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EN

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

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

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[1] Text with EEA relevance

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Contents (continued)

EN

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1601/2005

of 30 September 2005

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables [1], and in particular Article 4(1) thereof,

Whereas:

(1) Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission

J. M. SILVA RODRÍGUEZ

Director-General for Agriculture and Rural Development

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

ANNEX

to Commission Regulation of 30 September 2005 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	45,6
	096	29,4
	999	37,5
0707 00 05	052	102,6
	999	102,6
0709 90 70	052	65,0
	999	65,0
0805 50 10	052	69,0
	382	63,8
	388	63,3
	524	62,6
	528	56,2
	999	63,0
0806 10 10	052	85,6
	096	52,6
	624	181,7
	999	106,6
0808 10 80	388	89,4
	400	89,6
	508	26,4
	512	84,5
	528	46,8
	720	59,6
	800	143,1
	804	67,3
	999	75,8
0808 20 50	052	93,1
	388	69,5
	999	81,3

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

COMMISSION REGULATION (EC) No 1602/2005

of 30 September 2005

fixing 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 (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals [1], and in particular Article 15(2) thereof,

Whereas:

(1) Article 14(2) of Regulation (EC) No 1784/2003 provides that the export refund applicable to cereals on the day on which an application for an export licence is made must be applied on request to exports to be effected during the period of validity of the export licence. In this case, a corrective amount may be applied to the refund.

(2) Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules under Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the cereals and the measures to be taken in the event of disturbance on the market for cereals [2], allows for the fixing of a corrective amount for the products listed in Article 1(1)(c) of Regulation (EEC) No 1766/92 [3]. That corrective amount must be calculated taking account of the factors referred to in Article 1 of Regulation (EC) No 1501/95.

(3) The world market situation or the specific requirements of certain markets may make it necessary to vary the corrective amount according to destination.

(4) The corrective amount must be fixed at the same time as the refund and according to the same procedure; it may be altered in the period between fixings.

(5) It follows from applying the provisions set out above that the corrective amount must be as set out in the Annex hereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

The corrective amount referred to in Article 1(1)(a), (b) and (c) of Regulation (EC) No 1784/2003 which is applicable to export refunds fixed in advance except for malt shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

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[1] OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).
[2] OJ L 147, 30.6.1995, p. 7. Regulation as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50).
[3] OJ L 181, 1.7.1992, p. 21. Regulation as last amended by Regulation (EC) No 1104/2003 (OJ L 158, 27.6.2003, p. 1).

ANNEX

to the Commission Regulation of 30 September 2005 fixing the corrective amount applicable to the refund on cereals

(EUR/t)

Product code	Destination	Current 10	1st period 11	2nd period 12	3rd period 1	4th period 2	5th period 3	6th period 4
1001 10 00 9200	—	—	—	—	—	—	—	—
1001 10 00 9400	A00	0	0	0	0	0	—	—
1001 90 91 9000	—	—	—	—	—	—	—	—
1001 90 99 9000	C01	0	– 0,46	– 0,92	– 1,38	– 1,84	—	—
1002 00 00 9000	A00	0	0	0	0	0	—	—
1003 00 10 9000	—	—	—	—	—	—	—	—
1003 00 90 9000	C02	0	– 0,46	– 0,92	– 1,38	– 1,84	—	—
1004 00 00 9200	—	—	—	—	—	—	—	—
1004 00 00 9400	C03	0	– 0,46	– 0,92	– 1,38	– 1,84	—	—
1005 10 90 9000	—	—	—	—	—	—	—	—
1005 90 00 9000	A00	0	0	0	0	0	—	—
1007 00 90 9000	—	—	—	—	—	—	—	—
1008 20 00 9000	—	—	—	—	—	—	—	—
1101 00 11 9000	—	—	—	—	—	—	—	—
1101 00 15 9100	C01	0	– 0,63	– 1,26	– 1,89	– 2,52	—	—
1101 00 15 9130	C01	0	– 0,59	– 1,18	– 1,77	– 2,36	—	—
1101 00 15 9150	C01	0	– 0,54	– 1,09	– 1,63	– 2,17	—	—
1101 00 15 9170	C01	0	– 0,50	– 1,00	– 1,50	– 2,00	—	—
1101 00 15 9180	C01	0	– 0,47	– 0,94	– 1,41	– 1,88	—	—
1101 00 15 9190	—	—	—	—	—	—	—	—
1101 00 90 9000	—	—	—	—	—	—	—	—
1102 10 00 9500	A00	0	0	0	0	0	—	—
1102 10 00 9700	A00	0	0	0	0	0	—	—
1102 10 00 9900	—	—	—	—	—	—	—	—
1103 11 10 9200	A00	0	0	0	0	0	—	—
1103 11 10 9400	A00	0	0	0	0	0	—	—
1103 11 10 9900	—	—	—	—	—	—	—	—
1103 11 90 9200	A00	0	0	0	0	0	—	—
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 Regulation (EC) No 2081/2003 (OJ L 313, 28.11.2003, p. 11).

C01: All third countries with the exception of Albania, Bulgaria, Romania, Croatia, Bosnia and Herzegovina, Serbia and Montenegro, the former Yugoslav Republic of Macedonia, Lichtenstein and Switzerland.

C02: Algeria, Saudi Arabia, Bahrain, Egypt, United Arab Emirates, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Lybia, Morocco, Mauritania, Oman, Qatar, Syria, Tunisia and Yemen.

C03: All third countries with the exception of Bulgaria, Norway, Romania, Switzerland and Lichtenstein.

COMMISSION REGULATION (EC) No 1603/2005

of 30 September 2005

fixing the export refunds on malt

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals ([1]), and in particular Article 13(3) thereof,

Whereas:

(1) Article 13 of Regulation (EC) No 1784/2003 provides that the difference between quotations or prices on the world market for the products listed in Article 1 of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) The refunds must be fixed taking into account the factors referred to in Article 1 of Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules under Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals ([2]).

(3) The refund applicable in the case of malts must be calculated with amount taken of the quantity of cereals required to manufacture the products in question. The said quantities are laid down in Regulation (EC) No 1501/95.

(4) The world market situation or the specific requirements of certain markets may make it necessary to vary the refund for certain products according to destination.

(5) The refund must be fixed once a month. It may be altered in the intervening period.

(6) It follows from applying these rules to the present situation on markets in cereals, and in particular to quotations or prices for these products within the Community and on the world market, that the refunds should be as set out in the Annex hereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on malt listed in Article 1(1)(c) of Regulation (EC) No 1784/2003 shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

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

([2]) OJ L 147, 30.6.1995, p. 7. Regulation as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50).

ANNEX

to the Commission Regulation of 30 September 2005 fixing the export refunds on malt

Product code	Destination	Unit of measurement	Amount of refunds
1107 10 19 9000	A00	EUR/t	0,00
1107 10 99 9000	A00	EUR/t	0,00
1107 20 00 9000	A00	EUR/t	0,00

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 2081/2003 (OJ L 313, 28.11.2003, p. 11).

COMMISSION REGULATION (EC) No 1604/2005

of 30 September 2005

fixing 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 (EC) No 1784/2003 of 29 September 2003 on the common organization of the market in cereals [1], and in particular Article 15(2),

Whereas:

(1) Article 14(2) of Regulation (EC) No 1784/2003 provides that the export refund applicable to cereals on the day on which application for an export licence is made must be applied on request to exports to be effected during the period of validity of the export licence. In this case, a corrective amount may be applied to the refund.

(2) Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules under Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals [2] allows for the fixing of a corrective amount for the malt referred to in Article 1(1)(c) of Regulation (EEC) No 1766/92 [3]. That corrective amount must be calculated taking account of the factors referred to in Article 1 of Regulation (EC) No 1501/95.

(3) It follows from applying the provisions set out above that the corrective amount must be as set out in the Annex hereto.

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

HAS ADOPTED THIS REGULATION:

Article 1

The corrective amount referred to in Article 15(3) of Regulation (EC) No 1784/2003 which is applicable to export refunds fixed in advance in respect of malt shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

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

[2] OJ L 147, 30.6.1995, p. 7. Regulation as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50).

[3] OJ L 181, 1.7.1992, p. 21. Regulation as last amended by Regulation (EC) No 1104/2003 (OJ L 158, 27.6.2003, p. 1).

ANNEX

to the Commission Regulation of 30 September 2005 fixing the corrective amount applicable to the refund on malt

(EUR/t)

Product code	Destination	Current 10	1st period 11	2nd period 12	3rd period 1	4th period 2	5th period 3
1107 10 11 9000	A00	0	0	0	0	0	0
1107 10 19 9000	A00	0	0	0	0	0	0
1107 10 91 9000	A00	0	0	0	0	0	0
1107 10 99 9000	A00	0	0	0	0	0	0
1107 20 00 9000	A00	0	0	0	0	0	0

(EUR/t)

Product code	Destination	6th period 4	7th period 5	8th period 6	9th period 7	10th period 8	11th period 9
1107 10 11 9000	A00	0	0	0	0	0	0
1107 10 19 9000	A00	0	0	0	0	0	0
1107 10 91 9000	A00	0	0	0	0	0	0
1107 10 99 9000	A00	0	0	0	0	0	0
1107 20 00 9000	A00	0	0	0	0	0	0

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 Regulation (EC) No 2081/2003 (OJ L 313, 28.11.2003, p. 11).

COMMISSION REGULATION (EC) No 1605/2005

of 30 September 2005

fixing the refunds applicable to cereal and rice sector products supplied as Community and national food aid

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals [1] and in particular Article 13(3) thereof,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organisation of the market in rice [2] and in particular Article 13(3) thereof,

Whereas:

(1) Article 2 of Council Regulation (EEC) No 2681/74 of 21 October 1974 on Community financing of expenditure incurred in respect of the supply of agricultural products as food aid [3] lays down that the portion of the expenditure corresponding to the export refunds on the products in question fixed under Community rules is to be charged to the European Agricultural Guidance and Guarantee Fund, Guarantee Section.

(2) In order to make it easier to draw up and manage the budget for Community food aid actions and to enable the Member States to know the extent of Community participation in the financing of national food aid actions, the level of the refunds granted for these actions should be determined.

(3) The general and implementing rules provided for in Article 13 of Regulation (EC) No 1784/2003 and in Article 13 of Regulation (EC) No 3072/95 on export refunds are applicable *mutatis mutandis* to the abovementioned operations.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

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[1] OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).
[2] OJ L 329, 30.12.1995, p. 18. Regulation as last amended by Commission Regulation (EC) No 411/2002 (OJ L 62, 5.3.2002, p. 27).
[3] OJ L 288, 25.10.1974, p. 1.

ANNEX

to the Commission Regulation of 30 September 2005 fixing the refunds applicable to cereal and rice sector products supplied as Comunity and national food aid

(EUR/t)

Product code	Refund
1001 10 00 9400	0,00
1001 90 99 9000	0,00
1002 00 00 9000	0,00
1003 00 90 9000	0,00
1005 90 00 9000	0,00
1006 30 92 9100	0,00
1006 30 92 9900	0,00
1006 30 94 9100	0,00
1006 30 94 9900	0,00
1006 30 96 9100	0,00
1006 30 96 9900	0,00
1006 30 98 9100	0,00
1006 30 98 9900	0,00
1006 30 65 9900	0,00
1007 00 90 9000	0,00
1101 00 15 9100	10,28
1101 00 15 9130	9,60
1102 10 00 9500	0,00
1102 20 10 9200	56,20
1102 20 10 9400	48,17
1103 11 10 9200	0,00
1103 13 10 9100	72,25
1104 12 90 9100	0,00

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

COMMISSION REGULATION (EC) No 1606/2005

of 30 September 2005

amending Regulation (EC) No 1060/2005 as regards the quantity covered by the standing invitation to tender for the export of common wheat held by the Slovak intervention agency

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals [1], and in particular Article 6 thereof,

Whereas:

(1) Commission Regulation (EC) No 1060/2005 [2] opened a standing invitation to tender for the export of 114 757 tonnes of common wheat held by the Slovak intervention agency.

(2) Slovakia has informed the Commission of its intervention agency's intention to increase by 33 192 tonnes the quantity put out to tender for export. In view of the quantities available and the market situation, the request made by Slovakia should be granted.

(3) Regulation (EC) No 1060/2005 should therefore be amended.

(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

Article 2 of Regulation (EC) No 1060/2005 is replaced by the following:

'*Article 2*

The invitation to tender shall cover a maximum of 147 949 tonnes of common wheat for export to third countries with the exception of Albania, Bosnia and Herzegovina, Bulgaria, Croatia, the Former Yugoslav Republic of Macedonia, Liechtenstein, Romania, Serbia and Montenegro (*) and Switzerland.

(*) Including Kosovo as defined by United Nations Security Council Resolution 1244 of 10 June 1999.'

Article 2

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

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).
[2] OJ L 174, 7.7.2005, p. 18. Regulation as amended by Regulation (EC) No 1302/2005 (OJ L 207, 10.8.2005, p. 12).

COMMISSION REGULATION (EC) No 1607/2005

of 30 September 2005

amending Regulation (EC) No 296/96 on data to be transmitted by the Member States and the monthly booking of expenditure financed under the Guarantee Section of the European Agricultural and Guidance Fund (EAGGF)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1258/1999 of 17 May 1999 on the financing of the common agricultural policy [1], and in particular Article 7 (5) thereof,

Whereas:

(1) Article 1 of Commission Regulation (EC) No 296/96 [2] provides that the Commission is to place at the disposal of the Member States, within the framework of the budget appropriations, the funds needed to cover expenditure to be financed by the Guarantee Section of the European Agricultural and Guidance Fund.

(2) Article 7(1) of Regulation (EC) No 296/96 provides that expenditure declared in respect of a given month must in general fall within payments and receipts effected during this month. Some exceptions to that principle are provided for.

(3) To ensure the respect of the budget and to the extent necessary to comply with the provisions of Article 1 of Regulation (EC) No 296/96, it should be possible for Member States to adjust expenditure declarations other than those for measures covered by Council Regulation (EC) No 1257/1999 of 17 May 1999 on support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF) [3] and to declare expenditure in respect of the following month.

(4) Regulation (EC) No 296/96 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the European Agricultural Guidance and Guarantee Fund,

HAS ADOPTED THIS REGULATION:

Article 1

In the first subparagraph of Article 7 (1) of Regulation (EC) No 296/96, the following point is added:

'(d) expenditure effected by Member States from 1 to 15 October 2005, other than for measures covered by Council Regulation (EC) No 1257/1999 (*), may, if necessary to comply with the provisions of Article 1, be declared in respect of the month following the month of payment to the beneficiary.

