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Legislation

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Price: EUR 19,50

⁽¹⁾ Text with EEA relevance

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EN

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

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

Commission

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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 28/2002
of 9 January 2002
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 1498/98 ⁽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 10 January 2002.

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

Done at Brussels, 9 January 2002.

For the Commission
Franz FISCHLER
Member of the Commission

⁽¹⁾ OJ L 337, 24.12.1994, p. 66.

⁽²⁾ OJ L 198, 15.7.1998, p. 4.

ANNEX

to the Commission Regulation of 9 January 2002 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	107,2
	204	79,8
	212	130,7
	999	105,9
0707 00 05	052	226,5
	999	226,5
0709 90 70	052	202,1
	204	256,5
	999	229,3
0805 10 10, 0805 10 30, 0805 10 50	052	63,3
	204	50,1
	508	23,3
	999	45,6
0805 20 10	204	87,3
	999	87,3
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	052	71,9
	204	85,5
	464	104,3
	624	67,0
	999	82,2
0805 50 10	052	49,7
	600	58,4
	999	54,0
0808 10 20, 0808 10 50, 0808 10 90	060	35,7
	400	103,9
	404	111,5
	720	113,9
	728	109,0
	999	94,8
0808 20 50	064	70,7
	400	97,4
	720	126,9
	999	98,3

⁽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 29/2002
of 19 December 2001
amending Council Regulation (EEC) No 3037/90 on the statistical classification of economic activities in the European Community

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3037/90 of 9 October 1990 on the statistical classification of economic activities in the European Community ⁽¹⁾, as last amended by Commission Regulation (EEC) No 761/93 ⁽²⁾, and in particular Article 8(b) and Article 9 thereof,

Whereas:

- (1) Regulation (EEC) No 3037/90 established a classification of economic activities, hereinafter called NACE Rev. 1, to meet the requirement of statistics within the Community.
- (2) It is necessary to amend NACE Rev. 1 to take account of the technological and economic development, as well as the expiry of the European Coal and Steel Community Treaty.
- (3) It is necessary to amend NACE Rev. 1, to maintain the international linked system, as well as to bring about convergence at world level.

(4) Regulation (EEC) No 3037/90 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Statistical Programme Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EEC) No 3037/90 is replaced by the text in the Annex to this Regulation.

Article 2

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

This Regulation shall apply as from 1 January 2003.

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

Done at Brussels, 19 December 2001.

For the Commission

Pedro SOLBES MIRA

Member of the Commission

⁽¹⁾ OJ L 293, 24.10.1990, p. 1.

⁽²⁾ OJ L 83, 3.4.1993, p. 1.

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29.42	Manufacture of other metalworking machine toolss	2922x
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COMMISSION REGULATION (EC) No 30/2002**of 9 January 2002****opening an invitation to tender for the reduction in the duty on maize imported into Portugal from third countries**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ⁽¹⁾, as last amended by Regulation (EC) No 1666/2000 ⁽²⁾, and in particular Article 12(1) thereof,

Whereas:

- (1) Pursuant to the Agreement on Agriculture concluded during the Uruguay Round of multilateral trade negotiations, the Community has undertaken to import a certain quantity of maize into Portugal.
- (2) Commission Regulation (EC) No 1839/95 of 26 July 1995 laying down detailed rules for the application of tariff quotas for imports of maize and sorghum into Spain and imports of maize into Portugal ⁽³⁾, as last amended by Regulation (EC) No 2235/2000 ⁽⁴⁾, lays down the rules governing the administration of those special arrangements. This Regulation lays down the special additional detailed rules necessary for implementing the invitation to tender, in particular those relating to the lodging and release of the security to be lodged by operators to ensure compliance with their obligations and, in particular, the obligation to process or use the imported product on the Portuguese market.
- (3) In the light of current market needs in Portugal, an invitation to tender for the reduction in the duty on

imports of maize should be opened in the framework of these special arrangements for imports.

- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

1. An invitation to tender is hereby opened for the reduction in the import duty referred to in Article 10(2) of Regulation (EEC) No 1766/92 on maize to be imported into Portugal.
2. The invitation to tender shall be open until 7 March 2002. During that period, weekly invitations shall be issued with quantities and closing dates as shown in the notice of invitation to tender.
3. Regulation (EC) No 1839/95 shall apply save as otherwise provided for in this Regulation.

Article 2

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

Article 3

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

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

Done at Brussels, 9 January 2002.

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 177, 28.7.1995, p. 4.

⁽⁴⁾ OJ L 256, 10.10.2000, p. 13.

COMMISSION REGULATION (EC) No 31/2002**of 9 January 2002****amending Council Regulation (EC) No 669/97 opening and providing for the administration of Community tariff quotas for certain fish and fishery products originating in the Faroe Islands**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 669/97 of 14 April 1997 opening and providing for the administration of Community tariff quotas for certain fish and fishery products originating in the Faroe Islands, defining detailed provisions for amending and adapting these measures and repealing Regulation (EC) No 1983/95 ⁽¹⁾, as last amended by Commission Regulation (EC) No 2471/1999 ⁽²⁾, and in particular Articles 5 and 6 thereof,

Whereas:

- (1) Decision No 2/2001 of the EC/Denmark-Faroe Islands Joint Committee of 11 July 2001 has amended Table II of the Annex to Protocol 1 to the Agreement between the European Community, of the one part, and the Government of Denmark and the Home Government of the Faroe Islands, of the other part ⁽³⁾, by increasing the annual tariff quota for shrimps, prawns and Norway lobsters, prepared or preserved, from 2 000 to 3 000 tonnes. This Decision entered into force on 1 September 2001.

- (2) The volume of the annual tariff quota for shrimps, prawns and Norway lobsters, listed in the Annex to Regulation (EC) No 669/97 under order number 09.0679, should be amended to take account of that increase.

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

In the Annex to Regulation (EC) No 669/97 the volume of the annual tariff quota for shrimps, prawns and Norway lobsters, prepared or preserved, having order number 09.0679, is increased to 3 000 tonnes.

Article 2

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

It shall apply from 1 September 2001.

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

Done at Brussels, 9 January 2002.

For the Commission

Frederik BOLKESTEIN

Member of the Commission

⁽¹⁾ OJ L 101, 18.4.1997, p. 1.

⁽²⁾ OJ L 301, 24.11.1999, p. 3.

⁽³⁾ OJ L 219, 14.8.2001, p. 29.

COMMISSION REGULATION (EC) No 32/2002
of 9 January 2002
correcting Regulation (EC) No 13/2002 amending Regulation (EC) No 713/2001 on the purchase of
beef under Regulation (EC) No 690/2001

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1254/1999 of 17 May 1999 on the common organisation of the market in beef and veal ⁽¹⁾, as last amended by Regulation (EC) No 2345/2001 ⁽²⁾,

Having regard to Commission Regulation (EC) No 690/2001 of 3 April 2001 on special market support measures in the beef sector ⁽³⁾, as amended by Regulation (EC) No 2595/2001 ⁽⁴⁾, and in particular Article 2(2),

Whereas:

- (1) Commission Regulation (EC) No 13/2002 ⁽⁵⁾ opened the purchase of beef under Regulation (EC) No 690/2001 in a number of Member States.

- (2) An error has been discovered in the Annex to the above-mentioned Regulation. The Regulation in question should therefore be corrected,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 13/2002 is replaced by the Annex to this Regulation.

Article 2

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

It shall apply from 5 January 2002.

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

Done at Brussels, 9 January 2002.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 160, 26.6.1999, p. 21.

⁽²⁾ OJ L 315, 1.12.2001, p. 29.

⁽³⁾ OJ L 95, 5.4.2001, p. 8.

⁽⁴⁾ OJ L 345, 29.12.2001, p. 33.

⁽⁵⁾ OJ L 3, 5.1.2002, p. 36.

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LIITE — BILAGA

Estado miembro

Medlemsstat

Mitgliedstaat

Κράτος μέλος

Member State

État membre

Stati membri

Lidstaat

Estado-Membro

Jäsenvaltiot

Medlemsstat

Belgique/België

Deutschland

Österreich

Nederland

Ireland

España

France

Portugal

Sverige

Luxembourg

COMMISSION REGULATION (EC) No 33/2002
of 9 January 2002
fixing the import duties in the rice sector

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 Regulation (EC) No 1987/2001 ⁽²⁾,

Having regard to Commission Regulation (EC) No 1503/96 of 29 July 1996 laying down detailed rules for the application of Council Regulation (EC) No 3072/95 as regards import duties in the rice sector ⁽³⁾, as last amended by Regulation (EC) No 2831/98 ⁽⁴⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) Article 11 of Regulation (EC) No 3072/95 provides that the rates of duty in the Common Customs Tariff are to be charged on import of the products referred to in Article 1 of that Regulation. However, in the case of the products referred to in paragraph 2 of that Article, the import duty is to be equal to the intervention price valid for such products on importation and increased by a certain percentage according to whether it is husked or milled rice, minus the cif import price provided that duty does not exceed the rate of the Common Customs Tariff duties.
- (2) Pursuant to Article 12(3) of Regulation (EC) No 3072/95, the cif import prices are calculated on the basis of the representative prices for the product in question on the world market or on the Community import market for the product.

