

Official Journal

of the European Union

L 291

Volume 48

5 November 2005

English edition

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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1807/2005
of 4 November 2005
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 Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables ⁽¹⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) Regulation (EC) No 3223/94 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 the Annex thereto.

- (2) In compliance with the above criteria, the standard import values must be fixed at the levels set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 4 of Regulation (EC) No 3223/94 shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 5 November 2005.

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

Done at Brussels, 4 November 2005.

For the Commission

J. M. SILVA RODRÍGUEZ

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 386/2005 (OJ L 62, 9.3.2005, p. 3).

ANNEX

to Commission Regulation of 4 November 2005 establishing the 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	052	48,9
	096	41,4
	204	59,0
	999	49,8
0707 00 05	052	95,1
	204	23,7
	999	59,4
0709 90 70	052	110,1
	204	49,9
	999	80,0
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	624	88,1
	999	88,1
0805 50 10	052	72,9
	388	79,4
	528	60,8
	999	71,0
0806 10 10	052	116,8
	400	238,9
	508	242,7
	624	181,1
	720	95,2
	999	174,9
0808 10 80	052	93,3
	096	15,6
	388	90,8
	400	162,4
	404	88,7
	512	71,0
	720	36,6
	800	190,6
	804	71,1
	999	91,1
0808 20 50	052	88,2
	720	50,7
	999	69,5

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 750/2005 (OJ L 126, 19.5.2005, p. 12). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1808/2005**of 4 November 2005****opening an invitation to tender for the reduction in the duty on maize imported into Spain from third countries**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS REGULATION:

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals ⁽¹⁾, and in particular Article 12(1) thereof,

Whereas:

- (1) Pursuant to the Community's international obligations in the context of the Uruguay Round of Multilateral Trade Negotiations ⁽²⁾, it is necessary to create the conditions to import a certain quantity of maize into Spain.
- (2) Commission Regulation (EC) No 1839/95 of 26 July 1995 laying down detailed rules for the application of tariff quotas for imports of maize and sorghum into Spain and imports of maize into Portugal ⁽³⁾, lays down the special additional detailed rules necessary for implementing the invitation to tender.
- (3) In view of the current market demand in Spain, an invitation to tender for the reduction in the duty on maize is appropriate.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

Article 1

1. An invitation to tender is hereby opened for the reduction in the import duty referred to in Article 10(2) of Regulation (EC) No 1784/2003 on maize to be imported into Spain.

2. Regulation (EC) No 1839/95 shall apply save as otherwise provided for in this Regulation.

Article 2

The invitation to tender shall be open until 22 December 2005. During that period, weekly invitations shall be issued with quantities and closing dates as shown in the notice of invitation to tender.

Article 3

Import licences issued under these invitations to tender shall be valid 50 days from the date they are issued within the meaning of Article 10(4) of Regulation (EC) No 1839/95.

Article 4

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

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

Done at Brussels, 4 November 2005.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).

⁽²⁾ OJ L 336, 23.12.1994, p. 22.

⁽³⁾ OJ L 177, 28.7.1995, p. 4. Regulation as last amended by Regulation (EC) No 1558/2005 (OJ L 249, 24.9.2005, p. 6).

COMMISSION REGULATION (EC) No 1809/2005**of 4 November 2005****opening an invitation to tender for the reduction in the duty on maize imported into Portugal from third countries**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals ⁽¹⁾, and in particular Article 12(1) thereof,

Whereas:

- (1) Pursuant to the Community's international obligations in the context of the Uruguay Round of Multilateral Trade Negotiations ⁽²⁾, it is necessary to create the conditions to import a certain quantity of maize into Portugal.
- (2) Commission Regulation (EC) No 1839/95 of 26 July 1995 laying down detailed rules for the application of tariff quotas for imports of maize and sorghum into Spain and imports of maize into Portugal ⁽³⁾, lays down the special additional detailed rules necessary for implementing the invitation to tender.
- (3) In view of the current market demand in Portugal, an invitation to tender for the reduction in the duty on maize is appropriate.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

1. An invitation to tender is hereby opened for the reduction in the import duty referred to in Article 10(2) of Regulation (EC) No 1784/2003 on maize to be imported into Portugal.

2. Regulation (EC) No 1839/95 shall apply save as otherwise provided for in this Regulation.

Article 2

The invitation to tender shall be open until 30 March 2006. During that period, weekly invitations shall be issued with quantities and closing dates as shown in the notice of invitation to tender.

Article 3

Import licences issued under these invitations to tender shall be valid 50 days from the date they are issued within the meaning of Article 10(4) of Regulation (EC) No 1839/95.

Article 4

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

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

Done at Brussels, 4 November 2005.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).

⁽²⁾ OJ L 336, 23.12.1994, p. 22.

⁽³⁾ OJ L 177, 28.7.1995, p. 4. Regulation as last amended by Regulation (EC) No 1558/2005 (OJ L 249, 24.9.2005, p. 6).

COMMISSION REGULATION (EC) No 1810/2005**of 4 November 2005****concerning a new authorisation for 10 years of an additive in feedingstuffs, the permanent authorisation of certain additives in feedingstuffs and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽¹⁾, and in particular Articles 3, 9, 9d(1) and 9e(1) thereof,

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 ⁽²⁾, and in particular Article 25 thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.
- (2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.
- (3) The applications for the authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.
- (4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of

- (5) The use of the growth promoter 'Formi LHS (potassium diformate)' was provisionally authorised, for the first time, for piglets and pigs for fattening by Commission Regulation (EC) No 1334/2001 ⁽³⁾. The person responsible for putting into circulation 'Formi LHS (potassium diformate)' submitted an application to obtain a definitive authorisation for 10 years. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of this preparation, as specified in Annex I, should be authorised for 10 years.
- (6) The use of the additive 'clinoptilolite of sedimentary origin' as a member of the group of binders, anti-caking agents and coagulants was provisionally authorised, for the first time, for pigs, chickens and turkeys for fattening and for bovines and salmon by Commission Regulation (EC) No 1887/2000 ⁽⁴⁾. New data were submitted in support of an application for authorisation without time-limit of that additive. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that additive, as specified in Annex II, should be authorised without a time-limit.
- (7) The use of the additive 'sodium ferrocyanide' as a member of the group of binders, anti-caking agents and coagulants was provisionally authorised, for the first time, for all species or categories of animals by Commission Regulation (EC) No 256/2002 ⁽⁵⁾. New data were submitted in support of an application for authorisation without time-limit of that additive. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that additive, as specified in Annex II, should be authorised without a time-limit.

⁽¹⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

⁽²⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽³⁾ OJ L 180, 3.7.2001, p. 18. Regulation as amended by Regulation (EC) No 676/2003 (OJ L 97, 15.4.2003, p. 29).

⁽⁴⁾ OJ L 227, 7.9.2000, p. 13.

⁽⁵⁾ OJ L 41, 13.2.2002, p. 6.

- (8) The use of the additive 'potassium ferrocyanide' as a member of the group of binders, anti-caking agents and coagulants was provisionally authorised, for the first time, for all species or categories of animals by Regulation (EC) No 256/2002. New data were submitted in support of an application for authorisation without time-limit of that additive. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that additive, as specified in Annex II, should be authorised without a time-limit.
- (9) The use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (CNCM MA 6-10 W) was provisionally authorised for the first time for laying hens, by Commission Regulation (EC) No 418/2001⁽¹⁾. New data were submitted in support of an application for authorisation without a time-limit of that enzyme preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex III, should be authorised without a time-limit.
- (10) The use of the micro-organism preparation of *Enterococcus faecium* (NCIMB 11181) was authorised without a time-limit for calves and for piglets by Commission Regulation (EC) No 1333/2004⁽²⁾. New data were submitted in support of an application to extend the authorisation of the use of that micro-organism preparation to chickens for fattening. The European Food Safety Authority (EFSA) delivered a favourable opinion on 13 April 2005 on the safety of that additive when used in the animal category chickens for fattening, under the conditions of use set out in Annex IV to this Regulation. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation as specified in Annex IV, should be provisionally authorised for four years.
- (11) The use of the micro-organism preparation of *Enterococcus faecium* (CECT 4515) was provisionally authorised, for the first time, for piglets and for calves by Commission Regulation (EC) No 654/2000⁽³⁾. New data were submitted in support of an application to extend the authorisation of the use of that micro-organism preparation to chickens for fattening. The EFSA delivered a favourable opinion on 13 April 2005 on the safety of that additive when used in the animal category chickens for fattening, under the conditions of use set out in Annex IV to this Regulation. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation as specified in Annex IV, should be provisionally authorised for four years.
- (12) The assessment of these applications shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annexes. Such protection should be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁽⁴⁾.
- (13) 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 belonging to the group 'Growth promoters', as specified in Annex I, is authorised for 10 years for use as additive in animal nutrition under the conditions laid down in that Annex.
- Article 2*
- The additives belonging to the group 'Binders, anti-caking agents and coagulants', as specified in Annex II, are authorised without a time limit for use as additives in animal nutrition under the conditions laid down in that Annex.
- Article 3*
- The preparation belonging to the group 'Enzymes', as specified in Annex III, are authorised for use without a time-limit as additives in animal nutrition under the conditions laid down in that Annex.
- Article 4*
- The preparations belonging to the group 'Micro-organisms', as specified in Annex IV, are authorised provisionally for four years as additives in animal nutrition under the conditions laid down in that Annex.
- Article 5*
- This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 62, 2.3.2001, p. 3.

⁽²⁾ OJ L 247, 21.7.2004, p. 11.

⁽³⁾ OJ L 79, 30.3.2000, p. 26. Regulation as amended by Regulation (EC) No 2200/2001 (OJ L 299, 15.11.2001, p. 1).