(*) OJ L 160, 26.6.1999, p. 80.'

Article 2

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

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 103.
[2] OJ L 39, 17.2.1996, p. 5. Regulation as last amended by Regulation (EC) No 605/2005 (OJ L 100, 20.4.2005, p. 11).
[3] OJ L 160, 26.6.1999, p. 80. Regulation as last amended by Regulation (EC) No 2223/2004 (OJ L 379, 24.12.2004, p. 1).

COMMISSION REGULATION (EC) No 1608/2005

of 30 September 2005

amending Regulation (EEC) No 3149/92 laying down detailed rules for the supply of food from intervention stocks for the benefit of the most deprived persons in the Community

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3730/87 of 10 December 1987 laying down the general rules for the supply of food from intervention stocks to designated organisations for distribution to the most deprived persons in the Community [1], and in particular Article 6 thereof,

Whereas:

(1) Article 4 of Commission Regulation (EEC) No 3149/92 [2] lays down detailed rules for invitations to tender as regards the organisation of supplies in the Member States participating in the Community measure for the distribution of food from intervention stocks for the benefit of the most deprived persons.

(2) The products to be withdrawn from intervention stocks under the annual plan may be supplied unprocessed or processed for the manufacture of food, or withdrawn in payment for the supply or manufacture of food mobilised on the Community market. In the latter case, the products in intervention stocks which may be withdrawn in payment for the manufacture of cereal and milk products should be specified.

(3) To respond more effectively to the needs of charitable organisations and expand the range of food products supplied, it should be laid down that products from intervention stocks may, under certain conditions, be incorporated into other products for the purposes of manufacturing food.

(4) In accordance with Article 47, paragraph 1, of Council Regulation (EC) No 1254/1999 of 17 May 1999 on the common organisation of the market in beef and veal [3], public intervention in the beef and veal sector as a permanent market support instrument does not exist any more since 1 July 2002. The Regulation (EEC) 3149/92 should therefore be adapted to that new situation.

(5) Regulation (EEC) No 3149/92 should therefore be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinions of the Management Committees concerned,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 3149/92 is hereby amended as follows:

1. Article 4 is amended as follows:

(a) in paragraph 1, point (b), the third subparagraph is replaced by the following:

'However, where no rice is available in intervention stocks, the Commission may authorise the removal of cereals from intervention stocks to pay for the supply of rice or rice products mobilised on the market.';

(b) in paragraph 2, point (a), the following subparagraph is inserted after the third subparagraph:

'In the case referred to in the third indent of the second subparagraph, where supply involves rice or rice products in exchange for cereals withdrawn from intervention stocks, the invitation to tender shall specify that the product to be withdrawn is a specific cereal held by an intervention agency.';

(c) paragraph 2a is replaced by the following:

'2a. Products from intervention may be incorporated into or added to other products mobilised on the market for the manufacture of food to be supplied for the purposes of implementing the plan. In such cases, products from intervention stocks must represent at least 40 % of the net weight of the food product to be supplied.

In the case referred to in the first subparagraph, the invitation to tender shall clearly indicate the requirement that products from intervention stocks must represent at least 40 % of the net weight of the food product to be supplied.'.

[1] OJ L 352, 15.12.1987, p. 1. Regulation as amended by Regulation (EC) No 2535/95 (OJ L 260, 31.10.1995, p. 3).
[2] OJ L 313, 30.10.1992, p. 50. Regulation as last amended by Regulation (EC) No 1903/2004 (OJ L 328, 30.10.2004, p. 77).
[3] OJ L 160, 26.6.1999, p. 21. Regulation as last amended by Regulation (EC) No 1782/2003 (OJ L 270, 21.10.2003, p. 1).

2. In Article 5(1), the second indent is deleted.

3. The Annex is deleted.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

COMMISSION REGULATION (EC) No 1609/2005

of 30 September 2005

reducing, for the 2005/06 marketing year, the guaranteed quantity under the production quotas scheme for the sugar sector and the presumed maximum supply needs of sugar refineries under the preferential import arrangements

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [1], and in particular Articles 10(6) and 39(6) thereof,

Whereas:

(1) Article 10(3) and (4) of Regulation (EC) No 1260/2001 lay down that the guaranteed quantity under production quotas should be reduced before 1 October each marketing year if the forecasts for the year in question show an exportable balance (attracting a refund) greater than the maximum laid down by the Agriculture Agreement concluded under Article 300(2) of the Treaty.

(2) The forecasts for the 2005/06 marketing year indicate an exportable balance exceeding the maximum laid down by the Agriculture Agreement. It is therefore necessary to set the overall reduction of the guaranteed quantity and divide it up between sugar, isoglucose and inulin syrup on the one hand and the production regions concerned on the other, using the coefficients provided for in Article 10(4) of Regulation (EC) No 1260/2001.

(3) In accordance with Article 10(5) of Regulation (EC) No 1260/2001, each Member State must then allocate the difference to which it is subject among the producer undertakings established on its territory on the basis of the existing ratio between their A and B quotas for the product in question and the basic quantity A and the basic quantity B for the Member State for this product.

(4) Article 39(5) of Regulation (EC) No 1260/2001 lays down that a reduction in the guaranteed quantity entails a reduction in the presumed maximum raw sugar needs of Community refineries for the marketing year in question. It is therefore necessary to set the corresponding reduction for these needs and to allocate it among the Member States concerned.

(5) The time-limits by which the Member States must establish the reductions applying to each undertaking on their territory should be set.

(6) In view of the deadline imposed by Regulation (EC) No 1260/2001, this Regulation must enter into force on the day of its publication in the *Official Journal of the European Union*.

(7) The Management Committee for Sugar has not delivered an opinion within the time-limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

1. Pursuant to Article 10(4) of Regulation (EC) No 1260/2001, the guaranteed quantity under production quotas for the 2005/06 marketing year shall be reduced by 1 891 747,7 tonnes in white sugar equivalent.

2. The reduction referred to in paragraph 1 and the basic quantities used, once reduced, to allocate the production quotas to producer undertakings for the 2005/06 marketing year shall be those set out in part A of the Annex, broken down by product and by region.

3. The Member States shall establish before 1 November 2005 the specific reduction for each producer undertaking to which a production quota for the 2005/06 marketing year has been assigned, and its A and B quotas adjusted in accordance with this reduction.

Article 2

1. Pursuant to Article 39(5) of Regulation (EC) No 1260/2001, the presumed maximum supply needs of Community refineries for the 2005/06 marketing year shall be reduced by 14 676 tonnes in white sugar equivalent.

2. The reduction referred to in paragraph 1 shall be allocated among the Member States in accordance with Part B of the Annex.

Article 3

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

[1] OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 39/2004 (OJ L 6, 10.1.2004, p. 16).

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

ANNEX

PART A: Breakdown by product and by region of the reductions in the guaranteed quantities and the basic quantities used to allocate the A and B production quotas after reduction of the guaranteed quantity

1. **For sugar** (in tonnes of white sugar)

Regions	Reduction for sugar		Basic quantities for sugar	
	A	B	A	B
Czech Republic	18 207,7	563,5	423 001,3	13 089,5
Denmark	45 264,6	13 335,2	279 735,4	82 410,3
Germany	374 034,5	115 090,3	2 238 878,8	688 891,9
Greece	20 550,0	2 055,2	268 088,0	26 808,6
Spain	44 022,1	1 833,1	913 060,3	38 045,4
France (metropolitan) [1]	354 766,7	105 215,3	2 181 720,7	647 044,2
French (overseas departments) [1]	32 108,2	3 433,1	401 763,8	42 939,4
Ireland	12 898,2	1 289,5	168 247,0	16 825,0
Italy	137 245,8	25 812,6	1 173 658,1	220 726,7
Latvia	1 806,0	3,6	64 594,0	101,4
Lithuania	2 719,8	—	100 290,2	—
Hungary	11 182,5	34,3	389 271,5	1 195,7
Netherlands	88 833,4	23 430,5	595 279,0	157 016,6
Austria	37 722,9	8 804,1	276 306,0	64 493,4
Poland	84 735,7	4 930,3	1 495 264,3	86 995,7
Portugal (mainland)	3 864,8	386,5	59 515,4	5 951,5
Portugal (the autonomous region of the Azores)	644,7	65,0	8 403,5	839,8
Slovenia	3 438,6	343,1	44 718,4	4 472,9
Slovakia	13 015,6	1 211,8	176 744,4	16 460,2
Finland	9 456,0	944,5	123 350,3	12 335,9
Sweden	23 836,9	2 383,9	310 947,3	31 094,1
BLEU [2]	76 867,1	16 504,7	598 038,4	128 401,4
United Kingdom	73 699,5	7 370,1	961 415,9	96 141,4

[1] Account has been taken of the second subparagraph of Article 12(3) of Regulation (EC) No 1260/2001.
[2] Belgo-Luxembourg Economic Union.

2. **For isoglucose** (in tonnes of dry matter)

Regions	Reduction for isoglucose		Basic quantities for isoglucose	
	A	B	A	B
Germany	3 868,6	911,1	24 774,7	5 834,4
Greece	1 409,4	331,9	9 025,6	2 125,6
Spain	6 165,4	657,7	68 454,2	7 301,7
France (metropolitan)	2 266,7	590,0	13 480,4	3 508,6
Italy	2 219,3	522,6	14 212,8	3 347,2
Hungary	8 899,9	697,3	118 727,1	9 302,7
Netherlands	994,7	234,3	6 369,9	1 500,2
Poland	1 698,1	127,5	23 212,9	1 742,5
Portugal (mainland)	1 084,1	255,3	6 942,9	1 635,0
Slovakia	3 560,3	476,8	33 961,7	4 548,2
Finland	859,2	86,0	9 932,8	993,7
BLEU [1]	8 370,1	2 301,7	47 780,5	13 139,3
United Kingdom	3 143,7	838,5	18 358,3	4 896,8

[1] Belgo-Luxembourg Economic Union.

3. **For inulin syrup** (in tonnes of tonnes of dry matter expressed as white sugar/isoglucose equivalent)

Regions	Reduction for inulin syrup		Basic quantities for inulin syrup	
	A	B	A	B
France (metropolitan)	1 956,8	459,9	17 890,3	4 214,3
Netherlands	6 454,9	1 515,9	59 064,5	13 914,6
BLEU ([1])	18 473,7	4 349,0	155 744,9	36 679,2

([1]) Belgo-Luxembourg Economic Union.

PART B: Breakdown by Member State of the reduction in the presumed maximum supply needs of refineries

(Unit: tonnes of white sugar)

	Reduction	Maximum needs prior to application of the reduction
Metropolitan France	2 423	294 204
Mainland Portugal	2 383	289 250
Slovenia	160	19 425
Finland	490	59 435
United Kingdom	9 220	1 119 361

COMMISSION REGULATION (EC) No 1610/2005

of 30 September 2005

fixing the minimum selling prices for butter for the 171st individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], and in particular Article 10 thereof,

Whereas:

(1) The intervention agencies are, pursuant to Commission Regulation (EC) No 2571/97 of 15 December 1997 on the sale of butter at reduced prices and the granting of aid for cream, butter and concentrated butter for use in the manufacture of pastry products, ice-cream and other foodstuffs [2], to sell by invitation to tender certain quantities of butter from intervention stocks that they hold and to grant aid for cream, butter and concentrated butter. Article 18 of that Regulation stipulates that in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed for butter and maximum aid shall be fixed for cream, butter and concentrated butter. It is further stipulated that the price or aid may vary according to the intended use of the butter, its fat content and the incorporation procedure, and that a decision may also be taken to make no award in response to the tenders submitted. The amount(s) of the processing securities must be fixed accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

The minimum selling prices of butter from intervention stocks and processing securities applying for the 171st individual invitation to tender, under the standing invitation to tender provided for in Regulation (EC) No 2571/97, shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).
[2] OJ L 350, 20.12.1997, p. 3. Regulation as last amended by Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

ANNEX

to the Commission Regulation of 30 September 2005 fixing the minimum selling prices for butter for the 171st individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

(EUR/100 kg)

Formula			A		B	
Incorporation procedure			With tracers	Without tracers	With tracers	Without tracers
Minimum selling price	Butter ≥ 82 %	Unaltered	—	210	—	—
		Concentrated	204,1	—	—	—
Processing security		Unaltered	—	79	—	—
		Concentrated	79	—	—	—

COMMISSION REGULATION (EC) No 1611/2005

of 30 September 2005

fixing the maximum aid for cream, butter and concentrated butter for the 171st individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], and in particular Article 10 thereof,

Whereas:

(1) The intervention agencies are, pursuant to Commission Regulation (EC) No 2571/97 of 15 December 1997 on the sale of butter at reduced prices and the granting of aid for cream, butter and concentrated butter for use in the manufacture of pastry products, ice cream and other foodstuffs [2], to sell by invitation to tender certain quantities of butter of intervention stocks that they hold and to grant aid for cream, butter and concentrated butter. Article 18 of that Regulation stipulates that in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed for butter and maximum aid shall be fixed for cream, butter and concentrated butter. It is further stipulated that the price or aid may vary according to the intended use of the butter, its fat content and the incorporation procedure, and that a decision may also be taken to make no award in response to the tenders submitted. The amount(s) of the processing securities must be fixed accordingly.

(2) The Management Committee for Milk and Milk Products has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The maximum aid and processing securities applying for the 171st individual invitation to tender, under the standing invitation to tender provided for in Regulation (EC) No 2571/97, shall be fixed as indicated in the Annex hereto.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).
[2] OJ L 350, 20.12.1997, p. 3. Regulation as last amended by Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

ANNEX

to the Commission Regulation of 30 September 2005 fixing the maximum aid for cream, butter and concentrated butter for the 171st individual invitation to tender under the standing invitation to tender provided for in Regulation (EC) No 2571/97

(EUR/100 kg)

Formula		A		B	
Incorporation procedure		With tracers	Without tracers	With tracers	Without tracers
Maximum aid	Butter ≥ 82 %	39	35	—	—
	Butter < 82 %	—	—	—	—
	Concentrated butter	—	—	—	—
	Cream	—	—	—	15
Processing security	Butter	43	—	—	—
	Concentrated butter	—	—	—	—
	Cream	—	—	—	—

COMMISSION REGULATION (EC) No 1612/2005

of 30 September 2005

fixing the minimum selling price for skimmed-milk powder for the 90th individual invitation to tender issued under the standing invitation to tender referred to in Regulation (EC) No 2799/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], and in particular Article 10 thereof,

Whereas:

(1) Pursuant to Article 26 of Commission Regulation (EC) No 2799/1999 of 17 December 1999 laying down detailed rules for applying Council Regulation (EC) No 1255/1999 as regards the grant of aid for skimmed milk and skimmed-milk powder intended for animal feed and the sale of such skimmed-milk powder [2], intervention agencies have put up for sale by standing invitation to tender certain quantities of skimmed-milk powder held by them.