- (3) Regulation (EC) No 1503/96 lays down detailed rules for the application of Regulation (EC) No 3072/95 as regards import duties in the rice sector.
- (4) The import duties are applicable until new duties are fixed and enter into force. They also remain in force in cases where no quotation is available from the source referred to in Article 5 of Regulation (EC) No 1503/96 during the two weeks preceding the next periodical fixing.
- (5) In order to allow the import duty system to function normally, the market rates recorded during a reference period should be used for calculating the duties.
- (6) Application of Regulation (EC) No 1503/96 results in import duties being fixed as set out in the Annexes to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The import duties in the rice sector referred to in Article 11(1) and (2) of Regulation (EC) No 3072/95 shall be those fixed in Annex I to this Regulation on the basis of the information given in Annex II.

Article 2

This Regulation shall enter into force on 10 January 2002.

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

Done at Brussels, 9 January 2002.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 329, 30.12.1995, p. 18.

⁽²⁾ OJ L 271, 12.10.2001, p. 5.

⁽³⁾ OJ L 189, 30.7.1996, p. 71.

⁽⁴⁾ OJ L 351, 29.12.1998, p. 25.

ANNEX I

Import duties on rice and broken rice

(EUR/t)

CN code	Duties ⁽¹⁾				
	Third countries (except ACP and Bangladesh) ⁽²⁾	ACP ⁽¹⁾ ⁽²⁾ ⁽³⁾	Bangladesh ⁽⁴⁾	Basmati India and Pakistan ⁽⁵⁾	Egypt ⁽⁶⁾
1006 10 21	(7)	69,51	101,16		158,25
1006 10 23	(7)	69,51	101,16		158,25
1006 10 25	(7)	69,51	101,16		158,25
1006 10 27	(7)	69,51	101,16		158,25
1006 10 92	(7)	69,51	101,16		158,25
1006 10 94	(7)	69,51	101,16		158,25
1006 10 96	(7)	69,51	101,16		158,25
1006 10 98	(7)	69,51	101,16		158,25
1006 20 11	246,61	81,97	118,97		184,96
1006 20 13	246,61	81,97	118,97		184,96
1006 20 15	246,61	81,97	118,97		184,96
1006 20 17	264,00	88,06	127,66	14,00	198,00
1006 20 92	246,61	81,97	118,97		184,96
1006 20 94	246,61	81,97	118,97		184,96
1006 20 96	246,61	81,97	118,97		184,96
1006 20 98	264,00	88,06	127,66	14,00	198,00
1006 30 21	(7)	133,21	193,09		312,00
1006 30 23	(7)	133,21	193,09		312,00
1006 30 25	(7)	133,21	193,09		312,00
1006 30 27	(7)	133,21	193,09		312,00
1006 30 42	(7)	133,21	193,09		312,00
1006 30 44	(7)	133,21	193,09		312,00
1006 30 46	(7)	133,21	193,09		312,00
1006 30 48	(7)	133,21	193,09		312,00
1006 30 61	(7)	133,21	193,09		312,00
1006 30 63	(7)	133,21	193,09		312,00
1006 30 65	(7)	133,21	193,09		312,00
1006 30 67	(7)	133,21	193,09		312,00
1006 30 92	(7)	133,21	193,09		312,00
1006 30 94	(7)	133,21	193,09		312,00
1006 30 96	(7)	133,21	193,09		312,00
1006 30 98	(7)	133,21	193,09		312,00
1006 40 00	(7)	41,18	(7)		96,00

⁽¹⁾ The duty on imports of rice originating in the ACP States is applicable, under the arrangements laid down in Council Regulation (EC) No 1706/98 (OJ L 215, 1.8.1998, p. 12) and amended Commission Regulation (EC) No 2603/97 (OJ L 351, 23.12.1997, p. 22).

⁽²⁾ In accordance with Regulation (EC) No 1706/98, the duties are not applied to products originating in the African, Caribbean and Pacific States and imported directly into the overseas department of Réunion.

⁽³⁾ The import levy on rice entering the overseas department of Réunion is specified in Article 11(3) of Regulation (EC) No 3072/95.

⁽⁴⁾ The duty on imports of rice not including broken rice (CN code 1006 40 00), originating in Bangladesh is applicable under the arrangements laid down in Council Regulation (EEC) No 3491/90 (OJ L 337, 4.12.1990, p. 1) and amended Commission Regulation (EEC) No 862/91 (OJ L 88, 9.4.1991, p. 7).

⁽⁵⁾ No import duty applies to products originating in the OCT pursuant to Article 101(1) of amended Council Decision 91/482/EEC (OJ L 263, 19.9.1991, p. 1).

⁽⁶⁾ For husked rice of the Basmati variety originating in India and Pakistan, a reduction of EUR/t 250 applies (Article 4a of amended Regulation (EC) No 1503/96).

⁽⁷⁾ Duties fixed in the Common Customs Tariff.

⁽⁸⁾ The duty on imports of rice originating in and coming from Egypt is applicable under the arrangements laid down in Council Regulation (EC) No 2184/96 (OJ L 292, 15.11.1996, p. 1) and Commission Regulation (EC) No 196/97 (OJ L 31, 1.2.1997, p. 53).

ANNEX II

Calculation of import duties for rice

	Paddy	Indica rice		Japonica rice		Broken rice
		Husked	Milled	Husked	Milled	
1. Import duty (EUR/tonne)	(¹)	264,00	416,00	246,61	416,00	(¹)
2. Elements of calculation:						
(a) Arag cif price (EUR/tonne)	—	257,13	249,93	314,29	293,50	—
(b) fob price (EUR/tonne)	—	—	—	280,62	259,83	—
(c) Sea freight (EUR/tonne)	—	—	—	33,67	33,67	—
(d) Source	—	USDA and operators	USDA and operators	Operators	Operators	—

(¹) Duties fixed in the Common Customs Tariff.

COMMISSION REGULATION (EC) No 34/2002
of 9 January 2002
amending representative prices and additional duties for the import of certain products in the
sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1423/95 of 23 June 1995 laying down detailed implementing rules for the import of products in the sugar sector other than molasses ⁽²⁾, as last amended by Regulation (EC) No 624/98 ⁽³⁾, and in particular the second subparagraph of Article 1(2), and Article 3(1) thereof,

Whereas:

- (1) The amounts of the representative prices and additional duties applicable to the import of white sugar, raw sugar and certain syrups are fixed by Commission Regulation

(EC) No 1309/2001 ⁽⁴⁾, as last amended by Regulation (EC) No 2608/2001 ⁽⁵⁾.

- (2) It follows from applying the general and detailed fixing rules contained in Regulation (EC) No 1423/95 to the information known to the Commission that the representative prices and additional duties at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties on imports of the products referred to in Article 1 of Regulation (EC) No 1423/95 shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 10 January 2002.

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

Done at Brussels, 9 January 2002.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 178, 30.6.2001, p. 1.

⁽²⁾ OJ L 141, 24.6.1995, p. 16.

⁽³⁾ OJ L 85, 20.3.1998, p. 5.

⁽⁴⁾ OJ L 177, 30.6.2001, p. 21.

⁽⁵⁾ OJ L 345, 29.12.2001, p. 62.

ANNEX

to the Commission Regulation of 9 January 2002 amending representative prices and the amounts of additional duties applicable to imports of white sugar, raw sugar and products covered by CN code 1702 90 99

(EUR)

CN code	Amount of representative prices per 100 kg net of product concerned	Amount of additional duty per 100 kg net of product concerned
1701 11 10 ⁽¹⁾	23,11	4,74
1701 11 90 ⁽¹⁾	23,11	9,98
1701 12 10 ⁽¹⁾	23,11	4,55
1701 12 90 ⁽¹⁾	23,11	9,55
1701 91 00 ⁽²⁾	31,17	9,65
1701 99 10 ⁽²⁾	31,17	5,13
1701 99 90 ⁽²⁾	31,17	5,13
1702 90 99 ⁽³⁾	0,31	0,34

⁽¹⁾ For the standard quality as defined in Article 1 of amended Council Regulation (EEC) No 431/68 (OJ L 89, 10.4.1968, p. 3).

