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Legislation

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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.

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I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 842/2001
of 30 April 2001
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 1 May 2001.

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

Done at Brussels, 30 April 2001.

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 30 April 2001 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	87,0
	204	79,3
	212	110,1
	999	92,1
0707 00 05	052	76,1
	628	135,4
	999	105,8
0709 90 70	052	84,3
	999	84,3
0805 10 10, 0805 10 30, 0805 10 50	052	70,7
	204	47,5
	212	58,0
	220	55,8
	600	67,8
	624	59,6
	999	59,9
0808 10 20, 0808 10 50, 0808 10 90	388	94,3
	400	83,6
	404	89,8
	508	80,9
	512	96,7
	524	90,2
	528	87,5
	720	119,9
	804	95,6
	999	93,2

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2032/2000 (OJ L 243, 28.9.2000, p. 14). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 843/2001
of 30 April 2001
altering the export refunds on white sugar and raw sugar exported in the natural state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2038/1999 of 13 September 1999 on the common organisation of the markets in the sugar sector [1], as amended by Commission Regulation (EC) No 1527/2000 [2], and in particular the third subparagraph of Article 18(5) thereof,

Whereas:

(1) The refunds on white sugar and raw sugar exported in the natural state were fixed by Commission Regulation (EC) No 757/2001 [3], as amended by Regulation (EC) No 794/2001 [4].

(2) It follows from applying the detailed rules contained in Regulation (EC) No 757/2001 to the information known to the Commission that the export refunds at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1(1)(a) of Regulation (EC) No 2038/1999, undenatured and exported in the natural state, as fixed in the Annex to Regulation (EC) No 757/2001 are hereby altered to the amounts shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 175, 14.7.2000, p. 59.
[3] OJ L 109, 19.4.2001, p. 50.
[4] OJ L 116, 26.4.2001, p. 12.

ANNEX

to the Commission Regulation of 30 April 2001 altering the export refunds on white sugar and raw sugar exported in its unaltered state

Product code	Destination	Unit of measurement	Amount of refund
1701 11 90 9100	A00	EUR/100 kg	37,92 (1)
1701 11 90 9910	A00	EUR/100 kg	34,87 (1)
1701 11 90 9950	A00	EUR/100 kg	(2)
1701 12 90 9100	A00	EUR/100 kg	37,92 (1)
1701 12 90 9910	A00	EUR/100 kg	34,87 (1)
1701 12 90 9950	A00	EUR/100 kg	(2)
1701 91 00 9000	A00	EUR/1 % of sucrose × net 100 kg of product	0,4122
1701 99 10 9100	A00	EUR/100 kg	41,22
1701 99 10 9910	A00	EUR/100 kg	41,22
1701 99 10 9950	A00	EUR/100 kg	41,22
1701 99 90 9100	A00	EUR/1 % of sucrose × net 100 kg of product	0,4122

(1) Applicable to raw sugar with a yield of 92 %; if the yield is other than 92 %, the refund applicable is calculated in accordance with the provisions of Article 19 (4) of Council Regulation (EC) No 2038/1999.

(2) Fixing suspended by Commission Regulation (EEC) No 2689/85 (OJ L 255, 26.9.1985, p. 12), as amended by Regulation (EEC) No 3251/85 (OJ L 309, 21.11.1985, p. 14).

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1) as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 2032/2000 (OJ L 243, 28.9.2000, p. 14).

COMMISSION REGULATION (EC) No 844/2001
of 30 April 2001
fixing the export refunds on syrups and certain other sugar products exported in the natural state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2038/1999 of 13 September 1999 on the common organisation of the markets in the sugar sector [1], as amended by Commission Regulation (EC) No 1527/2000 [2], and in particular the second subparagraph of Article 18(5) thereof,

Whereas:

(1) Article 18 of Regulation (EC) No 2038/1999 provides that the difference between quotations or prices on the world market for the products listed in Article 1(1)(d) of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) Article 3 of Commission Regulation (EC) No 2135/95 of 7 September 1995 laying down detailed rules of application for the grant of export refunds in the sugar sector [3], provides that the export refund on 100 kilograms of the products listed in Article 1(1)(d) of Regulation (EC) No 2038/1999 is equal to the basic amount multiplied by the sucrose content, including, where appropriate, other sugars expressed as sucrose; the sucrose content of the product in question is determined in accordance with Article 3 of Commission Regulation (EC) No 2135/95.

(3) Article 21(3) of Regulation (EC) No 2038/1999 provides that the basic amount of the refund on sorbose exported in the natural state must be equal to the basic amount of the refund less one-hundredth of the production refund applicable, pursuant to Council Regulation (EEC) No 1010/86 of 25 March 1986 laying down general rules for the production refund on sugar used in the chemical industry [4], as last amended by Commission Regulation (EC) No 1888/2000 [5], to the products listed in the Annex to the last mentioned Regulation;

(4) According to the terms of Article 21(1) of Regulation (EC) No 2038/1999, the basic amount of the refund on the other products listed in Article 1(1)(d) of the said Regulation exported in the natural state must be equal to one-hundredth of an amount which takes account, on the one hand, of the difference between the intervention price for white sugar for the Community areas without deficit for the month for which the basic amount is fixed and quotations or prices for white sugar on the world market and, on the other, of the need to establish a balance between the use of Community basic products in the manufacture of processed goods for export to third countries and the use of third country products brought in under inward processing arrangements.

(5) According to the terms of Article 21(4) of Regulation (EC) No 2038/1999, the application of the basic amount may be limited to some of the products listed in Article 1(1)(d) of the said Regulation.

(6) Article 18 of Regulation (EC) No 2038/1999 makes provision for setting refunds for export in the natural state of products referred to in Article 1(1)(f) and (g) and (h) of that Regulation; the refund must be fixed per 100 kilograms of dry matter, taking account of the export refund for products falling within CN code 1702 30 91 and for products referred to in Article 1(1)(d) of Regulation (EC) No 2038/1999 and of the economic aspects of the intended exports; in the case of the products referred to in the said Article (1)(f) and (g), the refund is to be granted only for products complying with the conditions in Article 5 of Regulation (EC) No 2135/95; for the products referred to in Article 1(1)(h), the refund shall be granted only for products complying with the conditions in Article 6 of Regulation (EC) No 2135/95.

(7) The refunds referred to above must be fixed every month; they may be altered in the intervening period.

(8) Application of these quotas results in fixing refunds for the products in question at the levels given in the Annex to this Regulation.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 175, 14.7.2000, p. 59.
[3] OJ L 214, 8.9.1995, p. 16.
[4] OJ L 94, 9.4.1986, p. 9.
[5] OJ L 227, 7.9.2000, p. 15.

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1(1)(d)(f)(g) and (h) of Regulation (EC) No 2038/1999, exported in the natural state, shall be set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

to the Commission Regulation of 30 April 2001 fixing the export refunds on syrups and certain other sugar products exported in the natural state

Product code	Destination	Unit of measurement	Amount of refund
1702 40 10 9100	A00	EUR/100 kg dry matter	41,22 (2)
1702 60 10 9000	A00	EUR/100 kg dry matter	41,22 (2)
1702 60 80 9100	A00	EUR/100 kg dry matter	78,32 (4)
1702 60 95 9000	A00	EUR/1 % sucrose × net 100 kg of product	0,4122 (1)
1702 90 30 9000	A00	EUR/100 kg dry matter	41,22 (2)
1702 90 60 9000	A00	EUR/1 % sucrose × net 100 kg of product	0,4122 (1)
1702 90 71 9000	A00	EUR/1 % sucrose × net 100 kg of product	0,4122 (1)
1702 90 99 9900	A00	EUR/1 % sucrose × net 100 kg of product	0,4122 (1) (3)
2106 90 30 9000	A00	EUR/100 kg dry matter	41,22 (2)
2106 90 59 9000	A00	EUR/1 % sucrose × net 100 kg of product	0,4122 (1)

(1) The basic amount is not applicable to syrups which are less than 85 % pure (Regulation (EC) No 2135/95). Sucrose content is determined in accordance with Article 3 of Regulation (EC) No 2135/95.

(2) Applicable only to products referred to in Article 5 of Regulation (EC) No 2135/95.

(3) The basic amount is not applicable to the product defined under point 2 of the Annex to Regulation (EEC) No 3513/92 (OJ L 355, 5.12.1992, p. 12).

(4) Applicable only to products defined under Article 6 of Regulation (EC) No 2135/95.

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1) as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 2032/2000 (OJ L 243, 28.9.2000, p. 14).

COMMISSION REGULATION (EC) No 845/2001
of 30 April 2001
fixing the import duties in the cereals sector

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],

Having regard to Commission Regulation (EC) No 1249/96 of 28 June 1996 laying down detailed rules for the application of Council Regulation (EEC) No 1766/92 as regards import duties in the cereals sector [3], as last amended by Regulation (EC) No 2235/2000 [4], and in particular Article 2 (1) thereof,

Whereas:

(1) Article 10 of Regulation (EEC) No 1766/92 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 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.

(2) Pursuant to Article 10 (3) of Regulation (EEC) No 1766/92, the cif import prices are calculated on the basis of the representative prices for the product in question on the world market.

(3) Regulation (EC) No 1249/96 lays down detailed rules for the application of Council Regulation (EEC) No 1766/92 as regards import duties in the cereals 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 for the reference exchange referred to in Annex II to Regulation (EC) No 1249/96 during the two weeks preceding the next periodical fixing.

(5) In order to allow the import duty system to function normally, the representative market rates recorded during a reference period should be used for calculating the duties.

(6) Application of Regulation (EC) No 1249/96 results in import duties being fixed as set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The import duties in the cereals sector referred to in Article 10 (2) of Regulation (EEC) No 1766/92 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 1 May 2001.