(2) According to Article 30 of the said Regulation, in the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed or a decision shall be taken to make no award. The amount of the processing security shall also be fixed taking account of the difference between the market price of skimmed-milk powder and the minimum selling price.

(3) In the light of the tenders received, the minimum selling price should be fixed at the level specified below and the processing security determined accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

For the 90th individual invitation to tender pursuant to Regulation (EC) No 2799/1999, in respect of which the time limit for the submission of tenders expired on 27 September 2005, the minimum selling price and the processing security are fixed as follows:

— minimum selling price: 187,30 EUR/100 kg,

— processing security: 35,00 EUR/100 kg.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).

[2] OJ L 340, 31.12.1999, p. 3. Regulation as last amended by Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

COMMISSION REGULATION (EC) No 1613/2005

of 30 September 2005

fixing the maximum aid for concentrated butter for the 343rd special invitation to tender opened under the standing invitation to tender provided for in Regulation (EEC) No 429/90

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], and in particular Article 10 thereof,

Whereas:

(1) In accordance with Commission Regulation (EEC) No 429/90 of 20 February 1990 on the granting by invitation to tender of an aid for concentrated butter intended for direct consumption in the Community [2], the intervention agencies are opening a standing invitation to tender for the granting of aid for concentrated butter. Article 6 of that Regulation provides that in the light of the tenders received in response to each special invitation to tender, a maximum amount of aid is to be fixed for concentrated butter with a minimum fat content of 96 % or a decision is to be taken to make no award; the end-use security must be fixed accordingly.

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

(3) The Management Committee for Milk and Milk Products has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

For the 343rd tender under the standing invitation to tender opened by Regulation (EEC) No 429/90 the maximum aid and the end-use security are fixed as follows:

— maximum aid: 46 EUR/100 kg,

— end-use security: 51 EUR/100 kg.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).
[2] OJ L 45, 21.2.1990, p. 8. Regulation as last amended by Commission Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

COMMISSION REGULATION (EC) No 1614/2005

of 30 September 2005

fixing the minimum selling price for butter for the 27th individual invitation to tender issued under the standing invitation to tender referred to in Regulation (EC) No 2771/1999

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], and in particular Article 10(c) thereof,

Whereas:

(1) Pursuant to Article 21 of Commission Regulation (EC) No 2771/1999 of 16 December 1999 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention on the market in butter and cream [2], intervention agencies have put up for sale by standing invitation to tender certain quantities of butter held by them.

(2) In the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed or a decision shall be taken to make no award, in accordance with Article 24a of Regulation (EC) No 2771/1999.

(3) In the light of the tenders received, a minimum selling price should be fixed.

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

HAS ADOPTED THIS REGULATION:

Article 1

For the 27th individual invitation to tender pursuant to Regulation (EC) No 2771/1999, in respect of which the time limit for the submission of tenders expired on 27 September 2005, the minimum selling price for butter is fixed at 260,10 EUR/100 kg.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).
[2] OJ L 333, 24.12.1999, p. 11. Regulation as last amended by Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

COMMISSION REGULATION (EC) No 1615/2005

of 30 September 2005

fixing the minimum selling price for skimmed-milk powder for the 26th individual invitation to tender issued under the standing invitation to tender referred to in Regulation (EC) No 214/2001

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1255/1999 of 17 May 1999 on the common organisation of the market in milk and milk products [1], and in particular Article 10(c) thereof,

Whereas:

(1) Pursuant to Article 21 of Commission Regulation (EC) No 214/2001 of 12 January 2001 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention on the market in skimmed milk [2], intervention agencies have put up for sale by standing invitation to tender certain quantities of skimmed-milk powder held by them.

(2) In the light of the tenders received in response to each individual invitation to tender a minimum selling price shall be fixed or a decision shall be taken to make no award, in accordance with Article 24a of Regulation (EC) No 214/2001.

(3) In the light of the tenders received, a minimum selling price should be fixed.

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

HAS ADOPTED THIS REGULATION:

Article 1

For the 26th individual invitation to tender pursuant to Regulation (EC) No 214/2001, in respect of which the time limit for the submission of tenders expired on 27 September 2005, the minimum selling price for skimmed milk is fixed at 188,00 EUR/100 kg.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 160, 26.6.1999, p. 48. Regulation as last amended by Commission Regulation (EC) No 186/2004 (OJ L 29, 3.2.2004, p. 6).
[2] OJ L 37, 7.2.2001, p. 100. Regulation as last amended by Regulation (EC) No 2250/2004 (OJ L 381, 28.12.2004, p. 25).

COMMISSION REGULATION (EC) No 1616/2005

of 30 September 2005

fixing the import duties in the cereals sector applicable from 1 October 2005

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals [1],

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 [2], and in particular Article 2(1) thereof,

Whereas:

(1) Article 10 of Regulation (EC) No 1784/2003 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 (EC) No 1784/2003, 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 Regulation (EC) No 1784/2003 as regards import duties in the cereals sector.

(4) The import duties are applicable until new duties are fixed and enter into force.

(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 Annex I to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The import duties in the cereals sector referred to in Article 10(2) of Regulation (EC) No 1784/2003 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 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission

J. M. SILVA RODRÍGUEZ

Director-General for Agriculture and Rural Development

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[1] OJ L 270, 21.10.2003, p. 78.

[2] OJ L 161, 29.6.1996, p. 125. Regulation as last amended by Regulation (EC) No 1110/2003 (OJ L 158, 27.6.2003, p. 12).

ANNEX I

Import duties for the products covered by Article 10(2) of Regulation (EC) No 1784/2003 applicable from 1 October 2005

CN code	Description	Import duty [1] (EUR/tonne)
1001 10 00	Durum wheat high quality	0,00
	medium quality	0,00
	low quality	0,00
1001 90 91	Common wheat seed	0,00
ex 1001 90 99	Common high quality wheat other than for sowing	0,00
1002 00 00	Rye	38,82
1005 10 90	Maize seed other than hybrid	60,33
1005 90 00	Maize other than seed [2]	60,33
1007 00 90	Grain sorghum other than hybrids for sowing	43,81

[1] 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/t, where the port of unloading is on the Mediterranean Sea, or
— EUR 2/t, where the port of unloading is in Ireland, the United Kingdom, Denmark, Estonia, Latvia, Lithuania, Poland, Finland, Sweden or the Atlantic coasts of the Iberian peninsula.

[2] The importer may benefit from a flat-rate reduction of EUR 24/t, 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 16.9.2005-29.9.2005

1. Averages over the reference period referred to in Article 2(2) of Regulation (EC) No 1249/96:

Exchange quotations	Minneapolis	Chicago	Minneapolis	Minneapolis	Minneapolis	Minneapolis
Product (% proteins at 12 % humidity)	HRS2	YC3	HAD2	Medium quality (*)	Low quality (**)	US barley 2
Quotation (EUR/t)	125,07 (***)	66,77	170,91	160,91	140,91	93,02
Gulf premium (EUR/t)	—	13,92	—			—
Great Lakes premium (EUR/t)	34,49	—	—			—

(*) A discount of 10 EUR/t (Article 4(3) of Regulation (EC) No 1249/96).
(**) A discount of 30 EUR/t (Article 4(3) of Regulation (EC) No 1249/96).
(***) Premium of 14 EUR/t incorporated (Article 4(3) of Regulation (EC) No 1249/96).

2. Averages over the reference period referred to in Article 2(2) of Regulation (EC) No 1249/96:

Freight/cost: Gulf of Mexico–Rotterdam: 21,00 EUR/t; Great Lakes–Rotterdam: 25,19 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 1617/2005

of 30 September 2005

fixing the production refund on white sugar used in the chemical industry for the period from 1 to 31 October 2005

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [1], and in particular the fifth indent of Article 7(5) thereof,

Whereas:

(1) Pursuant to Article 7(3) of Regulation (EC) No 1260/2001, production refunds may be granted on the products listed in Article 1(1)(a) and (f) of that Regulation, on syrups listed in Article 1(1)(d) thereof and on chemically pure fructose covered by CN code 1702 50 00 as an intermediate product, that are in one of the situations referred to in Article 23(2) of the Treaty and are used in the manufacture of certain products of the chemical industry.

(2) Commission Regulation (EC) No 1265/2001 of 27 June 2001 laying down detailed rules for the application of Council Regulation (EC) No 1260/2001 as regards granting the production refund on certain sugar products used in the chemical industry [2] provides that these refunds shall be determined according to the refund fixed for white sugar.

(3) Article 9 of Regulation (EC) No 1265/2001 provides that the production refund on white sugar is to be fixed at monthly intervals commencing on the first day of each month.

(4) 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 production refund on white sugar referred to in Article 4 of Regulation (EC) No 1265/2001 shall be equal to 33,838 EUR/100 kg net for the period from 1 to 31 October 2005.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

[1] OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 39/2004 (OJ L 6, 10.1.2004, p. 16).

[2] OJ L 178, 30.6.2001, p. 63.

COMMISSION REGULATION (EC) No 1618/2005

of 30 September 2005

determining the world market price for unginned cotton

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Protocol 4 on cotton, annexed to the Act of Accession of Greece, as last amended by Council Regulation (EC) No 1050/2001 [1],

Having regard to Council Regulation (EC) No 1051/2001 of 22 May 2001 on production aid for cotton [2], and in particular Article 4 thereof,

Whereas:

(1) In accordance with Article 4 of Regulation (EC) No 1051/2001, a world market price for unginned cotton is to be determined periodically from the price for ginned cotton recorded on the world market and by reference to the historical relationship between the price recorded for ginned cotton and that calculated for unginned cotton. That historical relationship has been established in Article 2(2) of Commission Regulation (EC) No 1591/2001 of 2 August 2001 laying down detailed rules for applying the cotton aid scheme [3]. Where the world market price cannot be determined in this way, it is to be based on the most recent price determined.

(2) In accordance with Article 5 of Regulation (EC) No 1051/2001, the world market price for unginned cotton is to be determined in respect of a product of specific characteristics and by reference to the most favourable offers and quotations on the world market among those considered representative of the real market trend. To that end, an average is to be calculated of offers and quotations recorded on one or more European exchanges for a product delivered cif to a port in the Community and coming from the various supplier countries considered the most representative in terms of international trade. However, there is provision for adjusting the criteria for determining the world market price for ginned cotton to reflect differences justified by the quality of the product delivered and the offers and quotations concerned. Those adjustments are specified in Article 3(2) of Regulation (EC) No 1591/2001.

(3) The application of the above criteria gives the world market price for unginned cotton determined hereinafter,

HAS ADOPTED THIS REGULATION:

Article 1

The world price for unginned cotton as referred to in Article 4 of Regulation (EC) No 1051/2001 is hereby determined as equalling 21,667 EUR/100 kg.

Article 2

This Regulation shall enter into force on 1 October 2005.

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

Done at Brussels, 30 September 2005.

For the Commission

J. M. SILVA RODRÍGUEZ

Director-General for Agriculture and Rural Development

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[1] OJ L 148, 1.6.2001, p. 1.
[2] OJ L 148, 1.6.2001, p. 3.
[3] OJ L 210, 3.8.2001, p. 10. Regulation as amended by Regulation (EC) No 1486/2002 (OJ L 223, 20.8.2002, p. 3).

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular points (a) and (i) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements dealing with traceability, a Community procedure for notifying serious adverse reactions and events and the notification format.

(3) Notification of suspected serious adverse reactions or serious adverse events should be submitted to the competent authority as soon as known. This Directive therefore establishes the notification format defining the minimum data needed, without prejudice to the faculty of Member States to maintain or introduce in their territory more stringent protective measures which comply with the provisions of the Treaty as provided under Article 4(2) of Directive 2002/98/EC.

(4) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [2], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3], Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [4], and certain recommendations of the Council of Europe.

(5) Accordingly, blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma, intended for distribution in the Community, should meet equivalent Community standards and specifications relating to traceability and serious adverse reaction and serious adverse event notification requirements as set out in this Directive.

(6) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

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

(a) 'traceability' means the ability to trace each individual unit of blood or blood component derived thereof from the donor to its final destination, whether this is a recipient, a manufacturer of medicinal products or disposal, and vice versa;

(b) 'reporting establishment' means the blood establishment, the hospital blood bank or facilities where the transfusion takes place that reports serious adverse reactions and/or serious adverse events to the competent authority;

(c) 'recipient' means someone who has been transfused with blood or blood components;

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 91, 30.3.2004, p. 25.

(d) 'issue' means the provision of blood or blood components by a blood establishment or a hospital blood bank for transfusion to a recipient;

(e) 'imputability' means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process;

(f) 'facilities' means hospitals, clinics, manufacturers, and biomedical research institutions to which blood or blood components may be delivered.

Article 2

Traceability

1. Member States shall ensure the traceability of blood and blood components through accurate identification procedures, record maintenance and an appropriate labelling system.

2. Member States shall ensure that the traceability system in place in the blood establishment enables the tracing of blood components to their location and processing stage.

3. Member States shall ensure that every blood establishment has a system in place to uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given blood component has been delivered.

4. Member States shall ensure that all facilities have a system in place to record each blood unit or blood component received, whether or not locally processed, and the final destination of that received unit, whether transfused, discarded or returned to the distributing blood establishment.

5. Member States shall ensure that every blood establishment has a unique identifier that enables it to be precisely linked to each unit of blood that it has collected and to each blood component that it has prepared.

Article 3

Verification procedure for issuing blood or blood components

Member States shall ensure that the blood establishment, when it issues units of blood or blood components for transfusion, or the hospital blood bank has in place a procedure to verify that each unit issued has been transfused to the intended recipient or if not transfused to verify its subsequent disposition.

