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Price: EUR 3

[1] Text with EEA relevance

EN

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[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) No 1116/2010

of 2 December 2010

fixing the coefficients applicable to cereals exported in the form of Irish whiskey for the period 2010/2011

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 1670/2006 of 10 November 2006 laying down certain detailed rules for the application of Council Regulation (EC) No 1784/2003 as regards the fixing and granting of adjusted refunds in respect of cereals exported in the form of certain spirit drinks [2], and in particular Article 5 thereof,

Whereas:

(1) Article 4(1) of Regulation (EC) No 1670/2006 lays down that the quantities of cereals eligible for the refund are to be the quantities placed under control and distilled, weighted by a coefficient to be fixed annually for each Member State concerned. The coefficient is to express the average ratio between the total quantities exported and the total quantities marketed of the spirit drink concerned, on the basis of the trend noted in those quantities during the number of years corresponding to the average ageing period of the spirit drink in question.

(2) According to the information provided by Ireland in respect of the period 1 January to 31 December 2009, the average ageing period for Irish whiskey in 2009 was 5 years.

(3) The coefficients for the period 1 October 2010 to 30 September 2011 should therefore be fixed accordingly.

(4) Article 10 of Protocol 3 to the Agreement on the European Economic Area excludes the grant of refunds in respect of exports to Liechtenstein, Iceland and Norway. Moreover, the Union has concluded agreements abolishing export refunds with certain third countries. Under the terms of Article 7(2) of Regulation (EC) No 1670/2006, that should be taken into account in calculating the coefficients for 2010/2011.

(5) Commission Regulation (EU) No 81/2010 of 28 January 2010 fixing the coefficients applicable to cereals exported in the form of Irish whiskey for the period 2009/2010 [3] has exhausted its effects, as it concerns the coefficients applicable for the year 2009/2010. For reasons of legal security and clarity, the abovementioned Regulation should be repealed,

HAS ADOPTED THIS REGULATION:

Article 1

For the period 1 October 2010 to 30 September 2011, the coefficients provided for in Article 4 of Regulation (EC) No 1670/2006 applying to cereals used in Ireland for producing Irish whiskey shall be as set out in the Annex to this Regulation.

Article 2

Regulation (EU) No 81/2010 is hereby repealed.

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 312, 11.11.2006, p. 33.
[3] OJ L 25, 29.1.2010, p. 10.

Article 3

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

It shall apply from 1 October 2010 to 30 September 2011.

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

Done at Brussels, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Coefficients applicable in Ireland		
Period of application	Coefficient applicable	
	to barley used in the production of Irish whiskey, category B [1]	to cereals used in the production of Irish whiskey, category A
From 1 October 2010 to 30 September 2011	0,030	0,102

[1] Including malted barley.

COMMISSION REGULATION (EU) No 1117/2010

of 2 December 2010

concerning the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for weaned piglets (holder of the authorisation Vetagro SpA)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. The application was accompanied by the particulars and documents required pursuant to Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of a preparation of citric acid, sorbic acid, thymol and vanillin as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 25 May 2010 [2] that the preparation set out in the Annex, under the proposed conditions of use, do not have an adverse effect on animal health, human health or the environment, and that this additive has the potential to increase the growth rate and improve the feed to gain ratio of the target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of the preparation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following 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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] *EFSA Journal (2010); 8(6):1633.*

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical parameters)									
4d 3	Vetagro SpA	Preparation of protected citric acid, sorbic acid, thymol and vanillin	*Additive composition* Preparation of protected microbeads containing citric acid, sorbic acid, thymol and vanillin with a minimum of: Citric acid: 25 g/100 g Thymol: 1,7 g/100 g Sorbic acid: 16,7 g/100 g Vanillin: 1 g/100 g *Characterisation of active substances* Citric acid $C_6H_8O_7$ (purity ≥ 99,5 %) 2-hydroxy-1,2,3-propanetricarboxylic acid, CAS number 77-92-9 anhydrous Sorbic acid $C_6H_8O_2$ (purity ≥ 99,5 %) 2,4-hexadienoic acid, CAS number 110-44-1 Thymol (purity ≥ 98 %) 5-methyl-2-(1-methylethyl)phenol, CAS number 89-83-8) Vanillin (purity ≥ 99,5 %) 4-hydroxy-3-methoxybenzaldehyde, CAS number 121-33-5) *Analytical methods* (1) Determination of sorbic acid and thymol in feed: reverse phase high performance liquid chromatography method equipped with ultraviolet/diode array detection (RP-HPLC-UV/DAD). Determination of citric acid in the additive and premixtures: (RP-HPLC-UV/DAD). Determination of citric acid in feedingstuff: enzymatic determination of citric content-NADH (reduced form of nicotinamide adenine dinucleotide) spectrometric method.	Piglets (weaned)	—	1 000	—	1. For piglets (weaned) up to 35 kg. 2. For safety: breathing protection, glasses and gloves shall be used during handling.	23 December 2020

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

COMMISSION REGULATION (EU) No 1118/2010

of 2 December 2010

concerning the authorisation of diclazuril as a feed additive for chickens for fattening (holder of authorisation Janssen Pharmaceutica NV) and amending Regulation (EC) No 2430/1999

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Diclazuril, CAS No 101831-37-2, was authorised for 10 years in accordance with Directive 70/524/EEC as a feed additive for use on chickens for fattening, chickens reared for laying up to 16 weeks and turkeys up to 12 weeks by Commission Regulation (EC) No 2430/1999 ([3]). That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of diclazuril as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category 'coccidiostats and histomonostats'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 23 June 2010 that, under the proposed conditions of use, diclazuril does not have an adverse effect on animal health, consumer health or the environment, and that that additive is effective in controlling coccidiosis in chickens for fattening ([4]). It concluded that no safety concerns would arise provided that appropriate protective measures are taken. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of diclazuril shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.

(6) As a consequence of the granting of a new authorisation under Regulation (EC) No 1831/2003, the provisions on diclazuril for chickens for fattening in Regulation (EC) No 2430/1999 should be deleted.

(7) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'coccidiostats and histomonostats' is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

In Annex I to Regulation (EC) No 2430/1999, the entry under the registration number of additive E 771, concerning diclazuril for chickens for fattening, is deleted.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 296, 17.11.1999, p. 3.
([4]) EFSA Journal 2010; 8(7):1663.

Article 3

Premixtures and compound feed containing diclazuril labelled in accordance with Directive 70/524/EEC may continue to be placed on the market and used until stocks are exhausted.

Article 4

This Regulation shall enter into force on the 20th day following 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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
Coccidiostats and histomonostats										
5 1 771	Janssen Pharmaceutica NV	Diclazuril 0,5 g/ 100 g (Clinacox 0,5 %)	*Additive composition* Diclazuril: 0,50 g/100 g. Protein-poor soybean meal: 99,25 g/100 g Polyvidone K 30: 0,20 g/ 100 g Sodium hydroxide: 0,05 g/ 100 g *Characterisation of the active substance* Diclazuril, $C_{17}H_9Cl_3N_4O_2$, (±)-4-chlorophenyl[2,6-dichloro4- (2,3,4,5-tetrahydro-3,5-dioxo-1,2,4-triazin-2-yl)phenyl]acetonitrile, CAS number: 101831-37-2 Related impurities: Degradation compound (R064318): ≤ 0,1 % Other related impurities (T001434, R066891, R068610, R070156, R070016): ≤ 0,5 % individually Total impurities: ≤ 1,5 %	Chickens for fattening	—	1	1	1. The additive shall be incorporated in compound feed in form of a premixture. 2. Diclazuril shall not be mixed with other coccidiostats. 3. For safety: breathing protection, glasses and gloves shall be used during handling. 4. A post-market monitoring program on the resistance to bacteria and *Eimeria* spp. shall be planned and executed by the holder of authorisation.	23 December 2020	1 500 µg diclazuril/kg of wet liver 1 000 µg diclazuril/kg of wet kidney 500 µg diclazuril/kg of wet muscle 500 µg diclazuril/kg of wet skin/fat

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %				
			Analytical method (1) For determination of diclazuril in feed: reversed-phase high performance liquid chromatography (HPLC) using Ultraviolet detection at 280nm (Regulation (EC) No 152/2009) For determination of diclazuril in poultry tissues: HPLC coupled to triple quadrupole mass spectrometer (MS/MS) using one precursor ion and two product ions.							

