HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

1 TOELATING

Gelet op de aanvraag d.d. 29 augustus 2013 (20131213 TNBWE) van

BELGAGRI SA
Rue des Tuilliers 1
B-4480 ENGIS
BELGIË

tot verkrijging van een toelating als bedoeld in artikel 19 van de Verordening (EU) 528/2012, op basis van de werkzame stof brodifacoum,

STRONG

Mede gelet op artikel 89 lid 2 juncto artikel 91 van de Verordening (EU) 528/2012, juncto artikel 44, eerste lid, Wet gewasbeschermingsmiddelen en biociden zoals deze luidde voor de inwerkingtreding van Verordening (EU) 528/2012

BESLUIT HET COLLEGE als volgt:

1.1 Toelating

1. Het middel STRONG is toegelaten voor de in bijlage I genoemde toepassingen onder nummer 14379 N met ingang van datum dezes. Voor de gronden van dit besluit wordt verwezen naar bijlage II bij dit besluit.

2. De toelating geldt tot 31 januari 2017.

1.2 Samenstelling, vorm en verpakking

De toelating geldt uitsluitend voor het middel in de samenstelling, vorm en de verpakking als waarvoor de toelating is verleend.

1.3 Gebruik
Het middel mag slechts worden gebruikt met inachtneming van hetgeen in bijlage I bij dit besluit is voorgeschreven.

1.4 Classificatie en etikettering
Mede gelet op artikel 50 Wet gewasbeschermingsmiddelen en biociden worden voorschriften gegeven.

Dit leidt tot de volgende voorschriften:

De aanduidingen, welke moeten worden vermeld, worden hierbij vastgesteld als volgt:

aard van het preparaat: Lokmiddel (klaar voor gebruik)

werkzame stof:	*gehalte:*
brodifacoum	0,005 %

de identiteit van alle stoffen in het mengsel die bijdragen tot de indeling van het mengsel:
-

PICTOGRAM(MEN)

pictogram:

SIGNAALWOORD

-

Voorzorgsmaatregelen

P102	Buiten het bereik van kinderen houden.
P262	Contact met de ogen, de huid of de kleding vermijden.
P270	Niet eten, drinken of roken tijdens het gebruik van dit product.
P280A	Beschermende handschoenen dragen.
P301 + P310	NA INSLIKKEN: Onmiddellijk een ANTIGIFCENTRUM of een arts raadplegen.
P404	In gesloten verpakking bewaren.

Behalve de voorgeschreven aanduidingen en vermeldingen moeten op de verpakking voorkomen:

a. letterlijk en zonder enige aanvulling:
het wettelijk gebruiksvoorschrift
De tekst van het wettelijk gebruiksvoorschrift is opgenomen in Bijlage I, onder A.

b. hetzij letterlijk, hetzij naar zakelijke inhoud:
de gebruiksaanwijzing
De tekst van de gebruiksaanwijzing is opgenomen in Bijlage I, onder B.
De tekst mag worden aangevuld met technische aanwijzingen voor een goede bestrijding mits deze niet met die tekst in strijd zijn.

2 DETAILS VAN DE AANVRAAG

Het betreft een aanvraag tot verkrijging van een toelating van het middel STRONG (14379 N), een middel op basis van de werkzame stof brodifacoum. Het middel wordt aangevraagd als middel ter bestrijding van ratten en muizen in afgesloten ruimten.

2.2 Informatie met betrekking tot de stof

Er zijn in Nederland reeds andere middelen op basis van de werkzame stof brodifacoum toegelaten.
De werkzame stof brodifacoum is bij Richtlijn 2010/10/EG, dd 9 februari 2010 van de Europese Commissie van de Europese Gemeenschappen opgenomen in Bijlage I van Richtlijn 98/8/EG.

2.3 Karakterisering van het middel

STRONG is a ready-to-use cereal grain bait intended to control the brown rat (Rattus norvegicus), roof rat (Rattus rattus) and the house mouse mice (Mus musculus). The active substance in Strong is brodifacoum, a second generation anticoagulant.
Anticoagulant rodenticides are vitamin K antagonists. The main site of their action is the liver, where several of the blood coagulation precursors undergo vitamin K dependent post translation processing before they are converted into the respective procoagulant zymogens. The specific point of action is thought to be the inhibition of K_1 epoxide reductase. The anticoagulants accumulate and are stored in the liver until broken down. The plasma prothrombin (procoagulant factor II) concentration provides a suitable guide to the severity of acute intoxication and to the effectiveness and required duration of the antidoting therapy (vitamin K_1).