Article 4

Record of data on traceability

Member States shall ensure that blood establishments, hospital blood banks, or facilities retain the data set out in Annex I for at least 30 years in an appropriate and readable storage medium in order to ensure traceability.

Article 5

Notification of serious adverse reactions

1. Member States shall ensure that those facilities where transfusion occurs have procedures in place to retain the record of transfusions and to notify blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood and blood components.

2. Member States shall ensure that reporting establishments have procedures in place to communicate to the competent authority as soon as known all relevant information about suspected serious adverse reactions. The notification formats set out in Part A and Part C of Annex II shall be used.

3. Member States shall ensure that reporting establishments:

(a) notify to the competent authority all relevant information about serious adverse reactions of imputability level 2 or 3, as referred to in Part B of Annex II, attributable to the quality and safety of blood and blood components;

(b) notify the competent authority of any case of transmission of infectious agents by blood and blood components as soon as known;

(c) describe the actions taken with respect to other implicated blood components that have been distributed for transfusion or for use as plasma for fractionation;

(d) evaluate suspected serious adverse reactions according to the imputability levels set out in Part B of Annex II;

(e) complete the serious adverse reaction notification, upon conclusion of the investigation, using the format set out in Part C of Annex II;

(f) submit a complete report on serious adverse reactions to the competent authority on an annual basis using the format set out in Part D of Annex II.

Article 6

Notification of serious adverse events

1. Member States shall ensure that blood establishments and hospital blood banks have procedures in place to retain the record of any serious adverse events which may affect the quality or safety of blood and blood components.

2. Member States shall ensure that reporting establishments have procedures in place to communicate to the competent authority as soon as known, using the notification format set out in Part A of Annex III, all relevant information about serious adverse events which may put in danger donors or recipients other than those directly involved in the event concerned.

3. Member States shall ensure that reporting establishments:

(a) evaluate serious adverse events to identify preventable causes within the process;

(b) complete the serious adverse event notification, upon conclusion of the investigation, using the format set out in Part B of Annex III;

(c) submit a complete report on serious adverse events to the competent authority on an annual basis using the format set out in Part C of Annex III.

Article 7

Requirements for imported blood and blood components

1. Member States shall ensure that for imports of blood and blood components from third countries blood establishments have a system of traceability in place equivalent to that provided for in Article 2(2) to (5).

2. Member States shall ensure that for imports of blood and blood components from third countries blood establishments have a system of notification in place equivalent to that provided for in Articles 5 and 6.

Article 8

Annual reports

Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events received by the competent authority using the formats in Part D of Annex II and Part C of Annex III.

Article 9

Communication of information between competent authorities

Member States shall ensure that their competent authorities communicate to each other such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded.

Article 10

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 August 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 11

Entry into force

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

Article 12

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 30 September 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Record of data on traceability as provided for in Article 4

BY BLOOD ESTABLISHMENTS

1. Blood establishment identification

2. Blood donor identification

3. Blood unit identification

4. Individual blood component identification

5. Date of collection (year/month/day)

6. Facilities to which blood units or blood components are distributed, or subsequent disposition.

BY FACILITIES

1. Blood component supplier identification

2. Issued blood component identification

3. Transfused recipient identification

4. For blood units not transfused, confirmation of subsequent disposition

5. Date of transfusion or disposition (year/month/day)

6. Lot number of the component, if relevant.

ANNEX II

NOTIFICATION OF SERIOUS ADVERSE REACTIONS

PART A

Rapid notification format for suspected serious adverse reactions

Reporting establishment
Report identification
Reporting date (year/month/day)
Date of transfusion (year/month/day)
Age and sex of recipient
Date of serious adverse reaction (year/month/day)
Serious adverse reaction is related to **— Whole blood** **— Red blood cells** **— Platelets** **— Plasma** **— Other *(specify)***
Type of serious adverse reaction(s) **— Immunological haemolysis due to ABO incompatibility** **— Immunological haemolysis due to other allo-antibody** **— Non-immunological haemolysis** **— Transfusion-transmitted bacterial infection** **— Anaphylaxis/hypersensitivity** **— Transfusion related acute lung injury** **— Transfusion-transmitted viral infection (HBV)** **— Transfusion-transmitted viral infection (HCV)** **— Transfusion-transmitted viral infection (HIV-1/2)** **— Transfusion-transmitted viral infection, Other *(specify)*** **— Transfusion-transmitted parasitical infection (Malaria)** **— Transfusion-transmitted parasitical infection, Other *(specify)*** **— Post-transfusion purpura** **— Graft versus host disease** **— Other serious reaction(s) *(specify)***
Imputability level (NA, 0-3)

PART B

Serious adverse reactions — imputability levels

Imputability levels to assess serious adverse reactions.

Imputability level		Explanation
NA	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to alternative causes.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing adverse reaction either to the blood or blood component or to alternative causes.
2	Likely, Probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

PART C

Confirmation format for serious adverse reactions

Reporting establishment

Report identification

Confirmation date (year/month/day)

Date of serious adverse reaction (year/month/day)

Confirmation of serious adverse reaction (Yes/No)

Imputability level (NA, 0-3)

Change of type of serious adverse reaction (Yes/No)

If Yes, *specify*

Clinical outcome (if known)

— **Complete recovery**

— **Minor sequelae**

— **Serious sequelae**

— **Death**

PART D

Annual notification format for serious adverse reactions

Reporting establishment

Reporting period

This Table refers to **[ ] Whole blood** **[ ] Red blood cells** **[ ] Platelets** **[ ] Plasma** **[ ] Other** *(use separate table for each component)*		Number of units issued (total number of units issued with a given number of blood components)					
		Number of recipients transfused (total number of recipients transfused with a given number of blood components) *(if available)*					
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) *(if available)*					
		Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)				
		Number of deaths					
			not assessable	Level 0	Level 1	Level 2	Level 3
Immunological Haemolysis	Due to ABO incompatibility	Total					
		Deaths					
	Due to other allo-antibody	Total					
		Deaths					
Non-immunological haemolysis		Total					
		Deaths					
Transfusion-transmitted bacterial infection		Total					
		Deaths					
Anaphylaxis/hypersensitivity		Total					
		Deaths					
Transfusion related acute lung injury		Total					
		Deaths					
Transfusion-transmitted viral Infection	HBV	Total					
		Deaths					
	HCV	Total					
		Deaths					
	HIV-1/2	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					
Transfusion-transmitted parasitical infection	Malaria	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					

Post-transfusion purpura	Total					
	Deaths					
Graft versus host disease	Total					
	Deaths					
Other serious reactions *(specify)*	Total					
	Deaths					

ANNEX III

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid Notification Format for Serious Adverse Events

Reporting establishment

Report identification

Reporting date (year/month/day)

Date of serious adverse event (year/month/day)

Serious adverse event, which may affect quality and safety of blood component due to a deviation in:	**Specification**			
	Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection				
Apheresis collection				
Testing of donations				
Processing				
Storage				
Distribution				
Materials				
Others *(specify)*				

PART B

Confirmation Format for Serious Adverse Events

Reporting establishment

Report identification

Confirmation date *(year/month/day)*

Date of serious adverse event *(year/month/day)*

Root cause analysis (details)

Corrective measures taken (details)

PART C

Annual Notification Format for Serious Adverse Events

Reporting establishment

Reporting period	**1 January-31 December *(year)***

Total number of blood and blood components processed:

Serious adverse event, affecting quality and safety of blood component due to a deviation in:	**Total number**	**Specification**			
		Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection					
Apheresis collection					
Testing of donations					
Processing					
Storage					
Distribution					
Materials					
Others *(specify)*					

COMMISSION DIRECTIVE 2005/62/EC

of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC [1], and in particular point (h) of the second paragraph of Article 29 thereof,

Whereas:

(1) Directive 2002/98/EC lays down standards of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection.

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements including Community standards and specifications with regard to a quality system for blood establishments.

(3) A quality system for blood establishments should embrace the principles of quality management, quality assurance, and continuous quality improvement, and should include personnel, premises and equipment, documentation, collection, testing and processing, storage and distribution, contract management, non-conformance and self-inspection, quality control, blood component recall, and external and internal auditing.

(4) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [2], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [3], Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use [4], Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components [5], certain recommendations of the Council of Europe, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products, recommendations of the World Health Organisation, as well as international experience in this field.

(5) In order to ensure the highest quality and safety for blood and blood components, guidance on good practice should be developed to support the quality system requirements for blood establishments taking fully into account the detailed guidelines referred to in Article 47 of Directive 2001/83/EC so as to ensure that the standards required for medicinal products are maintained.

(6) Blood and blood components imported from third countries, including those used as starting material or raw material for the manufacture of medicinal products derived from human blood and human plasma intended for distribution in the Community, should meet equivalent Community standards and specifications relating to a quality system for blood establishments as set out in this Directive.

(7) It is necessary to specify that a quality system is to be applied for any blood and blood components circulating in the Community and that Member States therefore should ensure that for blood and blood components coming from third countries there is a quality system in place for blood establishments in the stages preceding importation equivalent to the quality system provided under this Directive.

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.
[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 262, 14.10.2003, p. 22.
[5] OJ L 91, 30.3.2004, p. 25.

(8) It is necessary to determine common definitions for technical terminology in order to ensure the consistent implementation of Directive 2002/98/EC.

(9) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

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

(a) 'standard' means the requirements that serve as the basis for comparison;

(b) 'specification' means a description of the criteria that must be fulfilled in order to achieve the required quality standard;

(c) 'quality system' means the organisational structure, responsibilities, procedures, processes, and resources for implementing quality management;

(d) 'quality management' means the co-ordinated activities to direct and control an organisation with regard to quality at all levels within the blood establishment;

(e) 'quality control' means part of a quality system focussed on fulfilling quality requirements;

(f) 'quality assurance' means all the activities from blood collection to distribution made with the object of ensuring that blood and blood components are of the quality required for their intended use;

(g) 'trace-back' means the process of investigating a report of a suspected transfusion-associated adverse reaction in a recipient in order to identify a potentially implicated donor;

(h) 'written procedures' means controlled documents that describe how specified operations are to be carried out;

(i) 'mobile site' means a temporary or movable place used for the collection of blood and blood components which is in a location outside of but under the control of the blood establishment;

(j) 'processing' means any step in the preparation of a blood component that is carried out between the collection of blood and the issuing of a blood component;

(k) 'good practice' means all elements in established practice that collectively will lead to final blood or blood components that consistently meet predefined specifications and compliance with defined regulations;

(l) 'quarantine' means the physical isolation of blood components or incoming materials/reagents over a variable period of time while awaiting acceptance, issuance or rejection of the blood components or incoming materials/reagents;

(m) 'validation' means the establishment of documented and objective evidence that the pre-defined requirements for a specific procedure or process can be consistently fulfilled;

(n) 'qualification', as part of validation, means the action of verifying that any personnel, premises, equipment or material works correctly and delivers the expected results;

(o) 'computerised system' means a system including the input of data, electronic processing and the output of information to be used either for reporting, automatic control or documentation.

Article 2

Quality system standards and specifications

1. Member States shall ensure that the quality system in place in all blood establishments complies with the Community standards and specifications set out in the Annex to this Directive.

2. Good practice guidelines shall be developed by the Commission, in accordance with Article 28 of Directive 2002/98/EC, for the interpretation of the Community standards and specifications referred to in paragraph 1. When developing these guidelines, the Commission shall take fully into account the detailed principles and guidelines of good manufacturing practice, as referred to in Article 47 of Directive 2001/83/EC.

3. Member States shall ensure that for blood and blood components imported from third countries and intended for use or distribution in the Community, there is a quality system for blood establishments in the stages preceding importation equivalent to the quality system provided for in Article 2.

Article 3

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 August 2006 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 4

Entry into force

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

Article 5

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 30 September 2005.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Quality system standards and specifications

1. INTRODUCTION AND GENERAL PRINCIPLES

1.1. **Quality system**

1. Quality shall be recognised as being the responsibility of all persons involved in the processes of the blood establishment with management ensuring a systematic approach towards quality and the implementation and maintenance of a quality system.

2. The quality system encompasses quality management, quality assurance, continuous quality improvement, personnel, premises and equipment, documentation, collection, testing and processing, storage, distribution, quality control, blood component recall, and external and internal auditing, contract management, non-conformance and self-inspection.

3. The quality system shall ensure that all critical processes are specified in appropriate instructions and are carried out in accordance with the standards and specifications set out in this Annex. Management shall review the system at regular intervals to verify its effectiveness and introduce corrective measures if deemed necessary.

1.2. **Quality assurance**

1. All blood establishments and hospital blood banks shall be supported by a quality assurance function, whether internal or related, in fulfilling quality assurance. That function shall be involved in all quality-related matters and review and approve all appropriate quality related documents.

2. All procedures, premises, and equipment that have an influence on the quality and safety of blood and blood components shall be validated prior to introduction and be re-validated at regular intervals determined as a result of these activities.

2. PERSONNEL AND ORGANISATION

1. Personnel in blood establishments shall be available in sufficient numbers to carry out the activities related to the collection, testing, processing, storage and distribution of blood and blood components and be trained and assessed to be competent to perform their tasks.

2. All personnel in blood establishments shall have up to date job descriptions which clearly set out their tasks and responsibilities. Blood establishments shall assign the responsibility for processing management and quality assurance to different individuals and who function independently.

3. All personnel in blood establishments shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice.

4. The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.

5. There shall be written safety and hygiene instructions in place adapted to the activities to be carried out and are in compliance with Council Directive 89/391/EEC [1] and Directive 2000/54/EC of the European Parliament and of the Council [2].

3. PREMISES

3.1. **General**

Premises including mobile sites shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

[1] OJ L 183, 29.6.1989, p. 1.
[2] OJ L 262, 17.10.2000, p. 21.

3.2. **Blood donor area**

There shall be an area for confidential personal interviews with and assessment of individuals to assess their eligibility to donate. This area shall be separated from all processing areas.

3.3. **Blood collection area**

Blood collection shall be carried out in an area intended for the safe withdrawal of blood from donors, appropriately equipped for the initial treatment of donors experiencing adverse reactions or injuries from events associated with blood donation, and organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

3.4. **Blood testing and processing areas**

There shall be a dedicated laboratory area for testing that is separate from the blood donor and blood component processing area with access restricted to authorised personnel.

