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Contents

[1] Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

DECISIONS

([1]) Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COUNCIL IMPLEMENTING REGULATION (EU) 2017/1374

of 25 July 2017

implementing Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EU) No 269/2014 of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine [1], and in particular Article 14(1) and (3) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 17 March 2014, the Council adopted Regulation (EU) No 269/2014.

(2) The Council has reviewed one individual designation set out in Annex I to Regulation (EU) No 269/2014. The entry for that person should be amended.

(3) Annex I to Regulation (EU) No 269/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EU) No 269/2014 shall be amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

[1] OJ L 78, 17.3.2014, p. 6.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Council
The President
M. MAASIKAS

ANNEX

In Annex I to Regulation (EU) No 269/2014, under the heading 'Persons', entry No 92 is replaced by the following:

	Name	Identifying information	Reasons	Date of listing
'92.	Arkady Romanovich ROTENBERG, Arkadii Romanovich ROTENBERG (Аркадий Романович РОТЕНБЕРГ)	DOB: 15.12.1951 POB: Leningrad (Saint Petersburg).	Arkady Rotenberg is a prominent Russian businessman who has close personal ties to President Putin. Since March 2014, Rotenberg, or his companies, have received State contracts totalling over USD 7 billion. In 2015, Rotenberg led the annual list of government contracts in terms of value, after being awarded contracts worth 555 billion roubles from the Russian Government. Many of these contracts were awarded without formal competitive processes. On 30 January 2015, Prime Minister Dmitry Medvedev signed a decree that awarded to Rotenberg's company, Stroygazmontazh, a State contract for the construction of the Kerch bridge from Russia to the illegally annexed Autonomous Republic of Crimea. Through these contracts he has financially benefited from Russian decision-makers responsible for the annexation of Crimea or the destabilisation of eastern Ukraine. He is the owner of the company Stroygazmontazh, which has been awarded a State contract for the construction of the Kerch bridge from Russia to the illegally annexed Autonomous Republic of Crimea, therefore consolidating its integration into the Russian Federation, which in turn further undermines the territorial integrity of Ukraine. Similarly, in January 2017, Stroygazmontazh was awarded the State contract worth 17 billion roubles for the construction of a railway line on the Kerch bridge, which again further undermines the territorial integrity of Ukraine. He is the chairman of the board of directors of publishing house Prosvescheniye, which has notably implemented the project "To the Children of Russia: Address — Crimea", a public relations campaign that was designed to persuade Crimean children that they are now Russian citizens living in Russia, and thereby supporting the Russian Government's policy to integrate Crimea into Russia.	30.7.2014'

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1375

of 25 July 2017

amending Implementing Regulation (EU) No 1191/2014 determining the format and means for submitting the report referred to in Article 19 of Regulation (EU) No 517/2014 of the European Parliament and of the Council on fluorinated greenhouse gases

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 517/2014 of the European Parliament and of the Council of 16 April 2014 on fluorinated greenhouse gases and repealing Regulation (EC) No 842/2006 ([1]), and in particular Article 19(7) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 1191/2014 ([2]) specifies the way information is reported pursuant to Article 19 of Regulation (EU) No 517/2014, in relation to the use of certain fluorinated greenhouse gases as feedstock or where products or equipment which contain those gases are placed on the market by producers, importers and exporters of those gases and by undertakings that destroy those gases.

(2) To enable the effective monitoring of compliance with the reporting obligations in Article 19 of Regulation (EU) No 517/2014, undertakings should be required, to register their use of the electronic reporting tool referred to in Article 1 of Implementing Regulation (EU) No 1191/2014 prior to carrying out relevant activities. This would enable Member State competent authorities to verify at the time of import, export or other relevant activity whether an undertaking would be subject to compliance verification based on its report under Article 19 of Regulation (EU) No 517/2014.

(3) The Annex to Implementing Regulation (EU) No 1191/2014 should be amended as regards the structure of the information required on certain characteristics of hydrofluorocarbons (HFC) in order to align it with the reporting format used by the parties to the Montreal Protocol on substances that deplete the ozone layer to the Vienna Convention for the Protection of the Ozone Layer ([3]) (Montreal Protocol). This would enable the Union to comply with its reporting obligations under Montreal Protocol. For the same reason, information on the destination of exports and the origin of imports should be also required to be reported as of 2020, which would provide sufficient time to adapt the electronic reporting tool.

(4) Additional differentiations and comments should added in Section 2 to reflect the reporting practice developed during the first two reporting cycles and the description in Section 12 should be clarified to avoid misinterpretations by reporting undertakings that occurred.

(5) Commission Implementing Regulation (EU) 2016/879 ([4]) established the electronic registry in relation to quotas for placing hydrofluorocarbons on the market in which all relevant data relating to authorisations referred to in Article 18(2) of Regulation (EU) No 517/2014 are recorded. The corresponding reporting format set out in Section 13 of the Annex to Implementing Regulation (EU) No 1191/2014 is therefore obsolete and should be deleted.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 24(1) of Regulation (EU) No 517/2014,

([1]) OJ L 150, 20.5.2014, p. 195.
([2]) Commission Implementing Regulation (EU) No 1191/2014 of 30 October 2014 determining the format and means for submitting the report referred to in Article 19 of Regulation (EU) No 517/2014 of the European Parliament and of the Council on fluorinated greenhouse gases (OJ L 318, 5.11.2014, p. 5).
([3]) Council Decision 88/540/EEC of 14 October 1988 concerning the conclusion of the Vienna Convention for the protection of the ozone layer and the Montreal Protocol on substances that deplete the ozone layer (OJ L 297, 31.10.1988, p. 8).
([4]) Commission Implementing Regulation (EU) 2016/879 of 2 June 2016 establishing, pursuant to Regulation (EU) No 517/2014 of the European Parliament and of the Council, detailed arrangements relating to the declaration of conformity when placing refrigeration, air conditioning and heat pump equipment charged with hydrofluorocarbons on the market and its verification by an independent auditor (OJ L 146, 3.6.2016, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) No 1191/2014 is amended as follows:

(1) Article 1 is replaced by the following:

'*Article 1*

1. The reports required in accordance with Article 19 of Regulation (EU) No 517/2014 shall be submitted electronically using the reporting tool based on the format set out in the Annex to this Regulation which is made available on the website of the Commission for that purpose.