⁽²⁾ For the standard quality as defined in Article 1 of Council Regulation (EEC) No 793/72 (OJ L 94, 21.4.1972, p. 1).

⁽³⁾ By 1 % sucrose content.

COMMISSION REGULATION (EC) No 35/2002**of 9 January 2002****on the issue of import licences for high-quality fresh, chilled or frozen beef and veal**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 936/97 of 27 May 1997 opening and providing for the administration of tariff quotas for high-quality fresh, chilled and frozen beef and for frozen buffalo meat ⁽¹⁾, as last amended by Regulation (EC) No 134/1999 ⁽²⁾,

Whereas:

- (1) Regulation (EC) No 936/97 provides in Articles 4 and 5 the conditions for applications and for the issue of import licences for meat referred to in Article 2(f).
- (2) Article 2(f) of Regulation (EC) No 936/97 fixes the amount of high-quality fresh, chilled or frozen beef and veal originating in and imported from the United States of America and Canada which may be imported on special terms for the period 1 July 2001 to 30 June 2002 at 11 500 t.

- (3) It should be recalled that licences issued pursuant to this Regulation will, throughout the period of validity, be open for use only in so far as provisions on health protection in force permit,

HAS ADOPTED THIS REGULATION:

Article 1

1. All applications for import licences from 1 to 5 January 2002 for high-quality fresh, chilled or frozen beef and veal as referred to in Article 2(f) of Regulation (EC) No 936/97 shall be granted in full.
2. Applications for licences may be submitted, in accordance with Article 5 of Regulation (EC) No 936/97, during the first five days of February 2002 for 7 080,167 t.

Article 2

This Regulation shall enter into force on 11 January 2002.

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

Done at Brussels, 9 January 2002.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 137, 28.5.1997, p. 10.

⁽²⁾ OJ L 17, 22.1.1999, p. 22.

COUNCIL DIRECTIVE 2001/102/EC
of 27 November 2001
amending Directive 1999/29/EC on the undesirable substances and products in animal nutrition
(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 1999/29/EC of 22 April 1999 on the undesirable substances and products in animal nutrition ⁽¹⁾, and in particular Article 10 point (a) thereof,

Having regard to the proposal from the Commission,

Whereas:

- (1) Directive 1999/29/EC provides that feed materials may only be put into circulation in the Community if they are sound, genuine and of merchantable quality.
- (2) The term 'dioxins' covers a group of 75 polychlorinated dibenzo-p-dioxin ('PCDD') and 135 polychlorinated dibenzofuran ('PCDF') congeners, of which 17 are of toxicological concern. The most toxic congener is 2,3,7,8-tetrachlordibenzo-p-dioxin (TCDD) classified by the International Agency for Research on Cancer and other reputable international organisations as a known human carcinogen. The Scientific Committee for Food ('SCF'), in line with the World Health Organisation ('WHO'), concluded that the carcinogenic effect of dioxins does not occur at levels below a certain threshold. Other adverse effects, such as endometriosis, neurobehavioural and immunosuppressive effects occur at much lower levels and are therefore considered relevant for the determination of a tolerable intake.
- (3) Polychlorinated biphenyls, ('PCBs'), are a group of 209 different congeners which can be divided into two groups according to their toxicological properties: 12 congeners exhibit toxicological properties similar to dioxins and are therefore often termed 'dioxin-like PCBs'. The other PCBs do not exhibit dioxin-like toxicity but have a different toxicological profile.
- (4) Each congener of dioxins or dioxin-like PCBs presents a different level of toxicity. In order to be able to sum up the toxicity of these different congeners, the concept of

toxic equivalency factors ('TEFs') has been introduced to facilitate risk assessment and regulatory control. This means that the analytical results relating to all 17 individual dioxin congeners and to the 12 dioxin-like PCB congeners are expressed in terms of a single quantifiable unit: 'TCDD toxic equivalent concentration' ('TEQ').

- (5) Dioxins and PCBs are extremely resistant to chemical and biological degradation and therefore persist in the environment and accumulate in the feed and food chain.
- (6) The distribution of dioxins, PCBs and dioxin-like PCBs throughout the environment causes background contamination affecting all terrestrial plants directly grazed or used as feed materials for animal feed as well as the aquatic feed chain. The same applies to the soil that might contaminate feed materials or be directly ingested by animals. In addition to background contamination, direct accidental pollution of feed materials may occur due to localised discharge of dioxins from industrial activities, contamination of feed materials during their production, processing and transportation, and illegal practices or management failures during feed production.
- (7) More than 90 % of human dioxin exposure derives from foodstuffs. Foodstuffs of animal origin normally contribute to approximately 80 % of overall exposure. The dioxin burden in animals derives mainly from feedingstuffs. Therefore feedingstuffs, and in some cases soil, are of concern as potential sources of dioxins.
- (8) The SCF adopted an opinion on the Risk Assessment of Dioxins and Dioxin-like PCBs in Food on 30 May 2001. This is an update based on new scientific information available since the adoption of the SCF opinion on this matter on 22 November 2000. The SCF fixed a tolerable weekly intake ('TWI') for dioxins and dioxin-like PCBs of 14 pg WHO-TEQ/kg body weight. Exposure estimates indicate that a considerable proportion of the Community population has a dietary intake in excess of the tolerable intake.

⁽¹⁾ OJ L 115, 4.5.1999, p. 32.

- (9) The reduction of human exposure to dioxins through food consumption is therefore important and necessary to ensure consumer protection. As food contamination is directly related to feed contamination, an integrated approach must be adopted to reduce dioxin incidence throughout the food chain, i.e. from feed materials through food-producing animals to humans. The introduction of measures relating to feed materials and feedingstuffs is therefore a crucial step towards reducing dioxin intake by humans.
- (10) The Scientific Committee for Animal Nutrition ('SCAN') has been asked to advise on the sources of contamination of feedingstuffs with dioxins and PCBs, including dioxin-like PCBs, the exposure of food-producing animals to dioxins and PCBs, the carry-over of these compounds to food products of animal origin, and any impact on animal health of dioxins and PCBs present in feedingstuffs. The SCAN adopted an opinion on 6 November 2000. It identified fish meal and fish oil as the most heavily contaminated feed materials, with products of European origin being more heavily contaminated. Animal fat was identified as the next most seriously contaminated material. All other feed materials of animal and plant origin had relatively low levels of dioxin contamination. Roughages presented a wide range of dioxin contamination depending on location, degree of contamination with soil and exposure to sources of aerial pollution.
- (11) Measures should be implemented with the aim of reducing the presence and release of dioxin contamination of the environment in order to reduce the impact of environmental pollution on the contamination of feed materials. The SCAN recommended, *inter alia*, that emphasis should be placed on reducing the impact of the most contaminated feed materials on overall diet contamination.
- (12) Maximum levels for dioxins and dioxin like PCBs should be an appropriate tool to prevent unacceptably high exposure of animals and to prevent the distribution of feedingstuffs with an unacceptably high level of contamination, e.g. in cases of accidental pollution and exposure. Furthermore, the setting of maximum levels is indispensable for the implementation of a regulatory control system and to ensure uniform application.
- (13) Measures based solely on establishing maximum levels for dioxins and dioxin-like PCBs in feedingstuffs would not be sufficiently effective in reducing human exposure to dioxins unless the levels were set so low that a large part of the feed supply would have to be declared unfit for animal consumption. It is generally recognised that, in order to actively reduce the presence of dioxins in feedingstuffs, maximum levels should be accompanied by measures stimulating an active approach, including action levels and target levels for feedingstuffs in combination with measures to limit emissions. Target levels indicate the levels to be achieved in order to ultimately bring human exposure for the majority of the population down to the TWI set by the SCF. Action levels are a tool for competent authorities and operators to identify those cases where it is appropriate to identify a source of contamination and to take measures for its reduction or elimination, not only in the event of non-compliance with this Directive but also where significant levels of dioxins above normal background levels are found. This will result in a gradual reduction of dioxin levels in feedingstuffs, and the target levels will ultimately be achieved. A recommendation from the Commission on this issue is therefore being addressed to the Member States.
- (14) Although, from a toxicological point of view, any level should apply to dioxins, furans and dioxin-like PCBs, for the time being the maximum levels are set only for dioxins and furans and not for dioxin-like PCBs, given the very limited data available on the prevalence of the latter. However, monitoring will continue, in particular on the presence of dioxin-like PCBs with a view to including these substances in the maximum levels.
- (15) The unacceptability of the dioxin content of feedingstuffs should be assessed in the light of the current background levels of contamination, which differ from feed material to feed material. The maximum level should be fixed, taking account of background contamination, at a strict but feasible level.
- (16) In order to ensure that all operators in the food and feed chain continue to make all possible efforts and do all that is necessary to limit the presence of dioxins in feed and food, the maximum levels applicable should be reviewed within a defined period with a view to setting lower maximum levels. An overall reduction of at least 25 % in human exposure to dioxins should be achieved by 2006.
- (17) Compound feedingstuffs and feed materials of plant origin do not normally contain high levels of dioxins. Since feed materials of plant origin are by far the largest component in the diet of many species of animals, it is appropriate to set a maximum level also for these feed materials. The more sensitive the method of analysis, the more expensive and time-consuming the analysis to check for dioxin. As it is important that as many samples as possible be analysed, the maximum levels proposed are somewhat higher than normal background levels given that they constitute upper-bound levels.