3.5. **Storage area**

1. Storage areas shall provide for properly secure and segregated storage of different categories of blood and blood components and materials including quarantine and released materials and units of blood or blood components collected under special criteria (e.g. autologous donation).

2. Provisions shall be in place in the event of equipment or power failure in the main storage facility.

3.6. **Waste disposal area**

An area shall be designated for the safe disposal of waste, disposable items used during the collection, testing, and processing and for rejected blood or blood components.

4. EQUIPMENT AND MATERIALS

1. All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.

2. Equipment shall be selected to minimise any hazard to donors, personnel, or blood components.

3. Only reagents and materials from approved suppliers that meet the documented requirements and specifications shall be used. Critical materials shall be released by a person qualified to perform this task. Where relevant, materials, reagents and equipment shall meet the requirements of Council Directive 93/42/EEC [1] for medical devices and Directive 98/79/EC of the European Parliament and of the Council [2] for in vitro diagnostic medical devices or comply with equivalent standards in the case of collection in third countries.

4. Inventory records shall be retained for a period acceptable to and agreed with the competent authority.

5. When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state. Hardware and software shall be protected against unauthorised use or unauthorised changes. The back-up procedure shall prevent loss of or damage to data at expected and unexpected down times or function failures.

5. DOCUMENTATION

1. Documents setting out specifications, procedures and records covering each activity performed by the blood establishment shall be in place and kept up to date.

2. Records shall be legible and may be handwritten, transferred to another medium such as microfilm or documented in a computerised system.

[1] OJ L 169, 12.7.1993, p. 1. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).
[2] OJ L 331, 7.12.1998, p. 1. Directive as amended by Regulation (EC) No 1882/2003.

3. All significant changes to documents shall be acted upon promptly and shall be reviewed, dated and signed by a person authorised to perform this task.

6. BLOOD COLLECTION, TESTING AND PROCESSING

6.1. **Donor eligibility**

1. Procedures for safe donor identification, suitability interview and eligibility assessment shall be implemented and maintained. They shall take place before each donation and comply with the requirements set out in Annex II and Annex III to Directive 2004/33/EC.

2. The donor interview shall be conducted in such a way as to ensure confidentiality.

3. The donor suitability records and final assessment shall be signed by a qualified health professional.

6.2. **Collection of blood and blood components**

1. The blood collection procedure shall be designed to ensure that the identity of the donor is verified and securely recorded and that the link between the donor and the blood, blood components and blood samples is clearly established.

2. The sterile blood bag systems used for the collection of blood and blood components and their processing shall be CE-marked or comply with equivalent standards if the blood and blood components are collected in third countries. The batch number of the blood bag shall be traceable for each blood component.

3. Blood collection procedures shall minimise the risk of microbial contamination.

4. Laboratory samples shall be taken at the time of donation and appropriately stored prior to testing.

5. The procedure used for the labelling of records, blood bags and laboratory samples with donation numbers shall be designed to avoid any risk of identification error and mix-up.

6. After blood collection, the blood bags shall be handled in a way that maintains the quality of the blood and at a storage and transport temperature appropriate to further processing requirements.

7. There shall be a system in place to ensure that each donation can be linked to the collection and processing system into which it was collected and/or processed.

6.3. **Laboratory testing**

1. All laboratory testing procedures shall be validated before use.

2. Each donation shall be tested in conformity with the requirements laid down in Annex IV to Directive 2002/98/EC.

3. There shall be clearly defined procedures to resolve discrepant results and ensure that blood and blood components that have a repeatedly reactive result in a serological screening test for infection with the viruses mentioned in Annex IV to Directive 2002/98/EC shall be excluded from therapeutic use and be stored separately in a dedicated environment. Appropriate confirmatory testing shall take place. In case of confirmed positive results, appropriate donor management shall take place including the provision of information to the donor and follow-up procedures.

4. There shall be data confirming the suitability of any laboratory reagents used in the testing of donor samples and blood component samples.

5. The quality of the laboratory testing shall be regularly assessed by the participation in a formal system of proficiency testing, such as an external quality assurance programme.

6. Blood group serology testing shall include procedures for testing specific groups of donors (e.g. first time donors, donors with a history of transfusion).

6.4. **Processing and validation**

1. All equipment and technical devices shall be used in accordance with validated procedures.

2. The processing of blood components shall be carried out using appropriate and validated procedures including measures to avoid the risk of contamination and microbial growth in the prepared blood components.

6.5. **Labelling**

1. At all stages, all containers shall be labelled with relevant information of their identity. In the absence of a validated computerised system for status control, the labelling shall clearly distinguish released from non-released units of blood and blood components.

2. The labelling system for the collected blood, intermediate and finished blood components and samples must unmistakably identify the type of content, and comply with the labelling and traceability requirements referred to in Article 14 of Directive 2002/98/EC and Commission Directive 2005/61/EC [1]. The label for a final blood component shall comply with the requirements of Annex III to Directive 2002/98/EC.

3. For autologous blood and blood components, the label also shall comply with Article 7 of Directive 2004/33/EC and the additional requirements for autologous donations specified in Annex IV to that Directive.

6.6. **Release of blood and blood components**

1. There shall be a safe and secure system to prevent each single blood and blood component from being released until all mandatory requirements set out in this Directive have been fulfilled. Each blood establishment shall be able to demonstrate that each blood or blood component has been formally released by an authorised person. Records shall demonstrate that before a blood component is released, all current declaration forms, relevant medical records and test results meet all acceptance criteria.

2. Before release, blood and blood components shall be kept administratively and physically segregated from released blood and blood components. In the absence of a validated computerised system for status control the label of a unit of blood or blood component shall identify the release status in accordance with 6.5.1.

3. In the event that the final component fails release due to a confirmed positive infection test result, in conformity with the requirements set out in Section 6.3.2 and 6.3.3, a check shall be made to ensure that other components from the same donation and components prepared from previous donations given by the donor are identified. There shall be an immediate update of the donor record.

7. STORAGE AND DISTRIBUTION

1. The quality system of the blood establishment shall ensure that, for blood and blood components intended for the manufacture of medicinal products, the storage and distribution requirements shall comply with Directive 2003/94/EC.

2. Procedures for storage and distribution shall be validated to ensure blood and blood component quality during the entire storage period and to exclude mix-ups of blood components. All transportation and storage actions, including receipt and distribution, shall be defined by written procedures and specifications.

3. Autologous blood and blood components as well as blood components collected and prepared for specific purposes shall be stored separately.

4. Appropriate records of inventory and distribution shall be kept.

5. Packaging shall maintain the integrity and storage temperature of blood or blood components during distribution and transportation.

6. Return of blood and blood components into inventory for subsequent reissue shall only be accepted when all quality requirements and procedures laid down by the blood establishment to ensure blood component integrity are fulfilled.

[1] See page 32 of this Official Journal.

8. CONTRACT MANAGEMENT

Tasks that are performed externally shall be defined in a specific written contract.

9. NON-CONFORMANCE

9.1. **Deviations**

Blood components deviating from required standards set out in Annex V to Directive 2004/33/EC shall be released for transfusion only in exceptional circumstances and with the recorded agreement of the prescribing physician and the blood establishment physician.

9.2. **Complaints**

All complaints and other information, including serious adverse reactions and serious adverse events, which may suggest that defective blood components have been issued, shall be documented, carefully investigated for causative factors of the defect and, where necessary, followed by recall and the implementation of corrective actions to prevent recurrence. Procedures shall be in place to ensure that the competent authorities are notified as appropriate of serious adverse reactions or serious adverse events in accordance with regulatory requirements.

9.3. **Recall**

1. There shall be personnel authorised within the blood establishment to assess the need for blood and blood component recall and to initiate and coordinate the necessary actions.

2. An effective recall procedure shall be in place, including a description of the responsibilities and actions to be taken. This shall include notification to the competent authority.

3. Actions shall be taken within pre-defined periods of time and shall include tracing all relevant blood components and, where applicable, shall include trace-back. The purpose of the investigation is to identify any donor who might have contributed to causing the transfusion reaction and to retrieve available blood components from that donor, as well as to notify consignees and recipients of components collected from the same donor in the event that they might have been put at risk.

9.4. **Corrective and preventive actions**

1. A system to ensure corrective and preventive actions on blood component non-conformity and quality problems shall be in place.

2. Data shall be routinely analysed to identify quality problems that may require corrective action or to identify unfavourable trends that may require preventive action.

3. All errors and accidents shall be documented and investigated in order to identify system problems for correction.

10. SELF-INSPECTION, AUDITS AND IMPROVEMENTS

1. Self-inspection or audit systems shall be in place for all parts of the operations to verify compliance with the standards set out in this Annex. They shall be carried out regularly by trained and competent persons in an independent way according to approved procedures.

2. All results shall be documented and appropriate corrective and preventive actions shall be taken in a timely and effective manner.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 20 September 2005

appointing two members and four alternate members of the Committee of the Regions

(2005/674/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the proposal from the Irish Government,

Whereas:

(1) On 22 January 2002 the Council adopted Decision 2002/60/EC [1] appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2002 to 25 January 2006.

(2) Two members' seats on the Committee of the Regions have become vacant following the resignations of Ms Annette McNAMARA and of Mr Royston BRADY; four alternate members' seats on the Committee of the Regions have become vacant following the resignations of Ms Angela LUPTON, Ms Vivian O'CALLAGHAN, Mr P.J. COGHILL and Ms Catherine MURPHY,

HAS DECIDED AS FOLLOWS:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, namely until 25 January 2006:

(a) as members:

Ms Maria CORRIGAN
Member of Dun Laoghaire-Rathdown Council
in place of Ms Annette McNAMARA

Mr Paul O'DONOGHUE
Member of Kerry County Council
in place of Mr Royston BRADY;

[1] OJ L 24, 26.1.2002, p. 38.

(b) as alternate members:

Ms Mary FREEHILL
Member of Dublin City Council
in place of Ms Angela LUPTON

Ms Michelle MULHERIN
Member of Mayo County Council
in place of Ms Catherine MURPHY

Mr Terry SHANNON
Member of Cork City Council
in place of Mr P.J. COGHILL

Mr Barney STEELE
Member of Longford County Council
in place of Ms Vivian O'CALLAGHAN.

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall take effect on the day of its adoption.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT

COUNCIL DECISION

of 20 September 2005

appointing three members and five alternate members of the Committee of the Regions

(2005/675/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the proposal from the Italian Government,

Whereas:

(1) On 22 January 2002 the Council adopted Decision 2002/60/EC appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2002 to 25 January 2006 [1].

(2) Three members' seats on the Committee of the Regions have become vacant following expiry of the mandates of Mr Francesco STORACE, Mr Vito d'AMBROSIO and Mr Raffaele FITTO; one alternate member's seat on the Committee of the Regions has become vacant following the resignation of Mr Giuseppe CHIARAVALLOTI and four alternate members' seats following expiry of the mandates of Mr Giovanni PACE, Mr Filippo BUBBICO, Mr Giandomenico BARCI and Mr Enzo GHIGO,

HAS DECIDED AS FOLLOWS:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the term of office still to run, namely until 25 January 2006:

(a) as members:

Mr Piero MARRAZZO
Presidente della Regione Lazio
(President of the Region of Latium)
to replace Mr Francesco STORACE

Mr Gian Mario SPACCA
Presidente della Regione Marche
(President of the Marches Region)
to replace Mr Vito d'AMBROSIO

Mr Nichi VENDOLA
Presidente della Regione Puglia
(President of the Region of Apulia)
to replace Mr Raffaele FITTO

(b) as alternate members:

Ms Mercedes BRESSO
Presidente della Regione Piemonte
(President of the Region of Piedmont)
to replace Mr Enzo GHIGO

[1] OJ L 24, 26.1.2002, p. 38.

Mr Claudio BURLANDO
Presidente della Regione Liguria
(President of the Region of Liguria)
to replace Mr Giandomenico BARCI

Mr Vito DE FILIPPO
Presidente della Regione Basilicata
(President of the Region of Basilicata)
to replace Mr Filippo BUBBICO

Mr Ottaviano DEL TURCO
Presidente della Regione Abruzzo
(President of the Region of Abruzzo)
to replace Mr Giovanni PACE

Mr Agazio LOIERO
Presidente della Regione Calabria
(President of the Region of Calabria)
to replace Mr Giuseppe CHIARAVALLOTI

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall take effect on the day of its adoption.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT

COUNCIL DECISION

of 20 September 2005

appointing an alternate member of the Committee of the Regions

(2005/676/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the proposal from the Slovene Government,

Whereas:

(1) On 22 January 2002 the Council adopted Decision 2002/60/EC appointing the members and alternate members of the Committee of the Regions for the period 26 January 2002 to 25 January 2006 [1].

(2) A seat as an alternate member of the Committee of the Regions has become vacant following the resignation of Mr Ivan ŽAGAR,

HAS DECIDED AS FOLLOWS:

Article 1

Ms Irena MAJCEN
(Mayor of Slovensko Bistrica)

is hereby appointed an alternate member of the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2006.

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall take effect on the date of its adoption.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT

[1] OJ L 24, 26.1.2002, p. 38.

COUNCIL DECISION

of 20 September 2005

appointing a member of the European Economic and Social Committee

(2005/677/EC, Euratom)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 259 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Article 167 thereof,

Having regard to Council Decision 2002/758/EC, Euratom of 17 September 2002 appointing the members of the Economic and Social Committee for the period from 21 September 2002 to 20 September 2006 [1],

Having regard to the nomination submitted by the French Government,

Having regard to the opinion of the European Commission,

Whereas a member's seat on the European Economic and Social Committee has fallen vacant, following the resignation of Mr Thierry UHLMANN, of which the Council was informed on 28 November 2004,

HAS DECIDED AS FOLLOWS:

Article 1

Mr Hervé COUPEAU is hereby appointed a member of the European Economic and Social Committee in place of Mr Thierry UHLMANN for the remainder of his term of office, namely until 20 September 2006.

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall take effect on the date of its adoption.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT

[1] OJ L 253, 21.9.2002, p. 9.

COUNCIL DECISION

of 20 September 2005

appointing two members and an alternate member of the Committee of the Regions

(2005/678/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the proposal from the Estonian Government,

Whereas:

(1) On 22 January 2002 the Council adopted Decision 2002/60/EC appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2002 to 25 January 2006 [1].

