rats) on 63 sites and the cleaning of 16 bait sites.

Dermal Exposure:

1.- Exposure for pest control operators during placing and cleaning of MURIDOX 30

Active substance content		0.005%
Dermal absorption		3%
Body weight		60 Kg
Loading	Amount of exposure to product during loading ($75t^h$ percentile for more than 4 manipulations)	2.04 mg b.p./ manipulation
	Nº of manipulation during loading	63
	Tier 1: Systemic dose (no gloves)	3.21×10^{-6} mg/Kg bw/day
	Tier 2: Systemic dose (with gloves, 10% penetration)	3.21×10^{-7} mg/Kg bw/day
Cleaning	Amount of exposure to product during loading (75^{th} percentile for more than 4 manipulations)	3.79 mg b.p/manipulation
	Nº of manipulation during cleaning	16
	Tier 1: Systemic dose (no gloves)	1.52×10^{-6} mg/Kg bw/day
	Tier 2: Systemic dose (with gloves, 10% penetration)	1.52×10^{-7} mg/Kg bw/day
Total	**Tier 1: Systemic dose (no gloves)**	**4.73×10^{-6} mg/Kg bw/day**
	Tier 2: Systemic dose (with gloves, 10% penetration)	**4.73×10^{-7} mg/Kg bw/day**

Inhalation Exposure

Due to the physical nature of the product, and due to the fact that difenacoum is non-volatile, the inhalation exposure is not considered relevant. Moreover, the product is supplied in sachets, therefore no inhalation exposure is expected.

Oral Exposure

It is not likely that baits reach the mouth of trained professionals if label instructions are followed and hands are washed after handling the bait. Therefore, oral exposure can be considered negligible.

3.6.3.3 Non-trained professional user

The biocidal product Muridox 30 will not be authorized for non-trained professional user.
Given that MURIDOX 30 classifies as Repr1B H360D and STOT RE 2 H373, the use of gloves is mandatory (P280). Therefore, risk assessment for non-trained professional user is covered by the trained professional because it should be noted that during the exposure assessment, the number of manipulation of non-trained professional user is lower than trained professional. In this sense the risk assessment for trained professional is a worse case.

3.6.3.4 Non-professional user

The biocidal product Muridox 30 will not be authorized for non- professional user

3.6.3.5 Exposure of the general public (Bystanders and children)

Secondary exposure as a result of use of the active substance in biocidal product may occur

In order to minimise the risk of ingestion of the bait by humans, the bait contains a bittering aversive agent. The bait stations have been manufactured to prevent incidental poisoning to both non-target animals and man, i.e. children. They are hard plastic and are either locked or sealed shut to prevent access to the bait.
However, secondary exposure, especially of infants may happen. Two different scenarios of secondary exposure are available, the 'handling of dead rodents' scenario and the 'mouthing of poison bait' scenario. The former is excluded from the risk assessment due to unrealistic assumptions. For the latter, either 5g (User Guidance) or 10 mg (TNsG) of the product is assumed to be swallowed by an infant per poisoning event. Neither of these scenarios is likely to lead to long term exposures but acute exposures may be experienced. The following systemic dose of difenacoum is then either 2.5 x 10-2 mg/kg bw or 5.0 x 10-5 mg/kg bw, respectively:

	Parameters	Value
Tier 1	Amount of BP ingested considering no a bittering agent	5g
	Oral absorption	100%
	A.S. content of BP	0.005%

	Children body weight:	10kg
	Estimated oral uptake	2.5 x 10^{-2} mg/kg bw
Tier 2	Amount of BP ingested, considering the presence of a bittering agent	10mg
	Estimated oral uptake	5 x 10^{-5} mg/kg bw

3.6.3.6 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.

3.6.3.7 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.

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

Please see “Cleaning” for trained professional exposure which is related with disposal of the biocidal product.

