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Contents

[1] Text with EEA relevance

(Continued overleaf)

EN

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

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

EN

[1] Text with EEA relevance

(Continued on inside back cover)

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COMMISSION REGULATION (EC) No 894/2009

of 28 September 2009

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 29 September 2009.

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

Done at Brussels, 28 September 2009.

For the Commission
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	MK	32,3
	ZZ	32,3
0707 00 05	TR	114,4
	ZZ	114,4
0709 90 70	TR	108,1
	ZZ	108,1
0805 50 10	AR	75,7
	CL	106,0
	TR	93,3
	UY	57,0
	ZA	72,3
	ZZ	80,9
0806 10 10	EG	109,7
	IL	111,8
	TR	98,3
	US	190,3
	ZZ	127,5
0808 10 80	AR	62,2
	BR	83,8
	CL	84,7
	NZ	80,8
	US	83,8
	ZA	74,4
	ZZ	78,3
0808 20 50	AR	81,8
	CN	65,0
	TR	101,7
	US	161,5
	ZA	71,0
	ZZ	96,2
0809 30	TR	110,4
	ZZ	110,4
0809 40 05	IL	117,2
	TR	99,1
	ZZ	108,2

(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'.

COMMISSION REGULATION (EC) No 895/2009

of 23 September 2009

concerning the classification of certain goods in the Combined Nomenclature

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff [1], and in particular Article 9(1)(a) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based thereon or which adds any additional subdivision thereto and which is established by specific Community provisions, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column 1 of the table set out in the Annex should be classified under the CN code indicated in column 2, by virtue of the reasons set out in column 3 of that table.

(4) It is appropriate to provide that binding tariff information which has been issued by the customs authorities of Member States in respect of the classification of goods in the Combined Nomenclature but which is not in accordance with this Regulation may, for a period of three months, continue to be relied on by the holder, under Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [2].

(5) The Customs Code Committee has not issued an opinion within the time limit set by its Chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column 1 of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column 2 of that table.

Article 2

Binding tariff information issued by the customs authorities of Member States, which is not in accordance with this Regulation, may continue to be relied on for a period of three months under Article 12(6) of Regulation (EEC) No 2913/92.

Article 3

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, 23 September 2009.

For the Commission
László KOVÁCS
Member of the Commission

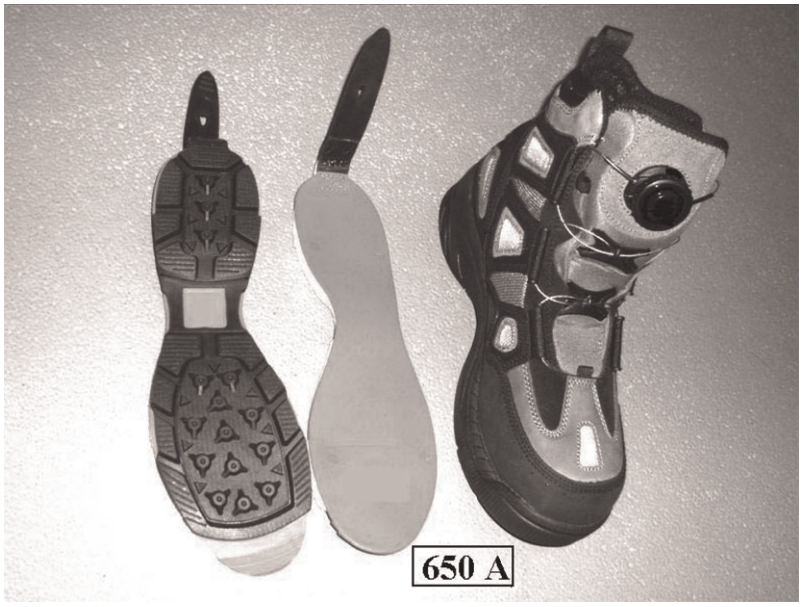
[1] OJ L 256, 7.9.1987, p. 1.

[2] OJ L 302, 19.10.1992, p. 1.

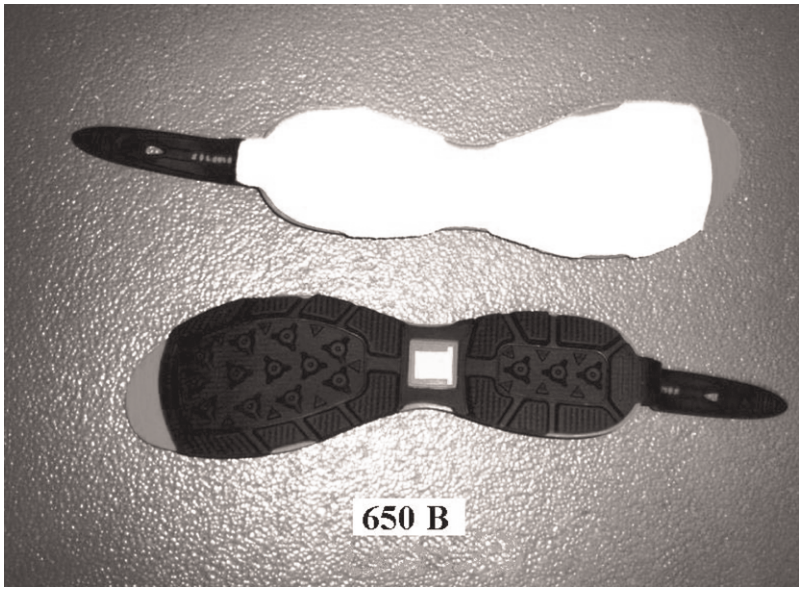
ANNEX

Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
Boot which covers the ankle. The sole of the boot is made of rubber, yet the majority of the outer sole is cut away and allows inserts holding different outer soles to be inserted into the hollowed out area of the sole. The boots are put up in a set for retail sale together with two pairs of inserts, each holding different outer soles, and a metal tool needed to attach the inserts. One pair of inserts holds outer soles of rubber which have a deeply carved sole typical for trekking boot soles. The other pair of inserts holds outer soles of textile material (approximately 8 mm of felt), which can be used when walking in shallow water according to the importer's documentation. The sole of the boot retains a small part of the outer sole, an almost continuous rim around the edge of the sole. This small part of the outer sole is of rubber matching the trekking sole insert. The footwear cannot be used without the inserts. The insoles have a length of more than 24 cm. The upper of the boot is made up of different leather pieces sewn together leaving 'windows' into which nine metallic-mesh pieces and four textile pieces are sewn. The leather makes up the greater part of the external surface area of the upper. The inside of the boot is lined with textile material. The boot is neither waterproof nor water resistant. The footwear can be used by men and women. (trekking boot) (See photographs Nos 650 A, 650 B and 650 C) (*)	6403 91 13	Classification is determined by General Rules 1, 2(a), 3(b) and 6 for the interpretation of the Combined Nomenclature, note 4(a) and (b) to Chapter 64 and the wording of CN codes 6403, 6403 91 and 6403 91 13. Since the typical trekking boot rubber outer sole inserts match the boot uppers, this footwear is intended to be used and assembled essentially as a trekking boot. Moreover, the small part of the outer soles retained around the edges of the soles of the boots, matches exactly the trekking sole inserts. Whereas, the indented use of the textile outer sole inserts is not obvious. Their use in water can only be very limited, because the upper of the boot is neither waterproof nor water resistant. Consequently, the textile sole inserts are accessories meant to be used in specific situations only and, thus, enhancing the use of the product. The boots and the rubber sole inserts have therefore to be classified as complete but unassembled footwear within the meaning of GIR (General rules for the interpretation of the Combined Nomenclature) 2(a), second sentence. The part of the sole of the assembled footwear in contact with the ground is of rubber within the meaning of note 4(b) to Chapter 64 and, thus, the footwear has outer soles of rubber. Given that the leather material makes up the greatest external surface area of the upper of the footwear, the material of the upper of the boots is leather within the meaning of note 4(a) to Chapter 64. The textile sole inserts are put up in a set for retail sale together with the unassembled trekking boot and the metal tool needed for assembling the footwear. That set is to be classified as if it consisted of the trekking boots only, because the trekking boots give the set its essential character within the meaning of GIR 3(b). The textile sole inserts and the metal tool are only accessories to the footwear. Thus, the set is to be classified as footwear with outer soles of rubber and uppers of leather.