(2) Two seats as members of the Committee of the Regions have become vacant following the resignations of Mr Andrus ANSIP and Mr Edgar SAVISAAR and one seat as an alternate member of the Committee of the Regions has become vacant following the nomination of Mr Väino HALLIKMÄGI as a member,

HAS DECIDED AS FOLLOWS:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of their term of office, namely until 25 January 2006:

(a) as members:

Mr Väino HALLIKMÄGI
Member of the Council of Pärnu
in place of Mr Andrus ANSIP

Mr Tõnis PALTS
Mayor of Tallinn
in place of Mr Edgar SAVISAAR

(b) as alternate member:

Ms Laine JÄNES
Mayor of Tartu
in place of Mr Väino HALLIKMÄGI

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall take effect on the day of its adoption.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT

[1] OJ L 24, 26.1.2002, p. 38.

COUNCIL DECISION

of 20 September 2005

appointing a member and an alternate member of the Committee of the Regions

(2005/679/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 263 thereof,

Having regard to the proposal from the Maltese Government,

Whereas:

(1) On 22 January 2002 the Council adopted Decision 2002/60/EC appointing the members and alternate members of the Committee of the Regions for the period 26 January 2002 to 25 January 2006 [1].

(2) A seat as a member of the Committee of the Regions has become vacant following the expiry of the mandate of Ms Antonia FARRUGIA and a seat as an alternate member has become vacant following the expiry of the mandate of Mr Keith GRECH,

HAS DECIDED AS FOLLOWS:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, namely until 25 January 2006:

(a) as a member:

Ms Claudette ABELA BALDACCHINO
(Deputy Mayor, Qrendi Local Council)

in place of Mrs Antonia FARRUGIA;

(b) as an alternate member:

Mr Joe CORDINA
(Member, Xagħra Local Council)

in place of Mr Keith GRECH.

Article 2

This Decision shall be published in the *Official Journal of the European Union*.

It shall take effect on the day of its adoption.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT

[1] OJ L 24, 26.1.2002, p. 38.

(Acts adopted under Title V of the Treaty on European Union)

COUNCIL DECISION 2005/680/CFSP

of 12 August 2005

concerning the conclusion of the Agreement between the European Union and the Democratic Republic of the Congo on the status and activities of the European Union Police Mission in the Democratic Republic of the Congo (EUPOL Kinshasa)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 24 thereof,

Having regard to the recommendation from the Presidency,

Whereas:

(1) On 9 December 2004, the Council adopted Joint Action 2004/847/CFSP on the European Union Police Mission in the Democratic Republic of the Congo (EUPOL Kinshasa) ([1]).

(2) Article 13 of the Joint Action provides that the status of EUPOL Kinshasa staff in the Democratic Republic of the Congo, including where appropriate the privileges, immunities and further guarantees necessary for the completion and smooth functioning of EUPOL Kinshasa shall be agreed in accordance with the procedure laid down in Article 24 of the Treaty.

(3) Following the authorisation of 24 January 2005 given by the Council to the Secretary-General/High Representative for the Common Foreign and Security Policy, assisting the Presidency, to open negotiations on its behalf, the Secretary-General/High Representative for the Common Foreign and Security Policy, negotiated an Agreement with the Government of the Democratic Republic of the Congo on the status and activities of EUPOL Kinshasa.

(4) Notwithstanding Article 11(4) of the Agreement, procurement of goods and services should comply with the principles of transparency, proportionality, equal treatment and non-discrimination.

(5) The Agreement should be approved,

HAS DECIDED AS FOLLOWS:

Article 1

The Agreement between the European Union and the Democratic Republic of the Congo on the status and activities of the European Union Police Mission in the Democratic Republic of the Congo (EUPOL Kinshasa) is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

Article 2

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement in order to bind the Union.

Article 3

This Decision shall be published in the *Official Journal of the European Union* ([2]).

Article 4

This Decision shall take effect on the day of its adoption.

Done at Brussels, 12 August 2005.

For the Council
The President
J. STRAW

([1]) OJ L 367, 14.12.2004, p. 30.

([2]) The date of entry into force of the Agreement will be published in the *Official Journal of the European Communities* by the General Secretariat of the Council.

TRANSLATION

AGREEMENT

between the European Union and the Democratic Republic of the Congo on the status and activities of the European Union police mission in the Democratic Republic of the Congo (EUPOL Kinshasa)

THE EUROPEAN UNION, hereinafter referred to as the 'EU',

on the one hand, and

THE GOVERNMENT OF THE DEMOCRATIC REPUBLIC OF THE CONGO, hereinafter referred to as the 'Host Party',

on the other hand,

Together hereinafter referred to as the 'Parties',

TAKING INTO ACCOUNT:

(a) the letter from the Minister of Foreign Affairs and International Cooperation of the Host Party to the Secretary General/High Representative for the Common Foreign and Security Policy (SG/HR) dated 20 October 2003, requesting the EU to assist in setting up the Integrated Police Unit (IPU), which should contribute to ensuring the protection of the State institutions and reinforce the internal security apparatus of the Democratic Republic of the Congo,

(b) the letter of the President of the Democratic Republic of the Congo to the SG/HR of 16 February 2004 inviting the European Union to deploy a Police Mission to Kinshasa, to monitor, mentor and advise the IPU, under certain conditions, and the response of the SG/HR of 4 April 2004 accepting the invitation under the mentioned conditions,

(c) the adoption by the Council of the European Union on 9 December 2004 of Joint Action 2004/847/CFSP on the European Union Police Mission in Kinshasa (CDR) regarding the integrated Police Unit (EUPOL 'Kinshasa') [1] to the Host Party,

(d) the duration of the EUPOL Kinshasa, expected to last until the end of the year 2005,

(e) that the purpose of the privileges and immunities as provided for in this Agreement are not to benefit individuals but to ensure the efficient performance of the EU Mission; and

(f) wishing to settle, by means of this Agreement, the Statute of the EU Police Mission in the Democratic Republic of the Congo and to define in consequence its privileges and immunities,

HAVE AGREED AS FOLLOWS:

Article 1

Scope of application and definitions

1. The provisions of this Agreement and any obligation undertaken by the Host Party or any privilege, immunity, facility or concession granted to EUPOL Kinshasa or to EUPOL Kinshasa personnel shall apply in the territory of the Host Party only.

2. For the purpose of this Agreement, the following definitions shall apply:

(a) 'EUPOL Kinshasa' means the EU Police Mission in the Host Party established by Joint Action 2004/847/CFSP, including its components, forces, units, headquarters and personnel deployed in the territory of the Host Party and assigned to EUPOL Kinshasa.

(b) 'Head of Mission/Police Commissioner' means the Head of Mission/Police Commissioner of EUPOL Kinshasa, appointed by the Council of the European Union.

(c) 'EUPOL Kinshasa personnel' means the Head of Mission/Police Commissioner, personnel seconded by EU Member States and EU institutions and third States invited by the EU to participate in EUPOL Kinshasa, and international staff recruited on a contractual basis by EUPOL Kinshasa deployed for the preparation, support and implementation of the Mission, and shall not include commercial contractors or local personnel.

[1] OJ L 367, 14.12.2004, p. 30.

(d) 'Headquarters' means the EUPOL Kinshasa main headquarters in Kinshasa and the training centre at Kasangulu.

(e) 'Sending State' means any EU Member State or third States that has seconded personnel to EUPOL Kinshasa.

(f) 'Premises' means all buildings, facilities and land required for the conduct of the activities of EUPOL Kinshasa, as well as for the accommodation of EUPOL Kinshasa personnel.

Article 2

General provisions

1. EUPOL Kinshasa and EUPOL Kinshasa personnel shall respect the laws and regulations of the Host Party and shall refrain from any action or activity incompatible with the impartial and international nature of their duties or inconsistent with the provisions of this Agreement.

2. EUPOL Kinshasa shall be autonomous with regard to the execution of its functions under this Agreement. The Host Party shall respect the unitary and international nature of EUPOL Kinshasa.

3. The Head of Mission/Police Commissioner shall notify the Government of the Host Party of the location of its Headquarters.

4. The Head of Mission/Police Commissioner shall regularly, and in a timely manner, inform the Government of the Host Party of the number, names and nationalities of EUPOL Kinshasa personnel stationed in the territory of the Host Party, through the submission of a notification list to the Ministry of Foreign Affairs of the Host Party.

Article 3

Identification

1. EUPOL Kinshasa personnel shall be provided with and identified by an EUPOL Kinshasa identification card, which they shall be obliged to carry with them at all times.

2. The Ministry of Foreign Affairs and of International Cooperation of the Host Party shall provide identity cards to EUPOL Kinshasa personnel in accordance with their status as set down in Article 6.

3. Vehicles and other means of transport of EUPOL Kinshasa shall bear distinctive EUPOL Kinshasa identification markings, an example of which shall be provided to the relevant authorities of the Host Party.

4. EUPOL Kinshasa shall be permitted to display the flag of the EU at its main headquarters and elsewhere, alone or together with the flag of the Host Party, as decided by the Head of Mission/Police Commissioner. National flags or insignia of the constituent national elements of EUPOL Kinshasa may be displayed on EUPOL Kinshasa premises, vehicles and uniforms, as decided by the Head of Mission/Police Commissioner.

Article 4

Border Crossing, movement, and presence on the territory of the Host Party

1. EUPOL Kinshasa personnel and EUPOL Kinshasa assets and means of transport shall cross the border of the Host Party at official border crossings, sea ports and via the international air corridors.

2. The Host Party shall facilitate the entry into and the departure from the territory of the Host Party for EUPOL Kinshasa and EUPOL Kinshasa personnel. Except for passport control on entry into and departure from the territory of the Host Party, EUPOL Kinshasa personnel, with proof of membership of the Mission, shall be exempt from passport, visa and immigration regulations and any form of immigration inspection.

3. EUPOL Kinshasa personnel shall be exempt from the regulations of the Host Party governing the registration and control of aliens, but shall not be considered as acquiring any right to permanent residence or domicile in the territory of the Host Party.

4. For EUPOL Kinshasa assets, including sidearms for EUPOL Kinshasa personnel, and means of transport entering, transiting or exiting the Host Party territory in support of the Mission, EUPOL Kinshasa shall provide a certificate of exemption accompanied by an inventory. They shall be exempt from any other customs documentation. A copy of the certificate shall be transmitted to the competent authorities when entering or exiting the Host Party. The format of the certificate shall be agreed between EUPOL Kinshasa and the competent authorities of the Host Party.

5. Vehicles and aircraft used in support of the Mission shall not be subject to local licensing or registration requirements. Relevant international standards and regulations shall continue to apply.

6. EUPOL Kinshasa personnel may drive motor vehicles in the territory of the Host Party provided they have a valid national driving licence. The Host Party shall accept as valid, without tax or fee, driving licences or permits issued to EUPOL Kinshasa personnel.

7. EUPOL Kinshasa and EUPOL Kinshasa personnel together with their vehicles, aircraft or any other means of transport, equipment and supplies shall enjoy free and unrestricted movement throughout the territory of the Host Party, including its airspace. If necessary, technical arrangements may be concluded in accordance with Article 17.

8. For the purpose of the Mission, EUPOL Kinshasa personnel, and local personnel employed by EUPOL Kinshasa when travelling on official duties, may use roads, bridges and airports without payment of duties, fees, tolls, taxes or other charges.

Article 5

Immunities and privileges of EUPOL Kinshasa

1. EUPOL Kinshasa shall be granted the status equivalent to that of a diplomatic mission under the Vienna Convention on Diplomatic Relations dated 18 April 1961, hereinafter referred to as 'the Vienna Convention'.

2. EUPOL Kinshasa, its property, funds and assets shall enjoy immunity from the criminal, civil, and administrative jurisdiction of the Host Party, in accordance with the Vienna Convention.

3. The premises of EUPOL Kinshasa shall be inviolable. At no time shall the agents of the Host Party enter them, except with the consent of the Head of Mission/Police Commissioner.

4. The premises of EUPOL Kinshasa, their furnishings and other assets thereon as well as their means of transport shall be immune from search, requisition, attachment or execution.

5. The archives and documents of EUPOL Kinshasa shall be inviolable at all times.

6. Correspondence of EUPOL Kinshasa shall be granted a status equivalent to that of official correspondence granted under the Vienna Convention.

7. For imported goods and services and in respect of its premises, provided these are intended for the purpose of the Mission, EUPOL Kinshasa shall be exempt from all national and communal dues, taxes or charges of similar nature.

8. For goods purchased and services contracted on the domestic market, provided these are intended for the purpose of the Mission, EUPOL Kinshasa shall be either exempt from or reimbursed by the Host Party for all national and communal dues and taxes, including VAT, and charges of similar nature according to the laws of the Host Party.

9. The Host Party shall permit entry of articles for the Mission and grant exemption from all custom duties, taxes and related charges other than charges for storage, cartage and similar services.

Article 6

Immunities and privileges of EUPOL Kinshasa personnel

1. EUPOL Kinshasa personnel shall be granted all privileges and immunities equivalent to that of diplomatic agents granted under the Vienna Convention, subject to which the EU Member States and other Sending States shall have priority of jurisdiction. These privileges and immunities shall be granted to EUPOL Kinshasa personnel during their mission, and thereafter, with respect to official acts previously performed in the exercise of their mission.

2. The Secretary General/High Representative shall, with the explicit consent of the competent authority of the Sending State or the sending EU institution, waive the immunity enjoyed by EUPOL Kinshasa personnel where such immunity would impede the course of justice and it can be waived without prejudice to the interests of the EU.

3. EUPOL Kinshasa personnel shall have the right to import free of duty or other restrictions items required for their personal use, and to export such items. EUPOL Kinshasa personnel shall have the right to purchase free of duty or other restrictions items required for their personal use, and to export such items; for goods and services purchased on the domestic market, EUPOL Kinshasa personnel shall be exempt from VAT and taxes according to the laws of the Host Party.

4. EUPOL Kinshasa personnel shall be exempt from dues and taxes in the Host Party on the emoluments and salaries they receive by reason of their employment. Where the incidence of any form of taxation depends upon residence, periods during which personnel seconded to EUPOL Kinshasa and international staff recruited on a contractual basis by EUPOL Kinshasa are present in the Host Party for the discharge of their duties shall not be considered as periods of residence.

Article 7

Local personnel employed by EUPOL Kinshasa

Local personnel employed by EUPOL Kinshasa who are nationals of or permanently resident in the Host Party shall enjoy a status equivalent to that enjoyed, in accordance with the Vienna Convention, by locally employed staff in diplomatic missions in the Host Party.