3.6.3.9 Aggregated exposure

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

Summary of exposure assessment

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**

Scenarios and values to be used in risk assessment			
Scenario number	**Exposed group (e.g. professionals, non-professionals, bystanders)**	**Tier/PPE**	**Estimated total uptake**
1. Loading	Trained professional user	Tier 1/ no PPE (unrealistic)	3.21 x 10^{-6} mg/Kg bw/day
1. Loading	Trained professional user	Tier 2/ PPE	3.21 x 10^{-7} mg/Kg bw/day
2. Cleaning	Trained professional user	Tier 1/ no PPE	1.52 x 10^{-6} mg/Kg bw/day
2. Cleaning	Trained professional user	Tier 2/ PPE	1.52 x 10^{-7} mg/Kg bw/day
Combined 1+2	Trained professional user	Tier 1/ no PPE	4.73 x 10^{-6} mg/Kg bw/day
Combined scenarios 1+2	Trained professional user	Tier 2/ PPE	4.73 x 10^{-7} mg/Kg bw/day
3	General public (Children)	Tier 1 (without efficient bitter agent)	2.5 x 10^{-2} mg/kg bw/day
3.	General public (Children)	Tier 2 (with bitter agent)	5 x 10^{-5} mg/kg bw/day

3.6.4 Risk characterisation for human health

Acute risks were not considered for professional users in view of the moderate to low dermal exposure, and the anticipated negligible inhalation and oral exposure. Instead, the risk assessment was restricted to the more relevant repeated exposure. Exposure assessment is based on measurements in simulated use conditions and on daily exposure frequencies according to a questionnaire answered by selected pest control companies in 15 EU countries. The calculations have been made using assumptions related to rat control and the estimates are considered to represent reasonable worst case scenarios.

Reference	**Study**	**NOAEL (LOAEL) (µg/kg bw/day)**	**AF**	**Correction for oral absorption**	**Value (µg/kg bw/day)**
AOEL (Operator/worker exposure)	Teratogenicity study in rabbit	0.001mg/kg bw/day	600	68%	0.0011

Drinking water	-	-	-	-	Not applicable
ARfD				-	Not applicable
ADI		-		-	Not applicable

3.6.4.1 Risk for trained professional users (pest control operators)

The exposure assessment for professional pest control operators under reasonable worst case assumptions (63 loadings and 16 clean-ups/day), yielded a potential dermal exposure leading to a systemic dose of 4.73 x 10-6 mg/kg/day for an unprotected operator during bait handling operations.

Comparison to the LOAEL of 0.001 mg/kg /day (based on a teratogenicity test in rabbits) shows that the use of rodenticide baits containing 0.005 % difenacoum causes a potential health risk for pest control operators not wearing appropriate PPE (gloves), as indicate by the resulting margin of exposure (%AEL:430 MOE:72).

A refined risk assessment has been conducted assuming pest control operators wear protective gloves during pest control operations. The resulting margin of exposure (%AEL:43 MOE: 719) indicates that the use of rodenticide baits containing 0.005 % difenacoum does not cause a risk for pest control operators if gloves are worn.

Overall

The result of the risk assessment concerning use of difenacoum is MURIDOX 30 indicates that the acceptable exposure level is not exceeded for trained professionals with PPE (gloves).

MOE value and comparison of AEL to exposure to MURIDOX 30 of professional users

User/Workplace operation	PPE	Exposure path	Body dose (mg/Kg/d)	MOE(1)	%AEL(2)
Trained professional Placing of bait (63 manipulations)	None	Dermal, hands	3.21×10^{-6} mg/Kg bw/day	106	292
Trained professional Placing of bait (63 manipulations)	Gloves	Dermal, hands	3.21×10^{-7} mg/Kg bw/day	1060	29.2
Trained professional (clean-up (15 manipulations)	None	Dermal, hands	1.52×10^{-6} mg/Kg bw/day	224	138
Trained professional (clean-up (15 manipulations)	Gloves	Dermal, hands	1.52×10^{-7} mg/Kg bw/day	2240	13.8
Trained professional Placing of bait (63 manipulations) and clean-up (15 mani pulations)	None	Dermal, hands	4.73×10^{-6} mg/Kg bw/day	72	430
	Gloves	Dermal, hands	4.73×10^{-7} mg/Kg bw/day	719	43