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

COMMISSION REGULATION (EU) No 1119/2010

of 2 December 2010

concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and amending Regulation (EC) No 1520/2007 (holder of the authorisation Prosol SpA)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised as a feed additive for 10 years for use on sows by Commission Regulation (EC) 896/2009 ([3]). In accordance with Directive 70/524/EEC, it was authorised without a time limit for use on weaned piglets by Commission Regulation (EC) No 1200/2005 ([4]), on cattle for fattening by Commission Regulation (EC) No 492/2006 ([5]) and on dairy cows by Commission Regulation (EC) No 1520/2007 ([6]). That additive was subsequently entered in the Community Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and, in accordance with Article 7 of that Regulation, for a new use on horses, requesting that additive to be classified in the additive category 'zootechnical additives'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 22 June 2010 ([7]) concerning the use as a feed additive for dairy cows that, under the proposed conditions of use, *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect on animal health, consumer health or the environment, and that it has a potential to increase milk production in dairy cows. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The Authority concluded in its opinion of 22 June 2010 ([8]) concerning the use as a feed additive for horses that the use of that preparation can improve the apparent fibre digestibility in the target species.

(6) The assessment of *Saccharomyces cerevisiae* MUCL 39885 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(7) As a consequence of the granting of a new authorisation under Regulation (EC) 1831/2003, the provisions on *Saccharomyces cerevisiae* MUCL 39885 contained in Regulation (EC) No 1520/2007 should be deleted.

(8) Since the modifications on the conditions of the authorisation are not related to safety reasons, it is appropriate to allow a transitional period for the disposal of existing stocks of the premixtures and compound feed.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) OJ L 270, 14.12.1970, p. 1.
([3]) OJ L 256, 29.9.2009, p. 6.
([4]) OJ L 195, 27.7.2005, p. 6.
([5]) OJ L 89, 28.3.2006, p. 6.
([6]) OJ L 335, 20.12.2007, p. 17.
([7]) *EFSA Journal* 2010; 8(7):1662.
([8]) *EFSA Journal* 2010; 8(7):1659.

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

In Regulation (EC) No 1520/2007, Article 1 and Annex I are deleted.

Article 3

Premixtures and compound feed containing *Saccharomyces cerevisiae* MUCL 39885 labelled in accordance with Directive 70/524/EEC may continue to be placed on the market and used until stocks are exhausted.

Article 4

This Regulation shall enter into force on the 20th day following 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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1710	Prosol SpA	*Saccharomyces cerevisiae* MUCL 39885	*Additive composition* Preparation of *Saccharomyces cerevisiae* MUCL 39885 containing a minimum of 1×10^9 CFU/g *Characterisation of active substance* Viable cells of *Saccharomyces cerevisiae* MUCL 39885 *Analytical methods* (1) Enumeration: pour plate method using chloramphenicol glucose yeast extract agar Identification: polymerase chain reaction (PCR) method)	Dairy cows Horses	—	2×10^9 3×10^9	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For safety: glasses and gloves shall be used during handling.	23 December 2020

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

COMMISSION REGULATION (EU) No 1120/2010

of 2 December 2010

concerning the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for weaned piglets (holder of the authorisation Lallemand SAS)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition [1], and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns the authorisation of *Pediococcus acidilactici* CNCM MA 18/5M as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.

(4) The use of *Pediococcus acidilactici* CNCM MA 18/5M has been authorised without a time limit for chickens for fattening by Commission Regulation (EC) No 1200/2005 [2], and for pigs for fattening by Commission Regulation (EC) No 2036/2005 [3], and for salmonids and shrimps by Commission Regulation (EC) No 911/2009 [4] for 10 years.

(5) New data were submitted in support of the application for the authorisation of the preparation for weaned piglets. The European Food Safety Authority (the Authority) concluded in its opinion of 23 June 2010 [5] that *Pediococcus acidilactici* CNCM MA 18/5M, under the proposed conditions of use, does not have an adverse effect on animal health, human health or the environment, and that its use showed a significant improvement either in growth performance or in feed efficiency in the target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(6) The assessment of *Pediococcus acidilactici* CNCM MA 18/5M shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this preparation should be authorised as specified in the Annex to this Regulation.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following 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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 195, 27.7.2005, p. 6.
[3] OJ L 328, 15.12.2005, p. 13.
[4] OJ L 257, 30.9.2009, p. 10.
[5] *EFSA Journal* 2010; 8(7):1660.

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4d1712	Lallemand SAS	*Pediococcus acidilactici* CNCM MA 18/5M	*Additive composition* Preparation of *Pediococcus acidilactici* CNCM MA 18/5M containing a minimum of 1×10^{10} CFU/g *Characterisation of active substance* Viable cells of *Pediococcus acidilactici* CNCM MA 18/5 M *Analytical methods* (1) Enumeration: spread plate method using MRS agar (EN 15786:2009) Identification: Pulsed Field Gel Electrophoresis (PFGE)	Piglets (weaned)	—	1×10^9	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. For piglets (weaned) up to 35 kg. 3. For safety: breathing protection, glasses and gloves shall be used during handling.	23 December 2020

(1) Details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives

COMMISSION REGULATION (EU) No 1121/2010

of 2 December 2010

entering a designation in the register of protected designations of origin and protected geographical indications [Edam Holland (PGI)]

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1], and in particular the third subparagraph of Article 7(5) thereof,

Whereas:

(1) In accordance with the first paragraph of Article 6(2) of Regulation (EC) No 510/2006, and pursuant to Article 17(2) of the same Regulation, the application of the Netherlands to enter the designation 'Edam Holland' in the register of protected designations of origin and protected geographical indications was published in the *Official Journal of the European Union* [2].

(2) The Czech Republic, Germany, Finland, Austria, Slovakia, the governments of Australia, New Zealand and the United States of America, as well as Diary Australia, Dairy Companies Association of New Zealand and the National Milk Producers Federation together with U.S. Dairy Export Council submitted objections to the registration under Article 7(1) of Regulation (EC) No 510/2006. The objections were deemed admissible under Article 7(3) of that Regulation, except the objections of Australia and of Dairy Australia, which were deemed inadmissible due to their late arrival.

(3) Statements of objection concerned non-compliance with the conditions laid down in Article 2 of Regulation (EC) No 510/2006, in particular the name and its use, specificity and reputation of the product, delimitation of geographical area as well as restrictions on the origin of raw materials. The objections also claimed that registration would be contrary to Article 3(3) of Regulation (EC) No 510/2006, would jeopardise the existence of names, trademarks or products which had been legally on the market for at least five years preceding the date of the publication provided for in Article 6(2) and that the name proposed for registration is generic.

(4) By letters dated 21 October 2008, the Commission asked the Netherlands and the objectors to seek agreement among themselves in accordance with their internal procedures.

(5) Given that no agreement with the objectors was reached within the designated time limit, the Commission should adopt a decision in accordance with the procedure referred to in Article 15(2) of Regulation (EC) No 510/2006.

(6) Concerning the alleged failure of compliance with Article 2 of Regulation (EC) No 510/2006 in respect of the name, geographical area, specificity of the product, link between the product characteristics and the geographical area, reputation and restrictions concerning the origin of raw material, the national authorities responsible provided confirmation that these elements were present and in addition no manifest error was identified. It should be pointed out that 'Holland' is not the name of the Member State concerned, and that 'Edam Holland' is considered a traditional geographical name encompassed by Article 2(2) of Regulation (EC) No 510/2006. The requirements of Article 2(1), point b) of the said Regulation are in this connection fulfilled since the related geographical area is delimited accordingly to the link and the main elements of the product specificity. The specificity of Edam Holland is due to a combination of factors linked to the geographical area: such as the quality of milk (high fat level and protein content), amino acids originating from β-CN and γ-glutamyl peptide, prevalence of grazing on meadows, use of calf rennet, natural ripening, as well as the skills of the farmers and cheese producers.