Article 8

Security

1. The Host Party, through its own capabilities, shall assume full responsibility for the security of EUPOL Kinshasa personnel.

2. To that end, the Host Party shall take all necessary measures for the protection, safety and security of EUPOL Kinshasa and EUPOL Kinshasa personnel. Any specific provisions, proposed by the Host Party, shall be agreed with the Head of Mission/Police Commissioner before implementation. The Host Party shall permit and support free of any charge activities relating to the medical evacuation of EUPOL Kinshasa personnel. If required, supplementary arrangements as referred to in Article 17 shall be concluded.

3. EUPOL Kinshasa personnel shall have the right to carry sidearms for self defence, subject to a decision by the Head of Mission/Police Commissioner.

4. EUPOL Kinshasa shall not have an executive policing role.

Article 9

Uniform and arms

1. EUPOL Kinshasa personnel shall wear national uniform or civilian dress with distinctive EUPOL Kinshasa identification.

2. The wearing of uniform shall be subject to rules issued by the Head of Mission/Police Commissioner.

3. In accordance with Article 8.3, EUPOL Kinshasa personnel may carry sidearms and ammunition.

Article 10

Cooperation and Access to Information

1. The Host Party shall provide full cooperation and support to EU Kinshasa and EU Kinshasa personnel.

2. If requested and necessary for the accomplishment of the EUPOL Kinshasa mission, the Host Party shall provide:

(a) EUPOL Kinshasa personnel with effective access to buildings, facilities, locations and official vehicles within the control of the Host Party;

(b) EUPOL Kinshasa personnel with effective access to documents, materials and information within its control relevant to the mandate of EUPOL Kinshasa.

3. The Head of Mission/Police Commissioner and the Government of the Host Party shall consult regularly and take appropriate measures to ensure close and reciprocal liaison at every appropriate level. The Host Party may appoint a liaison officer to EUPOL Kinshasa.

Article 11

Host Party Support and Contracting

1. The Host party agrees, if requested by EUPOL Kinshasa, to assist in finding suitable premises.

2. If required and available, premises owned by the Host Party shall be provided free of charge.

3. Within its means and capabilities, the Host Party shall assist and support the preparation, establishment, execution and support of EUPOL Kinshasa. The assistance and the support from the Host Party to EUPOL Kinshasa shall be provided under the same conditions as those provided to the IPU.

4. EUPOL Kinshasa will endeavour, to the maximum extent possible, to contract locally for services, goods and personnel, subject to the requirements of the Mission.

Article 12

Deceased EUPOL Kinshasa personnel

1. The Head of Mission/Police Commissioner shall have the right to take charge of and make suitable arrangements for the repatriation of any deceased EUPOL Kinshasa personnel, as well as any personal property belonging to the deceased.

2. Autopsies shall not be performed on deceased members of the EUPOL Kinshasa without the agreement of the Sending State or, in the case of international staff, the State of his/her nationality, and the presence of a representative of EUPOL Kinshasa and/or the State concerned.

Article 13

Communications

1. EUPOL Kinshasa shall have the right to install and operate radio sending and receiving stations, as well as satellite systems, using appropriate frequencies, subject to arrangements to be concluded in accordance with Article 17.

2. EUPOL Kinshasa shall enjoy the right to unrestricted communication by radio (including satellite, mobile or hand-held radio), telephone, telegraph, facsimile and other means, as well as the right to install, for the purpose of the Mission, the necessary means for maintaining such communications within and between EUPOL Kinshasa facilities, including the laying of cables and ground lines, in accordance with the regulations of the Host Party.

Article 14

Claims for death, injury, damage or loss

1. The Member States, other States participating in EUPOL Kinshasa, or EU Institutions, shall not be obliged to reimburse claims arising out of activities in connection with civil disturbances, protection of the EUPOL Kinshasa or its personnel, or which are incidental to operational necessities.

2. Any other claim of a civil law character, including claims of personnel locally employed by EUPOL Kinshasa, to which EUPOL Kinshasa or any member thereof is a party and over which the courts of the Host Party do not have jurisdiction because of any provision of the present Agreement, shall be submitted through the authorities of the Host Party to the Head of Mission/Police Commissioner and shall be dealt with by separate arrangements, as referred to in Article 17, whereby procedures for settling claims and for addressing claims shall be established. Settlement of claims will occur after previous consent of the State concerned.

Article 15

Disputes

1. All issues arising in connection with the application of this agreement shall be discussed by a Joint Coordination Group. This Group shall be composed of representatives of EUPOL Kinshasa and the competent authorities of the Host Party.

2. Failing any prior settlement, disputes with regard to the interpretation or application of this Agreement shall be settled between the Host Party and EU representatives by diplomatic means.

Article 16

Other provisions

1. Whenever this Agreement refers to the immunities, privileges and rights of EUPOL Kinshasa and EUPOL Kinshasa personnel, the Government of the Host Party shall be responsible for the implementation and fulfilment of such immunities, privileges and rights through the appropriate local authorities of the Host Party.

2. Nothing in this Agreement is intended or shall be construed to derogate from any rights that may attach with respect to an EU Member State or any other State contributing to EUPOL Kinshasa or their personnel under other agreements.

Article 17

Supplementary arrangements

The Head of Mission/Police Commissioner and the administrative authorities of the Host Party shall conclude such supplementary arrangements as may be necessary to implement this Agreement.

Article 18

Entry into force and termination

1. This Agreement shall enter into force on the date of signature by both Parties.

2. This Agreement may be amended on the basis of mutual written agreement between the Parties.

3. This Agreement shall remain in force until the final departure of EUPOL Kinshasa or all personnel thereof.

4. This Agreement may be denounced by written notification to the other Party. The denunciation shall take effect 60 days after receipt by the other Party of the notification of denunciation.

5. Termination or denunciation of this Agreement shall not affect any rights or obligations arising from the execution of the present Agreement prior to its termination or denunciation.

Done at Kinshasa, on 1 September 2005 in two originals in French.

For the European Union

For the Government of the Democratic Republic of the Congo

(Acts adopted under Title VI of the Treaty on European Union)

COUNCIL DECISION 2005/681/JHA

of 20 September 2005

establishing the European Police College (CEPOL) and repealing Decision 2000/820/JHA

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 30(1)(c) and Article 34(2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) At its meeting in Tampere on 15 and 16 October 1999, the European Council agreed that a European Police College, hereinafter referred to as 'CEPOL', should be established to train senior officers of police forces.

(2) The European Police College was established by Council Decision 2000/820/JHA [2].

(3) It has become apparent that the functioning of CEPOL could be improved if it were financed from the general budget of the European Union and if the Staff Regulations of officials of the European Communities and the Conditions of employment of other servants of the European Communities applied to the Director and the staff of the CEPOL Secretariat.

(4) The conclusions of the Council of 24 February 2005 therefore called for the aforementioned amendments to be implemented, which makes it necessary to repeal Decision 2000/820/JHA and to replace it by a new Council Decision concerning CEPOL.

(5) CEPOL should continue to function as a network, linking national training institutes whose tasks include the training of senior police officers of the Member States, in accordance with the general principles as laid down in Decision 2000/820/JHA.

(6) CEPOL should carry out its tasks by progressive stages in the light of the objectives set out in the annual work programmes and with due regard for available resources.

(7) A number of technical changes are necessary in order to bring the structure of CEPOL in line with the procedures to be followed in the framework of the general budget of the European Union and of the Staff Regulations of officials of the European Communities and the Conditions of employment of other servants of the European Communities.

(8) As regards other provisions, these are as far as possible based on Decision 2000/820/JHA.

(9) The technical changes include amendments to the provisions dealing with the relations with third States, the functioning of the Governing Board, the tasks of the Director, the staff of the CEPOL Secretariat, the financial requirements, access to documents and evaluation.

(10) In order to guarantee continuity, specific transitional provisions are required,

HAS DECIDED AS FOLLOWS:

CHAPTER I

ESTABLISHMENT, LEGAL PERSONALITY AND SEAT

Article 1

Establishment

1. A European Police College (CEPOL) is hereby established. It shall be regarded as the successor of CEPOL, as established by Decision 2000/820/JHA.

2. Without prejudice to future developments, CEPOL shall function as a network, by bringing together the national training institutes in the Member States whose tasks include the training of senior police officers, which shall cooperate closely to that end.

[1] Opinion delivered on 12 April 2005 (not yet published in the Official Journal).

[2] OJ L 336, 30.12.2000, p. 1. Decision as last amended by Decision 2004/567/JHA (OJ L 251, 27.7.2004, p. 20).

3. CEPOL's task shall be to implement the programmes and initiatives decided upon by the Governing Board.

Article 2

Legal personality

1. CEPOL shall have legal personality.

2. CEPOL shall enjoy in each Member State the most extensive legal and contractual capacity available to legal persons under national law. CEPOL may in particular acquire and dispose of movable or immovable property and be a party to legal proceedings.

3. The Director shall represent CEPOL in all legal acts and obligations.

Article 3

Privileges and Immunities

The Protocol on the Privileges and Immunities of the European Communities shall apply to the Director of CEPOL and the staff of its Secretariat, with the exception of staff seconded from the Member States.

Article 4

Seat

The seat of CEPOL shall be in Bramshill, United Kingdom.

CHAPTER II

PURPOSE, OBJECTIVES AND TASKS

Article 5

Purpose

The aim of CEPOL shall be to help train the senior police officers of the Member States by optimising cooperation between CEPOL's various components. It shall support and develop a European approach to the main problems facing Member States in the fight against crime, crime prevention, and the maintenance of law and order and public security, in particular the cross-border dimensions of those problems.

Article 6

Objectives

CEPOL's objectives shall be as follows:

1. to increase knowledge of the national police systems and structures of other Member States and of cross-border police cooperation within the European Union;

2. to improve knowledge of international and Union instruments, in particular in the following sectors:

   (a) the institutions of the European Union, their functioning and role, as well as the decision-making mechanisms and legal instruments of the European Union, in particular as regards their implications for law-enforcement cooperation;

   (b) Europol's objectives, structure and functioning, as well as ways to maximise cooperation between Europol and relevant law-enforcement services in the Member States in the fight against organised crime;

   (c) Eurojust's objectives, structure and functioning;

3. to provide appropriate training with regard to respect for democratic safeguards, with particular reference to the rights of defence.

Article 7

Tasks

In order to achieve those objectives, CEPOL may, in particular, undertake the following actions:

(a) provide training sessions, based on common standards, for senior police officers;

(b) contribute to the preparation of harmonised programmes for the training of middle-ranking police officers, middle-ranking police officers in the field and police officers in the field with regard to cross-border cooperation between police forces in Europe, and help set up appropriate advanced training programmes as well as develop and provide training for trainers;

(c) provide specialist training for police officers playing a key role in combating cross-border crime, with a particular focus on organised crime;

(d) disseminate best practice and research findings;

(e) develop and provide training to prepare police forces of the European Union for participation in non-military crisis management;

(f) develop and provide training for police authorities from the candidate countries, including training for police officers with a key role;

(g) facilitate relevant exchanges and secondments of police officers in the context of training;

(h) develop an electronic network to provide back-up for CEPOL in the performance of its duties, ensuring that the necessary security measures are put in place;

(i) enable the senior police officers of the Member States to acquire relevant language skills.

Article 8

Cooperation with other bodies

1. CEPOL may cooperate with relevant bodies of the European Union in the field of law enforcement and other related areas and with relevant training bodies in Europe.

2. CEPOL may cooperate with national training institutes of non-member States of the European Union, in particular with those of the candidate countries, as well as with those of Iceland, Norway and Switzerland.

3. The Governing Board may authorise the Director of CEPOL to negotiate cooperation agreements with any of the bodies mentioned in paragraphs 1 and 2.

Such cooperation agreements may be concluded only with the authorisation of the Governing Board.

Cooperation agreements with bodies of non-member States of the European Union can only be concluded after the approval of the Council has been obtained.

4. CEPOL may take into account recommendations made by Europol and/or the Task Force of Chiefs of Police of the Member States of the EU, without prejudice to the rules governing the adoption of the CEPOL work program.

CHAPTER III

ORGANS, STAFF AND CONTACT POINTS

Article 9

Organs

The organs of CEPOL shall be:

1. The Governing Board.

2. The Director, heading the CEPOL Secretariat.

Article 10

The Governing Board

1. The Governing Board shall be made up of one delegation from each Member State. Each delegation shall have one vote.

2. The members of the Governing Board shall preferably be directors of national training institutes. Where there are several directors from a single Member State, they shall together form a delegation. The Governing Board shall be chaired by the representative of the Member State holding the Presidency of the Council of the European Union.

3. Representatives of the Commission and of the General Secretariat of the Council of the European Union and Europol shall be invited to attend meetings as non-voting observers.

4. Members of the Governing Board may be accompanied by experts.

5. The Director of CEPOL shall participate in the meetings of the Governing Board, without the right to vote.

6. The Governing Board shall meet at least twice a year.

7. Except when otherwise indicated in this Decision, the Governing Board shall act by a two-thirds majority of its members.

8. The Governing Board shall establish its rules of procedure.

9. The Governing Board shall adopt:

(a) common curricula, training modules, learning methods, and any other learning and teaching tools;

(b) the decision appointing the Director;

(c) by unanimity, the draft budget to be submitted to the Commission;

(d) the work programme, after having consulted the Commission, to be submitted to the Council for approval;

(e) the annual report and the CEPOL five-year report to be submitted to the Commission and the Council, in order to allow the Council to take note of them and endorse them;

(f) the implementing rules applicable to the CEPOL staff, on a proposal from the Director and after seeking agreement from the Commission.

10. The Governing Board may decide, in cases of strict necessity, to establish working groups to make recommendations, to develop and propose strategies, training concepts and tools, or to perform any other advisory task deemed necessary by the Governing Board. The Governing Board shall draw up the rules governing the creation and functioning of the working groups.

11. The Governing Board shall exercise the powers laid down in Article 13(3) in respect of the Director.

12. Without prejudice to paragraph 9(d) and (e), the work programme, the annual report on CEPOL's activities and the CEPOL five-year report shall be forwarded to the European Parliament and the Commission for information and shall be made public.

Article 11

The Director

1. The Director shall be appointed by the Governing Board from a list of at least three candidates presented by a selection committee, for a four-year period extendable once.

