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	RATOX
Product type(s):	14 (Rodenticide)
Active ingredient(s):	DIFENACOUM
Case No. in R4BP	BC-RR000074-34 (NA-RNL) BC-DS030713-34 (NA-ADC)
Asset No. in R4BP	ES-0000375-0000
Evaluating Competent Authority	Spain
Internal registration/file no	ES/APP(NA)-2018-14-00095
Date	February 2018 (Update February 2021)

Table of content

Application type	**Ref MS**	**Case number/Asset number in the ref MS**	**Decision date**	**Assessment carried out (i.e. first authorisation / amendment /renewal)**
NA-AAT	ES	BC-HX064156-12 / ES-0000375-0000	19/02/2021	Amendment (post-authorisation: stability long term)

1 Conclusion

The assessment presented in this report has shown that the ready-to-use product, RATOX, 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 RATOX 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.

Physical, chemical and technical properties remain valid to the initial evaluation other than the stability tests. An accelerated and long-term stability tests have been submitted and the results fulfil the Guidance criteria, so a shelf-life of 2 years can be granted

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

Regarding to efficacy against target organisms and human exposure assessment, the conclusions remain valid.

According to Commission Regulation (EU) 2016/1179 the product RATOX, with the active substance difenacoum, at a level of 0.005% w/w is classified as REPRODUCTIVE TOXICITY CATEGORY 1B ; H360D and 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 conclusion for risk assessment for the environment remains valid.

Therefore, RATOX is granted 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 by trained professional. It is a ready to used block bait to be used in tamper-resistant bait stations.

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.

2 Summary of the product assessment

2.1 Administrative information

2.1.1 Identifier in R4BP

RATOX

2.1.2 Manufacturer(s) of the product

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

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

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

2.2 Composition and formulation

2.2.1 Qualitative and quantitative information on the composition

Table 1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Difenacoum	3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin	Active Substance	56073-07-5	259-978-4	0.005
-	-	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 0).
- 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, 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

3 Table 2

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

4

5 Table 3

Labelling	Code	Pictogram / Wording
Pictograms	GHS08	
Signal word	-	Danger
Hazard statements	H360D	May damage the unborn child
	H373	May causes damage to organs (blood) through prolonged or repeated exposure
Supplemental hazard information	-	-
Supplemental label elements	-	
Precautionary statements	P201	Obtain special instructions before use.
	P202	Do not handle until all safety precautions have been read and understood.
	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 evaluated in Spain further down:

Use(s) considered appropriate for authorisation after former assessment (uses currently <u>evaluated/authorised 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 and/or Brown rats – trained professionals - indoor
2	House mice and/or brown rats – professionals –indoor and outside around buildings	2	House mice and/or Brown rats – trained professionals – outdoor around buildings
3	House mice and/or brown rats – trained professionals – indoor and outside around buildings, outdoor open areas & waste dumps	3	Brown Rats – trained professionals – outdoor open areas & waste dumps

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 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:** up to 200 g of bait per baiting point **Mice:** up to 50 g of bait per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 20 kg Grams/kg of bait per packed bag: blocks of 10 and 15 g. Packaging material: cartoon boxes and polypropylene buckets

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.

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

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

- Do not use the product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities. - Do not use the product in pulsed baiting treatments. - This product shall only be used indoors and places that are not accessible to children or non-target animals.

2.4.1.3 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 2.5.4

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

-See section 2.5.5

2.4.2 Use 2 – 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:** up to 200 g of bait per baiting point **Mice:** up to 50 g of bait per baiting point

Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 20 kg Grams/kg of bait per packed bag: Blocks of 10 and 15 g. Packaging material: cartoon boxes and polypropylene buckets

2.4.2.1 Use-specific instructions for use

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

2.4.2.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- Consider preventive control measures (plug holes, remove potential food and drinking as far as possible) to improve product intake and reduce the likelihood of reinvasion.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.
- Do not use this product as permanent baits for the prevention of rodent infestation or monitoring of rodent activities.
- Do not use this product in pulsed baiting treatments.
- Do not apply this product directly in the burrows.

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

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

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

-See section 2.5.4

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

-See section 2.5.5

2.4.3 Use 3 – Brown Rats – 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:** up to 200 g of bait per baiting point
Category(ies) of users	Trained professionals
Pack sizes and packaging material	**Minimum pack size of 3 kg.** Number of packed bags per packaging: up to 20 kg Grams/kg of bait per packed bag: Blocks of 10 and 15 g. Packaging material: cartoon boxes and polypropylene buckets

2.4.3.1 Use-specific instructions for use

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

2.4.3.2 Use-specific risk mitigation measures

- Where possible, prior to the treatment inform any possible bystanders (e.g. users of the treated area and their surroundings) about the rodent control campaign.
- To reduce risk of secondary poisoning, search for and remove dead rodents during treatment at frequent intervals, in line with the recommendations provided by the relevant code of best practice.

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

- Do not use this product in pulsed baiting treatments.

- Do not apply this product directly in the burrows.

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

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

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

-See section 2.5.4

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

-See section 2.5.5

2.5 General directions for use

2.5.1 Instructions for use

- Read and follow the product information as well as any information accompanying the product or provided at the point of sale before using it.