⁽⁴⁾ OJ L 183, 29.6.1989, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

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

Done at Brussels, 4 November 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

Regis- tration number of additive	Name and registration number of person responsible for putting the additive into circulation	Additive (trade name)	Composition, chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff			
Growth promoters									
E 800	BASF Aktiengesellschaft	Potassium diformate (Formi LHS)	Additive composition Potassium diformate, solid min. 98 % Silicate max. 1,5 % Water max. 0,5 % Active substance: Potassium diformate, solid KH(COOH) ₂ CAS No 20642-05-1	Piglets (weaned)	—	6 000	18 000	For use in weaned piglets until approxi- mately 35 kg	25.11.2015
				Pigs for fattening	—	6 000	12 000	—	25.11.2015

ANNEX II

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg/kg of complete feedingstuff			
Binders, anti-caking agents and coagulants								
E 568	Clinoptilolite of sedimentary origin	Hydrated calcium aluminosilicate of sedimentary origin containing at least 80 % clinoptilolite and a maximum 20 % of clay minerals, free of fibres and quartz	Pigs for fattening	—	—	20 000	All feedingstuffs	Without a time-limit
			Chickens for fattening	—	—	20 000	All feedingstuffs	Without a time-limit
			Turkeys for fattening	—	—	20 000	All feedingstuffs	Without a time-limit
			Bovines	—	—	20 000	All feedingstuffs	Without a time-limit
			Salmon	—	—	20 000	All feedingstuffs	Without a time-limit
E 535	Sodium Ferrocyanide	Na ₄ [Fe(CN) ₆]· 10H ₂ O	All species or categories of animals	—	—	—	Maximum content: 80 mg/kg NaCl (calculated as ferrocyanide anion)	Without a time-limit
E 536	Potassium Ferrocyanide	K ₄ [Fe(CN) ₆]· 3H ₂ O	All species or categories of animals	—	—	—	Maximum content: 80 mg/kg NaCl (calculated as ferrocyanide anion)	Without a time-limit

ANNEX III

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1613	Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (CNCM MA 6-10 W) having a minimum activity of: Powder form: 70 000 IFP ⁽¹⁾ /g Liquid form: 7 000 IFP/ml	Laying hens	—	840 IFP	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: 840 IFP. 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans), e.g. containing more than 40 % wheat.	Without a time-limit

⁽¹⁾ 1 IFP is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat xylan per minute at pH 4,8 and 50 °C.

ANNEX IV

EC No or No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content CFU/kg of complete feedingsstuff		Maximum content	Other provisions	End of period of authorisation
Micro-organisms									
15	<i>Enterococcus faecium</i> NCIMB 11181	Preparation of <i>Enterococcus faecium</i> containing a minimum of: Powder form: 4 × 10 ¹¹ CFU/g additive Coated form: 5 × 10 ¹⁰ CFU/g additive	Chickens for fattening	—	2,5 × 10 ⁸		15 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	25.11.2009
18	<i>Enterococcus faecium</i> CECT 4515	Preparation of <i>Enterococcus faecium</i> containing a minimum of: 1 × 10 ⁹ CFU/g additives	Chickens for fattening	—	1 × 10 ⁹		1 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.	25.11.2009

COMMISSION REGULATION (EC) No 1811/2005

of 4 November 2005

concerning the provisional and permanent authorisations of certain additives in feedingstuffs and the provisional authorisation of a new use of an additive already authorised in feedingstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽¹⁾, and in particular Articles 3, 9d(1) and 9e(1) thereof,

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 ⁽²⁾, and in particular Article 25 thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.
- (2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.
- (3) The applications for the authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.
- (4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.
- (5) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised for the first time for piglets by Commission Regulation (EC) No 1436/98 ⁽³⁾. New

data were submitted in support of an application for authorisation without a time-limit of that enzyme preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex I, should be authorised without a time-limit.

- (6) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) was provisionally authorised for the first time for chickens for fattening by Commission Regulation (EC) No 1411/1999 ⁽⁴⁾. New data were submitted in support of an application for authorisation without a time-limit of that enzyme preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex I, should be authorised without a time-limit.
- (7) The use of the enzyme preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 74 252) was provisionally authorised for turkeys for fattening by Commission Regulation (EC) No 937/2001 ⁽⁵⁾ and for laying hens by Commission Regulation (EC) No 2188/2002 ⁽⁶⁾ and was authorised without a time-limit for chickens for fattening by Commission Regulation (EC) No 1259/2004 ⁽⁷⁾ and for turkey for fattening by Commission Regulation (EC) No 1206/2005 ⁽⁸⁾. New data were submitted in support of an application to extend the authorisation of the use of this enzyme preparation to ducks. The European Food Safety Authority (EFSA) has delivered an opinion on the use of this preparation which concludes that it does not present a risk for this additional animal category. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of that preparation for that use are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex II, should be authorised for four years.
- (8) Data were submitted in support of an application for authorisation of the use of the enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 529.94) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* (CBS 526.94) for chickens for

⁽¹⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

⁽²⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽³⁾ OJ L 191, 7.7.1998, p. 15.

⁽⁴⁾ OJ L 164, 30.6.1999, p. 56.

⁽⁵⁾ OJ L 130, 12.5.2001, p. 25.

⁽⁶⁾ OJ L 333, 10.12.2002, p. 5.

⁽⁷⁾ OJ L 239, 9.7.2004, p. 8.

⁽⁸⁾ OJ L 197, 28.7.2005, p. 12.

fattening and for turkeys for fattening. EFSA has delivered an opinion on the use of this preparation which concludes that it does not present a risk for the consumer, the user, the animal category or the environment. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for an authorisation of that preparation for that use are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex II, should be authorised for four years.

- (9) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (NCYC Sc 47) was provisionally authorised, for the first time, for dairy cows by Regulation (EC) No 937/2001. New data were submitted in support of an application for authorisation without a time-limit of that micro-organism preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex III, should be authorised without a time-limit.
- (10) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (CBS 493.94) was provisionally authorised, for the first time, for dairy cows by Regulation (EC) No 937/2001. New data were submitted in support of an application for authorisation without a time-limit of that micro-organism preparation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex III, should be authorised without a time-limit.
- (11) The assessment of these applications shows that certain procedures should be required to protect workers from

exposure to the additives set out in the Annexes. Such protection should be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽¹⁾.

- (12) 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 preparations belonging to the group 'Enzymes', as specified in Annex I, are authorised for use without a time-limit as additives in animal nutrition under the conditions laid down in that Annex.

Article 2

The preparations belonging to the group 'Enzymes', as specified in Annex II, are authorised for use for four years as additives in animal nutrition under the conditions laid down in that Annex.

Article 3

The preparations belonging to the group 'Micro-organisms', as specified in Annex III, are authorised for use without a time-limit as additives in animal nutrition under the conditions laid down in that Annex.

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, 4 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

ANNEX I

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedingstuff			
Enzymes								
E 1603	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Aspergillus aculeatus</i> (CBS 589.94) having a minimum activity of: Coated form: Endo-1,3(4)-beta-glucanase: 50 FBG ⁽¹⁾ /g Liquid form: Endo-1,3(4)-beta-glucanase: 120 FBG/ml	Piglets (weaned)	—	Endo-1,3(4)-beta-glucanase: 10 FBG	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: Endo-1,3(4)-beta-glucanase: 10-25 FBG 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 60 % vegetable ingredients (maize, lupin, wheat, barley, soya, oilseed rape or peas) 4. For use in weaned piglets until approximately 35 kg	Without a time-limit
E 1635	Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106) having a minimum activity of: Liquid form: Endo-1,3(4)-beta-glucanase: 200 U ⁽²⁾ /ml	Chickens for fattening	—	Endo-1,3(4)-beta-glucanase: 75 U	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting 2. Recommended dose per kg of complete feedingstuff: 75-100 U 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans), e.g. containing more than 30 % barley etc.	Without a time-limit

⁽¹⁾ 1 FBG is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.

⁽²⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.

⁽¹⁾ 1 FBG is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.

⁽²⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.

ANNEX II

EC No or No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedingsstuff			
Enzymes								
111	Endo-1,4-beta-glucanase EC 3.2.1.4 Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,4-beta-glucanase, endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 74 252) having a minimum activity of: Liquid and granular form: Endo-1,4-beta-glucanase: 8 000 U ⁽¹⁾ /ml or g Endo-1,3(4)-beta-glucanase: 18 000 U ⁽²⁾ /ml or g Endo-1,4-beta-xylanase: 26 000 U ⁽³⁾ /ml or g	Ducks	—	Endo-1,4-beta-glucanase: 400 U Endo-1,3(4)-beta-glucanase: 900 U Endo-1,4-beta-xylanase: 1 300 U	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life, and stability to pelleting 2. Recommended dose per kg of complete feedingsstuff: endo-1,4-beta-glucanase: 400-1 600 U endo-1,3(4)-beta-glucanase: 900-3 600 U endo-1,4-beta-xylanase: 1 300-5 200 U 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and beta-glucans), e.g. containing more than 45 % of either barley and/or triticale	25.11.2009
63	Endo-1,4-beta-xylanase EC 3.2.1.8 Endo-1,3(4)-beta-glucanase EC 3.2.1.6	Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> (CBS 529.94) and endo-1,3(4)-beta-glucanase produced by <i>Trichoderma reesei</i> (CBS 526.94) having minimum activities of: Solid form: Endo-1,4-beta-xylanase: 800 000 BXU ⁽⁴⁾ /g Endo-1,3(4)-beta-glucanase: 200 000 BU ⁽⁵⁾ /g Liquid form: Endo-1,4-beta-xylanase: 120 000 BXU/ml Endo-1,3(4)-beta-glucanase: 30 000 BU/ml	Chickens for fattening	—	Endo-1,4-beta-xylanase: 6 000 BXU Endo-1,3(4)-beta-glucanase: 1 500 BU	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting 2. Recommended dose per kg of complete feedingsstuff: Endo-1,4-beta-xylanase: 16 000-24 000 BXU Endo-1,3(4)-beta-glucanase: 4 000-6 000 BU 3. For use in compound feed rich in non-starch polysaccharides (mainly arabinoxylans and glucans), e.g. containing more than 54 % wheat	25.11.2009

EC No or No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedingsuff			
			Turkeys for fattening	—	Endo-1,4- beta-xylanase: 16 000 BXU Endo-1,3(4)- beta- glucanase: 4 000 BU	—	1. In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting 2. Recommended dose per kg of complete feedingsuff: Endo-1,4-beta-xylanase: 16 000-40 000 BXU Endo-1,3(4)-beta-glucanase: 4 000-10 000 BU 3. For use in compound feed rich in non-starch polysac- charides (mainly arabinoxylans and glucans), e.g. containing more than 44 % wheat	25.11.2009

⁽¹⁾ 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.

⁽²⁾ 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.

⁽³⁾ 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from oat spelt xylan per minute at pH 5,0 and 40 °C.

⁽⁴⁾ 1 BXU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (xylose equivalents) from birch xylan per minute at pH 5,3 and 50 °C.

⁽⁵⁾ 1 BU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °C.

(1) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from carboxymethylcellulose per minute at pH 5,0 and 40 °C.

(2) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from barley beta-glucan per minute at pH 5,0 and 40 °C.

(3) 1 U is the amount of enzyme which liberates 0,1 micromoles of glucose from oat spelt xylan per minute at pH 5,0 and 40 °C.

(4) 1 BXU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (xylose equivalents) from birch xylan per minute at pH 5,3 and 50 °C.

(5) 1 BU is the amount of enzyme which liberates 0,06 micromoles of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 4,8 and 50 °C.