2. Prior to carrying out the activities to be reported under Article 19 of Regulation (EU) No 517/2014, any undertaking shall register on the website of the Commission for using the electronic reporting tool.';

(2) the Annex is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

The Annex to Implementing Regulation (EU) No 1191/2014 is amended as follows:

(1) in Section 1, the table is replaced by the following:

	'INFORMATION TO BE REPORTED		**COMMENTS**
1A	Total quantity of production from facilities in the Union		
	1B	— quantity of production from facilities in the Union consisting of recovered by-production or unwanted products where that by-production or those products have been destroyed in the facilities prior to the placing on the market	Reports from producers which carry out destruction on the total quantities destroyed shall be made in reporting Section 8
	1C	— quantity of production from facilities in the Union consisting of recovered by-production or unwanted products where that by-production or those products have been handed over to other undertakings for destruction and had not been placed on the market previously	The undertaking carrying out the destruction shall be identified
	1C_a	Amount of hydrofluorocarbons produced for feedstock uses within the Union	
	1C_b	Amount of hydrofluorocarbons produced for uses within the Union exempted under the Montreal Protocol	The type of exempted use shall be specified
	AUTOMATICALLY CALCULATED QUANTITIES		
	1D	Total quantity of own production destroyed which has not been placed on the market previously	1D = 1B + 1C
1E	Production available for sale		1E = 1A – 1D'

(2) Section 2 is amended as follows:

(a) in the second paragraph, the following sentence is added:

'For the first time for the reporting on activities in 2019, quantities of hydrofluorocarbons shall be reported separately for each country of origin, except where indicated otherwise in the table below.';

(b) the table is replaced by the following:

	'INFORMATION TO BE REPORTED		**COMMENTS**
2A	Amount imported into the Union		
	2B	Amount imported into the Union by the reporting undertaking, not released for free circulation, and re-exported contained in products or equipment by the reporting undertaking	Reporting of hydrofluorocarbons by country of origin is not necessary. Bulk gases imported for inward processing, charged into products or equipment and subsequently re-exported. Where the re-export in products or equipment (Section 2B) does not take place in the same calendar year as the import, the quantities reported in Section 2B may include re-exports in products or equipment of 1 January stocks not placed on the Union market as reported in Section 4C Bulk gas exports shall only be reported in Section 3
	2C	Amount of used, recycled or reclaimed hydrofluorocarbons	
	2D	Amount of virgin hydrofluorocarbons imported for feedstock use	
	2E	Amount of virgin hydrofluorocarbons imported for uses exempted under the Montreal Protocol	The type of exempted use shall be specified'

(3) Section 3 is amended as follows:

(a) in the second paragraph, the following sentence is added:

'For the first time for the reporting on activities in 2019, quantities of hydrofluorocarbons shall be reported separately for each country of destination, except where indicated otherwise in the table below.';

(b) the table is replaced by the following:

	'INFORMATION TO BE REPORTED		**COMMENTS**
3A	Total amount exported from the Union		
	3B	Exported amounts from own production or import	Reporting by country of destination is not necessary
	AUTOMATICALLY CALCULATED QUANTITIES		
	3C	Exported amount purchased from other undertakings within the Union	3C = 3A – 3B

	INFORMATION TO BE REPORTED		COMMENTS
	INFORMATION TO BE REPORTED		
	3D	Amount exported for recycling	Reporting by country of destination is not necessary
	3E	Amount exported for reclamation	Reporting by country of destination is not necessary
	3F	Amount exported for destruction	Reporting by country of destination is not necessary
	3G	Amount of used, recycled or reclaimed hydrofluorocarbons exported	
	3H	Amount of virgin hydrofluorocarbons exported for feedstock use	
	3I	Amount of virgin hydrofluorocarbons exported for uses exempted under the Montreal Protocol	The type of exempted use shall be specified'

(4) in Section 4, the line referring to 4M of the table is replaced by the following:

'4M	Total amount physically placed on the market	4M = 1E + 2A − 2B − 3B + 4C − 4H'

(5) in Section 12, the table is replaced by the following:

	'INFORMATION TO BE REPORTED	**COMMENTS**
12A	Amount of hydrofluorocarbons charged into the imported equipment, released by customs for free circulation in the Union, for which the hydrofluorocarbons had previously been exported from the Union and which had been subject to the hydrofluorocarbon quota limitation for placing on the Union market	The hydrofluorocarbon exporting undertaking/s and the year/s of export shall be specified. The undertaking/s having placed the hydrofluorocarbons on the Union market for the first time and the year/s of that placing on the market shall be specified.'

(6) Section 13 is deleted.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1376

of 25 July 2017

renewing the approval of warfarin as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance warfarin is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Ireland as the evaluating competent authority.

(3) On 25 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of warfarin to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, warfarin meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1A. Warfarin therefore meets the exclusion criterion set in Article 5(1)(c) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing warfarin raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore warfarin also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of that Regulation.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on warfarin, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([4]), were discussed with Member States in the Standing Committee on Biocidal Products.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, warfarin is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of warfarin would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing warfarin can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of warfarin as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) is thus also satisfied.

(13) It is therefore appropriate to renew the approval of warfarin for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Warfarin is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) By Commission Implementing Decision (EU) 2016/135 [1], the initial expiry date of approval of flocoumafen, brodifacoum and warfarin for use in biocidal products of product-type 14 was postponed until 30 June 2018. As the examination of the applications for the renewal of those approvals is now finalised, it is appropriate to repeal Implementing Decision (EU) (EU) 2016/135.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of warfarin as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

Implementing Decision (EU) 2016/135 is repealed.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

[1] Commission Implementing Decision (EU) 2016/135 of 29 January 2016 postponing the expiry date of approval of flocoumafen, brodifacoum and warfarin for use in biocidal products for product-type 14 (OJ L 25, 2.2.2016, p. 65).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
Warfarin	IUPAC Name: (RS)-4-hydroxy-3-(3-oxo-1-phenylbutyl) coumarin EC No: 201-377-6 CAS No: 81-81-2	990 g/kg	30 June 2024	14	Warfarin is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. (2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. (3) The nominal concentration of warfarin in the products shall not exceed 790 mg/kg. (4) Products shall contain an aversive agent and a dye. (5) Products shall not be authorised in the form of tracking powder. (6) Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals. (7) Products shall not be authorised for use in permanent or pulse baiting treatments. (8) Only ready-to-use products shall be authorised. (9) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category. (10) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) Products shall only be authorised for use in tamper-resistant bait stations. (2) Products shall only be supplied with a maximum quantity of bait per pack of: (a) For products against mice only: (i) For grain, pellet or paste baits: 250 g. (ii) For wax block baits: 500 g. (b) For products against rats only, or mice and rats: (i) For grain, pellet or paste baits: 750 g. (ii) For wax block baits: 1 500 g. (3) Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings. (4) Products against *Mus musculus* shall only be authorised for use indoors. (5) Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken. (6) Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) Products shall not be authorised for use in sewers, open area or waste dumps. (2) Products shall only be authorised for use in tamper-resistant bait stations. (3) Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) Products may be authorised for use in sewers, open area or waste dumps. (2) Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. (3) Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1377

of 25 July 2017

renewing the approval of chlorophacinone as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance chlorophacinone is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Spain as the evaluating competent authority.

(3) On 25 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of chlorophacinone to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, chlorophacinone meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. Chlorophacinone therefore meets the exclusion criterion set out in Article 5(1)(c) of Regulation (EU) No 528/2012.

(6) In addition, the substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being persistent and toxic. The use of products containing chlorophacinone raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied. Therefore chlorophacinone also satisfies the criterion to be a candidate for substitution in accordance with points (d) and (e) of Article 10(1) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on chlorophacinone, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, chlorophacinone is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of chlorophacinone would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing chlorophacinone can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of chlorophacinone as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) is thus also satisfied.

(13) It is therefore appropriate to renew the approval of chlorophacinone for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Chlorophacinone is a candidate for substitution in accordance with points (a), (d) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) By Commission Implementing Decision (EU) 2015/1737 ([2]), the initial expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products of product-type 14 was postponed to 30 June 2018. As the examination of the applications for the renewal of those approvals is now finalised, it is appropriate to repeal Implementing Decision (EU) 2015/1737.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of chlorophacinone as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

Implementing Decision (EU) 2015/1737 is repealed.