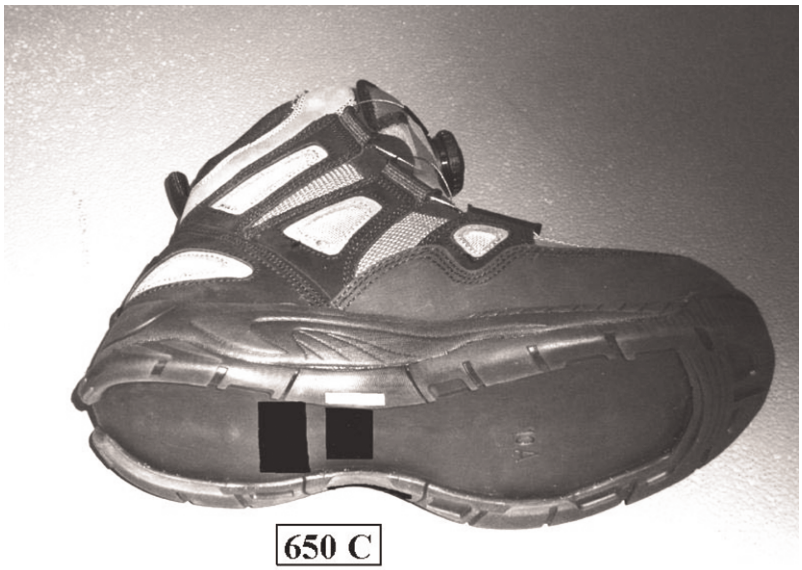
(*) The photographs are purely for information.



650 A



650 B



650 C

COMMISSION REGULATION (EC) No 896/2009

of 25 September 2009

concerning the authorisation of a new use of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows (holder of the authorisation Prosol SpA)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 a new use of the micro-organism preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows, to be classified in the additive category 'zootechnical additives'.

(4) The use of the micro-organism preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised without time limit for weaned piglets by Commission Regulation (EC) No 1200/2005 [2], for cattle for fattening by Commission Regulation (EC) No 492/2006 [3] and for dairy cows by Commission Regulation (EC) No 1520/2007 [4].

(5) New data were submitted in support of an application for authorisation for sows. The European Food Safety Authority (the Authority) concludes in its opinion of 3 February 2009 [5] that *Saccharomyces cerevisiae* MUCL 39885 can be considered safe for the target species, consumers and the wider environment. According to that opinion, the preparation can produce a significant beneficial effect on the weight of litters and individual piglets. 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 that preparation shows that the conditions for authorisation, 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.

(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, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

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[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 195, 27.7.2005, p. 6.
[3] OJ L 89, 28.3.2006, p. 6.
[4] OJ L 335, 20.12.2007, p. 17.
[5] *The EFSA Journal* (2009) 970, pp. 1-9.

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: powder and granulated form 1×10^9 CFU/g additive Characterisation of the active substance: *Saccharomyces cerevisiae* MUCL 39885 Analytical method (1): Enumeration: pour plate method using chloramphenicol glucose yeast extract agar Identification: polymerase chain reaction (PCR) method	Sows	—	$6{,}4 \times 10^9$	—	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	19 October 2019

(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 (EC) No 897/2009

of 25 September 2009

amending Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007 and (EC) No 209/2008 as regards the terms of the authorisation of the feed additive *Saccharomyces cerevisiae* NCYC Sc 47

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 13(3) thereof,

Whereas:

(1) The additive *Saccharomyces cerevisiae*, (NCYC Sc 47), trade name Biosaf, hereinafter referred to as 'Biosaf', belonging to the group of zootechnical additives, was authorised under certain conditions in accordance with Regulation (EC) No 1831/2003 for ten years by Commission Regulation (EC) No 1447/2006 [2] for lambs for fattening, by Commission Regulation (EC) No 186/2007 [3] for horses, by Commission Regulation (EC) No 188/2007 [4] for dairy goats and dairy sheep and by Commission Regulation (EC) No 209/2008 [5] for pigs for fattening. That additive was notified as an existing product in accordance with Article 10 of Regulation (EC) No 1831/2003. Since all the information required under that provision was submitted, that additive was entered into the Community Register of Feed Additives.

(2) Regulation (EC) No 1831/2003 provides for the possibility of modifying the authorisation of an additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority. LFA Lesaffre Feed Additives, holder of the authorisation of Biosaf, has submitted an application requesting to change the trade name of the additive from 'Biosaf' to 'Actisaf'.

(3) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additives concerned. The European Food Safety Authority was informed of the application.

(4) To allow the applicant to exploit its marketing rights under the trade name Actisaf, it is necessary to change the terms of the authorisations.

(5) Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007 and (EC) No 209/2008 should therefore be amended accordingly.

(6) It is appropriate to provide for a transitional period during which existing stocks may be used up.

(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

1. In the Annex to Regulation (EC) No 1447/2006, in column 3, the trade name 'Biosaf Sc 47' is replaced by 'Actisaf'.

2. In the Annex to Regulation (EC) No 186/2007, in column 3, the trade name 'Biosaf Sc 47' is replaced by 'Actisaf'.

3. In the Annex to Regulation (EC) No 188/2007, in column 3, the trade name 'Biosaf Sc 47' is replaced by 'Actisaf'.

4. In the Annex to Regulation (EC) No 209/2008, in column 3, the trade name 'Biosaf Sc 47' is replaced by 'Actisaf'.

Article 2

Existing stocks which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until six months after that date.

Article 3

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

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 271, 30.9.2006, p. 28.
[3] OJ L 63, 1.3.2007, p. 6.
[4] OJ L 57, 24.2.2007, p. 3.
[5] OJ L 63, 7.3.2008, p. 3.

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

Done at Brussels, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

COMMISSION REGULATION (EC) No 898/2009

of 25 September 2009

amending Annex II to Regulation (EC) No 998/2003 of the European Parliament and of the Council as regards the list of countries and territories

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC ([1]), and in particular Articles 10 and 19 thereof,

Whereas:

(1) Regulation (EC) No 998/2003 lays down the animal health requirements applicable to the non-commercial movement of pet animals and the rules applicable to checks on such movements.

(2) Part C of Annex II to Regulation (EC) No 998/2003 lists the third countries and territories which are free of rabies and the third countries and territories in respect of which the risk of rabies entering the Community as a result of movements of pet animals from those third countries and territories has been found to be no higher than the risk associated with movements between Member States.

(3) To be included on that list, a third country should demonstrate its status with regard to rabies and that it complies with certain requirements relating to the notification of suspicion of rabies, the monitoring system, the structure and organisation of its veterinary services, the implementation of all regulatory measures for the prevention and control of rabies and the regulations on the marketing of anti-rabies vaccines.

(4) The competent authorities of Saint Lucia have submitted information regarding the status of that third country with regard to rabies, as well as information concerning the compliance with the requirements laid down in Regulation (EC) No 998/2003. From the assessment of that information, it appears that Saint Lucia complies with the relevant requirements laid down in that Regulation and should therefore be included in the list set out in Part C of Annex II to Regulation (EC) No 998/2003.

(5) Part C of Annex II to Regulation (EC) No 998/2003 should therefore be amended accordingly.

(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

In Part C of Annex II to Regulation (EC) No 998/2003, the following entry is inserted between the entry for Cayman Islands and that for Montserrat:

'LC Saint Lucia'.

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, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

([1]) OJ L 146, 13.6.2003, p. 1.

COMMISSION REGULATION (EC) No 899/2009

of 25 September 2009

amending Regulation (EC) No 1290/2008 as regards the name of the holder of the authorisation of a preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 13(3) thereof,

Whereas:

(1) A preparation of *Lactobacillus rhamnosus* (CNCM-I-3698) and *Lactobacillus farciminis* (CNCM-I-3699) (Sorbiflore), belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', was authorised as an additive in animal nutrition by Commission Regulation (EC) No 1290/2008 [2] for authorisation holder Sorbial SAS.