ANNEX III

EC No or No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff			
Micro-organisms								
E 1702	<i>Saccharomyces cerevisiae</i> NCYC Sc 47	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of: 5×10^9 CFU/g additive	Dairy cows	—	4×10^8	2×10^9	In the directions for use of the additive and the pre-mixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of <i>Saccharomyces cerevisiae</i> in the daily ration must not exceed $5,6 \times 10^9$ CFU per 100 kg of body weight. Add $8,75 \times 10^9$ CFU per each additional 100 kg body weight.	Without a time-limit
E 1704	<i>Saccharomyces cerevisiae</i> CBS 493.94	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of: 1×10^9 CFU/g additive	Dairy cows	—	5×10^7	$3,5 \times 10^8$	In the directions for use of the additive and pre-mixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of <i>Saccharomyces cerevisiae</i> in the daily ration must not exceed $1,2 \times 10^9$ CFU for 100 kg of body weight. Add $1,7 \times 10^8$ CFU per each additional 100 kg body weight.	Without a time-limit

COMMISSION REGULATION (EC) No 1812/2005

of 4 November 2005

amending Regulations (EC) Nos 490/2004, 1288/2004, 521/2005 and 833/2005 as regards the conditions for the authorisation of certain additives in feedingstuffs belonging to the groups of enzymes and micro-organisms

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs ⁽¹⁾, and in particular Articles 3, 9d(1) and 9e(1) thereof,

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 ⁽²⁾, and in particular Article 25 thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.
- (2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.
- (3) The applications for authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.
- (4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.
- (5) The use of the micro-organism preparation No 5 of *Saccharomyces cerevisiae* (CBS 493.94) has been authorised

for horses provisionally for four years by Commission Regulation (EC) No 490/2004 ⁽³⁾. New data were submitted in support of an increase of the Colony Forming Units minimum content of this preparation in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex I, should be authorised until 20 March 2008.

- (6) The use of the micro-organism preparation No E 1704 of *Saccharomyces cerevisiae* (CBS 493.94) has been authorised for calves and cattle for fattening without a time-limit by Commission Regulation (EC) No 1288/2004 ⁽⁴⁾. New data were submitted in support of an increase of the Colony Forming Units minimum content of this preparation in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation, as specified in Annex II, should be authorised without a time-limit.
- (7) The use of the enzyme preparation No E 1623 of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) has been authorised for chickens for fattening without a time-limit by Commission Regulation (EC) No 521/2005 ⁽⁵⁾. New data were submitted in support of a change of the minimum enzyme activity in this preparation as described in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex III, should be authorised without a time-limit.

⁽¹⁾ OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

⁽²⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽³⁾ OJ L 79, 17.3.2004, p. 23.

⁽⁴⁾ OJ L 243, 15.7.2004, p. 10.

⁽⁵⁾ OJ L 84, 2.4.2005, p. 3.

- (8) The use of the enzyme preparation No E 1627 of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) has been authorised for pigs for fattening without a time-limit by Commission Regulation (EC) No 833/2005 ⁽¹⁾. New data were submitted in support of a change in the formulation of this preparation as described in the column 'chemical formula, description' without changing the maximum, minimum or recommended contents in complete feedingstuffs in the conditions of authorisation. The assessment shows that the conditions laid down in Article 3a of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation, as specified in Annex IV, should be authorised without a time-limit.
- (9) Regulations (EC) Nos 490/2004, 1288/2004, 521/2005 and 833/2005 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 490/2004 is replaced by Annex I to this Regulation.

Article 2

Annex I to Regulation (EC) No 1288/2004 is amended in accordance with Annex II to this Regulation.

Article 3

Annex I to Regulation (EC) No 521/2005 is replaced by Annex III to this Regulation.

Article 4

The Annex to Regulation (EC) No 833/2005 is amended in accordance with Annex IV to this Regulation.

Article 5

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, 4 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 138, 1.6.2005, p. 5.

ANNEX I

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content		Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingstuff				
Micro-organisms									
5	<i>Saccharomyces cerevisiae</i> CBS 493,94	Preparation of <i>Saccharomyces cerevisiae</i> containing a minimum of 1×10^9 CFU/g additive	Horses	—	4×10^9	$2,5 \times 10^{10}$	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of <i>Saccharomyces cerevisiae</i> in the daily ration must not exceed $4,17 \times 10^{10}$ CFU for 100 kg of body weight. Use permitted from two months post weaning onwards.	20.3.2008	

ANNEX II

In Annex I to Regulation (EC) No 1288/2004, the entry for E 1704 is replaced by the following:

No (or EC No)	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					CFU/kg of complete feedingsstuff			
Micro-organisms								
E 1704	Saccharomyces cerevisiae CBS 493,94	Preparation of Saccharomyces cerevisiae containing a minimum of 1 × 10 ⁹ CFU/g additive	Calves	6 months	2 × 10 ⁸	2 × 10 ⁹	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelletting.	Without a time-limit
			Cattle for fattening	—	1,7 × 10 ⁸	1,7 × 10 ⁸	In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelletting. The quantity of Saccharomyces cerevisiae in the daily ration must not exceed 7,5 × 10 ⁸ CFU for 100 kg body weight. Add 1 × 10 ⁸ CFU for each additional 100 kg of body weight.	Without a time-limit'

ANNEX III

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/kg of complete feedstuff			
Enzymes								
E 1623	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8 Subtilisin EC 3.4.21.62	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106), endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2105) and subtilisin produced by <i>Bacillus subtilis</i> (ATCC 2107) having a minimum activity of: endo-1,3(4)-beta-glucanase: 200 U ⁽¹⁾ /g endo-1,4-beta-xylanase: 5 000 U ⁽²⁾ /g subtilisin: 1 600 U ⁽³⁾ /g	Chickens for fattening	—	endo-1,3(4)-beta-glucanase: 25 U endo-1,4-beta-xylanase: 625 U subtilisin: 200 U	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedstuff: endo-1,3(4)-beta-glucanase: 25-100 U endo-1,4-beta-xylanase: 625-2 500 U subtilisin: 200-800 U. 3. For use in compound feed, e.g. containing more than 30 % wheat and 10 % barley.	Without a time-limit

⁽¹⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.

⁽²⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5.3 and 50 °C.

⁽³⁾ 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7.5 and 40 °C.

⁽¹⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5.0 and 30 °C.

⁽²⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5.3 and 50 °C.

⁽³⁾ 1 U is the amount of enzyme which liberates 1 microgram of phenolic compound (tyrosine equivalents) from a casein substrate per minute at pH 7.5 and 40 °C.

ANNEX IV

In the Annex to Regulation (EC) No 833/2005, the entry for E 1627 is replaced by the following:

E 1627	Endo-1,3(4)-beta-glucanase EC 3.2.1.6 Endo-1,4-beta-xylanase EC 3.2.1.8	Preparation of endo-1,3(4)-beta-glucanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2106) and endo-1,4-beta-xylanase produced by <i>Trichoderma longibrachiatum</i> (ATCC 2105) having a minimum activity of: powder form: endo-1,3(4)-beta-glucanase: 800 U ⁽¹⁾ /g endo-1,4-beta-xylanase: 800 U ⁽²⁾ /g liquid form: endo-1,3(4)-beta-glucanase: 800 U/ml endo-1,4-beta-xylanase: 800 U/ml	Pigs for fattening	—	endo-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 U	—	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. 2. Recommended dose per kg of complete feedingstuff: endo-1,3(4)-beta-glucanase: 400 U endo-1,4-beta-xylanase: 400 U. 3. For use in compound feed rich in non-starch polysaccharides (mainly beta-glucans and arabinoxylans) e.g. containing more than 65 % barley.	Without a time-limit
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⁽¹⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (glucose equivalents) from barley beta-glucan per minute at pH 5,0 and 30 °C.
⁽²⁾ 1 U is the amount of enzyme which liberates 1 micromole of reducing sugars (xylose equivalents) from oat spelt xylan per minute at pH 5,3 and 50 °C.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 27 October 2005

laying down rules for the procurement of food aid by NGOs authorised by the Commission to purchase and mobilise products to be supplied under Council Regulation (EC) No 1292/96 and repealing its Decision of 3 September 1998

(2005/769/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European community,

Having regard to Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security⁽¹⁾, and in particular Article 19(1) thereof,

Whereas:

- (1) Article 3(1) of Commission Regulation (EC) No 2519/97 of 16 December 1997 laying down general rules for the mobilisation of products to be supplied under Council Regulation (EC) No 1292/96 as Community food aid⁽²⁾, allows the Commission to authorise international and non-governmental organisations which are beneficiaries of Community aid to purchase and mobilise the products for use as aid supplies themselves, provided that the Commission establishes the rules and procedures which shall then apply.
- (2) Article 164 of Commission Regulation (EC, Euratom) No 2342/2002 of 23 December 2002 laying down detailed rules for the implementation of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities⁽³⁾ (the implementing rules), provides that where the implementation of an action for which a Community grant may be received involves procurement,

the grant agreement concluded for that purpose should include the procurement rules with which the beneficiary must comply.

- (3) Article 120 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities⁽⁴⁾ (Financial Regulation) subjects the award of procurement contracts by the beneficiary of a grant to the principles set out in the Financial Regulation and its Implementing Rules.
- (4) The procurement rules to be followed by the bodies identified in part 2 of the Annex to Regulation (EC) No 1292/96 for the implementation of food aid policy are already laid down in the contribution agreements concluded by the Commission with those international organisations for that purpose; for non-governmental organisations (NGOs), the procurement rules and other conditions which are necessary for the mobilisation of food aid and for respecting the financial principles laid down in the Financial Regulation and its implementing rules should be based in particular on those established by Regulation (EC) No 2519/97, adapted as necessary to take into account the financial management situation.
- (5) The procurement rules should apply where the Commission authorises NGOs to purchase and mobilise food aid in the framework of the contracts to be signed for implementing the annual food aid work programme, without prejudice to the discretion for the Commission's authorising officer to include in such contracts additional requirements for sound financial management purposes. Commission Decision of 3 September 1998 should therefore be repealed.

⁽¹⁾ OJ L 166, 5.7.1996, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 346, 17.12.1997, p. 23.

⁽³⁾ OJ L 357, 31.12.2002, p. 1.

⁽⁴⁾ OJ L 248, 16.9.2002, p. 1.

- (6) Pursuant to Article 29 of Regulation (EC) No 1292/96, the Food Aid and Food Security Committee has been informed of the present measure,

HAS DECIDED AS FOLLOWS:

Article 1

The rules for the procurement of food aid by non-governmental organisations authorised by the Commission to purchase and mobilise products to be supplied under Regulation (EC) No 1292/96 are laid down in the Annex to this Decision. Those rules shall form an integral part of the contracts and conventions concluded by the Commission for that purpose.