2.4 Voorgeschiedenis

De aanvraag is op 11 september 2013 ontvangen; op 7 oktober 2013 zijn de verschuldigde aanvraagkosten ontvangen.

2.5 Eindconclusie

Bij gebruik volgens het Wettelijk Gebruiksvoorschrift/Gebruiksaanwijzing is het middel STRONG op basis van de werkzame stof brodifacoum voldoende werkzaam en heeft het geen schadelijke uitwerking op de gezondheid van de mens en het milieu.

Degene wiens belang rechtstreeks bij dit besluit is betrokken kan gelet op artikel 4 van Bijlage 2 bij de Algemene wet bestuursrecht en artikel 7:1, eerste lid, van de Algemene wet bestuursrecht, binnen zes weken na de dag waarop dit besluit bekend is gemaakt een bezwaarschrift indienen bij: het College voor de toelating van gewasbeschermingsmiddelen en biociden (Ctgb), Postbus 217, 6700 AE WAGENINGEN. Het Ctgb heeft niet de mogelijkheid van het elektronisch indienen van een bezwaarschrift opengesteld.

Wageningen, 7 maart 2014

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN,

ir. J.F. de Leeuw
voorzitter

Dit middel is uitsluitend bestemd voor professioneel gebruik

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE I bij het besluit d.d. 7 maart 2014 tot toelating van het middel STRONG, toelatingnummer 14379 N

A.
WETTELIJK GEBRUIKSVOORSCHRIFT

Toegestaan is uitsluitend het gebruik als middel ter bestrijding van ratten en muizen in afgesloten ruimten, met dien verstande, dat het middel moet worden uitgelegd in speciaal hiervoor bestemde lokaasdozen. Plaats het lokaas buiten bereik van kinderen, vogels en (huis)dieren.

De gebruiksaanwijzing zoals opgenomen onder B. moet worden aangehouden.

Het middel is uitsluitend bestemd voor professioneel gebruik.

B.
GEBRUIKSAANWIJZING

Toepassingen:

STRONG is kant-en-klaar los lokaasgraan tegen zwarte en bruine ratten en huismuizen op basis van 0,005% brodifacoum.

Plaats het lokaas in lokaasdozen buiten bereik van andere dieren (bijvoorbeeld vogels, zoogdieren, huis- of landbouwdieren) en kinderen. Het lokaas zo vastmaken dat het niet weggesleept kan worden. De lokaasdozen markeren zodat duidelijk is dat ze rodenticiden bevatten. De lokaasdozen vervolgens uitzetten op plaatsen waar de knaagdieren geregeld komen: in de nabijheid van hol ingangen, op looppaden (sporen!), verlaagd plafond en op plaatsen waar de dieren voedsel halen of knagen.

De lokaasdozen niet toepassen in de buurt van waterafvoersystemen waar het middel met water in contact kan komen. Na gebruik handen wassen.

Het middel dient gedurende een aantal dagen in voldoende mate te worden gegeten door ratten en huismuizen.

Indien huisdieren vergiftigingsverschijnselen of onverwachte gezondheidsproblemen vertonen, een dierenarts raadplegen.

Dosering:

Bestrijding van ratten
Plaats STRONG lokaas in lokaaspunten, daar waar ratten komen. Kies voldoende lokaaspunten op verschillende droge plaatsen, langs hun looppaden, nabij hun nesten en daar waar men uitwerpselen vindt. N.B. In het geval van zwarte ratten vooral hooggelegen voerplaatsen inrichten.

Dosering: 100-200 g product per lokaaspunt. Lokaaspunten om de 5 tot 10 meter, afhankelijk van de grootte van de rattenplaag. Gebruik een schepje bij het vullen van lokaasdozen met los graanlokaas.

