

Official Journal

of the European Union

ISSN 1725-2555

L 105

Volume 46

26 April 2003

English edition

Legislation

Contents

I Acts whose publication is obligatory

Commission Regulation (EC) No 727/2003 of 25 April 2003 establishing the standard import values for determining the entry price of certain fruit and vegetables	1
★ Commission Regulation (EC) No 728/2003 of 25 April 2003 adapting certain fish quotas for 2003 pursuant to Council Regulation (EC) No 847/96 introducing additional conditions for year-to-year management of TACIS and quotas	3
Commission Regulation (EC) No 729/2003 of 25 April 2003 fixing the refunds applicable to cereal and rice sector products supplied as Community and national food aid	9
Commission Regulation (EC) No 730/2003 of 25 April 2003 fixing the maximum export refund on wholly milled long grain B rice to certain third countries in connection with the invitation to tender issued in Regulation (EC) No 1898/2002	11
Commission Regulation (EC) No 731/2003 of 25 April 2003 fixing the maximum export refund on wholly milled round grain rice to certain third countries in connection with the invitation to tender issued in Regulation (EC) No 1896/2002	12
Commission Regulation (EC) No 732/2003 of 25 April 2003 fixing the maximum export refund on wholly milled round grain, medium grain and long grain A rice to be exported to certain third countries in connection with the invitation to tender issued in Regulation (EC) No 1897/2002	13
Commission Regulation (EC) No 733/2003 of 25 April 2003 fixing the minimum selling prices for butter and the maximum aid for cream, butter and concentrated butter for the 118th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97	14
Commission Regulation (EC) No 734/2003 of 25 April 2003 fixing the maximum purchasing price for butter for the 71st invitation to tender carried out under the standing invitation to tender governed by Regulation (EC) No 2771/1999	16

Commission Regulation (EC) No 735/2003 of 25 April 2003 fixing the maximum aid for concentrated butter for the 290th special invitation to tender opened under the standing invitation to tender provided for in Regulation (EEC) No 429/90	17
★ Commission Directive 2003/32/EC of 23 April 2003 introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin ⁽¹⁾	18
II Acts whose publication is not obligatory	
Commission	
2003/289/EC:	
★ Commission Decision of 25 April 2003 concerning protection measures in relation to avian influenza in Belgium ⁽¹⁾ (notified under document number C(2003) 1438) ...	24
2003/290/EC:	
★ Commission Decision of 25 April 2003 concerning protective measures in relation to avian influenza in the Netherlands ⁽¹⁾ (notified under document number C(2003) 1437)	28
2003/291/EC:	
★ Commission Decision of 25 April 2003 laying down the requirements for the prevention of avian influenza in susceptible birds kept in zoos in Belgium and the Netherlands ⁽¹⁾ (notified under document number C(2003) 1439)	34

I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 727/2003
of 25 April 2003
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⁾, as last amended by Regulation (EC) No 1947/2002 ⁽²⁾, 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 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission
J. M. SILVA RODRÍGUEZ
Agriculture Director-General

⁽¹⁾ OJ L 337, 24.12.1994, p. 66.

⁽²⁾ OJ L 299, 1.11.2002, p. 17.

ANNEX

to the Commission Regulation of 25 April 2003 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	130,5
	204	90,3
	212	120,5
	999	113,8
0707 00 05	052	82,6
	068	110,0
	096	51,8
	204	32,5
	628	143,3
0709 90 70	999	84,0
	052	103,6
	204	101,8
0805 10 10, 0805 10 30, 0805 10 50	999	102,7
	052	95,2
	204	40,9
	220	26,6
	520	38,3
	600	43,0
	624	58,6
	999	50,4
0805 50 10	400	65,0
	999	65,0
0808 10 20, 0808 10 50, 0808 10 90	060	64,5
	388	83,2
	400	123,8
	404	112,7
	508	86,0
	512	85,4
	524	63,7
	528	77,4
	720	112,2
	804	104,5
0808 20 50	999	91,3
	388	86,9
	512	80,9
	528	73,2
	999	80,3

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 728/2003**of 25 April 2003****adapting certain fish quotas for 2003 pursuant to Council Regulation (EC) No 847/96 introducing additional conditions for year-to-year management of TACIS and quotas**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy ⁽¹⁾, as last amended by Regulation (EC) No 2846/98 ⁽²⁾, and in particular Article 23(1) thereof,

Having regard to Council Regulation (EC) No 847/96 of 6 May 1996 introducing additional conditions for year-to-year management of TACs and quotas ⁽³⁾, as amended by Commission Regulation (EC) No 1957/98 ⁽⁴⁾, and in particular Article 4(2) thereof,

Whereas:

- (1) Council Regulation (EC) No 2555/2001 of 18 December 2001 fixing for 2002 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks, applicable in Community waters and, for Community vessels, in waters where limitations in catch are required ⁽⁵⁾, as last amended by Regulation (EC) No 2256/2002 ⁽⁶⁾, stipulate which stocks may be subject to the measures foreseen by Regulation (EC) No 847/96.
- (2) Council Regulation (EC) No 2341/2002 ⁽⁷⁾, as amended by Regulation (EC) No 671/2003 ⁽⁸⁾, fixes fish quotas for certain stocks in 2003.
- (3) Within the terms of Article 4(2) of Regulation (EC) No 847/96, certain Member States have asked to withhold a fraction of their quotas to be transferred to the following year. Within the limits indicated in that Article, the quantities withheld shall be added to the quota for 2003.

(4) According to the information communicated to the Commission, certain Member States have fished in excess of permitted landings for some stocks in 2002. In accordance with Article 5(1) of Council Regulation (EC) No 847/96, deductions from national quotas for 2003 should be made at a level equivalent to the quantity fished in excess, without prejudice to the application of Article 5(2).

(5) In conformity with Article 5(2) of Council Regulation (EC) No 847/96, weighted deductions from national quotas for 2003 should be made in the case of over-fishing of permitted landings in 2002 for those stocks identified as such in Article 5 of and Annex III to Regulation (EC) No 2555/2001.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Fisheries and Aquaculture,

HAS ADOPTED THIS REGULATION:

Article 1

The quotas fixed in Regulation (EC) No 2341/2002 are increased as shown in Annex I or reduced as shown in Annex II.

Article 2

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

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 261, 20.10.1993, p. 1.

⁽²⁾ OJ L 358, 31.12.1998, p. 5.

⁽³⁾ OJ L 115, 9.5.1996, p. 3.

⁽⁴⁾ OJ L 254, 16.9.1998, p. 3.

⁽⁵⁾ OJ L 347, 31.12.2001, p. 1.

⁽⁶⁾ OJ L 343, 18.12.2002, p. 19.

⁽⁷⁾ OJ L 356, 31.12.2002, p. 12.

⁽⁸⁾ OJ L 97, 15.4.2003, p. 11.

TRANSFERS ONTO 2003 QUOTAS

Country	Stock	Penalties 2002 (*)	Species	Zone	Initial quantity 2002	Adapted quantity 2002	Catches 2002	% Adapted quantity	Transfers 2003	Initial quantity 2003	Revised quantity 2003
Belgium	ANF/07	n	Anglerfish	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	1 719	717	559,6	78,0	71,7	1 461	1 533
Belgium	ANF/8ABDE	n	Anglerfish	VIIIa), b), d), e	0	210	135,9	64,7	21	0	21
Belgium	LEZ/8ABDE	n	Megrim	VIIIa), b), d), e	0	15	4,4	29,3	1,5	0	2
Belgium	LEZ/07	n	Megrim	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	361	97	60,7	62,6	9,7	387	397
Belgium	SOL/24	y	Common sole	II, IV	1 333	1 537	1 368,6	89,0	153,7	1 321	1 475
Belgium	SOL/07A	y	Common sole	ICES division VIIa — Irish Sea	543	833	820,8	98,5	12,2	499	511
Belgium	SOL/07D	y	Common sole	ICES division VIId — eastern Channel	1 400	1 524	1 263,3	82,9	152,4	1 454	1 606
Germany	JAX/578/14	n	Horse mackerel	Vb(1), VI, VII, VIIIa), b), d), e), XII, XIV	10 371	14 752	13 274,1	90,0	1 475,2	9 428	10 903
Germany	SOL/24	y	Common sole	II, IV	1 067	1 158	756,1	65,3	115,8	1 057	1 173
Germany	SOL/3A/BCD	n	Common sole	IIIa); IIIb),c),d) (1)	24	17	10,8	63,5	1,7	17	19
Denmark	JAX/578/14	n	Horse mackerel	Vb(1), VI, VII, VIIIa), b), d), e), XII, XIV	12 975	13 148	10 093,8	76,8	1 314,8	11 796	13 111
Spain	ANE/08	n	European anchovy	ICES subarea VIII - Bay of Biscay	28 915	19 915	7 700,3	38,7	1 991,5	29 700	31 692
Spain	ANF/07	n	Anglerfish	ICES subarea VII — Irish Sea, West of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	683	2 973	2 513,4	84,5	297,3	581	878
Spain	ANF/8ABDE	n	Anglerfish	VIIIa), b), d), e	786	736	612,5	83,2	73,6	543	617

Country	Stock	Penalties 2002 (*)	Species	Zone	Initial quantity 2002	Adapted quantity 2002	Catches 2002	% Adapted quantity	Transfers 2003	Initial quantity 2003	Revised quantity 2003
Spain	ANF/8C3411	n	Anglerfish	VIIIc), IX, X; COPACE 34.1.1(1)	3 958	4 223	1 203,4	28,5	422,3	3 332	3 754
Spain	JAX/578/14	n	Horse mackerel	Vb(1), VI, VII, VIIIa), b), d), e), XII, XIV	14 163	4 163	2 797,4	67,2	416,3	12 875	13 291
Spain	JAX/8C9	n	Horse mackerel	VIIIc), IX	30 932	34 590	30 632,4	88,6	3 459	29 587	33 046
Spain	LEZ/07	n	Megrim	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	4 005	6 490	5 246,5	80,8	649	4 301	4 950
Spain	LEZ/8ABDE	n	Megrim	VIIIa), b), d), e	858	843	143,9	17,1	84,3	921	1 005
Spain	LEZ/8C3411	y	Megrim	VIIIc), IX, X; COPACE 34.1.1(1)	3 692	4 104	675,7	16,5	410,4	2 215	2 625
France	ANE/08	n	European anchovy	ICES subarea VIII — Bay of Biscay	3 300	12 300	8 346	67,9	1 230	3 300	4 530
France	LEZ/07	n	Megrim	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	4 861	3 367	2 353,3	69,9	336,7	5 220	5 557
France	LEZ/8ABDE	n	Megrim	VIIIa), b), d), e	692	872	553,4	63,5	87,2	743	830
France	LEZ/8C3411	y	Megrim	VIIIc), IX, X; COPACE 34.1.1(1)	185	208	14,2	6,8	20,8	111	132
United Kingdom	ANF/07	n	Anglerfish	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	3 345	3 825	3 400,2	88,9	382,5	2 843	3 226
United Kingdom	JAX/578/14	n	Horse mackerel	Vb(1), VI, VII, VIIIa), b), d), e), XII, XIV	14 026	13 041	10 728,9	82,3	1 304,1	12 751	14 055