(2) Regulation (EC) No 1831/2003 provides for the possibility of modifying the authorisation of an additive further to a request from the holder of the authorisation and an opinion of the European Food Safety Authority. Sorbial SAS has submitted an application requesting to change the name of the authorisation holder from Sorbial SAS to Danisco France SAS as regards Regulation (EC) No 1290/2008.

(3) The applicant claims that Sorbial SAS was converted into Danisco France SAS with effect from 18 May 2009. Danisco France SAS now owns the marketing rights for the additive. The applicant has submitted appropriate documents supporting its claims.

(4) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.

(5) To allow the applicant to exploit its marketing rights under the name of Danisco France SAS it is necessary to change the terms of the authorisations.

(6) Regulation (EC) No 1290/2008 should therefore be amended accordingly.

(7) It is appropriate to provide for a transitional period during which existing stocks may be used up.

(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

In column 2 of the Annex to Regulation (EC) No 1290/2008 the name 'Sorbial SAS' is replaced by 'Danisco France SAS'.

Article 2

Existing stocks which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until six months after that date.

Article 3

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, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 340, 19.12.2008, p. 20.

COMMISSION REGULATION (EC) No 900/2009

of 25 September 2009

concerning the authorisation of selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 authorisation of the preparation selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 as a feed additive for all species, to be classified in the additive category 'nutritional additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 5 March 2009 [2] that selenium enriched yeast, mainly selenomethionine, from *Saccharomyces cerevisiae* CNCM I-3399 does not have an adverse effect on animal health, human health or the environment and the use of that preparation can be considered as a source of bio-available selenium and fulfils the criteria of a nutritional additive for all species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verifies 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 that preparation shows that the conditions for authorisation, 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) 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 'nutritional additives' and to the functional group 'compounds of trace elements', 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, 25 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 268, 18.10.2003, p. 29.
[2] *The EFSA Journal* (2009) 992 pp. 1-24.

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
						Maximum content of element (Se) in mg/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: compounds of trace elements									
3b8.12	—	Selenomethionine Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 (Selenised yeast inactivated)	Characterisation of the additive: Organic selenium mainly selenomethionine (63 %) content of 2 000-2 400 mg Se/kg (97-99 % of organic selenium) Characterisation of the active substance: Selenomethionine produced by *Saccharomyces cerevisiae* CNCM I-3399 (Selenised yeast inactivated) Analytical method (1): Zeeman graphite furnace atomic absorption spectrometry (AAS) or hydride AAS	All species	—		0,50 (total)	1. The additive shall be incorporated in to feed in form of a premixture. 2. For user safety: breathing protection, safety glasses and gloves should be worn during handling.	19 October 2019

(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 (EC) No 901/2009

of 28 September 2009

concerning a coordinated multiannual Community control programme for 2010, 2011 and 2012 to ensure compliance with maximum levels of and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [1], in particular Article 29 thereof,

Whereas:

(1) By Commission Regulation (EC) No 1213/2008 [2] a first coordinated multiannual Community programme, covering the years 2009, 2010 and 2011, was established.

(2) Thirty foodstuffs constitute the major components of the diet in the Community. Since pesticide uses show significant changes over a period of three years, pesticides should be monitored in those 30 foodstuffs over a series of three-year cycles to allow consumer exposure and the application of Community legislation to be assessed.

(3) On the basis of a binomial probability distribution, it can be calculated that examination of 642 samples allows, with a certainty of more than 99 %, the detection of a sample containing pesticide residues above the limit of determination (LOD), provided that not less than 1 % of the products contain residues above that limit. Collection of these samples should be apportioned among Member States according to population numbers, with a minimum of 12 samples per product and per year.

(4) Where the residue definition of a pesticide includes other active substances, metabolites or breakdown products, those metabolites should be reported separately.

(5) Guidance concerning 'Method validation and quality control procedures for pesticide residue analysis in food and feed' is published on the Commission website [3].

(6) For the sampling procedures Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC [4] which incorporates the sampling methods and procedures recommended by the Codex Alimentarius Commission should apply.

(7) It is also necessary to assess whether maximum residue levels for baby food provided for in Article 10 of Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae [5] and Article 7 of Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children [6] are respected.

(8) It is necessary to assess possible aggregate, cumulative and synergistic effects of pesticides. This assessment should start with some organophosphates, carbamates, triazoles and pyrethroides, as set out in Annex I.

(9) Member States should submit by 31 August of each year the information concerning the previous calendar year.

(10) In order to avoid any confusion due to an overlap between consecutive multiannual programmes, Regulation (EC) No 1213/2008 should be repealed in the interest of legal certainty. It should, however, continue to apply to samples tested in 2009.

(11) 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

Member States shall, during the years 2010, 2011 and 2012 take and analyse samples for the product/pesticide residue combinations, as set out in Annex I.

The number of samples of each product shall be as set out in Annex II.

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[1] OJ L 70, 16.3.2005, p. 1.
[2] OJ L 328, 6.12.2008, p. 9.
[3] Document SANCO/3131/2007, 31 October 2007 http://ec.europa.eu/food/plant/protection/resources/qualcontrol_en.pdf
[4] OJ L 187, 16.7.2002, p. 30.
[5] OJ L 401, 30.12.2006, p. 1.
[6] OJ L 339, 6.12.2006, p. 16.

Article 2

1. The lot to be sampled shall be chosen randomly.

The sampling procedure, including the number of units, shall comply with Directive 2002/63/EC.

2. The samples taken and analysed shall include at least:

(a) 10 samples of baby food;

(b) one sample, where available, from products originating from organic farming that reflects the market share of organic products in each Member State.

Article 3

1. Member States shall submit the results of the analysis of samples tested in 2010, 2011 and 2012 by 31 August 2011, 2012 and 2013 respectively.

In addition to those results, Member States shall provide the following information:

(a) the analytical methods used and reporting levels achieved, in accordance with the guidance on Method validation and quality control procedures for pesticide residue analysis in food and feed;

(b) limit of determination applied in the national and Community control programmes;

(c) details of the accreditation status of the analytical laboratories involved in the control;

(d) where permitted by national legislation, details of enforcement measures taken;

(e) where maximum residue levels (MRLs) are exceeded, a statement of the possible reasons thereof, together with any appropriate observations regarding risk management options.

2. Where the residue definition of a pesticide includes active substances, metabolites and/or breakdown or reaction products, Member States shall report the analysis results in accordance with the legal residue definition. Where relevant, the results of each of the main isomers or metabolites mentioned in the residue definition shall be submitted separately.

Article 4

Regulation (EC) No 1213/2008 is repealed.

However, it shall continue to apply to samples tested in 2009.

Article 5

This Regulation shall enter into force on 1 January 2010.