The Governing Board shall establish rules regarding the selection of the candidates. Such rules shall be approved by the Council prior to their entry into force.

2. The Governing Board may decide to extend the term of office of the Director.

3. The Governing Board may remove the Director from his/her office.

4. The Director shall be responsible for the day-to-day administration of CEPOL's work. He or she shall support the work of the Governing Board. He or she shall:

(a) exercise, in respect of the staff, the powers laid down in Article 13(3);

(b) take all necessary steps, including the adoption of internal administrative instructions and the publication of notices, to ensure that CEPOL functions in accordance with the provisions of this Decision;

(c) draw up the preliminary draft budget, the preliminary draft annual report and the preliminary draft work programme to be submitted to the Governing Board;

(d) implement the budget;

(e) maintain contacts with the relevant services in the Member States;

(f) coordinate the implementation of the work programme;

(g) perform any other function attributed to him/her by the Governing Board.

5. The Director shall be accountable for his/her activities to the Governing Board.

6. If the Council so requests, the Director shall report on the carrying out of his/her duties. The Director may do the same if the European Parliament so requests.

7. The Director shall negotiate a headquarters agreement with the government of the host Member State, and submit it for approval to the Governing Board.

Article 12

The CEPOL Secretariat

The CEPOL Secretariat shall assist CEPOL with the administrative tasks necessary for it to function and implement the annual programme and, where appropriate, the additional programmes and initiatives.

Article 13

Staff of the CEPOL Secretariat

1. The Staff Regulations of officials of the European Communities, the Conditions of employment of other servants of the European Communities and the rules adopted jointly by the institutions of the European Communities for the purposes of the application of those Staff Regulations and Conditions of employment shall apply to the Director of CEPOL and the staff of CEPOL's Secretariat recruited after the entry into force of this Decision.

2. For the purpose of implementing Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff regulations of officials and the Conditions of employment of other servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission [1], CEPOL is an agency within the meaning of Article 1a, paragraph 2, of the Staff regulations of officials of the European Communities.

3. The powers conferred on the appointing authority by the Staff regulations and on the authority authorised to conclude contracts by the Conditions of employment of other servants shall be exercised by CEPOL in respect of the staff of its Secretariat in accordance with the provisions of Articles 10(11) and 11(4)(a) of this Decision.

[1] OJ L 56, 4.3.1968, p. 1. Regulation as last amended by Regulation (EC, Euratom) No 723/2004 (OJ L 124, 27.4.2004, p. 1).

4. The staff of CEPOL's Secretariat shall consist of officials seconded by an institution within the meaning of the Staff regulations of officials of the European Communities, of experts seconded by Member States, and of other servants recruited by CEPOL as necessary to carry out its tasks, all on a temporary basis.

5. The secondment of national experts from the Member States to the CEPOL Secretariat shall be in accordance with Council Decision 2003/479/EC of 16 June 2003 concerning the rules applicable to national experts and military staff on secondment to the General Secretariat of the Council [1], which shall apply by analogy.

Article 14

Contact points

A CEPOL national contact point may be set up in each Member State. Without prejudice to the Member States' right to organise this contact point as it sees fit, the contact point shall preferably be the Member State's delegation at the Governing Board. The national contact point shall ensure effective cooperation between CEPOL and the training institutes.

CHAPTER IV

FINANCIAL REQUIREMENTS

Article 15

Budget

1. The revenues of CEPOL shall consist, without prejudice to other types of income, of a subsidy from the Community entered in the general budget of the European Union (Commission section).

2. The expenditure of CEPOL shall include the staff, administrative, infrastructure and operational expenses.

3. The Director shall draw up an estimate of the revenues and expenditure of CEPOL for the following financial year and shall forward it to the Governing Board together with a provisional establishment plan.

4. Revenue and expenditure shall be in balance.

5. The Governing Board shall adopt the draft estimate, including the provisional establishment plan accompanied by the preliminary work programme, and forward them by 31 March of each year, at the latest, to the Commission. If the Commission has objections to the draft estimate, it shall consult the Governing Board within 30 days following receipt thereof.

6. The estimate shall be forwarded by the Commission to the European Parliament and the Council (hereinafter referred to as the budgetary authority) together with the preliminary draft budget of the European Union.

7. On the basis of the estimate, the Commission shall enter in the preliminary draft general budget of the European Union the estimates it deems necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Article 272 of the Treaty.

8. The budgetary authority shall authorise the appropriations for the subsidy to CEPOL. The budgetary authority shall adopt the establishment plan for CEPOL.

9. The Governing Board shall adopt the CEPOL budget and the establishment plan. They shall become definitive following the final adoption of the general budget of the European Union. Where appropriate, they shall be adjusted accordingly.

10. Any modification to the budget, including the establishment plan, shall follow the procedure laid down in paragraphs 5 to 9.

11. The Governing Board shall, as soon as possible, notify the budgetary authority of its intention to implement any project that may have significant financial implications for the funding of its budget, in particular any projects relating to property such as the rental or purchase of buildings. It shall inform the Commission thereof.

12. Where a branch of the budgetary authority has notified its intention to deliver an opinion, it shall forward its opinion to the Governing Board within a period of six weeks from the date of notification of the project.

Article 16

Implementation and control of the budget

1. The Director shall implement CEPOL's budget.

2. By 1 March at the latest following each financial year, CEPOL's accounting officer shall communicate the provisional accounts to the Commission's accounting officer together with a report on the budgetary and financial management for that financial year. The Commission's accounting officer shall consolidate the provisional accounts of the institutions and decentralised bodies in accordance with Article 128 of Council Regulation (EC, Euratom) No 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities [2] (Financial Regulation).

[1] OJ L 160, 28.6.2003, p. 72. Decision as last amended by Decision 2004/240/EC (OJ L 74, 12.3.2004, p. 17).

[2] OJ L 248, 16.9.2002, p. 1.

3. By 31 March at the latest following each financial year, the Commission's accounting officer shall forward CEPOL's provisional accounts to the Court of Auditors, together with a report on the budgetary and financial management for that financial year. The report on the budgetary and financial management for that financial year shall also be forwarded to the European Parliament and the Council.

4. On receipt of the Court of Auditors' observations on CEPOL's provisional accounts, pursuant to Article 129 of the Financial Regulation, the Director shall draw up CEPOL's final accounts under his/her own responsibility and forward them to the Governing Board for an opinion.

5. The Governing Board shall deliver an opinion on CEPOL's final accounts.

6. By 1 July of the following year at the latest, the Director shall send the final accounts, together with the opinion of the Governing Board, to the Commission, the Court of Auditors, the European Parliament and the Council.

7. The final accounts shall be published.

8. The Director shall send the Court of Auditors a reply to its observations by 30 September at the latest. He or she shall also send this reply to the Governing Board.

9. Upon a recommendation from the Council, the European Parliament shall, before 30 April of year n + 2, give a discharge to the Director of CEPOL in respect of the implementation of the budget for year n.

Article 17

Financial provision

The financial rules applicable to CEPOL shall unanimously be adopted by the Governing Board after having consulted the Commission. They may not depart from Commission Regulation (EC, Euratom) No 2343/2002 of 23 December 2002 on the framework Financial Regulation for the bodies referred to in Article 185 of Council Regulation (EC, Euratom) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities [1], unless specifically required for CEPOL's operation and with the Commission's prior consent. The budgetary authority shall be informed of these derogations.

Article 18

Combating fraud

1. In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 of the European Parliament and of the Council of 25 May 1999 concerning investigations conducted by the European Anti-fraud Office (OLAF) [2] shall apply without restriction.

2. CEPOL shall accede to the Inter-institutional Agreement of 25 May 1999 concerning internal investigations by the European Anti-fraud Office (OLAF) and shall issue, without delay, the appropriate provisions applicable to the Director of CEPOL and the staff of CEPOL's Secretariat.

3. The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and OLAF may, if necessary, carry out on-the-spot checks among the recipients of CEPOL's funding and the agents responsible for allocating it.

CHAPTER V

MISCELLANEOUS PROVISIONS

Article 19

Languages

The provisions laid down in Regulation No 1 of 15 April 1958 determining the languages to be used in the European Economic Community [3] shall apply to CEPOL. The annual report to the Council referred to in Article 10(9)(e) shall be drawn up in the official languages of the Union institutions.

Article 20

Access to documents

On the basis of a proposal by the Director, and not later than six months after this Decision takes effect, the Governing Board shall adopt rules for access to CEPOL documents, taking into account the principles and limits stated in Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents [4].

Article 21

Evaluation

1. Within five years after this Decision takes effect, and every five years thereafter, the Governing Board shall commission an independent external evaluation of the implementation of this Decision as well as of the activities carried out by CEPOL.

2. Each evaluation shall assess the impact of this Decision and the utility, relevance, effectiveness and efficiency of CEPOL and its working practices.

[1] OJ L 357, 31.12.2002, p. 72.

[2] OJ L 136, 31.5.1999, p. 1.

[3] OJ 17, 6.10.1958, p. 385/58. Regulation as last amended by the 2003 Act of Accession.

[4] OJ L 145, 31.5.2001, p. 43.

3. The Governing Board shall receive the evaluation and issue recommendations regarding CEPOL's structure and its working practices to the Commission. Both the evaluation findings and recommendations shall be part of the five-year report, to be established in accordance with the procedure provided for in Article 10(9)(e).

Article 22

Decisions by the Council

When acting pursuant to Articles 8(3), 10(9)(d) and (e), 11(1) and 16(9), the Council shall decide by a qualified majority of its members.

CHAPTER VI

TRANSITIONAL PROVISIONS

Article 23

General legal succession

1. CEPOL, as established by this Decision, shall be the general legal successor in respect of all contracts concluded by, liabilities incumbent on, and properties acquired by CEPOL, as established under Decision 2000/820/JHA.

2. Without prejudice to Article 11(7), the Headquarters Agreement, concluded on the basis of Article 4(1) of Decision 2000/820/JHA, shall remain in force for CEPOL, established by this Decision, until repealed.

Article 24

The Director and Staff

1. The Director, appointed on the basis of Article 4(2) of Decision 2000/820/JHA shall, for the remaining period of his/her term, be the Director within the meaning of Article 11 of this Decision.

2. In the event that he/she is unwilling or unable to act in accordance with paragraph 1, the Governing Board shall appoint an interim Director for a maximum period of 18 months, pending the appointment procedure as provided for in Article 11(1) of this Decision.

3. Employment contracts concluded before the adoption of this Decision shall be honoured.

4. The seconded national experts who are posted to CEPOL, established on the basis of Decision 2000/820/JHA, shall be entitled to continue their secondments to CEPOL in accordance with the rules referred to in Article 13(5) of this Decision.

Article 25

Budget

1. The discharge procedure in respect of the budgets, established on the basis of Article 5(3) of Decision 2000/820/JHA, shall be carried out in accordance with the financial regulation adopted on the basis of Article 5(3) of Decision 2000/820/JHA.

2. All expenditure resulting from commitments made by CEPOL in accordance with the financial regulation adopted on the basis of Article 5(3) of Decision 2000/820/JHA before the entry into force of this Decision which has not yet been paid at that time shall be covered by the budget of the CEPOL, as established by this Decision.

3. Before the expiry of a period of nine months after the entry into force of this Decision, the Governing Board shall unanimously establish the amount covering the expenditure referred to in paragraph 2. A corresponding amount, financed from the accumulated surplus of the budgets approved on the basis of Article 5(3) of Decision 2000/820/JHA, shall be transferred into the 2006 budget established by this Decision and shall constitute an assigned revenue to cover this expenditure.

If the surpluses are not sufficient to cover the expenditure referred to in paragraph 2, the Member States shall provide the financing necessary on the basis of Decision 2000/820/JHA.

4. The remainder of the surpluses of the budgets approved on the basis of Article 5(3) of Decision 2000/820/JHA shall be paid back to the Member States. The amount to be paid to each of the Member States shall be calculated on the basis of the annual contributions from the Member States to the CEPOL budgets, established on the basis of Article 5(2) of Decision 2000/820/JHA.

The remainder shall be paid back to the Member States within three months after the amount referred to in paragraph 3 has been established and the discharge procedures regarding the budgets approved on the basis of Article 5(3) of Decision 2000/820/JHA have been completed.

5. CEPOL shall continue to implement the Community financed projects in which CEPOL, established on the basis of Decision 2000/820/JHA, is participating, including projects adopted under the CARDS and MEDA programs.

Article 26

Work programme and annual report

1. The annual continuing education programme, adopted on the basis of Article 3 of Decision 2000/820/JHA, shall be regarded as the work programme referred to in Article 10(9)(d), subject to any amendments adopted in accordance with the provisions of this Decision.

2. The annual report on CEPOL's activities for the year 2005 shall be established in accordance with the procedure provided for in Article 3 of Decision 2000/820/JHA.

Article 27

Institutional arrangements

1. For the purpose of implementing the transitional provisions of this Decision, the Governing Board set up on the basis of Article 10 of this Decision shall substitute itself for the Governing Board set up on the basis of Decision 2000/820/JHA.

2. Notwithstanding Article 28 of this Decision, the relevant provisions of Decision 2000/820/JHA, and all rules and regulations adopted for their implementation, shall remain in force for the purpose of implementing the transitional provisions of this Decision.

Article 28

Measures to be prepared before entry into force

The Governing Board set up on the basis of Decision 2000/820/JHA, as well as the Director, appointed on the basis of that Decision, shall prepare the adoption of the instruments listed below:

(a) the rules of procedure of the Governing Board as referred to in Article 10(8);

(b) the implementing rules applicable to CEPOL staff as referred to in Article 10(9)(f);

(c) the rules regarding the selection of the candidates, as referred to in Article 11(1);

(d) the measures referred to in Article 11(4)(b);

(e) the financial rules applicable to CEPOL referred to in Arti cle 17;

(f) the measures required in Article 18(2); and

(g) the rules for access to CEPOL documents referred to in Article 20.

CHAPTER VII

FINAL PROVISIONS

Article 29

Repeal

Without prejudice to Chapter VI of this Decision, Decision 2000/820/JHA is repealed.

Article 30

Taking of effect

This Decision shall take effect on 1 January 2006. However, Article 28 shall apply from the day following the publication of this Decision in the *Official Journal of the European Union*.

Article 31

Publication

This Decision shall be published in the *Official Journal of the European Union*.

Done at Brussels, 20 September 2005.

For the Council
The President
M. BECKETT