Country	Stock	Penalties 2002 (*)	Species	Zone	Initial quantity 2002	Adapted quantity 2002	Catches 2002	% Adapted quantity	Transfers 2003	Initial quantity 2003	Revised quantity 2003
United Kingdom	LEZ/07	n	Megrim	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	1 914	2 099	1 714,5	81,7	209,9	2 055	2 265
United Kingdom	SOL/24	y	Common sole	II, IV	686	801	683,3	85,3	80,1	679	759
United Kingdom	SOL/07A	y	Common sole	ICES division VIIa — Irish Sea	244	241	168	69,7	24,1	224	248
United Kingdom	SOL/07D	y	Common sole	ICES division VIId — eastern Channel	1 000	1 089	975,5	89,6	108,9	1 038	1 147
United Kingdom	SOL/7FG	y	Common sole	VIIIf, g)	301	319	317,6	99,6	1,4	349	350
Ireland	JAX/578/14	n	Horse mackerel	Vb(1), VI, VII, VIIla), b), d), e, XII, XIV	33 763	36 596	33 426	91,3	3 170	30 693	33 863
Netherlands	HER/6AS7BC	n	Atlantic herring	VIa) South, VIIb), c	1 273	413	366,3	88,7	41,3	1 273	1 314
Netherlands	HER/7GK	n	Atlantic herring	VIIg), h), j), k	494	925	921,8	99,7	3,2	802	805
Netherlands	JAX/578/14	n	Horse mackerel	Vb(1), VI, VII, VIIla), b), d), e), XII, XIV	49 479	55 958	49 705,4	88,8	5 595,8	44 981	50 577
Netherlands	SOL/24	y	Common sole	II, IV	12 038	13 340	12 099,7	90,7	1 240,3	11 925	13 165
Portugal	ANF/8C3411	n	Anglerfish	VIIIc), IX, X; COPACE 34.1.1(1)	788	923	499,2	54,1	92,3	663	755
Portugal	JAX/8C9	n	Horse mackerel	VIIIc), IX	26 174	26 174	14 948	57,1	2 617,4	25 036	27 653
Portugal	LEZ/8C3411	y	Megrim	VIIIc), IX, X; COPACE 34.1.1(1)	123	173	132,2	76,4	17,3	74	91

Legend:

(*) Annex III to Council Regulation (EC) No 2555/2001 (deductions of Article 5(2)).

DEDUCTION ONTO 2003 QUOTAS

Country	Species	Area	Species	Zone	Penalties 2002 (*)	Adapted quantity 2002	Catches 2002	%	Deductions	Initial quantity 2003	Revised quantity 2003
Belgium	COD	7X7A34	Atlantic cod	VIIb, c, d, e, f, g, h, j, k, VIII, IX, X; COPACE 34.1.1(1)	y	393,00	575,50	146,438	- 212,27	289	77
Belgium	SOL	07E	Common sole	ICES division VIIe — western English Channel	y	19,00	31,40	165,263	- 12,40	19	7
Belgium	SOL	7FG	Common sole	VIIIf, g)	y	648,00	694,40	107,160	- 46,40	775	729
Germany	COD	1N2AB	Atlantic cod	Norway zone (North of 62° N): I, IIa), b	n	1 985,00	1 985,70	100,035	- 0,70	1 976	1 975
Germany	C/H	05B1-F	Cod and haddock	Faroe zone: Vb(1)	n	12,00	12,30	102,500	- 0,30	10	10
Denmark	NEP	3A/BCD	Norway lobster	IIIa; IIIb, c, d(1)	n	3 282,00	3 299,60	100,536	- 17,60	3 307	3 289
Denmark	SOL	3A/BCD	Common sole	IIIa; IIIb, c, d(1)	n	526,00	567,40	107,871	- 41,40	291	250
Denmark	HER	1/2NEZ	Atlantic herring	I, II (Norwegian EEZ)	n	5 896,00	6 076,00	103,053	- 180,00	0	0
France	HER	4AB	Atlantic herring	IVa, IVb	y	14 730,00	14 731,80	100,012	- 1,80	16 412	16 410
France	HER	4CXB7D	Atlantic herring	IVc, VIId	y	9 569,00	9 753,20	101,925	- 184,20	15 448	15 264
France	COD	1N2AB	Atlantic cod	Norway zone (North of 62° N): I, IIa, b	n	1 813,00	1 819,20	100,342	- 6,20	1 814	1 808
France	COD	1/2B	Atlantic cod	I, IIb	y	1 114,00	1 115,10	100,099	- 1,10	1 114	1 113
France	HER	7GK	Atlantic herring	VIIg, h, j, k	n	801,00	802,70	100,212	- 1,70	802	800
France	HER	7EF	Atlantic herring	VIIe, f	n	498,00	499,80	100,361	- 1,80	500	498
France	ANF	07	Anglerfish	ICES subarea VII — Irish Sea, west of Ireland, Porcupine Bank, eastern and western English Channel, Bristol Channel, Celtic Sea north and south, and south-west of Ireland — east and west	n	9 924,00	10 003,10	100,797	- 79,10	9 375	9 296
France	NEP	08C	Norway lobster	ICES division VIIIc — Bay of Biscay — South	y	14,00	17,40	124,286	- 3,40	7	4

Country	Species	Area	Species	Zone	Penalties 2002 (*)	Adapted quantity 2002	Catches 2002	%	Deduc- tions	Initial quantity 2003	Revised quantity 2003
France	PLE	7DE	European plaice	VIIId, e	y	3 649,00	3 683,30	100,940	– 34,30	3 256	3 222
Ireland	SOL	07A	Common sole	ICES division VIIa — Irish Sea	y	102,00	103,90	101,863	– 1,90	123	121
Netherlands	HER	4AB	Atlantic herring	IVa, IVb	y	30 947,00	31 034,10	100,281	– 87,10	44 727	44 640
Netherlands	SRX	2AC4-C	Rays, stingrays, mantas nei	IIa(1), IV(1)	n	714,00	792,20	110,952	– 78,20	592	514
Netherlands	MAC	04A-C	Atlantic mackerel	IVa(1)	n	9 800,00	9 837,30	100,381	– 37,30	8 702	8 665
Portugal	COD	1N2AB	Atlantic cod	Norway zone (North of 62° N): I, IIa, b	n	2 205,00	2 205,10	100,005	– 0,10	2 204	2 204
Sweden	HER	03A	Atlantic herring	ICES division IIIa — Skagerrak and Kattegat	y	33 986,00	34 333,70	101,023	– 347,70	34 917	34 569

(*) Penalties 2002 = Annex III of Regulation (EC) No 2555/2001 column of deductions Article 5(2) of Regulation No 847/96.

COMMISSION REGULATION (EC) No 729/2003**of 25 April 2003****fixing the refunds applicable to cereal and rice sector products supplied as Community and national food aid**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ⁽¹⁾, as last amended by Commission Regulation (EC) No 1666/2000 ⁽²⁾, and in particular the third subparagraph of Article 13(2) thereof,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ⁽³⁾, as last amended by Commission Regulation (EC) No 411/2002 ⁽⁴⁾, and in particular Article 13(3) thereof,

Whereas:

- (1) Article 2 of Council Regulation (EEC) No 2681/74 of 21 October 1974 on Community financing of expenditure incurred in respect of the supply of agricultural products as food aid ⁽⁵⁾ lays down that the portion of the expenditure corresponding to the export refunds on the products in question fixed under Community rules is to be charged to the European Agricultural Guidance and Guarantee Fund, Guarantee Section.
- (2) In order to make it easier to draw up and manage the budget for Community food aid actions and to enable the Member States to know the extent of Community participation in the financing of national food aid actions, the level of the refunds granted for these actions should be determined.

- (3) The general and implementing rules provided for in Article 13 of Regulation (EEC) No 1766/92 and in Article 13 of Regulation (EC) No 3072/95 on export refunds are applicable *mutatis mutandis* to the abovementioned operations.

- (4) The specific criteria to be used for calculating the export refund on rice are set out in Article 13 of Regulation (EC) No 3072/95.

- (5) 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

For Community and national food aid operations under international agreements or other supplementary programmes, and other Community free supply measures, the refunds applicable to cereals and rice sector products shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 1 May 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 181, 1.7.1992, p. 21.

⁽²⁾ OJ L 193, 29.7.2000, p. 1.

⁽³⁾ OJ L 329, 30.12.1995, p. 18.

⁽⁴⁾ OJ L 62, 5.3.2002, p. 27.

⁽⁵⁾ OJ L 288, 25.10.1974, p. 1.

ANNEX

to the Commission Regulation of 25 April 2003 fixing the refunds applicable to cereal and rice sector products supplied as Community and national food aid

(EUR/t)	
Product code	Refund
1001 10 00 9400	0,00
1001 90 99 9000	16,00
1002 00 00 9000	28,00
1003 00 90 9000	13,00
1005 90 00 9000	23,00
1006 30 92 9100	153,00
1006 30 92 9900	153,00
1006 30 94 9100	153,00
1006 30 94 9900	153,00
1006 30 96 9100	153,00
1006 30 96 9900	153,00
1006 30 98 9100	153,00
1006 30 98 9900	153,00
1006 30 65 9900	153,00
1007 00 90 9000	23,00
1101 00 15 9100	21,90
1101 00 15 9130	20,50
1102 10 00 9500	38,25
1102 20 10 9200	35,35
1102 20 10 9400	30,30
1103 11 10 9200	0,00
1103 13 10 9100	45,45
1104 12 90 9100	0,00

NB: The product codes are defined in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), amended.

COMMISSION REGULATION (EC) No 730/2003**of 25 April 2003****fixing the maximum export refund on wholly milled long grain B rice to certain third countries in connection with the invitation to tender issued in Regulation (EC) No 1898/2002**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ⁽¹⁾, as last amended by Commission Regulation (EC) No 411/2002 ⁽²⁾, and in particular Article 13(3) thereof,

Whereas:

(1) An invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 1898/2002 ⁽³⁾.(2) Article 5 of Commission Regulation (EEC) No 584/75 ⁽⁴⁾, as last amended by Regulation (EC) No 1948/2002 ⁽⁵⁾, allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund. In fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account. A contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund.

(3) The application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1.

(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

The maximum export refund on wholly milled long grain B rice to be exported to certain third countries pursuant to the invitation to tender issued in Regulation (EC) No 1898/2002 is hereby fixed on the basis of the tenders submitted from 21 to 24 April 2003 at 295,00 EUR/t.

Article 2

This Regulation shall enter into force on 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 329, 30.12.1995, p. 18.

⁽²⁾ OJ L 62, 5.3.2002, p. 27.

⁽³⁾ OJ L 287, 25.10.2002, p. 11.

⁽⁴⁾ OJ L 61, 7.3.1975, p. 25.

⁽⁵⁾ OJ L 299, 1.11.2002, p. 18.