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

Done at Brussels, 28 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX I

Pesticide/product combinations to be monitored

	2010	2011	2012
2,4-D (sum of 2,4-D and its esters expressed as 2,4-D) (*)	(c)	(a)	(b)
4,4′-Methoxychlor	(e)	(f)	(d)
Abamectin (sum of avermectin B1a, avermectin B1b and delta-8,9 isomer of avermectin B1a)	(c)	(a), (f)	(b) (d)
Acephate	(c)	(a)	(b)
Acetamiprid	(c)	(a)	(b)
Acrinathrin (*)	(c)	(a)	(b)
Aldicarb (sum of aldicarb, its sulfoxide and its sulfone, expressed as aldicarb)	(c)	(a)	(b)
Amitraz (amitraz including the metabolites containing the 2,4-dimethylaniline moity expressed as amitraz)	(Pears)	(a)	(b)
Amitrole (*)	(c)	(a)	(b)
Azinphos-ethyl (*)	(e)	(f)	(d)
Azinphos-methyl	(c)	(a)	(b)
Azoxystrobin	(c)	(a)	(b)
Benfuracarb (*)	(c)	(a)	(b)
Bifenthrin	(c) (e)	(a), (f)	(b) (d)
Bitertanol	(c)	(a)	(b)
Boscalid	(c)	(a)	(b)
Bromide ion (*) (see remark below)	(c)	(a)	(b)
Bromopropylate	(c)	(a)	(b)
Bromuconazole (sum of diasteroisomers) (*)	(c)	(a)	(b)
Bupirimate	(c)	(a)	(b)
Buprofezin	(c)	(a)	(b)
Cadusafos (*)	(c)	(a)	(b)
Camphechlor (sum of parlar Nos 26, 50 and 62) (*)	(e)	(f)	(d)
Captan	(c)	(a)	(b)
Carbaryl	(c)	(a)	(b)
Carbendazim (sum of Benomyl and carbendazim expressed as carbendazim)	(c)	(a)	(b)
Carbofuran (sum of Carbofuran and 3-Hydroxycarbofuran expressed as Carbofuran)	(c)	(a)	(b)
Carbosulfan (*)	(c)	(a)	(b)
Chlordane (sum of cis- and trans-isomers and oxychlordane expressed as chlordane)	(e)	(f)	(d)
Chlorfenapyr	(c)	(a)	(b)
Chlorfenvinphos	(c)	(a)	(b)
Chlormequat (**)	(c)	(a)	(b)
Chlorobenzilate (*)	(e)	(f)	(d)

	2010	2011	2012
Chlorothalonil	(c)	(a)	(b)
Chlorpropham (Chlorpropham and 3-Chloroaniline expressed as Chlorpropham (see remark below))	(c)	(a)	(b)
Chlorpyriphos	(c) (e)	(a), (f)	(b) (d)
Chlorpyriphos-methyl	(c) (e)	(a), (f)	(b) (d)
clofentezin (sum of all compounds containing the 2-Chlorbenzoyl-moiety expressed as Clofentezin)	(c)	(a)	(b)
Clothianidin	(c)	(a)	(b)
Cyfluthrin (Cyfluthrin incl. other mixtures of constituent isomers (sum of isomers))	(c) (e)	(a), (f)	(b) (d)
Cypermethrin (Cypermethrin incl. other mixtures of constituent isomers (sum of isomers))	(c) (e)	(a), (f)	(b) (d)
cyproconazole (*)	(c)	(a)	(b)
Cyprodinil	(c)	(a)	(b)
DDT (sum of p,p′-DDT, o,p′-DDT, p-p′-DDE and p,p′-DDD (TDE) expressed as DDT)	(e)	(f)	(d)
Deltamethrin (cis-deltamethrin)	(c) (e)	(a), (f)	(b) (d)
Diazinon	(c) (e)	(a), (f)	(b)
Dichlofluanid	(c)	(a)	(b)
Dichlorvos	(c)	(a)	(b)
Dicloran	(c)	(a)	(b)
Dicofol (sum of p,p′ and o,p′ isomers)	(c)	(a)	(b)
Dieldrin (Aldrin and dieldrin combined expressed as dieldrin)	(e)	(f)	(d)
Difenoconazole	(c)	(a)	(b)
Dimethoate (sum of Dimethoate and Omethoate expressed as dimethoate)	(c)	(a)	(b)
Dimethoate	(c)	(a)	(b)
Omethoate	(c)	(a)	(b)
Dimethomorph	(c)	(a)	(b)
Dinocap (sum of dinocap isomers and their corresponding phenols expressed as dinocap) (*)	(c)	(a)	(b)
Diphenylamine	(c)	(a)	(b)
Endosulfan (sum of alpha- and beta-isomers and Endosulfan-sulphate expressed as Endosulfan)	(c) (e)	(a), (f)	(b) (d)
Endrin	(e)	(f)	(d)
Epoxiconazole	(c)	(a)	(b)
Ethephon (*)	(c)	(a)	(b)
Ethion	(c)	(a)	(b)
Etofenprox (F) (*)	(c)	(a)	(b)

	2010	2011	2012
Ethoprophos (*)	(c)	(a)	(b)
Fenamiphos (sum of fenamiphos and its sulphoxide and sulphone expressed as fenamiphos) (*)	(c)	(a)	(b)
fenarimol	(c)	(a)	(b)
Fenazaquin	(c)	(a)	(b)
Fenbutatin oxide (F) (*)	(c)	(a)	(b)
Fenbuconazole (*)	(c)	(a)	(b)
Fenhexamid	(c)	(a)	(b)
Fenitrothion	(c)	(a)	(b)
Fenoxycarb	(c)	(a)	(b)
Fenpropathrin (*)	(c)	(a)	(b)
Fenpropimorph	(c)	(a)	(b)
Fenthion (sum of fenthion and its oxigen analogue, their sulfoxides and sulfone expressed as parent)	(c) (e)	(a), (f)	(d)
Fenvalerate/Esfenvalerate (sum) (sum of RS/SR and RR/SS isomers)	(c) (e)	(a), (f)	(d)
Fipronil (sum Fipronil + sulfone metabolite (MB46136) expressed as Fipronil)	(c)	(a)	(b)
Fluazifop (Fluazifop-P-butyl (fluazifop acid (free and conjugate))) (*)	(c)	(a)	(b)
Fludioxonil	(c)	(a)	(b)
Flufenoxuron	(c)	(a)	(b)
Fluquinconazole (*)	(c)	(a)	(b)
flusilazole	(c)	(a)	(b)
Flutriafol (*)	(c)	(a)	(b)
Folpet	(c)	(a)	(b)
Formetanate (sum of Formetanate and its salts expressed as Formetanate hydrochloride)	(c)	(a)	(b)
Fosthiazate (*)	(c)	(a)	(b)
Glyphosate (***)	(c)	(a)	(b)
Haloxyfop including haloxyfop-R (Haloxyfop-R methyl ester, haloxyfop-R and conjugates of haloxyfop-R expressed as haloxyfop-R) (F) (R) (*)	(c)	(a)	(b)
HCB	(e)	(f)	(d)
Heptachlor (sum of heptachlor and heptachlor epoxide expressed as heptachlor)	(e)	(f)	(d)
Hexachlorcyclohexan (HCH), Alpha-isomer	(e)	(f)	(d)
Hexachlorcyclohexan (HCH), Beta-isomer	(e)	(f)	(d)
Hexachlorocyclohexane (HCH) (Gamma-isomer) (Lindane)	(e)	(f)	(d)
Hexaconazole	(c)	(a)	(b)
Hexythiazox	(c)	(a)	(b)

	2010	2011	2012
Imazalil	(c)	(a)	(b)
Imidacloprid	(c)	(a)	(b)
Indoxacarb (Indoxacarb as sum of the isomers S and R)	(c)	(a)	(b)
Iprodione	(c)	(a)	(b)
Iprovalicarb	(c)	(a)	(b)
Kresoxim-methyl	(c)	(a)	(b)
Lambda-cyhalothrin (Lambda-cyhalothrin, incl. other mixtures of constituent isomers (sum of isomers))	(c)	(a)	(b)
Linuron	(c)	(a)	(b)
Lufenuron	(c)	(a)	
Malathion (sum of Malathion and Malaoxon expressed as Malathion)	(c)	(a)	(b)
Maneb group (sum expressed as CS2: Maneb, Mancozeb, Metiram, Propineb, Thiram, Ziram)	(c)	(a)	(b)
Mepanipyrim and its metabolite (2-anilino-4-(2-hydroxypropyl)-6-methylpyrimidine) expressed as mepanipyrim)	(c)	(a)	(b)
Mepiquat (**)	(c)	(a)	(b)
Metalaxyl (Metalaxyl incl. mixtures of constituent isomers incl. Metalaxyl-M (sum of isomers))	(c)	(a)	(b)
Metconazole (*)	(c)	(a)	(b)
Methamidophos	(c)	(a)	(b)
Methidathion	(c) (e)	(a), (f)	(b) (d)
Methiocarb (sum of Methiocarb and Methiocarb-Sulfoxide and Sulfone, expressed as Methiocarb)	(c)	(a)	(b)
Methomyl (sum of Methomyl and Thiodicarb expressed as Methomyl)	(c)	(a)	(b)
Methoxyfenozide	(c)	(a)	(b)
Monocrotophos	(c)	(a)	(b)
Myclobutanil	(c)	(a)	(b)
Oxadixyl	(c)	(a)	(b)
Oxamyl	(c)	(a)	(b)
Oxydemeton-methyl (sum of Oxydemeton-Methyl and Demeton-S-Methylsulfone expressed as Oxydemeton-Methyl)	(c)	(a)	(b)
Paclobutrazole (*)	(c)	(a)	(b)
Parathion	(c) (e)	(a), (f)	(b) (d)
Parathion-Methyl (sum of Parathion-Methyl and Paraoxon-Methyl expressed as Parathion-Methyl)	(c) (e)	(a), (f)	(b) (d)
Pencycuron	(c)	(a)	(b)
Penconazole	(c)	(a)	(b)