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

Done at Brussels, 30 April 2001.

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 161, 29.6.1996, p. 125.
[4] OJ L 256, 10.10.2000, p. 13.

ANNEX I

Import duties for the products covered by Article 10(2) of Regulation (EEC) No 1766/92

CN code	Description	Import duty by land inland waterway or sea from Mediterranean, the Black Sea or Baltic Sea ports (EUR/tonne)	Import duty by air or by sea from other ports (2) (EUR/tonne)
1001 10 00	Durum wheat high quality	0,00	0,00
	medium quality (1)	0,00	0,00
1001 90 91	Common wheat seed	3,53	0,00
1001 90 99	Common high quality wheat other than for sowing (3)	3,53	0,00
	medium quality	22,23	12,23
	low quality	56,06	46,06
1002 00 00	Rye	47,67	37,67
1003 00 10	Barley, seed	47,67	37,67
1003 00 90	Barley, other (3)	47,67	37,67
1005 10 90	Maize seed other than hybrid	73,86	63,86
1005 90 00	Maize other than seed (3)	73,86	63,86
1007 00 90	Grain sorghum other than hybrids for sowing	47,67	37,67

(1) In the case of durum wheat not meeting the minimum quality requirements for durum wheat of medium quality, referred to in Annex I to Regulation (EC) No 1249/96, the duty applicable is that fixed for low-quality common wheat.

(2) For goods arriving in the Community via the Atlantic Ocean or via the Suez Canal (Article 2(4) of Regulation (EC) No 1249/96), the importer may benefit from a reduction in the duty of:

— EUR 3 per tonne, where the port of unloading is on the Mediterranean Sea, or

— EUR 2 per tonne, where the port of unloading is in Ireland, the United Kingdom, Denmark, Sweden, Finland or the Atlantic Coasts of the Iberian Peninsula.

(3) The importer may benefit from a flat-rate reduction of EUR 24 or 8 per tonne, where the conditions laid down in Article 2(5) of Regulation (EC) No 1249/96 are met.

ANNEX II

Factors for calculating duties

(period from 16 April to 27 April 2001)

1. Averages over the two-week period preceding the day of fixing:

Exchange quotations	Minneapolis	Kansas City	Chicago	Chicago	Minneapolis	Minneapolis	Minneapolis
Product (% proteins at 12 % humidity)	HRS2. 14 %	HRW2. 11,5 %	SRW2	YC3	HAD2	Medium quality (*)	US barley 2
Quotation (EUR/t)	134,84	132,19	109,98	89,15	196,04 (**)	186,04 (**)	114,14 (**)
Gulf premium (EUR/t)	—	17,76	6,13	9,16	—	—	—
Great Lakes premium (EUR/t)	23,44	—	—	—	—	—	—

(*) A discount of 10 EUR/t (Article 4(1) of Regulation (EC) No 1249/96).
(**) Fob Duluth.

2. Freight/cost: Gulf of Mexico — Rotterdam: 19,57 EUR/t; Great Lakes — Rotterdam: 29,93 EUR/t.

3. Subsidy within the meaning of the third paragraph of Article 4(2) of Regulation (EC) No 1249/96: 0,00 EUR/t (HRW2)
0,00 EUR/t (SRW2).

COMMISSION REGULATION (EC) No 846/2001
of 30 April 2001
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 1667/2000 [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; whereas, 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; whereas 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 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 329, 30.12.1995, p. 18.
[2] OJ L 193, 29.7.2000, p. 3.
[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 [5]				
	Third countries (except ACP and Bangladesh) [3]	ACP [1] [2] [3]	Bangladesh [4]	Basmati India and Pakistan [6]	Egypt [8]
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	264,00	88,06	127,66		198,00
1006 20 13	264,00	88,06	127,66		198,00
1006 20 15	264,00	88,06	127,66		198,00
1006 20 17	216,55	71,45	103,93	0,00	162,41
1006 20 92	264,00	88,06	127,66		198,00
1006 20 94	264,00	88,06	127,66		198,00
1006 20 96	264,00	88,06	127,66		198,00
1006 20 98	216,55	71,45	103,93	0,00	162,41
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)	216,55	416,00	264,00	416,00	(1)
2. Elements of calculation:						
(a) Arag cif price (EUR/tonne)	—	327,68	249,16	242,23	251,13	—
(b) fob price (EUR/tonne)	—	—	—	208,43	217,33	—
(c) Sea freight (EUR/tonne)	—	—	—	33,80	33,80	—
(d) Source	—	USDA and operators	USDA and operators	Operators	Operators	—

(1) Duties fixed in the Common Customs Tariff.

COMMISSION REGULATION (EC) No 847/2001

of 30 April 2001

fixing the intervention thresholds for cauliflowers, peaches, nectarines and table grapes for the 2001/02 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables [1], as last amended by Commission Regulation (EC) No 718/2001 [2], and in particular Article 27(1) and (2) thereof,

Whereas:

(1) Article 27(1) of Regulation (EC) No 2200/96 provides for an intervention threshold to be fixed if the market in a product listed in Annex II thereto is suffering or at risk of suffering from imbalances giving or liable to give rise to too large a volume of withdrawals. Such a development might cause budget problems for the Community.

(2) Commission Regulation (EC) No 931/2000 [3] fixes intervention thresholds for cauliflowers, peaches, nectarines and table grapes for the 2000/01 marketing year. The conditions laid down in the abovementioned Article 27 are still met for those products and consequently intervention thresholds should be fixed for cauliflowers, peaches, nectarines and table grapes for the 2001/02 marketing year.

(3) The intervention threshold for each of those products should be fixed on the basis of a percentage of the average production intended for consumption in the natural state over the last five marketing years for which data are available. The period to be taken into account for assessing an overrun of the intervention threshold must also be established for each product.

(4) Pursuant to the abovementioned Article 27, an overrun of the intervention threshold gives rise to a reduction in the Community withdrawal compensation in the marketing year following the overrun. The implications of this overrun for each of the products in question should be determined and a reduction proportional to the size of the overrun should be fixed.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Fresh Fruit and Vegetables,

HAS ADOPTED THIS REGULATION:

Article 1

The following intervention thresholds shall apply for the 2001/02 marketing year:

cauliflowers:	112 200 tonnes
peaches:	232 000 tonnes
nectarines:	85 600 tonnes
table grapes:	160 900 tonnes.

Article 2

Overruns of the intervention thresholds for the products listed in Article 1 shall be assessed on the basis of withdrawals carried out in the period 1 March 2001 to 28 February 2002.

Article 3

If the quantity of one of the products listed in Article 1 withdrawn in the period laid down in Article 2 exceeds the threshold fixed in Article 1, the Community withdrawal compensation fixed pursuant to Article 26 of Regulation (EC) No 2200/96 shall be reduced in the following marketing year in proportion to the size of the overrun based on the production used to calculate the threshold.

Article 4

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, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 297, 21.11.1996, p. 1.
[2] OJ L 100, 11.4.2001, p. 12.
[3] OJ L 108, 5.5.2000, p. 7.

COMMISSION REGULATION (EC) No 848/2001

of 30 April 2001

fixing the storage aid for unprocessed dried grapes and unprocessed dried figs from the 2000/01 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2201/96 of 28 October 1996 on the common organisation of the market in processed fruit and vegetable products [1], as last amended by Regulation (EC) No 2699/2000 [2], and in particular Article 9(8) thereof,

Whereas:

(1) Article 9(4) of Regulation (EC) No 2201/96 provides for aid to be granted to storage agencies for the quantities of sultanas, currants and dried figs that they buy in and for the actual duration of storage.

(2) Article 2 of Commission Regulation (EC) No 504/97 of 19 March 1997 laying down detailed rules for the application of Council Regulation (EC) No 2201/96 as regards the system of production aid for products processed from fruit and vegetables [3], as last amended by Regulation (EC) No 1607/1999 [4], lays down the dates of the marketing years.

(3) The storage aid for unprocessed dried grapes and unprocessed dried figs from the 2000/01 marketing year should be fixed and, to that end, account should be taken of Article 7 of Commission Regulation (EC) No 1622/1999 of 23 July 1999 laying down detailed rules for applying Council Regulation (EC) No 2201/96 as regards the scheme for the storage of unprocessed dried grapes and unprocessed dried figs [5] and of the fact that the storage aid is to be calculated on the basis of the technical cost of storage and of financing the buying-in price paid for the products.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Processed Fruit and Vegetables,

HAS ADOPTED THIS REGULATION:

Article 1

For products from the 2000/01 marketing year, the storage aid provided for in Article 9(4) of Regulation (EC) No 2201/96 shall be:

(a) EUR 0,1446 per day and per tonne net weight until 28 February 2002 and EUR 0,1185 per day and per tonne net weight from 1 March 2002 for dried grapes;

(b) EUR 0,1328 per day and per tonne net weight for dried figs.

Article 2

This Regulation shall enter into force on the third day following 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, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 297, 21.11.1996, p. 29.
[2] OJ L 311, 12.12.2000, p. 9.
[3] OJ L 78, 20.3.1997, p. 14.
[4] OJ L 190, 23.7.1999, p. 11.
[5] OJ L 192, 24.7.1999, p. 33.

COMMISSION REGULATION (EC) No 849/2001

of 30 April 2001

reducing the Community withdrawal compensation for peaches and nectarines for the 2001/02 marketing year as a result of overruns of the intervention thresholds fixed for the 2000/01 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables [1], as last amended by Commission Regulation (EC) No 718/2001 [2], and in particular Article 27(1) and (2) thereof,

Whereas:

(1) Commission Regulation (EC) No 931/2000 [3] fixes the intervention thresholds for the 2000/01 marketing year at 238 200 tonnes for peaches and 83 200 tonnes for nectarines. Under Article 3 of that Regulation, if the quantity of peaches or nectarines withdrawn in the period between 1 March 2000 and 28 February 2001 exceeds the threshold fixed, the Community withdrawal compensation laid down in Annex V to Regulation (EC) No 2200/96 for the 2001/02 marketing year is to be reduced in proportion to the size of the overrun based on the production used to calculate the relevant threshold.