([1]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision (EU) 2015/1737 of 28 September 2015 postponing the expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products for product-type 14 (OJ L 252, 29.9.2015, p. 58).

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
Chlorophacinone	IUPAC Name: 2-[2-(4-chlorophenyl)-2-phenylacetyl] indan-1,3-dione EC No: 223-003-0 CAS No: 3691-35-8	978 g/kg	30 June 2024	14	Chlorophacinone is considered a candidate for substitution in accordance with points (a), (d) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2. Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. 3. The nominal concentration of chlorophacinone in the products shall not exceed 50 mg/kg in products other than contact formulations and shall not exceed 2 000 mg/kg in contact formulations. 4. Products shall contain an aversive agent and a dye. 5. Products shall not be authorised in the form of tracking powder. 6. Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals. 7. Products shall not be authorised for use in permanent or pulse baiting treatments. 8. Only ready-to-use products shall be authorised. 9. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category. 10. Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: 1. Products shall only be authorised for use in tamper-resistant bait stations. 2. Products shall only be supplied with a maximum quantity of bait per pack of: a) For products against mice only: i) For grain, pellet or paste baits: 250 g. ii) For wax block baits: 500 g. b) For products against rats only, or mice and rats: i) For grain, pellet or paste baits: 750 g. ii) For wax block baits: 1 500 g. 3. Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings. 4. Products against *Mus musculus* shall only be authorised for use indoors. 5. Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken. 6. Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: 1. Products shall not be authorised for use in sewers, open area or waste dumps. 2. Products shall only be authorised for use in tamper-resistant bait stations. 3. Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: 1. Products may be authorised for use in sewers, open area or waste dumps. 2. Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. 3. Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1378

of 25 July 2017

renewing the approval of coumatetralyl as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance coumatetralyl is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Denmark as the evaluating competent authority.

(3) On 23 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of coumatetralyl to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, coumatetralyl meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. Coumatetralyl therefore meets the exclusion criterion set out in Article 5(1)(c) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing coumatetralyl raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore coumatetralyl also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on coumatetralyl, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, coumatetralyl is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of coumatetralyl would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing coumatetralyl can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of coumatetralyl as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of coumatetralyl for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Coumatetralyl is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision (EU) 2015/1737 ([2]) is repealed by Implementing Regulation (EU) 2017/1377 ([3]).

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of coumatetralyl as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) *Risk mitigation measures for anticoagulant rodenticides — Final Report*. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision (EU) 2015/1737 of 28 September 2015 postponing the expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products for product-type 14 (OJ L 252, 29.9.2015, p. 58).

([3]) Commission Implementing Regulation (EU) 2017/1377 of 25 July 2017 renewing the approval of chlorophacinone as an active substance for use in biocidal products of product-type 14 (see page 15 of this Official Journal).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
Coumatetralyl	IUPAC Name: 4-hydroxy-3-(1, 2, 3, 4-tetrahydro-1-naphthyl) coumarin EC No: 227-424-0 CAS No: 5836-29-3	980 g/kg	30 June 2024	14	Coumatetralyl is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. (2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. (3) The nominal concentration of coumatetralyl in the products shall not exceed 375 mg/kg in products other than contact formulations and shall not exceed 4 000 mg/kg in contact formulations. (4) Products shall contain an aversive agent and a dye. (5) Products shall not be authorised in the form of tracking powder. (6) Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals. (7) Products shall not be authorised for use in permanent or pulse baiting treatments. (8) Only ready-to-use products shall be authorised. (9) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category. (10) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) Products shall only be authorised for use in tamper-resistant bait stations. (2) Products shall only be supplied with a maximum quantity of bait per pack of: (a) for products against mice only: (i) For grain, pellet or paste baits: 250 g; (ii) For wax block baits: 500 g; (b) for products against rats only, or mice and rats: (i) for grain, pellet or paste baits: 750 g; (ii) for wax block baits: 1 500 g. (3) Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings. (4) Products against *Mus musculus* shall only be authorised for use indoors. (5) Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken. (6) Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) Products shall not be authorised for use in sewers, open area or waste dumps. (2) Products shall only be authorised for use in tamper-resistant bait stations. (3) Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) Products may be authorised for use in sewers, open area or waste dumps. (2) Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. (3) Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1379

of 25 July 2017

renewing the approval of difenacoum as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance difenacoum is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Finland as the evaluating competent authority.

(3) On 24 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of difenacoum to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, difenacoum meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being very persistent, bioaccumulative and toxic. Difenacoum therefore meets the exclusion criteria set in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing difenacoum raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore difenacoum also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on difenacoum, including information on available substitutes.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

(10) The contributions to the two abovementioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk-mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, difenacoum is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of difenacoum would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing difenacoum can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of difenacoum as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of difenacoum for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Difenacoum is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) By Commission Implementing Decision 2014/397/EU ([2]), the initial expiry date of approval of difethialone and difenacoum for use in biocidal products of product-type 14 was postponed to 30 June 2018. As the examination of the applications for the renewal of those approvals is now finalised, it is appropriate to repeal Implementing Decision 2014/397/EU.

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of difenacoum as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

Implementing Decision 2014/397/EU is repealed.

([1]) *Risk mitigation measures for anticoagulant rodenticides — Final Report*. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision 2014/397/EU of 25 June 2014 postponing the expiry date of approval of difethialone and difenacoum for use in biocidal products for product-type 14 (OJ L 186, 26.6.2014, p. 111).

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Expiry date of approval	Product type	Specific conditions
Difenacoum	IUPAC Name: 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin EC No: 259-978-4 CAS No: 56073-07-5	960g/kg Sum of isomers in a ratio of 50 %-80 % cis and 20 %-50 % trans isomers	30 June 2024	14	Difenacoum is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union-level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. (2) Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. (3) The nominal concentration of difenacoum in the products shall not exceed 75 mg/kg. (4) Products shall contain an aversive agent and a dye. (5) Products shall not be authorised in the form of tracking powder. (6) Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals. (7) Only ready-to-use products shall be authorised. (8) Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk-mitigation measures. These include, for example, the restriction to professional or trained professional use when possible and setting additional specific conditions per user category. (9) Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) Products shall only be authorised for use in tamper-resistant bait stations. (2) Products shall only be supplied with a maximum quantity of bait per pack of: (a) for products against mice only: (i) for grain, pellet or paste baits: 50 g; (ii) for wax block baits: 100 g; (b) for products against rats only, or mice and rats: (i) for grain, pellet or paste baits: 150 g; (ii) for wax block baits: 300 g. (3) Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings. (4) Products against *Mus musculus* shall only be authorised for use indoors. (5) Products shall not be authorised for use in permanent or pulse baiting treatments. (6) Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken. (7) Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) Products shall not be authorised for use in sewers, open area or waste dumps. (2) Products shall not be authorised for use in permanent or pulse baiting treatments.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					(3) Products shall only be authorised for use in tamper-resistant bait stations. (4) Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) Products may be authorised for use in sewers, open area or waste dumps. (2) Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. (3) Products shall not be authorised for use in pulse baiting treatments. (4) Products may only be authorised for use in permanent baiting treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient. (5) Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1380

of 25 July 2017

renewing the approval of bromadiolone as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance bromadiolone is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Italy as the evaluating competent authority.