Bestrijding van muizen
Plaats STRONG lokaas in lokaaspunten op plaatsen waar de muizen komen. Muizen nuttigen kleine hoeveelheden op veel plaatsen. Plaats daarom lokaas op veel lokaaspunten, ongeveer om de 2 tot 5 meter, overal waar uitwerpselen, knaagschade of ander tekenen van muizenactiviteit waargenomen worden.

Dosering: 30-50 g product per lokaaspunt. Lokaaspunten om de 2 tot 5 meter, afhankelijk van de grootte van de muizenplaag. Gebruik een schepje bij het vullen van lokaasdozen met los graanlokaas.

Vervolg bestrijdingsactie:
Controleer de eerste opname na 3 dagen en vervolgens regelmatig op basis van opname (wekelijks of elke 14 dagen). Vervang verdwenen lokaas. Middel dat beschimmeld of verontreinigd is totaal vervangen. Indien bij een lokaaspunt alle lokaas verdwenen is, onmiddellijk lokaas bijvullen en meer lokaaspunten inrichten en/of de controlefrequentie verhogen. Het lokaas verversen tot er in het geheel geen opname meer plaatsvindt. Wanneer de opname van lokaas is gestopt, de resten van het lokaas verzamelen en veilig verwijderen als gevaarlijk afval (cf. Eural).

Dode dieren (de eerste kunnen na ca. 3 dagen gevonden worden) eveneens verzamelen en in plastic verpakt in het vuilnisvat deponeren, opdat huisdieren en andere dieren niet door het opeten van de kadavers worden vergiftigd. Katten en honden tijdens een bestrijdingsactie extra goed voeren. Verder de nodige maatregelen (laten) treffen in het belang van rat- en muiswering (ingangen afdichten, mogelijk voer verwijderen, etc.).

Het gebruik van dit middel is alleen toegestaan indien het een onderdeel vormt van een integrated pest management systeem (IPM). Het middel mag niet preventief gebruikt worden.

N.B. Indien in aangebouwde ruimten ook ratten of muizen aanwezig zijn, zullen de resultaten slechts blijvend zijn, wanneer ook daar een bestrijdingsactie wordt uitgevoerd.

Resistentiemanagement:
Voor de werkzame stof aanwezig in het middel, brodifacoum, is er een risico dat muizen of ratten resistentie ontwikkelen. Gebruik dit middel daarom niet in gevallen dat resistentie waarschijnlijk is, bijvoorbeeld in gevallen dat vorige bestrijdingsacties met brodifacoum bevattende middelen niet hebben geresulteerd in een duidelijke vermindering van de populatie.

Eerste Hulpmaatregelen:
Houd dit etiket beschikbaar wanneer medisch advies wordt ingewonnen.
In geval van nood contact opnemen met een dokter.
Tegengif: Vitamine K1 (onder medische begeleiding).

HET COLLEGE VOOR DE TOELATING VAN GEWASBESCHERMINGSMIDDELEN EN BIOCIDEN

BIJLAGE II bij het besluit d.d. 7 maart 2014 tot toelating van het middel STRONG, toelatingnummer 14379 N

Product Assessment Report Mutual Recognition

Strong

07-03-2014

Internal registration/file no:	20131213
Authorisation/Registration no:	14379N
Granting date/entry into force of authorisation/ registration:	07-03-2014
Expiry date of authorisation/ registration:	31-01-2017
Active ingredient:	Brodifacoum
Product type:	14

Biocidal product assessment report related to product authorisation under Regulation (EU) 528/2012

Contents

1 General information about the product application

1.1 Applicant

BELGAGRI SA
Rue des Tuiliers, 1
Engis
B-4480
Belgium

1.2 Current authorisation holder[1]

Not applicable

1.3 Proposed authorisation holder

BELGAGRI SA

1.4 Information about the product application

Application for authorisation based on mutual recognition. The primary assessment has been carried out by reference member state IE.

1.5 Information about the biocidal product

Productname: Strong
Productname in RMS: Strong
PT: 14
Active substance: Brodifacoum

[1] Applies only to existing authorisations

2 Summary of the product assessment

2.1 Identity related issues

For the assessment of the identity related issues we refer to Product Assessment Report of the original authorisation.

2.2 Classification, labelling and packaging

2.2.1 Proposal for the classification and labelling of the formulation concerning physical chemical properties

No classification is required based on the physical and chemical properties of the product based on both 1999/45/EC and Reg (EC) 1272/2008.