(1) Repeated dose toxicity: LOAEL 0.001 mg/kg/day, NOAEL 0.00034 mg/kg/day (factor 2 to extrapolate from LOAEL and corrected for bioavailability by multiplying with 0.68, because the mean oral absorption in males and females after 48 h of single oral dose of 0.1 mg/kg bw was 68%)

(2) Repeated dose toxicity: AEL = 0.0000011 mg /kg /day

Given that MURIDOX 30 classifies as Repr1B H360D and STOT RE 2 H373, the use of gloves is mandatory (P280). Therefore, risk assessment for non-trained professional user is covered by the trained professional because it should be noted that during the exposure assessment, the number of manipulation of non-trained professional user is lower than trained professional. In this sense the risk assessment for trained professional is a worse case.

3.6.4.2 Risk for the general public (Bystanders and children)

As a potential secondary exposure route, associated with the use of difenacoum in rodenticide products, ingestion of bait by infants has been assessed. The potential exposure due to dermal contact with poisoned rodents is not included in the risk assessment, because the available scenarios are unrealistic. Secondary exposure is anticipated to be acute in nature. The estimated exposure for the scenario, 2.5x10-2 mg/kg/day or 5.0x10-5 mg/kg/day, depending on the default assumptions, results in MOE values of 0.013 or 6.8, respectively. Therefore, the secondary exposure scenario of accidental poisoning of infants is of concern.

Task/ Scenario	**Tier**	**AEL mg/kg bw/d**	**Estimated uptake mg/kg bw/d**	**Estimated uptake/ AEL (%)**	**MOE**	**Acceptable (yes/no)**
Ingestion of bait / Scenario [3]	Tier 1 /no biter agent		2.5×10^{-2}	2.27×10^{6}	0.013	No
	Tier 2 /biter agent		5×10^{-5}	4550	6.8	No

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

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

Task/ Scenario	Tier	AOEL/ NOAEL mg/kg bw/d	Estimated uptake mg/kg bw/d	Estimated uptake/ AEL (%)	MOE	Acceptable (yes/no)
1. Trained professional: Placing of bait (63 manipulations)	Tier 1/No PPe	1.1×10^{-6} 0.00034	3.2×10^{-6}	292	106	No
1. Trained professional: Placing of bait (63 manipulations)	Tier 2/PPE	1.1×10^{-6} 0.00034	3.2×10^{-7}	29	1060	Yes
2. cleaning (15 manipulations)	Tier 1/No PPe	1.1×10^{-6} 0.00034	$1.5.x10^{-6}$	138	224	No
2. cleaning (15 manipulations)	Tier 2/PPE	1.1×10^{-6} 0.00034	$1.5.x10^{-7}$	13.8	2240	Yes
1+2- Placing of bait (63 manipulations) and clean-up (15 mani pulations)	Tier 1/No PPe	1.1×10^{-6} 0.00034	$4.73x10^{-6}$	430	72	No
1+2- Placing of bait (63 manipulations) and clean-up (15 mani pulations)	Tier 2/ PPE	1.1×10^{-6} 0.00034	$4.73x10^{-7}$	43	719	Yes
3. Ingestion of bait	Tier 1 /no biter agent	1.1×10^{-6} 0.00034	2.5×10^{-2}	$2.27x10^{6}$	0.013	No
3. Ingestion of bait	Tier 2 /biter agent	1.1×10^{-6} 0.00034	5×10^{-5}	4550	6.8	No