Article 2

The Commission Decision of 3 September 1998 authorising certain organisations receiving Community food aid to purchase certain products for supply as Community food aid themselves is repealed.

Article 3

This Decision takes effect on the date of its publication.

Done at Brussels, 27 October 2005.

For the Commission

Louis MICHEL

Member of the Commission

ANNEX

The non-governmental organisation beneficiary of Community aid (hereinafter the NGO) shall apply the following rules for the mobilisation of products to be supplied under Regulation (EC) No 1292/96 as Community food aid, without prejudice to any additional financial management requirements included in the contract concluded with the beneficiary for implementing food aid policy.

I. GENERAL PRINCIPLES

This Annex shall apply to goods to be supplied 'free at destination'.

II. PLACE OF PURCHASE OF THE GOODS

Depending on the conditions laid down for a particular supply, the product to be supplied shall be purchased in the European Community, or a developing country listed in the Annex to Regulation (EC) No 1292/96, belonging if possible to the same geographical region. To the extent possible, priority should be given to purchases in the country of operation or a neighbouring country.

In exceptional circumstances and in accordance with the procedures laid down in Article 11(2) of Regulation (EC) No 1292/96, products may be purchased on the market of a country other than those listed in the Annex to Regulation (EC) No 1292/96.

The NGO shall ensure that the products to be supplied as food aid can be freely imported in the beneficiary country and will not be subject to any import duty or tax having equivalent effect.

III. CHARACTERISTICS OF THE PRODUCTS

The products shall as much as possible match the nutritional habits of the beneficiary population.

The characteristics of the products to be mobilised as food aid shall be consistent with the requirements laid down in the Communication from the Commission relating to the characteristics of products to be supplied as Community food aid ⁽¹⁾.

Furthermore, packaging shall be consistent with the requirements laid down in the Communication from the Commission relating to the packaging of products to be supplied as Community food aid ⁽²⁾.

IV. NATIONALITY RULES

Participation in the tender procedures provided for in the framework of the mobilisation of products to be supplied as food aid shall be open on equal terms to any natural or legal person from the European Community or from a developing country listed in the Annex to Regulation (EC) No 1292/96.

The tenderer must be legally registered and able to show proof of it on request.

V. GROUNDS FOR EXCLUSION FROM PARTICIPATION IN PROCUREMENT PROCEDURES AND FROM AWARD OF CONTRACTS**1. Grounds for exclusion from participation in procurement procedures**

Tenderers are excluded from participation in a procurement procedure if:

- (a) they are bankrupt or being wound up, are having their affairs administered by the courts, have entered into an arrangement with creditors, have suspended business activities, are the subject of proceedings concerning those matters, or are in any analogous situation arising from a similar procedure provided for in national legislation or regulations;

⁽¹⁾ OJ C 312, 31.10.2000, p. 1.

⁽²⁾ OJ C 267, 13.9.1996, p. 1.

- (b) they have been convicted of an offence concerning their professional conduct by a judgment which has the force of *res judicata*;
- (c) they have been guilty of grave professional misconduct proven by any means which the beneficiary of the grant can justify;
- (d) they have not fulfilled obligations relating to the payment of social security contributions or the payment of taxes in accordance with the legal provisions of the country in which they are established or with those of the country of the grant beneficiary or those of the country where the contract is to be performed;
- (e) they have been the subject of a judgment which has the force of *res judicata* for fraud, corruption, involvement in a criminal organisation or any other illegal activity detrimental to the Communities' financial interests;
- (f) following another procurement procedure or grant award procedure financed by the Community budget, they have been declared to be in serious breach of contract for failure to comply with their contractual obligations.

Tenderers must certify that they are not in one of the situations listed above.

2. Exclusion from award of contracts

Contracts may not be awarded to tenderers who, during the procurement procedure:

- (a) are subject to a conflict of interest;
- (b) are guilty of misrepresentation in supplying the information required by the beneficiary of the grant as a condition of participation in the contract procedure or fail to supply this information.

VI. AWARD PROCEDURES

1. General provisions

The NGO shall launch an international open invitation to tender for supply contracts with a value of EUR 150 000 or more. In the case of an international open invitation to tender, the NGO shall publish a tender notice in all appropriate media, in particular on the NGO's web site, in the international press and the national press of the country in which the Action is being carried out, or in other specialist periodicals.

Supply contracts for a value of EUR 30 000 or more but less than EUR 150 000 shall be awarded by means of an open tender procedure published locally. In the case of a local open tender procedure, the tender notice shall be published in all appropriate media but only in the country in which the Action is being carried out. It must however provide other eligible suppliers with the same opportunities as local firms.

Supply contracts with a value of less than EUR 30 000 must be awarded by means of a competitive negotiated procedure without publication, in which the NGO consults at least three suppliers of its choice and negotiates the terms of the contract with one or more of them.

Supply contracts with a value of less than EUR 5 000 may be awarded on the basis of a single tender.

The time-limits for receipt of tenders and requests to participate must be long enough to allow interested parties a reasonable and appropriate period to prepare and submit their tenders.

2. Negotiated procedure

The beneficiary may use the negotiated procedure on the basis of a single tender in the following cases:

- (a) where, for reasons of extreme urgency brought about by events which the beneficiary could not have foreseen and which can in no way be attributed to him, the time-limit for the procedures referred to in section VI.1 above cannot be kept. The circumstances invoked to justify extreme urgency must in no way be attributable to the beneficiary.

Actions carried out in crisis situations identified by the Commission are considered to satisfy the test of extreme urgency. The Commission will inform the beneficiary if a crisis situation exists and when it comes to an end;

- (b) for additional deliveries by the original supplier intended either as a partial replacement of normal supplies or installations or as the extension of existing supplies or installations, where a change of supplier would oblige the beneficiary to acquire equipment having different technical characteristics which would result in either incompatibility or disproportionate technical difficulties in operation and maintenance;
- (c) where the tender procedure has been unsuccessful, that is where no qualitatively and/or financially worthwhile tender has been received. In such cases, after cancelling the tender procedure, the beneficiary may negotiate with one or more tenderers of its choice, from among those that took part in the tender procedure, provided that the initial terms of the tender procedure are not substantially altered;
- (d) where the contract concerned be awarded to bodies with a *de jure* or *de facto* monopoly, duly substantiated in the Commission's award decision;
- (e) a direct agreement contract may be undertaken where warranted by the particular conditions of a supply and, in particular, in the case of an experimental supply.

3. Obligations for the submission of a tender

The NGO shall specify in the tender notice the form and the deadline according to which the tenderer's bid must be made.

All requests to participate and tenders declared as satisfying the requirements must be evaluated and ranked by an evaluation committee on the basis of the exclusion, selection and award criteria announced in advance. This committee must have an odd number of members, at least three, with all the technical and administrative capacities necessary to give an informed opinion on the tenders.

One single tender may be submitted for each lot. It shall be valid only if it relates to a complete lot. Where a lot is subdivided into part lots, the tender shall be established as an average thereof. Where the invitation to tender relates to the supply of more than one lot, a separate tender shall be submitted per lot. The tenderer is not obliged to present a tender for all the lots.

Tenders shall provide:

- the tenderer's name and address,
- the reference numbers of the invitation to tender, lot and action,
- the net weight of the lot or the specific monetary amount to which the tender relates,
- the proposed price per net metric tonne of product at which the tenderer undertakes to carry out the supply in accordance with the conditions laid down;

or

- where the invitation to tender is for a contract to supply a maximum quantity of a given product for a specific monetary amount, the net quantity of products offered,
- the transport costs for the specified delivery stage,
- the delivery deadline.

The tender shall be valid only if it is accompanied by evidence that a tendering guarantee has been lodged. The amount of the tendering guarantee, expressed in the currency of the payment, and the period of validity, shall be laid down in the tender notice. The guarantee shall represent minimum 1 % of the total amount of the bid, and the period of validity shall be at least one month.

The guarantee shall be lodged in favour of the NGO in the form of a security from a credit establishment recognised by a Member State or accepted by the NGO. The guarantee shall be irrevocable and capable of being called at first request.

In case of mobilisation in the country which is itself the beneficiary of the food aid, the NGO may define in the tender notice other conditions for the guarantee taking account of the customs of the country.

The guarantee shall be released:

- by a letter or a fax by the NGO where the tender has not been accepted or has been rejected, or where no contract has been awarded,
- where the tenderer, designated as the supplier, has lodged the delivery guarantee.

The guarantee shall be forfeited if the supplier fails to provide the delivery guarantee within a reasonable deadline following the award of the contract and also if the tenderer withdraws his tender after it has been received.

A tender which is not submitted in accordance with these provisions or contains reservations or conditions other than those laid down for in the invitation to tender shall be rejected.

No tender may be changed or withdrawn after it has been received.

The award shall be made to the tenderer who submitted the lowest tender respecting all the conditions of the invitation to tender, in particular the characteristics of the products to be mobilised. Where the lowest tender is presented simultaneously by a number of tenderers, the contract shall be awarded by the drawing of lots.

When the contract is awarded, both the supplier and the unsuccessful tenderers shall be duly notified by letter or fax.

The NGO may decide not to award the contract on the expiry of the first or of the second dead-line, in particular where the tenders submitted are outside the range of normal market prices. The NGO shall not be required to give reasons for its decision. Tenderers shall be informed of the decision not to award the contract by written notice, within three working days.

VII. OBLIGATIONS OF THE SUPPLIER AND CONDITIONS OF SUPPLY

The NGO shall specify in the tender notice the conditions relevant to the responsibilities of the supplier under the present rules, and the supplier shall perform his obligations in accordance with all conditions laid down in the tender notice as well as those arising from his tender.

The supplier shall arrange transport at his own expense by the route most appropriate having regard to the approved deadline, from the port of shipment or loading quay indicated in his tender to the final place of destination specified in the tender notice.

However, at the supplier's written request the NGO may authorise the port of shipment or the loading quay to be changed, provided any costs this entails are borne by the supplier.

The supplier shall take out a maritime insurance policy or claim cover under a general policy. The insurance shall be for at least the tender amount and shall cover all risks associated with carriage and any other supply-related activity by the supplier up to the stage of delivery specified. It shall also cover all costs of sorting, withdrawal or destruction of damaged goods, repacking and analysis of goods where an average does not preclude their acceptance by the beneficiary.

The goods may not be delivered in split consignments on more than one vessel, unless the NGO so agrees. In that case, the NGO shall require the supplier to bear the additional checking costs.

Where appropriate, the tender notice may specify a date before which any delivery will be considered premature.

The supply shall be complete when all the goods have actually been delivered 'free at destination'. The supplier shall bear all the costs until the goods are made available at the warehouse of destination.

The supplier shall bear all risks, including loss or deterioration, to which the goods may be subject until completion of the supply and recording of that fact by the monitor in the final certificate of conformity (see point VIII).