	2010	2011	2012
Pendimethalin	(c)	(a)	(b)
Permethrin (sum of cis- and trans-permethrin)	(e)	(f)	(d)
Phenthoate (*)	(c)	(a)	(b)
Phosalone	(c)	(a)	(b)
Phosmet (Phosmet and Phosmet oxon expressed as Phosmet)	(c)	(a)	(b)
Phoxim (*)	(c)	(a)	(b)
Pyraclostrobin (F)	(c)	(a)	(b)
Pirimicarb (sum of Pirimicarb and Desmethylpirimicarb expressed as Pirimicarb)	(c)	(a)	(b)
Pirimiphos-methyl	(c) (e)	(a), (f)	(b) (d)
Prochloraz (sum of Prochloraz + its metabolites cont. the 2,4,6-Trichlorophenol moiety expressed as Prochloraz)	(c)	(a)	(b)
Procymidone	(c)	(a)	(b)
Profenofos	(c) (e)	(a), (f)	(b) (d)
Propamocarb (sum of Propamocarb and its salts expressed as Propamocarb) (*)	(c)	(a)	(b)
Propargite	(c)	(a)	(b)
Propiconazole	(c)	(a)	(b)
Propyzamide	(c)	(a)	(b)
Prothioconazole (Prothioconazole-desthio) (*)	(c)	(a)	(b)
Pyrazophos	(e)	(f)	(d)
Pyrethrins (*)	(c)	(a)	(b)
Pyridaben	(c)	(a)	(b)
Pyrimethanil	(c)	(a)	(b)
Pyriproxyfen	(c)	(a)	(b)
Quinoxyfen	(c)	(a)	(b)
Quintozene (sum of Quintozen und Pentachloraniline, expressed as Quintozene) (*)	(e)	(f)	(e)
Resmethrin (sum of isomers) (*)	(e)	(f)	(d)
Spinosad (sum of Spinosyn A and Spinosyn D, expressed as Spinosad)	(c)	(a)	(b)
Spiroxamine	(c)	(a)	(b)
Taufluvalinate	(c)	(a)	(b)
Tebuconazole	(c)	(a)	(b)
Tebufenozide	(c)	(a)	(b)
Tebufenpyrad	(c)	(a)	(b)
Tecnazene (*)	(e)	(f)	(d)
Teflubenzuron	(c)	(a)	(b)
Tefluthrin (*)	(c)	(a)	(b)

	2010	2011	2012
Tetraconazole	(c)	(a)	(b)
Tetradifon	(c)	(a)	(b)
Thiabendazole	(c)	(a)	(b)
Thiamethoxam (sum of Thiamethoxam and Clothianidin expressed as Thiamethoxam)	(c)	(a)	(b)
Thiacloprid	(c)	(a)	(b)
Thiophanate-methyl	(c)	(a)	(b)
Tolcloflos-methyl	(c)	(a)	(b)
Tolylfluanid (sum of Tolylfluanid and Dimethylaminosulfotoluidide expressed as Tolylfluanid)	(c)	(a)	(b)
Triadimefon and triadimenol (sum of triadimefon and triadimenol)	(c)	(a)	(b)
Triazophos	(c) (e)	(a), (f)	(b) (d)
Trichlorfon (*)	(c)	(a)	(b)
trifloxystrobin	(c)	(a)	(b)
Triflumuron (F) (*)	(c)	(a)	(b)
Trifluralin	(c)	(a)	(b)
Triticonazole (*)	(c)	(a)	(b)
Vinclozolin (sum of Vinclozolin and all metabolites cont. the 3,5-dichloraniniline moiety, expressed as Vinclozolin)	(c)	(a)	(b)
Zoxamide (*)	(c)	(a)	(b)

(a) Beans (fresh or frozen, without pod), carrots, cucumbers, oranges or mandarins, pears, potatoes, rice and spinach (fresh or frozen).
(b) Aubergines, bananas, cauliflower, table grapes, orange juice ([1]), peas (fresh/frozen, without pod), peppers (sweet) and wheat.
(c) Apples, head cabbage, leek, lettuce, tomatoes, peaches including nectarines and similar hybrids; rye or oats and strawberries.
(d) Butter, eggs.
(e) Milk, swinemeat.
(f) Poultrymeat, liver (bovine and other ruminants, swine and poultry).
(F) Fat soluble.
(*) To be analysed on voluntary basis in 2010. The decision for not analysing shall be justified with a risk/benefit Member State evaluation.
Bromide ion remark: bromide ion shall be analysed obligatory on lettuce and tomatoes in 2010, rice and spinach in 2011 and sweet pepper in 2012; and on voluntary basis in the rest of commodities foreseen for each year. The decision for not analysing any of the commodities foreseen shall be justified with a risk/benefit Member State evaluation.
Amitraz shall be analysed only in pears in 2010.
Chlorpropham residue definition for potatoes (chlorpropham only) has to be taken into account in 2011.
(**) Chlormequat and mepiquat shall be analysed in cereals (excluding rice), and pears.
(***) Only cereals.

([1]) For orange juice, Member States shall specify the source (concentrates or fresh fruits).

ANNEX II

Number of samples of each product to be taken and analysed by each Member State.

Member State	Samples
BE	12 (*) 15 (**)
BG	12 (*) 15 (**)
CZ	12 (*) 15 (**)
DK	12 (*) 15 (**)
DE	93
EE	12 (*) 15 (**)
EL	12 (*) 15 (**)
ES	45
FR	66
IE	12 (*) 15 (**)
IT	65
CY	12 (*) 15 (**)
LV	12 (*) 15 (**)
LT	12 (*) 15 (**)
LU	12 (*) 15 (**)
HU	12 (*) 15 (**)
MT	12 (*) 15 (**)
NL	17
AT	12 (*) 15 (**)
PL	45
PT	12 (*) 15 (**)
RO	17
SI	12 (*) 15 (**)
SK	12 (*) 15 (**)
FI	12 (*) 15 (**)
SE	12 (*) 15 (**)
UK	66

(*) Minimum number of samples for each single residue method applied.
(**) Minimum number of samples for each multi-residue method applied.

TOTAL MINIMUM NUMBER OF SAMPLES: 642

COMMISSION REGULATION (EC) No 902/2009

of 28 September 2009

concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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) This Regulation authorises an enzyme preparation of endo-1,4-beta-xylanase as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding.

(3) 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.

(4) The European Food Safety Authority (the Authority) performed the risk assessment in accordance with Article 8(3) of Regulation (EC) No 1831/2003.

(5) The application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding, to be classified in the additive category 'zootechnical additives'.

(6) The Authority concluded in its opinions of 21 May 2008 [2] and 21 April 2009 [3] that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can have a significant benefit on body weight gain and feed conversion. The Authority did 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.

(7) The assessment of that preparation shows that the conditions for authorisation, 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.

(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 'zootechnical additives' and to the functional group 'digestibility enhancers', 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*.

[1] OJ L 268, 18.10.2003, p. 29.

[2] *The EFSA Journal* (2008) 712, pp. 1-20.

[3] *The EFSA Journal* (2009) 1058, pp. 1-6.