(7) As regards objections based on non compliance with Article 3(3) of Regulation (EC) No 510/2006, the Netherlands submitted information regarding the distinction between the product bearing the registered name 'Noord-Hollandse Edammer' and that for which the name 'Edam Holland' is applied. No evidence was provided in the statement of objections that consumers would be liable to be misled or that the producers would be treated in an inequitable manner.

(8) It appears that the objectors did not refer to the entire name 'Edam Holland' when claiming that registration would jeopardize the existence of names, trademarks or products and that the name proposed for registration is generic, but only to one element of it, namely 'Edam'. However, protection is granted to the term 'Edam Holland' as a whole. Pursuant to the second subparagraph of Article 13(1) of Regulation (EC) No 510/2006, the term 'Edam' may continue to be used provided the principles and rules applicable in the Union's legal order are respected. For the sake of clarification, the specification and the summary have been modified accordingly.

[1] OJ L 93, 31.3.2006, p. 12.
[2] OJ C 57, 1.3.2008, p. 39.

(9) In the light of the above, the name 'Edam Holland' should be entered in the 'Register of protected designations of origin and protected geographical indications'.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Protected Geographical Indications and Protected Designations of Origin,

HAS ADOPTED THIS REGULATION:

Article 1

The designation contained in Annex I to this Regulation shall be entered in the Register.

Notwithstanding the first paragraph, the name 'Edam' may continue to be used within the territory of the Union, provided the principles and rules applicable in its legal order are respected.

Article 2

A consolidated version of the summary containing the main points of the specification is set out in Annex II to this Regulation.

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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Agricultural products intended for the human consumption listed in Annex I of the Treaty:

Class 1.3. Cheeses

THE NETHERLANDS

Edam Holland (PGI)

ANNEX II

SUMMARY

COUNCIL REGULATION (EC) No 510/2006

on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

'EDAM HOLLAND'

EC No: NL-PGI-0005-0329-27.11.2003

PDO ( ) PGI (X)

This summary sets out the main elements of the product specification for information purposes.

1. **Responsible department in the Member State**

Name: Hoofdproductschap Akkerbouw

Address: Postbus 29739 - 2502 LS 's-Gravenhage

Tel.: +31-70-3708708

Fax: +31-70-3708444

E-mail: plw@hpa.agro.nl

2. **Group**

Name: Nederlandse Zuivel Organisatie (NZO)

Address: Postbus 165 - 2700 AD Zoetermeer

Tel.: + 31-79-3430300

Fax: +31-79-3430320

E-mail: info@nzo.nl

Composition: Producers/processors (X) Other ( )

3. **Type of product**

Class 1.3 Cheese

4. **Specification**

(summary of requirements under Article 4(2) of Regulation (EC) No 510/2006)

4.1. *Name*

'Edam Holland'

4.2. *Description*

Edam Holland is a naturally matured semi-hard cheese. It is produced in the Netherlands from cows' milk obtained from Dutch dairy farms and is matured to a consumer-ready product in Dutch maturing rooms.

Composition

Edam Holland is produced from one or more of the following raw materials

— milk, cream and skimmed or semi-skimmed cows' milk (exclusively cows' milk) from Dutch dairy farms.

Characteristic properties

The cheese is shaped like a ball with a flattened top and bottom, or it may be shaped like a loaf or a block. The specifications are given in the table.

Type	Weight	Fat in dry matter	Moisture content (max)	Salt in dry matter (max)
Baby Edam Holland	max. 1,5 kg	40,0 – 44,0 %	46,5 %	5,4 %
Edam Holland (ball)	1,5 – 2,5 kg	40,0 – 44,0 %	45,5 %	5,0 %
Edam Holland Bros (hard)	1,5 – 2,5 kg	40,0 – 44,0 %	47,5 %	5,3 %
Edam Holland Stip (speckled)	1,5 – 2,5 kg	40,0 – 44,0 %	45,5 %	6,0 %
Edam Holland (block-shaped)	max. 20 kg	40,0 – 44,0 %	46,0 %	4,6 %
Edam Holland (large loaf-shaped)	4 – 5 kg	40,0 – 44,0 %	46,0 %	4,6 %
Edam Holland (small loaf-shaped)	2 – 3 kg	40,0 – 44,0 %	47,0 %	4,8 %

The moisture content applies 12 days from the first day of preparation, with the exception of Baby Edam Holland, where it applies 5 days after the first day of preparation.

The other characteristic properties are as follows:

— Flavour: mild to piquant, depending on age and type.

— Cross-section: must be uniform in colour with a few small round holes. Bros Edam Holland has a large number of small holes. The colour of the cheese varies from ivory to yellow.

— Rind: the rind is firm, smooth, dry, clean and has no fungal flora. It is produced by drying during the maturing stage.

— Texture: young Edam Holland must be sufficiently firm and suitable for cutting. Once the cheese has matured further, it becomes firmer and tighter in structure. Bros Edam Holland must be sufficiently firm and hard.

— Maturing period: a minimum of 28 days (a minimum of 21 days for Baby Edam Holland).

— Edam Holland is a naturally matured cheese. Foil maturing is not permitted for Edam Holland.

— Maturing temperature: a minimum of 12 °C.

— Age: the shelf-life varies from a minimum of 28 days after manufacture (Baby Edam Holland) to more than a year.

Special quality criteria

— When they reach and are stored by the cheese-maker, the milk, cream or semi-skimmed milk have undergone either no heat treatment at all or a non-pasteurising heat treatment.

— The cream and the skimmed or semi-skimmed milk should undergo pasteurisation immediately before being made into Edam Holland so as to meet the following criteria:

  — phosphatase activity is undetectable, unless peroxidase activity is undetectable;

  — acidity levels, for cream measured on the basis of the fat-free product, are no higher than 20 mmol NaOH per litre, unless the lactate content is 200 mg per 100 g of fat-free matter or less;

  — no coliform micro-organisms are detectable in 0,1 ml.

— Immediately before being made into Edam Holland, all raw materials must be pasteurised in such a way that the undenatured whey protein content does not deviate or deviates only slightly from that of unpasteurised raw material of a similar type and quality.

— Only non-genetically modified cultures of lactic-acid-forming and aroma-forming micro-organisms may be added when manufacturing Edam Holland. These cultures consist of appropriate mesophilic starter cultures for Edam Holland: Lactococcus and Leuconostoc L or LD, possibly in combination with thermophilic Lactobacillus and/or Lactococcus cultures. The available starter cultures play a very important role in the maturing process and the formation of the typical taste and aroma.

— Rennet: only calf rennet is used to manufacture Edam Holland. It is only in special circumstances, for example if required as a result of epizootic disease, that it may be necessary to switch to other types of rennet. In that case, the rennet used must comply with the requirements of the Warenwetbesluit Zuivel [Dairy Products (Commodities Act) Decree].

— The nitrite content of Edam Holland, in terms of nitrite ions, is no higher than 2 mg per kg cheese.

4.3. *Geographical area*

The geographical area covered by the application is Holland, i.e. the European part of the Kingdom of the Netherlands.

4.4. *Proof of origin*

A mark made from casein is placed on each Edam Holland cheese before the curds are pressed (see diagram). The mark contains the designation 'Edam Holland', together with a combination of numbers and letters that is unique for each cheese (in ascending alphabetical and numerical order).

The COKZ (the Dutch dairy inspection institute) keeps a register of these unique numbers, which also contains a record of all test data (including time and place). The indication is easily recognisable to consumers and can be verified by an approval authority on the basis of the casein mark and the COKZ register.

4.5. *Method of production*

Edam Holland cheese is made from milk obtained from dairy farms in the Netherlands. The milk is cooled on the farm to a maximum of 6 °C and stored in a cooling tank on the farm. It is transported to the cheese factory within 72 hours. When it arrives at the cheese factory, it is either processed immediately or thermised (a non-pasteurising, light heat treatment) and put into cold storage for a short period of time before being turned into cheese-milk.

The fat content of the milk is standardised so that the fat/protein ratio is such that the cheese eventually produced has a fat content of between 40 % and 44 % fat in dry matter. The cheese-milk is pasteurised at a temperature of at least 72 °C for 15 seconds. It is curdled at a temperature of approximately 30 °C. The separation and coagulation of the milk proteins that occurs during this process is typical of Edam Holland.