The supplier shall notify the beneficiary and the monitor promptly in writing of the means of transport used, the loading dates, the expected date of arrival at destination, and any incident occurring while the goods are in transit.

The supplier shall carry out the formalities relating to the export license and customs clearance, bearing the related costs and charges.

In order to ensure that he meets his obligations, the supplier shall lodge a delivery guarantee within a reasonable deadline following the notification of the award of the contract. That guarantee, expressed in the currency of the payment, shall represent 5 to 10 % of the total amount of the tender. The period of validity shall end one month after the date of the final delivery. It shall be lodged in the same way as the tendering guarantee.

The delivery guarantee shall be released in full by a letter or a fax by the NGO when the supplier:

— has carried out the supply in compliance with all his obligations, or

— has been released from his obligations;

or

— has not carried out the supply for reasons of *force majeure* recognised by the NGO.

VIII. MONITORING

As soon as the contract has been awarded, the NGO shall inform the supplier of the agency which will be responsible for verifying and certifying the quality, quantity, packing and marking of the goods to be delivered in respect of each supply, issuing the certificate of conformity or the certificate of delivery, and generally coordinating all stages of the supply operation (hereinafter referred to as the monitoring agency).

After the notification of the award of the contract, the supplier shall inform in writing the monitoring agency of the name and address of the manufacturer, packer or stockholder of the goods to be delivered, and the approximate date of manufacture or packaging, as well as of the name of his representative at the place of delivery.

The monitoring agency shall carry out at least two checks, based on terms of reference complying with international monitoring standards, as follows:

- (a) a provisional check shall be carried out when the goods are loaded or at the factory. The final check shall be carried out at the delivery stage specified;
- (b) when the provisional check is complete, the monitoring agency shall issue a provisional certificate of conformity to the supplier, subject to reservation if necessary. The monitoring agency shall state whether any reservation is such as to render the goods unacceptable at the delivery stage;
- (c) when the final check is complete, the monitoring agency shall issue a final certificate of conformity to the supplier specifying in particular the date of completion of the supply and the net quantity supplied; such certificate shall be subject to reservations if necessary;
- (d) where the monitoring agency issues a reasoned 'notice of reservation', it shall notify the supplier and the NGO in writing as soon as possible. If the supplier wishes to dispute the findings with the monitoring agency and the NGO, he shall do so within two working days of dispatch of this notice.

The costs of the checks referred to above shall be borne by the NGO. The supplier shall bear any financial consequences in the event of qualitative shortcomings or late presentation of the goods for checking.

If the supplier or the beneficiary objects to the findings of a check, the monitoring agency, after authorisation of the NGO, shall arrange for a review inspection involving, according to the nature of the objection, a review sampling, review analysis, and/or a reweighing or rechecking of the packaging. The review inspection shall be carried out by an agency or laboratory designated by agreement between the supplier, the final beneficiary and the monitoring agency.

The costs of this review inspection shall be borne by the losing party.

If the final certificate of conformity is not issued after the checks or review inspection has been carried out, the supplier shall be obliged to replace the goods.

The replacement and related checks' costs shall be borne by the supplier.

The monitoring agency shall issue written invitations to the representatives of the supplier and of the final beneficiary to be present at the checking operations, in particular for the taking of samples to be used for analyses. The taking of samples shall be carried out in accordance with professional practice. When sampling is undertaken, the monitoring agency shall take two additional samples which shall be kept under seal at the NGO's disposal for the purpose of any further check or in the event of objections being raised by the beneficiary or supplier.

The cost of the goods taken as samples shall be borne by the supplier.

Recipient of the goods shall issue a taking-over certificate to the supplier without delay after the goods have been supplied 'free at destination' and the supplier has provided the beneficiary with the original of the final certificate of conformity, and with a pro forma invoice establishing both the value of the goods and their transfer to the beneficiary free of charge.

For goods supplied in bulk, a tolerance of 3 % by weight (excluding the weight of samples) below the quantity requested is applicable. For goods supplied in packing, this tolerance is limited to 1 %. Where the tolerances are exceeded, the NGO may require the supplier to make an additional delivery on the same financial terms as the initial delivery.

IX. TERMS OF PAYMENT

The sum to be paid by the NGO to the supplier shall not exceed the amount of the tender plus any costs, less any reduction provided for below.

Where the quality, the packaging or the marking of the goods is found at the delivery stage not to correspond to the specifications, without being such as to have prevented the issuance of a taking over certificate, the NGO, in calculating the sum to be paid, may apply reductions.

Except in cases of *force majeure*, the delivery guarantee shall be partially forfeit on a cumulative basis in the following cases:

- 10 % of the value of the quantities not delivered, without prejudice to the tolerances referred to in point 8 above,
- 0,1 % of the value of the quantities supplied after the deadline, per day of delay,
- where appropriate, and only if this is specified in the tender notice, 0,1 % per day where the goods are delivered prematurely.

The amount of the guarantees to be forfeited shall be deducted from the final amount to be paid. The guaranties shall then be released simultaneously in full.

The NGO may repay to the supplier, at his written request, certain additional costs, such as warehousing or insurance actually paid by the supplier, but excluding any administrative costs, which the NGO shall assess on the basis of appropriate supporting documents, provided a taking-over certificate or delivery certificate has been issued without reservations relating to the nature of the costs claimed, and in the event of:

- an extension of the delivery period at the recipient's request, or
- a delay exceeding 30 days between the date of delivery and the issue of the taking-over certificate, or the issue of the final certificate of conformity.

Additional costs shall not be accepted if they exceed:

- EUR 1 per tonne of bulk goods and EUR 2 per tonne of processed goods per week in the case of warehousing costs,
- 0,75 % a year of the value of the goods in the case of insurance costs.

The sum to be paid shall be payable at the supplier's request submitted in duplicate. A request for payment of the full amount of the tender or balance thereof shall be accompanied by the following documents:

- an invoice for the sum claimed,
- the original of the taking-over certificate,
- a copy signed and certified by the supplier as conforming to the original of the final certificate of conformity.

When 50 % of the total quantity laid down in the tender notice has been delivered, the supplier may present a request for advance payment accompanied by an invoice for the sum claimed and a copy of the provisional certificate of conformity.

All requests for payment of the full amount of the tender or balance thereof shall be presented to the NGO after issuance of the taking-over certificate. All payments shall be made within 60 days of the receipt by the NGO of a complete and accurate request for payment. Unjustified delays shall attract post-maturity interest at the monthly rate applied by the European Central Bank.

X. FINAL PROVISION

It shall be for the NGO to decide whether the supplier's failure to supply the goods or to fulfil one of his obligations may be due to *force majeure*. Costs resulting from a case of *force majeure* recognised by the NGO shall be borne by the latter.

COMMISSION DECISION

of 3 November 2005

amending Annexes I and II to Decision 2003/634/EC approving programmes for the purpose of obtaining the status of approved zones and of approved farms in non-approved zones with regard to viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) in fish

*(notified under document number C(2005) 4185)***(Text with EEA relevance)**

(2005/770/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products ⁽¹⁾, and in particular Article 10(2) thereof,

Whereas:

(1) Commission Decision 2003/634/EC ⁽²⁾ approves and lists programmes submitted by various Member States. The programmes are designed to enable the Member State subsequently to initiate the procedures for a zone, or a farm situated in a non-approved zone, to obtain the status of approved zone or of approved farm situated in a non-approved zone, as regards one or more of the fish diseases viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN).

(2) The programme applicable to Finland with regard to IHN in its entire territory, and VHS in the continental parts of its territory has been finalised and should be deleted from Annex I to Decision 2003/634/EC.

(3) The programme applicable to Incubatoio ittico di valle — Loc. Cascina Prella — Traversella (TO) has been finalised and should be deleted from Annex II to Decision 2003/634/EC.

(4) Decision 2003/634/EC should therefore be amended accordingly.

(5) 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

Decision 2003/634/EC is amended as follows:

1. Annex I is replaced by Annex I to this Decision.
2. Annex II is replaced by Annex II to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 November 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

⁽¹⁾ OJ L 46, 19.2.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 220, 3.9.2003, p. 8. Decision as last amended by Decision 2005/414/EC (OJ L 141, 4.6.2005, p. 29).

ANNEX I

'ANNEX I

PROGRAMMES SUBMITTED FOR THE PURPOSE OF OBTAINING APPROVED ZONE STATUS WITH REGARD TO ONE OR MORE OF THE FISH DISEASES VHS AND IHN

1. DENMARK

THE PROGRAMMES SUBMITTED BY DENMARK ON 22 MAY 1995 COVERING:

- the catchment area of FISKEBÆK Å,
- all PARTS OF JUTLAND south and west of the catchment areas of Storåen, Karup å, Gudenåen and Grejs å,
- the area of all THE DANISH ISLES.

2. GERMANY

THE PROGRAMME SUBMITTED BY GERMANY ON 25 FEBRUARY 1999 COVERING:

- a zone in the water catchment area "OBERN NAGOLD".

3. ITALY

3.1. THE PROGRAMME SUBMITTED BY ITALY IN THE AUTONOMOUS PROVINCE OF BOLZANO ON 6 OCTOBER 2001 AS AMENDED BY LETTER OF 27 MARCH 2003, COVERING:

Zona Province of Bolzano

- The zone comprises all water catchment areas within the Province of Bolzano.

The zone includes the upper part of the zone ZONA VAL D'ADIGE — i.e. the water catchment areas of Adige river from its sources in the Province of Bolzano to the border with the Province of Trento.

(N.B. The remaining, lower part of the zone ZONA VAL D'ADIGE is under the approved programme of the Autonomous Province of Trento. The upper and lower parts of this zone have to be viewed as one epidemiological unit.)

3.2. THE PROGRAMMES SUBMITTED BY ITALY IN THE AUTONOMOUS PROVINCE OF TRENTO ON 23 DECEMBER 1996 AND 14 JULY 1997 COVERING:

Zona Val di Sole e Val di Non

- The water catchment area from the source of the stream Noce to the dam of S. Giustina.

Zona Val d'Adige — lower part

- The water catchment areas of the Adige river and its sources located within the territory of the Autonomous Province of Trento, from the border with the Province of Bolzano to the dam of Ala (hydroelectric generating station).

(N.B. The upstream part of the zone ZONA VAL D'ADIGE is under the approved programme of the Province of Bolzano. The upper and lower parts of this zone have to be viewed as one epidemiological unit.)

Zona del torrente Arnò

- The water catchment area from the source of Arnò torrent to the downstream barriers, situated before the Arnò torrent flows into the Sarca river.

Zona Val Banale

- The water catchment area of the Ambies stream basin to the dam of a hydroelectric generating station.