3.7 Risk assessment for animal health

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

3.8 Risk assessment for the environment

Neither new data was not provided nor had new guidance to be taken into account for re-assessment. Accordingly, the conclusion from the former assessment regarding the environment remains valid. Scenarios waste dumps and open areas not included the first assessment are included here:

EMISION ESTIMATION

Scenario [1]: waste dumps

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

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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in landfills and dumps			
Amount of product used at each refill/application	40	Kg	
Fraction of active substance in product	$5x10^{-3}$	%	
Number of emission days for control at waste dumps	365	days	

Number of application	7	-	
Fraction of active substance released to soil	0.9	-	
Area exposed to rodenticide	10000	m^2	
Depth of exposed soil	10	cm	
Bulk density of soil	$1.7x10^3$	Kg_{wwt}/m^3	

Calculations for Scenario [1]

Calculation of Elocal soil (equation 17, ESD PT14)

Parameter	Definition	Units	Value
Amount of product used per application	Qprod	g	40
Fraction of active substance in product	Fc_{prod}	-	0.00005
Number of application sites	N_{sites}	-	7
Fraction of active substance released directly to soil	$F_{release, soil}$	-	0.9
Local direct emission of active substance to soil from a campaign	**$Elocal_{soil\text{-}campaing} = Q_{prod} \times Fc_{prod} \times N_{sites} \times F_{release, soil}$ (17)**	**kg**	**$1.26x\text{-}10^{-2}$**

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

Parameter	Definition	Units	Value
Local direct emission of active substance to soil from a campaign	$Elocal_{soil, campaing}$ (2)	kg/m^3	$1.26x10^{-2}$
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]	**$Clocal_{soil\text{-}D} = (Elocal_{soil\text{-}D\text{-}campaign} x10E03)/ (AREA_{exposed\text{-}D} \times DEPTH_{soil} \times RHO_{soil} \times N_{sites})$ (18)**	**mg/kg**	**$7.41x10^{-4}$**

Scenario 2: open areas

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

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

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

Input parameters for calculating the local emission			
Input	**Value**	**Unit**	**Remarks**
Scenario: use in landfills and dumps			
Amount of product used at each refilling in the control operation	200	Kg	
Fraction of active substance in product	$5x10^{-3}$	%	
Number of emission days for control at open areas	6	days	
Number of application	2	-	
Fraction of product released to soil during application	0.05	-	
Fraction of product released to soil during use	0.20	-	
Soil volume exposed soil around the hole	0.0085	m^3	
Bulk density of soil	$1.7x10^3$	Kg_{wwt}/m^3	

Calculations for Scenario [*2*]

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

Parameter	**Definition**	**Units**	**Value**

Amount of product used at each refilling in the control operation	Q_{prod}	g	200
Fraction of active substance in product	Fc_{prod}	-	0.00005
Number of application sites	N_{sites}	-	1
Number of refills per site	N_{refil}	-	2
Fraction of the product released to soil during application	$F_{release, soil, appl}$	-	0.05
Fraction of product released to soil during use	$F_{release, soil, use}$		0.2
Local emission of active substance to soil during a campaign	**$Elocal_{soil\text{-}campaing} = (Q_{prod} \times Fc_{prod} \times N_{sites} \times N_{refil} \times (F_{release, soil, appli} + F_{release, soil})$ (9)**	**g**	**$5x10^{-3}$**

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	$5.x10^{-3}$
Soil volume exposed to rodenticide	$Vsoil_{exposed}$ (eq. 9a ESD)	m^3	$8.5x10^{-3}$
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**	**$3.46x10^{-1}$**

CALCULATED PEC VALUES

Summary table on calculated PEC values[1]								
	PEC_{STP}	**PEC_{water}**	**PEC_{sed}**	**$PEC_{seawater}$**	**PEC_{seased}**	**PEC_{soil}**	**PEC_{GW}[2]**	**PEC_{air}**
	[mg/l]	[mg/l]	[mg/kg_{wwt}]	[mg/l]	[mg/kg_{wwt}]	[mg/kg]	[µg/l]	[mg/m^3]
Scenario 1	-	-	-			7.410^{-4}	$2.33\ 10^{-5}$	
Scenario 2	-	-	-			0.346	$1.09\ 10^{-2}$	

Use in waste dumps

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

Calculation of PEC in soil

Direct release;

See in/around buildings calculus.