Supported shelf life of the formulation: 2 years in PP

The proposed classification and labelling of the preparation is identical to that proposed in the Product Assessment Report by the competent authority IE.

Professional

	Packaging authorised/ evaluated by RMS	**Packaging applied for in NL**	**Packaging authorised in NL**
Packaging size and type	Grain bait in wrapped PP sachets PP 25g, 50g, 100g	Not applied for	Not applied for
Packaging size and type	Grain bait PP sachets (25g, 50g and 100g) are packed in cardboard boxes Cardboard 600g, 1kg	Grain bait PP sachets (25g, 50g and 100g) are packed in cardboard boxes Cardboard 800g, 1kg	Grain bait PP sachets (25g, 50g and 100g) are packed in cardboard boxes Cardboard 800g, 1kg
Packaging size and type	Loose grain bait packed in PP pot 800g	Loose grain bait packed in PP pot 800g	Loose grain bait packed in PP pot 800g
Packaging size and type	Grain bait PP sachets (25g, 50g and 100g) are packed cardboard can Cardboard 1kg, 1.2kg, 1.5kg	Grain bait PP sachets (25g, 50g and 100g) are packed cardboard can Cardboard 1kg, 1.2kg, 1.5kg	Grain bait PP sachets (25g, 50g and 100g) are packed cardboard can Cardboard 1kg, 1.2kg, 1.5kg
Packaging size and type	Loose grain bait packed in PP bucket 2kg, 2.5kg, 3kg, 4kg, 5kg, 6kg, 10kg, 15kg	Loose grain bait packed in PP bucket 2kg, 2.5kg, 3kg, 4kg, 5kg, 6kg, 10kg, 15kg	Loose grain bait packed in PP bucket 2kg, 2.5kg, 3kg, 4kg, 5kg, 6kg, 10kg, 15kg
Packaging size and type	Grain bait sachets (100g) are packed in PP buckets PP 2kg, 3kg, 4kg, 5kg, 6kg	Grain bait sachets (100g) are packed in PP buckets PP 2kg, 3kg, 4kg, 5kg, 6kg	Grain bait sachets (100g) are packed in PP buckets PP 2kg, 3kg, 4kg, 5kg, 6kg
Packaging size and type	Grain bait sachets (50g) are packed in PP buckets PP 2.5kg	Grain bait sachets (50g) are packed in PP buckets PP 2.5kg	Grain bait sachets (50g) are packed in PP buckets PP 2.5kg

2.2.2 Proposal for the classification and labelling of the formulation concerning health

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	-	Signal word:	-
H-statements:	-	-	
P-statements:	P102	Keep out of reach of children	
	P262	Do not get in eyes, on skin or on clothing	
	P270	Do not eat, drink or smoke when using this product	
	P280a	Wear protective gloves.	
	P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor	
	P404	Store locked up.	
Supplemental Hazard information:	-		
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable

Explanation:	
Pictogram:	-
H-statements:	-
P-statements:	P103 is not indicated for professional user and would lead to > 6 P-statements. A combined P-statement P404+P405 does not exist, therefore only P404 is assigned. Other P-statements are assigned as proposed by the applicant.
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

2.2.3 Proposal for the classification and labelling of the formulation concerning the environment

Based on the profile of the substance, the provided toxicology of the preparation and the characteristics of the co-formulants, the following labeling of the preparation is proposed:

Pictogram:	-	Signal word:	-
H-statements:	-	-	
P-statements:	P273	Avoid release to the environment.	
	P501	Dispose of contents/container to hazardous or special waste collection point.	
Supplemental Hazard information:	-	-	

Explanation:	
Pictogram:	-
H-statements:	-

P-statements:	P273 and P501 are proposed by applicant.
Other:	-

* according to Reg. (EC) 1272/2008, Title III, article 18, 3 (b)

The proposed classification and labelling of the preparation is identical to that proposed in the Product Assessment Report by the competent authority IE (no indication of danger and no risk phrases).

2.3 Physico/chemical properties and analytical methods

For the assessment of the physical and chemical properties we refer to Product Assessment Report of the original authorisation.