**COMMISSION REGULATION (EC) No 731/2003
of 25 April 2003**

**fixing the maximum export refund on wholly milled round grain rice to certain third countries in
connection with the invitation to tender issued in Regulation (EC) No 1896/2002**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ⁽¹⁾, as last amended by Commission Regulation (EC) No 411/2002 ⁽²⁾, and in particular Article 13(3) thereof,

Whereas:

(1) An invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 1896/2002 ⁽³⁾.

(2) Article 5 of Commission Regulation (EEC) No 584/75 ⁽⁴⁾, as last amended by Regulation (EC) No 1948/2002 ⁽⁵⁾, allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund. In fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account. A contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund.

(3) The application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1.

(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

The maximum export refund on wholly milled round grain rice to be exported to certain third countries pursuant to the invitation to tender issued in Regulation (EC) No 1896/2002 is hereby fixed on the basis of the tenders submitted from 21 to 24 April 2003 at 153,00 EUR/t.

Article 2

This Regulation shall enter into force on 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 329, 30.12.1995, p. 18.

⁽²⁾ OJ L 62, 5.3.2002, p. 27.

⁽³⁾ OJ L 287, 25.10.2002, p. 5.

⁽⁴⁾ OJ L 61, 7.3.1975, p. 25.

⁽⁵⁾ OJ L 299, 1.11.2002, p. 18.

COMMISSION REGULATION (EC) No 732/2003**of 25 April 2003****fixing the maximum export refund on wholly milled round grain, medium grain and long grain A rice to be exported to certain third countries in connection with the invitation to tender issued in Regulation (EC) No 1897/2002**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice ⁽¹⁾, as last amended by Commission Regulation (EC) No 411/2002 ⁽²⁾, and in particular Article 13(3) thereof,

Whereas:

- (1) An invitation to tender for the export refund on rice was issued pursuant to Commission Regulation (EC) No 1897/2002 ⁽³⁾.
- (2) Article 5 of Commission Regulation (EEC) No 584/75 ⁽⁴⁾, as last amended by Regulation (EC) No 1948/2002 ⁽⁵⁾, allows the Commission to fix, in accordance with the procedure laid down in Article 22 of Regulation (EC) No 3072/95 and on the basis of the tenders submitted, a maximum export refund. In fixing this maximum, the criteria provided for in Article 13 of Regulation (EC) No 3072/95 must be taken into account. A contract is awarded to any tenderer whose tender is equal to or less than the maximum export refund.

(3) The application of the abovementioned criteria to the current market situation for the rice in question results in the maximum export refund being fixed at the amount specified in Article 1.

(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

The maximum export refund on wholly milled grain, medium grain and long grain A rice to be exported to certain third countries pursuant to the invitation to tender issued in Regulation (EC) No 1897/2002 is hereby fixed on the basis of the tenders submitted from 21 to 24 April 2003 at 153,00 EUR/t.

Article 2

This Regulation shall enter into force on 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 329, 30.12.1995, p. 18.

⁽²⁾ OJ L 62, 5.3.2002, p. 27.

⁽³⁾ OJ L 287, 25.10.2002, p. 8.

⁽⁴⁾ OJ L 61, 7.3.1975, p. 25.

⁽⁵⁾ OJ L 299, 1.11.2002, p. 18.

**COMMISSION REGULATION (EC) No 733/2003
of 25 April 2003**

fixing the minimum selling prices for butter and the maximum aid for cream, butter and concentrated butter for the 118th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products ⁽¹⁾, as last amended by Commission Regulation (EC) No 509/2002 ⁽²⁾, and in particular Article 10 thereof,

Whereas:

- (1) The intervention agencies are, pursuant to Commission Regulation (EC) No 2571/97 of 15 December 1997 on the sale of butter at reduced prices and the granting of aid for cream, butter and concentrated butter for use in the manufacture of pastry products, ice-cream and other foodstuffs ⁽³⁾, as last amended by Regulation (EC) No 635/2000 ⁽⁴⁾, to sell by invitation to tender certain quantities of butter that they hold and to grant aid for cream, butter and concentrated butter. Article 18 of that Regulation stipulates that in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed for butter and maximum aid shall be fixed for cream, butter and concentrated butter. It is further stipulated that the price

or aid may vary according to the intended use of the butter, its fat content and the incorporation procedure, and that a decision may also be taken to make no award in response to the tenders submitted. The amount(s) of the processing securities must be fixed accordingly.

- (2) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

The minimum selling prices and the maximum aid and processing securities applying for the 118th individual invitation to tender, under the standing invitation to tender provided for in Regulation (EC) No 2571/97, shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 160, 26.6.1999, p. 48.

⁽²⁾ OJ L 79, 22.3.2002, p. 15.

⁽³⁾ OJ L 350, 20.12.1997, p. 3.

⁽⁴⁾ OJ L 76, 25.3.2000, p. 9.

ANNEX

to the Commission Regulation of 25 April 2003 fixing the minimum selling prices for butter and the maximum aid for cream, butter and concentrated butter for the 118th individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

(EUR/100 kg)

Formula			A		B	
Incorporation procedure			With tracers	Without tracers	With tracers	Without tracers
Minimum selling price	Butter ≥ 82 %	Unaltered	—	—	—	—
		Concentrated	—	—	—	—
Processing security		Unaltered	—	—	—	—
		Concentrated	—	—	—	—
Maximum aid	Butter ≥ 82 %		85	81	85	81
	Butter < 82 %		83	79	—	—
	Concentrated butter		105	101	105	101
	Cream		—	—	36	34
Processing security	Butter		94	—	94	—
	Concentrated butter		116	—	116	—
	Cream		—	—	40	—

**COMMISSION REGULATION (EC) No 734/2003
of 25 April 2003**

**fixing the maximum purchasing price for butter for the 71st invitation to tender carried out under
the standing invitation to tender governed by Regulation (EC) No 2771/1999**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products ⁽¹⁾, as last amended by Commission Regulation (EC) No 509/2002 ⁽²⁾, and in particular Article 10 thereof,

Whereas:

- (1) Article 13 of Commission Regulation (EC) No 2771/1999 of 16 December 1999 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention on the market in butter and cream ⁽³⁾, as last amended by Regulation (EC) No 359/2003 ⁽⁴⁾, provides that, in the light of the tenders received for each invitation to tender, a maximum buying-in price is to be fixed in relation to the intervention price applicable and that it may also be decided not to proceed with the invitation to tender.

- (2) As a result of the tenders received, the maximum buying-in price should be fixed as set out below.

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

For the 71st invitation to tender issued under Regulation (EC) No 2771/1999, for which tenders had to be submitted not later than 22 April 2003, the maximum buying-in price is fixed at 295,38 EUR/100 kg.

Article 2

This Regulation shall enter into force on 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 160, 26.6.1999, p. 48.

⁽²⁾ OJ L 79, 22.3.2002, p. 15.

⁽³⁾ OJ L 333, 24.12.1999, p. 11.

⁽⁴⁾ OJ L 53, 28.2.2003, p. 17.

COMMISSION REGULATION (EC) No 735/2003**of 25 April 2003****fixing the maximum aid for concentrated butter for the 290th special invitation to tender opened under the standing invitation to tender provided for in Regulation (EEC) No 429/90**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products ⁽¹⁾, as last amended by Commission Regulation (EC) No 509/2002 ⁽²⁾, and in particular Article 10 thereof,

Whereas:

- (1) In accordance with Commission Regulation (EEC) No 429/90 of 20 February 1990 on the granting by invitation to tender of an aid for concentrated butter intended for direct consumption in the Community ⁽³⁾, as last amended by Regulation (EC) No 124/1999 ⁽⁴⁾, the intervention agencies are opening a standing invitation to tender for the granting of aid for concentrated butter; Article 6 of that Regulation provides that in the light of the tenders received in response to each special invitation to tender, a maximum amount of aid is to be fixed for concentrated butter with a minimum fat content of 96 % or a decision is to be taken to make no award; the end-use security must be fixed accordingly.

- (2) In the light of the tenders received, the maximum aid should be fixed at the level specified below and the end-use security determined accordingly.

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Milk and Milk Products,

HAS ADOPTED THIS REGULATION:

Article 1

For the 290th special invitation to tender under the standing invitation to tender opened by Regulation (EEC) No 429/90, the maximum aid and the amount of the end-use security shall be as follows:

- | | |
|---------------------|-----------------|
| — maximum aid: | EUR 105/100 kg, |
| — end-use security: | EUR 116/100 kg. |

Article 2

This Regulation shall enter into force on 26 April 2003.

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

Done at Brussels, 25 April 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 160, 26.6.1999, p. 48.

⁽²⁾ OJ L 79, 22.3.2002, p. 15.

⁽³⁾ OJ L 45, 21.2.1990, p. 8.

⁽⁴⁾ OJ L 16, 21.1.1999, p. 19.

COMMISSION DIRECTIVE 2003/32/EC**of 23 April 2003****introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽¹⁾, as last amended by Directive 2001/104/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 14(b) thereof,

Whereas:

(1) On 5 March 2001 France adopted a national measure prohibiting the manufacture, placing on the market, distribution, import, export and use of medical devices manufactured from materials of animal origin, where these are used as *dura mater* substitutes.

(2) France justified the measure by the uncertainties that exist with regard to the risk of transmission to humans of animal spongiform encephalopathies from such medical devices, and by the fact that alternatives are available, in the form of synthetic materials or autologous materials taken from the patient.

(3) Other Member States have taken unilateral national measures on other legal bases in relation to the use of certain raw materials originating from animal tissues and presenting specific risks of transmitting animal spongiform encephalopathies.

(4) All those national measures are related to the general protection of public health against the risks of transmitting the animal spongiform encephalopathies via medical devices.

(5) With regard to the sourcing of materials used in medical devices the provisions set out in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption ⁽³⁾ apply.

(6) In order to improve the level of safety and health protection, it is necessary to further reinforce the protective measures against the overall risk of transmitting animal spongiform encephalopathies via medical devices.

(7) The Scientific Committee on Medicinal Products and Medical Devices has adopted an opinion on the use of Transmissible Spongiform Encephalopathies (TSE) risk materials for the manufacture of implantable medical devices, which recommends that manufacturers of these devices that utilise animal tissues or derivatives be required, as an essential part of the risk management, to fully justify the use of these tissues in the context of the benefits to patients and of the comparison with alternative materials.

(8) The Scientific Steering Committee has adopted several opinions on specified risk materials and on the products derived from ruminant tissues, such as gelatine and collagen, which are of direct relevance to the safety of medical devices.

(9) Medical devices manufactured utilising non-viable animal tissues or derivatives rendered non-viable are Class III devices in accordance with the classification rules set out in Annex IX to Directive 93/42/EEC, except where such devices are intended to come into contact with intact skin only.

(10) Prior to being placed on the market, medical devices, whether they originate in the Community or are imported from third countries, are subject to the conformity assessment procedures laid down in Directive 93/42/EEC.