- (18) It is of utmost importance to reduce that overall levels of dioxin contamination in feedingstuffs be reduced. It is therefore absolutely necessary to prohibit the mixing of feed materials and feedingstuffs complying with the maximum levels with feed materials/feedingstuffs exceeding these maximum levels.
- (19) Directive 1999/29/EC should therefore be amended accordingly.
- (20) The Standing Committee for Feedingstuffs did not deliver a favourable opinion. The Commission has been therefore unable to adopt the provisions it envisaged according to the procedure laid down in Article 13 of Directive 1999/29/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I and II to Directive 1999/29/EC are hereby amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, before 1 July 2002 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply these provisions from 1 July 2002.

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

The methods of making such a reference shall be laid down by the Member States.

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 3

1. The provisions referred to in Article 1 shall be reviewed for the first time by 31 December 2004 at the latest in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set.

2. The provisions referred to in Article 1 shall be further reviewed by 31 December 2006 at the latest with the aim of significantly reducing the maximum levels.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 27 November 2001.

For the Council

The President

A. NEYTS-UYTTEBROECK

ANNEX

Annexes I and II to Directive 1999/29/EC are amended as follows:

1. Annex I shall be amended as follows:

(a) in the table, under point 'B. Products', point 21 shall be replaced by the following:

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
'21. Dioxin (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO — TEFs (toxic equivalency factors, 1997)) PCDD/F	All feed materials of plant origin including vegetable oils and by-products	0,75 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Minerals	1,0 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Animal fat, including milk fat and egg fat	2,0 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Other land animal products including milk and milk products and eggs and egg products	0,75 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Fish oil	6 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Fish, other aquatic animals, their products and by-products with the exception of fish oil ⁽⁷⁾	1,25 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Compound feedingstuffs, with the exception of feedingstuffs for fur animals, pet foods and feedingstuffs for fish	0,75 ng WHO-PCDD/F-TEQ/kg ^(5,6)
	Feedingstuffs for fish Pet foods	2,25 ng WHO-PCDD/F-TEQ/kg ^(5,6)

(b) at the end of Annex I, the following footnotes shall be added:

⁽⁵⁾ Upper-bound concentrations; upper-bound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.

⁽⁶⁾ These maximum limits shall be reviewed for the first time before 31 December 2004 in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set and will be further reviewed before 31 December 2006 with the aim of significantly reducing of the maximum levels.

⁽⁷⁾ Fresh fish directly delivered and used without intermediate processing for the production of feedingstuffs for fur animals is exempted from the maximum limit. The products, processed animal proteins produced from these fur animals cannot enter the food chain and the feeding thereof is prohibited to farmed animals which are kept, fattened or bred for the production of food.'

2. Annex II shall be amended as follows:

(a) in the table, point 4 of Part A shall be replaced by the following:

Substances, products	Feedingstuffs	Maximum content in mg/kg (ppm) relative to a feedingstuff with a moisture content of 12 %
(1)	(2)	(3)
4. Dioxin (sum of polychlorinated dibenzo-para-dioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) expressed in World Health Organisation (WHO) toxic equivalents, using the WHO — TEFs (toxic equivalency factors, 1997)) PCDD/F	All feed materials of plant origin including vegetable oils and by-products	0,75 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Minerals	1,0 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Animal fat, including milk fat and egg fat	2,0 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Other land animal products including milk and milk products and eggs and egg products	0,75 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Fish oil	6 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Fish, other aquatic animals, their products and by-products with the exception of fish oil ⁽⁴⁾	1,25 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Compound feedingstuffs, with the exception of feedingstuffs for fur animals, pet foods and feedingstuffs for fish	0,75 ng WHO-PCDD/F-TEQ/kg ^(2,3)
	Feedingstuffs for fish Pet foods	2,25 ng WHO-PCDD/F-TEQ/kg ^(2,3)

(b) at the end of Part A, footnote 2 shall be deleted and replaced by the following footnotes:

⁽²⁾ Upper-bound concentrations; upper-bound concentrations are calculated assuming that all values of the different congeners less than the limit of determination are equal to the limit of determination.

⁽³⁾ These maximum limits shall be reviewed for the first time before 31 December 2004 in the light of new data on the presence of dioxins and dioxin-like PCBs, in particular with a view to the inclusion of dioxin-like PCBs in the levels to be set and will be further reviewed before 31 December 2006 with the aim of significantly reducing of the maximum levels.

⁽⁴⁾ Fresh fish directly delivered and used without intermediate processing for the production of feedingstuffs for fur animals is exempted from the maximum limit. The products, processed animal proteins produced from these fur animals cannot enter the food chain and the feeding thereof is prohibited to farmed animals which are kept, fattened or bred for the production of food.'

DIRECTIVE 2001/104/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 7 December 2001
amending Council Directive 93/42/EEC concerning medical devices
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the Economic and Social Committee,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽¹⁾,

Whereas:

- (1) This Directive aims at including in the scope of Directive 93/42/EEC ⁽²⁾ only medical devices which incorporate, as an integral part, substances derived from human blood or human plasma. Medical devices incorporating other substances derived from human tissues remain excluded from the scope of the said Directive.
- (2) The essential aim of any rules governing the production, distribution or use of medical devices must be to safeguard public health.
- (3) National provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices should be harmonised in order to guarantee free movement of such devices within the internal market,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Article 1(5) of Directive 93/42/EEC is hereby amended as follows:

(a) point (c) shall be replaced by the following:

‘(c) medicinal products covered by Directive 65/65/EEC, including medicinal products derived from blood as covered by Directive 89/381/EEC;’

⁽¹⁾ Opinion of the European Parliament delivered on 23 October 2001 (not yet published in the Official Journal) and Council Decision of 3 December 2001.

⁽²⁾ OJ L 169, 12.7.1993, p. 1. Directive as last amended by Directive 2000/70/EC of the European Parliament and of the Council (OJ L 313, 13.12.2000, p. 22).

(b) point (e) shall be replaced by the following:

‘(e) human blood, blood products, plasma or blood cells of human origin or to devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of devices referred to in paragraph 4a.’

Article 2

Implementation, transitional provisions

1. Before 13 December 2001, Member States shall adopt and publish the laws, regulations and administrative provisions necessary to comply with this Directive. They shall immediately inform the Commission thereof.

Member States shall apply these measures with effect from 13 June 2002.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

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

3. Member States shall take the necessary action to ensure that the notified bodies which are responsible pursuant to Article 16 of Directive 93/42/EEC for conformity assessment take account of all relevant information regarding the characteristics and performance of devices incorporating stable derivatives of human blood or human plasma, including in particular the results of any pertinent tests and verification already carried out under the pre-existing national law, regulations or administrative provisions in respect of such devices.

4. For a period of five years following the entry into force of this Directive, Member States shall accept the placing on the market of devices incorporating stable derivatives of human blood or human plasma which conform to the rules in force in their territory on the date on which this Directive enters into force. For a further period of two years, the said devices may be put into service.

Article 3

This Directive shall enter into force on the date of its publication in *the Official Journal of the European Communities*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 7 December 2001.

For the European Parliament

The President

N. FONTAINE

For the Council

The President

I. DURANT

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 27 December 2001

on standard contractual clauses for the transfer of personal data to processors established in third countries, under Directive 95/46/EC

(notified under document number C(2001) 4540)

(Text with EEA relevance)

(2002/16/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data ⁽¹⁾, and in particular Article 26(4) thereof,

Whereas:

- (1) Pursuant to Directive 95/46/EC Member States are required to provide that a transfer of personal data to a third country may only take place if the third country in question ensures an adequate level of data protection and the Member States' laws, which comply with the other provisions of the Directive, are respected prior to the transfer.
- (2) However, Article 26(2) of Directive 95/46/EC provides that Member States may authorise, subject to certain safeguards, a transfer or a set of transfers of personal data to third countries which do not ensure an adequate level of protection. Such safeguards may in particular result from appropriate contractual clauses.
- (3) Pursuant to Directive 95/46/EC the level of data protection should be assessed in the light of all the circumstances surrounding the data transfer operation or set of data transfer operations. The Working Party on the Protection of Individuals with regard to the Processing of Personal Data established under that Directive ⁽²⁾ has issued guidelines to aid with the assessment ⁽³⁾.