2.4 Risk assessment for Physico-chemical properties

For the risk assessment for physico-chemical properties we refer to Product Assessment Report of the original authorisation.

2.5 Effectiveness against target organisms

For the assessment of the effectiveness against target organisms we refer to Product Assessment Report of the original authorisation. The conclusions of the RMS are acceptable.

2.5.1 The label claim

The applicant has provided a Dutch label (WG/GA). This has been adapted to our standards.

Professional/non-professional use
In the PAR efficacy was demonstrated for professional and non-professional use. However, authorisation for this product in NL was only requested for professional use.

Outdoor use
According to the PAR/SPC this product is intended for use in and around buildings. However, authorisation for this product in NL was only requested for indoor use.

Dose
According to the PAR, for rat infestations 45-60g and for mice infestations 10-25g of bait needs to be placed per bait point. The CMS NL is of the opinion that for rodenticides higher minimum application rates should be used to minimize risks for development of resistance. Based on expert opinion these have been determined at 100g for rats and 30g for mice. The dose on the WG/GA has been adapted by CMS NL to: 100-200g per bait point for rats and 30-50 g per bait point for mice. These doses were used in the field tests.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

For the description of the intended use(s) we refer to Product Assessment Report of the original authorisation.

2.6.2 Assessment of exposure to humans and the environment

Human toxicology
For the assessment of the exposure to humans we refer to Product Assessment Report of the original authorisation.

The formulation Strong is a grain bait containing 0.005% brodifacoum as an active substance and is intended for the use against rats and mice inside buildings (PT14). The intended doses are 200 g bait for the use against rats and 50 g bait for the use against mice. The formulation is supplied as a bulk grain or grain in sachets in the packs of 1.5, 2.5, 5, 10 and 20 kg and intended for professional use only. The Product Assessment Report (PAR) was prepared by the RMS Ireland.

Brodifacoum is an existing active substance, included in the Union List of approved active substances under Regulation (EU) 528/2012. The classification and labelling of brodifacoum in the PAR is identical to classification and labelling of brodifacoum in the final CAR of brodifacoum (2009, RMS Italy). For brodifacoum also specific concentration limits were set in May 2006 by the Technical Committee on Classification and Labelling of Dangerous Substances. These specific concentration limits were also considered by the RMS Ireland.

The applicant has submitted acute oral and acute dermal toxicity, skin and eye irritation studies with a brodifacoum grain bait formulation, which were found acceptable by the RMS Ireland. Based on the results of these studies, the formulation Strong does not need to be classified for acute oral (LD50 > 2000 mg/kg bw) and acute dermal toxicity (LD50 > 2000 mg/kg bw). The formulation Strong is considered to be not irritating to skin and eyes. The evaluation of the RMS is accepted by the Ctgb.

For brodifacoum two sets of AELs were derived in the two CARs of two notifiers of the active substance. In the CAR of the notifier Syngenta Limited the AEL_{acute} and $AEL_{chronic}$ of 0.0000033 mg/kg bw/day have been derived, while in the CAR of the notifier Pelgar Brodifacoum and Difenacoum Task Force the $AEL_{medium\text{-}term}$ of 6.7×10^{-6} mg/kg bw/day and $AEL_{long\text{-}term}$ of 3.3×10^{-6} mg/kg bw/day were derived. At the TM III 2009 the following AELs were agreed upon:

- AEL_{acute} of 3.3×10^{-6} mg/kg/day
- $AEL_{medium\ term}$ of 6.7×10^{-6} mg/kg bw/day
- $AEL_{chronic}$ of 3.3×10^{-6} mg/kg bw/day

The same AELs were used in the risk assessment of Strong performed by the RSM Ireland. This is considered acceptable by the Ctgb.

The exposure assessment was conducted based on the operator exposure study of Chambers and Snowdon (2004)[2] in which the exposure of a professional operator during the loading of the grain bait into the bait box using a scoop and subsequent cleaning of the bait box was determined. The indicative exposure per loading of one bait box with 200 g of loose grain bait was 2.04 mg biocidal product on hands. For cleaning of the bait boxes the

[2] Chambers JG, Snowdon PJ. Study to determine potential exposure to operators during simulated use of anticoagulant rodenticide baits. Synergy Laboratories Limited, study number SYN/1302, 8 March 2004.

indicative value of 3.79 mg biocidal products on hands was derived in the Chambers and Snowdon (2004)[1] study. The loading of 63 bait boxes per day and cleaning of 16 bait boxes per day was considered by the RMS Ireland in agreement with the HEEG Opinion on the harmonization of the number of manipulations in the assessment of rodenticides (2010) agreed at TM III 2010. This is considered acceptable by the Ctgb.