(2) The information supplied by the Member States indicates that 251 515 tonnes of peaches and 117 961 tonnes of nectarines were withdrawn in the 2000/01 marketing year.

(3) Consequently, the Community withdrawal compensation set by Regulation (EC) No 2200/96 for the 2001/02 marketing year must be reduced by 0,57 % for peaches and 4,18 % for nectarines.

(4) Article 3 of Regulation (EC) No 931/2000 lays down that the consequences of an overrun of the threshold are to apply in the following marketing year. The reduction in the Community withdrawal compensation for peaches and nectarines should thereofe apply in the 2001/02 marketing year.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Fresh Fruit and Vegetables,

HAS ADOPTED THIS REGULATION:

Article 1

The Community withdrawal compensation for the 2001/02 marketing year shall be:

— EUR 11,65 per 100 kilograms net for peaches,

— EUR 13,33 per 100 kilograms net for nectarines.

Article 2

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, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 297, 21.11.1996, p. 1.
[2] OJ L 100, 11.4.2001, p. 12.
[3] OJ L 108, 5.5.2000, p. 7.

COMMISSION REGULATION (EC) No 850/2001

of 30 April 2001

fixing the rates of refunds applicable to certain products from the sugar sector exported in the form of goods not covered by Annex I to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2038/1999 of 13 September 1999 on the common organisation of the market in sugar [1], as amended by Commission Regulation (EC) No 1527/2000 [2], and in particular Article 18(5)(a) and (15),

Whereas:

(1) Article 18(1) and (2) of Regulation (EEC) No 1785/81 provides that the differences between the prices in international trade for the products listed in Article 1(1)(a), (c), (d), (f), (g) and (h) of that Regulation and prices within the Community may be covered by an export refund where these products are exported in the form of goods listed in the Annex to that Regulation. Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty and the criteria for fixing the amount of such refunds [3], as amended by Regulation (EC) No 2390/2000 [4], specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex I to Regulation (EC) No 2038/1999.

(2) In accordance with Article 4(1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month.

(3) Article 18(3) of Regulation (EC) No 2038/1999 and Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lay down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.

(4) The refunds fixed under this Regulation may be fixed in advance as the market situation over the next few months cannot be established at the moment.

(5) The commitments entered into with regard to refunds which may be granted for the export of agricultural products contained in goods not covered by Annex I to the Treaty may be jeopardized by the fixing in advance of high refund rates. It is therefore necessary to take precautionary measures in such situations without, however, preventing the conclusion of long-term contracts. The fixing of a specific refund rate for the advance fixing of refunds is a measure which enables these various objectives to be met.

(6) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products appearing in Annex A to Regulation (EC) No 1520/2000 and listed in Article 1(1) and (2) of Regulation (EC) No 2038/1999, exported in the form of goods listed in Annex I to Regulation (EC) No 2038/1999, are fixed as shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Erkki LIIKANEN

Member of the Commission

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[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 175, 14.7.2000, p. 59.
[3] OJ L 177, 15.7.2000, p. 1.
[4] OJ L 276, 28.10.2000, p. 3.

ANNEX

to the Commission Regulation of 30 April 2001 fixing the rates of the refunds applicable to certain products in the sugar sector exported in the form of goods not covered by Annex I to the Treaty

Product	Rate of refund in EUR/100 kg	
	In case of advance fixing of refunds	Other
White sugar:	41,22	41,22

COMMISSION REGULATION (EC) No 851/2001

of 30 April 2001

fixing the rates of the refunds applicable to certain milk products exported in the form of goods not covered by Annex I to the Treaty

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 15 May 1999 on the common organisation of the market in milk and milk products [1], as last amended by Regulation (EC) No 1670/2000 [2], and in particular Article 31(3) thereof,

Whereas:

(1) Article 31(1) of Regulation (EC) No 1255/1999 provides that the difference between prices in international trade for the products listed in Article 1 (a), (b), (c), (d), (e), and (g) of that Regulation and prices within the Community may be covered by an export refund. Whereas Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and criteria for fixing the amount of such refunds [3], as amended by Regulation (EC) No 2390/2000 [4], specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in the Annex to Regulation (EC) No 1255/1999.

(2) In accordance with the first subparagraph of Article 4 (1) of Regulation (EC) No 1520/2000, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month.

(3) Article 4(3) of Regulation (EC) No 1520/2000 provides that, when the rate of the refund is being fixed, account should be taken, where necessary, of production refunds, aids or other measures having equivalent effect applicable in all Member States in accordance with the Regulation on the common organisation of the market in the product in question to the basic products listed in Annex A to that Regulation or to assimilated products.

(4) Article 11(1) of Regulation (EC) No 1255/1999 provides for the payment of aid for Community-produced skimmed milk processed into casein if such milk and the casein manufactured from it fulfil certain conditions.

(5) 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 [5], as last amended by Regulation (EC) No 635/2000 [6], lays down that butter and cream at reduced prices should be made available to industries which manufacture certain goods.

(6) It is necessary to ensure continuity of strict management taking account of expenditure forecasts and funds available in the budget.

(7) 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

1. The rates of the refunds applicable to the basic products appearing in Annex A to Regulation (EC) No 1520/2000 and listed in Article 1 of Regulation (EC) No 1255/1999, exported in the form of goods listed in the Annex to Regulation (EC) No 1255/1999, are hereby fixed as shown in the Annex to this Regulation.

2. No rates of refund are fixed for any of the products referred to in the preceding paragraph which are not listed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 1 May 2001.

[1] OJ L 160, 26.6.1999, p. 48.
[2] OJ L 193, 29.7.2000, p. 10.
[3] OJ L 177, 15.7.2000, p. 1.
[4] OJ L 276, 28.10.2000, p. 3.
[5] OJ L 350, 20.12.1997, p. 3.
[6] OJ L 76, 25.3.2000, p. 9.

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

Done at Brussels, 30 April 2001.

For the Commission
Erkki LIIKANEN
Member of the Commission

ANNEX

to the Commission Regulation of 30 April 2001 fixing the rates of the refunds applicable to certain milk products exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)

CN code	Description	Rate of refund
ex 0402 10 19	Powdered milk, in granules or other solid forms, not containing added sugar or other sweetening matter, with a fat content not exceeding 1,5 % by weight (PG 2):	
	(a) On exportation of goods of CN code 3501	—
	(b) On exportation of other goods	15,00
ex 0402 21 19	Powdered milk, in granules or other solid forms, not containing added sugar or other sweetening matter, with a fat content of 26 % by weight (PG 3):	
	(a) Where goods incorporating, in the form of products assimilated to PG 3, reduced-price butter or cream obtained pursuant to Regulation (EC) No 2571/97 are exported	34,88
	(b) On exportation of other goods	68,00
ex 0405 10	Butter, with a fat content by weight of 82 % (PG 6):	
	(a) Where goods containing reduced-price butter or cream which have been manufactured in accordance with the conditions provided for in Regulation (EC) No 2571/97 are exported	75,00
	(b) On exportation of goods of CN code 2106 90 98 containing 40 % or more by weight of milk fat	177,25
	(c) On exportation of other goods	170,00

COMMISSION REGULATION (EC) No 852/2001

of 30 April 2001

setting the amounts of aid for the supply of rice products from the Community to the Azores and Madeira

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1600/92 of 15 June 1992 introducing specific measures in respect of certain agricultural products for the benefit of the Azores and Madeira [1], as last amended by Regulation (EC) No 2826/2000 [2], and in particular Article 10 thereof,

Whereas:

(1) Pursuant to Article 10 of Regulation (EEC) No 1600/92, the requirements of the Azores and Madeira for rice are to be covered in terms of quantity, price and quality by the mobilization, on disposal terms equivalent to exemption from the levy, of Community rice, which involves the grant of an aid for supplies of Community origin. This aid is to be fixed with particular reference to the costs of the various sources of supply and in particular is to be based on the prices applied to exports to third countries.

(2) Commission Regulation (EEC) No 1696/92 [3], as last amended by Regulation (EEC) No 2596/93 [4], lays down common detailed rules for implementation of the specific arrangements for the supply of certain agricultural products, including rice, to the Azores and Madeira. Commission Regulation (EEC) No 1983/92 of 16 July 1992 laying down detailed rules for implementation of the specific arrangements for the supply of rice products to the Azores and Madeira and establishing the forecast supply balance for these products [5], as last amended by Regulation (EC) No 1683/94 [6], lays down detailed rules which complement or derogate from the provisions of the aforementioned Regulation.

(3) As a result of the application of these detailed rules to the current market situation in the rice sector, and in particular to the rates of prices for these products in the European part of the Community and on the world market the aid for supply to the Azores and Madeira should be set at the amounts given in the Annex.

(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

Pursuant to Article 10 of Regulation (EEC) No 1600/92, the amount of aid for the supply of rice of Community origin under the specific arrangements for the supply of the Azores and Madeira shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 173, 27.6.1992, p. 1.
[2] OJ L 328, 23.12.2000, p. 2.
[3] OJ L 179, 1.7.1992, p. 6.
[4] OJ L 238, 23.9.1993, p. 24.
[5] OJ L 198, 17.7.1992, p. 37.
[6] OJ L 178, 12.7.1994, p. 53.