⁽¹⁾ OJ L 281, 23.11.1995, p. 31.

⁽²⁾ The web address of the Working Party is:
http://europa.eu.int/comm/internal_market/en/dataprot/wpdocs/index.htm.

⁽³⁾ **WP 4 (5020/97)**: 'First orientations on Transfers of Personal Data to Third Countries — Possible Ways Forward in Assessing Adequacy', a discussion document adopted by the Working Party on 26 June 1997.

WP 7 (5057/97): Working document: 'Judging industry self-regulation: when does it make a meaningful contribution to the level of data protection in a third country?', adopted by the Working Party on 14 January 1998.

WP 9 (5005/98): Working Document: 'Preliminary views on the use of contractual provisions in the context of transfers of personal data to third countries', adopted by the Working Party on 22 April 1998.

WP 12: Transfers of personal data to third countries: Applying Articles 25 and 26 of the EU data protection directive, adopted by the Working Party on 24 July 1998, available on the website
'http://europa.eu.int/comm/internal_market/en/dataprot/wpdocs/wp12en.htm' hosted by the European Commission.

- (4) The standard contractual clauses relate only to data protection. The data exporter and the data importer are free to include any other clauses on business related issues which they consider as being pertinent for the contract as long as they do not contradict the standard contractual clauses.
- (5) This Decision should be without prejudice to national authorisations Member States may grant in accordance with national provisions implementing Article 26(2) of Directive 95/46/EC. This Decision only has the effect of requiring the Member States not to refuse to recognise as providing adequate safeguards the contractual clauses set out in it and does not therefore have any effect on other contractual clauses.
- (6) The scope of this Decision is limited to establishing that the clauses which it sets out may be used by a data controller established in the Community in order to adduce adequate safeguards within the meaning of Article 26(2) of Directive 95/46/EC for the transfer of personal data to a processor established in a third country.
- (7) This Decision should implement the obligation provided for in Article 17(3) of Directive 95/46/EC and does not prejudice the content of the contracts or legal acts established pursuant to that provision. However, some of the standard contractual clauses, in particular as regards the data exporter's obligations, should be included in order to increase clarity as to the provisions which may be contained in a contract between a controller and a processor.
- (8) Supervisory authorities of the Member States play a key role in this contractual mechanism in ensuring that personal data are adequately protected after the transfer. In exceptional cases where data exporters refuse or are unable to instruct the data importer properly, with an imminent risk of grave harm to the data subjects, the standard contractual clauses should allow the supervisory authorities to audit data importers and, where appropriate, take decisions which are binding on data importers. The supervisory authorities should have the power to prohibit or suspend a data transfer or a set of transfers based on the standard contractual clauses in those exceptional cases where it is established that a transfer on contractual basis is likely to have a substantial adverse effect on the warranties and obligations providing adequate protection for the data subject.
- (9) The Commission may also consider in the future whether standard contractual clauses for the transfer of personal data to data processors established in third countries not offering an adequate level of data protection, submitted by business organisations or other interested parties, offer adequate safeguards in accordance with Article 26(2) of Directive 95/46/EC.
- (10) A disclosure of personal data to a data processor established outside the Community is an international transfer protected under Chapter IV of Directive 95/46/EC. Consequently, this Decision does not cover the transfer of personal data by controllers established in the Community to controllers established outside the Community who fall within the scope of Commission Decision 2001/497/EC of 15 June 2001 on standard contractual clauses for the transfer of personal data to third countries, under Directive 95/46/EC ⁽¹⁾.
- (11) The standard contractual clauses should provide for the technical and organisational security measures ensuring a level of security appropriate to the risks represented by the processing and the nature of the data to be protected that a data processor established in a third country not providing adequate protection must apply. Parties should make provision in the contract for those technical and organisational measures which, having regard to applicable data protection law, the state of the art and the cost of their implementation, are necessary in order to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access or any other unlawful forms of processing.
- (12) In order to facilitate data flows from the Community, it is desirable that processors providing data processing services to several data controllers in the Community be allowed to apply the same technical and organisational security measures irrespective of the Member State from which the data transfer originates, in particular in those cases where the data importer receives data for further processing from different establishments of the data exporter in the Community, in which case the law of the designated Member State of establishment should apply.

⁽¹⁾ OJ L 181, 4.7.2001, p. 19.

- (13) It is appropriate to lay down the minimum information that the parties must specify in the contract dealing with the transfer. Member States should retain the power to particularise the information the parties are required to provide. The operation of this Decision should be reviewed in the light of experience.
- (14) The data importer should process the transferred personal data only on behalf of the data exporter and in accordance with his instructions and the obligations contained in the clauses. In particular the data importer should not disclose the personal data to a third party unless in accordance with certain conditions. The data exporter should instruct the data importer throughout the duration of the data processing Services to process the data in accordance with his instructions, the applicable data protection laws and the obligations contained in the clauses. The transfer of personal data to processors established outside the Community does not prejudice the fact that the processing activities should be governed in any case by the applicable data protection law.
- (15) The standard contractual clauses should be enforceable not only by the organisations which are parties to the contract, but also by the data subjects, in particular where the data subjects suffer damage as a consequence of a breach of the contract.
- (16) The data subject should be entitled to take action and, where appropriate, receive compensation from the data exporter who is the data controller of the personal data transferred. Exceptionally, the data subject should also be entitled to take action, and, where appropriate, receive compensation from the data importer in those cases, arising out of a breach by the data importer of any of his obligations referred to in the second paragraph of clause 3, where the data exporter has factually disappeared or has ceased to exist in law or has become insolvent.
- (17) In the event of a dispute between a data subject, who invokes the third-party beneficiary clause and the data importer, which is not amicably resolved, the data importer should agree to provide the data subject with the choice between mediation, arbitration or litigation. The extent to which the data subject will have an effective choice should depend on the availability of reliable and recognised systems of mediation and arbitration. Mediation by the data protection supervisory authorities of the Member State in which the data exporter is established should be an option where they provide such a service.
- (18) The contract should be governed by the law of the Member State in which the data exporter is established enabling a third-party beneficiary to enforce a contract. Data subjects should be allowed to be represented by associations or other bodies if they so wish and if authorised by national law.
- (19) The Working Party on the Protection of Individuals with regard to the processing of Personal Data established under Article 29 of Directive 95/46/EC has delivered an opinion on the level of protection provided under the standard contractual clauses annexed to this Decision, which has been taken into account in the preparation of this Decision ⁽¹⁾.
- (20) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 31 of Directive 95/46/EC,

HAS ADOPTED THIS DECISION:

Article 1

The standard contractual clauses set out in the Annex are considered as offering adequate safeguards with respect to the protection of the privacy and fundamental rights and freedoms of individuals and as regards the exercise of the corresponding rights as required by Article 26(2) of Directive 95/46/EC.

⁽¹⁾ Opinion No 7/2001 adopted by the Working Party on 13 September 2001 (DG MARKT...), available on the website 'Europa' hosted by the European Commission.

Article 2

This Decision concerns only the adequacy of protection provided by the standard contractual clauses set out in the Annex for the transfer of personal data to processors. It does not affect the application of other national provisions implementing Directive 95/46/EC that pertain to the processing of personal data within the Member States.

This Decision shall apply to the transfer of personal data by controllers established in the Community to recipients established outside the territory of the Community who act only as processors.

Article 3

For the purposes of this Decision:

- (a) the definitions in Directive 95/46/EC shall apply;
- (b) 'special categories of data' means the data referred to in Article 8 of that Directive;
- (c) 'supervisory authority' means the authority referred to in Article 28 of that Directive;
- (d) 'data exporter' means the controller who transfers the personal data;
- (e) 'data importer' means the processor established in a third country who agrees to receive from the data exporter personal data intended for processing on the data exporter's behalf after the transfer in accordance with his instructions and the terms of this Decision and who is not subject to a third country's system ensuring adequate protection;
- (f) 'applicable data protection law' means the legislation protecting the fundamental rights and freedoms of natural persons and, in particular, their right to privacy with respect to the processing of personal data applicable to a data controller in the Member State in which the data exporter is established;
- (g) 'technical and organisational security measures' means those measures aimed at protecting personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

Article 4

1. Without prejudice to their powers to take action to ensure compliance with national provisions adopted pursuant to Chapters II, III, V and VI of Directive 95/46/EC, the competent authorities in the Member States may exercise their existing powers to prohibit or suspend data flows to third countries in order to protect individuals with regard to the processing of their personal data in cases where:

- (a) it is established that the law to which the data importer is subject imposes upon him requirements to derogate from the applicable data protection law which go beyond the restrictions necessary in a democratic society as provided for in Article 13 of Directive 95/46/EC where those requirements are likely to have a substantial adverse effect on the guarantees provided by the applicable data protection law and the standard contractual clauses; or
- (b) a competent authority has established that the data importer has not respected the contractual clauses in the Annex; or
- (c) there is a substantial likelihood that the standard contractual clauses in the Annex are not being or will not be complied with and the continuing transfer would create an imminent risk of grave harm to the data subjects.