Based on this the following exposure estimates are derived:

Total amount of biocidal product on hands for 63 loading and 16 cleaning operations:
2.04 x 63 + 3.79 x 16 = 189.16 mg

Corrected for 0.005% brodifacoum and 3% dermal absorption and considering 60 kg body weight for a professional user this results in the systemic exposure to brodifacoum of:
189.16 x 0.005% x 3% / 60 = 4.7×10^{-6} mg/kg bw/day.

It should be noted that the use of a scoop for the filling of bait boxes was considered in the risk assessment. Therefore as a precaution the following sentence will be added to WG/GA: “Use a scoop to fill the bait boxes”.

Furthermore, the formulation is supplied in packs of 1.5, 2.5, 5, 10 and 20 kg. It is presumed that in case of 20 kg packaging a professional user will need to decant the portions of 3 kg of bait from a 20 kg pack into a plastic bucket before filling the baits. During the decanting both dermal and inhalation exposure will occur. The indicative inhalation exposure during the decanting was derived based on the Chambers and Snowdon (2004)[1] study and was 9.62 mg/m^3. The RMS has performed the calculation of the total amount of bait which needs to be decanted by considering that 63 bait boxes will need to be filled with 200 g biocidal product each. To fill 63 bait boxes with 200 g of the product in total (63 x 200 =) 12.6 kg bait is required, which implies that (12.6/3 =) 4.2 operations need to be performed per day. The RMS assumed the total exposure duration of 5 minutes for decanting operations. In the study of Chambers and Snowdon (2004)[1] the time required to perform 5 or 10 decanting operations varied between 1 and 4 minutes. Therefore the assumption is considered acceptable by the Ctgb.

The indicative dermal exposure during decanting operations was 52.34 mg biocidal product on hands based on the study of Chambers and Snowdon (2004). Considering 4.2 decanting operations per day, the total amount of biocidal product on hands is (52.34 x 4.2 =) 220 mg. Considering 0.005% brodifacoum in the formulation, 3% dermal absorption and 60 kg body weight, the following systemic exposure to brodifacoum is calculated:

220 x 0.005% x 3% / 60 = 5.5×10^{-6} mg/kg bw/day

For inhalation exposure, considering 100% inhalation absorption, breathing rate of 1.25 m^3/h and 5 minutes exposure duration, the total amount of inhaled biocidal product is:

9.62 x 5 x 1.25 x 100% / 60 = 1.0 mg biocidal product

Corrected for 0.005% brodifacoum and 60 kg professional user body weight, this corresponds to (1.0 x 0.005% / 60 =) 8.35×10^{-7} mg/kg bw/day brodifacoum

In summary, the total systemic exposure following 4.2 decanting operations, loading of 63 bait boxes and cleaning of 16 bait boxes is:

$8.35 \times 10^{-7} + 5.5 \times 10^{-6} + 4.7 \times 10^{-6} = 1.1 \times 10^{-5}$ mg/kg bw/day brodifacoum.

If this value is compared with the $AEL_{long\text{-}term}$ of 3.3×10^{-6} mg/kg bw/day, the resulting risk index is ($1.1 \times 10^{-5} / 3.3 \times 10^{-6}$ =) 3.34. Based on this, adverse systemic effects from systemic exposure to brodifacoum cannot be excluded for unprotected professional user during the use of Strong as a loose grain bait.

The use of personal protective equipment (gloves) will result 90% reduction of dermal exposure. Respectively, the following exposure estimates are derived:
$8.35 \times 10^{-7} + 5.5 \times 10^{-6}/10 + 4.7 \times 10^{-6}/10 = 1.9 \times 10^{-6}$ mg/kg bw/day

By comparing this value with $AEL_{long\text{-}term}$ of 3.3×10^{-6} mg/kg bw/day, the resulting risk index of ($1.9 \times 10^{-6}/3.3 \times 10^{-6}$ =) 0.56 is derived. Therefore no adverse effects from exposure to brodifacoum are expected for protected (gloves) professional user due to the application of Strong as a loose grain bait against rats and mice.