ANNEX

to the Commission Regulation of 30 April 2001 setting the amounts of aid for the supply of rice products from the Community to the Azores and Madeira

(EUR/t)

Product (CN code)	Amount of aid	
	Destination	
	Azores	Madeira
Milled rice (1006 30)	246,00	246,00

COMMISSION REGULATION (EC) No 853/2001

of 30 April 2001

setting the amounts of aid for the supply of rice products from the Community to the Canary Islands

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1601/92 of 15 June 1992 introducing specific measures in respect of certain agricultural products for the benefit of the Canary Islands [1], as last amended by Regulation (EC) No 2826/2000 [2], and in particular Article 3 thereof,

Whereas:

(1) Pursuant to Article 3 of Regulation (EEC) No 1601/92, the requirements of the Canary Islands for rice are to be covered in terms of quantity, price and quality by the mobilisation, on disposal terms equivalent to exemption from the levy, of Community rice, which involves the grant of an aid for supplies of Community origin. This aid is to be fixed with particular reference to the costs of the various sources of supply and in particular is to be based on the prices applied to exports to third countries.

(2) Commission Regulation (EC) No 2790/94 [3], as last amended by Regulation (EC) No 1620/1999 [4], lays down common detailed rules for implementation of the specific arrangements for the supply of certain agricultural products, including rice, to the Canary Islands.

(3) As a result of the application of these detailed rules to the current market situation in the rice sector, and in particular to the rates of prices for these products in the European part of the Community and on the world market, the aid for supply to the Canary Islands should be set at the amounts given in the Annex.

(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

Pursuant to Article 3 of Regulation (EEC) No 1601/92, the amount of aid for the supply of rice of Community origin under the specific arrangements for the supply of the Canary Islands shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 173, 27.6.1992, p. 13.
[2] OJ L 328, 23.12.2000, p. 2.
[3] OJ L 296, 17.11.1994, p. 23.
[4] OJ L 192, 24.7.1999, p. 19.

ANNEX

to the Commission Regulation of 30 April 2001 setting the amounts of aid for the supply of rice products from the Community to the Canary Islands

(EUR/t)

Product (CN code)	Amount of aid
Milled rice (1006 30)	246,00
Broken rice (1006 40)	54,00

COMMISSION REGULATION (EC) No 854/2001

of 30 April 2001

fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [1], as last amended by Regulation (EC) No 1300/97 [2], and in particular Article 5(2) (a) thereof,

Whereas:

Pursuant to Article 2 (2) and Article 3 of abovementioned Regulation (EEC) No 4088/87, Community import and producer prices are fixed each fortnight for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses and apply for two-weekly periods. Pursuant to Article 1b of Commission Regulation (EEC) No 700/88 of 17 March 1988 laying down detailed rules for the application of the arrangements for the import into the Community of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [3], as last amended by Regulation (EC) No 2062/97 [4], those prices are determined for fortnightly periods on the basis of weighted prices provided by the Member States. Those prices should be fixed immediately so the customs duties applicable can be determined. To that end, provision should be made for this Regulation to enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

The Community producer and import prices for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses as referred to in Article 1b of Regulation (EEC) No 700/88 for a fortnightly period shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 1 May 2001.

It shall apply from 2 to 15 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 382, 31.12.1987, p. 22.
[2] OJ L 177, 5.7.1997, p. 1.
[3] OJ L 72, 18.3.1988, p. 16.
[4] OJ L 289, 22.10.1997, p. 1.

ANNEX

to the Commission Regulation of 30 April 2001 fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

(EUR/100 pieces)

Period: from 2 to 15 May 2001

Community producer price	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
	15,72	11,04	25,59	14,76
Community import prices	**Uniflorous (bloom) carnations**	**Multiflorous (spray) carnations**	**Large-flowered roses**	**Small-flowered roses**
Israel	10,30	—	10,53	11,60
Morocco	14,60	14,10	—	—
Cyprus	—	—	—	—
Jordan	—	—	—	—
West Bank and Gaza Strip	—	—	—	—

COMMISSION REGULATION (EC) No 855/2001

of 30 April 2001

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 2038/1999 of 13 September 1999 on the common organisation of the markets in the sugar sector [1], as amended by Commission Regulation (EC) No 1527/2000 [2],

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 [3], as last amended by Regulation (EC) No 624/98 [4], 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 1411/2000 [5], as last amended by Regulation (EC) No 740/2001 [6].

(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 1 May 2001.

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

Done at Brussels, 30 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 252, 25.9.1999, p. 1.
[2] OJ L 175, 14.7.2000, p. 59.
[3] OJ L 141, 24.6.1995, p. 16.
[4] OJ L 85, 20.3.1998, p. 5.
[5] OJ L 161, 1.7.2000, p. 22.
[6] OJ L 102, 12.4.2001, p. 53.

ANNEX

to the Commission Regulation of 30 April 2001 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)	25,80	3,55
1701 11 90 (1)	25,80	8,63
1701 12 10 (1)	25,80	3,41
1701 12 90 (1)	25,80	8,20
1701 91 00 (2)	27,14	11,66
1701 99 10 (2)	27,14	7,14
1701 99 90 (2)	27,14	7,14
1702 90 99 (3)	0,27	0,38

(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 856/2001
of 30 April 2001
altering the corrective amount applicable to the refund on malt

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 13(8) thereof,

Whereas:

(1) The corrective amount applicable to the refund on malt was fixed by Commission Regulation (EC) No 624/2001 [3].

(2) On the basis of today's cif prices and cif forward delivery prices, taking foreseeable developments on the market into account, the corrective amount at present applicable to the refund on malt should be altered,

HAS ADOPTED THIS REGULATION:

Article 1

The corrective amount referred to in Article 13(4) of Regulation (EEC) No 1766/92 which is applicable to the export refunds fixed in advance in respect of the products referred to is hereby altered to the amount set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

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 90, 30.3.2001, p. 39.

ANNEX

to the Commission Regulation of 30 April 2001 altering the corrective amount applicable to the refund on malt

(EUR/t)

Product code	Destination	Current 5	1st period 6	2nd period 7	3rd period 8	4th period 9	5th period 10
1107 10 11 9000	A00	0	0	0	0	0	0
1107 10 19 9000	A00	0	−1,27	−2,54	−3,81	−5,08	—
1107 10 91 9000	A00	0	0	0	0	0	0
1107 10 99 9000	A00	0	−1,27	−2,54	−3,81	−5,08	—
1107 20 00 9000	A00	0	−1,49	−2,98	−4,47	−5,96	—

(EUR/t)

Product code	Destination	6th period 11	7th period 12	8th period 1	9th period 2	10th period 3	11th period 4
1107 10 11 9000	A00	0	0	0	0	0	0
1107 10 19 9000	A00	—	—	—	—	—	—
1107 10 91 9000	A00	0	0	0	0	0	0
1107 10 99 9000	A00	—	—	—	—	—	—
1107 20 00 9000	A00	—	—	—	—	—	—

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1) as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 2543/1999 (OJ L 307, 2.12.1999, p. 46).

COMMISSION REGULATION (EC) No 857/2001
of 30 April 2001
amending the corrective amount applicable to the refund on cereals

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 13(8) thereof,

Whereas:

(1) The corrective amount applicable to the refund on cereals was fixed by Commission Regulation (EC) No 623/2001 [3], as amended by Regulation (EC) No 803/2001 [4].

(2) On the basis of today's cif prices and cif forward delivery prices, taking foreseeable developments on the market into account, the corrective amount at present applicable to the refund on cereals should be altered.

(3) The corrective amount must be fixed according to the same procedure as the refund. It may be altered in the period between fixings,

HAS ADOPTED THIS REGULATION:

Article 1

The corrective amount referred to in Article 1(1)(a), (b) and (c) of Regulation (EEC) No 1766/92 which is applicable to the export refunds fixed in advance in respect of the products referred to, except for malt, is hereby altered to the amounts set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 May 2001.

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

Done at Brussels, 30 April 2001.

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 90, 30.3.2001, p. 37.
[4] OJ L 116, 26.4.2001, p. 30.

ANNEX

to the Commission Regulation of 30 April 2001 amending the corrective amount applicable to the refund on cereals

(EUR/t)

Product code	Destination	Current 5	1st period 6	2nd period 7	3rd period 8	4th period 9	5th period 10	6th period 11
1001 10 00 9200	—	—	—	—	—	—	—	—
1001 10 00 9400	—	—	—	—	—	—	—	—
1001 90 91 9000	—	—	—	—	—	—	—	—
1001 90 99 9000	C01	0	0,00	—	–0,93	–1,86	—	—
1002 00 00 9000	A00	0	0,00	–35,00	–35,00	–35,00	—	—
1003 00 10 9000	—	—	—	—	—	—	—	—
1003 00 90 9000	A00	0	0,00	0,00	–0,93	–1,86	—	—
1004 00 00 9200	—	—	—	—	—	—	—	—
1004 00 00 9400	A00	0	0,00	–35,00	–35,00	–35,00	—	—
1005 10 90 9000	—	—	—	—	—	—	—	—
1005 90 00 9000	A00	0	–1,00	–2,00	–3,00	–3,00	—	—
1007 00 90 9000	—	—	—	—	—	—	—	—
1008 20 00 9000	—	—	—	—	—	—	—	—
1101 00 11 9000	—	—	—	—	—	—	—	—
1101 00 15 9100	C01	0	0,00	–10,00	–10,00	–10,00	—	—
1101 00 15 9130	C01	0	0,00	–10,00	–10,00	–10,00	—	—
1101 00 15 9150	C01	0	0,00	–10,00	–10,00	–10,00	—	—
1101 00 15 9170	C01	0	0,00	–10,00	–10,00	–10,00	—	—
1101 00 15 9180	C01	0	0,00	–10,00	–10,00	–10,00	—	—
1101 00 15 9190	—	—	—	—	—	—	—	—
1101 00 90 9000	—	—	—	—	—	—	—	—
1102 10 00 9500	C01	0	0,00	–50,00	–50,00	–50,00	—	—
1102 10 00 9700	C01	0	0,00	–40,00	–40,00	–40,00	—	—
1102 10 00 9900	—	—	—	—	—	—	—	—
1103 11 10 9200	A00	0	0,00	0,00	–1,40	–2,80	—	—
1103 11 10 9400	A00	0	0,00	0,00	–1,25	–2,50	—	—
1103 11 10 9900	—	—	—	—	—	—	—	—
1103 11 90 9200	A00	0	0,00	0,00	–1,27	–2,54	—	—
1103 11 90 9800	—	—	—	—	—	—	—	—

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1) as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 2032/2000 (OJ L 243, 28.9.2000, p. 14).