(3) On 25 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of bromadiolone to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, bromadiolone meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being persistent, bioaccumulative and toxic. Bromadiolone therefore meets the exclusion criteria set out in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing bromadiolone raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore bromadiolone also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on bromadiolone, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, bromadiolone is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of bromadiolone would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing bromadiolone can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of bromadiolone as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of bromadiolone for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Bromadiolone is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision (EU) 2015/1737 ([2]) is repealed by Implementing Regulation (EU) 2017/1377 ([3]).

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of bromadiolone as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision (EU) 2015/1737 of 28 September 2015 postponing the expiry date of approval of bromadiolone, chlorophacinone and coumatetralyl for use in biocidal products for product-type 14 (OJ L 252, 29.9.2015, p. 58).

([3]) Commission Implementing Regulation (EU) 2017/1377 of 25 July 2017 renewing the approval of chlorophacinone as an active substance for use in biocidal products of product-type 14 (see page 15 of this Official Journal).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
Bromadiolone	IUPAC Name: 3-[(1RS,3RS;1RS,3SR)-3-(4′-bromobiphenyl-4-yl)-3-hydroxy-1-phenyl-propyl]-4-hydroxy-coumarin EC No: 249-205-9 CAS No: 28772-56-7	969 g/kg	30 June 2024	14	Bromadiolone is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied; (2) products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied; (3) the nominal concentration of bromadiolone in the products shall not exceed 50 mg/kg; (4) products shall contain an aversive agent and a dye; (5) products shall not be authorised in the form of tracking powder; (6) products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals; (7) only ready-to-use products shall be authorised; (8) primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category; (9) dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) products shall only be authorised for use in tamper-resistant bait stations; (2) products shall only be supplied with a maximum quantity of bait per pack of: (a) for products against mice only: (i) for grain, pellet or paste baits: 50 g; (ii) for wax block baits: 100 g; (b) for products against rats only, or mice and rats: (i) for grain, pellet or paste baits: 150 g; (ii) for wax block baits: 300 g; (3) products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings; (4) products against *Mus musculus* shall only be authorised for use indoors; (5) products shall not be authorised for use in permanent or pulse baiting treatments; (6) persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken; (7) products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) products shall not be authorised for use in sewers, open area or waste dumps; (2) products shall not be authorised for use in permanent or pulse baiting treatments;

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					(3) products shall only be authorised for use in tamper-resistant bait stations; (4) persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) products may be authorised for use in sewers, open area or waste dumps; (2) products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations; (3) products shall not be authorised for use in pulse baiting treatments; (4) products may only be authorised for use in permanent baiting treatments at those sites with a high potential for reinvasion when other methods of control have proven insufficient; (5) persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1381

of 25 July 2017

renewing the approval of brodifacoum as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance brodifacoum is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, two applications were submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. These applications were evaluated by the competent authorities of the Netherlands and Italy as the evaluating competent authorities.

(3) On 26 March 2016, the evaluating competent authority of the Netherlands submitted its recommendation on the renewal of the approval of brodifacoum to the Agency, covering also the application evaluated by Italy.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, brodifacoum meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1A. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being very persistent, bioaccumulative and toxic. Brodifacoum therefore meets the exclusion criteria set out in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing brodifacoum raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore brodifacoum also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on brodifacoum, including information on available substitutes.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

(10) The contributions to the two abovementioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, brodifacoum is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of brodifacoum would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing brodifacoum can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of brodifacoum as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of brodifacoum for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Brodifacoum is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of flocoumafen, brodifacoum and warfarin for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision (EU) 2016/135 ([2]) is repealed by Implementing Regulation (EU) 2017/1376. ([3])

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of brodifacoum as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision (EU) 2016/135 of 29 January 2016 postponing the expiry date of approval of flocoumafen, brodifacoum and warfarin for use in biocidal products for product-type 14 (OJ L 25, 2.2.2016, p. 65).

([3]) Implementing Regulation (EU) 2017/1376 of 25 July 2017 renewing the approval of warfarin as an active substance for use in biocidal products of product-type 14 (see page 9 of this Official Journal).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
Brodifacoum	IUPAC Name: 3-[(1RS,3RS;1RS,3SR)-3-(4′-bromobiphenyl-4-yl)-1,2,3,4-tetrahydro-1-naphthyl]-4-hydroxy-coumarin EC No: 259-980-5 CAS No: 56073-10-0	950 g/kg	30 June 2024	14	Brodifacoum is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied; (2) products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied; (3) the nominal concentration of brodifacoum in the products shall not exceed 50 mg/kg; (4) products shall contain an aversive agent and a dye; (5) products shall not be authorised in the form of tracking powder; (6) products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals; (7) only ready-to-use products shall be authorised; (8) primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category; (9) dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) products shall only be authorised for use in tamper-resistant bait stations; (2) products shall only be supplied with a maximum quantity of bait per pack of: (a) for products against mice only: (i) for grain, pellet or paste baits: 50 g; (ii) for wax block baits: 100g; (b) for products against rats only, or mice and rats: (i) for grain, pellet or paste baits: 150 g; (ii) for wax block baits: 300g; (3) products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings; (4) products against *Mus musculus* shall only be authorised for use indoors; (5) products shall not be authorised for in permanent or pulse baiting treatments; (6) persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken; (7) products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) products shall not be authorised for use in sewers, open area or waste dumps; (2) products shall not be authorised for use in permanent or pulse baiting treatments;

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					(3) products shall only be authorised for use in tamper-resistant bait stations; (4) persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) products may be authorised for use in sewers, open area or waste dumps; (2) products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations; (3) products may be authorised for use in pulse baiting treatments; (4) products shall not be authorised for use in permanent baiting treatments; (5) persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1382

of 25 July 2017

renewing the approval of difethialone as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance difethialone is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of Norway as the evaluating competent authority.

(3) On 21 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of difethialone to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, difethialone meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being very persistent, bioaccumulative and toxic. Difethialone therefore meets the exclusion criteria set in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing difethialone raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore difethialone also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of Regulation (EU) No 528/2012.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on difethialone, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, difethialone is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of difethialone would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) of Regulation (EU) No 528/2012 is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing difethialone can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of difethialone as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) of Regulation (EU) No 528/2012 is thus also satisfied.

(13) It is therefore appropriate to renew the approval of difethialone for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Difethialone is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of difethialone and difenacoum for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision 2014/397/EU ([2]) is repealed by Implementing Regulation (EU) 2017/1379 ([3]).

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of difethialone as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision 2014/397/EU of 25 June 2014 postponing the expiry date of approval of difethialone and difenacoum for use in biocidal products for product-type 14 (OJ L 186, 26.6.2014, p. 111).