- Carry out a pre-baiting survey of the infested area and an on-site assessment in order to identify the rodent species, their places of activity and determine the likely cause and the extent of the infestation.

- Remove food which is readily attainable for rodents (e.g. spilled grain or food waste). Apart from this, do not clean up the infested area just before the treatment, as this only disturbs the rodent population and makes bait acceptance more difficult to achieve.

- The product should only be used as part of an integrated pest management (IPM) system, including, amongst others, hygiene measures and, where possible, physical methods of control.

- The product should be placed in the immediate vicinity of places where rodent activity has been previously explored (e.g. travel paths, nesting sites, feedlots, holes, burrows etc.).

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

- Bait stations must be clearly labelled to show they contain rodenticides and that they must not be moved or opened *(see section 2.5.3 for the information to be shown on the label)*.

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

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

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

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

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

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

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

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

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

2.5.2 Risk mitigation measures:

- 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

2.6 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.

3 Assessment of the product

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

3.1.1 Use 1 – House mice and/or brown rats – general public– indoor and outside around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	Indoor Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats:** 3-5 bait stations with a maximum of 200g of product every 100m^2 **Mice:** 2 bait stations with a maximum of 50g of product every 10m^2.
Category(ies) of users	General public

Pack sizes and packaging material	Blocks of 6, 8, 10 and 15 g in 25, 50, 100, 180, 250 and 500 g, and 1kg.

3.1.2 House mice and/or brown rats – professional– indoor and outside around buildings

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	Indoor Outdoor around buildings
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	**Rats:** 3-5 bait stations with a maximum of 200g of product every 100m^2 **Mice:** 2 bait stations with a maximum of 50g of product every 10m^2.
Category(ies) of users	Professionals
Pack sizes and packaging material	Blocks of 6, 8, 10 and 15 g in 25, 50, 100, 180, 250 and 500 g, and 1kg.

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

Product Type(s)	14
Where relevant, an exact description of the use	Rodenticide
Target organism(s) (including development stage)	*Mus musculus* (house mice) *Rattus norvegicus* (brown rats)
Field(s) of use	Indoor and outside around buildings, outdoor open areas & waste dumps
Application method(s)	Ready-to-use bait to be used in tamper-resistant bait stations
Application rate(s) and frequency	Mice: 2 bait stations with a maximum of 50g of product every 10m2. Rats: 3-5 bait stations with a maximum of 200g of product every 100m2
Category(ies) of users	Trained Professional

Pack sizes and packaging material	Blocks of 6, 10 and 15 g in 1, 2.5, 3, 9, 10, 20 and 25 kg.

3.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Storage stability test – **Accelerated**	CIPAC MT 46.3	0.005	READ ACROSS (Ratonex Bloque) $[C]_0$ = 0.0037% $[C]_f$ = 0.0034% Δ[C] = -8.1% The results is lower than 10% therefore the biocidal product is stable 14 days at 54°C.	IUCLID 3.4.1.
Storage stability test – **Long term**		0.005	T^a: ambient Time: 2 years $[C]_0$: 0.0042% w/w $[C]_{12M}$: 0.0042% Δ[C] = 0%. $[C]_0$: 0.0042% w/w $[C]_{24M}$: 0.0040% Δ[C] = -4.76%. Appearance: No significant differences were found before and after storage. Density δ_0 = 1.2574 g/cc δ_{12M} = 1.3106 g/cc δ_{24M} = 1.3242 g/cc Based on the results obtained a shelf life of 2 years can be granted.	IUCLID 3.4.1

Apart from the properties mentioned above, neither new data was not provided nor had new guidance to be taken into account for re-assessment.

Accordingly, the conclusion from the former assessment regarding those physical, chemical and technical properties not provided 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.

3.6.3 Exposure assessment

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

3.6.4 Risk characterisation for human health

3.6.4.1 Risk for trained professional users

Bearing in mind that in the former assessment the number of contacts was considered with a block size of 6 g and in the renewal the minimum block size is 10 g, the conclusion from the former assessment regarding the risk characterisation for trained professional user remains valid, being considered a worst case.

3.6.4.2 Risk for professional users

Due to national legislation in relation to categories of users which three categories of users are established (general public, professional and trained professional user) based on the qualification obtained, therefore the professional is extrapolated to the general public (under this national regulation the professional user is not bounded to use PPE when they apply the product). For that, the biocidal product rodenticides containing 0.005 %w/w 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.

3.6.4.3 Risk for the general public

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

3.6.4.4 Risk for consumers via residues in food

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

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

The biocidal product does not contain other substances in quantities that would be of toxicological concern in the production formulation.

3.6.4.6 Summary of risk characterisation

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

3.7 Risk assessment for animal health

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

3.8 Risk assessment for the environment

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

3.9 Assessment of a combination of biocidal products

A use with other biocidal products is not intended.

3.10 Comparative assessment

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

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

The opinion states that:

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

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

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

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

4.1 Full composition of the product

See Confidential PAR

4.2 List of studies for the biocidal product

See Confidential PAR