The other destinations are as follows:

C01 All destinations except for Poland.

DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 4 April 2001

on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

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 [1],

Having regard to the opinion of the Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products [4] requires that applications for authorisation to place a medicinal product on the market should be accompanied by a dossier containing particulars and documents relating to the results of tests and clinical trials carried out on the product. Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of medicinal products [5] lays down uniform rules on the compilation of dossiers including their presentation.

(2) The accepted basis for the conduct of clinical trials in humans is founded in the protection of human rights and the dignity of the human being with regard to the application of biology and medicine, as for instance reflected in the 1996 version of the Helsinki Declaration. The clinical trial subject's protection is safeguarded through risk assessment based on the results of toxicological experiments prior to any clinical trial, screening by ethics committees and Member States' competent authorities, and rules on the protection of personal data.

(3) Persons who are incapable of giving legal consent to clinical trials should be given special protection. It is incumbent on the Member States to lay down rules to this effect. Such persons may not be included in clinical trials if the same results can be obtained using persons capable of giving consent. Normally these persons should be included in clinical trials only when there are grounds for expecting that the administering of the medicinal product would be of direct benefit to the patient, thereby outweighing the risks. However, there is a need for clinical trials involving children to improve the treatment available to them. Children represent a vulnerable population with developmental, physiological and psychological differences from adults, which make age- and development- related research important for their benefit. Medicinal products, including vaccines, for children need to be tested scientifically before widespread use. This can only be achieved by ensuring that medicinal products which are likely to be of significant clinical value for children are fully studied. The clinical trials required for this purpose should be carried out under conditions affording the best possible protection for the subjects. Criteria for the protection of children in clinical trials therefore need to be laid down.

(4) In the case of other persons incapable of giving their consent, such as persons with dementia, psychiatric patients, etc., inclusion in clinical trials in such cases should be on an even more restrictive basis. Medicinal products for trial may be administered to all such individuals only when there are grounds for assuming that the direct benefit to the patient outweighs the risks. Moreover, in such cases the written consent of the patient's legal representative, given in cooperation with the treating doctor, is necessary before participation in any such clinical trial.

(5) The notion of legal representative refers back to existing national law and consequently may include natural or legal persons, an authority and/or a body provided for by national law.

(6) In order to achieve optimum protection of health, obsolete or repetitive tests will not be carried out, whether within the Community or in third countries. The harmonisation of technical requirements for the development

[1] OJ C 306, 8.10.1997, p. 9 and OJ C 161, 8.6.1999, p. 5.
[2] OJ C 95, 30.3.1998, p. 1.
[3] Opinion of the European Parliament of 17 November 1998 (OJ C 379, 7. 12. 1998, p. 27). Council Common Position of 20 July 2000 (OJ C 300, 20.10.2000, p. 32) and Decision of the European Parliament of 12 December 2000. Council Decision of 26 February 2001.
[4] OJ 22, 9.2.1965, p. 1/65. Directive as last amended by Council Directive 93/39/EEC (OJ L 214, 24.8.1993, p. 22).
[5] OJ L 147, 9.6.1975, p. 1. Directive as last amended by Commission Directive 1999/83/EC (OJ L 243, 15.9.1999, p. 9).

of medicinal products should therefore be pursued through the appropriate fora, in particular the International Conference on Harmonisation.

(7) For medicinal products falling within the scope of Part A of the Annex to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products [1], which include products intended for gene therapy or cell therapy, prior scientific evaluation by the European Agency for the Evaluation of Medicinal Products (hereinafter referred to as the 'Agency'), assisted by the Committee for Proprietary Medicinal Products, is mandatory before the Commission grants marketing authorisation. In the course of this evaluation, the said Committee may request full details of the results of the clinical trials on which the application for marketing authorisation is based and, consequently, on the manner in which these trials were conducted and the same Committee may go so far as to require the applicant for such authorisation to conduct further clinical trials. Provision must therefore be made to allow the Agency to have full information on the conduct of any clinical trial for such medicinal products.

(8) A single opinion for each Member State concerned reduces delay in the commencement of a trial without jeopardising the well-being of the people participating in the trial or excluding the possibility of rejecting it in specific sites.

(9) Information on the content, commencement and termination of a clinical trial should be available to the Member States where the trial takes place and all the other Member States should have access to the same information. A European database bringing together this information should therefore be set up, with due regard for the rules of confidentiality.

(10) Clinical trials are a complex operation, generally lasting one or more years, usually involving numerous participants and several trial sites, often in different Member States. Member States' current practices diverge considerably on the rules on commencement and conduct of the clinical trials and the requirements for carrying them out vary widely. This therefore results in delays and complications detrimental to effective conduct of such trials in the Community. It is therefore necessary to simplify and harmonise the administrative provisions governing such trials by establishing a clear, transparent procedure and creating conditions conducive to effective coordination of such clinical trials in the Community by the authorities concerned.

(11) As a rule, authorisation should be implicit, i.e. if there has been a vote in favour by the Ethics Committee and the competent authority has not objected within a given period, it should be possible to begin the clinical trials. In exceptional cases raising especially complex problems, explicit written authorisation should, however, be required.

(12) The principles of good manufacturing practice should be applied to investigational medicinal products.

(13) Special provisions should be laid down for the labelling of these products.

(14) Non-commercial clinical trials conducted by researchers without the participation of the pharmaceuticals industry may be of great benefit to the patients concerned. The Directive should therefore take account of the special position of trials whose planning does not require particular manufacturing or packaging processes, if these trials are carried out with medicinal products with a marketing authorisation within the meaning of Directive 65/65/EEC, manufactured or imported in accordance with the provisions of Directives 75/319/EEC and 91/356/EEC, and on patients with the same characteristics as those covered by the indication specified in this marketing authorisation. Labelling of the investigational medicinal products intended for trials of this nature should be subject to simplified provisions laid down in the good manufacturing practice guidelines on investigational products and in Directive 91/356/EEC.

(15) The verification of compliance with the standards of good clinical practice and the need to subject data, information and documents to inspection in order to confirm that they have been properly generated, recorded and reported are essential in order to justify the involvement of human subjects in clinical trials.

(16) The person participating in a trial must consent to the scrutiny of personal information during inspection by competent authorities and properly authorised persons, provided that such personal information is treated as strictly confidential and is not made publicly available.

(17) This Directive is to apply without prejudice to Directive 95/46/EEC 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 [2].

(18) It is also necessary to make provision for the monitoring of adverse reactions occurring in clinical trials using Community surveillance (pharmacovigilance) procedures in order to ensure the immediate cessation of any clinical trial in which there is an unacceptable level of risk.

[1] OJ L 214, 24.8.1993, p. 1. Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7)

[2] OJ L 281, 23.11.1995, p. 31.

(19) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1],

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Scope

1. This Directive establishes specific provisions regarding the conduct of clinical trials, including multi-centre trials, on human subjects involving medicinal products as defined in Article 1 of Directive 65/65/EEC, in particular relating to the implementation of good clinical practice. This Directive does not apply to non-interventional trials.

2. Good clinical practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible.

3. The principles of good clinical practice and detailed guidelines in line with those principles shall be adopted and, if necessary, revised to take account of technical and scientific progress in accordance with the procedure referred to in Article 21(2).

These detailed guidelines shall be published by the Commission.

4. All clinical trials, including bioavailability and bioequivalence studies, shall be designed, conducted and reported in accordance with the principles of good clinical practice.

Article 2

Definitions

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

(a) 'clinical trial': any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy; This includes clinical trials carried out in either one site or multiple sites, whether in one or more than one Member State;

(b) 'multi-centre clinical trial': a clinical trial conducted according to a single protocol but at more than one site, and therefore by more than one investigator, in which the trial sites may be located in a single Member State, in a number of Member States and/or in Member States and third countries;

(c) 'non-interventional trial': a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorisation. The assignment of the patient to a particular therapeutic strategy is not decided in advance by a trial protocol but falls within current practice and the prescription of the medicine is clearly separated from the decision to include the patient in the study. No additional diagnostic or monitoring procedures shall be applied to the patients and epidemiological methods shall be used for the analysis of collected data;

(d) 'investigational medicinal product': a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form;

(e) 'sponsor': an individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial;

(f) 'investigator': a doctor or a person following a profession agreed in the Member State for investigations because of the scientific background and the experience in patient care it requires. The investigator is responsible for the conduct of a clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the leader responsible for the team and may be called the principal investigator;

(g) 'investigator's brochure': a compilation of the clinical and non-clinical data on the investigational medicinal product or products which are relevant to the study of the product or products in human subjects;

(h) 'protocol': a document that describes the objective(s), design, methodology, statistical considerations and organisation of a trial. The term protocol refers to the protocol, successive versions of the protocol and protocol amendments;

(i) 'subject': an individual who participates in a clinical trial as either a recipient of the investigational medicinal product or a control;

[1] OJ L 184, 17.7.1999, p. 23.