The curds obtained by coagulation are separated from the whey and processed and washed to ensure that the moisture content and pH reach the desired levels.

The curds are pressed into the correct shape and desired weight in vats. The resulting 'cheese' is then immersed in the brine bath.

Edam Holland is only ever matured naturally, i.e. it is left open to the air to mature and is regularly turned and checked. As the cheese matures, a dry rind forms. Time and temperature play an important role in ensuring that the enzymatic and ageing processes are given sufficient opportunity to allow the cheese to develop the physical and organoleptic quality that is so characteristic of Edam Holland. It can take more than a year for Edam Holland to mature, depending on the type of flavour desired.

Edam Holland may be cut and pre-packaged either in or outside the Netherlands, provided that the pre-packager has a comprehensive administrative monitoring system to ensure that the cut Edam Holland can be traced by means of the unique combination of numbers and letters on the mark and that the consumer can be sure of its origin.

4.6. *Link*

The geographical component of this product name is 'Holland'. As is common knowledge, 'Holland' is a synonym of the more official name, 'the Netherlands'. During the time of the Republic of the United Netherlands (from the 17th to the 19th century), Holland was the most influential of the seven provinces.

Historical background

Edam Holland is an exponent of the Dutch tradition of cheese making, which stretches back to the Middle Ages and reached maturity as early as the 17th century (the Golden Age).

It is largely the geographical position of the Netherlands (mostly below sea level), its climate (a maritime climate) and the composition of the grass that grows there (predominantly on sandy and clay soils) that make the milk so suitable for producing a high-quality cheese that is packed with flavour.

The quality assurance systems in place on dairy farms and the intensive quality assessment system (each delivery of milk is tested and assessed according to various quality parameters) together guarantee the quality of the milk. Furthermore, there is an unbroken cold chain until the moment the milk is processed, with the milk being put into cold storage on the farm (maximum 6 °C) and transported to the factory in refrigerated tankers. The relatively short distances involved also help maintain the quality of the milk.

From its beginnings in farm-based production, Edam Holland has developed, by way of production in local factories, to become a nationally produced product with a worldwide reputation and is an important, stable component in optimising the value of farm milk. At the beginning of the 20th century, national laws were introduced for Edam cheese, and the name of Edam Holland was established in the Landbouwkwaliteitsbeschikking kaasproducten [Agricultural Quality (Cheese Products) Decision].

Edam Holland's image among European consumers

A large-scale survey carried out in six European countries showed that European consumers see the Netherlands as the most important producer of Edam (and Gouda).

Edam Holland (and Gouda Holland) are symbols of Dutch cultural heritage. European consumers regard Edam Holland (and Gouda Holland) cheese as brands. Edam Holland (and Gouda Holland) are synonymous with Dutch quality. Market research (carried out on a representative sample of 1 250 respondents per Member State, with 97,5 % reliability) in the six Member States where Edam (and Gouda) consumption is highest shows that:

— there is a strong association between Edam and the Netherlands;

— Edam Holland is more popular than Edam produced outside the Netherlands;

— almost half of consumers in the Member States surveyed believe that all Edam is produced in the Netherlands;

— Edam from Holland scores significantly higher on the variables 'excellent quality', 'traditionally manufactured' and 'the original product'.

Over a number of centuries, various measures and laws have been introduced, both by the Dutch Government and by the industry, to ensure that the quality of Edam Holland (and Gouda Holland) is maintained at a very high level. Moreover, the Dutch dairy industry has invested a substantial amount in meeting these high quality standards and opening up, cultivating and maintaining markets. Since 1950, more than NLG 1,4 billion (EUR 635 million) has been invested in advertising, awareness-raising and promotion in Europe (excluding investment in the Netherlands).

4.7. *Inspection body*

Name: Stichting Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel (COKZ)

Address: Kastanjelaan 7, 3833 AN LEUSDEN

Tel.: +31-33-4965696

Fax: +31-33-4965666

E-mail: productcontrole@cokz.nl

4.8. *Labelling*

'Edam Holland' is a European Union Protected Geographical Indication (PGI).

This indication must be displayed in a prominent position on all whole cheeses on the label applied to the flat side of the cheese and/or on the band around the cheese. This is not compulsory if the cheese is sold in pre-cut and pre-packaged form as described in section 4.5. In that case, 'Edam Holland' must be displayed on the packaging.

A clear distinguishing mark must be displayed on the packaging to enable consumers to identify Edam Holland on the shelves. Through naming, the use of a separate identity (a logo is being developed) and the EU PGI symbol, it must be made clear to consumers that Edam Holland is a different product from other Edam cheeses.

COMMISSION REGULATION (EU) No 1122/2010

of 2 December 2010

entering a designation in the register of protected designations of origin and protected geographical indications [Gouda Holland (PGI)]

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs [1], and in particular the third subparagraph of Article 7(5) thereof,

Whereas:

(1) In accordance with the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, and pursuant to Article 17(2) of the same Regulation, the application of the Netherlands to enter the designation 'Gouda Holland' in the register of protected designations of origin and protected geographical indications was published in the *Official Journal of the European Union* [2].

(2) The Czech Republic, Germany, France, Austria, the governments of Australia, New Zealand and the United States of America, as well as Dairy Australia, Dairy Companies Association of New Zealand and the National Milk Producers Federation together with the US Dairy Export Council submitted objections to the registration under Article 7(1) of Regulation (EC) No 510/2006. These objections were deemed admissible under Article 7(3) of that Regulation.

(3) Statements of objection concerned non-compliance with the conditions laid down in Article 2 of Regulation (EC) No 510/2006, in particular the name and its use, specificity and reputation of the product, delimitation of geographical area as well as restrictions on the origin of raw materials. The objections also claimed that registration would be contrary to Article 3(3) of Regulation (EC) No 510/2006, would jeopardise the existence of names, trademarks or products which had been legally on the market for at least five years preceding the date of the publication provided for in Article 6(2), and that the name proposed for registration was generic.

(4) By letters dated 4 November 2008, the Commission asked the Netherlands and the objectors to seek agreement among themselves in accordance with their internal procedures.

(5) Given that no agreement with the objectors was reached within the designated time limit, with the exception of an agreement reached between the Netherlands and France, the Commission should adopt a decision in accordance with the procedure referred to in Article 15(2) of Regulation (EC) No 510/2006.

(6) Concerning the alleged failure of compliance with Article 2 of Regulation (EC) No 510/2006 in respect of the name, geographical area, specificity of the product, link between the product characteristics and the geographical area, reputation and restrictions concerning the origin of raw material, the national authorities responsible provided confirmation that these elements were present and in addition no manifest error was identified. It should be pointed out that Holland is not the name of the Member State concerned and that 'Gouda Holland' is considered a traditional geographical name encompassed by Article 2(2) of Regulation (EC) No 510/2006. The requirements of Article 2(1) point (b) of the said Regulation are in this connection fulfilled since the related geographical area is delimited according to the link and the main elements of the product specificity. The specificity of Gouda Holland is due to a combination of factors linked to the geographical area such as the quality of milk (high fat level and protein content), amino acids originating from β-CN and γ-glutamyl peptide, prevalence of grazing on meadows, use of calf rennet, natural ripening, as well as the skills of the farmers and cheese producers.

(7) As regards objections based on non compliance with Article 3(3) of Regulation (EC) No 510/2006, the Netherlands submitted information regarding the distinction between the product bearing the registered name 'Noord-Hollandse Gouda' and that for which the name 'Gouda Holland' is applied. No evidence was provided in the statement of objections that consumers would be liable to be misled or that the producers would be treated in an inequitable manner.

[1] OJ L 93, 31.3.2006, p. 12.
[2] OJ C 61, 6.3.2008 p. 15.

(8) It appears that the objectors did not refer to the entire name 'Gouda Holland' when claiming that registration would jeopardize the existence of names, trademarks or products and that the name proposed for registration is generic, but only to one element of it, namely 'Gouda'. However, protection is granted to the term 'Gouda Holland' as a whole. Pursuant to the second subparagraph of Article 13(1) of Regulation (EC) No 510/2006, the term 'Gouda' may continue to be used provided the principles and rules applicable in the Union's legal order are respected. For the sake of clarification, the specification and the summary have been modified accordingly.