Zona Varone

- The water catchment area from the source of the Magnone stream to the waterfall.

Zona Alto e Basso Chiese

- The water catchment area of the Chiese river from the source to the dam of Condino, except the Adanà and Palvico torrents basins.

Zona del torrente Palvico

- The water catchment area of the Palvico torrent basin to a barrier made of concrete and stones.

3.3. THE PROGRAMME SUBMITTED BY ITALY IN THE REGION OF VENETO ON 21 FEBRUARY 2001 COVERING:**Zona del torrente Astico**

- The water catchment area of Astico river, from its sources (in the Autonomous Province of Trento and in the Province of Vicenza, the Region of Veneto) to the dam located close to the Pedescala bridge in the Province of Vicenza.

The downstream part of Astico river, between the dam close to the Pedescala bridge and the Pria Maglio dam, is considered as a buffer zone.

3.4. THE PROGRAMME SUBMITTED BY ITALY IN THE REGION OF UMBRIA ON 20 FEBRUARY 2002 COVERING:

Zona Fosso di Monterivoso: the water catchment area of Monterivoso river, from its sources to the impassible barriers near Ferentillo.

3.5. THE PROGRAMME SUBMITTED BY ITALY IN THE REGION OF LOMBARDIA ON 23 DECEMBER 2003 COVERING:

Zona valle del torrente Venina: the water catchment area of the Vienna river from its sources and the following boundaries:

- west: Livrio valley,
- south: Orobic Alps from Publino Pass to Redorta Peak,
- east: Armisa and Armisola valleys.

3.6. THE PROGRAMME SUBMITTED BY ITALY IN THE REGION OF TOSCANA ON 23 SEPTEMBER 2004 COVERING:

Zona valle di Tosi: the water catchment area of the Vicano di S. Ellero river from its sources to the barrier at Il Greto near the village of Raggioli.

4. FINLAND

4.1. THE PROGRAMME FOR VHS-FREEDOM ⁽¹⁾ INCLUDING SPECIFIC ERADICATION MEASURES SUBMITTED BY FINLAND ON 29 MAY 1995, AS AMENDED BY LETTERS OF 27 MARCH 2002, 4 JUNE 2002, 12 MARCH 2003, 12 JUNE 2003, 20 OCTOBER 2003 AND 17 MAY 2005 COVERING:

- all coastal areas of FINLAND with special eradication measures in:
 - the Province of Åland,
 - the restriction area in Pyhtää,
 - the restriction area covering the municipalities of Uusikaupunki, Pyhäranta and Rauma.

5. CYPRUS

THE PROGRAMMES SUBMITTED BY CYPRUS ON 20 APRIL 2004 COVERING:

- the entire territory of Cyprus.'

⁽¹⁾ The programme has been terminated by the present Decision with respect to IHN, for which approved status has been granted.

ANNEX II

'ANNEX II

PROGRAMMES SUBMITTED FOR THE PURPOSE OF OBTAINING STATUS AS APPROVED FARM SITUATED IN A NON-APPROVED ZONE WITH REGARD TO ONE OR MORE OF THE FISH DISEASES VHS AND IHN

1. ITALY

- 1.1. THE PROGRAMME SUBMITTED BY ITALY IN THE REGION OF FRIULI VENEZIA GIULIA, PROVINCE OF UDINE ON 2 MAY 2000 COVERING:

Farms in the drainage basin of the Tagliamento river:

— Azienda Vidotti Giulio s.n.c., Sutrio.

- 1.2. THE PROGRAMME SUBMITTED BY ITALY IN THE REGION OF VENETO ON 21 DECEMBER 2003 COVERING:

The farm:

— Azienda agricola Bassan Antonio.'

COMMISSION DECISION

of 3 November 2005

amending Decision 93/195/EEC on animal health conditions and veterinary certification for the re-entry of registered horses for racing, competition and cultural events after temporary export*(notified under document number C(2005) 4186)***(Text with EEA relevance)**

(2005/771/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae ⁽¹⁾, and in particular Article 19(ii) thereof,

Whereas:

- (1) In accordance with the general rules laid down in Annex II to Commission Decision 93/195/EEC ⁽²⁾, the re-entry of registered horses for racing, competition and cultural events after temporary export is restricted to horses kept for less than 30 days in any of the third countries listed in the same group in Annex I to that Decision.
- (2) Registered horses participating in the Olympic Games, in preparatory test events for the latter and in the Paralympics will be subject to the veterinary supervision of the competent authorities of the host third country and the organising body, the International Federation for Equestrian Sports (FEI).
- (3) Given the degree of veterinary supervision and the fact that the horses concerned are kept separate from animals of lower health status, the period of temporary export should be extended to less than 90 days and the animal health conditions and the veterinary certification should accordingly be laid down for the re-entry of registered horses after temporary export to participate in equestrian events for the Olympic Games, including preparatory test events, and the Paralympics.

(4) Decision 93/195/EEC should therefore be amended accordingly.

(5) 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

Decision 93/195/EEC is amended as follows:

1. In Article 1, the following indent is added:

‘— have taken part in equestrian events for the Olympic Games, the preparatory test events or the Paralympics and meet the requirements laid down in a health certificate in accordance with the model health certificate set out in Annex IX to this Decision.’

2. The text in the Annex to this Decision is added as Annex IX.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 3 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 224, 18.8.1990, p. 42. Directive as last amended by Directive 2004/68/EC (OJ L 139, 30.4.2004, p. 320).

⁽²⁾ OJ L 86, 6.4.1993, p. 1. Decision as last amended by Decision 2005/605/EC (OJ L 206, 9.8.2005, p. 16).

ANNEX

ANNEX IX

HEALTH CERTIFICATE

for re-entry of registered horses after temporary export for less than 90 days to participate in equestrian events for the Olympic Games, preparatory test events for the latter or the Paralympics

Certificate No:

Specific event:	Test event in preparation for the Olympic Games in ⁽¹⁾
	Olympic Games in ⁽¹⁾
	Paralympics in ⁽¹⁾

Exporting third country:
(insert name of country)

Responsible ministry:
(insert name of Ministry)

I. Identification of horse

(a) No of identification document:

(b) Validated by:
(name of competent authority)

II. Origin of horse

The horse is to be sent from:
(place whence consigned)

to:
(place of destination)

by air ⁽¹⁾:
(provide flight number)

by road transport ⁽¹⁾:
(provide licence plate number)

Name and address of consignor:

Name and address of consignee:

III. Health information

I, the undersigned, certify that the horse described above meets the following requirements:

- (a) it comes from a country where the following diseases are compulsorily notifiable: African horse sickness, dourine, glanders, equine encephalomyelitis (of all types including Venezuelan equine encephalomyelitis), equine infectious anaemia, vesicular stomatitis, rabies, anthrax;
- (b) it has been examined today and shows no clinical signs of disease ⁽²⁾;
- (c) it is not intended for slaughter under a national programme of infectious or contagious disease eradication;
- (d) since its entry into the country of dispatch, it has been resident on holdings under veterinary supervision, accommodated in separated stables without coming into contact with equidae of lower health status, except during the competitions;

- (e) it comes from the territory or, in the case of official regionalisation according to Community legislation, from a part of the territory of a third country in which:
 - (i) Venezuelan equine encephalomyelitis has not occurred during the last two years,
 - (ii) dourine has not occurred during the last six months,
 - (iii) glanders has not occurred during the last six months;
- (f) it does not come from the territory or from a part of the territory of a third country considered, in accordance with Community legislation, as infected with African horse sickness;
- (g) it neither comes from a holding which was/has been subject to a prohibition order for animal health reasons nor has had contact with equidae from a holding which was/has been subject to a prohibition order for animal health reasons which laid down the following conditions:
 - (i) If not all animals of species susceptible to one or more of the diseases referred to hereinafter were removed from the holding, the prohibition lasted for:
 - six months in the case of vesicular stomatitis,
 - six months in the case of equine encephalomyelitis, beginning on the date on which the equidae suffering from the disease are slaughtered or removed from the premises,
 - a period required to carry out two Coggins tests three months apart giving negative results on samples taken from the animals remaining after infected animals have been slaughtered, in the case of equine infectious anaemia,
 - one month from the last recorded case, in the case of rabies,
 - 15 days from the last recorded case, in the case of anthrax.
 - (ii) If all the animals of species susceptible to the disease have been slaughtered or removed from the holding, the period of prohibition shall be 30 days, or 15 days in the case of anthrax, beginning on the day on which the premises were cleaned and disinfected following the destruction or removal of the animals.
- (h) to the best of my knowledge, it has not been in contact with equidae suffering from an infectious or contagious disease in the 15 days prior to this declaration.

IV. Residence and quarantine information:

- (a) The horse entered the territory of the country of dispatch on (insert date).
- (b) The horse arrived in the country of dispatch from either a Member State of the European Union⁽¹⁾ or from⁽¹⁾ (insert name of country from where the horse arrived in the country of export), the latter being one of the countries listed in the same sanitary group in Annex I to Decision 2004/211/EC.
- (c) The horse entered the country of dispatch under animal health conditions at least as strict as those laid down in this certificate.
- (d) As far as can be ascertained and based on the attached declaration (which forms part of the certificate) by the owner⁽¹⁾ or the representative of the owner⁽¹⁾ of the horse, the horse has not been continuously outside the European Union for 90 days or more, including the date of scheduled return in accordance with this certificate, and has not been outside the countries referred to above.

V. The horse will be sent in a vehicle cleaned and disinfected in advance with a disinfectant officially recognised in the country of dispatch and designed in a way that droppings, litter or fodder cannot escape during transportation.

VI. The certificate is valid for 10 days.

Date	Place	Stamp and signature of the official veterinarian ⁽³⁾

Name in block capitals and capacity:

DECLARATION

I, the undersigned,
 (insert in block letters name of owner ⁽¹⁾ or representative ⁽¹⁾ of owner of the horse described above)

declare:

- the horse will be sent directly from the premises of dispatch to the premises of destination without coming into contact with other equidae not of the same health status,
- the horse will be moved only between premises under the supervision of central competent authorities of the country of dispatch,
- the horse was exported from a Member State of the European Union on (insert date).

..... ,
 (Place, date) (Signature)

⁽¹⁾ Delete as appropriate.

⁽²⁾ The certificate must be issued on the day of loading of the animal for dispatch to the European Union or on the last working day before embarkation.

⁽³⁾ The colour of the stamp and the signature must be different from that of the printed model.'