([3]) Commission Implementing Regulation (EU) 2017/1379 of 25 July 2017 renewing the approval of difenacoum as an active substance for use in biocidal products of product-type 14 (see page 27 of this Official Journal).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
Difethialone	IUPAC Name: 3-[3-(4′-bromo[1,1′biphenyl]-4-yl)-1,2,3,4-tetrahydronaphth-1-yl]-4-hydroxy-2H-1-benzothiopyran-2-one EC No: Not available CAS No: 104653-34-1	976 g/kg The specification of purity is based on the combined concentration of both diastereoisomers (cis and trans).	30 June 2024	14	Difethialone is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: 1. The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. 2. Products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied. 3. The nominal concentration of difethialone in the products shall not exceed 25 mg/kg. 4. Products shall contain an aversive agent and a dye. 5. Products shall not be authorised in the form of tracking powder. 6. Products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals. 7. Only ready-to-use products shall be authorised. 8. Primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category. 9. Dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: 1. Products shall only be authorised for use in tamper-resistant bait stations. 2. Products shall only be supplied with a maximum quantity of bait per pack of: a) For products against mice only: i) For grain, pellet or paste baits: 50 g. ii) For wax block baits: 100 g. b) For products against rats only, or mice and rats: i) For grain, pellet or paste baits: 150 g. ii) For wax block baits: 300 g. 3. Products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings. 4. Products against *Mus musculus* shall only be authorised for use indoors. 5. Products shall not be authorised for use in permanent or pulse baiting treatments. 6. Persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken. 7. Products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: 1. Products shall not be authorised for use in sewers, open area or waste dumps. 2. Products shall not be authorised for use in permanent or pulse baiting treatments.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Expiry date of approval	Product type	Specific conditions
					3. Products shall only be authorised for use in tamper-resistant bait stations. 4. Persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: 1. Products may be authorised for use in sewers, open area or waste dumps. 2. Products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. 3. Products may be authorised for use in pulse baiting treatments. 4. Products shall not be authorised for use in permanent baiting treatments. 5. Persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

(1) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1383

of 25 July 2017

renewing the approval of flocoumafen as an active substance for use in biocidal products of product-type 14

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(4)(a) thereof,

Whereas:

(1) The active substance flocoumafen is approved for use in biocidal products of product-type 14 as a rodenticide under Regulation (EU) No 528/2012.

(2) In accordance with Article 13(1) of Regulation (EU) No 528/2012, an application was submitted to the European Chemicals Agency ('the Agency') for the renewal of the approval of that active substance. This application was evaluated by the competent authority of the Netherlands as the evaluating competent authority.

(3) On 26 March 2016, the evaluating competent authority submitted its recommendation on the renewal of the approval of flocoumafen to the Agency.

(4) On 16 June 2016, the opinion of the Agency was formulated by its Biocidal Products Committee ([2]), having regard to the conclusions of the evaluating competent authority.

(5) According to that opinion, flocoumafen meets the criteria in Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([3]) to be classified as toxic for reproduction category 1B. The substance also meets the criteria in Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([4]) for being very persistent, very bioaccumulative and toxic. Flocoumafen therefore meets the exclusion criteria set out in points (c) and (e) of Article 5(1) of Regulation (EU) No 528/2012.

(6) In addition, the use of products containing flocoumafen raises concerns in relation to instances of primary and secondary poisoning, even where restrictive risk management measures are applied and therefore flocoumafen also satisfies the criterion to be a candidate for substitution in accordance with Article 10(1)(e) of that Regulation.

(7) Pursuant to Article 12 of Regulation (EU) No 528/2012, the approval of active substances meeting the exclusion criteria may only be renewed when at least one of the conditions for derogation set out in Article 5(2) of that Regulation continues to be satisfied.

(8) In accordance with Article 10(3) of Regulation (EU) No 528/2012, the Agency organised a public consultation in order to collect relevant information on flocoumafen, including information on available substitutes.

(9) The Commission also carried out a specific public consultation in order to gather information as to whether the conditions for derogation set out in Article 5(2) of Regulation (EU) No 528/2012 were satisfied. The Commission made the contributions to that consultation publicly available.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/bpc-opinions-on-active-substance-approval
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).
([4]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

(10) The contributions to the two above-mentioned public consultations, as well as the information regarding the availability of alternatives to anticoagulant rodenticides included in Annex 1 to the Commission report on risk mitigation measures for anticoagulant rodenticides ([1]), were discussed with Member States in the Standing Committee on Biocidal Products.

(11) Rodents can carry pathogens that are responsible for many zoonoses, which can pose serious dangers for human or animal health. Non-chemical controls or prevention methods for rodent control, such as mechanical, electrical or glue traps, may not be sufficiently efficient and may raise further questions as to whether they are humane or whether they cause unnecessary suffering to rodents. Alternative active substances approved for use as rodenticides may not be suitable for all user categories or efficient for all rodent species. As effective rodent control cannot rely on those non-chemical controls or prevention methods only, flocoumafen is considered essential to ensure appropriate rodent control in support of those alternatives. As a consequence the use of flocoumafen would be to prevent or control a serious danger to human and animal health in which rodents are involved. Therefore, the condition set out in Article 5(2)(b) is satisfied.

(12) Rodent control currently relies largely on the use of anticoagulant rodenticides, the non-approval of which could lead to insufficient rodent control. This may not only cause significant negative impacts on human or animal health or the environment, but also affect the public's perception of its safety with regard to exposure to rodents or the security of a number of economic activities that could be vulnerable to rodents, resulting in economic and social consequences. On the other hand, the risks to human health, animal health or the environment arising from use of products containing flocoumafen can be mitigated if they are used according to certain specifications and conditions. Therefore, the non-approval of flocoumafen as an active substance would have a disproportionate negative impact on society in comparison to the risks arising from the use of the substance. The condition set out in Article 5(2)(c) is thus also satisfied.

(13) It is therefore appropriate to renew the approval of flocoumafen for use in biocidal products of product-type 14, subject to compliance with certain specifications and conditions.

(14) Flocoumafen is a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012 and therefore the period of renewal set out in Article 10(4) of that Regulation should apply.

(15) As the examination of the applications for the renewal of the approval of flocoumafen, brodifacoum and warfarin for use in biocidal products of product-type 14 is now finalised, Commission Implementing Decision (EU) 2016/135 ([2]) is repealed by Commission Implementing Regulation (EU) 2017/1376 ([3]).

(16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

The approval of flocoumafen as an active substance for use in biocidal products of product-type 14 is renewed, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

([1]) Risk mitigation measures for anticoagulant rodenticides — Final Report. European Commission (2014), Brussels, Belgium. 100 pp. ISBN 978-92-79-44992-5.

([2]) Commission Implementing Decision (EU) 2016/135 of 29 January 2016 postponing the expiry date of approval of flocoumafen, brodifacoum and warfarin for use in biocidal products for product-type 14 (OJ L 25, 2.2.2016, p. 65).