(9) In the light of the above, the name 'Gouda Holland' should be entered in the 'Register of protected designations of origin and protected geographical indications'.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Protected Geographical Indications and Protected Designations of Origin,

HAS ADOPTED THIS REGULATION:

Article 1

The designation contained in Annex I to this Regulation shall be entered in the Register.

Notwithstanding the first paragraph, the name 'Gouda' may continue to be used within the territory of the Union, provided the principles and rules applicable in its legal order are respected.

Article 2

A consolidated version of the summary containing the main points of the specification is set out in Annex II to this Regulation.

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, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX I

Agricultural products intended for the human consumption listed in Annex I of the Treaty:

Class 1.3. Cheeses

THE NETHERLANDS

Gouda Holland (PGI)

ANNEX II

SUMMARY

COUNCIL REGULATION (EC) No 510/2006

on the protection of geographical indications and designations of origin for agricultural products and foodstuffs

'GOUDA HOLLAND'

EC No: NL-PGI-0005-0328-27.11.2003

PDO ( ) PGI (X)

This summary sets out the main elements of the product specification for information purposes.

1. **Responsible department in the Member State**

Name: Hoofdproductschap Akkerbouw

Address: Postbus 29739 - 2502 LS 's-Gravenhage

Tel.: +31-70-3708708

Fax: +31-70-3708444

E-mail: plw@hpa.agro.nl

2. **Group**

Name: Nederlandse Zuivel Organisatie (NZO)

Address: Postbus 165 - 2700 AD Zoetermeer

Tel.: + 31-79-3430300

Fax: +31-79-3430320

E-mail: info@nzo.nl

Composition: Producers/processors (X) Other ( )

3. **Type of product**

Class 1.3. Cheese

4. **Specification**

(summary of requirements under Article 4(2) of Regulation (EC) No 510/2006)

4.1. *Name*

'Gouda Holland'

4.2. *Description*

Gouda Holland is a full-fat (48 % +), naturally matured semi-hard cheese.

It is produced in the Netherlands from cows' milk obtained from Dutch dairy farms and is matured to a consumer-ready product in Dutch maturing rooms.

Composition

Gouda Holland is produced from one or more of the following raw materials:

— milk, cream and skimmed or semi-skimmed cows' milk (exclusively cows' milk) from Dutch dairy farms.

Characteristic properties

The cheese is shaped like a flattened cylinder, a block or a loaf and weighs from 2,5 kg to 20 kg. A flattened cylindrical shape is a shape with convex sides that curve smoothly into a flat top and bottom and a height that is a quarter to a third of the diameter.

The fat content is a minimum of 48,0 % and a maximum of 52,0 % in dry matter. The (maximum) moisture content 12 days after the first day of manufacture is 42,5 % and the salt content in dry matter is a maximum of 4,0 %. The other characteristic properties are as follows:

— Flavour: aromatic, pleasant and mild to strong, depending on its age. Cumin may be added.

— Cross-section: after slicing the cheese, hole formation is visible but may not be evenly distributed. The colour of the cheese varies from ivory to yellow.

— Rind: the rind is firm, smooth, dry, clean and has no fungal flora. It is produced by drying during the maturing stage.

— Texture: the cheese is slightly soft to pliable at an age of four weeks. Once the cheese has matured further, it becomes firmer and tighter in structure. The cheese is easy to cut.

— Maturing period: at least 28 days. Gouda Holland is a naturally matured cheese. Foil maturing is not permitted for Gouda Holland.

— Maturing temperature: a minimum of 12 °C.

— Age: the shelf-life varies from a minimum of 28 days after manufacture to more than a year.

Special quality criteria

— When they reach and are stored by the cheese-maker, the milk, cream or semi-skimmed milk have undergone either no heat treatment at all or a non-pasteurising heat treatment.

— The cream and the skimmed or semi-skimmed milk should undergo pasteurisation immediately before being made into Gouda Holland so as to meet the following criteria:

  — phosphatase activity is undetectable, unless peroxidase activity is undetectable;

  — acidity levels, for cream measured on the basis of the fat-free product, are no higher than 20 mmol NaOH per litre, unless the lactate content is 200 mg per 100 g of fat-free matter or less;

  — no coliform micro-organisms are detectable in 0,1 ml.

— Immediately before being made into Gouda Holland, all raw materials must be pasteurised in such a way that the undenatured whey protein content does not deviate or deviates only slightly from that of unpasteurised raw material of a similar type and quality. Only non-genetically modified cultures of lactic-acid-forming and aroma-forming micro-organisms may be added when manufacturing Gouda Holland. These cultures consist of appropriate mesophilic starter cultures for Gouda Holland: Lactococcus and Leuconostoc L or LD, possibly in combination with thermophilic Lactobacillus and/or Lactococcus cultures. The available cultures are protected. Their use is mandatory in the production of Gouda Holland.

— Rennet: only calf rennet is used to manufacture Gouda Holland. It is only in special circumstances, for example if required as a result of epizootic disease, that it may be necessary to switch to other types of rennet. In that case, the rennet used must comply with the requirements of the Warenwetbesluit Zuivel [Dairy Products (Commodities Act) Decree].

— The nitrite content of Gouda Holland, in terms of nitrite ions, is no higher than 2 mg per kg cheese.

4.3. *Geographical area*

The geographical area covered by the application is Holland, i.e. the European part of the Kingdom of the Netherlands.

4.4. *Proof of origin*

A mark made from casein is placed on each Gouda Holland cheese before the curds are pressed (see diagram). The mark contains the designation 'Gouda Holland', together with a combination of numbers and letters that is unique for each cheese (in ascending alphabetical and numerical order).

The COKZ (the Dutch dairy inspection institute) keeps a register of these unique numbers, which also contains a record of all test data (including time and place). The indication is easily recognisable to consumers and can be verified by an approval authority on the basis of the casein mark and the COKZ register.

4.5. *Method of production*

Gouda Holland cheese is made from milk obtained from dairy farms in the Netherlands. The milk is cooled on the farm to a maximum of 6 °C and stored in a cooling tank on the farm. It is transported to the cheese factory within 72 hours. When it arrives at the cheese factory, it is either processed immediately or thermised (a non-pasteurising, light heat treatment) and put into cold storage for a short period of time before being turned into cheese-milk.

The fat content of the milk is standardised so that the fat/protein ratio is such that the cheese eventually produced has a fat content of between 48 % and 52 % fat in dry matter. The cheese-milk is pasteurised at a temperature of at least 72 °C for 15 seconds. It is curdled at a temperature of approximately 30 °C. The separation and coagulation of the milk proteins that occurs during this process is typical of Gouda Holland.

The curds obtained by coagulation are separated from the whey and processed and washed to ensure that the moisture content and pH reach the desired levels.

The curds are pressed into the correct form and desired weight in vats. The resulting 'cheese' is then immersed in the brine bath.

Gouda Holland is only ever matured naturally, i.e. it is left open to the air to mature and is regularly turned and checked. As the cheese matures, a dry rind forms. Time and temperature play an important role in ensuring that the enzymatic and ageing processes are given sufficient opportunity to allow the cheese to develop the physical and organoleptic quality that is so characteristic of Gouda Holland.

It can take more than a year for Gouda Holland to mature, depending on the type of flavour desired.

Gouda Holland may be cut and pre-packaged either in or outside the Netherlands, provided that the pre-packager has a comprehensive administrative monitoring system to ensure that the cut Gouda Holland can be traced by means of the unique combination of numbers and letters on the mark and that the consumer can be sure of its origin.

4.6. *Link*

The geographical component of this product name is 'Holland'. As is common knowledge, 'Holland' is a synonym of the more official name, 'the Netherlands'. During the time of the Republic of the United Netherlands (from the 17th to the 19th century), Holland was the most influential of the seven provinces.

It is largely the geographical position of the Netherlands (mostly below sea level), its climate (a maritime climate) and the composition of the grass that grows there (predominantly on sandy and clay soils) that make the milk so suitable for producing a high-quality cheese that is packed with flavour. The quality assurance systems in place on dairy farms and the intensive quality assessment system (each delivery of milk is tested and assessed according to various quality parameters) together guarantee the quality of the milk. Furthermore, there is an unbroken cold chain until the moment the milk is processed, with the milk being put into cold storage on the farm (maximum 6 °C) and transported to the factory in refrigerated tankers. The relatively short distances involved also help maintain the quality of the milk.