2. The prohibition or suspension pursuant to paragraph 1 shall be lifted as soon as the reasons for the suspension or prohibition no longer exist.

3. When Member States adopt measures pursuant to paragraphs 1 and 2, they shall, without delay, inform the Commission which will forward the information to the other Member States.

Article 5

The Commission shall evaluate the operation of this Decision on the basis of available information three years after its notification to the Member States. It shall submit a report on the findings to the Committee established under Article 31 of Directive 95/46/EC. It shall include any evidence that could affect the evaluation concerning the adequacy of the standard contractual clauses in the Annex and any evidence that this Decision is being applied in a discriminatory way.

Article 6

This Decision shall apply from 3 April 2002.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 27 December 2001.

For the Commission

Frederik BOLKESTEIN

Member of the Commission

ANNEX

Standard Contractual Clauses (processors)

For the purposes of Article 26(2) of Directive 95/46/EC for the transfer of personal data to processors established in third countries which do not ensure an adequate level of data protection

Name of the data exporting organisation:

address

.....

tel.:; fax:; e-mail:

Other information needed to identify the organisation

.....

(the data **exporter**)

and

Name of the data importing organisation:

address

.....

tel.:; fax:; e-mail:

Other information needed to identify the organisation:

.....

(the data **importer**)

HAVE AGREED on the following Contractual Clauses (the Clauses) in order to adduce adequate safeguards with respect to the protection of privacy and fundamental rights and freedoms of individuals for the transfer by the data exporter to the data importer of the personal data specified in Appendix 1.

*Clause 1***Definitions**

For the purposes of the Clauses:

- (a) 'personal data', 'special categories of data', 'process/processing', 'controller', 'processor', 'data subject' and 'supervisory authority' shall have the same meaning as in Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (the Directive) ⁽¹⁾;
- (b) 'the data exporter' shall mean the controller who transfers the personal data;
- (c) 'the data importer' shall mean the processor who agrees to receive from the data exporter personal data intended for processing on his behalf after the transfer in accordance with his instructions and the terms of these Clauses and who is not subject to a third country's system ensuring to adequate protection;
- (d) 'the applicable data protection law' shall mean the legislation protecting the fundamental rights and freedoms of natural persons and, in particular, their right to privacy with respect to the processing of personal data applicable to a data controller in the Member State in which the data exporter is established;
- (e) 'technical and organisational security measures' shall mean those measures aimed at protecting personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing.

*Clause 2***Details of the transfer**

The details of the transfer and in particular the special categories of personal data where applicable are specified in Appendix 1 which forms an integral part of the Clauses.

⁽¹⁾ Parties may reproduce definitions and meanings contained in Directive 95/46/EC within this Clause if they considered it better for the contract to stand alone.

*Clause 3***Third-party beneficiary clause**

The data subject can enforce against the data exporter this Clause, Clause 4(b) to (h), Clause 5(a) to (e), and (g), Clause 6(1) and (2), Clause 7, Clause 8(2), and Clauses 9, 10 and 11, as third-party beneficiaries.

The data subject can enforce against the data importer this Clause, Clause 5(a) to (e) and (g), Clause 6(1) and (2), Clause 7, Clause 8(2), and Clauses 9, 10 and 11, in cases where the data exporter has factually disappeared or has ceased to exist in law.

The parties do not object to a data subject being represented by an association or other body if the data subject so expressly wishes and if permitted by national law.

*Clause 4***Obligations of the data exporter**

The data exporter agrees and warrants:

- (a) that the processing, including the transfer itself, of the personal data has been and will continue to be carried out in accordance with the relevant provisions of the applicable data protection law (and, where applicable, has been notified to the relevant authorities of the Member State where the data exporter is established) and does not violate the relevant provisions of that State;
- (b) that he has instructed and throughout the duration of the personal data processing services will instruct the data importer to process the personal data transferred only on the data exporter's behalf and in accordance with the applicable data protection law and these clauses;
- (c) that the data importer shall provide sufficient guarantees in respect of the technical and organisational security measures specified in Appendix 2 to this contract;
- (d) that after assessment of the requirements of the applicable data protection law, the security measures are appropriate to protect personal data against accidental or unlawful destruction or accidental loss, alteration, unauthorised disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing, and that these measures ensure a level of security appropriate to the risks presented by the processing and the nature of the data to be protected having regard to the state of the art and the cost of their implementation;
- (e) that he will ensure compliance with the security measures;
- (f) that, if the transfer involves special categories of data, the data subject has been informed or will be informed before, or as soon as possible after, the transfer that his data could be transmitted to a third country not providing adequate protection;
- (g) that he agrees to forward the notification received from the data importer pursuant to Clause 5(b) to the data protection supervisory authority if he decides to continue the transfer or to lift his suspension;
- (h) to make available to the data subjects upon request a copy of the Clauses set out in this Annex, with the exception of Appendix 2 which shall be replaced by a summary description of the security measures.

*Clause 5***Obligations of the data importer ⁽¹⁾**

The data importer agrees and warrants:

- (a) to process the personal data only on behalf of the data exporter and in compliance with his instructions and the clauses; if he cannot provide such compliance for whatever reasons, he agrees to inform promptly the data exporter of his inability to comply, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract;
- (b) that he has no reason to believe that the legislation applicable to him prevents him from fulfilling the instructions received from the data exporter and his obligations under the contract and that in the event of a change in this legislation which is likely to have a substantial adverse effect on the warranties and obligations provided by the Clauses, he will promptly notify the change to the data exporter as soon as he is aware, in which case the data exporter is entitled to suspend the transfer of data and/or terminate the contract;
- (c) that he has implemented the technical and organisational security measures specified in Appendix 2 before processing the personal data transferred;

⁽¹⁾ Mandatory requirements of the national legislation applicable to the data importer which do not go beyond what is necessary in a democratic society on the basis of one of the interests listed in Article 13(1) of Directive 95/46/EC, that is, if they constitute a necessary measure to safeguard national security defence, public security, the prevention, investigation, detection and prosecution of criminal offences or of breaches of ethics for the regulated professions, an important economic or financial interest of the State or the protection of the data subject or the rights and freedoms of others, are not in contradiction with the standard contractual clauses. Some examples of such mandatory requirements which do not go beyond what is necessary in a democratic society are, *inter alia*, internationally recognised sanctions, tax-reporting requirements or anti-money-laundering reporting requirements.

- (d) that he shall promptly notify the data exporter about:
 - (i) any legally binding request for disclosure of the personal data by a law enforcement authority unless otherwise prohibited, such as a prohibition under criminal law to preserve the confidentiality of a law enforcement investigation;
 - (ii) any accidental or unauthorised access; and
 - (iii) any request received directly from the data subjects without responding to that request, unless he has been otherwise authorised to do so;
- (e) to deal promptly and properly with all inquiries from the data exporter relating to his processing of the personal data subject to the transfer and to abide by the advice of the supervisory authority with regard to the processing of the data transferred;
- (f) at the request of the data exporter to submit his data processing facilities for audit of the processing activities covered by the clauses which shall be carried out by the data exporter or an inspection body composed of independent members and in possession of the required professional qualifications bound by a duty of confidentiality, selected by the data exporter, where applicable, in agreement with the supervisory authority;
- (g) to make available to the data subject upon request a copy of the Clauses set out in this Annex, with the exception of Appendix 2 which shall be replaced by a summary description of the security measures in those cases where the data subject is unable to obtain a copy from the data exporter.

Clause 6

Liability

1. The parties agree that a data subject, who has suffered damage as a result of any violation of the provisions referred to in Clause 3 is entitled to receive compensation from the data exporter for the damage suffered.
2. If a data subject is not able to bring the action referred to in paragraph 1 arising out of a breach by the data importer of any of his obligations referred to in Clause 3 against the data exporter because the data exporter has disappeared factually or has ceased to exist in law or became insolvent, the data importer agrees that the data subject may issue a claim against the data importer as if he were the data exporter.
3. The parties agree that if one party is held liable for a violation of the clauses committed by the other party, the latter will, to the extent to which it is liable, indemnify the first party for any cost, charge, damages, expenses or loss it has incurred.