COMMISSION DECISION

of 3 November 2005

concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium

(notified under document number C(2005) 4192)

(Only the Dutch text is authentic)

(2005/772/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC ⁽¹⁾, and in particular the first subparagraph of Article 18(1) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Pursuant to Directive 2001/18/EC, the placing on the market of a product containing or consisting of a genetically modified organism or a combination of genetically modified organisms is subject to written consent being granted by the competent authority of a Member State, in accordance with the procedure laid down in that Directive.
- (2) A notification concerning the placing on the market of a genetically modified maize product (*Zea mays* L., line 1507) was submitted by Pioneer Hi-Bred International, INC and Mycogen Seeds to the competent authority of the Netherlands (ref C/NL/00/10).
- (3) The notification covers importation and use as for any other maize grains including feed, with the exception of cultivation and uses as or in food, in the Community, of varieties derived from the 1507 transformation event.
- (4) In accordance with the procedure provided for in Article 14 of Directive 2001/18/EC, the competent authority of the Netherlands prepared an assessment report, which was submitted to the Commission and the competent authorities of the other Member States; whereby the assessment report concluded that no reasons have

emerged on the basis of which consent for the placing on the market of *Zea mays* L. line 1507 should be withheld, provided that specific conditions are fulfilled.

- (5) The competent authorities of other Member States raised objections to the placing on the market of the product.
- (6) The opinion adopted on 24 September 2004 by the European Food Safety Authority, concluded that *Zea mays* L. line 1507 is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use. The European Food Safety Authority also deemed that the monitoring plan provided by the applicant was in line with the intended uses of 1507 maize.
- (7) An examination of each of the objections in the light of Directive 2001/18/EC, of the information submitted in the notification and of the opinion of the European Food Safety Authority, discloses no reason to believe that the placing on the market of *Zea mays* L. line 1507 will adversely affect human or animal health or the environment.
- (8) A unique identifier should be assigned to the 1507 maize for the purposes of Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ⁽²⁾ and Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms ⁽³⁾.
- (9) Adventitious or technically unavoidable traces of genetically modified organisms in products are exempted from labelling and traceability requirements in accordance with thresholds established under Directive 2001/18/EC and Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ⁽⁴⁾.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).

⁽²⁾ OJ L 268, 18.10.2003, p. 24.

⁽³⁾ OJ L 10, 16.1.2004, p. 5.

⁽⁴⁾ OJ L 268, 18.10.2003, p. 1.

- (10) In view of the opinion of the European Food Safety Authority, it is not necessary to establish specific conditions for the intended uses with regard to the handling or packaging of the product and the protection of particular ecosystems, environments or geographical areas.
- (11) Prior to the placing on the market of the product, the necessary measures to ensure its labelling and traceability at all stages of its placing on the market, including verification by appropriate validated detection methodology, should be applicable.
- (12) The measures provided for in this Decision are not in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC and the Commission therefore submitted to the Council a proposal relating to these measures. Since on the expiry of the period laid down in Article 30(2) of Directive 2001/18/EC the Council had neither adopted the proposed measures nor indicated its opposition to them in accordance with Article 5(6) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽¹⁾ the measures should be adopted by the Commission;

HAS ADOPTED THIS DECISION:

Article 1

Consent

Without prejudice to other Community legislation, in particular Regulation (EC) No 258/97 of the European Parliament and of the Council ⁽²⁾ and Regulation (EC) No 1829/2003, written consent shall be granted by the competent authority of the Netherlands to the placing on the market, in accordance with this Decision, of the product identified in Article 2, as notified by Pioneer Hi-Bred International, Inc. and Mycogen Seeds (Reference C/NL/00/10).

The consent shall, in accordance with Article 19(3) of Directive 2001/18/EC, explicitly specify the conditions to which the consent is subject, which are set out in Articles 3 and 4.

Article 2

Product

1. The genetically modified organisms to be placed on the market as or in products, hereinafter 'the product', are grains of maize (*Zea mays* L.), with resistance to the European corn borer

(*Ostrinia nubilalis*) and certain other lepidopteran pests and with tolerance to the herbicide glufosinate-ammonium, derived from *Zea mays* line 1507, which has been transformed using particle acceleration technology with the linear DNA fragment PHI8999A containing the following DNA in two cassettes:

(a) cassette 1:

a synthetic version of the truncated *cry1F* gene derived from *Bacillus thuringiensis* subsp. *aizawai*, which confers resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests such as the pink borer (*Sesamia* spp.), fall armyworm (*Spodoptera frugiperda*), black cutworm (*Agrotis ipsilon*) and southwestern corn borer (*Diatraea grandiosella*), under the regulation of the ubiquitin promoter *ubiZM1(2)* derived from *Zea mays* and the ORF25PolyA terminator from *Agrobacterium tumefaciens* pTi15955;

(b) cassette 2:

a synthetic version of the *pat* gene derived from *Streptomyces viridochromogenes* strain Tü494, which confers tolerance to the herbicide glufosinate-ammonium, under the regulation of the 35S *Cauliflower Mosaic Virus* promoter and terminator sequences.

2. The consent shall cover grains from progeny derived from crosses of maize line 1507 with any traditionally bred maize as or in products.

Article 3

Conditions for placing on the market

The product may be put to the same uses as any other maize, with the exception of cultivation and uses as or in food, and may be placed on the market subject to the following conditions:

- (a) the period of validity of the consent shall be 10 years starting from the date on which the consent is issued;
- (b) the unique identifier of the product shall be DAS-Ø15Ø7-1;
- (c) without prejudice to Article 25 of Directive 2001/18/EC, the consent holder shall, whenever requested to do so, make positive and negative control samples of the product, or its genetic material, or reference materials available to the competent authorities and inspection services of Member States as well as to the Community control laboratories;

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ OJ L 43, 14.2.1997, p. 1.

- (d) without prejudice to specific labelling requirements provided by Regulation (EC) No 1829/2003 the words 'This product contains genetically modified organisms' or 'This product contains genetically modified 1507 maize' shall appear either on a label or in a document accompanying the product, except where other Community legislation sets a threshold below which such information is not required;
- (e) as long as the product has not been authorised for the placing on the market for the purpose of cultivation, the words 'not for cultivation' shall appear either on a label or in a document accompanying the product.

Article 4

Monitoring

1. Throughout the period of validity of the consent, the consent holder shall ensure that the monitoring plan contained in the notification, and consisting of a general surveillance plan, to check for any adverse effects on human and animal health or the environment arising from handling or use of the product, is put in place and implemented.
2. The consent holder shall directly inform the operators, users, national agencies for animal nutrition and feed research as well as veterinary services of the introduction of 1507 maize into the Community as well as on the safety and general characteristics of the product and of the conditions as to monitoring.
3. The consent holder shall submit to the Commission and to the competent authorities of the Member States annual reports on the results of the monitoring activities.
4. Without prejudice to Article 20 of Directive 2001/18/EC the monitoring plan as notified shall, where appropriate and subject to the agreement of the Commission and the competent authority of the Member State which received the original notification, be revised by the consent holder, and/or by the competent authority of the Member State which received the original notification, in the light of the results of the monitoring activities.

toring activities. Proposals for a revised monitoring plan shall be submitted to the competent authorities of the Member States.

5. The consent holder shall be in the position to give evidence to the Commission and the competent authorities of the Member States:

- (a) that the monitoring networks as specified in the monitoring plan contained in the notification collect the information relevant for the monitoring of the product and
- (b) that the members of these networks have agreed to make available that information to the consent holder before the date of the submission of the monitoring reports to the Commission and competent authorities of the Member States in accordance with paragraph 3.

Article 5

Applicability

This Decision shall apply from the date on which a Community Decision authorising the placing on the market of the product referred to in Article 1 for uses as or in food within the meaning of Regulation (EC) No 178/2002 of the European Parliament and of the Council⁽¹⁾ and including a method, validated by the Community reference laboratory, for detection of the product is applicable.

Article 6

Addressee

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 3 November 2005.

For the Commission

Stavros DIMAS

Member of the Commission

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

COMMISSION DECISION**of 3 November 2005****repealing Decision 2003/136/EC on the approval of the plans for the eradication of classical swine fever in feral pigs and emergency vaccination of feral pigs against classical swine fever in Luxembourg***(notified under document number C(2005) 4193)***(Only the French text is authentic)***(2005/773/EC)*

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever ⁽¹⁾, and in particular Articles 16(1), 25(3) and 29(2) thereof,

Whereas:

(1) In 2001 classical swine fever was confirmed in the feral pig population in Luxembourg.

(2) By Commission Decision 2003/136/EC ⁽²⁾ the Commission approved the plans presented by Luxembourg for the eradication of classical swine fever in the feral pig population and the emergency vaccination of feral pigs.

(3) By Decision 2005/224/EC the Commission approved the termination of the plan for the emergency vaccination of feral pigs.

(4) It is apparent from information supplied by Luxembourg that classical swine fever in the feral pig population has been successfully eradicated and that the approved eradication plan no longer needs to be applied.

(5) It is therefore appropriate to repeal Decision 2003/136/EC.

(6) 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

Decision 2003/136/EC is repealed.

Article 2

This Decision is addressed to the French Republic and the Grand Duchy of Luxembourg.

Done at Brussels, 3 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 316, 1.12.2001, p. 5. Directive as amended by the 2003 Act of Accession.

⁽²⁾ OJ L 53, 28.2.2003, p. 52. Decision as amended by Decision 2005/224/EC (OJ L 71, 17.3.2005, p. 69).

COMMISSION DECISION

of 3 November 2005

amending Decision 92/452/EEC as regards embryo collection teams in the United States of America

(notified under document number C(2005) 4195)

(Text with EEA relevance)

(2005/774/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species ⁽¹⁾, and in particular Article 8(1) thereof,

Whereas:

- (1) Commission Decision 92/452/EEC of 30 July 1992 establishing lists of embryo collection teams and embryo production teams approved in third countries for export of bovine embryos to the Community ⁽²⁾ provides that Member States are only to import embryos from third countries where they have been collected, processed and stored by embryo collection teams listed in that Decision.
- (2) The United States of America has requested that amendments be made to the list as regards entries for that country, notably the addition of one team and the deletion of one team.
- (3) The United States of America has provided guarantees regarding compliance with the appropriate rules set out in Directive 89/556/EEC and the embryo collection team concerned has been officially approved for exports to the Community by the veterinary services of that country.

(4) Decision 92/452/EEC should therefore be amended accordingly.

(5) 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 Annex to Decision 92/452/EEC is amended in accordance with the Annex to this Decision.

Article 2

This Decision shall apply from 8 November 2005.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 3 November 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

⁽¹⁾ OJ L 302, 19.10.1989, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 250, 29.8.1992, p. 40. Decision as last amended by Decision 2005/450/EC (OJ L 158, 21.6.2005, p. 24).