(11) Annex I to Directive 93/42/EEC sets out the essential requirements that medical devices must meet pursuant to that Directive. Points 8.1 and 8.2 of that Annex set out specific requirements intended to eliminate or reduce as far as possible the risk of infection for the patient, user and third parties due to tissues of animal origin and specifies that the solutions adopted by the manufacturer in the design and construction of the devices must conform to safety principles taking into account the generally acknowledged state of the art.

(12) With regard to medical devices manufactured utilising tissues of animal origin it is necessary to adopt more detailed specifications in relation to the requirements of point 8.2 of Annex I to Directive 93/42/EEC and to specify certain aspects relating to the risk analysis and risk management in the framework of the conformity assessment procedures referred to in Article 11 of that Directive.

⁽¹⁾ OJ L 169, 12.7.1993, p. 1.

⁽²⁾ OJ L 6, 10.1.2002, p. 50.

⁽³⁾ OJ L 273, 10.10.2002, p. 1.

- (13) Some of the terms used in Directive 93/42/EEC should be further clarified in order to ensure a uniform implementation of this Directive.
- (14) It is necessary to provide for an adequate transitional period for medical devices already covered by an EC design-examination certificate or by an EC type examination certificate.
- (15) The measures provided for in this Directive are in accordance with the opinion of the Committee on Medical Devices set up by Article 6(2) of Council Directive 90/385/EEC ⁽¹⁾,
- (f) 'reduction, elimination or removal' means a process by which the number of transmissible agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction;
- (g) 'inactivation' means a process by which the ability to cause infection or pathogenic reaction by transmissible agents is reduced;
- (h) 'source country' means the country in which the animal was born, has been reared and/or has been slaughtered;
- (i) 'starting materials' means raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in Article 1(1) are produced.

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive lays down detailed specifications in relation to risks of transmitting transmissible spongiform encephalopathies (TSE) under normal conditions of use to patients or others, via medical devices manufactured utilising animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

2. The animal tissues covered by this Directive are those originating from bovine, ovine and caprine species, as well as deer, elk, mink and cats.

3. Collagen, gelatin and tallow used for the manufacturing of medical devices, shall meet at least the requirements as fit for human consumption.

4. This Directive does not apply to medical devices referred to in paragraph 1, which are not intended to come into contact with the human body or which are intended to come into contact with intact skin only.

Article 2

For the purposes of this Directive, the following definitions shall apply in addition to the definitions set out in Directive 93/42/EEC:

- (a) 'cell' means the smallest organised unit of any living form which is capable of independent existence and of replacement of its own substance in a suitable environment;
- (b) 'tissue' means an organisation of cells and/or extra-cellular constituents;
- (c) 'derivative' means a material obtained from an animal tissue by a manufacturing process such as collagen, gelatine, monoclonal antibodies;
- (d) 'non-viable' means having no potential for metabolism or multiplication;
- (e) 'transmissible agents' means unclassified pathogenic entities, prions and such entities as bovine spongiform encephalopathies agents and scrapie agents;

⁽¹⁾ OJ L 189, 20.7.1990, p. 17.

Article 3

Before lodging an application for a conformity assessment pursuant to Article 11(1) of Directive 93/42/EEC, the manufacturer of medical devices referred to in Article 1(1), shall carry out the risk analysis and the risk management scheme set out in the Annex to this Directive.

Article 4

Member States shall verify that bodies notified under Article 16 of Directive 93/42/EEC have up-to-date knowledge of the medical devices referred to in Article 1(1), in order to assess the conformity of those devices referred to in Article 1(1) with the provisions of Directive 93/42/EEC and with the specifications laid down in the Annex to this Directive.

If, on the basis of that verification, it is necessary for a Member State to amend the tasks of a notified body, that Member State shall notify the Commission and the other Member States accordingly.

Article 5

1. Conformity assessment procedures for medical devices referred to in Article 1(1), shall include the evaluation of their compliance with the essential requirements of Directive 93/42/EEC and the specifications laid down in the Annex to this Directive.

2. Notified bodies shall evaluate the manufacturer's risk analysis and risk management strategy, and in particular:

- (a) the information provided by the manufacturer;
- (b) the justification for the use of animal tissues or derivatives;
- (c) the results of elimination and/or inactivation studies or of literature search;
- (d) the manufacturer's control of the sources of raw materials, finished products and subcontractors;
- (e) the need to audit matters related to sourcing, including third party supplies.

3. Notified bodies shall, during the evaluation of the risk analysis and risk management in the framework of the conformity assessment procedure, take account of the TSE certificate of suitability issued by the European Directorate for the Quality of Medicines, hereinafter 'TSE certificate', for starting materials, where available.

4. Except for medical devices using starting materials for which a TSE certificate has been issued as referred to in paragraph 3, national bodies shall, through their competent authority, seek the opinion of the competent authorities of the other Member States on their evaluation of and conclusions on the risk analysis and risk management of the tissues or the derivatives intended to be incorporated in the medical device as established by the manufacturer.

Before issuing an EC design-examination certificate or an EC type-examination certificate, the notified bodies shall give due consideration to any comments received within 12 weeks from the date on which the opinion of the national competent authorities was sought.

Article 6

Member States shall take all necessary steps to ensure that medical devices referred to in Article 1(1) are placed on the market and put into service only if they comply with the provisions of Directive 93/42/EEC and the specifications laid down in the Annex to this Directive.

Article 7

1. Holders of EC design-examination certificates or EC type-examination certificates issued before 1 April 2004 for medical devices referred to in Article 1(1) shall apply for a complementary EC design-examination certificate or EC type-examination certificate attesting to compliance with the specifications laid down in the Annex to this Directive.

2. Until 30 September 2004, Member States shall accept the placing on the market and the putting into service of medical devices referred to in Article 1(1) which are covered by an EC design-examination certificate or an EC type-examination certificate issued before 1 April 2004.

Article 8

1. Member States shall adopt and publish before 1 January 2004 the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions with effect from 1 April 2004.

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

2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 9

This Directive shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

Article 10

This Directive is addressed to the Member States.

Done at Brussels, 23 April 2003.

For the Commission

Erkki LIIKANEN

Member of the Commission

ANNEX

1. RISK ANALYSIS AND RISK MANAGEMENT

1.1. **Justification for the use of animal tissues or derivatives**

The manufacturer must justify, on the basis of his overall risk analysis and risk management strategy for a specific medical device, the decision to use animal tissues or derivatives, referred to in Article 1, (specifying animal species and tissues) taking into account the expected clinical benefit, potential residual risk and suitable alternatives.

1.2. **Assessment procedure**

In order to ensure a high level of protection for patients or users, the manufacturer of devices utilising animal tissues or derivatives referred to in point 1.1 must implement an appropriate and well documented risk analysis and risk management strategy, to address all relevant relating aspects to TSE. He must identify the hazards associated with those tissues or derivatives, establish documentation on measures taken to minimise the risk of transmission and demonstrate the acceptability of the residual risk associated with the device utilising such tissues or derivatives, taking into account the intended use and the benefit of the device.

The safety of a device, in terms of its potential for passing on a transmissible agent, is dependent on all the factors described in points 1.2.1 to 1.2.7, which must be analysed, evaluated and managed. These measures in combination determine the device safety.

There are two key steps that must be considered.

These are:

- selecting starting materials (tissues or derivatives) considered appropriate regarding their potential contamination with transmissible agents (see 1.2.1, 1.2.2 and 1.2.3) taking into account further processing,
- applying a production process to remove or inactivate transmissible agents on controlled sourced tissues or derivatives (see 1.2.4).

Furthermore, the characteristics of the device and its intended use must be taken into account (see 1.2.5, 1.2.6 and 1.2.7).

In performing the risk analysis and risk management strategy, due consideration must be given to opinions adopted by the relevant scientific committees, and where appropriate to the opinions of the Committee for Proprietary Medicinal Products CPMP, the references of which have been published in the *Official Journal of the European Union*.

1.2.1. *Animals as a source of material*

The TSE risk is related to the source species, strains and nature of the starting tissue. As the accumulation of TSE infectivity occurs over an incubation period of several years, sourcing from young healthy animals is considered to be a factor reducing the risk. Risk animals such as fallen stock, emergency slaughtered and TSE suspected animals must be excluded.

1.2.2. *Geographical sourcing*

Pending the classification of countries according to the BSE status in Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies ⁽¹⁾, the Geographical BSE risk (GBR) is used when assessing the risk of the source country. The GBR is a qualitative indicator of the likelihood of the presence of one or more cattle being infected with BSE, pre-clinically as well as clinically, at a given point in time, in a country. Where presence is confirmed, the GBR gives an indication of the level of infection as specified in the table below.

GBR level	Presence of one or more cattle clinically or pre-clinically infected with the BSE agent in a geographical region/country
I	Highly unlikely
II	Unlikely but not excluded
III	Likely but not confirmed or confirmed, at a lower level
IV	Confirmed, at a higher level

⁽¹⁾ OJ L 147, 31.5.2001, p. 1.

Certain factors influence the geographical risk of BSE infection associated with the use of raw tissues or derivatives from individual countries. These factors are defined in Article 2.3.13.2, point 1) of the International Animal Health Code of the OIE (Office International des Épidémiologies), which is available at web-site www.oie.int/eng/normes/Mcode/A_00067.htm

The Scientific Steering Committee has made an assessment of Geographical BSE Risk (GBR) of several third countries and Member States, and will continue to do so for all the countries, which applied for BSE status categorisation, taking the main OIE factors into account.

1.2.3. *Nature of starting tissue*

The manufacturer must take into account the classification of the hazards relating to different type of starting tissue. Sourcing of animal tissue must be subject to control and individual inspection by a veterinarian and the animal carcass must be certified as fit for human consumption.

The manufacturer must ensure that no risk of cross-contamination occurs at the time of slaughtering.

The manufacturer must not source animal tissue or derivatives classified as potentially high TSE infectivity, unless sourcing of these materials is necessary in exceptional circumstances, taking into account the important benefit for the patient and the absence of an alternative starting tissue.

In addition, the provisions in Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption must be applied.

1.2.3.1. *Sheep and goats*

A classification of infectivity in tissues for sheep and goats has been established based on actual knowledge on the basis of the titres of transmissible agents in tissues and body fluids from naturally infected sheep and goats with clinical scrapie. A table was presented in the Scientific Steering Committee (SSC) opinion of 22-23 July 1999 on 'The policy of breeding and genotyping of sheep', (as an annex)⁽¹⁾ and further updated in the opinion of the SSC — TSE infectivity distributed in ruminant tissues state of knowledge December 2001 — adopted 10-11 January 2002⁽²⁾.

The classification may be reviewed in the light of new scientific evidence (for example using relevant opinions from the Scientific Committees, the Committee for Proprietary Medicinal Products CPMP and Commission Measures regulating the use of material presenting risks as regards TSE). A review of the references to relevant documents/opinions will be published in the *Official Journal of the European Union* and will be listed after a Commission Decision has been taken.

1.2.3.2. *Cattle*

The list of specified risk material (SRM) laid down in Regulation (EC) No 999/2001 shall be considered as potentially high TSE infective.