(j) 'informed consent': decision, which must be written, dated and signed, to take part in a clinical trial, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

(k) 'ethics committee': an independent body in a Member State, consisting of healthcare professionals and non-medical members, whose responsibility it is to protect the rights, safety and wellbeing of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, expressing an opinion on the trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform trial subjects and obtain their informed consent;

(l) 'inspection': the act by a competent authority of conducting an official review of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by the competent authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;

(m) 'adverse event': any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment;

(n) 'adverse reaction': all untoward and unintended responses to an investigational medicinal product related to any dose administered;

(o) 'serious adverse event or serious adverse reaction': any untoward medical occurrence or effect that at any dose results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect;

(p) 'unexpected adverse reaction': an adverse reaction, the nature or severity of which is not consistent with the applicable product information (e.g. investigator's brochure for an unauthorised investigational product or summary of product characteristics for an authorised product).

Article 3

Protection of clinical trial subjects

1. This Directive shall apply without prejudice to the national provisions on the protection of clinical trial subjects if they are more comprehensive than the provisions of this Directive and consistent with the procedures and time-scales specified therein. Member States shall, insofar as they have not already done so, adopt detailed rules to protect from abuse individuals who are incapable of giving their informed consent.

2. A clinical trial may be undertaken only if, in particular:

(a) the foreseeable risks and inconveniences have been weighed against the anticipated benefit for the individual trial subject and other present and future patients. A clinical trial may be initiated only if the Ethics Committee and/or the competent authority comes to the conclusion that the anticipated therapeutic and public health benefits justify the risks and may be continued only if compliance with this requirement is permanently monitored;

(b) the trial subject or, when the person is not able to give informed consent, his legal representative has had the opportunity, in a prior interview with the investigator or a member of the investigating team, to understand the objectives, risks and inconveniences of the trial, and the conditions under which it is to be conducted and has also been informed of his right to withdraw from the trial at any time;

(c) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with Directive 95/46/EC are safeguarded;

(d) the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial; if the individual is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation;

(e) the subject may without any resulting detriment withdraw from the clinical trial at any time by revoking his informed consent;

(f) provision has been made for insurance or indemnity to cover the liability of the investigator and sponsor.

3. The medical care given to, and medical decisions made on behalf of, subjects shall be the responsibility of an appropriately qualified doctor or, where appropriate, of a qualified dentist.

4. The subject shall be provided with a contact point where he may obtain further information.

Article 4

Clinical trials on minors

In addition to any other relevant restriction, a clinical trial on minors may be undertaken only if:

(a) the informed consent of the parents or legal representative has been obtained; consent must represent the minor's presumed will and may be revoked at any time, without detriment to the minor;

(b) the minor has received information according to its capacity of understanding, from staff with experience with minors, regarding the trial, the risks and the benefits;

(c) the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation or to be withdrawn from the clinical trial at any time is considered by the investigator or where appropriate the principal investigator;

(d) no incentives or financial inducements are given except compensation;

(e) some direct benefit for the group of patients is obtained from the clinical trial and only where such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods; additionally, such research should either relate directly to a clinical condition from which the minor concerned suffers or be of such a nature that it can only be carried out on minors;

(f) the corresponding scientific guidelines of the Agency have been followed;

(g) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress have to be specially defined and constantly monitored;

(h) the Ethics Committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol; and

(i) the interests of the patient always prevail over those of science and society.

Article 5

Clinical trials on incapacitated adults not able to give informed legal consent

In the case of other persons incapable of giving informed legal consent, all relevant requirements listed for persons capable of giving such consent shall apply. In addition to these requirements, inclusion in clinical trials of incapacitated adults who have not given or not refused informed consent before the onset of their incapacity shall be allowed only if:

(a) the informed consent of the legal representative has been obtained; consent must represent the subject's presumed will and may be revoked at any time, without detriment to the subject;

(b) the person not able to give informed legal consent has received information according to his/her capacity of understanding regarding the trial, the risks and the benefits;

(c) the explicit wish of a subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical trial at any time is considered by the investigator or where appropriate the principal investigator;

(d) no incentives or financial inducements are given except compensation;

(e) such research is essential to validate data obtained in clinical trials on persons able to give informed consent or by other research methods and relates directly to a life-threatening or debilitating clinical condition from which the incapacitated adult concerned suffers;

(f) clinical trials have been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage; both the risk threshold and the degree of distress shall be specially defined and constantly monitored;

(g) the Ethics Committee, with expertise in the relevant disease and the patient population concerned or after taking advice in clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;

(h) the interests of the patient always prevail over those of science and society; and

(i) there are grounds for expecting that administering the medicinal product to be tested will produce a benefit to the patient outweighing the risks or produce no risk at all.

Article 6

Ethics Committee

1. For the purposes of implementation of the clinical trials, Member States shall take the measures necessary for establishment and operation of Ethics Committees.

2. The Ethics Committee shall give its opinion, before a clinical trial commences, on any issue requested.

3. In preparing its opinion, the Ethics Committee shall consider, in particular:

(a) the relevance of the clinical trial and the trial design;

(b) whether the evaluation of the anticipated benefits and risks as required under Article 3(2)(a) is satisfactory and whether the conclusions are justified;

(c) the protocol;

(d) the suitability of the investigator and supporting staff;

(e) the investigator's brochure;

(f) the quality of the facilities;

(g) the adequacy and completeness of the written information to be given and the procedure to be followed for the purpose of obtaining informed consent and the justification for the research on persons incapable of giving informed consent as regards the specific restrictions laid down in Article 3;

(h) provision for indemnity or compensation in the event of injury or death attributable to a clinical trial;

(i) any insurance or indemnity to cover the liability of the investigator and sponsor;

(j) the amounts and, where appropriate, the arrangements for rewarding or compensating investigators and trial subjects and the relevant aspects of any agreement between the sponsor and the site;

(k) the arrangements for the recruitment of subjects.

4. Notwithstanding the provisions of this Article, a Member State may decide that the competent authority it has designated for the purpose of Article 9 shall be responsible for the consideration of, and the giving of an opinion on, the matters referred to in paragraph 3(h), (i) and (j) of this Article.

When a Member State avails itself of this provision, it shall notify the Commission, the other Member States and the Agency.

5. The Ethics Committee shall have a maximum of 60 days from the date of receipt of a valid application to give its reasoned opinion to the applicant and the competent authority in the Member State concerned.

6. Within the period of examination of the application for an opinion, the Ethics Committee may send a single request for information supplementary to that already supplied by the applicant. The period laid down in paragraph 5 shall be suspended until receipt of the supplementary information.

7. No extension to the 60-day period referred to in paragraph 5 shall be permissible except in the case of trials involving medicinal products for gene therapy or somatic cell therapy or medicinal products containing genetically modified organisms. In this case, an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy, there shall be no time limit to the authorisation period.

Article 7

Single opinion

For multi-centre clinical trials limited to the territory of a single Member State, Member States shall establish a procedure providing, notwithstanding the number of Ethics Committees, for the adoption of a single opinion for that Member State.

In the case of multi-centre clinical trials carried out in more than one Member State simultaneously, a single opinion shall be given for each Member State concerned by the clinical trial.

Article 8

Detailed guidance

The Commission, in consultation with Member States and interested parties, shall draw up and publish detailed guidance on the application format and documentation to be submitted in an application for an ethics committee opinion, in particular regarding the information that is given to subjects, and on the appropriate safeguards for the protection of personal data.

Article 9

Commencement of a clinical trial

1. Member States shall take the measures necessary to ensure that the procedure described in this Article is followed for commencement of a clinical trial.

The sponsor may not start a clinical trial until the Ethics Committee has issued a favourable opinion and inasmuch as the competent authority of the Member State concerned has not informed the sponsor of any grounds for non-acceptance. The procedures to reach these decisions can be run in parallel or not, depending on the sponsor.

2. Before commencing any clinical trial, the sponsor shall be required to submit a valid request for authorisation to the competent authority of the Member State in which the sponsor plans to conduct the clinical trial.

3. If the competent authority of the Member State notifies the sponsor of grounds for non-acceptance, the sponsor may, on one occasion only, amend the content of the request referred to in paragraph 2 in order to take due account of the grounds given. If the sponsor fails to amend the request accordingly, the request shall be considered rejected and the clinical trial may not commence.

4. Consideration of a valid request for authorisation by the competent authority as stated in paragraph 2 shall be carried out as rapidly as possible and may not exceed 60 days. The Member States may lay down a shorter period than 60 days within their area of responsibility if that is in compliance with current practice. The competent authority can nevertheless notify the sponsor before the end of this period that it has no grounds for non-acceptance.

No further extensions to the period referred to in the first subparagraph shall be permissible except in the case of trials involving the medicinal products listed in paragraph 6, for which an extension of a maximum of 30 days shall be permitted. For these products, this 90-day period may be extended by a further 90 days in the event of consultation of a group or a committee in accordance with the regulations and procedures of the Member States concerned. In the case of xenogenic cell therapy there shall be no time limit to the authorisation period.

5. Without prejudice to paragraph 6, written authorisation may be required before the commencement of clinical trials for such trials on medicinal products which do not have a marketing authorisation within the meaning of Directive 65/65/EEC and are referred to in Part A of the Annex to Regulation (EEC) No 2309/93, and other medicinal products with special characteristics, such as medicinal products the active ingredient or active ingredients of which is or are a biological product or biological products of human or animal origin, or contains biological components of human or animal origin, or the manufacturing of which requires such components.

6. Written authorisation shall be required before commencing clinical trials involving medicinal products for gene therapy, somatic cell therapy including xenogenic cell therapy and all medicinal products containing genetically modified organisms. No gene therapy trials may be carried out which result in modifications to the subject's germ line genetic identity.

7. This authorisation shall be issued without prejudice to the application of Council Directives 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms [1] and 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms [2].