Indemnification is contingent upon:

- (a) the data exporter promptly notifying the data importer of a claim; and
- (b) the data importer being given the possibility to cooperate with the data exporter in the defence and settlement of the claim ⁽¹⁾.

Clause 7

Mediation and jurisdiction

1. The data importer agrees that if the data subject invokes against him third-party beneficiary rights and/or claims compensation for damages under the clauses, the data importer will accept the decision of the data subject:
 - (a) to refer the dispute to mediation, by an independent person or, where applicable, by the supervisory authority;
 - (b) to refer the dispute to the courts in the Member State in which the data exporter is established.
2. The data importer agrees that, by agreement with the data subject, the resolution of a specific dispute can be referred to an arbitration body if the data importer is established in a country which has ratified the New York Convention on enforcement of arbitration awards.
3. The parties agree that the choice made by the data subject will not prejudice his substantive or procedural rights to seek remedies in accordance with other provisions of national or international law.

Clause 8

Cooperation with supervisory authorities

1. The data exporter agrees to deposit a copy of this contract with the supervisory authority if it so requests or if such deposit is required under the applicable data protection law.
2. The parties agree that the supervisory authority has the right to conduct an audit of the data importer which has the same scope and is subject to the same conditions as would apply to an audit of the data exporter under the applicable data protection law.

⁽¹⁾ Paragraph 3 is optional.

Clause 9

Governing Law

The Clauses shall be governed by the law of the Member State in which the data exporter is established, namely

Clause 10

Variation of the contract

The parties undertake not to vary or modify the terms of the Clauses.

Clause 11

Obligation after the termination of personal data processing services

1. The parties agree that on the termination of the provision of data processing services, the data importer shall, at the choice of the data exporter, return all the personal data transferred and the copies thereof to the data exporter or shall destroy all the personal data and certify to the data exporter that he has done so, unless legislation imposed upon the data importer prevents him from returning or destroying all or part of the personal data transferred. In that case, the data importer warrants that he will guarantee the confidentiality of the personal data transferred and will not actively process the personal data transferred anymore.

2. The data importer warrants that upon request of the data exporter and/or of the supervisory authority, he will submit his data processing facilities for an audit of the measures referred to in paragraph 1.

On behalf of the data exporter:

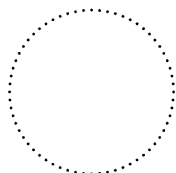
Name (written out in full):

Position:

Address:

Other information necessary in order for the contract to be binding (if any):

Signature



(stamp of organisation)

On behalf of the data importer:

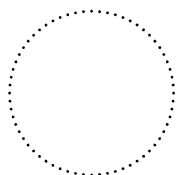
Name (written out in full):

Position:

Address:

Other information necessary in order for the contract to be binding (if any):

Signature



(stamp of organisation)

*Appendix 1***to the Standard Contractual Clauses**

This Appendix forms part of the Clauses and must be completed and signed by the parties

(*) The Member States may complete or specify, according to their national procedures, any additional necessary information to be contained in this Appendix)

Data exporter

The data exporter is (please specify briefly your activities relevant to the transfer):

.....

Data importer

The data importer is (please specify briefly activities relevant to the transfer):

.....

Data subjects

The personal data transferred concern the following categories of data subjects (please specify):

.....

Categories of data

The personal data transferred concern the following categories of data (please specify):

.....

Special categories of data (if appropriate)

The personal data transferred concern the following special categories of data (please specify):

.....

Processing operations

The personal data transferred will be subject to the following basic processing activities (please specify):

.....

DATA EXPORTER

DATA IMPORTER

Name:

Authorised signature

.....

*Appendix 2***to the Standard Contractual Clauses**

This Appendix forms part of the Clauses and must be completed and signed by the parties

Description of the technical and organisational security measures implemented by the data importer in accordance with Clauses 4(d) and 5(c) (or document/legislation attached):

.....

.....

.....

.....

COMMISSION DECISION

of 31 December 2001

amending Decision 2001/765/EC authorising Member States to permit temporarily the marketing of forest reproductive material not satisfying the requirements of Council Directives 66/404/EEC and 71/161/EEC

(notified under document number C(2001) 4769)

(Text with EEA relevance)

(2002/17/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 66/404/EEC of 14 June 1966 on the marketing of forest reproductive material ⁽¹⁾, as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 15(1) thereof,

Having regard to Council Directive 71/161/EEC of 30 March 1971 on external quality standards for forest reproductive material marketed within the Community ⁽²⁾, as last amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 15 thereof,

Whereas:

- (1) The production of reproductive material of the species indicated in Article 1 of this Decision is at present insufficient in Spain and France, with the result that their requirements for reproductive material of those species conforming to the provisions of Directives 66/404/EEC or 71/161/EEC cannot be met.
- (2) Other Member States and third countries are not in a position to supply sufficient reproductive material of the relevant species affording the same guarantees as Community reproductive material and conforming to the provisions of Directives 66/404/EEC or 71/161/EEC.
- (3) Accordingly, Spain and France have requested the Commission, on 17 September and 29 October 2001 respectively, pursuant to those Directives to authorise them to accept for marketing seed satisfying less stringent requirements than those laid down by those Directives.
- (4) In order to cover the shortage, the applicant Member States should therefore be authorised to permit, for a limited period, the marketing of seed of the relevant species which satisfies less stringent requirements.
- (5) For genetic reasons, the seed should be collected at places of origin within the natural range of the relevant species and the strictest possible guarantees should be given to ensure the identity of the seed. Furthermore,

seed should be marketed only if it is accompanied by a document bearing certain details of the seed in question.

- (6) Any Member State should furthermore be authorised to permit, in its territory, the marketing of seed which satisfies less stringent requirements in respect of provenance, if the marketing of such seed has been authorised in Spain or France under this Decision.
- (7) Commission Decision 2001/765/EC ⁽³⁾ should be amended accordingly.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 2001/765/EC is hereby amended as follows:

1. under the columns headed '*Abies alba*, kg, Provenance' in the entry in respect of Spain and are replaced by '70' and 'EC (E/OEP)';
2. under the columns headed '*Larix leptolepis*, kg, Provenance' in the entry in respect of Spain and are replaced by '15' and 'CN, JP';
3. under the columns headed '*Pinus strobus*, kg, Provenance' in the entry in respect of Spain and are replaced by '3' and 'US';
4. under the columns headed '*Picea sitchensis*, kg, Provenance' in the entry in respect of Spain and are replaced by '30' and 'US';
5. under the columns headed '*Pseudotsuga taxifolia*, kg, Provenance' in the entry in respect of Spain and are replaced by '280' and 'EC (E/OEP), US (California, Oregon, Washington)';
6. under the columns headed '*Larix decidua* Mill., Provenance' in the entry in respect of France, 'CZ (Sudeten), CZ and SK (origin Polish)' is replaced by 'CZ (Sudeten), SK (Sudeten) and PL (central Poland)';

⁽¹⁾ OJ 125, 11.7.1966, p. 2326/66.

⁽²⁾ OJ L 87, 17.4.1971, p. 14.

⁽³⁾ OJ L 288, 1.11.2001, p. 40.

7. under the columns headed '*Quercus pedunculata* Ehrh., kg, Provenance' in the entry in respect of France and are replaced by '1 500' and 'EC (F/OEP)';
8. under the columns headed '*Quercus sessiliflora* Sal., kg, Provenance' in the entry in respect of France and are replaced by '5 200' and 'EC (F/OEP)'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 31 December 2001.