Historical background

Gouda Holland is an exponent of the Dutch tradition of cheese making, which stretches back to the Middle Ages and reached maturity as early as the 17th century (the Golden Age).

The cheese sold in Gouda became known as Gouda cheese from the 18th century onwards. Later, the name Gouda came to be associated with all full-fat cheeses produced in Holland and shaped like a flattened cylinder.

From its beginnings in farm-based production, Gouda Holland has developed, by way of production in local factories, to become a nationally produced product with a worldwide reputation and is an important, stable component in optimising the value of farm milk. At the beginning of the 20th century, national laws were introduced for Gouda cheese, and the name of Gouda Holland was established in the Landbouwkwaliteitsbeschikking kaasproducten [Agricultural Quality (Cheese Products) Decision].

Gouda Holland's image among European consumers

A large-scale survey carried out in six European countries showed that European consumers see the Netherlands as the most important producer of Gouda and Edam. Gouda Holland (and Edam Holland) are symbols of Dutch cultural heritage. European consumers regard Gouda Holland (and Edam Holland) cheese as brands. Market research (carried out on a representative sample of 1 250 respondents per Member State, with 97,5 % reliability) in the six Member States where Gouda (and Edam) consumption is highest shows that:

— there is a strong association between Gouda and the Netherlands;

— Gouda Holland is more popular than Gouda produced outside the Netherlands;

— almost half of consumers in the Member States surveyed believe that all Gouda is produced in the Netherlands;

— Gouda from Holland scores significantly higher on the variables 'excellent quality', 'traditionally manufactured' and 'the original product'.

Gouda Holland (and Edam Holland) are synonymous with Dutch quality. Over a number of centuries, various measures and laws have been introduced, both by the Dutch Government and by the industry, to ensure that the quality of Gouda Holland (and Edam Holland) is maintained at a very high level. Moreover, the Dutch dairy industry has invested a substantial amount in meeting these high quality standards and opening up, cultivating and maintaining markets. Since 1950, more than NLG 1,4 billion (EUR 635 million) has been invested in advertising, awareness-raising and promotion in Europe (excluding investment in the Netherlands).

4.7. *Inspection body*

Name: Stichting Centraal Orgaan voor Kwaliteitsaangelegenheden in de Zuivel (COKZ)

Address: Kastanjelaan 7, 3833 AN LEUSDEN

Tel.: +31-33-4965696

Fax: +31-33-4965666

e-mail: productcontrole@cokz.nl

4.8. *Labelling*

'Gouda Holland' is a European Union Protected Geographical Indication (PGI).

This indication must be displayed in a prominent position on all whole cheeses, on the label applied to the flat side of the cheese and/or on the band around the cheese.

This is not compulsory if the cheese is sold in pre-cut and pre-packaged form as described in section 4.5. In that case, 'Gouda Holland' must be displayed on the packaging.

A clear distinguishing mark must be displayed on the packaging to enable consumers to identify Gouda Holland on the shelves. By using the name 'Gouda Holland', developing a separate identity and displaying the EU PGI symbol, it must be made clear to consumers that Gouda Holland is a different product from other 'Gouda' cheeses.

COMMISSION REGULATION (EU) No 1123/2010

of 2 December 2010

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) [1],

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector [2], and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 3 December 2010.

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

Done at Brussels, 2 December 2010.

For the Commission,
On behalf of the President,
Jean-Luc DEMARTY
Director-General for Agriculture and Rural Development

[1] OJ L 299, 16.11.2007, p. 1.
[2] OJ L 350, 31.12.2007, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	AL	64,0
	MA	96,2
	MK	68,6
	TR	131,8
	ZZ	90,2
0707 00 05	EG	145,5
	JO	182,1
	TR	76,2
	ZZ	134,6
0709 90 70	MA	86,7
	TR	146,6
	ZZ	116,7
0805 10 20	BR	57,8
	MA	56,2
	TR	54,8
	ZA	52,0
	ZW	43,6
	ZZ	52,9
0805 20 10	MA	73,7
	ZZ	73,7
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	HR	60,9
	IL	72,8
	TR	66,6
	ZZ	66,8
0805 50 10	AR	45,9
	TR	57,2
	UY	57,1
	ZZ	53,4
0808 10 80	AR	74,9
	AU	164,5
	BR	50,3
	CA	65,9
	CL	84,2
	CN	86,4
	CO	50,3
	MK	26,7
	NZ	99,4
	US	113,6
	ZA	125,5
	ZZ	85,6
0808 20 50	CN	105,3
	US	112,9
	ZZ	109,1

(1) Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DIRECTIVE 2010/85/EU

of 2 December 2010

amending Council Directive 91/414/EEC to include zinc phosphide as active substance and amending Decision 2008/941/EC

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 1112/2002 [2] and (EC) No 2229/2004 [3] lay down the detailed rules for the implementation of the fourth stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included zinc phosphide.

(2) In accordance with Article 24e of Regulation (EC) No 2229/2004 the applicant withdrew its support of the inclusion of that active substance in Annex I to Directive 91/414/EEC within 2 months from receipt of the draft assessment report. Consequently, Commission Decision 2008/941/EC of 8 December 2008 concerning the non-inclusion of certain active substances in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances [4] was adopted on the non-inclusion of zinc phosphide.

(3) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier (hereinafter 'the applicant') submitted a new application requesting the application of the accelerated procedure provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I [5].

(4) The application was submitted to Germany, which had been designated rapporteur Member State by Regulation (EC) No 2229/2004. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as were the subject of Decision 2008/941/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008.

(5) Germany evaluated the additional data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 20 July 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on zinc phosphide to the Commission on 2 July 2010 [6]. The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 28 October 2010 in the format of the Commission review report for zinc phosphide.

(6) It has appeared from the various examinations made that plant protection products containing zinc phosphide may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which have been examined and detailed in the Commission review report. It is therefore appropriate to include zinc phosphide in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance can be granted in accordance with the provisions of that Directive.

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 168, 27.6.2002, p. 14.
[3] OJ L 379, 24.12.2004, p. 13.
[4] OJ L 335, 13.12.2008, p. 91.
[5] OJ L 15, 18.1.2008, p. 5.
[6] *European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance zinc phosphide. EFSA Journal 2010; 8(7):1671. [48pp].doi:10.2903/j.efsa.2010.1671. Available online: www.efsa.europa.eu*

(7) A reasonable period should be allowed to elapse before an active substance is included in Annex I in order to permit Member States and the interested parties to prepare themselves to meet the new requirements which will result from the inclusion.

(8) Without prejudice to the obligations defined by Directive 91/414/EEC as a consequence of including an active substance in Annex I, Member States should be allowed a period of 6 months after inclusion to review existing authorisations of plant protection products containing zinc phosphide to ensure that the requirements laid down by Directive 91/414/EEC, in particular in its Article 13 and the relevant conditions set out in Annex I, are satisfied. Member States should vary, replace or withdraw, as appropriate, existing authorisations, in accordance with the provisions of Directive 91/414/EEC. By derogation from the above deadline, a longer period should be provided for the submission and assessment of the complete Annex III dossier of each plant protection product for each intended use in accordance with the uniform principles laid down in Directive 91/414/EEC.

(9) The experience gained from previous inclusions in Annex I to Directive 91/414/EEC of active substances assessed in the framework of Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1] has shown that difficulties can arise in interpreting the duties of holders of existing authorisations in relation to access to data. In order to avoid further difficulties it therefore appears necessary to clarify the duties of the Member States, especially the duty to verify that the holder of an authorisation demonstrates access to a dossier satisfying the requirements of Annex II to that Directive. However, this clarification does not impose any new obligations on Member States or holders of authorisations compared to the directives which have been adopted until now amending Annex I.

(10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(11) Decision 2008/941/EC concerning the non-inclusion of certain active substances in Annex I to Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing these substances provides for the non-inclusion of zinc phosphide and the withdrawal of authorisation of plant protection products containing that substance by 31 December 2011. It is necessary to delete the line concerning zinc phosphide in the Annex to that Decision.