1.2.4. *Inactivation or removal of transmissible agents*

1.2.4.1. For devices which cannot withstand an inactivation/elimination process without undergoing unacceptable degradation, the manufacturer must rely principally on the control of sourcing.

1.2.4.2. For other devices, if claims are made by the manufacturer for the ability of manufacturing processes to remove or inactivate transmissible agents, these will have to be substantiated by appropriate documentation.

Relevant information from an appropriate scientific literature search and analysis can be used to support inactivation/elimination factors, where the specific processes referred to the literature are comparable to those used for the device. This search and analysis should also cover the available scientific opinions that may have been adopted by a EU Scientific Committee. These opinions shall serve as a reference, in cases where there are conflicting opinions.

When the literature search failed to substantiate the claims, the manufacturer must set up a specific inactivation and/or elimination study on a scientific basis and the following need to be considered:

- the identified hazard associated with the tissue,
- identification of the relevant model agents,
- rationale for the choice of the particular combinations of model agents,

⁽¹⁾ Available on the website of the Commission
http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html.

⁽²⁾ Available on the website of the Commission
http://europa.eu.int/comm/food/fs/sc/ssc/outcome_en.html.

- identification of stage chosen to eliminate and/or inactivate the transmissible agents,
- calculation of the reduction factors.

A final report must identify manufacturing parameters and limits that are critical to the effectiveness of the inactivation or elimination process.

Appropriate documented procedures must be applied to ensure that the validated processing parameters are applied during routine manufacture.

1.2.5. *Quantities of animal starting tissues or derivatives required to produce one unit of the medical device*

The manufacturer must evaluate the quantity of raw tissues or derivatives of animal origin required to produce a single unit of the medical device. Where a purification process is involved, the manufacturer must assess whether it may have the potential to concentrate levels of transmissible agents present in the animal starting tissues or derivatives.

1.2.6. *Tissues or derivatives of animal origin coming into contact with the patients and users*

The manufacturer must consider:

- (i) the quantity of animal tissues or derivatives;
- (ii) the contact area: its surface, type (e.g. skin, mucous tissue, brain) and condition (e.g. healthy or damaged);
- (iii) the type of the tissues or derivatives coming into contact with the patients and/or users; and
- (iv) how long the device is intended to remain in contact with the body (including bioresorption effect).

The number of medical devices that could be used in a given procedure shall be taken into account.

1.2.7. *Route of administration*

The manufacturer must take into account the route of administration recommended in the product information, from the highest risk down to the lowest.

1.3. **Review of the assessment**

The manufacturer must establish and maintain a systematic procedure to review information gained about their medical device or similar devices in the post-production phase. The information must be evaluated for possible relevance to safety, especially:

- (a) if previously unrecognised hazards are detected;
- (b) if the estimated risk arising from a hazard is no longer acceptable;
- (c) if the original assessment is otherwise invalidated.

If any of the above apply, the results of the evaluation shall be fed back as an input to the risk management process.

In the light of this new information, a review of the appropriate risk management measures for the device must be considered (including rationale for choosing an animal tissue or derivative). If there is a potential that the residual risk or its acceptability has changed, the impact on previously implemented risk control measures must be re-evaluated and justified.

The results of this evaluation must be documented.

2. **EVALUATION OF CLASS III MEDICAL DEVICES BY NOTIFIED BODIES**

For devices falling into Class III under rule 17 ⁽¹⁾ of Annex IX to Directive 93/42/EEC, manufacturers must provide to the notified bodies referred to in Article 4 of this Directive all relevant information to allow evaluation of their current risk analysis and risk management strategy. Any new information on TSE risk, collected by the manufacturer and relevant for their devices must be sent to the notified body for information.

Any change in relation to processes of sourcing, collection, handling and inactivation/elimination and that could modify the result of the manufacturer's risk management dossier must be transmitted to the notified body for the purpose of an additional approval prior to its implementation.

⁽¹⁾ All medical devices utilising animal tissue or derivatives rendered non-viable except devices intended to come into contact with intact skin only.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 25 April 2003

concerning protection measures in relation to avian influenza in Belgium

(notified under document number C(2003) 1438)

(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

(2003/289/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-community trade in certain live animals and products with a view to the completion of the internal market ⁽¹⁾, as last amended by Council Directive 2002/33/EC ⁽²⁾, and, in particular, Article 10 thereof,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽³⁾, as last amended by Directive 92/118/EEC ⁽⁴⁾, in particular Article 9 thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽⁵⁾, and in particular Article 4(1) and (3) thereof,

Whereas:

- (1) On 16 April 2003 the veterinary authorities of Belgium have informed the Commission about a strong suspicion of avian influenza in the province of Limburg, which was subsequently officially confirmed.

- (2) Avian influenza is a highly contagious poultry disease that can pose a serious threat for the poultry industry.

- (3) The Belgian authorities have immediately, before the official confirmation of the disease, implemented the measures foreseen in Council Directive 92/40/EEC of 19 May 1992 introducing Community measures for the control of avian influenza ⁽⁶⁾.

- (4) Directive 92/40/EEC sets out the minimum control measures to be applied in the event of an outbreak of avian influenza. The Member State may take more stringent action in the field covered by this Directive if deemed necessary and proportionate to contain the disease, taking into account the particular epidemiological, animal husbandry, commercial and social conditions prevailing.

- (5) The Belgian authorities have in cooperation with the Commission, put in place a nation-wide standstill for transport of live poultry and hatching eggs, which includes a prohibition of dispatch of live poultry and hatching eggs to Member States and third countries. However, in view of the specificity of poultry production, movements of hatching eggs, day-old chicks, ready-to-lay pullets and poultry for immediate slaughter may be authorised within Belgium. Furthermore, the dispatch to Member States and third countries of fresh, unprocessed manure and litter of poultry should also be prohibited.

⁽¹⁾ OJ L 224, 18.8.1990, p. 29.

⁽²⁾ OJ L 315, 19.11.2002, p. 14.

⁽³⁾ OJ L 395, 30.12.1989, p. 13.

⁽⁴⁾ OJ L 62, 15.3.1993, p. 49.

⁽⁵⁾ OJ L 18, 23.1.2003, p. 11.

⁽⁶⁾ OJ L 167, 22.6.1992, p. 1.

- (6) For the sake of clarity and transparency the Commission after consultation with the Belgian authorities, thereby reinforcing the measures taken by Belgium, has taken Decision 2003/275/EC of 16 April 2003 concerning protection measures in relation to strong suspicion of avian influenza in Belgium ⁽¹⁾.
- (7) Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field ⁽²⁾, as last amended by Decision 2001/572/EC ⁽³⁾, establishes in Article 3(4) that the Commission may lay down any measures which the Member State concerned must take in order to ensure the success of the action; it appears appropriate that taking into account the existing situation in Belgium, all poultry within a surrounding zone of an outbreak of avian influenza should be preventively depopulated.
- (8) In order to better understand the epidemiology of the disease a serological survey shall be carried out in pigs that are kept on holdings where poultry have been found infected with avian influenza.
- (9) The Belgian authorities should furthermore ensure that precautionary measures are taken for persons at risk.
- (10) The measures laid down in Decision 2003/275/EC should be prolonged and adapted in the light of the evolution of the disease.
- (11) The other Member States have already adjusted the measures they apply to trade, and they are sufficiently informed by the Commission, and in particular in the context of the Standing Committee on the Food Chain and Animal Health on the appropriate period for their implementation.
- (12) 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

1. Without prejudice to the measures taken by Belgium within the framework of Directive 92/40/EEC applied to the surveillance zones, the Belgian veterinary authorities shall ensure that no live poultry, hatching eggs and fresh, unprocessed and non-heat-treated poultry manure or litter are dispatched from Belgium to other Member States and to third countries.

2. Without prejudice to the measures taken by Belgium within the framework of Directive 92/40/EEC within the surveillance zones the Belgian veterinary authorities shall ensure that no live poultry and hatching eggs are transported within Belgium.

3. By way of derogation from paragraph 2 the competent veterinary authority, taking all appropriate bio-security measures in accordance with Articles 4 and 5 to avoid the spread of avian influenza, may authorise the transport from areas situated outside the surveillance zones of:

- (a) poultry for immediate slaughter, including spent laying hens, to a slaughterhouse that has been designated by the competent veterinary authority;
- (b) day-old chicks and ready-to-lay pullets to a holding under official control, where no other poultry is kept;
- (c) hatching eggs to a hatchery under official control.

If live poultry transported in accordance with (a) or (b) originate in another Member State or third country the transport has to be approved by the Belgian authorities and the competent authority of the Member State or third country of dispatch.

4. By way of derogation from paragraph 2 the competent veterinary authority, taking all appropriate bio-security measures to avoid the spread of avian influenza, may authorise transport of live poultry and hatching eggs not prohibited by Directive 92/40/EEC and in particular in respect to movements of day-old chicks in accordance with the provisions of Article 9(4)(a), (b) and (c), which shall be transported to holdings within Belgium under official control.

Article 2

Fresh poultrymeat obtained from slaughter poultry transported by taking all appropriate bio-security measures in accordance with Articles 4 and 5 and originating from the established surveillance zones:

- (a) shall be marked with a round format mark in accordance with the further requirements of the competent authorities;
- (b) shall not be dispatched to other Member States or third countries;
- (c) must be obtained, cut, stored and transported separately from other fresh poultry meat destined for intra-Community trade and for exports to third countries and must be used in such a way as to avoid it being introduced into meat products or meat preparations intended for intra-Community trade or for export to third countries, unless it has undergone the treatment specified in table 1 (a), (b) or (c) of Annex III to Directive 2002/99/EC.

Article 3

Without prejudice to the measures already taken in the framework of Directive 92/40/EEC, Belgium shall ensure that the preventive depopulation of poultry holdings in the area as described in the Annex is completed as soon as possible.

The precautionary measures referred to in the first subparagraph shall be taken without prejudice to Council Decision 90/424/EEC.

⁽¹⁾ OJ L 99, 17.4.2003, p. 57.

⁽²⁾ OJ L 224, 18.8.1990, p. 19.

⁽³⁾ OJ L 203, 28.7.2001, p. 16.

Article 4

In order to enhance bio-security in the poultry sector, the competent veterinary authority of Belgium shall ensure that:

- (a) table eggs shall only be transported from a holding to a packing station either in disposable packaging or in containers, trays and other non-disposable equipment, which must be cleaned and disinfected before and after each use in accordance with d). In addition, in case of table eggs originating from another Member State, the competent veterinary authority shall ensure that the packaging, containers, trays and other non-disposable equipment used for their transport are returned;
- (b) slaughter poultry intended for immediate slaughter shall be transported with trucks and in crates or cages which must be cleaned and disinfected before and after each use in accordance with (d). In addition, in case of slaughter poultry originating from another Member State, the competent veterinary authority shall ensure that the crates and cages and containers are returned;
- (c) day-old chicks are transported in disposable packing material to be destroyed after use;
- (d) the disinfectants and the method of cleaning and disinfection must be approved by the competent authority.