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

Done at Brussels, 28 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

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 (Units of activity/kg of complete feedingstuff with a moisture content of 12 %)		Other provisions	End of period of authorisation
Category of zootechnical additives. Functional group: digestibility enhancers									
4a8	Roal Oy	Endo-1,4-beta-xylanase EC 3.2.1.8	Additive composition: Preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) having a minimum activity of: solid form: 4×10^6 BXU (1)/g liquid form: 4×10^5 BXU/g Characterisation of the active substance: endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) Analytical method (2): In the additive and the premixture: reducing sugar assay for endo-1,4-beta-xylanase by colorimetric reaction of dinitrosalicylic acid reagent on reducing sugar yield at pH 5,3 and 50 °C In the feedingstuffs: colorimetric method measuring water soluble dye released by the enzyme from azurine crosslinked wheat arabinoxylan substrate	Piglets (weaned)	—	24 000 BXU	—	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 of body weight. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 20 % wheat. 4. For safety reasons: breathing protection, glasses and gloves shall be used during handling.	19 October 2019
				Chickens for fattening		8 000 BXU			
				Chickens reared for laying		8 000 BXU			
				Turkeys for fattening		16 000 BXU			
				Turkeys reared for breeding		16 000 BXU			

(1) 1 BXU is the amount of enzyme which liberates 1 nmol reducing sugars as xylose from birch xylan per second at pH 5,3 and 50 °C.
(2) 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 (EC) No 903/2009

of 28 September 2009

concerning the authorisation of the preparation of *Clostridium butyricum* MIYAIRI 588 (FERM-P 1467) as a feed additive for chickens for fattening (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Mitsui & Co. Deutschland GmbH)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the preparation of *Clostridium butyricum* MIYAIRI 588 (FERM-P 1467) as a feed additive for chickens for fattening, to be classified in the additive category 'zootechnical additives'.

(4) From the opinion of the European Food Safety Authority (the Authority) of 2 April 2009 [2] it results that the preparation of *Clostridium butyricum* MIYAIRI 588 (FERM-P 1467) does not have an adverse effect on animal health, human health or the environment and that the use of that preparation can have a significant benefit on feed to gain ratio. 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 that preparation shows that the conditions for authorisation, 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) 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, 28 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 268, 18.10.2003, p. 29.
[2] *The EFSA Journal* (2009) 1039, p. 1.

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									
4b1830	Miyarisan Pharmaceutical Co. Ltd represented by Mitsui & Co. Deutschland GmbH	*Clostridium butyricum* MIYAIRI 588 (FERM-P 1467)	Additive composition: Preparation of *Clostridium butyricum* MIYAIRI 588 (FERM-P 1467) containing a minimum of solid form 5×10^8 CFU/g additive Characterisation of the active substance: *Clostridium butyricum* MIYAIRI 588 (FERM-P 1467) Analytical method (1): Quantification: iron sulphite agar for the additive and premixtures and selective *Clostridium butyricum* MIYAIRI 588 agar for feedingstuffs Identification: pulsed-field gel electrophoresis (PFGE) method	Chickens for fattening	—	5×10^8 CFU	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. The use is allowed in feed containing the permitted coccidiostats: monensin sodium, diclazuril, maduramicin ammonium, robenidine, narasin, narasin/nicarbazin, semduramycin, decoquinate. 3. For safety reasons: breathing protection shall be used during handling.	19 October 2019

(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 (EC) No 904/2009

of 28 September 2009

concerning the authorisation of guanidinoacetic acid as a feed additive for chickens for fattening

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 guanidinoacetic acid (CAS No 352-97-6) as a feed additive for chickens for fattening, to be classified in the additive category 'nutritional additives and the functional group amino acids their salts and analogues'.

(4) From the opinion of the European Food Safety Authority (the Authority) of 3 March 2009 [2] it results that guanidinoacetic acid (CAS No 352-97-6) does not have an adverse effect on animal health, human health and the environment. 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 that preparation shows that the conditions for authorisation, 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) 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 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', 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, 28 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 268, 18.10.2003, p. 29.
[2] *The EFSA Journal* (2009) 988, p. 1.

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 nutritional additives. Functional group: amino acids, their salts and analogues									
3c3.7.2	—	Guanidinoacetic acid	Additive composition: Guanidinoacetic acid with a purity of at least 98 % (on dry matter basis) Characterisation of the active substance: Guanidinoacetic acid CAS No 352-97-6 ($C_3H_7N_3O_2$) produced by chemical synthesis with: ≤ 0,5 % dicyanamide ≤ 0,03 % cyanamide Analytical method (1): Ion chromatography (IC) with UV detection (λ = 200 nm)	Chickens for fattening	—	600	600	The moisture content shall be indicated. The additive shall be incorporated into feed in the form of a premixture.	19 October 2019

(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 (EC) No 905/2009

of 28 September 2009

amending Regulation (EC) No 537/2007 as regards the name of the holder of the authorisation of the fermentation product of *Aspergillus oryzae* (NRRL 458) (Amaferm)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 13(3) thereof,

Whereas:

(1) Trouw Nutrition BV has submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation as regards Commission Regulation (EC) No 537/2007 of 15 May 2007 concerning the authorisation of the fermentation product of *Aspergillus oryzae* (NRRL 458) (Amaferm) [2] as a feed additive for dairy cows. The authorisation is linked to the holder of the authorisation. The holder is Trouw Nutrition BV.

(2) The applicant claims that it transferred its marketing authorisation for that additive to Biozyme Incorporated which now owns the marketing rights for that additive. The applicant has submitted appropriate documents supporting its allegations.

(3) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.

(4) To allow Biozyme Incorporated to exploit its marketing rights it is necessary to change the terms of the authorisations.

(5) Regulation (EC) No 537/2007 should therefore be amended accordingly.

(6) It is appropriate to provide for a transitional period during which existing stocks may be used up.

(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

In the Annex to Regulation (EC) No 537/2007, in column 2, the words 'Trouw Nutrition BV' are replaced by the words 'Biozyme Incorporated'.

Article 2

Existing stocks which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until 1 April 2010.

Article 3

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, 28 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

[1] OJ L 268, 18.10.2003, p. 29.
[2] OJ L 128, 16.5.2007, p. 13.

COMMISSION REGULATION (EC) No 906/2009

of 28 September 2009

on the application of Article 81(3) of the Treaty to certain categories of agreements, decisions and concerted practices between liner shipping companies (consortia)

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 246/2009 of 26 February 2009 on the application of Article 81(3) of the Treaty to certain categories of agreements, decisions and concerted practices between liner shipping companies (consortia) ([1]), and in particular Article 1 thereof,

Having published a draft of this Regulation ([2]),

After consulting the Advisory Committee on Restrictive Practices and Dominant Positions,

Whereas:

(1) Regulation (EC) No 246/2009 empowers the Commission to apply Article 81(3) of the Treaty by regulation to certain categories of agreements, decisions and concerted practices between shipping companies relating to the joint operation of liner shipping services (consortia), which, through the cooperation they bring about between the shipping companies that are parties thereto, are liable to restrict competition within the common market and to affect trade between Member States and may therefore be caught by the prohibition contained in Article 81(1) of the Treaty.

(2) The Commission has made use of its power by adopting Commission Regulation (EC) No 823/2000 of 19 April 2000 on the application of Article 81(3) of the Treaty to certain categories of agreements, decisions and concerted practices between liner shipping companies (consortia) ([3]), which will expire on 25 April 2010. On the basis of the Commission's experience to date it can be concluded that the justifications for a block exemption for liner consortia are still valid. However, certain changes are necessary in order to remove references to Council Regulation (EEC) No 4056/86 of 22 December 1986 laying down detailed rules for the application of Articles 85 and 86 of the Treaty to maritime transport ([4]) which allowed liner shipping lines to fix prices and capacity, but has now been repealed. Modifications are also necessary to ensure a greater convergence with other block exemption regulations for horizontal cooperation in force whilst taking into account current market practices in the liner industry.