(12) It is therefore appropriate to amend Decision 2008/941/EC accordingly.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

The line concerning zinc phosphide in the Annex to Decision 2008/941/EC is deleted.

Article 3

Member States shall adopt and publish by 31 October 2011 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from 1 November 2011.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 4

1. Member States shall in accordance with Directive 91/414/EEC, where necessary, amend or withdraw existing authorisations for plant protection products containing zinc phosphide as an active substance by 1 November 2011.

By that date they shall in particular verify that the conditions in Annex I to that Directive relating to zinc phosphide are met, with the exception of those identified in part B of the entry concerning that active substance, and that the holder of the authorisation has, or has access to, a dossier satisfying the requirements of Annex II to that Directive in accordance with the conditions of Article 13 of that Directive.

2. By way of derogation from paragraph 1, for each authorised plant protection product containing zinc phosphide as either the only active substance or as one of several active substances all of which were listed in Annex I to Directive 91/414/EEC by 30 April 2011 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive and taking into account part B of the entry in Annex I to that Directive concerning zinc phosphide. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

[1] OJ L 366, 15.12.1992, p. 10.

Following that determination Member States shall:

(a) in the case of a product containing zinc phosphide as the only active substance, where necessary, amend or withdraw the authorisation by 30 April 2015 at the latest; or

(b) in the case of a product containing zinc phosphide as one of several active substances, where necessary, amend or withdraw the authorisation by 30 April 2015 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

Article 5

This Directive shall enter into force on 1 May 2011.

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 2 December 2010.

For the Commission
The President
José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EC:

No	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'319	Zinc phosphide CAS No: 1314-84-7 CIPAC No: 69	*Trizinc diphosphide*	≥ 800 g/kg	1 May 2011	30 April 2021	PART A Only uses as rodenticide in the form of ready-to-use baits placed in bait stations or target locations may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on zinc phosphide, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010, shall be taken into account. In this overall assessment Member States should pay particular attention to: — the protection of non-target organisms. Risk mitigation measures should be applied as appropriate in particular to avoid the spread of baits where only part of the content has been consumed.'

(*) Further details on identity and specification of active substance are provided in the review report.

COMMISSION DIRECTIVE 2010/86/EU

of 2 December 2010

amending Council Directive 91/414/EEC to include haloxyfop-P as an active substance

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market ([1]), and in particular Article 6(1) thereof,

Whereas:

(1) Commission Regulations (EC) No 451/2000 ([2]) and (EC) No 703/2001 ([3]) lay down the detailed rules for the implementation of the second stage of the programme of work referred to in Article 8(2) of Directive 91/414/EEC and establish a list of active substances to be assessed, with a view to their possible inclusion in Annex I to Directive 91/414/EEC. That list included haloxyfop-R. By Commission Decision 2007/437/EC ([4]) it was decided not to include haloxyfop-R in Annex I to Directive 91/414/EEC.

(2) Pursuant to Article 6(2) of Directive 91/414/EEC the original notifier, hereinafter 'the applicant', submitted a new application requesting the accelerated procedure to be applied, as provided for in Articles 14 to 19 of Commission Regulation (EC) No 33/2008 of 17 January 2008 laying down detailed rules for the application of Council Directive 91/414/EEC as regards a regular and an accelerated procedure for the assessment of active substances which were part of the programme of work referred to in Article 8(2) of that Directive but have not been included into its Annex I ([5]).

(3) The application was submitted to Denmark, which had been designated rapporteur Member State by Regulation (EC) No 451/2000. The time period for the accelerated procedure was respected. The specification of the active substance and the supported uses are the same as those that were the subject of Decision 2007/437/EC. That application also complies with the remaining substantive and procedural requirements of Article 15 of Regulation (EC) No 33/2008. In that application the ISO name, 'haloxyfop-P', is used to refer to the active substance rather than the previously used term, 'haloxyfop-R'.

(4) Denmark evaluated the new information and data submitted by the applicant and prepared an additional report. It communicated that report to the European Food Safety Authority (hereinafter 'the Authority') and to the Commission on 3 April 2009. The Authority communicated the additional report to the other Member States and the applicant for comments and forwarded the comments it had received to the Commission. In accordance with Article 20(1) of Regulation (EC) No 33/2008 and at the request of the Commission, the Authority presented its conclusion on haloxyfop-P to the Commission on 9 October 2009 ([6]). The draft assessment report, the additional report and the conclusion of the Authority were reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health and finalised on 28 October 2010 in the format of the Commission review report for haloxyfop-P.

(5) The additional report by the rapporteur Member State and the new conclusion by the EFSA concentrate on the concerns that lead to the non-inclusion. Those concerns were in particular the potential contamination of groundwater - and possibly drinking water – by a number of metabolites and the risk to mammals.

(6) The new data submitted by the applicant show the following. The metabolites concerned are neither of toxicological, nor of biological relevance and they present a low risk from an ecotoxicological point of view.

(7) Consequently, the additional data and information provided by the applicant permit to eliminate the specific concerns that led to the non-inclusion. No other open scientific questions have arisen.

(8) It has appeared from the various examinations made that plant protection products containing haloxyfop-P may be expected to satisfy, in general, the requirements laid down in Article 5(1) (a) and (b) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include haloxyfop-P in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing this active substance may be granted in accordance with the provisions of that Directive.

([1]) OJ L 230, 19.8.1991, p. 1.
([2]) OJ L 55, 29.2.2000, p. 25.
([3]) OJ L 98, 7.4.2001, p. 6.
([4]) OJ L 163, 23.6.2007, p. 22.
([5]) OJ L 15, 18.1.2008, p. 5.

([6]) *European Food Safety Authority: Conclusion on the peer review of the pesticide risk assessment of the active substance haloxyfop-P (haloxyfop-R)* EFSA Journal 2009; 7(11): 1348. [102 pp.]. doi:10.2903/j.efsa.2009.1348. Available online: www.efsa.europa.eu

(9) Without prejudice to that conclusion, it is appropriate to obtain further information on certain specific points. Article 6(1) of Directive 91/414/EC provides that the inclusion of a substance in Annex I may be subject to conditions. Therefore, it is appropriate to require that the applicant submit information confirming the groundwater exposure assessment as regards the active substance and its soil metabolites DE-535 phenol, DE-535 pyridinol and DE-535 pyridinone.

(10) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(11) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 June 2011 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

This Directive shall enter into force on 1 January 2011.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 2 December 2010.

For the Commission

The President

José Manuel BARROSO

ANNEX

The following entry shall be added at the end of the table in Annex I to Directive 91/414/EEC:

No	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Entry into force	Expiration of inclusion	Specific provisions
'314	Haloxyfop-P CAS No: Acid: 95977-29-0 *Ester: 72619-32-0* CIPAC No: Acid: 526 *Ester: 526.201*	Acid: (*R*)-2-[4-(3-chloro-5-trifluoromethyl-2-pyridyloxy)phenoxy]propanoic acid *Ester: Methyl (R)-2-{4-[3-chloro-5-(trifluoromethyl)-2-pyridyloxy]phenoxy}propionate*	≥ 940 g/kg *(Haloxyfop-P-methyl ester)*	1 January 2011	31 December 2020	PART A Only uses as herbicide may be authorised. PART B For the implementation of the uniform principles of Annex VI, the conclusions of the review report on haloxyfop-P, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 28 October 2010 shall be taken into account. In this overall assessment Member States shall pay particular attention to: — operator safety: conditions of use shall prescribe the use of adequate personal protective equipment; — protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones; — consumer safety as regards the occurrence in groundwater of metabolites DE-535 pyridinol and DE-535 pyridinone. The Member States concerned shall ensure that the applicant presents to the Commission, by 31 December 2012 at the latest, information confirming the groundwater exposure assessment as regards the active substance and its soil metabolites DE-535 phenol, DE-535 pyridinol and DE-535 pyridinone.'

(*) Further details on identity and specification of active substance are provided in the review report.