Article 5

The competent veterinary authority of Belgium shall ensure that stringent bio-security measures are taken on all levels of poultry and egg production in order to avoid risky contacts that may cause the spread of avian influenza between farms. These measures aim in particular to avoid risky contacts of poultry, transport means, equipment and people entering or leaving poultry farms, egg packing stations, hatcheries, slaughterhouses, feedmills, litter processing and rendering plants. For this purpose all poultry farmers shall keep a register for all professional visits to their farms as well as their professional visits to other poultry holdings.

Article 6

1. The Belgian authorities shall ensure that appropriate precautionary measures are adopted as regards the prevention of influenza infections in poultry workers and other persons at risk. These measures may include:

- (a) the use of protective clothing, gloves and glasses;

- (b) vaccination against human influenza;
- (c) prophylactic antiviral treatment.

2. The Belgian authorities shall regularly inform the Commission in the framework of the Standing Committee of the Food Chain and Animal Health of the measures adopted.

Article 7

1. The Belgian authorities shall carry out serological investigations in pigs kept on all holdings where poultry have been found infected with avian influenza.

2. In case of positive findings the pigs may only be moved to other pig holdings or a slaughterhouse following authorisation by the competent veterinary authority if subsequent appropriate tests have revealed that the risk of spread of avian influenza viruses is negligible.

3. Movement to other pig holdings may take place only after all restrictions related to avian influenza in the holding of origin have been lifted.

4. The Belgian authorities shall regularly inform the Commission in the framework of the Standing Committee of the Food Chain and Animal Health of the results of the survey.

Article 8

This Decision shall apply from 00.00 on 26 April 2003 until 24.00 on 12 May 2003.

Article 9

This Decision is addressed to the Kingdom of Belgium.

Done at Brussels, 25 April 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Het toezichtsgebied Limburg, afgebakend op 20 april 2003 om 10.00 uur, omvat het deel van het Belgische grondgebied dat gelegen is binnen de omtrek gevormd door:

- de N74 vanaf de Nederlandse grens in zuidelijke richting tot aan de Overpelterbaan (Overpelt),
 - vervolgens de Overpelterbaan in zuidelijke richting tot aan de kruising met de N747,
 - vervolgens de N747 in zuidelijke richting tot aan de kruising met de N15,
 - vervolgens de N15 in zuidelijke richting tot aan de kruising met de E314 (A2),
 - vervolgens de E314 (A2) in oostelijke richting tot aan de kruising met de gemeentegrens tussen Houthalen-Helchteren en Genk,
 - vervolgens de gemeentegrens tussen Houthalen-Helchteren en Genk, tussen Opglabbeek en achtereenvolgens As en Maaseik, en tussen Meeuwen-Gruitrode en Maaseik in noordoostelijke richting tot aan de kruising met de N771,
 - vervolgens de N771 in zuidoostelijke richting en voorbij de kruising met de N78 in dezelfde richting verlengd tot aan de grens met Nederland,
 - vervolgens de grens met Nederland in noordelijke richting tot aan de N74.
-

COMMISSION DECISION
of 25 April 2003
concerning protective measures in relation to avian influenza in the Netherlands

(notified under document number C(2003) 1437)

(Only the Dutch text is authentic)

(Text with EEA relevance)

(2003/290/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-community trade in certain live animals and products with a view to the completion of the internal market ⁽¹⁾, as last amended by Directive 2002/33/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 10 thereof,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽³⁾, as last amended by Directive 92/118/EEC ⁽⁴⁾, in particular Article 9 thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ⁽⁵⁾, and in particular Article 4(1) and (3) thereof,

Whereas:

- (1) Since 28 February 2003 the Netherlands have declared several outbreaks of highly pathogenic avian influenza.
- (2) Avian influenza is a highly contagious poultry disease that can pose a serious threat for the poultry industry.
- (3) The Netherlands took immediate action as provided for by Council Directive 92/40/EEC ⁽⁶⁾ of 19 May 1992 introducing Community measures for the control of avian influenza, as amended by the Act of Accession of Austria, Finland and Sweden, before the disease was officially confirmed.
- (4) Council Directive 92/40/EEC sets out the minimum control measures to be applied in the event of an outbreak of avian influenza. The Member State may take

more stringent action in the field covered by this Directive if deemed necessary and proportionate to contain the disease, taking into account the particular epidemiological, animal husbandry, commercial and social conditions prevailing.

- (5) For the sake of clarity and transparency the Commission after consultation with the Dutch authorities, thereby reinforcing the measures taken by the Netherlands, has taken Decision 2003/153/EC of 3 March 2003 concerning protection measures in relation to strong suspicion of avian influenza in the Netherlands ⁽⁷⁾.
- (6) Subsequently Decisions 2003/156/EC ⁽⁸⁾, 2003/172/EC ⁽⁹⁾, 2003/186/EC ⁽¹⁰⁾, 2003/191/EC ⁽¹¹⁾, 2003/214/EC ⁽¹²⁾ and 2003/258/EC ⁽¹³⁾ were adopted after consultation with the Dutch authorities and evaluation of the situation with all Member States.
- (7) Council Decision 90/424/EEC on expenditure in the veterinary field ⁽¹⁴⁾, as last amended by Decision 2001/572/EC ⁽¹⁵⁾, establishes in Article 3(4) that the Commission may lay down any measures which the Member State concerned must take in order to ensure the success of the action; it appears appropriate that all poultry in holdings and areas at risk in the restricted zones should be preventively depopulated.
- (8) The Dutch authorities have started serological investigations in pigs in order to better understand the epidemiology of the disease. This survey should be carried out in pigs which are kept on holdings where poultry have been found infected with avian influenza.
- (9) The Dutch authorities should furthermore ensure that precautionary measures are taken for persons at risk.
- (10) The measures laid down in Decision 2003/258/EC should be prolonged and adapted in the light of the evolution of the disease.

⁽¹⁾ OJ L 224, 18.8.1990, p. 29.

⁽²⁾ OJ L 315, 19.11.2002, p. 14.

⁽³⁾ OJ L 395, 30.12.1989, p. 13.

⁽⁴⁾ OJ L 62, 15.3.1993, p. 49.

⁽⁵⁾ OJ L 18, 23.1.2003, p. 11.

⁽⁶⁾ OJ L 167, 22.6.1992, p. 1.

⁽⁷⁾ OJ L 59, 4.3.2003, p. 32.

⁽⁸⁾ OJ L 64, 7.3.2003, p. 36.

⁽⁹⁾ OJ L 69, 13.3.2003, p. 27.

⁽¹⁰⁾ OJ L 71, 15.3.2003, p. 30.

⁽¹¹⁾ OJ L 74, 20.3.2003, p. 30.

⁽¹²⁾ OJ L 81, 28.3.2003, p. 48.

⁽¹³⁾ OJ L 95, 11.4.2003, p. 65.

⁽¹⁴⁾ OJ L 224, 18.8.1990, p. 19.

⁽¹⁵⁾ OJ L 203, 28.7.2001, p. 16.

- (11) The other Member States have already adjusted the measures they apply to trade, and they are sufficiently informed by the Commission, and in particular in the context of the Standing Committee on the Food Chain and Animal Health on the appropriate period for their implementation.
- (12) 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

1. Without prejudice to the measures taken by the Netherlands within the framework of Directive 92/40/EEC applied to the surveillance zones, the Dutch veterinary authorities shall ensure that no live poultry, hatching eggs and fresh, unprocessed and non-heat-treated poultry manure or litter are dispatched from the Netherlands to other Member States and to third countries.

2. Without prejudice to the measures taken by the Netherlands within the framework of Directive 92/40/EEC within the surveillance zones and buffer zones as described in the Annex, the Dutch veterinary authorities shall ensure that no live poultry and hatching eggs are transported within the Netherlands.

3. By way of derogation from paragraph 2 the competent veterinary authority, taking all appropriate bio-security measures in accordance with Articles 4 and 5 to avoid the spread of avian influenza, may authorise the transport from areas situated outside the surveillance zones of:

- (a) poultry for immediate slaughter, including spent laying hens, to a slaughterhouse that has been designated by the competent veterinary authority;
- (b) day-old chicks and ready-to-lay pullets to a holding under official control, where no other poultry is kept;
- (c) hatching eggs to a hatchery under official control.

If live poultry transported in accordance with point (a) or (b) originate in another Member State or third country, the transport has to be approved by the Dutch authorities and the competent authority of the Member State or third country of dispatch.

4. By way of derogation from paragraph 2, the competent veterinary authority, taking all appropriate bio-security measures to avoid the spread of avian influenza, may authorise transport of live poultry and hatching eggs not prohibited by Directive 92/40/EEC and in particular in respect to movements of day-old chicks in accordance with the provisions of Article 9(4)(a), (b) and (c), which shall be transported to holdings within the Netherlands under official control.

Article 2

Fresh poultry meat obtained from slaughter poultry transported by taking all appropriate bio-security measures in accordance with Articles 4 and 5 and originating from the established surveillance zones:

- (a) shall be marked with a round format mark in accordance with the further requirements of the competent authorities;
- (b) shall not be dispatched to other Member States or third countries;
- (c) must be obtained, cut, stored and transported separately from other fresh poultry meat destined for intra-Community trade and for exports to third countries and must be used in such a way as to avoid it being introduced into meat products or meat preparations intended for intra-Community trade or for export to third countries, unless it has undergone the treatment specified in table 1(a), (b) or (c) of Annex III to Directive 2002/99/EC.

Article 3

Without prejudice to the measures already taken in the framework of Directive 92/40/EEC, the Netherlands shall ensure that the preventive depopulation of poultry in holdings and areas at risk in the restricted zones and the zones described in the Annex is completed as soon as possible.

The precautionary measures referred to in the first subparagraph shall be taken without prejudice to Council Decision 90/424/EEC.

Article 4

In order to enhance bio-security in the poultry sector, the competent veterinary authority of the Netherlands shall ensure that:

- (a) table eggs shall only be transported from a holding to a packing station either in disposable packaging or in containers, trays and other non-disposable equipment, which must be cleaned and disinfected before and after each use in accordance with point (d). In addition, in the case of table eggs originating from another Member State, the competent veterinary authority shall ensure that the packaging, containers, trays and other non-disposable equipment used for their transport are returned;
- (b) slaughter poultry intended for immediate slaughter shall be transported with trucks and in crates or cages which must be cleaned and disinfected before and after each use in accordance with point (d). In addition, in case of slaughter poultry originating from another Member State, the competent veterinary authority shall ensure that the crates and cages and containers are returned;
- (c) day-old chicks are transported in disposable packing material to be destroyed after use;
- (d) the disinfectants and the method of cleaning and disinfection must be approved by the competent authority.

Article 5

The competent veterinary authority of the Netherlands shall ensure that stringent bio-security measures are taken on all levels of poultry and egg production in order to avoid risky contacts that may cause the spread of avian influenza between farms. These measures aim in particular to avoid risky contacts of poultry, transport means, equipment and people entering or leaving poultry farms, egg packing stations, hatcheries, slaughterhouses, feedmills, litter processing and rendering plants. For this purpose all poultry farmers shall keep a register for all professional visits to their farms as well as their professional visits to other poultry holdings.