([3]) Commission Implementing Regulation (EU) 2017/1376 of 25 July 2017 renewing the approval of warfarin as an active substance for use in biocidal products of product-type 14 (see page 9 of this Official Journal).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Expiry date of approval	Product type	Specific conditions
Flocoumafen	IUPAC Name: 4-hydroxy-3-[(1RS,3RS;1RS,3RS)-1,2,3,4-tetrahydro-3-[4-(4-trifluoromethylbenzyloxy)phenyl]-1-naphthyl]coumarin EC No: 421-960-0 CAS No: 90035-08-8	955 g/kg (sum of isomers in a ratio of 50-80 % cis and 20-50 % trans isomers)	30 June 2024	14	Flocoumafen is considered a candidate for substitution in accordance with points (a) and (e) of Article 10(1) of Regulation (EU) No 528/2012. The authorisations of biocidal products are subject to the following general conditions: (1) the product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied; (2) products shall only be authorised for use in Member States where at least one of the conditions set out in Article 5(2) of Regulation (EU) No 528/2012 is satisfied; (3) the nominal concentration of flocoumafen in the products shall not exceed 50 mg/kg; (4) products shall contain an aversive agent and a dye; (5) products shall not be authorised in the form of tracking powder; (6) products in the form of contact formulations, other than tracking powder, shall only be authorised for use by trained professionals indoors in places not accessible to children or non-target animals; (7) only ready-to-use products shall be authorised; (8) primary as well as secondary exposure of humans, non-target animals and the environment are minimised, by considering and applying all appropriate and available risk mitigation measures. These include for example the restriction to professional or trained professional use when possible and setting additional specific conditions per user category; (9) dead bodies and uneaten bait shall be disposed of in accordance with local requirements. The method of disposal shall be described specifically in the summary of the product characteristics of the national authorisation and be reflected on the product label.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance [1]	Expiry date of approval	Product type	Specific conditions
					In addition to the general conditions, the authorisations of biocidal products to be used by the general public are subject to the following conditions: (1) products shall only be authorised for use in tamper-resistant bait stations; (2) products shall only be supplied with a maximum quantity of bait per pack of: (a) for products against mice only: (i) for grain, pellet or paste baits: 50 g; (ii) for wax block baits: 100 g; (b) for products against rats only, or mice and rats: (i) for grain, pellet or paste baits: 150 g; (ii) for wax block baits: 300 g; (3) products against *Rattus norvegicus* and *Rattus rattus* shall only be authorised for use indoors or in and around buildings; (4) products against *Mus musculus* shall only be authorised for use indoors; (5) products shall not be authorised for use as in permanent or pulse baiting treatments; (6) persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken; (7) products in the form of loose bait formulations, such as grain or pellets, shall only be authorised in formulations that are supplied in sachets or other packaging to reduce exposure to humans and the environment. In addition to the general conditions, the authorisations of biocidal products to be used by professionals are subject to the following conditions: (1) products shall not be authorised for use in sewers, open area or waste dumps; (2) products shall not be authorised for use in permanent or pulse baiting treatments;

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ([1])	Expiry date of approval	Product type	Specific conditions
					(3) products shall only be authorised for use in tamper-resistant bait stations; (4) persons making products for professional users available on the market shall make sure that these products are not supplied to the general public. In addition to the general conditions, the authorisations of biocidal products to be used by trained professionals are subject to the following conditions: (1) products may be authorised for use in sewers, open area or waste dumps; (2) products may be authorised for use in covered and protected bait points as long as they provide the same level of protection for non-target species and humans as tamper-resistant bait stations; (3) products may be authorised for use in pulse baiting treatments; (4) products shall not be authorised for use in permanent baiting treatments; (5) persons making products for trained professional users available on the market shall make sure that the products are not supplied to other persons than trained professionals.

([1]) The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1384

of 25 July 2017

on the issue of licences for importing rice under the tariff quotas opened for the July 2017 subperiod by Implementing Regulation (EU) No 1273/2011

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]), and in particular Article 188 thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 1273/2011 ([2]) opened and provided for the administration of certain import tariff quotas for rice and broken rice, broken down by country of origin and split into several subperiods in accordance with Annex I to that Implementing Regulation.

(2) July is the third subperiod for the quota provided for under Article 1(1)(a) of Implementing Regulation (EU) No 1273/2011 and the second subperiod for the quotas provided for under Article 1(1)(b), (c) and (d) of that Implementing Regulation.

(3) The notifications sent in accordance with point (a) of Article 8 of Implementing Regulation (EU) No 1273/2011 show that, for the quotas with order number 09.4154 and 09.4166, the applications lodged in the first 10 working days of July 2017 under Article 4(1) of that Implementing Regulation cover a quantity greater than that available. The extent to which import licences may be issued should therefore be determined by fixing the allocation coefficient to be applied to the quantities requested under the quotas concerned, calculated in accordance with Article 7(2) of Commission Regulation (EC) No 1301/2006 ([3]).

(4) Those notifications also show that, for the quotas with order number 09.4127 — 09.4128 — 09.4129 — 09.4148 — 09.4149 — 09.4150 — 09.4152 and 09.4153, the applications lodged in the first 10 working days of July 2017 under Article 4(1) of Implementing Regulation (EU) No 1273/2011 cover a quantity less than that available.

(5) The total quantity available for the following subperiod should also be fixed for the quotas with order number 09.4127 — 09.4128 — 09.4129 — 09.4130 — 09.4148 — 09.4112 — 09.4116 — 09.4117 — 09.4118 — 09.4119 and 09.4166, in accordance with the first subparagraph of Article 5 of Implementing Regulation (EU) No 1273/2011.

(6) In order to ensure sound management of the procedure of issuing import licences, this Regulation should enter into force immediately after its publication,

HAS ADOPTED THIS REGULATION:

Article 1

1. For import licence applications for rice under the quotas with order number 09.4154 and 09.4166 referred to in Implementing Regulation (EU) No 1273/2011 lodged in the first 10 working days of July 2017, licences shall be issued for the quantity requested, multiplied by the allocation coefficient set out in the Annex to this Regulation.

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) Commission Implementing Regulation (EU) No 1273/2011 of 7 December 2011 opening and providing for the administration of certain tariff quotas for imports of rice and broken rice (OJ L 325, 8.12.2011, p. 6).
([3]) Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences (OJ L 238, 1.9.2006, p. 13).

2. The total quantity available for the following subperiod under the quotas with order number 09.4127 — 09.4128 — 09.4129 — 09.4130 — 09.4148 — 09.4112 — 09.4116 — 09.4117 — 09.4118 — 09.4119 and 09.4166 referred to in Implementing Regulation (EU) No 1273/2011 is set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 25 July 2017.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General
Directorate-General for Agriculture and Rural Development

ANNEX

Quantities to be allocated for the July 2017 subperiod and quantities available for the following subperiod under Implementing Regulation (EU) No 1273/2011

(a) Quota of wholly milled or semi-milled rice covered by CN code 1006 30 as provided for in Article 1(1)(a) of Implementing Regulation (EU) No 1273/2011:

Origin	Order number	Allocation coefficient for July 2017 subperiod	Total quantity available for September 2017 subperiod (kg)
United States	09.4127	— (1)	12 629 487
Thailand	09.4128	— (1)	369 596
Australia	09.4129	— (1)	911 500
Other origins	09.4130	— (2)	4 796

(1) Applications cover quantities less than or equal to the quantities available: all applications are therefore acceptable.
(2) No quantity available for this subperiod.

(b) Quota of husked rice covered by CN code 1006 20 as provided for in Article 1(1)(b) of Implementing Regulation (EU) No 1273/2011:

Origin	Order number	Allocation coefficient for July 2017 subperiod	Total quantity available for October 2017 subperiod (kg)
All countries	09.4148	— (1)	1 610 500

(1) No allocation coefficient applied for this subperiod: no licence applications were notified to the Commission.