DECISIONS

COMMISSION DECISION

of 2 December 2010

establishing the classes of reaction-to-fire performance for certain construction products as regards steel sheets with polyester coating and with plastisol coating

(notified under document C(2010) 389)

(Text with EEA relevance)

(2010/737/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/106/EEC of 21 December 1988, on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products [1], and in particular Article 20(2)(a) thereof,

After consulting the Standing Committee on Construction,

Whereas:

(1) Directive 89/106/EEC envisages that in order to take account of different levels of protection for the construction works at national, regional or local levels, it may be necessary to establish in the interpretative documents classes corresponding to the performance of products in respect of each essential requirement. Those documents have been published as the 'Communication of the Commission with regard to the interpretative documents of Directive 89/106/EEC [2]'.

(2) With respect to the essential requirement of safety in the event of fire, interpretative document No 2 lists a number of interrelated measures which together define the fire safety strategy to be variously developed in the Member States.

(3) Interpretative document No 2 identifies one of those measures as the limitation of the generation and spread of fire and smoke within a given area by limiting the potential of construction products to contribute to the full development of a fire.

(4) The level of that limitation may be expressed only in terms of the different levels of reaction-to-fire performance of the products in their end-use application.

(5) By way of harmonised solution, a system of classes was adopted in Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regards the classification of the reaction-to-fire performance of construction products [3].

(6) In the case of steel sheets with polyester coating and with plastisol coating it is necessary to use the classification established in Decision 2000/147/EC.

(7) The reaction-to-fire performance of many construction products and/or materials, within the classification provided for in Decision 2000/147/EC, is well established and sufficiently well known to fire regulators in Member States that they do not require testing for this particular performance characteristic,

HAS ADOPTED THIS DECISION:

Article 1

The construction products and/or materials which satisfy all the requirements of the performance characteristic 'reaction-to-fire' without need for further testing are set out in the Annex.

Article 2

The specific classes to be applied to different construction products and/or materials, within the reaction-to-fire classification adopted in Decision 2000/147/EC, are set out in the Annex to this Decision.

Article 3

Products shall be considered in relation to their end-use application, where relevant.

[1] OJ L 40, 11.2.1989, p. 12.
[2] OJ C 62, 28.2.1994, p. 1.
[3] OJ L 50, 23.2.2000, p. 14.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 2 December 2010.

For the Commission
Antonio TAJANI
Vice-President

ANNEX

The tables set out in this Annex, list construction products and/or materials which satisfy all of the requirements for the performance characteristic 'reaction-to-fire' without need for testing.

Table 1

Classes of reaction to fire performance for steel sheets with polyester coating used as single skin (without insulation behind)

Product	Nominal thickness 't' of metallic coated steel sheet (mm)	Profile	Class (1)
Metallic coated steel sheet, profiled or flat, of nominal thickness t (mm) and coated on the surface exposed to the fire with a polyester coating of maximum nominal thickness 25 µm, according to the relevant part of EN 14782 and EN 10169, if the coating has a mass of no more than 70 g/m^2 and a PCS of no more than 1,0 MJ/m^2. The steel sheet surface not exposed to the fire may have an organic coating, provided that this coating has a thickness of no more than 15 µm and a PCS of no more than 0,7 MJ/m^2.	0,40 ≤ t ≤ 1,50	Flat or profiled (2)	A1

(1) Class as provided for in Table 1 of the Annex to Decision 2000/147/EC.
(2) The profiled (corrugated) surface area shall not be more than twice as much as the overall (coverage) area of the product.
Symbol used: PCS = gross calorific potential.

Table 2

Classes of reaction to fire performance for steel sheets with plastisol coating

Product (1)	Nominal thickness 't' of metallic coated steel sheet (mm)	Assembly detail	Class (2)
Metallic coated steel sheet, profiled or flat, of nominal thickness t (mm) and coated on the surface exposed to the fire with a plastisol coating of maximum nominal thickness 200 µm and having a coating mass ≤ 300 g/m^2 and a PCS ≤ 7,0 MJ/m^2. The steel sheet surface not exposed to the fire may have an organic coating, provided that this coating has a thickness ≤ 15 µm and a PCS ≤ 0,7 MJ/m^2.	0,55 ≤ t ≤ 1,00	Flat or profiled product used as a single skin (without insulation behind) or backed by mineral wool as part of a built up assembly (which may be a double skin). If the product is profiled, the profiled (corrugated) surface area shall be no more than twice as much as the overall (coverage) area of the product. The mineral wool shall be of at least class A2-s1,d0. The mineral wool shall be of thickness at least 100 mm, unless the material (if any) immediately behind the mineral wool — including any vapour barrier — is of at least class A2-s1,d0. The supporting structure shall be of at least class A2-s1,d0.	C-s3,d0

(1) Tolerances on nominal thickness shall conform to the relevant standards as referenced in EN 14782 and EN 14783.
(2) Class as provided for in Table 1 of the Annex to Decision 2000/147/EC.
Symbol used: PCS = gross calorific potential.

COMMISSION DECISION

of 2 December 2010

establishing the classes of reaction-to-fire performance for certain construction products as regards fibrous gypsum plaster casts

(notified under document C(2010) 392)

(Text with EEA relevance)

(2010/738/EU)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/106/EEC of 21 December 1988, on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products [1], and in particular Article 20(2)(a) thereof,

After consulting the Standing Committee on Construction,

Whereas:

(1) Directive 89/106/EEC envisages that in order to take account of different levels of protection for the construction works at national, regional or local levels, it may be necessary to establish in the interpretative documents classes corresponding to the performance of products in respect of each essential requirement. Those documents have been published as the 'Communication of the Commission with regard to the interpretative documents of Directive 89/106/EEC [2]'.

(2) With respect of the essential requirement of safety in the event of fire, interpretative document No 2 lists a number of interrelated measures which together define the fire safety strategy to be variously developed in the Member States.

(3) Interpretative document No 2 identifies one of those measures as the limitation of the generation and spread of fire and smoke within a given area by limiting the potential of construction products to contribute to the full development of a fire.

(4) The level of that limitation may be expressed only in terms of the different levels of reaction-to-fire performance of the products in their end-use application.

(5) By way of a harmonised solution, a system of classes was adopted in Commission Decision 2000/147/EC of 8 February 2000 implementing Council Directive 89/106/EEC as regards the classification of the reaction to fire performance of construction products [3].

(6) In the case of fibrous gypsum plaster casts it is necessary to use the classification established in Decision 2000/147/EC.

(7) The reaction-to-fire performance of many construction products and/or materials, within the classification provided for in Decision 2000/147/EC, is well established and sufficiently well known to fire regulators in Member States that they do not require testing for this particular performance characteristic,

HAS ADOPTED THIS DECISION:

Article 1

The construction products and/or materials which satisfy all the requirements of the performance characteristic 'reaction-to-fire' without need for further testing are set out in the Annex.

Article 2

The specific classes to be applied to different construction products and/or materials, within the reaction-to-fire classification adopted in Decision 2000/147/EC, are set out in the Annex to this Decision.

Article 3

Products shall be considered in relation to their end-use application, where relevant.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 2 December 2010.

For the Commission
Antonio TAJANI
Vice-President

[1] OJ L 40, 11.2.1989, p. 12.
[2] OJ C 62, 28.2.1994, p. 1.
[3] OJ L 50, 23.2.2000, p. 14.

ANNEX

The table set out in this Annex lists construction products and/or materials which satisfy all of the requirements for the performance characteristic reaction-to-fire without need for testing.

Table

Classes of reaction-to-fire performance for fibrous gypsum plaster casts reinforced with sisal fibres or jute fibres

Product	Product detail	Minimum density (kg/m^3)	Class [1]
Fibrous gypsum plaster casts	Product according to EN 13815, made by casting gypsum plaster mixed with water, reinforced by uniformly dispersed sisal or jute fibres at the rate of no more than 2,5 % by mass.	1 000	A1

[1] Class as provided for in Table 1 of the Annex to Decision 2000/147/EC.

CORRIGENDA

Corrigendum to Agreement between the European Union and Montenegro on security procedures for exchanging and protecting classified information

(Official Journal of the European Union L 260 of 2 October 2010)

On page 5, signatures:

for:	*'For Montenegro* *The Minister for Foreign Affairs*	*For the European Union* *The High Representative of the Union for Foreign Affairs and Security Policy',*
read:	*'For the European Union*	*For Montenegro'.*

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