8. In consultation with Member States, the Commission shall draw up and publish detailed guidance on:

(a) the format and contents of the request referred to in paragraph 2 as well as the documentation to be submitted to support that request, on the quality and manufacture of the investigational medicinal product, any toxicological and pharmacological tests, the protocol and clinical information on the investigational medicinal product including the investigator's brochure;

(b) the presentation and content of the proposed amendment referred to in point (a) of Article 10 on substantial amendments made to the protocol;

(c) the declaration of the end of the clinical trial.

Article 10

Conduct of a clinical trial

Amendments may be made to the conduct of a clinical trial following the procedure described hereinafter:

(a) after the commencement of the clinical trial, the sponsor may make amendments to the protocol. If those amendments are substantial and are likely to have an impact on the safety of the trial subjects or to change the interpretation of the scientific documents in support of the conduct of the trial, or if they are otherwise significant, the sponsor shall notify the competent authorities of the Member State or Member States concerned of the reasons for, and content of, these amendments and shall inform the ethics committee or committees concerned in accordance with Articles 6 and 9.

On the basis of the details referred to in Article 6(3) and in accordance with Article 7, the Ethics Committee shall give an opinion within a maximum of 35 days of the date of receipt of the proposed amendment in good and due form. If this opinion is unfavourable, the sponsor may not implement the amendment to the protocol.

If the opinion of the Ethics Committee is favourable and the competent authorities of the Member States have raised no grounds for non-acceptance of the abovementioned substantial amendments, the sponsor shall proceed to conduct the clinical trial following the amended protocol. Should this not be the case, the sponsor shall either take account of the grounds for non-acceptance and adapt the proposed amendment to the protocol accordingly or withdraw the proposed amendment;

(b) without prejudice to point (a), in the light of the circumstances, notably the occurrence of any new event relating to the conduct of the trial or the development of the investigational medicinal product where that new event is likely to affect the safety of the subjects, the sponsor and the investigator shall take appropriate urgent safety measures to protect the subjects against any immediate hazard. The sponsor shall forthwith inform the competent authorities of those new events and the measures taken and shall ensure that the Ethics Committee is notified at the same time;

(c) within 90 days of the end of a clinical trial the sponsor shall notify the competent authorities of the Member State or Member States concerned and the Ethics Committee that the clinical trial has ended. If the trial has to be terminated early, this period shall be reduced to 15 days and the reasons clearly explained.

Article 11

Exchange of information

1. Member States in whose territory the clinical trial takes place shall enter in a European database, accessible only to the competent authorities of the Member States, the Agency and the Commission:

(a) extracts from the request for authorisation referred to in Article 9(2);

(b) any amendments made to the request, as provided for in Article 9(3);

[1] OJ L 117, 8.5.1990, p. 1. Directive as last amended by Directive 98/81/EC (OJ L 330, 5.12.1998, p. 13).
[2] OJ L 117, 8.5.1990, p. 15. Directive as last amended by Commission Directive 97/35/EC (OJ L 169, 27.6.1997, p. 72).

(c) any amendments made to the protocol, as provided for in point a of Article 10;

(d) the favourable opinion of the Ethics Committee;

(e) the declaration of the end of the clinical trial; and

(f) a reference to the inspections carried out on conformity with good clinical practice.

2. At the substantiated request of any Member State, the Agency or the Commission, the competent authority to which the request for authorisation was submitted shall supply all further information concerning the clinical trial in question other than the data already in the European database.

3. In consultation with the Member States, the Commission shall draw up and publish detailed guidance on the relevant data to be included in this European database, which it operates with the assistance of the Agency, as well as the methods for electronic communication of the data. The detailed guidance thus drawn up shall ensure that the confidentiality of the data is strictly observed.

Article 12

Suspension of the trial or infringements

1. Where a Member State has objective grounds for considering that the conditions in the request for authorisation referred to in Article 9(2) are no longer met or has information raising doubts about the safety or scientific validity of the clinical trial, it may suspend or prohibit the clinical trial and shall notify the sponsor thereof.

Before the Member State reaches its decision it shall, except where there is imminent risk, ask the sponsor and/or the investigator for their opinion, to be delivered within one week.

In this case, the competent authority concerned shall forthwith inform the other competent authorities, the Ethics Committee concerned, the Agency and the Commission of its decision to suspend or prohibit the trial and of the reasons for the decision.

2. Where a competent authority has objective grounds for considering that the sponsor or the investigator or any other person involved in the conduct of the trial no longer meets the obligations laid down, it shall forthwith inform him thereof, indicating the course of action which he must take to remedy this state of affairs. The competent authority concerned shall forthwith inform the Ethics Committee, the other competent authorities and the Commission of this course of action.

Article 13

Manufacture and import of investigational medicinal products

1. Member States shall take all appropriate measures to ensure that the manufacture or importation of investigational medicinal products is subject to the holding of authorisation. In order to obtain the authorisation, the applicant and, subsequently, the holder of the authorisation, shall meet at least the requirements defined in accordance with the procedure referred to in Article 21(2).

2. Member States shall take all appropriate measures to ensure that the holder of the authorisation referred to in paragraph 1 has permanently and continuously at his disposal the services of at least one qualified person who, in accordance with the conditions laid down in Article 23 of the second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products [1], is responsible in particular for carrying out the duties specified in paragraph 3 of this Article.

3. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 21 of Directive 75/319/EEC, without prejudice to his relationship with the manufacturer or importer, is responsible, in the context of the procedures referred to in Article 25 of the said Directive, for ensuring:

(a) in the case of investigational medicinal products manufactured in the Member State concerned, that each batch of medicinal products has been manufactured and checked in compliance with the requirements of Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use [2], the product specification file and the information notified pursuant to Article 9(2) of this Directive;

(b) in the case of investigational medicinal products manufactured in a third country, that each production batch has been manufactured and checked in accordance with standards of good manufacturing practice at least equivalent to those laid down in Commission Directive 91/356/EEC, in accordance with the product specification file, and that each production batch has been checked in accordance with the information notified pursuant to Article 9(2) of this Directive;

(c) in the case of an investigational medicinal product which is a comparator product from a third country, and which has a marketing authorisation, where the documentation certifying that each production batch has been manufactured in conditions at least equivalent to the standards of good manufacturing practice referred to above cannot be obtained, that each production batch has undergone all relevant analyses, tests or checks necessary to confirm its quality in accordance with the information notified pursuant to Article 9(2) of this Directive.

Detailed guidance on the elements to be taken into account when evaluating products with the object of releasing batches within the Community shall be drawn up pursuant to the good manufacturing practice guidelines, and in particular Annex 13 to the said guidelines. Such guidelines will be adopted in accordance with the procedure referred to in Article 21(2) of this Directive and published in accordance with Article 19a of Directive 75/319/EEC.

[1] OJ L 147, 9.6.1975, p. 13. Directive as last amended by Council Directive 93/39/EC (OJ L 214, 24.8.1993, p. 22).
[2] OJ L 193, 17.7.1991, p. 30.

Insofar as the provisions laid down in (a), (b) or (c) are complied with, investigational medicinal products shall not have to undergo any further checks if they are imported into another Member State together with batch release certification signed by the qualified person.

4. In all cases, the qualified person must certify in a register or equivalent document that each production batch satisfies the provisions of this Article. The said register or equivalent document shall be kept up to date as operations are carried out and shall remain at the disposal of the agents of the competent authority for the period specified in the provisions of the Member States concerned. This period shall in any event be not less than five years.

5. Any person engaging in activities as the qualified person referred to in Article 21 of Directive 75/319/EEC as regards investigational medicinal products at the time when this Directive is applied in the Member State where that person is, but without complying with the conditions laid down in Articles 23 and 24 of that Directive, shall be authorised to continue those activities in the Member State concerned.

Article 14

Labelling

The particulars to appear in at least the official language(s) of the Member State on the outer packaging of investigational medicinal products or, where there is no outer packaging, on the immediate packaging, shall be published by the Commission in the good manufacturing practice guidelines on investigational medicinal products adopted in accordance with Article 19a of Directive 75/319/EEC.

In addition, these guidelines shall lay down adapted provisions relating to labelling for investigational medicinal products intended for clinical trials with the following characteristics:

— the planning of the trial does not require particular manufacturing or packaging processes;

— the trial is conducted with medicinal products with, in the Member States concerned by the study, a marketing authorisation within the meaning of Directive 65/65/EEC, manufactured or imported in accordance with the provisions of Directive 75/319/EEC;

— the patients participating in the trial have the same characteristics as those covered by the indication specified in the abovementioned authorisation.

Article 15

Verification of compliance of investigational medicinal products with good clinical and manufacturing practice

1. To verify compliance with the provisions on good clinical and manufacturing practice, Member States shall appoint inspectors to inspect the sites concerned by any clinical trial conducted, particularly the trial site or sites, the manufacturing site of the investigational medicinal product, any laboratory used for analyses in the clinical trial and/or the sponsor's premises.

The inspections shall be conducted by the competent authority of the Member State concerned, which shall inform the Agency; they shall be carried out on behalf of the Community and the results shall be recognised by all the other Member States. These inspections shall be coordinated by the Agency, within the framework of its powers as provided for in Regulation (EEC) No 2309/93. A Member State may request assistance from another Member State in this matter.

2. Following inspection, an inspection report shall be prepared. It must be made available to the sponsor while safeguarding confidential aspects. It may be made available to the other Member States, to the Ethics Committee and to the Agency, at their reasoned request.

3. At the request of the Agency, within the framework of its powers as provided for in Regulation (EEC) No 2309/93, or of one of the Member States concerned, and following consultation with the Member States concerned, the Commission may request a new inspection should verification of compliance with this Directive reveal differences between Member States.