(c) Quota of broken rice covered by CN code 1006 40 00 as provided for in Article 1(1)(c) of Implementing Regulation (EU) No 1273/2011:

Origin	Order number	Allocation coefficient for July 2017 subperiod
Thailand	09.4149	— (1)
Australia	09.4150	— (2)
Guyana	09.4152	— (2)
United States	09.4153	— (1)
Other origins	09.4154	78,636985 %

(1) Applications cover quantities less than or equal to the quantities available: all applications are therefore acceptable.
(2) No allocation coefficient applied for this subperiod: no licence applications were notified to the Commission.

(d) Quota of wholly milled or semi-milled rice covered by CN code 1006 30 as provided for in Article 1(1)(d) of Implementing Regulation (EU) No 1273/2011:

Origin	Order number	Allocation coefficient for July 2017 subperiod	Total quantity available for September 2017 subperiod (kg)
Thailand	09.4112	— (1)	20 965
United States	09.4116	— (1)	822

Origin	Order number	Allocation coefficient for July 2017 subperiod	Total quantity available for September 2017 subperiod (kg)
India	09.4117	— (1)	89 276
Pakistan	09.4118	— (1)	55 110
Other origins	09.4119	— (1)	14 199
All countries	09.4166	0,703025 %	0

(1) No quantity available for this subperiod.

DECISIONS

COUNCIL DECISION (CFSP) 2017/1385

of 25 July 2017

amending Decision (CFSP) 2015/778 on a European Union military operation in the Southern Central Mediterranean (EUNAVFOR MED operation SOPHIA)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 42(4) and 43(2) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 18 May 2015, the Council adopted Decision (CFSP) 2015/778 ([1]).

(2) On 20 June 2016, the Council adopted Decision (CFSP) 2016/993, ([2]) which amended Decision (CFSP) 2015/778 by extending the operation's mandate until 27 July 2017 and by adding two supporting tasks to EUNAVFOR MED operation SOPHIA's mandate, namely capacity building and training of the Libyan Coastguard and Navy, and contributing to information sharing and to the implementation of the UN arms embargo on the high seas off the coast of Libya.

(3) On 19 December 2016, the Council adopted Decision (CFSP) 2016/2314, ([3]) which enhanced the authorisations granted to EUNAVFOR MED operation SOPHIA to exchange information with relevant actors.

(4) On 3 February 2017, the Malta Declaration by the members of the European Council on *the external aspects of migration: addressing the Central Mediterranean route* affirmed that priority will notably be given to training, equipment and support to the Libyan national Coast Guard and other relevant agencies and to further efforts to disrupt the business model of smugglers through enhanced operational action, within an integrated approach involving Libya and other countries on the route as well as relevant international partners, engaged Member States, CSDP missions and operations, Europol and the European Border and Coast Guard Agency (Frontex).

(5) On 6 February 2017, in its conclusions on Libya, the Council stated that EUNAVFOR MED operation SOPHIA will continue to focus on disrupting the business model of human smuggling and trafficking networks; in addition, it will continue to implement its two supporting tasks.

(6) The contribution by EUNAVFOR MED operation SOPHIA to information sharing may also contribute to implementing UN Security Council Resolutions ('UNSCR') 2146 (2014) and UNSCR 2362 (2017).

(7) On 12 June 2017, by UNSCR 2357 (2017), the UN Security Council renewed the authorisations granted by UNSCR 2292 (2016), which concerns the strict implementation of the arms embargo on the high seas off the coast of Libya.

(8) On 23 June 2017, the European Council notably underlined in its conclusions that the disruption of the business model of human smugglers and traffickers remains a key objective, and that training and equipping the Libyan Coast Guard is a key component of the EU approach in this regard.

(9) On 4 July 2017, based on the strategic review of the operation, the Political and Security Committee agreed to extend the mandate of EUNAVFOR MED operation SOPHIA until 31 December 2018.

([1]) Council Decision (CFSP) 2015/778 of 18 May 2015 on a European Union military operation in the Southern Central Mediterranean (EUNAVFOR MED operation SOPHIA) (OJ L 122, 19.5.2015, p. 31).

([2]) Council Decision (CFSP) 2016/993 of 20 June 2016 amending Decision (CFSP) 2015/778 on a European Union military operation in the Southern Central Mediterranean (EUNAVFOR MED operation SOPHIA) (OJ L 162, 21.6.2016, p. 18).

([3]) Council Decision (CFSP) 2016/2314 of 19 December 2016 amending Decision (CFSP) 2015/778 on a European Union military operation in the Southern Central Mediterranean (EUNAVFOR MED operation SOPHIA) (OJ L 345, 20.12.2016, p. 62).

(10) Decision (CFSP) 2015/778 should be amended accordingly.

(11) In accordance with Article 5 of Protocol No 22 on the position of Denmark annexed to the TEU and to the Treaty on the Functioning of the European Union (TFEU), Denmark does not participate in the elaboration and implementation of decisions and actions of the Union which have defence implications. Consequently, Denmark is not participating in the adoption of this Decision, is neither bound by it nor subject to its application, and does not participate in the financing of this operation,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2015/778 is amended as follows:

(1) In Article 2(4), the last sentence is replaced by the following:

'It may transmit such data as well as data related to the vessels and equipment used by such persons, and the relevant information acquired while carrying out this core task, to the relevant law enforcement authorities of Member States and to competent Union bodies.'.

(2) In Article 2a, the following paragraph is added:

'4a. For the purpose of the supporting task referred to in paragraph 1, a monitoring mechanism shall be established in close coordination with other relevant stakeholders.'.

(3) In Article 2b, the following paragraph is added:

'4. In addition, in the Area of Operation, and within its means and capabilities, EUNAVFOR MED operation SOPHIA shall conduct surveillance activities and gather information on illegal trafficking, including information on crude oil and other illegal exports that are contrary to UNSCR 2146 (2014) and UNSCR 2362 (2017), thereby contributing to situational awareness and to maritime security in the Central Mediterranean. The information gathered in this context may be released to the legitimate Libyan authorities and to the relevant law enforcement authorities of Member States and to competent Union bodies.'.

(4) In Article 11, the following paragraph is added:

'4. For the period 28 July 2017 to 31 December 2018, the reference amount for the common costs of EUNAVFOR MED operation SOPHIA shall be EUR 6 000 000. The percentage of the reference amount referred to in Article 25(1) of Decision (CFSP) 2015/528 shall be 0 % both in commitments and payments.'.

(5) In Article 13, the second paragraph is replaced by the following:

'EUNAVFOR MED operation SOPHIA shall end on 31 December 2018.'.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 25 July 2017.

For the Council
The President
M. MAASIKAS

COUNCIL DECISION (CFSP) 2017/1386

of 25 July 2017

amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

Having regard to Council Decision 2014/145/CFSP of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine ([1]), and in particular Article 3(1) thereof,

Having regard to the proposal of the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

(1) On 17 March 2014, the Council adopted Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine.

(2) On 13 March 2017, the Council adopted Decision (CFSP) 2017/445 ([2]), thereby renewing those measures for a further 6 months.