The RMS Ireland has also considered the application of Strong grain bait in protective sachets. Due to the sachets no exposure will occur during the loading phase, therefore only the exposure during the cleaning phase needs to be estimated. Based on the indicative value of 3.79 mg biocidal products on hands derived from the study of Chambers and Snowdon (2004)[1], the resulting exposure in case of 16 cleaning operations is:

3.79 x 16 = 60.64 mg biocidal product on hands

Correcting this value for 0.005% brodifacoum, 3% dermal absorption and 60 kg professional user body weight, the resulting systemic exposure to brodifacoum is:

60.64 x 0.005% x 3% / 60 = 1.5×10^{-6} mg/kg bw/day.

If this value is compared with the $AEL_{long\text{-}term}$ of 3.3×10^{-6} mg/kg bw/day, the resulting risk index is ($1.5 \times 10^{-6}/3.3 \times 10^{-6}$ =) 0.46. Based on this, no adverse systemic effects from systemic exposure to brodifacoum are expected for unprotected professional user during the use of Strong grain bait supplied in protective sachets.

The RMS Ireland has also considered a secondary exposure of children due to incidental swallowing of bait. For “transient mouthing of poison bait” scenario, an ingestion of 10 mg bait is considered by TNsG. This results in internal exposure of (10 x 0.005% x 100% / 10 kg =) 5×10^{-5} mg/kg bw for a 10 kg infant, considering 100% oral absorption of brodifacoum. Compared with the AEL_{acute} of 0.0000033 mg/kg bw/day, this results in the risk index of 15. Based on this, a concern for adverse effects due to secondary exposure of an infant that swallowed the bait exists.

Environment:
STRONG is a rodenticide, which is a ready-to-use cereal bait for professional use in buildings. The target organisms are rats and mice.
For details on the assessment of the exposure to the environment we refer to Product Assessment Report of the original authorisation.

2.7 Risk assessment for human health

For the risk assessment for human health we refer to Product Assessment Report of the original authorisation.

Based on the risk assessment no adverse effects from exposure to brodifacoum are expected for protected (gloves) professionals user during the application of Strong supplied as a loose grain bait for the control of rats and mice.
Based on the risk assessment no adverse effects from exposure to brodifacoum are expected for unprotected professional user during the application of Strong bait grain supplied in protective sachets for the control of rats and mice.

Based on the risk assessment adverse effects from secondary exposure to brodifacoum cannot be excluded for an infant incidentally swallowing the bait. Therefore the following precautionary phrases should be added to the product label:

- Keep out of the reach of children (P102)
- Prevent access to bait by children, domesticated animals and pets, (particularly cats, dogs and pigs).

When these risk management measures are taken into consideration, the risk of secondary exposure for children is considered to be mitigated.

2.8 Risk assessment for the environment

For the risk assessment for the environment we refer to Product Assessment Report of the original authorisation.

The product contains the active substance brodifacoum (0.005% w/w).
None of the co-formulants that carry an environmental classification are present at a sufficient concentration to trigger the classification of the product according to Regulation EC 1272/2008.

As the uncertainties with regard to the B-criterion cannot be clarified at the moment Brodifacoum should be considered a potential PBT. The CAR of brodifacoum of the Activa /Pelgar Brodifacoum and Difenacoum Task Force does not give information on endocrine disruptive properties of brodifacoum. According to the Commission staff working document on implementation of the Community Strategy for Endocrine Disrupters - a range of *substances suspected of interfering with the hormone systems of humans and wildlife (COM (1999) 706)*) the active substance is not considered as an endocrine disruptor.

In the CAR no major metabolites of brodifacoum were identified in water, sediment or soil, therefore an environmental assessment of major metabolites was not required.

The intended use concerns indoor use of the product for the professional control of mice and rats. Considering the risk of primary and secondary poisoning determined in the PAR the use needs to be restricted to indoors which is the case for mutual recognition of the product in the Netherlands. Furthermore, for the control of rats the product can only be authorised in the Netherlands for professional use. Further restrictions are necessary to prevent access of non-target animals to the product see section 2.9.