(3) Consortium agreements vary significantly ranging from those that are highly integrated, requiring a high level of investment for example due to the purchase or charter by their members of vessels specifically for the purpose of setting up the consortium and the setting up of joint operations centres, to flexible slot exchange agreements. For the purposes of this Regulation a consortium agreement consists of one or a set of separate but interrelated agreements between liner shipping companies under which the parties operate the joint service. The legal form of the arrangements is less important than the underlying economic reality that the parties provide a joint service.

(4) The benefit of the block exemption should be limited to those agreements for which it can be assumed with a sufficient degree of certainty that they satisfy the conditions of Article 81(3) of the Treaty. However, there is no presumption that consortia which do not benefit from this Regulation fall within the scope of Article 81(1) of the Treaty or, if they do, that they do not satisfy the conditions of Article 81(3) of the Treaty. When conducting a self-assessment of the compatibility of their agreement with Article 81 of the Treaty, parties to such consortia may consider the specific features of markets with small volumes carried or situations where the market share threshold is exceeded as a result of the presence in the consortium of a small carrier without important resources and whose increment to the overall market share of the consortium is only insignificant.

(5) Consortia, as defined in this Regulation, generally help to improve the productivity and quality of available liner shipping services by reason of the rationalisation they bring to the activities of member companies and through

([1]) OJ L 79, 25.3.2009, p. 1.
([2]) OJ C 266, 21.10.2008, p. 1.
([3]) OJ L 100, 20.4.2000, p. 24.
([4]) OJ L 378, 31.12.1986, p. 4.

the economies of scale they allow in the operation of vessels and utilisation of port facilities. They also help to promote technical and economic progress by facilitating and encouraging greater utilisation of containers and more efficient use of vessel capacity. For the purpose of establishing and running a joint service, an essential feature inherent in consortia is the ability to make capacity adjustments in response to fluctuations in supply and demand. By contrast, unjustified limitation of capacity and sales as well as the joint fixing of freight rates or market and customer allocation are unlikely to bring any efficiency. Therefore, the exemption provided for in this Regulation should not apply to consortium agreements that involve such activities, irrespective of the market power of the parties.

(6) A fair share of the benefits resulting from the efficiencies should be passed on to transport users. Users of the shipping services provided by consortia may benefit from the improvements in productivity which consortia can bring about. Those benefits may also take the form of an improvement in the frequency of sailings and port calls, or an improvement in scheduling as well as better quality and personalised services through the use of more modern vessels and other equipment, including port facilities.

(7) Users can benefit effectively from consortia only if there is sufficient competition in the relevant markets in which the consortia operate. This condition should be regarded as being met when a consortium remains below a given market share threshold and can therefore be presumed to be subject to effective actual or potential competition from carriers that are not members of that consortium. In order to assess the relevant market, account should be taken not only of direct trade between the ports served by a consortium but also of any competition from other liner services sailing from ports which may be substituted for those served by the consortium and, where appropriate, of other modes of transport.

(8) This Regulation should not exempt agreements containing restrictions of competition which are not indispensable to the attainment of the objectives justifying the grant of the exemption. To that end, severely anti-competitive restraints (hardcore restrictions) relating to the fixing of prices charged to third parties, the limitation of capacity or sales and the allocation of markets or customers should be excluded from the benefit of this Regulation. Other than the activities which are expressly exempted by this Regulation, only ancillary activities which are directly related to the operation of the consortium, necessary for its implementation and proportionate to it should be covered by this Regulation.

(9) The market share threshold and the other conditions set out in this Regulation, as well as the exclusion of certain conduct from its benefit, should normally ensure that the agreements to which the block exemption applies do not give the companies concerned the possibility of eliminating competition in a substantial part of the relevant market in question.

(10) For the assessment of whether a consortium fulfils the market share condition, the overall market shares of the consortium members should be added up. The market share of each member should take into account the overall volumes it carries within and outside the consortium. In the latter case account should be taken of all volumes carried by a member within another consortium or in relation to any service provided individually by the member, be it on its own vessels or on third party vessels pursuant to contractual arrangements such as slot charters.

(11) In addition, the benefit of the block exemption should be subject to the right of each consortium member to withdraw from the consortium provided that it gives reasonable notice. However, provision should be made for a longer notice period and a longer initial lock-in period in the case of highly integrated consortia in order to take account of the higher investments undertaken to set them up and the more extensive reorganisation entailed in the event of a member leaving.

(12) In particular cases in which the agreements falling under this Regulation nevertheless have effects incompatible with Article 81(3) of the Treaty, the Commission may withdraw the benefit of the block exemption, on the basis of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty [1]. In that respect, the negative effects that may derive from the existence of links between the consortium and/or its members and other consortia and/or liner carriers on the same relevant market are of particular importance.

(13) Furthermore, where agreements have effects which are incompatible with Article 81(3) of the Treaty in the territory of a Member State, or in a part thereof, which has all the characteristics of a distinct geographic market, the competition authority of that Member State may withdraw the benefit of the block exemption in respect of that territory pursuant to Regulation (EC) No 1/2003.

(14) This Regulation is without prejudice to the application of Article 82 of the Treaty.

(15) In view of the expiry of Regulation (EC) No 823/2000, it is appropriate to adopt a new Regulation renewing the block exemption,

[1] OJ L 1, 4.1.2003, p. 1.

HAS ADOPTED THIS REGULATION:

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Scope

This Regulation shall apply to consortia only in so far as they provide international liner shipping services from or to one or more Community ports.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. 'consortium' means an agreement or a set of interrelated agreements between two or more vessel-operating carriers which provide international liner shipping services exclusively for the carriage of cargo relating to one or more trades, the object of which is to bring about cooperation in the joint operation of a maritime transport service, and which improves the service that would be offered individually by each of its members in the absence of the consortium, in order to rationalise their operations by means of technical, operational and/or commercial arrangements;

2. 'liner shipping' means the transport of goods on a regular basis on a particular route or routes between ports and in accordance with timetables and sailing dates advertised in advance and available, even on an occasional basis, to any transport user against payment;

3. 'transport user' means any undertaking (such as shipper, consignee or forwarder) which has entered into, or intends to enter into, a contractual agreement with a consortium member for the shipment of goods;

4. 'commencement of the service' means the date on which the first vessel sails on the service.

CHAPTER II

EXEMPTIONS

Article 3

Exempted agreements

Pursuant to Article 81(3) of the Treaty and subject to the conditions laid down in this Regulation, it is hereby declared that Article 81(1) of the Treaty shall not apply to the following activities of a consortium:

1. the joint operation of liner shipping services including any of the following activities:

   (a) the coordination and/or joint fixing of sailing timetables and the determination of ports of call;

   (b) the exchange, sale or cross-chartering of space or slots on vessels;

   (c) the pooling of vessels and/or port installations;

   (d) the use of one or more joint operations offices;

   (e) the provision of containers, chassis and other equipment and/or the rental, leasing or purchase contracts for such equipment;

2. capacity adjustments in response to fluctuations in supply and demand;

3. the joint operation or use of port terminals and related services (such as lighterage or stevedoring services);

4. any other activity ancillary to those referred to in points 1, 2 and 3 which is necessary for their implementation, such as:

   (a) the use of a computerised data exchange system;

   (b) an obligation on members of a consortium to use in the relevant market or markets vessels allocated to the consortium and to refrain from chartering space on vessels belonging to third parties;

   (c) an obligation on members of a consortium not to assign or charter space to other vessel-operating carriers in the relevant market or markets except with the prior consent of the other members of the consortium.

Article 4

Hardcore restrictions

The exemption provided for in Article 3 shall not apply to a consortium which, directly or indirectly, in isolation or in combination with other factors under the control of the parties, has as its object:

1. the fixing of prices when selling liner shipping services to third parties;

2. the limitation of capacity or sales except for the capacity adjustments referred to in Article 3(2);

3. the allocation of markets or customers.

CHAPTER III

CONDITIONS FOR EXEMPTION

Article 5

Conditions relating to market share

1. In order for a consortium to qualify for the exemption provided for in Article 3, the combined market share of the consortium members in the relevant market upon which the consortium operates shall not exceed 30 % calculated by reference to the total volume of goods carried in freight tonnes or 20-foot equivalent units.