Article 6

1. The Dutch authorities shall ensure that appropriate precautionary measures are adopted as regards the prevention of influenza infections in poultry workers and other persons at risk. These measures may include:

- (a) the use of protective clothing, gloves and glasses;
- (b) vaccination against human influenza;
- (c) prophylactic antiviral treatment.

2. The Dutch authorities shall regularly inform the Commission within the framework of the Standing Committee of the Food Chain and Animal Health of the measures adopted.

Article 7

1. The Dutch authorities shall carry out serological investigations in pigs kept on all holdings where poultry have been found infected with avian influenza.

2. In the case of positive findings, the pigs may only be moved to other pig holdings or a slaughterhouse following authorisation by the competent veterinary authority, if subsequent appropriate tests have revealed that the risk of spread of avian influenza viruses is negligible.

3. Movement to other pig holdings may take place only after all restrictions related to avian influenza in the holding of origin have been lifted.

4. The Dutch authorities shall regularly inform the Commission within the framework of the Standing Committee of the Food Chain and Animal Health of the results of the survey.

Article 8

This Decision shall apply from 0.00 on 26 April 2003 until 24.00 on 12 May 2003.

Article 9

The Netherlands shall amend the measures which they apply to trade so as to bring them into compliance with this Decision and they shall give immediate appropriate publicity to the measures adopted. They shall immediately inform the Commission thereof.

Article 10

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 25 April 2003.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Area A: Buffergebied Wageningen 24.3.2003

1. Vanaf de kruising Werftweg/Veensteeg (De Kraats) de Veensteeg volgend zuidoostelijke richting tot aan Heuvelweg.
2. Heuvelweg volgend in noordoostelijke richting tot aan Slagsteeg.
3. Slagsteeg volgend in zuidelijke richting tot aan de Weerdjesweg.
4. Weerdjesweg volgend in oostelijke richting tot aan Harsloweg.
5. Harsloweg volgend in zuidelijk richting tot aan Lange Rijnsteeg.
6. Lange Rijnsteeg volgend in oostelijke richting overgaand in Dijkgraaf overgaand in Lange Steeg tot aan Doctor Willem Dreeslaan (N781).
7. Doctor Willem Dreeslaan (N781) volgend in zuidoostelijke richting overgaand in Mansholtlaan overgaand in de Diedenweg overgaand in Westerbergweg overgaand in Onderlangs overgaand in Veerdam tot aan de rivier de Rijn.
8. De rivier de Rijn stroomafwaarts volgend tot aan de Rijnbrug N233 (Rhenen).
9. De Rijnbrug (N233) volgend in noordelijke richting overgaand in Lijnweg (N233) overgaand in Cuneraweg (N233) tot aan Zuidelijke Meentsteeg.
10. Zuidelijke Meentsteeg volgend in noordoostelijke richting overgaand in Werftweg.
11. Werftweg volgend in oostelijke richting tot de kruising Werftweg/Veensteeg (De Kraats).

Area B: Buffergebied Putten 24.3.2003

1. Vanaf Strand Horst de Palmbosweg volgend in zuidelijke richting tot aan de Buitenbrinkweg.
2. Buitenbrinkweg volgend in zuidoostelijke richting tot aan de Schaapsdijk.
3. Schaapsdijk volgend in zuidoostelijke richting tot aan de Zeeweg.
4. Zeeweg volgend in oostelijke richting tot aan Telgterweg.
5. Telgterweg volgend in zuidelijke richting overgaand in Telgterengweg tot aan Bulderweg.
6. Bulderweg volgend in oostelijke richting tot aan Volenbeekweg.
7. Volenbeekweg volgend in zuidelijke richting tot aan de Oude Telgterweg.
8. Oude Telgterweg volgend in westelijke richting tot aan de Watervalweg.
9. Watervalweg volgend in zuidelijke richting tot aan de kruising van de Watervalweg/Telgterweg (Ermelo).
10. Vanaf de kruising van de Watervalweg/Telgterweg (Ermelo), de Telgterweg volgend in zuidelijke richting tot aan de Oude Rijksweg N798 (Putten).
11. Oude Rijksweg N798 (Putten) volgend in zuidwestelijke richting tot aan de Stationsstraat.
12. Stationsstraat volgend in westelijke richting overgaand in Zuiderzeestraatweg tot aan de Waterweg.
13. Waterweg volgend in zuidwestelijke richting tot aan Hoornsdam.
14. Hoornsdam volgend in westelijke richting tot aan het Nulderneauw.
15. Nulderneauw volgend in noordoostelijke richting tot Strand Horst.

Area C: Buffergebied Opheusden 25.3.2003

1. Vanaf de kruising Nederrijn en de Veerweg, Veerweg volgend in zuidelijk richting overgaand in Randwijkse Rijndijk overgaand in Knoppersweg (N836) volgend in zuidoostelijke richting overgaand in Wageningsestraat (N836) tot aan de snelweg A15 (E31).
2. De snelweg A15 volgend in oostelijk richting tot aan knooppunt Valburg snelweg (A50).
3. De snelweg (A50) volgend in zuidwestelijke richting tot aan de rivier de Waal.
4. De rivier de Waal volgend in westelijke richting tot aan Cuneraweg.
5. Cuneraweg volgend in noordelijke richting overgaand in N233 overgaand in Rijnburg tot aan de rivier Nederrijn.
6. De rivier Nederrijn volgend in oostelijke richting tot aan Veerweg.

Area D: Buffergebied Beneden-Leeuwen 25.3.2003

1. De rivier de Waal ter hoogte van Kanaal van Sint Andries in noordoostelijke richting volgend tot het verlengde van Noord-Zuidweg (Boven-Leeuwen).
2. Verlengde van de Noord-Zuidweg (Boven-Leeuwen) volgend in zuidelijke richting overgaand in de Noord-Zuidweg overgaand in Noord-Zuid (N322) overgaand in Noord-Zuid (N329) tot de rivier de Maas.
3. Rivier de Maas volgend in westelijke richting tot het kanaal van Sint Andries.
4. Kanaal van Sint Andries volgend in noordwestelijke richting tot de rivier de Waal.

Area E: Buffergebied Druten 27.3.2003

1. Vanaf de kruising van verlengde weg van de Noord-Zuidweg (Beneden Leeuwen) en de Waal (rivier), de Waal volgend in oostelijke richting tot aan A50.
2. A50 volgend in zuidelijke richting tot aan Maas (rivier).
3. Maas volgend in westelijke richting tot aan Noord-Zuid (N329).
4. Noord-Zuid (N329) volgend in noordoostelijke richting overgaand in Noord-Zuidweg tot aan de Waal.

Area F: Buffergebied Nijkerk 27.3.2003

1. Vanaf de Hoornsdam volgend in westelijke richting tot aan oprit 10 van de A28 (Strand Nulde).
2. A28 volgend in zuidelijke richting tot verkeersknooppunt Hoevelaken.
3. Vanaf verkeersknooppunt Hoevelaken de A1 volgend in noordwestelijke richting tot de kruising A1 en de Oude Zevenhuizerstraat (Amersfoort).
4. Oude Zevenhuizerstraat volgend in noordelijke richting overgaand in de Groenweg tot het Nijkerkernauw.
5. Nijkerkernauw volgend in oostelijke richting tot de Hoornsdam.

Area G: Buffergebied Lienden 27.3.2003

1. Vanaf Wijk bij Duurstede de Neder-Rijn volgend in oostelijke richting tot de Rijnbrug N233 (Rhenen).
2. De Rijnbrug N233 (Rhenen) volgend in zuidelijke richting overgaand in provinciale weg N233 overgaand in de Cunerauweg tot de rivier de Waal.
3. Rivier de Waal volgend in westelijke richting tot het Amsterdam-Rijnkanaal.
4. Amsterdam-Rijnkanaal volgend in noordwestelijke richting tot de Neder-Rijn (Wijk bij Duurstede).

Area H: Buffergebied Oss 3.4.2003

1. Vanaf de kruising van de rivier de Maas met de A50 ter hoogte van afslag 17 (Ravensteijn) de A50 volgend in zuidwestelijke richting tot afslag 15 (Oss).
2. Afslag 15 volgen tot de Cereslaan.
3. Cereslaan volgend in noordwestelijke richting tot Ruwaardsingel (Oss).
4. Ruwaardsingel (Oss) volgend in noordoostelijke richting tot Doctor Saal van Zwanenbergsingel.
5. Doctor Saal van Zwanenbergsingel volgend in noordwestelijke richting overgaand in Hertogin Johannasingel overgaand in John F. Kennedylaan tot de Gewandeweg.
6. Gewandeweg volgend in westelijke richting overgaand in de Burgemeester Smitsweg overgaand in de Wildseweg tot aan Nieuwe Provincialeweg (N625).
7. Nieuwe Provincialeweg (N625) volgend in noordelijke richting overgaand in Wildsedijk (N625) tot de Veerweg.
8. Veerweg volgend in westelijke richting tot aan de rivier de Maas.
9. De rivier de Maas volgend in noordoostelijke richting tot aan de kruising met de A50.

Area I: Buffergebied Ravenstein 14.4.2003

1. Vanaf knooppunt Bankhoef A50 en A326, de A326 volgend in noordoostelijke richting tot aan afslag Wijchen 14.
2. Afslag Wijchen 14 de snelweg A73 volgend in zuidelijke richting tot aan de Graafseweg (N324).

3. Graafseweg (N324) volgend in zuidwestelijke richting overgaand in Maasbrug (Nederasselt) overgaand in Arnoud van Gelderweg (Grave) overgaand in Elftweg overgaand in Bosschebaan overgaand in Rijksweg tot aan snelweg A50 afslag Oss-Oost 16.
4. Snelweg A50 volgend in noordoostelijk richting tot aan knooppunt Bankhoef.

Area J: Buffergebied Stramproy 14.4.2003

1. Vanaf Weert de spoorlijn volgend in oostelijke richting tot Roermondseweg (N280).
2. Roermondseweg (N280) volgend in zuidoostelijke richting overgaand in Ittervoortseweg overgaand in Swartbroekstraat volgend in oostelijke richting tot Niesstraat (E11).
3. Niesstraat (E11) volgend in zuidoostelijke richting overgaand in Hoogstraat tot Kapittelstraat.
4. Kapittelstraat volgend in oostelijke richting tot Varenstraat.
5. Varenstraat volgend in noordoostelijke richting tot Scheidingsweg.
6. Scheidingsweg volgend in oostelijke richting tot Wessemerdijk.
7. Wessemerdijk volgend in zuidoostelijke richting tot Napoleonsweg (N273).
8. Napoleonsweg (N273) volgend in zuidwestelijke richting tot oprit Grathem 41 van de snelweg A2.
9. Snelweg A2 volgend in zuidoostelijke richting tot rivier de Maas.
10. Rivier de Maas stroomopwaarts volgen tot Nederlands-Belgische grens.
11. Nederlands-Belgische grens volgend in noordwestelijke richting tot Kempenweg (N564).
12. Kempenweg (N564) volgend in noordoostelijke richting overgaand in Suffolkweg (N564) tot de spoorlijn bij Weert.