4. Subject to any arrangements which may have been concluded between the Community and third countries, the Commission, upon receipt of a reasoned request from a Member State or on its own initiative, or a Member State may propose that the trial site and/or the sponsor's premises and/or the manufacturer established in a third country undergo an inspection. The inspection shall be carried out by duly qualified Community inspectors.

5. The detailed guidelines on the documentation relating to the clinical trial, which shall constitute the master file on the trial, archiving, qualifications of inspectors and inspection procedures to verify compliance of the clinical trial in question with this Directive shall be adopted and revised in accordance with the procedure referred to in Article 21(2).

Article 16

Notification of adverse events

1. The investigator shall report all serious adverse events immediately to the sponsor except for those that the protocol or investigator's brochure identifies as not requiring immediate reporting. The immediate report shall be followed by detailed, written reports. The immediate and follow-up reports shall identify subjects by unique code numbers assigned to the latter.

2. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations shall be reported to the sponsor according to the reporting requirements and within the time periods specified in the protocol.

3. For reported deaths of a subject, the investigator shall supply the sponsor and the Ethics Committee with any additional information requested.

4. The sponsor shall keep detailed records of all adverse events which are reported to him by the investigator or investigators. These records shall be submitted to the Member States in whose territory the clinical trial is being conducted, if they so request.

Article 17

Notification of serious adverse reactions

1. (a) The sponsor shall ensure that all relevant information about suspected serious unexpected adverse reactions that are fatal or life-threatening is recorded and reported as soon as possible to the competent authorities in all the Member States concerned, and to the Ethics Committee, and in any case no later than seven days after knowledge by the sponsor of such a case, and that relevant follow-up information is subsequently communicated within an additional eight days.

(b) All other suspected serious unexpected adverse reactions shall be reported to the competent authorities concerned and to the Ethics Committee concerned as soon as possible but within a maximum of fifteen days of first knowledge by the sponsor.

(c) Each Member State shall ensure that all suspected unexpected serious adverse reactions to an investigational medicinal product which are brought to its attention are recorded.

(d) The sponsor shall also inform all investigators.

2. Once a year throughout the clinical trial, the sponsor shall provide the Member States in whose territory the clinical trial is being conducted and the Ethics Committee with a listing of all suspected serious adverse reactions which have occurred over this period and a report of the subjects' safety.

3. (a) Each Member State shall see to it that all suspected unexpected serious adverse reactions to an investigational medicinal product which are brought to its attention are immediately entered in a European database to which, in accordance with Article 11(1), only the competent authorities of the Member States, the Agency and the Commission shall have access.

(b) The Agency shall make the information notified by the sponsor available to the competent authorities of the Member States.

Article 18

Guidance concerning reports

The Commission, in consultation with the Agency, Member States and interested parties, shall draw up and publish detailed guidance on the collection, verification and presentation of adverse event/reaction reports, together with decoding procedures for unexpected serious adverse reactions.

Article 19

General provisions

This Directive is without prejudice to the civil and criminal liability of the sponsor or the investigator. To this end, the sponsor or a legal representative of the sponsor must be established in the Community.

Unless Member States have established precise conditions for exceptional circumstances, investigational medicinal products and, as the case may be, the devices used for their administration shall be made available free of charge by the sponsor.

The Member States shall inform the Commission of such conditions.

Article 20

Adaptation to scientific and technical progress

This Directive shall be adapted to take account of scientific and technical progress in accordance with the procedure referred to in Article 21(2).

Article 21

Committee procedure

1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use, set up by Article 2b of Directive 75/318/EEC (hereinafter referred to as the Committee).

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 22

Application

1. Member States shall adopt and publish before 1 May 2003 the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply these provisions at the latest with effect from 1 May 2004.

When Member States adopt these provisions, 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 provisions of national law which they adopt in the field governed by this Directive.

Article 23

Entry into force

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

Article 24

Addressees

This Directive is addressed to the Member States.

Done at Luxembourg, 4 April 2001.

For the European Parliament	*For the Council*
The President	*The President*
N. FONTAINE	B. ROSENGREN

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 18 April 2001

concerning an Exchange of Letters amending point B of the Annex to the Agreement between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names

(notified under document number C(2001) 1080)

(2001/339/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 93/722/EC of 23 November 1993 concerning the conclusion of an Agreement between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names [1], and in particular Article 3 thereof,

Whereas:

(1) Article 3 of the Council Decision concerning the conclusion of an Agreement between the European Community and Republic of Bulgaria on the reciprocal protection and control of wine names lays down that, for the purposes of Article 13 of the Agreement, the Commission is authorised to conclude the necessary acts amending the Agreement, in accordance with the procedure laid down in Article 83 of Council Regulation (EEC) No 822/87 of 16 March 1987 on the common organisation of the market in wine [2]. Regulation (EEC) No 822/87 was replaced by Regulation (EC) No 1493/1999 [3], as last amended by Regulation (EC) No 2826/2000 [4].

(2) The Commission, on behalf of the Community, and the Republic of Bulgaria have reached agreement in the form of an Exchange of Letters. That Exchange of Letters should be approved.

(3) The Management Committee for Wine has not delivered an opinion within the time limit laid down by its Chairman,

HAS DECIDED AS FOLLOWS:

Article 1

The Exchange of Letters amending point B of the Annex to the Agreement between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names is approved on behalf of the Community.

The text of the Exchange of Letters is attached to this Decision.

Article 2

This Decision and the text of the Exchange of Letters referred to in Article 1 shall be published in the *Official Journal of the European Communities*.

Done at Brussels, 18 April 2001.

For the Commission

Franz FISCHLER

Member of the Commission

[1] OJ L 337, 31.12.1993, p. 11.
[2] OJ L 84, 27.3.1987, p. 1.
[3] OJ L 179, 14.7.1999, p. 1.
[4] OJ L 328, 23.12.2000, p. 2.

ANNEX

AGREEMENT IN THE FORM OF AN EXCHANGE OF LETTERS

amending the Annex to the Agreement between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names

A. *Letter from the Commission of the European Communities*

Brussels, 23 April 2001

Sir,

I have the honour to refer to the Agreement of 29 November 1993 between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names, hereinafter called 'the Agreement', and to the consultations which have taken place between the Commission of the European Communities and the Government of the Republic of Bulgaria with a view to amending the Annex to the Agreement, as provided for by Article 13(a) of the Agreement.

I hereby confirm that following the consultations and taking into account the entry into force on 1 January 2000 of the Bulgarian Law on wine and spirits, the Commission of the European Communities and the Government of the Republic of Bulgaria have agreed to amend the Annex to the Agreement as follows:

The following footnote is inserted at the end of the title of point B.2.3. *Wines bearing one of the following geographical names of the sub-Balkan viniviticultural region Rozova Dolina/Pod-Balkanski Rayon*: '— For a transitional period expiring on 31 December 2006, the term "Rosenthaler", as described in "Ordinance on indication and trade presentation of wines, spirits, grape and wine products" (Decree No 55 of the Council of Ministers of 6 April 2000) and which corresponds to the translation into German of the name "Rozova Dolina", can be used to describe wines originating in Bulgaria. These wines are not protected under point B of the Annex to this Agreement.'

This amendment shall enter into force on the day of the signature of this Exchange of Letters.

I should be obliged if you would confirm that your Government is in agreement with the contents of this letter.

Please accept, Sir, the assurance of my highest consideration.

For the Commission of the European Communities

B. *Letter from the Government of the Republic of Bulgaria*

Brussels, 23 April 2001

Sir,

I have the honour to acknowledge receipt of your letter of today's date, which reads as follows:

'I have the honour to refer to the Agreement of 29 November 1993 between the European Community and the Republic of Bulgaria on the reciprocal protection and control of wine names, hereinafter called "the Agreement", and to the consultations which have taken place between the Commission of the European Communities and the Government of the Republic of Bulgaria with a view to amending the Annex to the Agreement, as provided for by Article 13(a) of the Agreement.

I hereby confirm that following the consultations and taking into account the entry into force on 1 January 2000 of the Bulgarian Law on wine and spirits, the Commission of the European Communities and the Government of the Republic of Bulgaria have agreed to amend the Annex to the Agreement as follows:

The following footnote is inserted at the end of the title of point B.2.3. *Wines bearing one of the following geographical names of the sub-Balkan viniviticultural region Rozova Dolina/Pod-Balkanski Rayon*: "— For a transitional period expiring on 31 December 2006, the term "Rosenthaler", as described in "Ordinance on indication and trade presentation of wines, spirits, grape and wine products" (Decree No 55 of the Council of Ministers of 6 April 2000), and which corresponds to the translation into German of the name "Rozova Dolina", can be used to describe wines originating in Bulgaria. These wines are not protected under point B of the Annex to this Agreement."

This amendment shall enter into force on the day of the signature of this Exchange of Letters.

I should be obliged if you would confirm that your Government is in agreement with the contents of this letter.'

I have the honour to confirm that my Government is in agreement with the contents of your letter.

Please accept, Sir, the assurance of my highest consideration.

For the Government of the Republic of Bulgaria

CORRIGENDA

Corrigendum to Council Regulation (EC) No 2220/2000 of 28 September 2000 amending Regulation (EEC) No 302/93 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction

(Official Journal of the European Communities L 253 of 7 October 2000)

On page 1, in Article 1(2):

for: '2. the following point shall be added to Article 2(D):

"14. It may transfer in applicant countries eligible for the PHARE programme, at the request of the Commission of the European Communities, its know-how and assist in the creation and reinforcement of structural links with the Reitox network and the setting up and the consolidation of the national focal points.'"

read: '2. the following point shall be added to Article 2(D):

"14. It may transfer in applicant countries and in countries eligible for the PHARE programme, at the request of the Commission of the European Communities, its know-how and assist in the creation and reinforcement of structural links with the Reitox network and the setting up and the consolidation of the national focal points.'"