For the Commission

David BYRNE

Member of the Commission

EUROPEAN ECONOMIC AREA

EFTA SURVEILLANCE AUTHORITY

RECOMMENDATION OF THE EFTA SURVEILLANCE AUTHORITY

No 228/01/COL

of 2 July 2001

on a coordinated programme for the official control of foodstuffs for 2001

THE EFTA SURVEILLANCE AUTHORITY,

Having regard to the EEA Agreement, and in particular Article 109 and Protocol 1 thereof,

Having regard to the Surveillance and Court Agreement, and in particular Article 5(2)(b) and Protocol 1 thereof,

Having regard to the Act referred to in point 50 of Chapter XII of Annex II to the EEA Agreement on the official control of foodstuffs (Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs) ⁽¹⁾, and in particular Article 14(3) thereof,

After consulting the EFTA Foodstuffs Committee assisting the EFTA Surveillance Authority,

Whereas:

- (1) It is necessary, with a view to the sound operation of the European Economic Area, to arrange for coordinated food inspection programmes within the EEA.
- (2) Such programmes place emphasis on compliance with the foodstuffs legislation in force under the EEA Agreement, the protection of public health, consumer interests and fair trade practices.
- (3) Article 3 of the Act referred to in point 54n of Chapter XII of Annex II to the EEA Agreement (Council Directive 93/99/EC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs) ⁽²⁾ requires the laboratories referred to in Article 7 of Directive 89/397 to comply with the criteria in the European Standard EN 45000 series. Only such laboratories may be considered suitable to carry out analyses within the coordinated programme of official controls.
- (4) The results from simultaneous implementation of national programmes and coordinated programmes can provide information and experience on which to base future control activities.
- (5) The European Commission, in its recommendation of 18 April 2001 concerning a coordinated programme for the official control of foodstuffs for 2001, has recommended the Member States of the European Union to apply a corresponding programme,

HEREBY RECOMMENDS THE EFTA STATES TO:

1. Carry out inspections and controls during 2001 including, where indicated, taking samples and analysing such samples in laboratories, with the aim of:
 - monitoring compliance with the EEA labelling rules concerning the Quantitative Ingredients Declaration (QUID);
 - assessing the bacteriological quality of smoked fish products.

⁽¹⁾ Hereinafter referred to as Directive 89/397.

⁽²⁾ Hereinafter referred to as Directive 93/99.

2. Although sampling and/or inspection rates have not been set in this Recommendation, ensure that they are sufficient to provide an overview of the subject under consideration.
3. Provide information as requested following the format of the record sheets provided in the Annex to this Recommendation to help enhance the comparability of results.
4. Ensure that foodstuffs submitted for analysis under this programme are submitted to laboratories complying with the provisions of Article 3 of Directive 93/99.

SCOPE AND METHODS:

A. Quantitative Ingredients Declaration (QUID)

1. Scope of the programme

A statement of the quantity of an ingredient or category of ingredients used in the manufacture or preparation of foodstuff provides the consumer with better information and helps ensuring fair trade. According to Article 7 of Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽¹⁾, a declaration of quantity is compulsory if ⁽²⁾:

- the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer; or
- the ingredient or category of ingredients concerned is emphasised on the labelling in words, picture or graphics; or
- the ingredient or category of ingredients concerned is essential to characterise a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance.

Products not labelled in accordance with the requirements of the abovementioned Directive should not be traded. However, products labelled before 14 February 2000 are permitted until the stocks are depleted. The aim of this element of the programme is to check the compliance of foodstuffs with the new provisions for Quantitative Ingredient Declaration.

2. Method

The examinations should concern, in particular, milk products (i.e. yoghurt, cheese, etc.), fruits juices, and dry biscuits. The competent authorities of the EFTA States should carry out inspections on premises of manufacturers or importers of foodstuffs in order to check compliance with the provisions for Quantitative Ingredients Declaration. Samples could be taken in addition to the inspections in order to determine the quantity of an ingredient or category of ingredients.

The results of the control should be recorded on the record sheet in Annex I.

B. Bacteriological quality of smoked fish

1. Scope of the programme

There is no Community legislation fixing specific microbiological standards for smoked fish. Experience shows that a considerable percentage of these products may be contaminated by pathogenic micro-organisms, including *Listeria monocytogenes*, and that the adoption of new techniques of production and processing may increase the risk of bacteriological contamination.

Listeria monocytogenes is known to cause foodborne outbreaks of *listeriosis* in humans, with potentially fatal consequences for susceptible categories of the population and therefore actions shall be taken to reduce the risk of human *listeriosis* from food consumption, in particular ready-to-eat food, such as smoked fish.

Certain measures may be adopted relating to the management of risk at the level of food business operators. Implementation of good hygiene practices and principles used to develop the HACCP (Hazard analysis and critical control points) system are important tools in ensuring food safety.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

⁽²⁾ The Directive is not yet incorporated into the EEA Agreement, but the provisions of the Directive are the same as in Directive 79/112/EEC, as amended, and as incorporated into the EEA Agreement.

The aim of this element of the programme is to assess the level of contamination on smoked fish, specifically on smoked salmon, in particular as concerns *Listeria monocytogenes* and indicator organisms for faecal contamination. The programme should allow the assessment of the bacteriological quality of these products and possible risks for human health.

2. Method

The examinations should concern refrigerated and pre-packaged salmon and other hot or cold smoked fish. The competent authorities of the EFTA States should take samples of products at retail level, possibly close to the date of minimum durability. In those countries with important volumes of production it is recommended to take samples also at the site of production (raw material and/or finished products). These samplings should be in the form of samples, from the same lot, comprising, when possible, five units of one hundred grams minimum each and the product should be kept in its original packaging. Products should be refrigerated as soon as samples have been taken and they should be sent immediately, in this state, to the laboratory.

The level of sampling is left to the judgement of the competent authorities of the EFTA States. In this regard, volume and characteristics of production, trade and consumption patterns are important factors to be taken into account.

Laboratories are allowed to use methods of their choice provided their level of performance matches the aims to be achieved. However, for detection and enumeration of *Listeria monocytogenes*, it is recommended to use the most recent version of standard EN/ISO 11290-1 and EN/ISO 11290-2. Additional equivalent methods recognised by competent authorities may also be used.

The results of the control should be recorded on the record sheet in Annex II. In the case of sampling at the site of production a separate record sheet should be used.

This Recommendation is addressed to Iceland, Liechtenstein and Norway.

Done at Brussels, 2 July 2001.

For the EFTA Surveillance Authority

Hannes HAFSTEIN

College Member

QUANTITATIVE INGREDIENTS DECLARATION

EFTA State:

Product identification	Number of product inspections	Number of infringements	Kind of infringement		Measures taken (number)							
			Not applying QUID	Giving wrong %	None	Verbal warning	Written warning	Improved in-house control required	Sales prohibition	Administrative penalty	Court action	Other

BACTERIOLOGICAL QUALITY OF SMOKED FISH (hot or cold smoked salmon, haddock, herrings and other smoked fish)

EFTA State:

Site of sampling: distribution/retail ☐ production/raw material ☐ production/finished product ☐

Microbiological criteria	Product identification	Number of samples	Analysis results (*)			Method used (ref.)	Measures taken (number)			
			S	A	U		None	Action as regard the products	Action as regard the establishment of production	Other
Aerobic micro-organisms 30 °C Smoked salmon, haddock and other smoked fish: n=5, c=2, m=10 ⁶ /g, M=10 ⁷ /g smoked herring' anchovies in brine: n=5, c=2, m=10 ⁵ /g, M=10 ⁶ /g										
Coagulase positive Staphylococcus Smoked salmon, haddock and other smoked fish: n=5, c=2, m=1/g, M=10/g sliced vacuum packed smoked salmon: n=5, c=2, m=10/g, M=100/g										
Escherichia coli n=5, c=1, m=10/g, M=100/g or faecal coliforms n=5, c=1, m=1/g, M=10/g										
			Absent in 25 g	≤ m	>					
Listeria monocytogenes (**) n=5, c=0, m=100/g										

n: Number of sample units.

c: Number of sample units between m and M.

(*) The batch is considered: satisfactory (S) if the value in all sample units are equal to or less than m; acceptable (A) if a maximum of c sample units are between m and M and all other sample units are equal to or less than m; unsatisfactory: (U) if one or more sample units have value over M or more than c sample units have value between m and M.

(**) Indicate the value obtained where enumeration was performed.

CORRIGENDA**Corrigendum to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices**

(Official Journal of the European Communities L 331 of 7 December 1998)

On page 13, in Article 21(1), first line:

for: '1. In Directive 89/392/EEC, ...'

read: '1. In Directive 98/37/EC, ...'

Corrigendum to Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

(Official Journal of the European Communities L 200 of 30 July 1999)

On page 33, in Annex III, Part A, point (a)l:

for: '... takes into account all the hazards that a substance may entail ...',

read: '... takes into account all the hazards that a preparation may entail ...'.

On page 43, in Annex V, Part A.8:

for: '... "Warning — substance not yet tested completely" ...',

read: '... "Caution — substance not yet fully tested" ...'.

Corrigendum to Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society

(Official Journal of the European Communities L 167 of 22 June 2001)

On page 16, in Article 5(1), introductory phrase:

for: '1. Temporary acts of reproduction referred to in Article 2, which are transient or incidental [and] an integral and essential part of a technological process and whose sole purpose is to enable:',

read: '1. Temporary acts of reproduction referred to in Article 2, which are transient or incidental, which are an integral and essential part of a technological process and the sole purpose of which is to enable:'.