2. For the purpose of establishing the market share of a consortium member the total volumes of goods carried by it in the relevant market shall be taken into account irrespective of whether those volumes are carried:

(a) within the consortium in question;

(b) within another consortium to which the member is a party; or

(c) outside a consortium on the member's own or on third party vessels.

3. The exemption provided for in Article 3 shall continue to apply if the market share referred to in paragraph 1 of this Article is exceeded during any period of two consecutive calendar years by not more than one tenth.

4. Where one of the limits specified in paragraphs 1 and 3 of this Article is exceeded, the exemption provided for in Article 3 shall continue to apply for a period of six months following the end of the calendar year during which it was exceeded. That period shall be extended to 12 months if the excess is due to the withdrawal from the market of a carrier which is not a member of the consortium.

Article 6

Other conditions

In order to qualify for the exemption provided for in Article 3, the consortium must give members the right to withdraw without financial or other penalty such as, in particular, an obligation to cease all transport activity in the relevant market or markets in question, whether or not coupled with the condition that such activity may be resumed after a certain period has elapsed. That right shall be subject to a maximum period of notice of six months. The consortium may, however, stipulate that such notice can only be given after an initial period of a maximum of 24 months starting from the date of entry into force of the agreement or, if later, from the commencement of the service.

In the case of a highly integrated consortium the maximum period of notice may be extended to 12 months and the consortium may stipulate that such notice can only be given after an initial period of a maximum of 36 months starting from the date of entry into force of the agreement or, if later, from the commencement of the service.

CHAPTER IV

FINAL PROVISIONS

Article 7

Entry into force

This Regulation shall enter into force on 26 April 2010.

It shall apply until 25 April 2015.

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

Done at Brussels, 28 September 2009.

For the Commission

Neelie KROES

Member of the Commission

II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 28 September 2009

authorising certain Member States to revise their annual BSE monitoring programmes

(notified under document C(2009) 6979)

(Text with EEA relevance)

(2009/719/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies [1], and in particular the second subparagraph of Article 6(1b) thereof,

Whereas:

(1) Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of transmissible spongiform encephalopathies (TSEs) in animals and requires each Member State to carry out an annual monitoring programme for TSEs based on active and passive surveillance, in accordance with Annex III to that Regulation.

(2) Those annual monitoring programmes are to cover as a minimum certain sub-populations of bovine animals as provided in Regulation (EC) No 999/2001. Those sub-populations are to include all bovine animals above 24 or 30 months of age, the age limit depending on categories laid down in points 2.1, 2.2 and 3.1 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001.

(3) Article 6(1b) of Regulation (EC) No 999/2001 says that Member States which can demonstrate an improvement in their epidemiological situation, according to certain criteria, may apply for their annual monitoring programmes to be revised.

(4) Annex III (Chapter A, Part I, Point 7) to Regulation (EC) No 999/2001 says which information has to be submitted to the Commission and which epidemiological criteria have to be complied with by Members States wishing to revise their annual monitoring programmes.

(5) On 17 July 2008, the European Food Safety Authority (EFSA) published a scientific opinion [2] which provided an assessment on the level of additional risk to human and animal health following the implementation of a revised bovine spongiform encephalopathy (BSE) monitoring regime in the 15 countries which were members of the Community before 1 May 2004. The opinion concluded that less than one BSE case would be missed annually in those Member States if the age of bovine animals covered by the programme was increased from 24 months to 48 months.

[1] OJ L 147, 31.5.2001, p. 1.

[2] 'Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on the risk for human and animal health related to the revision of the BSE monitoring regime in some Member States', *The EFSA Journal* (2008) 762, p. 1.

(6) Commission Decision 2008/908/EC of 28 November 2008 authorising certain Member States to revise their annual BSE monitoring programme [1] was adopted, based on that EFSA opinion, as well as on the assessment of individual applications by those 15 Member States.

(7) On 1 September 2008, Slovenia submitted to the Commission an application to revise its annual BSE monitoring programme.

(8) The Food and Veterinary Office (FVO) carried out an inspection in that Member State in January 2009 in order to verify compliance with the epidemiological criteria laid down in point 7 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001.

(9) The results of that inspection acknowledged the proper implementation in Slovenia of the rules on protective measures laid down in Regulation (EC) No 999/2001. In addition, all the requirements laid down in the third subparagraph of Article 6(1b) and all the epidemiological criteria set out in point 7 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001 were checked and found to be met by Slovenia.

(10) On 29 April 2009, EFSA published a new scientific opinion on the updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States [2]. That opinion also assessed the situation in Slovenia and concluded that less than one BSE case would be missed annually in those Member States if the age of the bovine animals covered by the BSE monitoring was increased from 24 months to 48 months.

(11) In view of all available information, the application submitted by Slovenia to revise its annual BSE monitoring programme has been favourably evaluated. It is therefore appropriate to authorise Slovenia to revise its annual monitoring programme and to lay down 48 months as the new age limit for BSE testing in that Member State.

(12) For epidemiological reasons, it should be provided that the revised monitoring programmes may only be applied to bovine animals which were born in a Member State that is authorised to revise its monitoring programme.

(13) In order to ensure the uniform application of Community legislation, it is appropriate to lay down rules on the age limit for testing in the case of bovine animals born in one Member State but tested in a second one.

(14) In the interest of clarity and consistency of Community legislation, Decision 2008/908/EC should be repealed and replaced by this Decision.

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

HAS ADOPTED THIS DECISION:

Article 1

The Member States listed in the Annex may revise their annual monitoring programmes as provided for in Article 6(1b) of Regulation (EC) No 999/2001 (the revised annual monitoring programmes).

Article 2

1. The revised annual monitoring programmes shall apply only to the bovine animals born in the Member States listed in the Annex and shall cover at least all bovine animals above 48 months of age belonging to the following sub-populations:

(a) animals as referred to in point 2.1 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001;

(b) animals as referred to in point 2.2 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001;

(c) animals as referred to in point 3.1 of Part I of Chapter A of Annex III to Regulation (EC) No 999/2001.

2. When bovine animals belonging to the sub-populations referred to in paragraph 1 and born in one of the Member States listed in the Annex are tested for BSE in another Member State, the age limits for testing in force in the Member State where the tests are performed shall apply.

[1] OJ L 327, 5.12.2008, p. 24.

[2] 'Scientific Opinion of the Panel on Biological Hazards on a request from the European Commission on the updated risk for human and animal health related to the revision of the BSE monitoring regime in some Member States', *The EFSA Journal* (2009) 1059, p. 1.

Article 3

Decision 2008/908/EC is repealed.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 28 September 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX

LIST OF MEMBER STATES AUTHORISED TO REVISE THEIR BSE ANNUAL MONITORING PROGRAMMES

— Belgium
— Denmark
— Germany
— Ireland
— Greece
— Spain
— France
— Italy
— Luxembourg
— Netherlands
— Portugal
— Austria
— Slovenia
— Finland
— Sweden
— United Kingdom

CORRIGENDA

Corrigendum to Commission Directive 2009/5/EC of 30 January 2009 amending Annex III to Directive 2006/22/EC of the European Parliament and of the Council on minimum conditions for the implementation of Council Regulations (EEC) Nos 3820/85 and 3821/85 concerning social legislation relating to road transport activities

(Text with EEA relevance)

(Official Journal of the European Union L 29 of 31 January 2009)

On page 47, entry A1 of the table:

for: 'Not respecting minimum ages for drivers',

read: 'Not respecting minimum ages for conductors';

on page 50, entry I5 of the table:

for: 'Unable to produce manual records and printouts made during the current week and the previous 28 days',

read: 'Unable to produce manual records and printouts made during the current day and the previous 28 days';

on page 50, entry I7 of the table:

for: 'Unable to produce printouts made during the current week and the previous 28 days',

read: 'Unable to produce printouts made during the current day and the previous 28 days'.

II *Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory*

EN

[1] Text with EEA relevance

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