Overall conclusion for the aspect environment: The conclusions in the risk assessment of the RMS are valid for indoor use of the product by professionals.

2.9 Measures to protect man, animals and the environment

For the measures to protect animals and the environment we refer to Product Assessment Report of the original authorisation (annex 1). In the table below the measures are listed and evaluated whether the measures are appropriate for the Dutch legal instructions and directions for use (WG/GA). There are additional restrictions in the assessment report of the active substance that need to be put on the WG/GA, see bottom of table.

Measure	In WG/GA	WG/GA (in Dutch)
To avoid risks to human health and the environment,	Yes, partly	De dosering zoals aangegeven in de gebruiksaanwijzing moet worden

comply with the instructions for use		aangehouden.
Use bait containers clearly marked "poison" at all surface baiting points	Yes	De lokaasdozen markeren zodat duidelijk is dat ze rodenticiden bevatten.
Remove all remains of bait, dead rodents during and after treatment and dispose of safely	Yes	Wanneer de opname van lokaas is gestopt, de resten van het lokaas verzamelen en veilig verwijderen als gevaarlijk afval (cf. Eural). Dode dieren (de eerste kunnen na ± 3 dagen gevonden worden) eveneens verzamelen en in plastic verpakt in het vuilnisvat deponeren, opdat huisdieren en andere dieren niet door het opeten van de kadavers worden vergiftigd. Katten en honden tijdens een bestrijdingsactie extra goed voeren.
Prevent access to bait by children, domesticated animals and pets, (particularly cats, dogs and pigs).	Yes	Plaats het lokaas in lokaasdozen buiten bereik van andere dieren (bijvoorbeeld vogels, zoogdieren, huis- of landbouwdieren) en kinderen. Het lokaas zo vastmaken dat het niet weggesleept kan worden.
Harmful to wildlife		
It is illegal to use this product for uses or in a manner other than that prescribed on this label	No	Not applicable – the product will be used by highly trained professional users.
NOT for Amateur Sale	Yes	Het middel is uitsluitend bestemd voor professioneel gebruik.
Read attached instructions before use	No	Not applicable – the product will be used by highly trained professional users.
First Aid: In case of accident, suspected exposure or if you feel unwell, seek medical advice immediately (show the label where possible). In case of contact with skin, wash with soap and water. Remove and launder any contaminated clothing. In case of contact with eyes, remove contact lenses if present and rinse the eye slowly and gently with water for 15-20 minutes. Seek medical advice immediately. In case of ingestion or if swallowed seek medical advice immediately.	No	The first safety measures are not included in WG/GA, except the sentence “Tegengif: Vitamine K1 (onder medische begeleiding).”
Additional		
		Gebruik een schepje bij het vullen van lokaasdozen met los graanlokaas
		De lokaasdozen niet toepassen in de buurt van waterafvoersystemen waar het middel met water in contact kan komen.
		Het gebruik van dit middel is alleen toegestaan indien het een onderdeel vormt van een integrated pest

		management systeem (IPM). Het middel mag niet preventief gebruikt worden.
		Na gebruik handen wassen

3 Proposal for decision

The authorisation of Strong is based on mutual recognition of the authorisation of RMS IE. For the evaluation we refer to the product assessment report which has been composed by the RMS conform the Common Principles.

It is expected that the application of Strong according to the use instructions, will be effective and that there will be no harm for the health of humans, for those who use the product, and for the environment.

Proposal for the classification and labelling of the formulation
Based on the profile of the substance, the provided toxicology of the preparation, the characteristics of the co-formulants, the method of application and the risk assessment, the following labelling of the formulation is proposed:

The identity of all substances in the mixture that contribute to the classification of the mixture *:			
-			
Pictogram:	-	Signal word:	-
H-statements:	-	-	
P-statements:	P102	Keep out of reach of children	
	P262	Do not get in eyes, on skin or on clothing	
	P270	Do not eat, drink or smoke when using this product	
	P280a	Wear protective gloves.	
	P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor	
	P404	Store locked up	
Supplemental Hazard information:	-		
Child-resistant fastening obligatory?			Not applicable
Tactile warning of danger obligatory?			Not applicable