(3) The Council has reviewed one individual designation set out in the Annex to Decision 2014/145/CFSP. The entry concerning that person should be amended.

(4) The Annex to Decision 2014/145/CFSP should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2014/145/CFSP shall be amended as set out in the Annex to this Decision.

Article 2

This Decision shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 25 July 2017.

For the Council
The President
M. MAASIKAS

([1]) OJ L 78, 17.3.2014, p. 16.
([2]) Council Decision (CFSP) 2017/445 of 13 March 2017 amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 67, 14.3.2017, p. 88).

ANNEX

In the Annex to Decision 2014/145/CFSP, under the heading 'Persons', entry No 92 is replaced by the following:

	Name	Identifying information	Reasons	Date of listing
'92.	Arkady Romanovich ROTENBERG, Arkadii Romanovich ROTENBERG (Аркадий Романович РОТЕНБЕРГ)	DOB: 15.12.1951 POB: Leningrad (Saint Petersburg).	Arkady Rotenberg is a prominent Russian businessman who has close personal ties to President Putin. Since March 2014, Rotenberg, or his companies, have received State contracts totalling over USD 7 billion. In 2015, Rotenberg led the annual list of government contracts in terms of value, after being awarded contracts worth RUB 555 billion from the Russian Government. Many of these contracts were awarded without formal competitive processes. On 30 January 2015, Prime Minister Dmitry Medvedev signed a decree that awarded to Rotenberg's company, Stroygazmontazh, a State contract for the construction of the Kerch bridge from Russia to the illegally annexed Autonomous Republic of Crimea. Through these contracts, he has financially benefited from Russian decision-makers responsible for the annexation of Crimea or the destabilisation of eastern Ukraine. He is the owner of the company Stroygazmontazh, which has been awarded a State contract for the construction of the Kerch bridge from Russia to the illegally annexed Autonomous Republic of Crimea, therefore consolidating its integration into the Russian Federation which in turn further undermines the territorial integrity of Ukraine. Similarly, in January 2017, Stroygazmontazh was awarded the State contract worth RUB 17 billion for the construction of a railway line on the Kerch bridge, which again further undermines the territorial integrity of Ukraine. He is the chairman of the board of directors of publishing house Prosvescheniye, which has notably implemented the project "To the Children of Russia: Address — Crimea", a public relations campaign that was designed to persuade Crimean children that they are now Russian citizens living in Russia, and thereby supporting the Russian Government's policy to integrate Crimea into Russia.	30.7.2014'

COMMISSION IMPLEMENTING DECISION (EU) 2017/1387

of 24 July 2017

authorising the placing on the market of an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2017) 4975)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ([1]), and in particular Article 7(1) thereof,

Whereas:

(1) On 13 June 2012, the company DSM Food Specialties made a request to the competent authorities of France to place an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger*, on the Union market as a novel food ingredient within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97. The target population is the general adult population.

(2) On 31 July 2014, the competent food assessment body of France issued its initial assessment report. In that report it came to the conclusion that an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* meets the criteria for novel food ingredient set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 11 November 2014, the Commission forwarded the initial assessment report to the other Member States.

(4) Reasoned objections were raised by other Member States within the 60-day period laid down in the first sub-paragraph of Article 6(4) of Regulation (EC) No 258/97.

(5) On 25 November 2015, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for an enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as a novel food ingredient in accordance with Regulation (EC) No 258/97.

(6) On 13 December 2016, EFSA in its opinion on the safety of prolyl oligopeptidase as a novel food ingredient pursuant to Regulation (EC) No 258/97 concluded that the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* is safe for the proposed use and use levels ([2]).

(7) That opinion gives sufficient grounds to establish that the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* in the proposed use and use levels complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) Enzyme preparation of prolyl oligopeptidase falls outside the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the Council ([3]) on genetically modified food and feed as the genetically modified strain of *Aspergillus niger* is used as a processing aid and the material derived from the genetically modified microorganism is not present in the novel food.

(9) Directive 2002/46/EC of the European Parliament and of the Council ([4]) lays down requirements on food supplements. The use of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* should be authorised without prejudice to the provisions of that Directive.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) *EFSA Journal* 2017; 15(2): 4681.
([3]) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1).
([4]) Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Without prejudice to Directive 2002/46/EC, the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient to be used in food supplements intended for the general adult population with a maximum dose established in Annex II to this Decision.

Article 2

The designation of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger* authorised by this Decision on the labelling of the foodstuffs shall be 'prolyl oligopeptidase'.

Article 3

This Decision is addressed to DSM Nutritional Products Ltd, Wurmisweg 576, 4303 Kaiseraugst, Switzerland.

Done at Brussels, 24 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX I

Specifications of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger*

Specification of the enzyme

Systematic name	Prolyl oligopeptidase
Synonyms	Prolyl endopeptidase, proline-specific endopeptidase, endoprolylpeptidase
Molecular weight	66 kDa
Enzyme Commission number	EC 3.4.21.26
CAS number	72162-84-6
Source	A genetically modified strain of *Aspergillus niger* (GEP-44)

Description: Prolyl oligopeptidase is available as an enzyme preparation containing approximately 30 % maltodextrin.

Specifications of the enzyme preparation of prolyl oligopeptidase

Parameter	Specifications Limits
Activity	> 580 000 PPI ([1])/g (> 34,8 PPU ([2])/g)
Appearance	Microgranulate
Colour	Off-white to orange yellowish. The colour may change from batch to batch
Dry Matter	> 94 %
Gluten	< 20 ppm
Heavy metals	
Total heavy metals (as lead)	≤ 10 mg/kg
Lead	≤ 1,0 mg/kg
Arsenic	≤ 1,0 mg/kg
Cadmium	≤ 0,5 mg/kg
Mercury	≤ 0,1 mg/kg
Microbiological specifications	
Total aerobic plate count	≤ 10^3 CFU/g
Total yeasts and moulds	≤ 10^2 CFU/g
Sulphite reducing anaerobes	≤ 30 CFU/g
Enterobacteriaceae	< 10 CFU/g
Salmonella	Absent in 25 g

Escherichia coli	Absent in 25 g
Staphylococcus aureus	Absent in 10 g
Pseudomonas aeruginosa	Absent in 10 g
Listeria monocytogenes	Absent in 25 g
Antimicrobial activity	Absent
Mycotoxins	Below limits of detection: Aflatoxin B1, B2, G1, G2 (< 0,25 µg/kg), total Aflatoxins (< 2,0 µg/kg), Ochratoxin A (< 0,20 µg/kg), T-2 Toxin (< 5 µg/kg), Zearalenone (< 2,5 µg/kg), Fumonisin B1 and B2 (< 2,5 µg/kg)

(1) PPI — Protease Picomole International.
(2) PPU — Prolyl Peptidase Units or Proline Protease Units.

ANNEX II

Authorised uses of the enzyme preparation of prolyl oligopeptidase produced with a genetically modified strain of *Aspergillus niger*

Food category	Maximum dose
Food supplements as defined in Directive 2002/46/EC	120 PPU [1]/day (2,7 g of enzyme preparation/day) (2×10^6 PPI [2]/day) for general adult population

[1] PPU — Prolyl Peptidase Units or Proline Protease Units.
[2] PPI — Protease Picomole International.

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