Area K: Buffergebied Roermond 15.4.2003

1. Vanaf de kruising van de rivier de Maas en de snelweg A73 de A73 volgend in zuidoostelijke richting tot aan Kaldenkerkerweg.
2. Kaldenkerkerweg volgend in oostelijke richting tot aan de Nederlands-Duitse grens.
3. Nederlands-Duitse grens volgend in zuidelijke richting tot aan de Herkenbosserweg (N570).
4. Herkenbosserweg (N570) volgend in noordwestelijke richting overgaand in Keulsebaan (N570) tot Sint Wirosingel.
5. Sint Wirosingel volgend in noordelijke richting tot Koninginnelaan.
6. Koninginnelaan volgend in westelijke richting overgaand in Willem II-Singel overgaand in Minderbroederssingel overgaand in Roerkade overgaand in Buitenop tot aan Hornerweg (N280).
7. Hornerweg (N280) volgend in westelijke richting tot aan de rivier de Maas.
8. De rivier de Maas volgend in noordelijke richting tot aan de kruising van de Maas met de A73.

Area L: Buffergebied Schaijk 18.4.2003

1. Vanaf de kruising Holenbergstraat en Rijksweg (N324) volgend in oostelijke richting tot aan de Udensedreef.
2. Udensedreef volgend in zuidelijke richting en dan in westelijke richting lopend in noordwestelijke richting overgaand in Holenbergstraat tot aan de Rijksweg (N324).

Area M: Buffergebied Eindhoven 23.4.2003

1. Eindhoven volgend A67 oostwaarts tot aan Venlo.
 2. Vanaf Venlo de Maas volgend tot aan de Belgische grens.
 3. De Belgische grens volgend westwaarts tot aan de N69.
 4. De N69 noordwaarts volgend tot aan de A67.
-

COMMISSION DECISION

of 25 April 2003

laying down the requirements for the prevention of avian influenza in susceptible birds kept in zoos in Belgium and the Netherlands

(notified under document number C(2003) 1439)

(Only the French and Dutch texts are authentic)

(Text with EEA relevance)

(2003/291/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ⁽¹⁾, as last amended by Directive 2002/33/EC of the European Parliament and of the Council ⁽²⁾, and in particular Article 10 thereof,

Whereas:

- (1) Council Directive 92/40/EEC ⁽³⁾ sets out the minimum control measures to be applied in the event of an outbreak of avian influenza in poultry, without prejudice to Community provisions governing intra-Community trade. This Directive does not apply where avian influenza is detected in other birds. However, in this case, the Member State concerned must inform the Commission of any measure it takes.
- (2) 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⁾, as last amended by Commission Regulation (EC) No 1282/2002 ⁽⁵⁾, and in particular Article 3 thereof, provides that trade in and imports of the animals, semen, ova and embryos concerned must not be prohibited or restricted for animal health reasons, other than those arising from the application of Community legislation, and in particular any safeguard measures taken.
- (3) Council Directive 1999/22/EC of 29 March 1999 relating to the keeping of wild animals in zoos ⁽⁶⁾, and in particular Article 2 thereof sets out the definition of a

zoo. This definition should however be complemented with regard to trade for the purpose of the present Decision.

- (4) Since 28 February 2003 the Netherlands have declared several outbreaks of highly pathogenic avian influenza in poultry.
- (5) The Netherlands took immediate action as provided for by Directive 92/40/EEC introducing Community measures for the control of avian influenza, as amended by the Act of Accession of Austria, Finland and Sweden, before the disease was officially confirmed.
- (6) For the sake of clarity and transparency the Commission after consultation with the Dutch authorities, thereby reinforcing the measures taken by the Netherlands, has taken Decision 2003/153/EC ⁽⁷⁾ of 3 March 2003 concerning protection measures in relation to strong suspicion of avian influenza in the Netherlands.
- (7) Subsequently Decision 2003/156/EC ⁽⁸⁾, Decision 2003/172/EC ⁽⁹⁾, Decision 2003/186/EC ⁽¹⁰⁾ and Decision 2003/191/EC ⁽¹¹⁾, Decision 2003/214/EC ⁽¹²⁾, Decision 2003/258/EC ⁽¹³⁾ and Decision 2003/290/EC ⁽¹⁴⁾ were adopted after consultation with the Dutch authorities and evaluation of the situation with all Member States.
- (8) On basis of Decision 2003/214/EC the Dutch authorities started preventive emptying and culling of poultry in holdings and areas at risk, in order to avoid further spreading of the virus.
- (9) On 16 April 2003 the veterinary authorities of Belgium have informed the Commission about a strong suspicion of avian influenza in the province of Limburg, which was subsequently officially confirmed.

⁽¹⁾ OJ L 224, 18.8.1990, p. 29.

⁽²⁾ OJ L 315, 19.11.2002, p. 14.

⁽³⁾ OJ L 167, 22.6.1992, p. 1.

⁽⁴⁾ OJ L 268, 14.9.1992, p. 52.

⁽⁵⁾ OJ L 187, 16.7.2002, p. 3.

⁽⁶⁾ OJ L 94, 9.4.1999, p. 24.

⁽⁷⁾ OJ L 59, 4.3.2003, p. 32.

⁽⁸⁾ OJ L 64, 7.3.2003, p. 36.

⁽⁹⁾ OJ L 69, 13.3.2003, p. 27.

⁽¹⁰⁾ OJ L 71, 15.3.2003, p. 30.

⁽¹¹⁾ OJ L 74, 20.3.2003, p. 30.

⁽¹²⁾ OJ L 81, 28.3.2003, p. 48.

⁽¹³⁾ OJ L 95, 11.4.2003, p. 65.

⁽¹⁴⁾ See page 28 of this Official Journal.

- (10) The Belgian authorities have immediately, before the official confirmation of the disease, implemented the measures foreseen in Directive 92/40/EEC introducing Community measures for the control of avian influenza while further confirmatory diagnostic procedures were carried out.
- (11) For the sake of clarity and transparency the Commission after consultation with the Belgian authorities, thereby reinforcing the measures taken by Belgium, has taken Decision 2003/275/EC⁽¹⁾ concerning protection measures in relation to strong suspicion of avian influenza in Belgium.
- (12) Subsequently Decision 2003/289/EC⁽²⁾ was adopted after consultation with the Belgian authorities and evaluation of the situation with all Member States.
- (13) On basis of Decision 2003/275/EC the Belgian authorities started preventive emptying and culling of poultry in holdings and areas at risk, in order to avoid further spreading of the virus.
- (14) In order to protect wild fauna and to conserve bio-diversity, Belgium and the Netherlands however may decide to carry out an emergency vaccination against avian influenza of susceptible birds in zoos.
- (15) It is appropriate to provide that essential information concerning the emergency vaccination should be specified in a programme to be submitted by Belgium and the Netherlands to the Commission and the other Member States.
- (16) The emergency vaccination, even though limited to special categories of animals not primarily concerned by trade, may contribute to jeopardise the avian influenza status in terms of international trade, not only for the Member State or part of its territory where vaccination is carried out. Therefore the vaccinated birds should not be traded.
- (17) 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

For the purpose of this Decision the following definitions shall apply:

- 'Zoo': an establishment as referred to in Article 2 of Council Directive 1999/22/EC and, with regard to trade, an 'approved body, institute or centre' as referred to in Article 2(1)(c) of Council Directive 92/65/EEC,
- 'Susceptible bird': any bird species likely susceptible to avian influenza and not intended for the production of animal products.

Article 2

The competent veterinary authority of Belgium and the Netherlands shall ensure that stringent bio-security measures are taken in zoos where birds susceptible to avian influenza are kept, in order to avoid risky contacts that may cause the introduction and spread of avian influenza. These measures shall aim in particular at avoiding risky contacts with the public and with poultry holdings.

Article 3

Belgium and the Netherlands may decide to apply emergency vaccination against avian influenza to susceptible birds kept in zoos, which are considered to be at risk from the disease, in accordance with the requirements set out in the Annex to this Decision.

Article 4

Belgium and the Netherlands shall officially present in the Standing Committee on the Food Chain and Animal Health a programme on the vaccination of susceptible birds kept in zoos against avian influenza to other Member States and the Commission. The programme shall at least comprise detailed information on:

- the exact address and location of the zoos where the vaccination is to be carried out,
- the specific identification and number of susceptible birds,
- the individual identification of the birds to be vaccinated,
- the type of vaccine to be used, the vaccination scheme and the timing of the vaccination,
- the motivation of the decision to implement the measures,
- the timetable of the vaccinations to be carried out.

Article 5

Belgium and the Netherlands shall apply the measures in compliance with this Decision and immediately inform the Commission thereof.

Article 6

This Decision is addressed to the Kingdom of Belgium and to the Kingdom of the Netherlands.

Done at Brussels, 25 April 2003.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 99, 17.4.2003, p. 57.

⁽²⁾ See page 24 of this Official Journal.

ANNEX

Requirements for the use of emergency vaccination in the control and eradication of avian influenza

1. Extent of the vaccination to be carried out	The vaccination shall only take place on susceptible birds in a zoo.
2. Species of the animals to be vaccinated	A list of all the birds to be vaccinated together with the individual identification shall be laid down and kept for at least 10 years.
3. Duration of the vaccination	All birds to be vaccinated in a zoo shall be vaccinated as quickly as possible. In any case each vaccination in a zoo shall be completed within 96 hours.
4. Specific standstill of vaccinated animals and products of vaccinated animals	Vaccinated animals shall not be traded or moved unless under official supervision between zoos in the same Member State, or after specific authorisation of another Member State. Animal products from such animals shall not enter the food chain
5. Special identification and special registration of the vaccinated animals	Vaccinated animals must be individually identifiable and the identity records of these animals must be clearly annotated accordingly. An indelible identification indicating the animals that have been vaccinated shall be applied at the time of vaccination wherever possible.
6. Other matters appropriate to the emergency vaccination	
6.1. Execution of the vaccination campaign	Vaccination shall be carried out under the supervision of an official veterinarian of the competent authorities. Necessary measures must be in place to avoid possible spread of virus. Any residual quantities of vaccine shall be returned to the point of vaccine distribution with a written record on number of animals vaccinated and the number of doses used. Wherever possible blood samples shall be taken prior to and at least 30 days after vaccination for serological testing for avian influenza. A record of the test results must be kept for at least 10 years.
6.2. Vaccine to be used	The inactivated vaccine to be used shall be suitably formulated and be effective against the virus type circulating. It shall be used in accordance with the instructions of the manufacturer and/or the veterinary authorities.
6.3. Information on implementation of this programme to the Commission	A detailed report on the execution of the programme including results of testing carried out shall be provided to the Commission and the Member States in the framework of a Standing Committee on the Food Chain and Animal Health.