Clocalsoil-D = Elocalsoil-D-campaign * 106 / (Areaexposed-D * Depthsoil * RHOsoil)

Where;

Elocalsoil-D-campaign = Qprod*Fcprod*Napp*103*Frelease-ID,soil

Areaexposed-D * Depthsoil = 1000 m3 (10 000 m2 x 0.01 m assumed by ESD)

RHOsoil = 1700 kg m-3 (TGD II)

Frelease-ID,soil = 0.9

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

ESD worst and proposed case

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

= (40 * 0.00005 * 7 * 0.9) * 106 / 1.7 x 106

= 0.000741 mg/kg soil

In this scenario according to ESD PEClocalsoil = Clocalsoil-D and considering the worst case,

PEClocalsoil = 0.000741 mg/kg

Calculation of PEC in groundwater

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

PEClocalsoil, porewater = PEClocalsoil * RHOsoil / (ksoil-water*1000)

PEClocalsoil, porewater = 0.000741 * 1700 / (54090.74*1000) = 2.33 10-8 mg/l

An average Koc value of 1803018 ml/g was used in the calculations for derivation of ksoil-water.

Use in open areas

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

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

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

Calculation of PEC in soil

Direct release;

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

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

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

Thus the total soil volume is:

ESD worst case

Vsoilexposed = 0.0085 m3 (ESD page 31)

Clocalsoil-D = Elocalsoil-D-campaign * 1000 / (Vsoilexposed * RHOsoils)

= (200 * 0.000005 * 1 * 2 * (0.05+0.2)) * 1000 / 14.45

= 0.346 mg/kg

In this scenario according to ESD PEClocalsoil = Clocalsoil-D then,

PEClocalsoil = 0.346 mg/kg

Calculation of PEC in groundwater

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

PEClocalsoil, porewater = PEClocalsoil * RHOsoil / (ksoil-water*1000)

PEClocalsoil, porewater = 0.346 * 1700 / (54090.74 *1000)
= 1.09 10-5 mg/l

An average Koc value of 1803018 ml/g was used in the calculations for derivation of ksoil-water.

RISK CHARACTERISATION

For this risk assessment the new value for PNECsoil has been used, 0.625 mg/kg

Terrestrial compartment

Calculated PEC/PNEC values	
	PEC/PNEC$_{soil}$
Scenario 1	0.12 10^{-2}
Scenario 2	0.55

Groundwater

No risk has been identified for ground water.

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

As difenacoum is a Candidate for Substitution, a comparative assessment must be carried out as part of the evaluation process.

The Biocidal Products Committee of the European Chemicals Agency published its Opinion on Questions regarding the comparative assessment of anticoagulant rodenticides on 02 March 2017 (Document no. ECHA/BPC/145/2017).

The Opinion states that:

- In the absence of anticoagulant rodenticides, the use of rodenticide biocidal products containing other active substances would lead to an inadequate chemical diversity to minimize the occurrence of resistance in the target harmful organisms. These products also show some significant practical or economical disadvantages for the relevant uses.
- There is insufficient scientific evidence to prove that non-chemical alternative methods of rodent control are sufficiently effective according to the criteria established in agreed Union guidance with a view to prohibit or restrict the authorised uses of anticoagulant rodenticides.

The Opinion forms the basis of the COMMISSION IMPLEMENTING DECISION (EU) 2017/1532 of 7 September 2017 addressing questions regarding the comparative assessment of anticoagulant rodenticides in accordance with Article 23(5) of Regulation (EU) No 528/2012 of the European Parliament and of the Council.

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