ANNEX

In the Annex to Decision 92/452/EEC, the list for the United States of America is amended as follows:

- (a) the row for embryo collection team No 91NJ021 E503 is deleted:

'US		91NJ021 E503		Huff-N-Puff ET 221 Newbold's Corner Road Southampton, NJ	Dr William H. Pettitt'
-----	--	-----------------	--	--	------------------------

- (b) the following row is added:

'US		05NC114 E705		Kingsmill Farm II 5914 Kemp Road Durham, NC 27703	Dr Samuel P. Galphin'
-----	--	-----------------	--	---	-----------------------

CORRIGENDA

Corrigendum to Commission Decision 2005/759/EC of 27 October 2005 concerning certain protection measures in relation to highly pathogenic avian influenza in certain third countries and the movement from third countries of birds accompanying their owners

(Official Journal of the European Union L 285 of 28 October 2005)

Decision 2005/759/EC should read as follows:

‘COMMISSION DECISION**of 27 October 2005****concerning certain protection measures in relation to highly pathogenic avian influenza in certain third countries and the movement from third countries of birds accompanying their owners**

(notified under document number C(2005) 4287)

(Text with EEA relevance)

(2005/759/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) 998/2003 of 26 May 2003 of the European Parliament and of the Council 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 Article 18 thereof,

Whereas:

- (1) Avian influenza is an infectious viral disease in poultry and birds, causing mortality and disturbances which can quickly take epizootic proportions liable to present a serious threat to animal and public health and to reduce sharply the profitability of poultry farming. There is a risk that the disease agent might be introduced via international trade in live birds other than poultry, including birds accompanying their owners (pet birds).
- (2) Commission Decision 2000/666/EC of 16 October 2000 laying down the animal health requirements and the veterinary certification for the import of birds, other than poultry and the conditions for quarantine ⁽²⁾ provides that Member States are to authorise the import of birds from the third countries listed as members of the World Organisation for Animal Health (OIE). The countries listed in the Annex to the present Decision are members of the OIE and accordingly Member States are required to accept imports of birds, other than poultry, from those countries under Decision 2000/666/EC.
- (3) Where necessary, reference should also be made to Council Decision 79/542/EEC of 21 December 1976 drawing up a list of third countries or parts of third countries, and laying down animal and public health

and veterinary certification conditions, for importation into the Community of certain live animals and their fresh meat ⁽³⁾.

- (4) 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 provides for different veterinary control regimes depending on the number of animals. It is appropriate to use those differentiations in number for the sake of this Decision.
- (5) Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC ⁽⁴⁾ requires imported animals to undergo the checks in accordance with Council Directive 91/496/EEC.
- (6) In accordance with Article 18 of Regulation (EC) No 998/2003 the safeguard measures taken in accordance with Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC ⁽⁵⁾, and in particular Article 18 (1) thereof, shall apply.
- (7) Highly pathogenic avian influenza was detected in imported birds in quarantine in a Member State, it appears therefore appropriate to suspend movement of pet birds from certain areas at risk and to use for the definition of the areas a reference to the relevant Regional Commissions of the OIE.

⁽¹⁾ OJ L 146, 13.6.2003, p. 1. Regulation as last amended by Regulation (EC) No 529/2004 (OJ L 94, 31.3.2004, p. 7).

⁽²⁾ OJ L 278, 31.10.2000, p. 26. Decision as last amended by Decision 2002/279/EC (OJ L 99, 16.4.2002, p. 17).

⁽³⁾ OJ L 146, 14.6.1979, p. 15. Decision as last amended by Commission Decision 2004/372/EC (OJ L 118, 23.4.2004, p. 45).

⁽⁴⁾ OJ L 268, 14.9.1992, p. 54. Directive as last amended by the 2003 Act of Accession.

⁽⁵⁾ OJ L 268, 24.9.1991, p. 56. Directive as last amended by the 2003 Act of Accession.

- (8) 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

Movement from third countries

1. Member States shall only authorise the movement of consignments of less than 5 live pet birds. Such a movement is authorised if these birds proceed from a member country of the OIE belonging to a relevant Regional Commission not listed in Annex I.
2. Member States shall only authorise the movement of consignments of less than 5 live pet birds. Such a movement is authorised if these birds proceed from a member country of the OIE belonging to a relevant Regional Commission listed in Annex I, and
 - (a) have undergone a 30 days pre-export isolation at the place of departure in a third country listed in Decision 79/542/EEC, or
 - (b) are subjected to a 30 days post-import quarantine in the Member State of destination on premises approved in accordance with Article 3 (4) of Decision 2000/666/EC, or
 - (c) have been vaccinated and at least on one occasion re-vaccinated within the last 6 months and not later than 60 days prior to dispatch, in accordance with the manufacturer's instructions against avian influenza using an H5 vaccine approved for the species concerned, or
 - (d) have been isolated for at least 10 days prior to export and have been subjected to a test for the detection of H5N1 antigen or genome, as prescribed in Chapter 2.1.14 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals carried out on a sample taken not earlier than on the third day of isolation.
3. Compliance with the conditions in paragraphs 1 and 2 shall be certified by an official veterinarian, in the case of the conditions in 2 (b) based on owners' declaration, in the third country of dispatch in accordance with the model certificate provided for in Annex II.
4. The veterinary certificate shall be complemented by
 - (a) a declaration of the owner or the representative of the owner in accordance with Annex III,

- (b) a confirmation as follows:

'Pet birds in accordance with Article 2 of Decision 2005/759/EC'

Article 2

Veterinary checks

1. Member States shall take the measures necessary to ensure that pet birds moved into Community territory from a third country are subject to documentary and identity checks by the competent authorities at the travellers' point of entry into Community territory.
2. Member States shall designate the authorities referred to in paragraph 1 which is responsible for such checks and immediately inform the Commission thereof.
3. Each Member State shall draw up a list of points of entry as referred to in paragraph 1 and forward it to the other Member States and to the Commission.
4. Where such checks reveal that the animals do not meet the requirements laid down in this Decision, the third subparagraph of Article 14 of Regulation (EC) No 998/2003 shall apply.

Article 3

This Decision shall not apply to the movement onto Community territory of birds accompanying their owners from Andorra, Faeroe Islands, Greenland, Iceland, Liechtenstein, Norway, San Marino or Switzerland.

Article 4

Member States shall immediately take the necessary measures to comply with this Decision and publish those measures. They shall immediately inform the Commission thereof.

Article 5

This Decision shall apply until 30 November 2005.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 27 October 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Third countries belonging to the OIE Regional Commissions, as referred to in Article 1, of:

- Africa,
 - Americas,
 - Asia, Far East and Oceania,
 - Europe, and
 - Middle East.
-

ANNEX II

COUNTRY

Veterinary certificate to EU

Part I: Details of dispatched consignment	I.1. Consignor Name Address Postal code		I.2.	I.2.a. Local reference number:	
			I.3. Central Competent Authority		
			I.4. Local Competent Authority		
	I.5. Consignee Name Address Postal code		I.6.		
	I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code	
	I.11. Place of origin Holding <input type="checkbox"/> Other <input type="checkbox"/> Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Holding <input type="checkbox"/> Quarantine <input type="checkbox"/> Approved body <input type="checkbox"/> Other <input type="checkbox"/> Name Approval number Address Postal code		
	I.13. Place of loading Address Approval number		I.14. Date and time of departure Estimated date and time of arrival		
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:		I.16. I.17. No(s) of CITES		
	I.18. Description of commodity		I.19. Commodity code (HS code)		I.20. Quantity
	I.21.		I.22. Number of packages		
I.23. Identification of container/Seal number		I.24.			
I.25. Commodities certified for: Pets <input type="checkbox"/> Quarantine <input type="checkbox"/>					
I.26. For transit through EU to 3rd Country <input type="checkbox"/> 3rd country ISO code		I.27. For import or admission into EU <input type="checkbox"/> Definitive import <input type="checkbox"/>			
I.28. Identification of the commodities Species Identification system Identification number Age Sex Quantity (Scientific name)					

COUNTRY

Pet birds

II. Health information		II.a. Certificate reference number	II.b. Local reference number
Part II: Certification	I, the undersigned official veterinarian of (insert name of third country) certify that:		
	1. The country of dispatch is a member country of the World Organisation for Animal Health (OIE and is belonging to the OIE Regional Commission for (insert name of Regional Commission).		
	2. The birds described in point I.28 have been subjected today, within 48 hour or the last working day prior to dispatch, to a clinical inspection and found free of obvious signs of disease;		
	3. The birds comply with at least one of the following conditions:		
	either [they have been confined on the premises specified in point I.11 under official supervision for at least 30 days prior to dispatch and effectively protected from contacts with other birds] ⁽¹⁾		
	or [they are destined, as indicated in point I.12 for a quarantine station approved in accordance with Article 3 (4) of Decision 2000/666/EC] ⁽¹⁾		
	or [they have been vaccinated and at least on one occasion re-vaccinated within the last 6 months and not later than 60 days prior to dispatch, in accordance with the manufacturer's instructions against avian influenza using an H5 vaccine approved for the species concerned] ⁽¹⁾		
	or [they have been isolated for at least 10 days prior to export and have been subjected to a test for the detection of H5N1 antigen or genome, as prescribed in Chapter 2.1.14 of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, carried out on a sample taken not earlier than on the third day of isolation] ⁽¹⁾		
	4. The owner or the representative of the owner has declared:		
	4.1. The birds will be accompanied during the movement by a person that is responsible for the animals.		
4.2. The animals are not intended for commercial purposes.			
4.3. During the period between the pre-movement veterinary inspection and the factual departure the birds will remain isolated from any possible contact with other birds.			
either [4.4. The animals have undergone the 30 days pre-movement isolation without coming into contact to any other birds not covered by this certificate.] ⁽¹⁾			
or [4.4. I have made arrangements for the 30 days post-introduction quarantine at the quarantine premises of, as indicated in point I.12 of the certificate.] ⁽¹⁾			
Notes			
⁽¹⁾ Delete as necessary.			
⁽²⁾ The certificate is valid for 10 days. In case of transport by boat the validity is prolonged by the time of the sea voyage.			
Official veterinarian:			
Name (in Capital):		Qualification and title:	
Date:		Signature:	
Stamp:			

ANNEX III

Declaration of the owner or representative of the owner of the pet birds

I, the undersigned owner ^(a)/representative of the owner ^(a) declare that:

1. The birds will be accompanied during the movement by a person that is responsible for the animals.
2. The animals are not intended for commercial purposes.
3. During the period between the pre-movement veterinary inspection and the factual departure the birds will remain isolated from any possible contact with other birds.
4. The animals have undergone the 30 days pre-movement isolation without coming into contact to any other birds not covered by this certificate. ^(a)
5. I have made arrangements for the 30 days post-introduction quarantine at the quarantine premises of, as indicated in point L12 of the certificate. ^(a)

.....
Date and Place

.....
Signature

^(a) Delete as appropriate.'